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# DISCUSSION DRAFT OF THE FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT LEGISLATION: DRUG SAFETY

## HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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[1] Ms. DeGette did not submit a prepared statement for the record in time for printing.
[2] Ms. Solis did not submit a prepared statement for the record in time for printing.
[3] Dr. Woodcock did not answer submitted questions for the record.

# DISCUSSION DRAFT OF THE FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT LEGISLATION: DRUG SAFETY

**THURSDAY, MAY 1, 2008**

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

The subcommittee met, pursuant to call, at 10:11 a.m., in room 2322 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. (chairman) presiding.

Members present: Representatives Pallone, Waxman, Towns, Green, DeGette, Schakowsky, Solis, Hooley, Matheson, Dingell (ex officio), Buyer, Pitts, Murphy, Burgess, and Barton (ex officio).

Staff present: Jeanne Ireland, Jack Maniho, Virgil Miller, Melissa Sidman, Ryan Long, and Chad Grant.

Mr. PALLONE. The hearing of the subcommittee is called to order, and today we are having a second hearing on the Food and Drug Administration Globalization Act today, specifically with regard to the drug provisions. As I think you know, last week we discussed the food-related provisions and today we will be focusing on the drug-related provisions only. I recognize myself for an opening statement.

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

In recent years, there have been a number of revelations about drug safety that have shaken public confidence in the FDA's ability to ensure that consumers are using safe and effective drugs. Tens of thousands of patients have been placed in harm's way due to the failings of our current drug safety system, and while we boast that America has the safest drug supply in the world, clearly more needs to be done. The American people must be able to trust that the drugs they take to save their lives will not cause additional harm.

Earlier this week, the Subcommittee on Oversight and Investigations held a hearing to examine the events of the recent tainted heparin tragedy. The heparin case resulted in the deaths of at least 81 Americans, caused 785 severe allergic reactions in the United States, and affected patients in 10 other countries as well. The O&I findings revealed that not only are FDA's inspection policies inadequate, but worse, they actually could have contributed to the hep-

arin-related deaths. This is simply unacceptable, and I have to say that I am outraged by the fact that this type of situation could have occurred and I would like to express my sympathy to the individuals and families affected by the incidents. But what worries me is that without congressional intervention, this could happen again. We have an obligation to the American people to ensure that the FDA has the resources it needs to protect them from these types of situations.

We have heard from a number of sources including the GAO, the FDA's Science Board, and other stakeholders that the FDA is woefully underfunded and that this underfunding is the driving force behind the Agency's inadequacies, and finally the Agency itself during the hearing on Tuesday confirmed this fact. They cited that they need $100 million more for domestic inspection and regulation activities and $225 million additional to adequately inspect and regulate foreign manufacturers. Clearly, the paltry $11 million budget for foreign inspections in 2008 doesn't even come close to being enough to enable the FDA to ensure a safe drug supply. At present, 80 percent of all active ingredients in drugs sold in the United States are made in other countries and yet the FDA only inspects foreign facilities in countries such as China and India once every 30 years.

The draft we are discussing today would change that. As with the food companies, it would require all facilities, foreign and domestic, to register annually with the FDA, providing the Agency with an up-to-date list of all drug manufacturing facilities and active ingredient manufacturing facilities as well. It will generate the revenue needed to allow the FDA to conduct frequent inspections of all facilities by charging an annual fee that we are fully intending to specify in the final bill. It establishes new and stronger enforcement tools that the FDA can use against bad actors and requires manufacturers of drugs and biologics to test their products carefully for contaminants. And I do also want to point out that the funding proposed in this discussion draft is intended to supplement, not supplant, current FDA appropriations.

I feel confident that we will be able to put together a strong bill and I am pleased that the industry, pharmaceutical companies, biologic companies, and generic companies have been so far willing to cooperate and assist in our endeavors. We have even received letters of support for this bill from leading drug manufacturing companies. I know there are still areas that we need to work on and details we need to iron out, and I look forward to hearing your testimony today highlighting those areas from the witnesses.

I also wanted to mention that my colleagues, Mr. Buyer and Mr. Matheson, are particularly concerned about the surge in counterfeit drugs in the marketplace and I welcome a discussion of their proposed legislation, H.R. 5839, Safeguarding America's Pharmaceutical Act, during today's hearing. Particularly I am looking forward to a discussion around the issue of leveraging information technology to protect our Nation's drug supply. It has been identified in multiple GAO reports that the FDA is currently operating with a severely under-equipped information technology system which actually also may have played a role in the heparin case. While I applaud the initial progress that has been made on FDA's

part by hiring a new chief information officer and centralizing the existing systems, more can be done to support the Agency in their IT investments, which I believe will not only benefit the patients but will also enable the Agency to be more efficient and effective in carrying out the required tasks.

Finally, patients and their health providers have to have confidence that the medicines they take to treat diagnosed illnesses meet the highest standards of safety and efficacy, and again, I look forward to hearing from today's witnesses and the discussion around some of these issues.

Mr. PALLONE. I understand Mr. Deal is not here today so Mr. Buyer is going to act as the ranking member, and I yield to the gentleman 5 minutes for his opening statement.

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

Mr. BUYER. I thank Chairman Pallone for holding the hearing today and I appreciate Chairman Dingell's willingness to include H.R. 5839, a bill I introduced along with Jim Matheson, Mike Rogers, and Gene Green 2 weeks ago, in this hearing. I appreciate the chairman's comments in reference to this bill.

Our committee has been committed to addressing the dangers of counterfeit, adulterated, and misbranded pharmaceuticals affecting our Nation. When I use the word pharmaceuticals I also include biologics in that, and with that comment, I welcome our colleague, Jim Greenwood, to take special attention to that.

I believe H.R. 5839, Safeguarding America's Pharmaceuticals Act, aligns well with our commitments to not only providing for improved safety within our regulated drug supply chain but also protecting our drug supply chain from outside threats. I think we all understand the cost to America's health from accepting the norm and disregarding and failing to protect our Nation from a new public health threat. Our Nation has set the gold standard for safety and efficacy of pharmaceuticals. However, even with the many steps that we have taken to protect this gold standard, our pharmaceutical market is attractive to criminal interests seeking to make tremendous profits by praying on America's most vulnerable populations: the sick, the disabled, and the elderly.

America is not insulated from the exploding counterfeit drug market, which is expected to earn an annual global profit in excess of $75 billion by year 2010. In fact, due to our weak adverse event reporting system, we cannot even grasp the effects of counterfeit and adulterated and misbranded medications upon people in our society. We do have some idea about the quality of prescription drug packages entering our Nation through testing that FDA has conducted in our international mail facilities. FDA periodically conducts blitz exams to test samples of pharmaceuticals entering our ports of entry. After a 2003 blitz exam of 4 of our international mail facilities, the FDA found that 88 percent of the drug products the Agency examined during this blitz contained unapproved drugs.

Furthermore, within our own regulated pharmaceutical supply chain, we know counterfeiting and diversion occurs. In 2003, the FDA announced a recall of some 200,000 bottles of Lipitor that were believed to be fake, and in previous years 110,000 bottles of

other counterfeit drugs were used to boost red blood cell production in people with cancer and kidney disease that made their way into the marketplace.

The main reason for the rash of counterfeit drugs is not surprising: it is money. Pharmaceutical counterfeiters are what I refer to as the new drug lords of the world. In fact, experts have claimed that it is more lucrative to sell counterfeit drugs than narcotics, and the criminal penalties for engaging in counterfeiting drugs are far less than those selling narcotics. I think when you use the term "drug lord," Mr. Chairman, people think of Colombians. I would say the analogy here is that Colombians are rather foolish. A drug lord who is a Colombian selling cocaine or marijuana is the equivalent of someone taking a gun down to the 7-11 and doing a robbery. Those criminal penalties are pretty stiff. But these new drug lords are highly sophisticated criminal syndicates that move their counterfeits through many different nations to insulate themselves from criminal prosecution and they do that because it is a highly leveraged, lucrative market, not only in the United States but around the world. Americans, I believe, must have the assurances that the medications they take are those manufactured and FDA-related pharmaceutical entities.

H.R. 5839 is about patient safety. The bill ensures the destruction of unapproved and potentially dangerous drugs coming through our ports of entry and allows for the creation of a uniform Federal drug pedigree system. It raises the licensure standards for pharmaceutical wholesalers and calls for a study on how we can better protect Americans from counterfeit drugs. With our legislation, patients will benefit greatly in knowing that the medications they consume, in fact, the medication their doctor prescribed, is not a medication which has been counterfeited, adulterated, or diluted. I recognized earlier we had had a conversation on whether we should actually require our doctors to ask of their patients when you prescribe a drug, where are you buying your pharmaceuticals. The AMA did not want us to do further mandates upon docs, and I understand that, but docs today when they come up with their diagnosis and have a prognosis, they write their scrip, they believe their patient is going down to a local pharmacy, not realizing that many of their patients are buying them over these Internet Web sites, thousands of them, of which only 15 are even FIP-certified. So we have a real problem here that we are going to need to face.

Congressman Matheson and I have carefully constructed H.R. 5839. We have learned from experiences in States like Indiana, California, and Florida, which have taken a strong lead in strengthening their pharmaceutical distribution systems. We have engaged in extensive discussions with stakeholders across the supply chain, and I wanted Chairman Dingell to know that, that over this last 6 months Congressman Matheson and I, Chairman Dingell, have done everything we possibly can in discussions with everyone in the industry, and it is very difficult to come up with a consensus. You know that. You created the paper pedigree system. So we are just trying to modernize that into electronic form, and it is very challenging. I believe our approach provides for a great flexibility and a tremendous input from the stakeholders and I appreciate the support from some of the companies throughout the

supply chain including the manufacturers, big and small drug wholesalers, and pharmacists.

I look forward to working with Chairman Pallone and Chairman Dingell and other members of the subcommittee as we move forward the Buyer-Matheson legislation, and with that I yield back.

Mr. PALLONE. Thank you.

I yield to Chairman Dingell for an opening statement.

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

Mr. DINGELL. Mr. Chairman, I thank you for your courtesy. I commend you for the hearing and I look forward to good things coming from this effort today.

The hearing is an important one and it relates to how the Food and Drug Administration is going to better carry out its functions, and we are dealing specifically with our Food and Drug Administration Globalization Act discussion draft. Since last fall, under your leadership and that of Mr. Stupak, Mr. Shimkus, and others, and the Subcommittee on Oversight and Investigations, we have found many dangerous gaps in the foreign inspection system of Food and Drug Administration. What was found and what was confirmed by the Government Accountability Office and FDA's own Science Board was a system which is grossly and grotesquely underfunded, with authorities largely outdated, based on a lot of trust but very little verification and quite small success. We cannot any longer follow this important regulatory function on blind faith. What was shown clearly at the hearing on the heparin disaster earlier this week by the Oversight Subcommittee confirms that. The consequences of this system led to the deaths of 81 people of whom we know, injuries and sickness of serious character for hundreds or perhaps thousands more.

An important step toward addressing this occurred at the hearing on Tuesday. During this hearing, Dr. Janet Woodcock, director of the Center for Drug Evaluation and Research at FDA, candidly acknowledged the need for substantial new funding for inspections and stated that at least $225 million would be needed to put foreign facilities inspections on par with inspection of our domestic firms. Dr. Woodcock also indicated her agreement with the need for key authorities proposed in a discussion draft circulated 2 weeks ago by Congressman Stupak, Congressman Pallone, and I. She is to be commended for her leadership, frankness, and courage in this matter.

The discussion draft would require FDA to conduct more inspections of foreign drug firms and to give the Agency authority to deny entry to those imports produced in facilities that refuse to be inspected or impede an inspection. We would also require drug manufacturing facilities to register with FDA annually, pay a registration fee and be assigned a unique identifier to provide a more accurate accounting of facilities and allow FDA to move quickly in the event of safety incidents.

Finally, we would enable FDA to explicitly require manufacturers to know and verify the safety of their suppliers. This is the first time we have heard from a high-ranking Administration official in

ways which would enable that agency or this committee to see to it that FDA does and has the resources it needs to do the job.

And again, I want it known that I appreciate Dr. Woodcock's candor. To her credit, she has stepped forward in the midst of a public health crisis to deal honestly with the Congress and tell the Congress what her agency needs to better protect the American people from unsafe drugs. How I wish that others in the Administration would show the same vigor, responsibility and leadership. I hope that we can continue our dialog today with the same degree of candor on the part of all of the persons involved, including members of the Committee.

I am pleased to note that the drug industry's willingness to work with us in addressing these problems is rather better than that of the Administration or of some other industries. While we may differ on details, in marked contrast to food manufacturers, the drug industry appears to recognize that a safer drug supply is not only in the interests of the public health but is also a matter of interest in their bottom line. I appreciate the letters of support we have received from two generic manufacturers, Ranbaxy and Teva, as well as consumer groups, such as Consumers Union and Center for Science and the Public Interest.

Mr. Chairman, food, drug, device, and cosmetic safety are important to American consumers. The discussion draft is a good and meaningful step forward in providing what FDA needs to serve as a premier public health agency of the United States government. I remember when this was so. Regrettably, it needs some rather serious effort to get us back to where Food and Drug will again serve in that capacity.

I look forward to working with all my colleagues on the Committee and with FDA and interested stakeholders to craft good, responsible and bipartisan legislation so that the Food and Drug Administration is able to competently fulfill its critical mission.

Mr. Chairman, I commend you for the hearing and I thank you for your courtesy.

Mr. PALLONE. Thank you, Chairman Dingell.

Next I would recognize the gentleman from Pennsylvania, Mr. Murphy.

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

Mr. MURPHY. Thank you, Mr. Chairman.

In this Congress, we have had numerous Oversight and Investigation hearings regarding drug safety. During one such hearing last November, I asked the witnesses if they would allow their children to take prescription drugs, knowing they contained active ingredients all imported from China. All the witnesses somewhat reluctantly answered "yes," but given that the GAO estimates the FDA only has about 7 percent of foreign establishments inspected per year, I understand the witnesses' reluctance. Unfortunately, we don't even know if the FDA really inspects 7 percent of foreign establishments, as the GAO reports that one FDA database indicated there were 3,000 establishments. Another one indicated there were

6,800 establishments. Clearly, we need to manage our information technology infrastructure better.

Regardless of the number of actual inspections, we know the number is low and that importing active pharmaceutical ingredients from countries like China can be dangerous. Sixty-two deaths have been linked to the nationwide recall of heparin. Every death was linked to an active pharmaceutical ingredient produced in China. The FDA admitted it did not perform a pre-approval for the facility and obviously domestic quality control measures in place were not adequate. We must raise the bar, and I hope we hear from the witnesses today how we can improve drug safety without crippling the supply chain.

After speaking with drug manufacturers in my district like Mylan and GlaxoSmithKline, I believe we have universal agreement that we must improve drug safety. The question is how we improve drug safety in a way that best maximizes the limited resources of the FDA and the robust quality control measures already in place at most of our domestic facilities. This bill provides additional authorities to conduct inspections, destroy counterfeit imported products, and mandate recalls, all worthy improvements. However, if we are to institute a registration fee on manufacturers, I am concerned that the fee be targeted to increasing oversight of foreign drug manufacturing facilities rather than just placing additional burdens on domestic manufacturer facilities.

I also want to applaud the good bipartisan work of Congressmen Buyer and Matheson for introducing legislation to improve our drug pedigree system. States like California are undertaking individual efforts to establish track-and-trace policies that could lead to a patchwork of State laws. The Buyer-Matheson bill would produce an updated Federal standard to our drug pedigree system. From my work developing legislation to harmonize the reporting of hospital-associated infections where you now have over 26 different State laws, there is real value in introducing a Federal standard.

I look forward to witnesses' testimony today, and with that, I yield back, Mr. Chairman.

Mr. PALLONE. Thank you.

I recognize Mr. Waxman for an opening statement.

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

Mr. WAXMAN. Thank you, Mr. Chairman, and I want to commend you for holding this hearing and also to commend you, Chairman Dingell and Chairman Stupak, for their efforts in pulling together the strong legislation to address the dangerous gap in FDA's authority and the critical lack of resources.

As Americans are all too aware, the demands being placed on the FDA have essentially overwhelmed the Agency's ability to effectively respond and FDA is now indeed in a crisis. That strain is in large part due to an increasingly globalized drug development and manufacturing model. Twenty years ago, 90 percent of U.S. drugs came from the United States or the European Union. Today that number has dropped to 20 percent. This clearly means that FDA must amplify its international presence if it is to have the

hope of keeping up. FDA will need a serious infusion of resources and multiple new authorities to do the job we all expect it to do. In a moment of much appreciated candor, FDA told us on Tuesday it would take an additional $225 million for the Agency to inspect the 3,300 drug manufacturing facilities abroad, but according to GAO, FDA's information technology systems are so out-of-date that the Agency cannot even be sure that there are actually only 3,300 facilities abroad in need of inspection. In 2001, one of FDA's databases said there were 3,000 foreign establishments while another said there were 6,800. FDA's inability to even assess basic information, like how many facilities abroad it should be inspecting, is simply unacceptable. By creating a mandatory registration fee for drug and device manufacturers, both in the United States and abroad, the bill will generate critical dollars that will enable FDA to conduct more inspections, and I hope the industry will get behind those fees. We must also ensure FDA gets the necessary funding to revamp its IT systems. Otherwise it won't be able to effectively use the information gleaned from an increased inspection force.

The bill fills some critical gaps in FDA's authority by granting FDA recall and administrative detention authority and enhanced enforcement tools like civil monetary penalties for improper import filings. At the heparin hearing, FDA highlighted the fact that they currently lack subpoena authority and indicated that authority would be helpful. The bill doesn't have that in its present form but I think we should look at adding it and other authorities as well.

On the drug pedigree issue, I commend Mr. Matheson and Mr. Buyer for their work on this legislation. I hope we will proceed with great caution when talking about a bill that might preempt the efforts of States. As many of you know, California has enacted a strong bill, so any Federal legislation that seeks to nullify California's law must provide the same or greater degree of protection or else preserve California's ability to proceed with its legislation.

Let me finally stress the importance of moving this legislation now. Without the authorities and resources provided in the bill, we leave ourselves vulnerable to another heparin debacle. I want to congratulate the people who have authored the strong legislation before us and look forward to working with them and others to pass it into law.

Mr. PALLONE. Thank you, Mr. Waxman.

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

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

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

Today we are focusing specifically on drug safety. I have had the opportunity to participate in several hearings led by Chairman Stupak in the Oversight and Investigation Subcommittee on drug safety. Last week we had a hearing on the foreign drug inspection program and this week we had a hearing on the heparin incident. All these hearings have clearly shown that the FDA does not have the

resources, funding, or technology it needs to protect the American public from counterfeit or tainted drugs entering this country.

In light of these hearings and the recent heparin incident, I signed on as an original cosponsor of Mr. Buyer, Mr. Matheson, and Mr. Rogers' legislation, H.R. 5839, the Safeguarding America's Pharmaceuticals Act. I believe the Safeguarding America's Pharmaceuticals Act and Chairman Dingell's discussion draft can help us address many of the concerns we have with regard to drug safety. This discussion draft calls for increased resources for overseas facility inspections by FDA, an up-to-date registry of all foreign drug manufacturing facilities, country-of-origin labeling, verification of drug purity and safety, and gives the FDA the ability to issue fines and mandatory recalls.

H.R. 5839, the Safeguarding America's Pharmaceuticals Act, is an especially well thought through approach. It makes changes to help protect our Nation's pharmaceutical supply as well. Currently, FDA does not have the authority to destroy adulterated, misbranded, or inadmissible drugs at the Nation's international mail facilities. The FDA must waste time and money returning the packages to the sender. Often the FDA sees the same rejected packages with their own return-to-sender stamps at the mail facilities that have been sent in a second attempt to pass through the FDA system. H.R. 5839 gives the FDA the ability to destroy these packages when they are first rejected. Safeguarding America's Pharmaceuticals Act gives us one national pedigree system to allow for consistency and efficiency when pharmaceuticals are moving about the country. The bill also creates a track-and-trace system that would establish a drug identification and tracking system through which drug manufacturers, repackagers, wholesale distributors, and dispensers can authenticate the wholesale distribution history of any prescription drug that has a standardized numerical identifier. I know the National Association of Chain Drug Stores that are testifying before us today have some concerns regarding the track-and-trace system. I am hopeful we can work out their concerns because they are definitely part of our healthcare delivery system. The discussion draft of the Safeguarding America's Pharmaceuticals Act makes great strides toward assuring drug safety at home and abroad.

Again, I want to thank you for your leadership, for holding the hearing. I want to thank our witnesses for appearing today, and I yield back my time.

Mr. PALLONE. Thank you.

Next, the gentlewoman from Oregon, Ms. Hooley, for an opening statement.

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

Ms. HOOLEY. Mr. Chairman, thank you and your staff for this extraordinary effort in putting this discussion draft together. The American people want to know that their pharmaceuticals are safe and this bill goes a long way toward achieving that assurance.

This bill creates a registration process and fee for domestic and foreign drug and device establishments. I have said for years that the FDA is underfunded. This bill begins to address the much-

needed resources for drug safety in a fair manner. I especially appreciate the fee amount will be determined by the Secretary based on a case-by-case basis per facility.

This bill also improves the inspection of facilities that produce drugs, active pharmaceutical ingredients, devices and device parts. This bill requires inspection before a product is put into the stream of commerce as well as a portion that inspects facilities already producing products that are in commerce. One of the most innovative aspects of the bill is that it requires for the first time the inspection of foreign as well as domestic drug and device establishments every 2 years.

This bill also has a section on country-of-origin labeling, or what we call COOL. Being a longtime proponent of COOL, I am pleased that this portion of the bill takes COOL one step further to make the well-documented origin of drug ingredients the norm for the industry. Under Section 204, this bill allows the Secretary to deem a drug adulterated if upon request the manufacturer of the ingredient and each drug that contains that ingredient does not have adequate documentation to establish where the ingredient was made. Country-of-origin labeling allows the Secretary to deem misbranded a drug or device if its labeling fails to identify the country which is the source of the active pharmaceutical ingredient in whole or in part and of its place of manufacturing in the case of a drug, or the country of manufacturing in the case of a device.

Our citizens want to know that their medications and their medical devices are safe. This discussion draft provides additional authority for the FDA's efforts to assure the safety of imported foreign-manufactured drugs and devices. I am looking forward to working with you as this bill moves forward so that we can assure the public that their drugs and devices are safe.

Thank you.

Mr. PALLONE. Thank you.

I recognize the gentleman from Utah, Mr. Matheson.

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

Mr. MATHESON. Well, thank you, Mr. Chairman. As my colleagues before stated, I do want to thank you for allowing consideration of the legislation that Representative Buyer and I have been working on. I want to thank Representative Buyer for all of his efforts on this issue. He has been a real leader and it has been a very good experience to work with him in forming this legislation. And in the tradition of this committee working in a bipartisan way, when this bill was originally introduced, in addition to Representative Buyer and myself, we also had Representative Green and Representative Rogers from the Committee as original cosponsors, and I think that speaks well to the broad-based support for this legislation.

I just want to highlight three key points that bear noting with regard to this legislation. I want to be clear with my colleagues regarding the intent of this legislation is to protect our Nation's pharmaceutical supplies from domestic and international counterfeiting threats. I think this is a carefully thought-out approach to achieving this goal.

So specifically this legislation does the following. It creates a system by which we will be able to track drugs from the time they leave the manufacturing facility until the time they reach patients in the pharmacy, hospital, nursing home, or doctor's office. Counterfeiting of drugs is a public health concern. People need to know that when they take a prescribed pill, it is real, undiluted and not laced with phony ingredients. By implementing these steps now, we can go a long way toward safeguarding the medicine people need to get well and stay healthy.

Second, the legislation provides for one uniform national pedigree system. By having one Federal standard, we can ensure our Nation's drug market is efficient and can ensure products flow safety and freely throughout the country. This is a guiding principle that seems to unite a majority of the members of the supply chain.

And third, this legislation raises the standards for drug wholesalers while maintaining States' rights to regulate drug wholesalers. I believe this is a necessary step to ridding the market of bad actors and ensuring that anyone handling American's pharmaceuticals should be held to high standards.

Counterfeit drugs harm people. Our families, our friends, and our constituents need to know that they have secure sources of medication. The victims are often people who need real quality drugs the most: cancer patients, AIDS patients, and people being treated for heart disease. And the main reason, as Mr. Buyer indicated in his testimony, the main reason for why we are so concerned about the counterfeit drug issue, not surprisingly, is money. The Centers for Medicine and the Public Interest predicts that the worldwide market for counterfeit drugs will go to $75 billion annually by 2010, and some experts say it is more lucrative to sell a counterfeit drug than a narcotic. Counterfeiters are alarmingly good at their jobs. They can create pills and drug packages that are so close to the real products that they are indistinguishable to consumers. By strengthening current laws and regulations and by creating a uniform national standard, our legislation further secures the healthcare supply chain. This enhances our country's current high standard of patient safety.

I look forward to the witnesses' testimony regarding this important issue and, Mr. Chairman, I will yield back.

Mr. PALLONE. Thank you.

The gentleman from Pennsylvania, Mr. Pitts, recognized for an——

Mr. PITTS. I will waive.

Mr. PALLONE. Thank you.

The gentleman from New York, Mr. Towns.

**OPENING STATEMENT OF HON. EDOLPHUS TOWNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK**

Mr. TOWNS. Thank you very much, Mr. Chairman. Let me thank you also, Mr. Buyer, and of course, Mr. Matheson and Chairmen Dingell and Stupak and other members who took the leadership on the discussion draft and topic. I support the intent of these efforts to eliminate threats to our Nation's safety from drug and medical device products regardless of where they actually emanate. I pledge

to work with my colleagues to achieve the overall safety goal as we better understand the challenges. I look forward to hearing from the FDA and other witnesses this morning.

I am particularly interested in the FDA's plan to establish a foreign office in China and the agencies beyond our borders initiative, which seeks to provide for certification by third parties and the FDA plans to upgrade its system to gain the necessary information about the entire life cycle of imported products. In our current modern day America, I cannot imagine that a record 81 deaths could occur from an unsafe prescription drug produced outside of the United States. That to me is something that I have difficulty understanding in this day and age. I believe the overarching problem of a resource challenged FDA can be solved and foreign country regulatory gaps can be closed in order to keep the door on trade open to allow for all to have a win-win outcome.

In 2007, America's biopharmaceutical research companies may have spent an estimated $59 billion in domestic drug research and development, yet it may take a mere $71 million for the FDA to be able to biannually inspect drug manufacturers. For the United States to effectively meet this critical aspect of our challenge, the bottom line is, the FDA must be able to take a science- and risk-based approach and perform surveillance inspections of foreign drug manufacturing places and implement other methods to ensure compliance with U.S. requirements for drug products which come into the U.S. market.

Mr. Chairman, I would like to thank you and the staff and everyone who is really working on this. I think this is a very serious and very important issue, and I hope we stay with it until we come up with some kind of resolution. Thank you so much for your involvement. I yield back.

Mr. PALLONE. Thank you, Mr. Towns.

Ranking Member, Mr. Barton, for an opening statement.

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

Mr. BARTON. Thank you, Mr. Chairman. I appreciate the regular order that is being used on this issue.

As we learned during Tuesday's hearing, drug imports are not very well supervised currently, but it is an issue that I think can be addressed in a successful fashion if we work together across the aisle and also work with the stakeholders and the FDA to solve this problem.

I think everyone understands that the Food and Drug Administration lacks sufficient resources to conduct its core mission. Both the Agency and industry recognized that fact last year, and we were able to work together to negotiate the fourth installment of the Prescription Drug User Fee Act, or PDUFA. PDUFA 4 did have significant increases in user fees that were paid by the industry, and as we said, that has now become law. We did find out though, during the debate on PDUFA, that many witnesses and members of this committee began to express the fear that the Agency might become too dependent on industry user fees. The draft that is currently before this subcommittee, which, I might add, the Minority had no input into, would exacerbate this problem by becoming even

more user fee oriented. I think that, as I said a minute ago, we obviously need more assets and more resources for the FDA. We should really pay attention to how we give them those resources, and it might better to just authorize out of the general revenue as opposed to becoming more and more dependent on user fees.

There are some ideas in the draft before us that are worth exploring. One is the idea to give the FDA mandatory recall authority. I support that, and I think most members of the Minority would support that. I also believe that the premise that the FDA should be conducting more frequent inspections overseas is valid. We need to work to find a way to make that happen. I do believe, however, that instead of setting a specific amount, we should work with the FDA and develop an inspection priority system based on real risk. We also need to ensure that the quality systems are in place to conduct those inspections and to protect the integrity of the products that are being inspected. We do not need, in my opinion, to just waste more resources by scheduling mandatory inspections at specific times. I am not sure that that would be a worthwhile use of our resources.

The draft offers other concepts that are important. I think that nobody should mistake country-of-origin labeling and restrictions on ports of entry as safety provisions, however. That is something that may come up in the discussion and the questions of the witnesses.

Chairman Dingell has told me and he has stated publicly that he is willing to work with the Minority to develop a bipartisan product. I am going to take him at his word. We are going to work in a positive way. Hopefully we can come to a consensus to develop a product that is worthy of support not only in the subcommittee but in full committee and on the Floor. But it is going to take work and we on the Republican Minority side are not going to be a rubber stamp for the draft that is currently before the subcommittee.

With that, Mr. Chairman, I appreciate your regular order process and I yield back.

Mr. PALLONE. Thank you, Mr. Barton.

Ms. DeGette passes.

Ms. DEGETTE. I will put my opening statement into the record.

Mr. PALLONE. She will insert her statement into the record.

The gentlewoman from California, Ms. Solis.

Ms. SOLIS. I will also insert my statement in the record.

Mr. PALLONE. Thank you. I think that concludes our opening statements so we will now turn to our witness. Dr. Woodcock, come up and take a seat at the panel. I want to welcome Janet Woodcock. Dr. Woodcock is director for the Center for Drug Evaluation and Research at the FDA, and I understand you are accompanied by Doctor—is it Elisa Bernstein—who is director of pharmacy affairs of the Office of Policy at FDA, but you are going to speak and she is going to be available to answer questions, correct?

Dr. WOODCOCK. Yes, that is correct.

Mr. PALLONE. You know we have 5-minute opening statements. The statement becomes part of the hearing record and each witness may in the discretion of the Committee submit additional brief and pertinent statements in writing for inclusion in the record.

I now recognize you, Dr. Woodcock. Thank you for being here.

**STATEMENT OF JANET WOODCOCK, M.D., DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION**

Dr. WOODCOCK. Thank you, Mr. Chairman, and members of the subcommittee. I am Janet Woodcock. I am director of the Center for Drug Evaluation and Research at FDA. I am accompanied by Elisa Bernstein, who is director of pharmacy affairs at FDA. Dr. Bernstein is an expert in the pharmaceutical distribution chain and track-and-trace technologies.

Thank you for the opportunity to testify on the important issue of globalization of our pharmaceutical supply. The rapid and now rapidly accelerating shift in drug manufacturing from the United States to other countries has caused a great deal of concern over the past decade. Currently, as the members have already alluded to, a substantial majority of active pharmaceutical ingredients used in the United States are made outside its borders, and many of these are being increasingly made in developing countries. Questions have been raised about FDA's ability to oversee the quality of this large and very rapidly growing inventory of foreign manufacturing establishments.

The Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce has actually held a number of hearings on many aspects of this issue over the years. In 1998, the GAO issued a report entitled "Improvements Needed in the Foreign Drug Inspection Program" that detailed many of the challenges that FDA faces.

Over the last decade, FDA has made extensive efforts to improve its ability to oversee the quality of imported drugs, including negotiating data-sharing agreements with other countries, devising risk-based approaches to selecting foreign sites that we go inspect, developing international guidance on good manufacturing practices for active pharmaceutical ingredients—that guidance has been adopted around the world—publishing a regulation requiring foreign establishments to register, and many other efforts.

Last year, President Bush issued an Executive Order creating a cabinet-level working group on import safety to promote the safety of imported products and asked the HHS Secretary to lead the group. This group included representatives from 12 Federal departments and agencies including FDA. It reviewed the procedures, regulations and practices for ensuring that imported food, drugs, and other consumer products are safe.

On November 6, Secretary Leavitt presented the Import Safety Action Plan to the President. Several new authorities pertinent to drug importation were recommended, including authorizing FDA to refuse admission of imported products if access to the foreign establishment was unduly delayed, limited, or denied, providing authority to expedite destruction of drugs of low value and high risk that were inappropriate, providing FDA with the authority to require under certain circumstances a certificate or other assurance that an imported product complies with FDA requirements, and providing the FDA with the authority to accredit independent third parties to evaluate compliance with FDA requirements. In addition, the Administration has announced plans to establish FDA offices in several countries, including India and China.

In January of this year, FDA and then the world became aware of deaths and adverse reactions that ultimately were traced to contaminated heparin sourced from China. This problem of contaminated heparin is continuing to unfold in countries worldwide. So the introduction of this discussion draft is certainly timely. We are the process of reviewing the discussion draft in detail and look forward to working with you on this legislation. At this time I can make some general comments using the framework that guided the Action Plan for Import Safety, which could guide the development of drug safety legislation.

Any legislation should allow flexibility for FDA to set requirements and priorities based on scientific risk assessments. Any legislation should not rely on inspection as the sole or primary means of assuring quality. Quality must be built in. That is a premise of the quality movement. It cannot be tested or inspected into a product. FDA in 2003, I believe, introduced the concept of quality by design, which puts the responsibility on the manufacturer to ensure that the quality of their products is high by managing the quality of the components, the manufacturing process, and the systems surrounding the manufacturing process. Quality is a system property and cannot be assured by a single component of a quality system. It must be maintained by multiple surrounding components of the quality system.

While the Administration is supportive of user fee programs in which regulated industry provides funding for additional performance designed to recoup costs, the Administration will carefully review any proposed user fee program to ensure it is being assessed against identifiable recipients for special benefits derived from Federal activities beyond those received by the general public, and any legislation should be carefully designed to avoid creating real or perceived trade barriers. The legislation should explicitly incorporate the Administration's strategy of levering efforts by certification bodies and foreign nations that is already underway. And finally, several provisions of this bill may need to be reviewed in light of U.S. trade agreement obligations and we are reaching out to the United States Trade Representative for further insight.

As you can see, efforts are underway at FDA to further ensure the safety of human drugs regardless of where they are manufactured. We share your interest in enhancing the safety of imported products and look forward to working with members and staff on the Committee and Subcommittee. The Administration is carefully evaluating the provisions in the discussion draft.

Thank you for the opportunity to testify today, and I am happy to respond to any questions.

[The prepared statement of Dr. Woodcock follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
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**STATEMENT OF**

**JANET WOODCOCK, M.D.**
**DIRECTOR**
**CENTER FOR DRUG EVALUATION AND RESEARCH**

**FOOD AND DRUG ADMINISTRATION**
**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE**

**SUBCOMMITTEE ON HEALTH**

**COMMITTEE ON ENERGY AND COMMERCE**

**UNITED STATES HOUSE OF REPRESENTATIVES**

**"DISCUSSION DRAFT OF THE 'FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT' LEGISLATION: DRUG SAFETY"**

**MAY 1, 2008**

**Release Only Upon Delivery**

**INTRODUCTION**

Mr. Chairman and Members of the Subcommittee, I am Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to discuss FDA's progress in responding to the challenges created by drugs for the United States (U.S.) market that are either fully manufactured overseas or that are manufactured in the U.S. but contain foreign components. FDA's mission is to ensure that safe and effective medical products are available to patients in the U.S., regardless of where they are produced. In my testimony today, I will outline activities the Agency is undertaking to accomplish this goal.

**ACTION PLAN FOR IMPORT SAFETY**

As you know, last year, President Bush issued an Executive Order creating a Cabinet-level Working Group on Import Safety to promote the safety of imported products, and asked Secretary Leavitt to lead the group. The working group, which includes representatives from twelve Federal departments and agencies, including the U.S. Department of Agriculture (USDA), and the Department of Commerce, reviewed the procedures, regulations, and practices for ensuring that imported food, drugs, and other consumer products are safe.

On November 6, Secretary Leavitt presented the "Action Plan for Import Safety" to the President. This Action Plan presents broad recommendations and specific short- and long-term action steps, categorized under the organizing principles of prevention, intervention, and response. Each action item is based on the building blocks identified in the Strategic Framework, released in September 2007. That report 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 model that 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 phases. In the Action Plan, we identified several new legislative authorities that are needed to do this.

**Prevention**

To comply with the Food, Drug, and Cosmetic (FD&C) Act, any entity that intends to import drugs into the U.S. must ensure that the drug meets a number of quality and labeling requirements. In the FD&C Act, Congress enacted provisions to create a relatively "closed" distribution system for imported drug products to help ensure the domestic supply is safe and effective. Generally, drugs may be imported into the U.S. only by a manufacturer with an approved application. This manufacturer may receive products or components from its foreign facility or another company's facility that was listed in that particular drug application. All "new drugs," which includes all finished prescription drug products, must be approved by FDA as safe and effective for their intended use. FDA approvals are manufacturer-specific and product-specific, and include many requirements related to the product, such as manufacturing location, formulation, source and specifications of active ingredients, manufacturing controls, the container/closure system, and labeling. Facilities that manufacture drugs for the U.S. market are referenced in an approved application and must meet FDA's current Good Manufacturing Practice (cGMP) requirements.

FDA is seeking to ensure that imported drug products are safe and effective and meet all applicable FDA standards *prior* to reaching U.S. ports-of-entry. FDA is pursuing this goal through the following key efforts.

*Maximizing Foreign Medical Product Pre-Approval Inspections.* Prior to the approval of a new drug application or abbreviated new drug application, FDA must determine that the manufacturing processes are adequate to produce a safe and effective drug, and ensure its identity, strength, quality and purity. Each year, FDA performs hundreds of foreign pre-approval inspections which assess data in applications and a firm's cGMP compliance. These inspections are designed to evaluate the capability of manufacturing facilities to generate a safe and high-quality product. FDA conducted more foreign inspections in Fiscal Year (FY) 2007 than any other in the Agency's history. For example, in FY 2007, FDA conducted 332 inspections of foreign drug manufacturers, compared to 260 in FY 2004, 266 in FY 2005, and 212 in FY 2006. We plan to conduct 500 in FY 2009. While, inspections are an important component of the Agency's systematic approach to ensuring the safety of imported medical products, they alone cannot fully address these challenges.

*Beyond Our Borders Initiative.* The FDA Beyond Our Borders Initiative is a multi-pronged approach to promote and verify compliance of imported food, cosmetics, and medical products with FDA requirements. This Initiative includes increased FDA presence in China, increased FDA inspections, greater sharing and use of foreign competent authority inspection reports and other information, use of third party

certification, and increased capacity building with countries that have less developed regulatory systems to ensure product safety.

*Foreign Presence.* China is one of the largest exporters of drug products for the U.S. market. Recently, FDA and HHS leadership, the Department of State, and the U.S. Ambassador to China committed to establishing an FDA office in China this year. On March 8, 2008, the Department of State approved FDA to place 13 total staff in China (eight FDA personnel and five Foreign Nationals). This staff will be responsible for building closer working relationships with our Chinese counterparts, carrying out inspections, and working with Chinese inspectors to provide training. FDA is in the process of making the necessary arrangements and preparing to hire staff. This effort builds on two recently-signed Memoranda of Agreements (MOA) with two Chinese FDA counterpart agencies that facilitate broader access to Chinese production facilities on an expedited basis. This is a significant step toward ensuring the safety and efficacy of medical products produced for the U.S. market. FDA's efforts will build stronger cooperative relationships with counterpart agencies in China, enhance technical cooperation with these agencies, and foster the flow of information between regulatory systems. Having an overseas presence in China will improve our ability to inspect facilities in China and, very importantly, foster greater interactions between FDA staff and Chinese manufacturers to help ensure that products shipped to the U.S. meet FDA standards for safety and manufacturing quality. In addition, FDA is working to establish beneficial collaborations with India, another large exporter of drug products to the U.S.

*Ramping Up The Field & International Staff.* To meet the challenges posed by the increase in the globalization of U.S. drug development, FDA must significantly strengthen its field and international inspection operations. Goals for FY 2009 include increasing foreign and domestic inspections and sampling, improving our laboratory infrastructures, continuing to develop tools for rapid analysis, and, as previously mentioned, establishing an in-country presence in China.

*Sharing Foreign Inspection Reports.* FDA currently has in place more than 70 cooperative arrangements with foreign counterparts. As previously mentioned, Secretary Leavitt signed a MOA with the State Food and Drug Administration of the People's Republic of China to enhance the safety of drugs and medical devices imported into the U.S. from China. In addition, FDA now has over 30 confidentiality arrangements with trusted foreign counterparts, many of which provide mechanisms for sharing inspection reports. FDA intends to increase the use of these arrangements to obtain useful information that can help the Agency make more informed judgments about the acceptability of foreign-sourced products, in prioritizing our foreign inspection activities, and on detaining unsafe products.

*Providing for Certification by Third Parties.* Another component of the Agency's Beyond Our Borders Initiative leverages private sector resources. As recommended in the President's Action Plan for Import Safety, FDA is pursuing the use of third party certification to verify compliance with FDA requirements. These third parties may include foreign government agencies and independent entities who have been accredited by FDA or accreditation organizations recognized by FDA. With proper structuring to

stimulate the use of third party certification, this certification would complement, but not supplant, FDA inspectional and other regulatory activities.

*Providing Technical Assistance.* Another essential element of the Agency Beyond Our Borders initiative focuses on helping foreign regulators understand FDA standards, laws and regulations by providing technical assistance to counterpart foreign regulators and outreach assistance to foreign industries that engage in trade with the U.S.

**Intervention**

FDA recognizes the importance of a strong and effective intervention capacity to identify problems as they occur.

*Information Technology (IT).* FDA has several plans to enhance its IT systems in ways that will enable the Agency to better utilize risk-based information from the entire life-cycle of imported products. These projects will improve databases, enhance interoperability of systems within the Agency and among other regulatory agencies, and provide better analytical function to assess and control risk. We expect these improvements will help to target our intervention efforts related to foreign firms. For example, FDA plans to improve its listing and registration systems to allow the Agency to more accurately identify who is manufacturing medical products and what is being commercially distributed in the U.S.

*Expanding Laboratory Capacity & Development of Rapid Test Methods.* FDA must be agile and scientifically sophisticated, with the ability to develop rapid test methods for detection of pathogens and other contaminants in drugs, and to ensure that these test

methods are available at ports-of-entry to assist in determining whether a product should be admitted into the U.S. FDA research laboratories develop and validate methods, such as the test FDA developed to determine the contaminant in heparin ingredients imported from China. This novel testing method is now accepted and used worldwide to detect the presence of hypersulfated chondroitin sulfate in heparin.

*Increasing Surveillance Inspections.* In addition to pre-approval inspections mentioned previously, FDA conducts surveillance inspections of domestic and foreign manufacturers and uses a risk-based priority model to determine which facilities may pose a risk to the American consumer. FDA staff must consider a number of elements in making a risk-based priority determination. In part, these elements include: the dosage form coming to the U.S. from the foreign country, the date the facility was last inspected, the compliance history of the firm, the firm's shipping volume and history, and information from the local regulatory authorities regarding the manufacturing quality and regulatory status of the establishment.

*Holding U.S. Manufacturers Accountable.* The President's Action Plan for Import Safety outlines several action steps intended to help ensure that domestic companies importing foreign source material meet their responsibility to import safe and effective medical products. These manufacturers have a responsibility to ensure the safety of foreign-manufactured components and ingredients used in their finished products. FDA inspects all facilities listed in a drug application, both foreign and domestic, to determine if they meet the Agency's quality standards. During these inspections, FDA routinely evaluates the domestic drug manufacturer's testing and controls of ingredients (domestic

and foreign-sourced) and supplies. If deficiencies are discovered, the Agency may take enforcement action.

**Response**

When a health threat emerges with any FDA-regulated product, whether manufactured domestically or abroad, FDA must be ready to take immediate action.

*Making the Border an Integrated Checkpoint.* FDA works with Customs and Border Protection (CBP) at the border to refuse admission of products that appear to violate the FD&C Act. When we have sufficient information to refuse future shipments of a product, FDA can issue an Import Alert for Detention Without Physical Examination. This means FDA can detain regulated articles based on information that the articles appear to violate the FD&C Act, rather than on the results of actual sample examination. The Action Plan for Import Safety calls for increased FDA and CBP cooperation, including the development of interdepartmental procedures for clearing and controlling shipments at ports-of-entry, co-locating FDA and CBP at locations to improve coordination and efficient use of resources, and greater import information sharing between FDA and CBP through new technology applications.

*Rapid Deployment of "For Cause" Inspections.* When FDA has information that raises doubts about the safety of a regulated product, it will rapidly conduct domestic or foreign "for cause" inspections. In such cases, the Agency targets a particular firm or product as an inspection priority based on this information and rapidly deploys an inspection team.

*Expanded Use of Track-and-Trace Technologies.* FDA is working to facilitate the adoption of track-and-trace technologies to identify and track a product along the product life-cycle. These technologies will facilitate the timely recovery of the violative product and reduce the opportunity for harm, as well as secure the integrity of the supply chain by providing an "e-pedigree," an electronic record documenting that the drug was manufactured and distributed under secure conditions. The use of track-and-trace technologies will give FDA the ability to connect the dots and link important life-cycle information back to the point-of-origin. Under the Food and Drug Administration Amendments Act of 2007, FDA is working to develop or recognize electronic standards and validation for track and trace technologies.

**NEW AUTHORITIES REQUIRED**

The Action Plan for Import Safety called for providing a number of new authorities in order to enhance the safety of imported products. It requests authority to establish both voluntary and mandatory import certification programs -- using accredited third parties (which could include federal departments, foreign governments, or private entities) -- to verify compliance of foreign products with U.S. safety and security standards. As appropriate, import certification would include periodic on-site inspections, random testing and certification renewal based on product risk. Product certification could be mandatory for certain high-risk products coming from countries with which the U.S. has entered into agreements. Under the agreements, the countries or accredited third-parties would certify products as meeting U.S. standards prior to their export to the U.S. Such a procedure would be limited to high-risk products that have been shown to pose a threat to

public health. Additionally, the plan recommends authorizing FDA to refuse admission of a foreign manufacturer's product when FDA encounters undue delay, limits, or denials of access to the foreign manufacturing sites where the product was produced. At present, foreign firms can deny inspectors access to their facilities without any adverse consequence. The plan also requests authority to expedite destruction of refused medical products, which will prevent unsafe medical products for personal use from entering the U.S. market. Finally, amending the FD&C Act to include asset forfeiture remedies for certain criminal offenses involving fraudulent or counterfeit products would allow the forfeiture of all vessels, vehicles, aircraft and other equipment used to aid in the importing, exporting, transporting, selling, receiving, acquiring and purchasing of violative products by those who knowingly and willingly violate the Act.

The lack of explicit jurisdiction for the FD&C Act offenses can hamper FDA's ability to investigate the overseas offenders that violate the FD&C Act, but whose conduct occurs entirely outside the territorial jurisdiction of the U.S. For example, foreign firms can often deny U.S. officials access to their facilities without any adverse consequences. Amending the FD&C Act to provide for explicit extraterritorial jurisdiction for conduct that occurs outside the U.S. where products subject to the FD&C Act are intended to be imported into the U.S. would be consistent with principles of due process. Such an amendment would better enable FDA to address criminal conduct that occurs entirely outside of the U.S. and threatens the health and safety of consumers within the U.S.

**FDA GLOBALIZATION ACT OF 2008**

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

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

- Any legislation should allow FDA to set requirements and priorities based on a strong scientific FDA risk assessment.
- Given the breadth and scope of drug products imported into the U.S., as well as those produced domestically, FDA cannot rely on inspection as its primary means of ensuring product safety. Any legislation should build on the framework in the Action Plan for Import Safety, i.e., building in safety measures to address risks throughout a product's life cycle and focus efforts on preventing problems first, and then using risk-based interventions to ensure preventive approaches are effective, coupled with a rapid response as soon as a problem is detected.
- While the Administration is supportive of user fee programs in which regulated industry provides funding for additional performance and efforts or programs designed to recoup the costs of regulatory actions resulting from findings of violations (such as reinspections), the Administration will carefully review any

proposed user fee program to ensure that it is being assessed against identifiable recipients of special benefits derived from Federal activities beyond those received by the general public.

- Any legislation should be carefully designed to avoid creating real or perceived trade barriers, and several provisions of the bill may need to be reviewed in light of U.S. trade agreement obligations. We are reaching out to the U.S. Trade Representative for further insight on these.
- Any legislation should empower robust voluntary private sector efforts already underway.

With these in mind, we believe the proposed legislation should be more closely targeted and prioritized according to risk. Several of the legislative sections appear not to be sufficiently focused on high-risk products. Some of these requirements would divert resources, which could detract from important drug safety and security priorities. In addition, the legislation should more explicitly incorporate the Administration's strategy of leveraging third party certification and efforts by foreign nations already underway.

**CONCLUSION**

As you can see, efforts are underway at FDA to ensure the safety and efficacy of human drugs, regardless of where they are manufactured. We share your interest in enhancing the safety of imported products and look forward to continuing to work with Members and staff on the Committee and Subcommittee. We also look forward to working with you on the Action Plan for Import Safety. Thank you for the opportunity to testify today, and I am happy to respond to any questions you may have.

Mr. PALLONE. Thank you, Dr. Woodcock.

I am going to recognize myself for 5 minutes to begin the questioning, and I want to thank you, not only for being here today but also for being at the O&I hearing on Tuesday. Everyone was talking about your candor there, and we certainly appreciate that with regard to this discussion draft that we are circulating.

I wanted to ask some questions that I think probably were asked Tuesday as well but I want this subcommittee to have the benefit of hearing your response.

As you stated in Tuesday's testimony before O&I, well, you said then that the FDA needs $225 million annually to inspect foreign drug facilities at the same rate that is required currently for domestic facilities. Is that correct?

Dr. WOODCOCK. That is what I stated. I wasn't given the chance to explain the assumptions behind that.

Mr. PALLONE. Well, I will probably get into some of those with these additional questions, if that is OK.

Dr. WOODCOCK. OK.

Mr. PALLONE. According to the FDA budget documents reviewed by GAO for its testimony last week, FDA estimates that it will dedicate a total of $13 million in fiscal year 2009 to conduct foreign inspections. But you stated that an additional $100 million would be needed to meet the current statutory requirement to inspect domestic facilities every 2 years. So is that correct, this additional money for domestic?

Dr. WOODCOCK. Yes. If I can explain how we arrived at those figures?

Mr. PALLONE. You can explain it to me by probably answering this, whether that estimate includes the cost of compliance, the staff needed to review the reports, the inspectors. Does it include costs for information technology infrastructure to ensure that the FDA can access these reports? I wanted to know if those things are part of that.

Dr. WOODCOCK. The estimates that I gave were based on a 2011 projection of the inventory based on the current rate of change of the domestic and foreign inventory and they were based on the current productivity rate of inspectors both domestic and foreign and was based on what we call fully loaded cost of inspector per annum, which would include overhead costs, processing, enforcement, and so on but would not include information technology improvements. So that estimate did not include any estimates for improving the drug registration and listing or OASIS and so forth. And obviously we can't send our inspectors over there unless they know where to go.

Mr. PALLONE. OK. Now, is it your view that FDA should have the ability to deny entry to imports if the facilities in which they were produced refuse, delay, or impede in inspection?

Dr. WOODCOCK. Yes, and I believe that is reflected in the Import Safety Action Plan that I referred to as well.

Mr. PALLONE. And now, what about drug facilities? Should they be subject to an initial inspection before they can begin shipping products or ingredients?

Dr. WOODCOCK. We try now to make sure that inspection is accomplished for any new facility that we haven't seen. However,

some facilities make multiple products. They may add another product in a line of products, and we would like to preserve the ability to have flexibility to send our inspectors to what we deem to be the highest risk plants.

Mr. PALLONE. So does that mean you don't think that every facility should be subject to an initial inspection?

Dr. WOODCOCK. Yes, we believe—let me explain again. Every facility should be subject to an initial inspection. However, a facility that is making multiple products and adds a product that is very similar to its product line, it might be lower risk than another facility that perhaps added an injectable product to its existing line. So we believe it would be best for FDA to have its flexibility preserved to put our resources, whatever they are, against the highest risks.

Mr. PALLONE. All right. Now, what about——

Dr. WOODCOCK. That said——

Mr. PALLONE. OK. What about requiring the drug facilities to register and pay a fee on an annual basis to help clean up FDA's databases and provide a more accurate accounting of firms providing drugs to American consumers?

Dr. WOODCOCK. Well, this puts the finger on one of our major problems, which has already been alluded to by the members. Right now we don't have a means of assuring an accurate inventory of what firms are producing drugs that are imported into the United States around the world. We believe we need a unique identifier in addition to having an annual registration and listing of all products that are produced. The mechanism, by ensuring that firms do this, there are probably several options for that.

Mr. PALLONE. That was my next question. You already answered it. Now, in your view, would it be helpful to have additional enforcement tools to use against bad actors, for example, strong civil money penalties, mandatory recall, the ability to destroy contaminated imports when they are discovered so they can't just be shopped to a new point of entry?

Dr. WOODCOCK. As I said, the Administration is evaluating the provisions in the bill, but in my testimony on Tuesday, I stated that I believe that it would be helpful for FDA to have additional authorities to go after those who are performing improper acts, misrepresenting imports, and so forth.

Mr. PALLONE. Well, would you include those additional enforcement tools, the civil money penalties, mandatory recall, ability to destroy contaminated imports? Would you suggest that those be included?

Dr. WOODCOCK. My personal opinion is that those would improve our efficiency of being able to accomplish our operations. For example, if the products that we are not letting in have to sit at the port and we have to deal with them, that creates great efficiency problems for us and actually for Customs as well. So we need mechanisms that enable us to efficiently deal with products that are violative or should not get into this country.

Mr. PALLONE. OK. Thank you. My time is up.

Mr. Buyer.

Mr. BUYER. Thank you very much, Dr. Woodcock, for being here, and thank you for bringing Dr. Bernstein. The foundation of her

expertise is well recognized and we appreciate your service to country.

I have a series of questions I am going to ask, so please take some notes, and I would ask each of you the best field of your expertise on this to provide these answers.

Can you explain the return-to-sender policy that FDA employs at the international mail facilities when it returns products which it deems inadmissible to our country? Next, can you explain why FDA does not destroy counterfeit, adulterated, or misbranded products that come into the international mail facilities and the express carrier hubs? Next, does FDA support section III of H.R. 5839, which gives the Agency the express authority to destroy pharmaceutical products which appear to be counterfeit, adulterated, or misbranded? Next, I have reviewed an alternate proposal circulated by the chain drug stores that wants to—their proposal is for a certification process which would do away with the Federal-State pedigree systems. Is that something which you would endorse or not? The next is, the FDA Commissioner was quoted as stating at the NACDS/HDMA RFID health industry adoption summit that it is vital to get this technology implemented now, stressing that a wait-and-see attitude is not good enough. The industry needs action and it needs it now. The question is, do you agree with the Commissioner's assessment that we need action on a track-and-trace now, and if so, can you update us on the FDA's work on developing the unique identifier standard and the standard for track-and-trace system, and does FDA support a phased-in approach to implementing such an identification and track-and-trace system? With that, I will pause and allow you to munch on that.

Dr. WOODCOCK. To begin with the return-to-sender policy, I will ask Dr. Bernstein to respond to that.

Dr. BERNSTEIN. There are current authorities in the law——

Mr. PALLONE. Is your mic on, Dr. Bernstein, or maybe put the mic closer to you.

Dr. BERNSTEIN. If it is OK with you, can I answer a couple of those together? OK. There are current authorities in the law that require us to go through certain steps when we look at a package and we detain a package, and we work with CBP at the international mail facilities, and the current law provides some challenges and some—in order to destroy products, and so what we do, the process of what we do is, when we get a product that CBP hands over to us, we will send a letter, a notice of detention, to the person who is supposed to get that package and give them 20 days to get back to us to whether that product should be admitted and is compliant with the Food, Drug and Cosmetic Act. Because of some of the measures in the current law, after 20 days we will often return it to sender, otherwise it has to sit on the shelves for at least 90 days before we can destroy it. Well, you yourself have been to these international mail facilities and seen the number of products that are piled because they are going through this detention process, and CBP and FDA have been working together to try to come up with ways to make this process easier, and in the Import Safety Action Plan that Dr. Woodcock mentioned, we did say that streamlining the destruction authority would be very beneficial, and I know there are provisions in your bill, and we are look-

ing at those provisions now and we will be glad to work with you on how we can make sure that those streamlined authorities and destruction authorities——

Mr. BUYER. To have that express authority to be able to destroy?

Dr. BERNSTEIN. To streamline the current process to destroy products, yes.

Mr. BUYER. Thank you.

Dr. Woodcock?

Dr. WOODCOCK. I don't have——

Mr. BUYER. You didn't take a list?

Dr. WOODCOCK. I have the list. I don't have any further comments. I think Dr. Bernstein is our expert on this. Do you want to go down the list further? All right. Why don't we use, does FDA support authority to destroy, you have already covered adequately. What about the Federal-State pedigree?

Dr. BERNSTEIN. Should we do away with the pedigree, the Federal and State pedigree system? I believe we should not. The pedigree system, although we have had the Prescription Drug Marketing Act pedigree system in place, a pedigree provides accountability and transparency and a chain of custody for products as they move through the supply chain. We need that transparency, we need that accountability in the supply chain to know where the drugs—where they come from, where they are going, where they have been, where they are supposed to go, and who had them along the way. That helps not only to ensure that you have a safe and effective product that the patient gets but also allows for law enforcement and regulators to actually trace back the product through the supply chain if there was any suspicious activity with respect to that product along the way.

Mr. PALLONE. Mr. Buyer, you are a minute over. What I was going to suggest——

Mr. BUYER. I will go to the second round on the follow-up.

Mr. PALLONE. Well, I don't know if we are going to have a second round, but what I would definitely ask is that you answer those questions in writing and get back to us as soon as possible because I don't know that we are going to have a second round because we have another panel.

Dr. WOODCOCK. I would be happy to do that.

Mr. PALLONE. If you could do that, please.

Next is the gentlewoman from Oregon if she has some questions. No?

Mr. Matheson?

Mr. MATHESON. Thank you, Mr. Chairman. Thank you, Dr. Woodcock, for being here today.

As you know, and Mr. Buyer just asked you questions related to the legislation that he has introduced and I have joined him in doing that, let me ask you—and there may be a little repetition but first of all, does the FDA support looking at track-and-trace technology and maintaining or improving from the 1988 pedigree law in doing that?

Dr. WOODCOCK. Yes. Again, I will turn to Dr. Bernstein because she has been spearheading that effort.

Dr. BERNSTEIN. The FDA, we have in 2004, 2005, 2006, we have continuously put out reports on ways that the drug supply chain

and measures that could be taken to further supply the drug supply chain. Tracking-and-tracing and electronic technology measures and solutions are one of the cornerstones of that approach. So yes, we do support it. The Food and Drug Administration Amendments Act of 2007 had provisions in it that requires FDA to develop standards for tracking-and-tracing, authentication and identification and we think these measures will further move the supply chain and provide incentives for them to implement track-and-trace.

Mr. MATHESON. You are probably also familiar that our legislation will create the one uniform national pedigree standard to prevent proliferation of 50 different State requirements in this area. In your opinion, does the FDA support a uniform national pedigree standard as opposed to having the 50 State standards?

Dr. BERNSTEIN. We have said that a single national uniform standard would be ideal to help the distribution of drugs in the United States.

Mr. MATHESON. This may sound like an obvious question but I think it is important to have it on the record. What is the importance of having chain of custody information for drugs as they flow through the supply chain?

Dr. BERNSTEIN. As I said, the measures for tracking, tracing and pedigree and chain of custody is to ensure accountability and transparency, and that chain of custody where you know where the drug has been, where it is going, who has had it, makes that—allows you to be accountable, allows everyone to be accountable to ensure that that patient gets a safe, effective drug and genuine drug.

Mr. MATHESON. Where do you think the technology is now? We are hearing different opinions from different witnesses about if we are ready to do this.

Dr. BERNSTEIN. There has been tremendous progress and movement in the technology and standards, though as part of the provisions in the Food and Drug Administration Amendments Act, FDAAA, we are in the process right now of a data call. We have put out a Federal Register notice and asked for comments on the state of technology and the technologies that are available and, in addition, where the standards are. So we should know very soon because by May 19, that docket is closing and we will have more information. But in my opinion, the technology has progressed significantly since we first called for the use of technology in 2004.

Mr. MATHESON. Excellent.

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

Mr. PALLONE. Thank you.

The gentleman from Pennsylvania, Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman.

You stated that FDA cannot rely on inspections as a primary means of ensuring product safety and that any legislation should allow FDA to set requirements and priorities based on a strong scientific FDA risk assessment. Can you explain that further?

Dr. WOODCOCK. Certainly. We have—as I said, we have developed a modern program for pharmaceutical quality, which involves a quality systems approach, and quality systems is what is used to ensure quality in many industries, for example, semiconductors, aeronautics, what have you, cars, automobiles. That involves con-

trol of every part of the manufacturer process, from the components, the supply chain of each component, the understanding that manufacturing process, having a scientific understanding of the product, and then making sure all the systems around that are under a state of control.

When we do an inspection, what we do nowadays, modern inspection, make sure that those systems are functioning. We don't serve as the quality control unit for the plant. We make sure they have one and that they have a quality assurance program that is functioning and that they are managing their supply chain. So we need to make sure that the scientific standards are in place, that the entire supply chain is under control and that includes, for example, the brokers, the customs agents at the borders, the distributors inside the United States, as Elisa was saying. Any place that chain is broken, then quality problems can be introduced into the product, or counterfeits, for that matter. So inspection is a form of verification that the systems that are in place are working, but those systems have to be run by the manufacturers, by the importers and so forth. They have to act properly for the quality of the product to be maintained.

Mr. PITTS. Can you describe the type and scope of training that FDA inspectors receive? How long, on average, does it take for an FDA inspector to be fully trained to conduct facility inspections?

Dr. WOODCOCK. It takes about 3 years, and there is a rigorous progression of training. Furthermore, a number of years ago, we established something known as the pharmaceutical inspectorate, which is even another level of training to allow our inspectors to be fully able to inspect modern, complicated pharmaceutical operations. So that takes about 3 years to be an investigator, and then if you are going to be a foreign investigator, investigate foreign facilities, we would like our inspectors have a number of domestic inspections under their belts and be well trained at that before they go and deal with the challenges of another country, additional languages, and so forth.

Mr. PITTS. How long would you estimate it would take the Agency to recruit and train a sufficient number of new inspectors to conduct the requisite number of foreign inspections, and are there any difficulties or challenges that FDA faces in recruiting and training new inspectors?

Dr. WOODCOCK. Our difficulties are mainly, I would say, resources. We brought on a very large number of investigators in 2001 after that crisis and we were able to get them on board and begin their training, but regardless of how many we would hire, it would take us 3 years to train them up, and even 4 years if we are talking about a foreign inspectorate and fully trained investigators who can work on their own in foreign countries. So there is a significant training component, and we would have to keep working on that over a number of years, and that is why my estimate for the resources was that 2011 estimate, the trajectory that we would get to by 2011.

Mr. PITTS. And that would permit you to make how many foreign inspections?

Dr. WOODCOCK. That was an estimate of what would be required to inspect 50 percent of the firms each year, of the inventory abroad.

Mr. PITTS. OK. There has been a lot of discussion about manufacturers of active pharmaceutical ingredients. Does the FDA currently have the authority to inspect those facilities and do those inspections differ from inspections conducted on facilities making a finished product?

Dr. WOODCOCK. Yes, we definitely have the authority and we do inspect manufacturers of active—the manufacturing plants for active pharmaceutical ingredients. They are different in the sense that they are making different kinds of products. They are making what we call bulk ingredients rather than finished pharmaceuticals. They are not making pills or vials of product, they are making an ingredient that goes into, then, a finished product. So in that respect it is different, but the basic fundamentals of inspecting quality systems are very much the same.

Mr. PITTS. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Pitts.

Ms. DeGette is recognized for questions for 5 minutes.

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

Mr. PALLONE. I am sorry. You have 8 minutes.

Ms. DEGETTE. That is what I thought. Thank you very much, Mr. Chairman.

I would like to ask you a little bit about this heparin situation because, Dr. Woodcock, you had testified earlier, in response I think to Mr. Pallone's questioning, that—to paraphrase what you said—while it was important for the FDA to have the authority to inspect all of these foreign factories, you also felt like it shouldn't be a mandate that you inspect all of those facilities because it would probably be better if you could put your resources on the most high-risk areas. Would that be a fair summary of your testimony?

Dr. WOODCOCK. Yes, that the FDA should be given flexibility.

Ms. DEGETTE. So my question is, then, at least according to the media accounts, the FDA did not inspect the Chinese manufacturer of the active ingredient in heparin because of a clerical error. I know there is some dispute about this, but there is some view that if it had been inspected, then we may have found the problems on an initial inspection. What is your view on that?

Dr. WOODCOCK. Well, we may have found problems on initial inspection but we don't think we would have found contamination because we don't have any evidence from testing that there was contamination in the heparin supply in 2004.

Ms. DEGETTE. Now, aside from the clerical error, would the heparin ingredient manufacturer have been one of those high-risk facilities that you would have inspected as a matter of routine?

Dr. WOODCOCK. Yes, we would have gone to that pre-approval inspection. It was simply flagged wrong.

Ms. DEGETTE. OK. So you wouldn't think that that would be a lower-priority inspection? Aside from the clerical error, you would have inspected that facility?

Dr. WOODCOCK. Well, let me clarify this so you completely understand the situation.

Ms. DEGETTE. OK.

Dr. WOODCOCK. The firm came online in 2004 and we didn't—it would have been a pre-approval inspection at that point, and we didn't inspect because of a clerical error but we would have inspected.

Ms. DEGETTE. Great. Thanks.

Dr. WOODCOCK. But we would not have inspected probably subsequently to that. The contaminant, as far as we can tell, was introduced into the bulk heparin supply in China, at least headed to the United States, in many different plants in 2006.

Ms. DEGETTE. Let me just stop you right there. I am sorry. I just don't have a lot of time. But that goes to some of the other questions that I want to ask, and that is, how do we catch some of this contamination that comes in along the line? In your testimony, you said that the FDA conducted 332 inspections of foreign drug manufacturers last year, which was the most ever in the Agency's history. That still, however, is staggeringly low in proportion to the number of U.S. inspections that same year. So I guess the question is, what else can we do? I mean, we can increase resources, but as you say, it will take several years to bring those inspections online. I want to explore some other areas. For example, do you think that we can develop a pathway so that FDA inspectors can inspect foreign facilities without advance notice or invitation from the foreign government? This is one of the issues that we have been exploring for several years in the Oversight and Investigation Subcommittee.

Dr. WOODCOCK. Yes. I am not a lawyer but I understand we could do that now. It is simply there are practical barriers. We have to get visas from the country. We have to state our purpose of coming in. Perhaps we could make international agreements with countries, but——

Ms. DEGETTE. And do you think that would help the FDA in its mission of finding these problems?

Dr. WOODCOCK. We would like to do unannounced inspections.

Ms. DEGETTE. So if there are things we can do to help you get that authority, that would be useful?

Dr. WOODCOCK. Although I do believe we have the authority, there is just a host of practical problems. For example, we can't go find the plant has shut down for a month-long national holiday and have our inspectors wait around a month until they get online again because we need to inspect them when they are producing product. So those are some of the practical——

Ms. DEGETTE. All right. Well, perhaps you can have your staff get back to us and tell us if there are some barriers that we could help you break as we propose legislation.

Here are a couple of other questions. Unfortunately, I couldn't be at Tuesday's hearing because I was busy flying in, but you said that the FDA currently lacks subpoena authority and it would be helpful if you had it. Is that correct?

Dr. WOODCOCK. That is what I stated.

Ms. DEGETTE. And can you briefly describe how subpoena authority would benefit the Agency?

Dr. WOODCOCK. I would like to, but it would be better to get back to you since I am not a lawyer, I am a doctor, and what would help is for us obviously to be able to subpoena witnesses and documents

and things like that to aid in our investigations but it is hard for me——

Ms. DEGETTE. But you have been advised by your legal counsel——

Dr. WOODCOCK. Correct.

Ms. DEGETTE [continuing]. That it would be helpful to have subpoena authority?

Dr. WOODCOCK. I have been advised by our compliance experts.

Ms. DEGETTE. OK. I understand that historically your inability to copy and retain a firm's records during an inspection has been a problem. Would it be helpful if you had clear authority to copy and retain records?

Dr. WOODCOCK. I don't know the answer to that question.

Ms. DEGETTE. I would appreciate it if you could get back to me as we develop the legislation. Some of us think the bill probably needs to be clarified on that point, and I will tell you, I am a lawyer, and although I am on inactive status, I can tell you that it is helpful if you can get documentation as you go forward and be able to retain it.

One last question. You mentioned some of this, but I want to talk about the new FDA office in China for a second. I am assuming that having foreign-based staff would help improve some of the current issues with foreign inspections, like the language barriers, cultural barriers, and insufficient time for thorough inspections, but I am wondering if the new FDA office in China will facilitate sufficient changes within the inspection process to ensure that the inspections are adequate in nature and on par with domestic inspections. Is that the goal of the FDA?

Dr. WOODCOCK. Certainly we want to attain that. However, having an office in China, although it will help with the issues you raised, will not put the resources against doing the every-2-year inspection, which is the goal domestically is to not just do pre-approval inspection of a plant but be in that plant every 2 years.

Ms. DEGETTE. And so what would help us meet that goal?

Dr. WOODCOCK. That requires, as I said on Tuesday, additional resources to have more inspectors.

Ms. DEGETTE. And will the FDA officials in China with this office now be able to perform unannounced inspections?

Dr. WOODCOCK. Well, potentially they could. As I said, my understanding is that FDA has the authority to do that. However, China is a very big country and we are talking about a small office of FDA officials, and it isn't to address the entire problem of——

Ms. DEGETTE. So I am confused, because you say that you think unannounced inspections are important. You say that you think you have the authority, but you are saying that you are not so sure you are going to do it because the office is small?

Dr. WOODCOCK. I just believe there is a resource issue in covering all the facilities in China.

Ms. DEGETTE. Right. So you are saying you don't think you are going to do unannounced inspections or you are going to try to do them, or what?

Dr. WOODCOCK. It would increase the probability of us being able to do any given inspection on an unannounced basis.

Ms. DEGETTE. OK. Thank you very much, Mr. Chairman.

Mr. PALLONE. Thank you, Ms. DeGette.

Next for questions, I recognize the gentleman from Texas, Mr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman.

Dr. Woodcock, good to see you again. I am not a lawyer. I am a doctor too. Let us go through this together. Now, Representative DeGette was talking a little bit about the cultural and language barriers that exist. When we were working through our problems on the consumer product side of this in November and December of last year, I went out to the Consumer Product Safety Commission testing facility out at Bethesda, and one of the things they mentioned was just exactly that, the language and cultural barriers that exist, and when we talk about voluntary inspections or voluntary recalls here in this country, it has a different meaning than it does in China. Here a voluntary recall is one which the manufacturer will enter into an agreement with the Agency in order to expedite things, get the product off the shelves faster, rather than going through a prolonged court proceeding with all due process and defendants' rights. In China parlance, apparently voluntary means you do it if you feel like it and no penalty for not complying, and they had to get past that on the voluntary compliance aspect at CPSC in order to get some of the withdrawals of lead-based paint in toys. Has that problem, has that presented itself in what we are dealing with with the importation of active ingredients, pharmaceutical ingredients from China? When we talk about things as being on a voluntary basis, does that not get interpreted properly on the other side of the ocean?

Dr. WOODCOCK. We generally are dealing with global manufacturers, large manufacturers who are sourcing the active ingredient from a Chinese source and so the entity that would be responsible for recall of finished product would ordinarily be the large manufacturer who would have been responsible and then the voluntary operation of a recall, as you alluded to, would come into play. However, heparin in the United States in the sourced for many different purposes including for compounding, it is imported to be placed into medical devices and so forth, and so with the smaller manufacturers, it has been difficult for us actually to identify all sources of heparin that might be entering the country.

Mr. BURGESS. And I appreciate that. It just underscores the—when something is lost in translation, you have got so many people involved, I think Congresswoman DeGette is onto something and it does behoove us to pay attention to that. On Tuesday when we were talking about the heparin issue, I brought up some of the aspects of the funding, and we have heard a lot of different numbers and I know no one could answer some of the budgetary questions I had on Tuesday. I suspect the answer today would be the same, we don't know, and I have spent some time with the budget resolution that we just passed in March and the appropriations bill of the USDA agriculture appropriations bill from last summer and I am having a very, very difficult time finding out the number of dollars that this Congress has said, at least last year, was appropriate for doing these foreign inspections. Since we talked on Tuesday, do you have any better sense of what we appropriated last July in our bill and what we have asked for in the budget this year?

Dr. WOODCOCK. Well, I can tell you it isn't appropriated that way. There is appropriation to the drugs program, if you have looked at the appropriations, and part of it is to the field operation and part of it is to the center for drugs and then it isn't line-directed further down than that. I can tell you, more or less, what we spent, if you would like to, or I can get back to you with that information. That might be more productive.

Mr. BURGESS. I think that would be productive, and I think the subcommittee would be interested in that. We are hearing a lot of talk about user fees in the legislation that is before us. Are any of the user fees that are in the recently passed Prescription Drug User Fee Act of last June, does any of that apply to the—are any user fees applied currently to the active pharmaceutical ingredients that are imported from other countries?

Dr. WOODCOCK. Yes, and this is confusing so let me walk through it a little bit.

Mr. BURGESS. I don't have much time.

Dr. WOODCOCK. The Prescription Drug User Fee Act is for new drugs, not generics. Now, as we have heard, about 60 percent of the medicines that Americans actually consume are generics. They don't have a user fee program. So the Prescription Drug User Fee program that applies to new drugs does allow and pay for pre-approval inspection of any given plant, including the API plant, as part of the program, but that, as you can see, is a small amount of inventory compared to the entire inventory. It doesn't pay for surveillance inspections, which are the every-2-year inspections, after approval for a new drug.

Mr. BURGESS. I don't have much time left. From a philosophical standpoint, I mean, Congress, we don't have many things that we are really required to do under the Constitution but defending the borders, delivering the mail are some of the things that we should do. To me, this is a defending-the-borders issue so this to me is one of those things for which we should appropriate money, and I don't know how deeply we have gotten into the discussion of user fees for this activity but when we looked at user fees last June, it almost seemed to be that user fees became a way of supplanting us having to appropriate dollars, and for me, this is such a fundamental issue of protecting the borders, defending our country, protecting our borders, that this should be one of the activities for which direct appropriation of funds occurs. If we need to make it up somewhere else with other fees or reducing spending, God forbid, in some other area—goodness knows, every dollar in that $3 trillion budget that is spent is worthwhile, but it seems to me that this is an area where we should appropriate the money and not leave it to user fees. The other thing that concerns me is that there seems to be a lot of reprogramming going on in last year's appropriations bill so that if we come up with a number, and I have heard various figures mentioned from $11 million up to $600 million, if we oversubscribe user fees, we are merely going to reprogram that money into other activities that has nothing to do with defending our borders or import drug safety, and I know I have gone over, Mr. Chairman. I will yield back my time.

Mr. PALLONE. Thank you.

The gentlewoman from California, Ms. Solis.

Ms. SOLIS. Thank you, Mr. Chairman.

I wanted to ask you, Dr. Woodcock, if you could explain for us, you gave an amount at a previous hearing what you might need for foreign inspections. We talked about that already. But you could give me a more descriptive amount that would be needed so that you could upgrade your systems, which would include technology, and go a little bit further in detail and if you could do that quickly?

Dr. WOODCOCK. Yes, I think I can answer factual questions on that. The FDA's Science Board report, the subcommittee report, which I don't know whether all of you have seen, went over the state of FDA's information technology and our systems, and they could best be described as in a crisis, they are obsolete. So we need—FDA will need to invest at least $20 million this year and for many upcoming years to put our basic infrastructure, IT infrastructure in place. There is no use us building new systems for imports if we can't run them on our infrastructure. So that will cost probably about a $20 million investment each year for a number of years. And then I think for imports, what we need to do is do electronic drug registration and listing, OK, so it is totally electronic. That would be a very modest amount of money, perhaps $10 million to build a quick fix type of system. We have done a business plan for this. I was requested by Mrs. Emerson to develop a business plan and we have developed that. So that would be a modest amount of money. Then fixing the interface, the processing at the border, the interface with Customs would probably require again tens of millions of dollars for a number of years to get that repaired, but none of those I think are extreme expenditures that would be required.

Ms. SOLIS. So could you provide our committee with more detailed figures about how—I mean, this is probably not the time for you to give us all that but if could come back and give us something in writing as an approximation. I mean, when you are saying years, 5 years, 10 years or——

Dr. WOODCOCK. Three years. I don't think we can wait.

Ms. SOLIS. That is what we need to know.

Dr. WOODCOCK. I would be happy to do that.

Ms. SOLIS. And one concern I have, I mean, given that we got this information, I mean, our consumers that were affected by the importation of heparin from China and the detection was so late and unfortunately we had numerous deaths as a result of that. I am very concerned about what we are doing to reach communities, particularly communities of color that speak different languages that may not understand information that is provided by your office. I know that you have a website so people who have Internet access can get that information but for the most part, we have a lot of people including those in my community who don't have access to the Internet and they may not even be able to read at the 12th-grade level the information that you post, and you have been told that you need to lower that level of literacy to the 4th- and—well, the 8th and even 4th-grade level. So I want you to touch on that, and I want to know what you are doing to help provide more information to people of different—that speak different languages, and I am talking right now especially the Hispanic population,

which is the largest ethnic minority and has a tendency to—the first language they speak is Spanish in some cases.

Dr. WOODCOCK. Certainly, I can't agree with you more. This is on the other end of our efforts, which is not—that is sort of prevention, but if something has happened, how do we respond and how do we actually reach out and make sure people are kept safe by using the knowledge, getting the knowledge that we actually have and being able to utilize it. We are working on our early alert system, evaluating translating that into different languages. We write patient-level information that we put on the Internet. But as part of our Safety First and Safe Use Initiative, as we move into our Safe Use Initiative in the Center for Drugs, it is going to involve partnering with healthcare organizations and professional and patient advocacy information to make sure that that handoff works so that what we know, they know, and that they can help provide that information to their group, whatever it might be.

Ms. SOLIS. Would that be an additional cost, then, that you would—I mean, you are going to need funding, I would imagine, some resource to be able to do that, but again, many in our community don't have access—even if you are in rural American, may not have Internet access. So, what kind of plan—is that in your business plan, I would ask?

Dr. WOODCOCK. Well, our business plan is on the other end, which is finding these events and picking that up. This is on our other initiative that has to do with patient safety and drug safety, adverse events and so forth. Certainly we could do more if we had more resources but we do plan to do this. We received additional resources for patient drug safety under the Amendments Act and this is part of our implementation of that.

Ms. SOLIS. What is that budget, by the way?

Dr. WOODCOCK. Well, we received $25 million additional, but to do a very large number of things.

Ms. SOLIS. Can you get back to me with that information?

Dr. WOODCOCK. I would be happy to do that.

Ms. SOLIS. Because I think it is really important to be able to have a rapid response.

Dr. WOODCOCK. I agree with you.

Ms. SOLIS. And you mentioned—well, we talked about inspections and the lack of inspections abroad, and could you tell me if there is any data on how many inspections are conducted for facilities that manufacture brand-name drugs versus generic?

Dr. WOODCOCK. Yes, I have that information and can get it back to you. We have it cut that way.

Ms. SOLIS. Can you just briefly give me an idea of what that is?

Dr. WOODCOCK. I can't right now. There is a higher proportion of the generics have their API sourced in foreign countries and so—and also the pre-approval inspections are supported by user fees for the new drugs. So naturally we are able to get to more of the new drug facilities that are producing those drugs than to the generic drug facilities because we don't have support, as much support for that activity, and a higher number of them are in foreign countries. But it is——

Ms. SOLIS. Doesn't that raise—I mean, for me, that raises a red flag.

Dr. WOODCOCK. Absolutely.

Ms. SOLIS. OK. I will yield back the balance of my time, Mr. Chairman.

Mr. PALLONE. Thank you.

The gentleman, our chairman, Mr. Dingell, is recognized for 5 minutes.

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

Dr. Woodcock, I want to thank you again for your testimony today and for your testimony the other day. Your candor does you great credit as a public servant, and I must say, it comforts me to know that somebody down at Food and Drug is not intimidated and not inhibited in coming up here and telling us the situation as they see it, and I want to commend you for that and thank you.

You and others have mentioned to the Committee a desire to move towards a more risk-based inspection system. We all appreciate the need to focus on areas of greatest concern and risk. However, I am concerned about the ability of FDA to identify facilities that present the highest risk when its information systems are in shambles. So I am concerned about that. I am further concerned that risk-based has become a code for, we don't have adequate resources for proper oversight so we are going to try and only reach the facilities that appear to be most dangerous and not to address all of the areas of concern and not to proceed with the business of FDA in a way which assures that we do not allow things like heparin or other things to take place because they don't fit properly into this, quote, risk-based, close quote, approach. What comments do you have on that?

Dr. WOODCOCK. I agree with you that our current inspectional coverage is inadequate and that the first priority ought to be to improve that coverage. We agree, there is no use doing a risk-based approach if you are only inspecting such a small percentage of the high-risk firms that you are sort of rearranging the deck chairs.

Mr. DINGELL. One of the problems we have had is, that on the basis of pressure from the Office of Management and Budget, the White House, Department of Health and Human Services, FDA has constantly been compelled to come forward to the Congress and say, "oh, we want to go with a risk-based approach," and to say, "oh, we have a new stronger and better way of addressing this for less money, and this goes back, as I have told the Commissioner in this set of hearings, better than 40 years. I have been listening to commissioners of Food and Drug come up here and tell us how we are going to do better with less, and I have found in each instance that that has been a lot of hooey, and my concern is that I don't want to hear people coming in here and telling us the urgent need for risk-based approach, which appears to be just an excuse for doing less with less money, and for allowing matters to fall between the cracks and the public to be put at risk on food, on pharmaceuticals, on devices, and on cosmetics. So how are we to establish a good risk-based mechanism for dealing with these problems, which first of all, doesn't permit the matters to fall between the cracks, which does have proper inspections and other safety mechanisms utilized, but which also doesn't allow important matters and important investigations or inspections to fall between the cracks? How is that to be done?

Dr. WOODCOCK. Well, that is a very challenging question. Obviously doing routine inspections provides a deterrent function. Otherwise people will get——

Mr. DINGELL. And we do need routine inspections, do we not?

Dr. WOODCOCK. Right. Otherwise there is sloppiness that leads to harm and death, and we see that all the time where people just make mistakes and then they manufacture products improperly and then there are the criminal elements that were talked about earlier, and we need to have a strong deterrent function by having a presence. If we are not there, if we are not expected to be there, then of course people will feel free to relax their standards or there would be an opportunity for other types of elements to intrude.

Mr. DINGELL. What I am hearing you say is, you have to continue with the routine inspection system.

Dr. WOODCOCK. We have to.

Mr. DINGELL. You have to continue with other things which are important in terms of dealing with the routine events and that risk-based, if it is to be properly used, has to mean that we are talking about assuring that we put the greatest emphasis on the areas of highest risk but that we do not disregard other areas of concern or the general responsibilities of FDA under the law. Is that correct?

Dr. WOODCOCK. That is correct, and we believe that even the low-risk facilities should believe they are at risk for having an FDA inspection.

Mr. DINGELL. And of course, that cannot be done without adequate resources to the Agency. Now, Doctor, again I want to thank you for your response to Mr. Pallone's questions about the bill. I view those questions as being extremely important to the Committee in terms of addressing the business before you. Can you tell us whether—and I am going to ask you to submit this for the record rather than to say so in our hearing today. Are there additional authorities not in the draft that is before the Committee at this time which in your professional opinion you believe we should consider adding, and would you please submit that to the Committee at your convenience?

Dr. WOODCOCK. I would be delighted to.

Mr. DINGELL. Now, let us look back. We have had bad fish and seafood coming in. We had the heparin disaster. We had the mushroom disaster of time back. We have had problems with people getting sick from leafy green vegetables and strawberries and all kinds of things, and we had the animal food supplement scandal of not long back. We seem to have a succession of scandals, misbehavior, unsafe commodities marketed to the communities and to the people of the United States. How am I not to be concerned and how are you not to be concerned that a similar case or similar cases of contamination of food or pharmaceuticals will not occur in the immediate future?

Dr. WOODCOCK. I am extremely concerned about pharmaceuticals. The world is changing and our ability to assure the quality of the drug supply has become diminished, and we all need to recognize that, and I think heparin is a wake-up call that we are not as able as we were to assure that quality.

Mr. DINGELL. It tells us that that could happen again at any time unless some rather startling changes are made. Isn't that so?

Dr. WOODCOCK. I believe we must act swiftly and decisively.

Mr. DINGELL. Doctor, I thank you.

Mr. Chairman, I thank you for your courtesy.

Mr. PALLONE. Thank you, Mr. Chairman, and that concludes our questions. But I want to thank both of you for being here today. It was very helpful, as was your testimony the other day before the O&I Subcommittee. We appreciate it.

Mr. BUYER. Mr. Chairman?

Mr. PALLONE. Yes?

Mr. BUYER. I will have additional questions to submit for the record for the FDA.

Mr. PALLONE. Absolutely. Any member that would like to submit additional questions to Dr. Woodcock or Dr. Bernstein, feel free to do so.Thank you very much, and we are going to move to the second panel. Now, let me explain that we expect votes about 12:15 so I would like the second panel to come forward. If the votes are called, then we won't complete your opening statements and we will just complete them when we come back and then do the questions as well, but we are going to try to move forward with the second panel and hopefully complete at least the opening statements before we have the votes. So if you could all come forward, please.

As you can see, we have a large number. It is hard to squeeze in but we will do the best we can. Let me welcome all of you and go from my left to right to introduce each of you. First on my left is Dr. William K. Hubbard, senior advisor for the Coalition for a Stronger FDA. And then next to him is Ms. Lori Reilly, who is vice president of policy for PhRMA, the Pharmaceutical Research and Manufacturers of America. And then next to her we have one of our colleagues, Congressman Greenwood, who is now president and CEO of the Biotechnology Industry Organization. Thanks for being here today. And next to Jim Greenwood is Ms. Christine Mundkur, who is chief executive officer of Barr Laboratories. And then we have Mr. Ron Bone, who is senior vice president, distribution support for McKesson Corporation out of San Francisco, California. And then Mr. Kevin Nicholson, who is both a Ph.D. and a lawyer—that is an interesting combination—vice president for pharmacy regulatory affairs for the National Association of Chain Drug Stores. And then the last is Ms. Ami Gadhia, who is policy counsel for the Consumers Union.

Now, as I said before, we have 5-minute opening statements. Those statements become part of the hearing record. Each witness may in the discretion of the Committee submit additional brief and pertinent statements in writing for inclusion in the record, and we will start with Mr. Hubbard.

## STATEMENT OF WILLIAM K. HUBBARD, SENIOR ADVISOR, COALITION FOR A STRONGER FDA

Mr. HUBBARD. Thank you, Mr. Chairman. I have a written statement but I will just make a few opening remarks.

I want to both thank you and commend you for your work on this bill and moving quickly. The committee has well documented the problem so obviously you are moving now into the phase of fixing

it. I think your bill has tremendous potential for addressing these problems.

The way I look at the bill, there are three principles we need to follow in trying to fix this problem. First, we need to strengthen the FDA. The FDA has a very old paradigm for imported drugs with all the responsibilities on the Agency to find the problem at the border, and that needs to be shifted, and I think your bill does that by saying we need to shift more of that to the source of these drugs' origin. We need to give FDA the authority to register these folks and know who is making our drugs, where they are, what they are making, and FDA needs the inspectors, as your bill would provide, to go to these foreign countries. And then of course, FDA needs authority here at the port to be looking at more of these drugs, destroying them if necessary, turning them back or whatever.

But also, I think we need to take into account the fact that pharmaceutical leaders already do a good job in many cases of securing their supply chain, and I think your bill suggests that everyone needs to come up to that there are companies that in the case of heparin, for instance, traced the drug all the way back to the pig, and that is the kind of concept that I think you are looking for with registration and universal identifiers to know where all of these products are coming from. So trying to get the entire industry to follow these leaders, I think, is a worthy goal.

And then lastly, we have got to send a signal to these foreign countries. It is well documented, as Mr. Dingell said, that some of these countries have demonstrated they simply cannot uniformly produce safe products and there is a long stream of examples that I won't go through today. But they need to understand there is a cop on the beat and that FDA will be looking at them, and I think the registration provisions will do that, and letting them know that when you do find a bad drug, it is going to get turned back or destroyed, and having that presence by FDA in these countries I think will be tremendous, which, as you know, does not exist now.

So I think, Mr. Chairman, your bill is a historic opportunity to fix these problems and I wish you well in the endeavor. There is one point I would raise some concerns about though and that is these user fees. The reliance on user fees I believe is a problem. There has been a disconcerting trend that the existing user fees have shifted appropriate dollars out of FDA and there have been programs that have been simply lost I believe because of the user fee program. So I am concerned about that continuing if the Agency is funded more and more by user fees. While some of the fees like requiring a foreign firm to pay a fee to register, I think that is good because, first of all, you are going to be assured of where they are, and second, you may actually give some disincentives to some people that don't know what they are doing to get out of the business, which would be a good thing.

But all in all, we as taxpayers pay about a penny and a half a year for the FDA, and I think if you polled people, they would say they would be more than willing to pay 2 or 3 cents a day for safe and effective food and drug supply. So I certainly would encourage you to also find ways to increase FDA's appropriations rather than keep moving more and more toward user fees.

With that, I thank you.

[The prepared statement of Mr. Hubbard follows:]

## STATEMENT OF WILLIAM K. HUBBARD

### INTRODUCTION

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. Today, I serve as an advisor to The Alliance for a Stronger FDA, a consortium of patient, public interest, and industry organizations whose mission is to urge that FDA's appropriations be increased. The Alliance and its constituent members are greatly concerned that FDA's resource limitations have hampered the Agency's ability to ensure the safety of our food and drug supply. Today's hearing is focused on proposed solutions to the ever increasing numbers of drugs and medical devices being imported into the United States. I will focus my comments on pharmaceuticals, but many of those comments would apply as well to medical devices.

### BACKGROUND

As you know, Congress created the current regulatory structure for assuring the safety of human drugs in 1938, through its enactment of the Food, Drug and Cosmetic Act. That statute recognized that drugs could be a key component of our health care system, but that drugs were also powerful chemicals with the capability to produce great harm if not carefully regulated. Thus, Congress determined it necessary to create a relatively pervasive regulatory system, which has served us well. Under that construct, American patients have access to safe and effective new drugs as fast or faster than anywhere else in the world, and FDA is widely recognized internationally as the "gold standard" for pharmaceutical regulation. FDA is also tasked with assuring that a drug, once approved for marketing, is actually the same compound that is manufactured and is of consistently high quality. To do that, FDA requires that a drug be manufactured under specific controls mandated by the Agency—known as Good Manufacturing Practices (GMPs). These include requirements that active ingredients of the drug be of a prescribed purity, strength and quality; that the drug be made in well-controlled, sanitary conditions; that its labeling and packaging be equally well controlled; and that laboratory tests of the drug be performed routinely using well established scientific methods and properly calibrated equipment to confirm that the drug is always produced in the form approved by the FDA.

Those controls have resulted in a remarkable record of success for American pharmaceuticals. The U.S. manufacturers of our drugs agree with the need for such strict controls and take great care to implement them faithfully. Accordingly, FDA inspectors generally find adherence to GMPs when they examine a U.S. drug manufacturing facility, and the occurrence of injuries and deaths from improper drug manufacturing in this country is rare.

### THE GLOBAL SITUATION

The portrait of pharmaceuticals elsewhere around the world is not so positive. Drugs developed and produced in other countries do not always have the same record of therapeutic success as American pharmaceuticals. But perhaps more importantly, drugs made in other countries—particularly less developed nations—are often purchased from suppliers who have little or no oversight by regulatory bodies; where key elements of safe drug production are ignored—such as quality testing, expiration dating, and labeling controls; and where producers of substandard and counterfeit drugs have a relatively easy access to the marketplace.

In recent years, this Committee has documented numerous reasons for concern about drugs made offshore:

- 80% of our domestic drug supply is now comprised of ingredients produced in other countries, and increasingly those are less developed nations such as China and India.
- FDA has the capability to inspect only a small percentage of foreign drug manufacturing facilities, and inspection rates of drugs arriving at U.S. ports are equally dismal.

• Deaths and injuries from compounds made overseas are seemingly more and more common—from antifreeze substituted for glycerin, melamine in pet food, antibiotics that don't effectively treat bacterial infections, and, of course, most recently, heparin contaminated with chondroitin.

• Counterfeiting of drugs is increasingly common in many countries, and has been steadily growing in the United States. The World Health Organization has reported that in some areas of the world, particularly parts of Africa and Asia, more than one-half of the pharmaceutical supply is counterfeit. Indeed, drug counterfeiting is considered to be endemic around the world, with China alleged to be a principle world supplier of such products.

## FDA AND IMPORTED DRUGS—NEED FOR A NEW PARADIGM

At a time in which drug safety problems overseas have become more and more prevalent, the FDA has simply not been able to keep up. While it can continue to ensure that drugs made in United States meet our high safety standards, the Agency is not positioned and funded to assure the safety of imported drugs. FDA is asked to regulate these products with a law that was enacted 70 years ago—at a time in which there were few drugs being made anywhere in the world, and none being imported into the United States. The system created in 1938, with origins dating all the way to the turn of the last century, authorized FDA to examine imported drugs at the border and refuse entry to any drug that "appeared" to be unsatisfactory. Thus, the law placed the responsibility on the FDA to catch a problem and stop the drug's entry into our country, as opposed to asking the foreign manufacturer to demonstrate that they were taking care to follow established standards for drug production. So, while domestic drug manufacturers are held to a high standard of drug safety, with regular GMP inspections, foreign producers often need worry only about the remote possibility that an FDA inspector at a border crossing will find a problem and stop the drug's entry. Moreover, a domestic drug manufacturer using foreign ingredients can adhere to strict quality control procedures, yet be victimized by a contaminated ingredient that was unsuspected.

More specifically, we have failed to provide FDA with the appropriations and other tools it needs to carry out the mission we have assigned to them, such as:

• Staff to conduct regular inspections in foreign facilities as are now done for domestic manufacturing plants. The Food, Drug and Cosmetic Act dictates that each U.S. drug manufacturer be inspected at least every 2 years, but the current rate of foreign inspections is infrequent at best. Thus, we are buying ever larger percentages of our drug ingredients from producers in developing countries who receive virtually no FDA inspection, despite a congressional determination that domestic manufacturers be inspected regularly.

• Modern IT systems that would allow FDA to effectively track and monitor the production and movement of imports. The import data system is so old and communicates so poorly with other FDA information systems that it is difficult for FDA officials to use risk as a predominant driver of their compliance;

• Registration procedures for foreign drug manufacturing that would allow us to know who is making drugs for our market, where they are located, and what they are manufacturing; and

• Port inspectors to examine the almost 20 million annual shipments of foods, drugs, and other products that FDA is expected to regulation. For over 400 ports of entry, FDA has only 450 inspectors, meaning that most ports aren't staffed at all and many can be staffed only part time.

## THE HEPARIN EXAMPLE

We are, of course, especially mindful today of the recent deaths from contaminated heparin. It is, sadly, a realistic example of the problem FDA faces in assuring the safety of imported drugs. Indeed, I believe one could use the well worn cliche of a "perfect storm" in describing the conditions upon which the heparin incident unfolded —initial extraction of heparin on pig farms that have been described as "primitive," no regulation by authorities in the producing country, no FDA inspection of the heparin exporter's manufacturing facility, and violative conditions found by FDA in the manufacturing facility when subsequently inspected. When you add to that the technical capability of chemists to modify and substitute chondroitin for heparin, the resulting profit margin by using cheaper ingredients, the low risk of being caught substituting another ingredient, and the even more remote likelihood of being punished by U.S. authorities, one could accurately conclude that there was highly fertile ground upon which this could occur.

But the heparin case also demonstrates FDA's inherent weaknesses in its ability to adequately oversee foreign drug production. The facility in China had not been

inspected by FDA, the suppliers of raw material to that facility were not registered with the FDA, and the Agency's IT systems were not up to the task of identifying and tracking the facilities in China and the movements of their products. In sum, the FDA's poor capabilities, in my view, contributed to the likelihood that a counterfeiter could feel emboldened to substitute the chondroitin with relatively little fear of regulatory action by the United States.

WHAT MUST BE FIXED

We must find a way forward to ensure that drugs made with foreign ingredients meet the same high standards as those of fully domestic origin, by assuring the enforcement of the rules that govern drug production and the promulgation of needed new rules. It does no good to have rules if they are not obeyed, no good to set high standards if they are not used, and no good to develop advanced scientific skills if they are not employed. That some less developed countries have a record of serious problems in drug manufacturing is indisputable. And the disparity in drug inspections—in which FDA inspects U.S. facilities regularly and those in China and India almost never—is indefensible.

Some would say that we should not be buying products such as drugs from developing nations, but that flies in the face of the reality of global free trade. Others would rely upon agreements negotiated with foreign countries, under which those nations would assure the safety of drugs exported to the United States. I believe that a developing country without a strong counterpart to the FDA is incapable of effectively implementing such an agreement, and that such a course of action is a prescription for frustration. In the end, I believe we must rely upon what we know has worked in the past to protect our drug supply—rigorous control of pharmaceuticals within a system closed to unregulated and unscrupulous suppliers and overseen by a strong FDA.

I believe that there are three main principles to be considered in correcting the imbalance between the strong safety oversight of US-produced pharmaceuticals and medical devices and those made overseas:

1) FDA's statutory construct must be changed to take into account the globalization of drug and devices. As you know, the current version of the Food, Drug and Cosmetic Act places much of the burden for assuring the safety of imported drugs onto the FDA and at the point of entry—the border ports. That paradigm is outdated in a world that is far more globalized today, and more of the responsibility needs to be shifted to the source of production—to preventing problems from occurring rather than relying on FDA to find them at the border. FDA also needs to know that imports are equally important in the development of policy and the allocation of resources as domestic programs. Your proposal, if enacted, would make that point in several ways—by requiring the same frequency of inspection for foreign and domestic manufacturing facilities; allocating new resources for foreign inspections; creating a foreign inspectorate dedicated to overseeing manufacturing in exporting countries; giving FDA the information it needs about who is making these products and where they are located; and strengthening inspection of these products when the arrive at our borders with new powers to detain, destroy or recall drugs and devices that are deemed to be dangerous.

While inspections are not the only solution to these problems, they are an absolutely necessary piece. It is particularly important that we place a focus on drugs and devices made in countries without a history of safe manufacturing and internal regulation. Without GMP inspections in less developed nations, we essentially have no oversight of those manufacturers. A GMP inspection is far more than just a snapshot of that facility the day the inspector arrives. It is a detailed survey of how that plant has been operating for months, which allows a realistic conclusion about whether that facility can and does follow accepted drug production procedures. Relying on testing by the FDA or the U.S. drug company that receives the foreign ingredients is not a substitute for examining the source of production.

Your proposed creation of a dedicated foreign inspectorate will go far in ensuring that the inspection requirement can be successful. Currently, FDA must utilize its domestic inspection force to travel overseas to conduct inspections. That practice is expensive and often a hardship on inspectors. The agency needs to recruit an inspection force that is hired and trained to do foreign inspections, and many will need to be housed in the countries with the greatest number of manufacturing facilities.

2) Build upon the best practices many U.S. firms already use in securing their supply chain. Supply chain integrity is increasingly a watch word among leading pharmaceutical manufacturers. The most advanced firms today have contractual arrangements with suppliers that require strict conformance to quality control procedures, and insistence that every party to their supply chain be known to them and

of sufficient technical competence. And those firms regularly inspect and monitor the performance of their suppliers, as well as test ingredients for purity, stability and other necessary qualities. I believe that your bill will reinforce the commitment of those firms already utilizing such practices and should encourage others to join in them. For example, the bill would ease entry into the United States of drugs and drug ingredients that can document compliance with applicable FDA drug safety requirements. Further, it will provide for additional contaminant testing which, in the light of the heparin injuries, will be a necessary part of a strengthened system of import controls.

3) Send a message to foreign manufacturers and their nations' governments that the focus of regulation will shift from FDA's border inspection of drugs to the conditions in the overseas manufacturing facilities. In the past, there have been relatively few incentives for foreign manufacturers to be assertive in protecting exported drugs and devices from contamination or other violations of FDA drug safety standards. Indeed, some contend that the current system—of placing most of the burden for catching unsafe drugs onto the FDA—has comprised a disincentive, thus indirectly encouraging ingredient substitution and other cost saving "short cuts." Your bill will start an important shift toward expecting exporters to take greater care in manufacturing drugs for our market—by requiring all foreign producers to declare their identity and location, by permitting FDA to suspend a facility's registration if it impedes an FDA inspector's ability to carry out his duties, by ensuring parity among U.S. and foreign drug inspections, by encouraging certification and other evidence of quality controls on the part of foreign drug facilities, by requiring foreign drug manufacturers to pay facility registration fees that mostly been limited in the past to American facilities, by ensuring that violative drug imports are more likely in the future to be either detained or destroyed if found at U.S. ports, and by requiring contaminant testing of drug ingredients before they leave the exporting country.

## ADDITIONAL CONSIDERATIONS

While I believe that your bill contains most of the elements that FDA's scientists would like to have instituted for a safer drug import system, there are two additional considerations that I would urge you to include:

- Appropriated funds to strengthen the FDA. Your bill includes user fees to pay for more FDA oversight. Such fees are reasonable for facility registration, as domestic manufacturers must now pay such a fee, and bringing foreign facilities on par would be a logical addition. Plus, fees could have the complementary effect of driving from pharmaceutical manufacturing business some inadequate foreign facilities for which registration would trigger an eventual inspection. However, I am skeptical that user fees are the solution to FDA's funding problems, as budget officials have tended in recent years to shift agency funding from appropriated dollars to user fees, leaving the Agency with little or no net gain. Indeed, some programs, such as food safety and FDA's inspection corps, have absorbed large staff cuts over the past decade, and I believe those cuts are largely attributable to the fact that other parts of FDA were receiving new funding from user fees (for drug and device application review). We, as American taxpayers, today spend only 1-and-a-half cents per day on the FDA. I believe the vast majority of our citizens would gladly pay 2 or 3 cents a day for an effective FDA that can vigorously protect our food and drug supply.
- A commitment to information technology improvements. As your Oversight and Investigations Subcommittee, the GAO, and FDA's Science Board have all documented, FDA's inadequate IT systems are a fundamental lag on the Agency's ability to improve its import program. I urge you to make IT enhancements a key goal of your legislation, even if that is achieved merely by a sense of the Congress statement about your expectations for IT begin the process of improving our coverage of imports. The IT systems should be configured in a way that allows the Agency to use a myriad of risk factors, including potential impact on the public health, to direct its inspectional and import efforts. The Science Board recommends increased appropriations of $800 million for FDA's overall IT needs, so there is a long way to go if FDA is to have state-of-the-art information systems, but we could at least start with funding an effective import information system.

In conclusion, I believe FDA's scientists and regulatory officials are nothing short of terrific. They are well trained, intensely dedicated to the public health, and a true bargain for the American taxpayer. But they have been handed a task—an expectation—that they realistically cannot fulfill with their current resources. History has shown that when FDA is given the resources and tools it needs to be effective, it will perform well and in doing so protect the health of those who depend every day on this critical agency.

Thank you for inviting me to give my views on this subject.

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Mr. PALLONE. Thank you, and thank you for keeping well within the 5 minutes.

Ms. Reilly.

**STATEMENT OF LORI REILLY, VICE PRESIDENT OF POLICY, THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA**

Ms. REILLY. Thank you for the opportunity to be here today and testify. I am Lori Reilly, vice president for policy and research at PhRMA. I am here today on behalf of Billy Tauzin, our chairman and president, who apologizes for not being able to be here himself. This is an issue that he is extremely passionate about and wanted to offer his thoughts in terms of commending the Committee in looking at this important issue. I think we share your goals in ensuring a safe and effective pharmaceutical drug supply.

The work of this committee over many years has helped to ensure the safety of the prescription drug supply, going back to the 1980s and the extensive investigative work this committee did that led up to the Prescription Drug Marketing Act, which closed the current drug supply system to drugs that had circulated outside the jurisdiction of the FDA, outside the control of the manufacturer, and this was as a result of counterfeit drugs that had proliferated inside the United States, and we applaud the Committee for that work and its interest in taking additional steps to secure the supply chain.

As Dr. Woodcock testified earlier, the current regulatory system in this country is built on good manufacturing practices and the notion that you need to build quality into every element of the product, and our companies do that. They abide by GMP requirements. They often go way above and beyond those requirements by having their own systems, vendor qualification programs, vendor audit programs. In fact, one of our companies testified just last week before the Senate about the extensive amount of additional resources they spend to ensure the suppliers they use meet these very stringent requirements.

As stated previously though, this comprehensive system, while excellent and arguably the safest in the world, there is always room for improvement, even with the very best systems, and once again, we commend the Committee for looking at opportunities to further strengthen the system.

In response to concerns regarding the rate and extent to which FDA is currently conducting inspections, I am pleased to offer several ideas for consideration as you continue to work on the discussion draft as well as our own comments on the draft that has been put forward to date.

Previous congressional testimony has revealed a great disparity in the number of foreign facilities that exist and thus are subject to FDA inspections. In addition, concerns have been raised about the interoperability of the Agency's databases for tracking and monitoring foreign establishments. We agree with the Committee that foreign establishments should and need to be registered with FDA to the extent they are already not required to do so by law,

and we also agree we need a better accounting of what those facilities are and where they are located. Having a more accurate picture of the number of facilities that exist abroad in a single database will allow the Agency to ensure that inspections are occurring on a more timely basis.

With respect to funding, the committee draft, specifically section 201 of the draft bill, sets up a new annual registration fee for the purpose of defraying costs of inspecting establishments registered with the FDA. We believe a strong, well-funded FDA is critical to the health and safety of American patients and we, along with other stakeholders, have been supportive of increased funding for the FDA. We have lobbied Congress as a part of a coalition to argue for increased appropriations so that FDA has the needed resources to meet its many mandates.

We have also supported user fees for other purposes. For example, PhRMA endorsed user fees as part of the PDUFA program, and in general we believe they have worked well. With regard to whether user fees are appropriate in this instance, we still have some outstanding questions that we would like to work with the Committee on in the future, for example, what the amount of any user fee may be, whether there will be a cap on such user fees, what FDA can specifically use these resources for, what performance measures will exist for the FDA, whether the fees will have a sunset date and whether there is any link to appropriated funds. Moreover, we believe, as others have stated previously today, that any new user fees should not supplant appropriations and should support specific identified FDA activities. And as stated previously, we believe that the Agency is currently underfunded and we would love to work with the Committee and Congress to address this issue as well.

With regards to enhancements to FDA's current inspection regime, sections 202, 403 and 404 of the discussion draft set out targeted reforms to the FDA's current inspection regime, including a 2-year interval for foreign inspections as well as a requirement for initial facility inspection before a product can be offered in the United States. We agree with the Committee that FDA should increase its inspections of foreign facilities. The FDA currently has broad authority to conduct inspections of domestic and foreign establishments and we recommend that FDA increase its GMP inspections of foreign facilities, including API facilities.

In addition, we support the Committee's recommendation that would require FDA to establish and maintain a core of inspectors dedicated to inspections of foreign facilities. The current discussion draft, as I said, requires those inspections to occur at least once every 2 years, which would be consistent with FDA's current mandate for domestic establishments. While we believe it is a laudable goal, it is important to recognize that it will take time. As we heard from Dr. Woodcock this morning, training of inspectors alone could take anywhere from 3 to 4 years. So it will take time to get individuals up to speed and allocated to do this. Therefore, we believe Congress should give FDA flexibility to develop a risk-based approach to efficiently use its resources to prioritize foreign establishments for inspections, particularly in light of the practical realities regarding the time it will take to establish an enhanced FDA pro-

gram. In our view, categorizing and prioritizing FDA inspections of foreign establishments based on the risk they present, looking at such criteria as time since last inspection, their compliance history and type of product produced, geographic location and volume of product import will enhance their ability to target their inspection resources more efficiently.

Given the reality that the Agency——

Mr. PALLONE. Ms. Reilly, I hate to interrupt because I like that you are being very specific about the bill, but you are over a minute, so you have to wrap up.

Ms. REILLY. I will wrap up, and let me do that by briefly mentioning the legislation offered by Congressmen Buyer and Matheson, and again, we applaud the leadership that they have taken on the issue and the tireless efforts they have gone to in trying to work with all stakeholders on the bill. We appreciate their thoughtful approach, and we look forward to working with them further on this bill.

Again, I thank you for the opportunity to be here today and look forward to your questions.

[The prepared statement of Ms. Reilly follows:]

**BILLY TAUZIN**
**PRESIDENT AND CHIEF EXECUTIVE OFFICER**
**PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA**

**BEFORE THE**
**U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE**
**SUBCOMMITTEE ON HEALTH**

**HEARING ON THE DRUG AND DEVICE PROVISIONS OF THE "FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT"**

**SUBCOMMITTEE ON HEALTH**
**MAY 1, 2008**

Mr. Chairman, Ranking Member and Distinguished Members of the Committee:

Thank you for the opportunity to participate in today's hearing on the drug provisions of the "Food and Drug Administration Globalization Act of 2008." I am Lori Reilly, Vice President of Policy & Research at the Pharmaceutical Research and Manufacturers of America (PhRMA), and I am testifying on behalf of Billy Tauzin, PhRMA's President and Chief Executive Officer. PhRMA is the nation's leading trade association representing the research-based pharmaceutical and biotechnology companies that are devoted to inventing new, life-saving medicines that help patients achieve longer, healthier, more productive lives.

In 2007, America's biopharmaceutical research companies invested an estimated record $58.8 billion in research and development. PhRMA members alone invested an estimated $44.5 billion in 2007 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 they and their loved ones take meet the high standards set by the Food and Drug Administration (FDA) for safety and efficacy and are not substandard or

counterfeit, and they rely on our complex and comprehensive regulatory system to ensure that is the case. Patients also depend on a secure pharmaceutical supply chain, and this is a responsibility our companies share with the FDA. The increasing globalization of the pharmaceutical supply chain presents new challenges that require us and the FDA to be more adaptive and flexible in our oversight of entities located around the world. The lifeblood of America's research-based pharmaceutical companies is dependent on a safe, secure prescription drug supply chain and that is why our companies go to great lengths to help assure the quality, safety and integrity of materials used from third party sources in our finished products. This is also one of the reasons PhRMA has urged Congress to increase appropriations to FDA. A strong, well-funded FDA is critical to the health and safety of the American public, both for the purposes of helping to assure the safety, effectiveness and availability of medicines and to help ensure continued access to innovative new therapies for American patients.

Today, my testimony will focus on the current regulatory structure governing prescription drugs sold in the U.S., including a discussion of the importance of quality systems and the Good Manufacturing Practice (GMP) requirements applicable to drugs, which are the gold standard for pharmaceutical manufacturing worldwide. Next, I will briefly discuss the application of GMPs to active pharmaceutical ingredients, and describe additional mechanisms to help assure the quality, safety, and integrity of prescription drugs marketed in the U.S. Third, I will discuss PhRMA's concepts to help preserve the continued safety and security of our nation's prescription drug supply and how those concepts are reflected in the recent "Food and Drug Administration Globalization Act of 2008" discussion draft. Finally, I will offer initial thoughts on H.R.

5839, the "Safeguarding America's Pharmaceuticals Act of 2008," which was recently introduced by Reps. Buyer and Matheson.

## I. Current Regulatory Structure Governing Prescription Drugs in the U.S.

The regulatory system that governs the development, approval, marketing, and surveillance of new drugs in the United States is the most complex and comprehensive in the world. To ensure that Americans have the safest drug supply in the world, it has become increasingly comprehensive and robust over time. As far back as 1938, the Federal Food, Drug, and Cosmetic Act (FDCA)[1] — which remains in place today — prohibited the marketing of any drug not shown to be "safe for use under the conditions prescribed, recommended, or suggested" in its labeling.[2] In 1962, FDA obtained explicit authority to demand proof that a drug is effective and to prescribe the tests that a manufacturer must perform before its product can be approved for marketing.[3]

Since that time, several amendments have expanded, strengthened, and refined the FDA regulatory scheme.[4] These include the Prescription Drug Marketing Act of 1987 (PDMA), authored principally by Reps. Dingell and Waxman. Under the PDMA, which Congress passed following an investigation of incidents of counterfeit drugs reaching American consumers, closed the U.S. prescription drug supply to products that

1 Pub. L. No. 75-717, 52 Stat 1040 (1938).

2 21 U.S.C. § 355(d)(1).

3 Pub. L No. 87-781, 76 Stat 780 (1962), codified at 21 U.S.C. § 355(d)(5).

4 See, e.g., the Durham-Humphrey Act, Pub. L. No. 82-215, 65 Stat. 648 (1951) (concerning prescription requirement); the Drug Listing Act of 1972, Pub. L. No. 92-387, 86 Stat. 559 (1972); the Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (subsequently amended); the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984); the Drug Export Amendments of 1986, Pub. L. No. 99-660, 100 Stat. 3743 (1986), the Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1988) (subsequently amended); the Generic Drug Enforcement Act of 1992, Pub. L. No. 102-282, 106 Stat. 149 (1992); and the Prescription Drug User Fee Act, Pub. L. No. 102-571, 106 Stat. 4491 (1992).

have circulated overseas, beyond the jurisdiction of FDA and outside the control of the manufacturer. The PDMA, coupled with exacting FDA regulatory requirements such as GMPs, has helped significantly minimize the possibility that a consumer receives a counterfeit drug.

### A. Quality Systems and Good Manufacturing Practices: The FDA's "Gold Standard" for Pharmaceutical Manufacturing

As a consequence of this comprehensive framework, FDA currently regulates virtually every stage in the life of a prescription medicine sold in the U.S., from pre-clinical testing in animals and human clinical trials before the medicine can be marketed, to manufacturing, labeling, packaging, and advertising when the drug is marketed, to monitoring actual experience with the drug after its sale to consumers.

More specifically, manufacturers of pharmaceuticals sold legally in the U.S. must comply with the "gold standard" of quality manufacturing – FDA's GMP regulations. The GMP regulations are applicable to all pharmaceuticals sold in the U.S., wherever they are made, and extend to all components of a finished drug product, including active pharmaceutical ingredients (APIs), without regard to where those ingredients are sourced. These regulations are extensive and thorough and require manufacturers to build quality into the design and production of pharmaceuticals, thereby helping to assure the safety, integrity and quality of every product approved and sold in the U.S. from the outset. Pharmaceutical manufacturers employ extensive quality systems and take extraordinary measures to secure the supply chain throughout the life cycle of the product since any loophole or breakdown in the pharmaceutical distribution system may provide an opportunity for diversion or counterfeiting to occur.

FDA's GMP regulations are based on the fundamental quality assurance principle that quality, safety and effectiveness "cannot be inspected or tested into a finished product," but instead must be designed and built into a product.[5] While FDA inspections are an important part of FDA's regulatory authority and oversight, GMPs represent a comprehensive, systems-based approach that requires a company to build quality directly into the entire manufacturing operation, in order to ensure that the process itself is under control and therefore will consistently produce a drug product that meets designated specifications. No amount of FDA inspections or testing by itself can assure the safety, integrity or quality of a finished drug product. Instead, inspections are one important mechanism for FDA to verify that pharmaceutical manufacturers have in place adequate quality systems and are complying with GMP requirements.

At their core, FDA's GMPs require that each manufacturer have in place a quality control unit that has the responsibility and authority to approve or reject all raw materials, packaging materials, labels, and pharmaceutical ingredients. As FDA has noted, "[i]mplementing comprehensive quality systems can help manufacturers to achieve compliance with" FDA's GMP requirements.[6] These requirements touch on all aspects related to the manufacture of a pharmaceutical product, including, in addition to the requirement to establish and maintain a quality control unit:

- **Design and Construction Features.** Buildings and facilities used in the manufacture, processing, packing, or holding of drug products or intermediates should be of suitable design, size, construction and location to facilitate cleaning, maintenance, and proper operations.

[5] 61 Fed. Reg. 20104, 20105 (May 3, 1996).
[6] FDA, Draft "Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations," Sept. 2006, at 3.

- **Processing Equipment.** Manufacturers must assure the adequacy of manufacturing equipment design, size, and location; equipment construction and installation; equipment cleaning and maintenance procedures; and equipment cleaning methods.

- **Control of Ingredients.** Manufacturers must maintain and update as appropriate detailed written procedures that describe the purchase, receipt, identification, quarantine, storage, handling, sampling, testing, and approval or rejection of raw materials.

    - Upon receipt and before acceptance, each container or grouping of containers of raw materials must be examined visually for appropriate labeling, container damage, seal integrity (where appropriate), and contamination.

    - Representative samples of each shipment of each lot must be collected for testing or examination in accordance with an established procedure.

- **Production and Process Controls.** Manufacturers establish and follow written production procedures to help assure that pharmaceutical ingredients and intermediates exhibit the appropriate quality and purity.

- **Packaging and Labeling Controls.** Manufacturers must establish and follow written procedures describing the receipt, preparation, identification, storage, handling, sampling, examination, and testing of pharmaceutical labeling and packaging materials. These materials must be representatively sampled and examined or tested before use.

- **Laboratory Controls.** Manufacturers must implement procedures to determine compliance with specifications for the acceptance of each lot of raw materials, containers, intermediates, and ingredients. Manufacturers must conduct tests on each lot of pharmaceutical ingredients or intermediates to determine satisfactory conformance to established quality specifications and lack of objectionable microorganisms.

- **Batch Records.** Any production, control, or distribution record associated with a batch of active ingredient or finished medicine must be retained for at least one year after the expiration date of the batch and available for FDA inspection.

- **Distribution and Complaint Files.** Manufacturers must keep distribution records of the person to whom they shipped the finished product, date, quantity shipped, and lot number. Manufacturers must establish and follow written procedures describing the handling and retention of all complaints and investigations involving the possible failure of a product to meet any of its specifications.

- **Manufacturing Process Validation.** A manufacturer must establish and follow a detailed written program for assuring that its specific manufacturing process is capable of performing in a consistent manner and results in a homogeneous product that consistently meets predetermined specifications. This involves creation of a protocol that outlines all manufacturing steps, equipment, sampling, and acceptance criteria.

- **Change Control.** To provide for ongoing manufacturing improvements, a formal system must be established to evaluate and approve proposed changes to specifications, test procedures, raw materials, facilities, equipment, processing, and packaging materials.

- **Control of Contaminants.** Manufacturers must implement written procedures to prevent chemical, biological, and physical contamination, including cross-contamination in ingredients and intermediates.[7]

### B. Active Pharmaceutical Ingredients and GMPs

As stated above, FDA's comprehensive regulations are designed to help assure the safety and efficacy of pharmaceutical products in the U.S. These requirements extend to all components of a finished drug product, including bulk APIs, which are the ingredients used in prescription drug products that give a drug its pharmacological effect.[8] APIs may be sourced domestically or in foreign countries and subsequently used in the manufacture of a finished drug product sold in the U.S. Recent news stories have focused attention on the use of APIs that are produced in countries such as China and India and then used to manufacture finished prescription drug products sold domestically. To be clear, APIs are considered "drugs" by FDA, and as such, are also subject to FDA's GMP requirements, similar to finished pharmaceuticals.[9] FDA's expectations for APIs include:

- Personnel, facility and equipment requirements;
- Control of raw materials, including visual examination and sample testing to verify the identity of each raw material;
- Performance of appropriate laboratory tests on each lot of active pharmaceutical ingredients to determine conformance to established specifications;
- Microbiological testing as appropriate;
- Establishment and testing against impurity profiles;
- Stability testing;
- Retention of samples representative of each lot;
- Validation of manufacturing processes;

[7] See generally, 21 C.F.R. Parts 210 and 211.
[8] FDA defines API as "any component that provides pharmacological activity or other...effect in the diagnosis, cure, mitigation, treatment of prevention of disease, or to affect...structure or any function of the body of man or animals."
[9] 21 U.S.C. § 321(g).

- Packaging, labeling and storage controls;
- Retention of applicable production, control, or distribution records; and
- Detailed written procedures addressing all aspects of the production of active pharmaceutical ingredients, and to analyze the impact of any changes to the process.[10]

Pharmaceutical companies are ultimately responsible for the testing and validation of the safety, purity and consistency of APIs used in the manufacturing of finished drug products. Manufacturers are required to disclose the source of the API used in their applications for drug approval submitted to the FDA. Many companies often choose to employ vendor qualification programs to audit potential suppliers prior to engaging in transactions with an API supplier. The Agency also has authority to inspect domestic and foreign API manufacturing facilities, and conducts those inspections either directly or through inspection of finished product manufacturers.

In sum, pharmaceutical manufacturers comply with rigorous controls over all aspects of the pharmaceutical manufacturing process – known as GMPs – which are recognized world-wide as the "gold standard" for pharmaceutical manufacturing. The complex and comprehensive GMP provisions help assure that raw materials and components used in the manufacture of prescription drugs are safe, pure and potent, without regard to where they are sourced, and help to assure that a quality product is produced every time.

## II. Preserving and Improving the Safety and Security of our Nation's Prescription Drug Supply

[10] FDA, Draft "Guidance for Industry: Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients," March 1998.

The prescription drug supply system in the U.S. is extremely safe and arguably the best and safest in the world. And, while a great deal of recent attention has been placed on the rate of FDA's foreign inspections, it goes without saying that while extremely important, FDA inspections of domestic and regulatory facilities manufacturing pharmaceutical products are just one important piece to helping assure the quality, safety, efficacy, and integrity of the prescription drugs Americans take. Other key pieces include the establishment of quality systems and adherence to FDA's GMP requirements, as described above, as well as postmarket surveillance activities, including adverse event reporting, recordkeeping and reporting obligations, and prescription drug establishment registrations and product listings. All of these activities are part of the FDA's comprehensive system designed to help assure the safety of prescription drug products in the U.S. Each component in this system plays an important and critical role and the importance of the entire system – and each component in that system -- should be recognized in any policy debate.

Even with FDA's comprehensive regulatory system, there is evidence that additional safeguards could be added to the already robust U.S. drug regulatory and oversight system to help ensure that American consumers are adequately protected. In order to preserve the safety and integrity of our country's drug supply, Congress could consider several additional measures or safeguards, which I will outline below.

Before I do so, however, I want to reiterate the importance of protecting and preserving the sanctity of the current prescription drug supply chain. While this hearing and the legislation that is the subject of this hearing focuses primarily on issues related to FDA's foreign inspections capabilities, a key component of any safe system is a

secure supply chain. As such, one basic element to preserve the safety of our country's drug supply is maintenance of a closed distribution system. Our current system is by and large a "closed" distribution system and even with such a system, from time to time counterfeit and tainted products surface, and the public health could be placed at risk. Domestic challenges thus remain great. These challenges would, however, be multiplied exponentially by the added complexities and burdens of an expanded international supply of drugs from various wholesalers and pharmacies. In fact, the European Commission recently reported the seizure of a total of more than 2.7 million medicinal products (articles) at EU customs borders in 2006. This is an increase of 384% compared to 2005.[11] As such, Congress should reject proposals, such as proposals to legalize prescription drug importation, which would further strain and compromise the FDA's ability to protect Americans from potentially dangerous counterfeit medicines and maintain the current "closed" distribution system.

In response to concerns regarding the rate and extent to which FDA is currently conducting inspections of foreign drug establishments, PhRMA is pleased to offer the following ideas for consideration as Congress examines this important issue. At the outset, let me make clear that PhRMA member companies are used to and comfortable undergoing FDA inspections. Rather, PhRMA offers the following ideas to help all of us gain a greater understanding of the scope of foreign entities manufacturing products and components destined for sale in the U.S., and to help increase FDA oversight of such activities occurring beyond our borders while at the same time not weakening our

[11] http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/counterf_comm_2006_en.pdf

existing regulatory system, which is the strongest in the world. The draft includes several proposals to modify FDA's inspection and oversight of drug products introduced into U.S. commerce. PhRMA also has proposals to respond to concerns underlying the modifications suggested in the draft bill. Included below is a comparison between the current discussion draft and our proposals.

*A. Formal Assessment and Establishment Registration*

Congressional testimony has revealed a great deal of disparity in the number of foreign facilities that exist and thus are subject to FDA inspections. Further, concern has been expressed about the interoperability of the Agency's databases for tracking and monitoring foreign establishments and their inspection outcomes. In order to appropriately address these concerns, we propose two ideas: (1) a formal assessment of and recommendations regarding the rate and frequency of FDA foreign inspections, and (2) registration with FDA for all foreign facilities, to the extent such entities are not required to do so under current law.

GAO (or a similar entity) should be asked: (a) to assess the number of foreign facilities and the adequacy of the FDA's current information technology systems to track those facilities; (b) make recommendations regarding the appropriate frequency of inspection for foreign facilities manufacturing products destined for U.S. markets; (c) make recommendations regarding resources and staffing needed to improve FDA's information technology infrastructure, and (d) make recommendations regarding the number of FDA inspectors necessary to conduct the recommended number of FDA foreign inspections. We understand that parts of this study may be underway by GAO.

PhRMA agrees with the concept that all foreign establishments manufacturing products or components destined for import into the U.S. should be directed to register with FDA and list their products, to the extent they are not already required to do so under current law. By requiring such facilities to register, the FDA will be able to establish a single database that will contain information on all facilities that manufacture products or components of products that are sold in the U.S. This will allow the FDA to ensure that foreign inspections are occurring on a regular basis. While such information reportedly exists, Congressional testimony suggests that it appears in several different formats and databases managed by FDA, and, therefore, it is not easily accessible by Agency personnel.

*B. Funding Mechanisms*

A strong, well-funded FDA is critical to the health and safety of the American public, both for the purposes of helping to assure the safety, effectiveness and availability of medicines and to help ensure continued access to innovative new therapies for American patients. With respect to funding, section 201 of the discussion draft sets up a new annual registration fee for drug and device establishments "for the purpose of defraying the costs of inspecting establishments registered" with the FDA and a new annual importer registration fee.

In general, user fees for FDA have worked to support other FDA functions. As you know, PhRMA and its member companies endorsed the creation of user fee programs to fund FDA's review activities in the original Prescription Drug User Fee Act of 1992. With regards to whether user fees are appropriate to fund increased foreign inspections, questions that must be addressed include how such fees would be

assessed and constructed, and what guidance and parameters would be set around the timing, scope and designated activities supported by any user fee. Key issues will include the amount of any user fee, whether such fees are capped, whether such fees would sunset, and whether any fees would be linked to appropriated dollars. Moreover, any new user fees should not supplant appropriations and should support specific, identified FDA activities.

We also believe that the Agency is currently underfunded and as a result it has become increasingly difficult to meet its many mandates. In our view, it is in the best interest of the public health and safety for Congress to significantly increase appropriated resources to help the FDA carry out its vital mission. The FDA's responsibilities have consistently expanded; however, appropriated funding has not kept pace to meet the Agency's increasing regulatory responsibilities and demands. We look forward to continuing to work with Congress on these important issues and urge Congress to increase appropriations to help the Agency meet its mandates.

*C. Enhancements to FDA's Current Inspection Regime*

Sections 202, 403 and 404 of the discussion draft set out targeted reforms to the FDA's current inspection regime, including a two-year interval for foreign inspections, as well as a requirement for an initial facility inspection before a product may be offered for entry into the U.S., and a recommendation to consult with Congress before FDA seeks to close or consolidate any of its federal testing laboratories or district offices. We agree with the Committee that the rate of FDA foreign inspections should be increased, and that FDA should increase its foreign inspectorate.

**Increase FDA Foreign GMP Inspections.** We also believe, consistent with the policy goals outlined in the discussion draft, that while FDA has broad authority to conduct inspections of domestic and foreign facilities, it currently conducts limited numbers of GMP inspections of foreign facilities, including API manufacturers. Therefore, we recommend that FDA generally increase its GMP inspections of foreign facilities, including API manufacturers, to help ensure that GMPs are being followed. The targeting of these increased foreign inspections should be accomplished by utilizing the risk-based approach described below.

**Establish FDA Regional Offices around the world.** Additionally, the current discussion draft would amend section 704 of the FDCA to require FDA to establish and maintain a corps of inspectors dedicated to inspections of foreign facilities. We support this effort, and suggest that these foreign offices could include FDA personnel dedicated to educating and training foreign government personnel regarding the importance of the FDA's quality system and good manufacturing standards to helping ensure product quality, safety and efficacy. FDA personnel stationed in FDA worldwide offices could also conduct or assist with inspections of foreign entities manufacturing or processing products for import into the United States. Establishing worldwide FDA offices in specific regions and/or countries could help ensure that foreign governments receive hands-on, side-by-side training from FDA itself, and that FDA inspectors conducting inspections in foreign countries are dedicated employees to that office and thus are more familiar with the country, its language, and the facilities located therein. In addition, this would be responsive to concerns regarding the Agency's current reliance on employee volunteers to conduct inspections in foreign countries.

**Use of Risk-Based Approach to Prioritizing Foreign Facilities for FDA Inspections.** The current discussion draft directs FDA to conduct inspections of foreign facilities at least once every two years, which would be consistent with FDA's mandate for inspecting domestic establishments. While conducting foreign establishment inspections every two years is a laudable goal, it's important to recognize that it will take time – possibly years -- for FDA to recruit and train investigators in conducting foreign inspections. Therefore, PhRMA believes that Congress should give FDA the flexibility to develop a risk-based approach to efficiently use its resources to prioritize foreign establishments for inspections, particularly in light of the practical realities regarding the time it will take to establish an enhanced FDA foreign inspectorate. In our view, categorizing and prioritizing FDA inspections of foreign establishments based on the risks they present – and relying on set criteria such as compliance history, time since last inspection, and type of products produced – will enhance the FDA's ability to target its inspection resources efficiently and effectively.

The use of risk-based approaches to GMP inspections is not a new concept.[12] In fact, the Administration has endorsed the use of risk-based models in other regulatory contexts (such as to focus FDA inspections of food facilities and in the recently-issued Import Safety Action Plan). Three categories of risk should be created -- high, moderate, and low – and FDA's inspection resources should be targeted to facilities that are highest priority in this classification. Criteria should be set out in any new legislation to guide FDA's placement of specific foreign establishments into each risk category. These criteria could include: (a) compliance history; (b) time since last inspection (by

[12] See e.g., "FDA Guidance: Risk-Based Method for Prioritizing GMP Inspections of Pharmaceutical Manufacturing Sites – A Pilot Risk Ranking Model," (Sept. 2004).

FDA/qualified third party/audit by finished product manufacturer for component supplier); (c) type of product imports (e.g, Class III medical device, sterile drug products), including any unique considerations presented by the patient population to be treated by the product; (d) volume of product imports; and (e) geographic location, if Congress deems appropriate. FDA should also retain flexibility to move foreign facilities within the three risk categories. For example, a formerly high-priority facility with a good track record of FDA compliance over a period of time should be allowed to be moved to the moderate or low- priority category. Similarly, foreign facilities that present unforeseen risks based on new information should be able to be ranked in another priority category.

A risk-based approach would allow the agency to prioritize its inspections and maximize its resources to conduct foreign inspections. Moreover, a risk-based approach will give the FDA flexibility to efficiently and effectively target its resources to foreign establishments that it identifies as the highest priority.

**Use of Accredited Third Parties.** In recognition of the fact that the Agency does not have unlimited resources and in order to help ensure that foreign inspections occur on a more regular basis, Congress should consider allowing FDA to use accredited third parties to conduct some foreign inspections (such as those classified in the moderate to low risk categories). These inspections would not necessarily take the place of FDA inspections, which are a necessary and important part of its mandate. Nonetheless, it would give the FDA flexibility to maximize its resources without foreclosing its ability to inspect any facility. Granting FDA the flexibility to use accredited third parties as appropriate to help assure moderate and low risk foreign

facilities continue to meet FDA requirements would allow the Agency to focus its resources on inspections of foreign facilities the Agency has determined are of the highest priority.

*D. Enforcement Authorities and Penalties*

**Refusal or Delayed Entry into the U.S.** Section 202 of the Committee's most recent discussion draft provides that a registration could be suspended if the establishment – or any employee of an establishment – "delays, limits or denies" an FDA inspection under the FDCA. In our view, failure to register with FDA or to participate in FDA's foreign inspection program should be considered grounds for refusal of products offered into the U.S., and could be coupled with other existing penalty mechanisms, as appropriate. In recent testimony before the Oversight & Investigations Subcommittee, the FDA Commissioner stated that FDA believes products should be refused admission into the U.S. if the Agency "encounters undue delay, limits, or denials of access to foreign manufacturing sites".[13] Clearly delineating the conduct that would satisfy these criteria will be important, but FDA and Customs and Border Protection should be able to refuse or delay entry into the U.S. of products manufactured by facilities in foreign countries that fail to register with FDA as required or do not undergo an FDA inspection as required.

[13] Statement of Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs, U.S. Food and Drug Administration, before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, "FDA Actions to Improve Safety of Medical Products with Foreign Components," April 22, 2008, at 13.

**Limited Waiver or Exemption from Import Delays or Refusals in Limited Circumstances** Congress could consider granting discretion to the FDA to allow a limited waiver or exemption from any new authority to refuse or delay products for entry into the U.S. for: (a) products or components used in clinical trials or other qualified investigations; (b) products or components used to manufacture products in short supply or orphan products; (c) as necessary to protect the public health (at FDA's discretion); (d) products or components imported or offered for import by a company that has recently qualified its downstream supplier (e.g., finished product manufacturer attests to quality and purity of components used in finished product whether manufactured by affiliate or third party); (e) intra-company transfers where the parent company is in compliance with FDA requirements and has submitted to required FDA inspections; or (f) products or components necessary for use in medical emergencies or to respond to a bioterror attack or pandemic. These exemptions would help ensure that FDA has the flexibility to protect patient safety and ensure vital clinical research is not unduly compromised due to supply shortages.

**Increase Criminal Penalties for Counterfeiting.** Recent media reports regarding a contaminated drug product entering the U.S. suggest adulteration of a product component that was not readily detected and may have been intentional. Counterfeiting of pharmaceutical products is a significant concern, and counterfeiting of finished pharmaceuticals is expected to increase to $75 billion in sales by 2010, according to the Center for Medicines in the Public Interest.[14] However, the current

[14] WHO IMPACT Fact Sheet, No. 275, Nov. 14, 2006, available at: <http://www.who.int/mediacentre/factsheets/fs275/en/index.html>.

penalties for counterfeiting a drug product are less than the penalties for counterfeiting a single dime. The penalties associated with counterfeiting should be commensurate with the significant public health threat posed by counterfeit drugs; and sufficient to deter counterfeiting activities, particularly by organized crime. Accordingly, Congress should increase the maximum penalty for counterfeiting drug products from 3 years to 20 years.

## III. "Safeguarding America's Pharmaceuticals Act of 2008"

Finally, I would like to provide our preliminary comments on H.R. 5839, the "Safeguarding America's Pharmaceuticals Act of 2008." PhRMA commends Congressmen Buyer and Matheson for their leadership on this issue and their tireless efforts in working with all stakeholders on this bill. PhRMA also appreciates the thoughtful and phased process set out in the bill to apply anti-counterfeiting technologies to prescription medicines based initially on the potential risks posed by counterfeiting and diversion of such products. Supply chain security is the responsibility of all parties involved in the distribution of products to American patients. It is important to recognize that any requirement to apply electronic technologies to prescription drug products will necessarily need to be applied using a phased approach, both in terms of the scope of products selected, and phased across all partners in the prescription drug supply chain.

In PhRMA's view, any legislative or regulatory requirements to authenticate products and pass pedigree information should be uniform, should apply to all parties in the pharmaceutical supply chain, and should recognize the recent federal requirement

for a standardized numerical identifier. The bill introduced by Reps. Buyer and Matheson meets these criteria.

In our view, the only effective way to combat counterfeiting is to adopt a multi-pronged strategy that addresses weaknesses throughout the distribution system. There is no technological "magic bullet" that will prevent counterfeiting, and the Buyer-Matheson allows the use of flexible technologies. PhRMA member companies currently employ and routinely enhance a variety of anti-counterfeiting technologies, including covert and overt features on the packaging of high-risk prescription drugs. Many companies have also adopted certain business processes to better secure the supply chain and help facilitate the early detection of criminal counterfeiting activity. PhRMA also supports raising the minimum licensure requirements for wholesale distributors, to prevent diverters and counterfeiters from re-locating to states without strong licensure requirements. We also support increasing federal oversight over repackaging operations, which has been identified as a weak spot in the drug distribution system and increased penalties for drug counterfeiters, as previously stated.

Finally, the proliferation of differing state and federal requirements in this area would create confusion and could potentially negatively impact the pharmaceutical supply chain; therefore, one uniform, national standard is necessary. The "Safeguarding America's Pharmaceuticals Act of 2008" sets up a process to create a single, national standard, and thus, appropriately recognizes the need for uniformity in this area.

While these comments are preliminary, we appreciate your demonstrated leadership on this issue and look forward to continuing to work with Congress and other interested stakeholders to help assure that the integrity of America's drug supply system continues to be safeguarded from the increasing worldwide counterfeit threat.

## IV. Conclusion

PhRMA believes a science-driven, risk-based approach to conducting FDA foreign inspections is the most efficient and effective means to target FDA's resources. Moreover, PhRMA encourages Congress to appropriate sufficient resources to help the FDA meet its statutorily-prescibed mandates. PhRMA also supports a uniform national standard for the application of any electronic anti-counterfeiting technologies to prescription drug products.

We commend the Committee for its thoughtful approach to helping ensure that the health and safety of American patients is protected. We recognize the importance of ensuring that the regulatory system in place today for prescription drugs remains the best in the world and the safest in the world. The recent events regarding a contaminated drug product entering the U.S. underscores the potential that exists for unsafe and potentially dangerous counterfeit drugs to enter the U.S. should Congress act to open our borders to more expansive prescription drug importation proposals. Our system today is very, very good but even good systems can be improved upon. We look forward to continuing to work with the Committee on these important legislative issues and with the FDA to help make our current robust system even safer and

stronger. Thank you for the opportunity to testify today and I welcome any questions you may have.

Mr. PALLONE. Thank you. I appreciate the fact that you were very specific about the bill but we only have 5 minutes.

Jim, thank you for being here.

Mr. GREENWOOD. My pleasure.

Mr. PALLONE. You are recognized for 5 minutes.

**STATEMENT OF JAMES C. GREENWOOD, PRESIDENT AND CEO, BIOTECHNOLOGY INDUSTRY ORGANIZATION**

Mr. GREENWOOD. Thank you, Mr. Chairman, Mr. Acting Ranking Member Buyer, Mr. Matheson. It is my privilege to provide testimony before this subcommittee today on behalf of the Biotechnology Industry Organization, BIO, on the efforts of BIO member companies to ensure the safety of the ingredients that they use to manufacture their pharmaceutical and biological products for the American public. We applaud the subcommittee for convening this hearing and we are committed to collaborating closely with you and the FDA to better ensure the safety, purity and potency of imported drugs and biologics. We welcome this opportunity to inform you of the steps that our members have been taking to ensure the quality of their products as part of the successful closed regulatory system for imported drugs and drug products.

I want to reiterate that the commitment of BIO and its member companies to work with you and this subcommittee in this endeavor. We do so because the continuing safety of our products is our responsibility to the patients we serve and it is number one priority.

Regarding the draft FDA Globalization Act, BIO has previously publicly acknowledged that the FDA is woefully underfunded, particularly given the enormous and rightful demands that this Congress and the American public have placed upon it. In fact, BIO led the formation of the Alliance for a Stronger FDA, which successfully advocated for $40 million in additional appropriated funds for FDA's Human Drug Review Program last year, and we are advocating for more this year. While we respect the fact that user fees are and will continue to be a part of the solution to the Agency's funding crisis, BIO strongly believes that the imbalance between user fees and appropriated fees within the Agency's budget has become too great, hence the need for a much larger appropriation. BIO would urge the subcommittee to ensure that if new user fees are created, that the amount and the use, and I believe Mr. Pallone has already acknowledged that you will have a specific amount in the bill, but also that the use of any new user fees are set forth clearly in any new legislation, to ensure both transparency and accountability. It is also essential that inspection user fees for drug and biologic manufacturers are not duplicative of existing registration and establishment fees and are not used to subsidize unrelated activities or other agency functions.

Second, any new legislation in this area should recognize the significant differences between biologics and small molecule drugs, as well as between and among different types of biologics. This is particularly relevant with respect to the type of testing that may be required to ensure safety and purity. Biologics are complex products that are derived from living organisms. In some instances, the active substance may not be well characterized. In other cases, it

may be known but not easily separable from other components of the product using current scientific methods. Of course, all biologics like all other drugs are regularly tested for purity and to ensure that they continue to meet their approved regulatory standards but it is important that Congress not seek to create a one-size-fits-all testing requirement to ensure purity and identity because a one-size-fits-all approach will not work for all safe, pure, and potent biologics. Rather, FDA must have the responsibility and the discretion to ensure appropriate testing based on each particular product.

Third, there currently exists a highly detailed regulatory framework governing approval and post-approval manufacturing of drugs and biologics including requirements for ensuring the consistent manufacture of a safe and effective product in accord with its FDA-approved package. If the Congress is to enact new requirements or programs in this area, it is critical that they build upon and strengthen FDA's GMP requirements to ensure that the manufacture of drugs and biologics can be reproduced consistently in accordance with agency standards and avoid imposing confusing or vague new mandates.

Fourth, any new legislation should ensure that the FDA has the time, resources and direction to successfully implement the new requirements and programs in a way that will not result in shortages or disruptions to the supply chain of life-saving and life-enhancing medicines because of FDA's failure to conduct timely inspections in accordance with the time frames in the legislation. It is important to recognize that the current closed regulatory system has been successful overall and improvements to this system should not result in the unintended consequences of limiting patient access to needed therapies.

Finally, it bears emphasis that the closed regulatory system for imported drugs and biologics is an essential element in ensuring drug safety here in the United States. As we seek to strengthen the closed system together, we must keep in mind that any efforts to broaden permissible importation of drugs that are currently illegal to import in the United States will only undermine such efforts and add to the FDA's already heavy burden.

I want to thank the subcommittee in advance for the consideration of these views.

[The prepared statement of Mr. Greenwood follows:]

TESTIMONY OF THE HONORABLE JAMES C. GREENWOOD, PRESIDENT & CEO,
BIOTECHNOLOGY INDUSTRY ORGANIZATION
HOUSE COMMITTEE ON ENERGY & COMMERCE, SUBCOMMITTEE ON HEALTH HEARING
"DISCUSSION DRAFT OF THE 'FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT'
LEGISLATION: DRUG SAFETY PROVISIONS"

May 1, 2008

Chairmen Pallone and Dingell, and Ranking Members Deal and Barton, it is my privilege to provide testimony before this Subcommittee today on behalf of the Biotechnology Industry Organization (BIO) on the efforts of BIO's member companies to ensure the safety of the ingredients that they use to manufacture their pharmaceutical and biological products for the American public. We applaud the Subcommittee for convening this hearing, and we are committed to collaborating closely with you and the FDA to better assure the safety, purity, and potency of imported drugs and biologics. We welcome this opportunity to inform you of the steps that our members have been taking to ensure the quality of their products, as part of the successful "closed" regulatory system for imported drugs and drug products.

I want to reiterate the commitment of BIO and its member companies to work with you and this Subcommittee in this endeavor. We do so because the continuing safety of our products is our responsibility to the patients we serve, and it's our top priority.

By way of background, BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare,

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agricultural, industrial and environmental biotechnology products. BIO and its member companies have worked closely with the Food & Drug Administration (FDA) to ensure that the United States' drug supply is safe, secure, and reliable, and that Americans can be confident that when they use an FDA-approved prescription drug or biologic, the medicine will be safe and effective and work as intended. As you know, FDA's regulatory standards are among the most rigorous in the world and BIO's members will continue to comply with the requirements of the Federal Food, Drug, and Cosmetic Act (the Act) that ensure the safety of prescription drugs.

For example, the Act requires that all new prescription drugs must be approved by FDA as safe and effective for their intended use. FDA approvals are both manufacturer- and product-specific, and include requirements that the sponsor of a new drug application (NDA) or biological license application (BLA) disclose to FDA the manufacturing location and the manufacturing controls that will be used by the manufacturer to ensure the production of a safe prescription drug or biologic. In addition, our members' facilities that manufacture prescription drugs and biologics for the U.S. market must also comply with FDA's Good Manufacturing Practice (GMP) requirements to ensure that the manufacture of their prescription drugs and biologics can be reproduced consistently and in accordance with the agency's quality standards.

Our members are responsible for ensuring the safety of both the domestic- and foreign-manufactured ingredients used for their prescription drugs and biologics. BIO members that are U.S. manufacturers of finished dosages that use imported ingredients test and validate the safety, purity, and consistency of those ingredients that they use in the manufacture of their products. BIO members, like all prescription drug and biologic manufacturers, also are required to disclose the source and specifications of their ingredients in their applications, and their domestic and foreign active ingredient manufacturers must be in compliance with GMPs prior to the approval of our members' NDA or BLA.

In fact, FDA's Drug Master Files (DMFs) were established through FDA regulations to allow producers of active ingredients and other formulation materials to submit this confidential commercial information directly to FDA. In addition to containing information regarding the source and specifications of active ingredients and their manufacturer, FDA's DMFs contain manufacturing information pertinent to the formulation material. The particular DMF is referenced by an applicant for a new drug or biologic and is considered part of the NDA or BLA. Therefore, FDA conducts a pre-approval inspection that includes the inspectional verification of the information submitted to the DMF by the ingredient manufacturer prior to approving an NDA or a BLA submitted by a BIO member. Foreign and domestic ingredient manufacturers may then be subject to a periodic reevaluation for GMP compliance, either during a pre-approval inspection for a different product, or pursuant to a routine post-approval GMP inspection.

BIO recognizes that FDA may inspect both finished prescription drug and ingredient manufacturing facilities that are outside the U.S. less frequently due to the agency's resource constraints. However, irrespective of the frequency of FDA's inspections, BIO members employ processes and procedures to ensure that the prescription drugs that they manufacture are genuine and safe. BIO members realize that it is their responsibility to ensure that the foreign facilities that they use to manufacture finished goods or contract to supply active ingredients meet FDA's GMP requirements. They audit or inspect foreign facilities so that their products meet the requisite quality standards regardless of whether they contract with an outside company or produce the pharmaceuticals or biologics themselves, and they strive to achieve a level of quality assurance that often exceeds FDA's regulatory requirements.

Our members also protect the quality of their products by securing the distribution chains for imported ingredients and strengthening the procedures used to qualify potential suppliers of active ingredients. These steps help ensure the safety, identity, and purity of batches of ingredients that will be used to manufacture

their products.

The Act's provisions create a "closed" regulatory system for imported drug products to help ensure that the domestic drug supply is safe by limiting the drugs and biologics that may be imported into the United States. FDA and industry increasingly face challenges due to globalization of drug development and manufacturing. The changing world has required both FDA and industry to devise and evaluate more complex risk scenarios and apply more sophisticated technologies to screen and evaluate prescription drugs and biologics entering the U.S. to ensure their quality. The "closed" regulatory system of importation has been successful, however, because our industry has implemented rigorous manufacturing and quality control practices. Although the overall quality of drug products in the United States is still very high, the recent FDA announcement regarding the contamination of heparin is a reminder that we need to continue to be vigilant in our efforts to ensure the safety, efficacy, purity, and potency of prescription drugs and biologics and work cooperatively with FDA to achieve this goal.

With that goal in mind, BIO recently met with FDA and Health and Human Services to discuss how we can continue to work together to ensure that Americans can be confident that when they use an FDA approved prescription drug, the medicine will be safe and work as intended. I also sent a letter to BIO's 705 Health Section members asking for their continued commitment to work with FDA to ensure the safety of the prescription drugs that they manufacture, and to ensure that their DMFs are up to date. I know that BIO's member companies are taking this issue very seriously.

On behalf of BIO's member companies, I also want to provide my personal commitment to work with this Subcommittee as it begins to consider legislative options for strengthening the "closed" imported drug

regulatory system. In this regard, I would like to respectfully emphasize several key issues for your consideration.

First, BIO has previously publicly acknowledged that the FDA is woefully underfunded, particularly given the enormous and rightful demands that this Congress and the American public have placed upon this small agency. In fact, BIO led the formation of the Alliance for a Stronger FDA, which successfully advocated for $40 million in additional appropriated funds for FDA's human drug review program last year, and is advocating this year for, among other items, increases in funding for FDA's foreign inspection and import program. While we respect the fact that user fees are and will continue to be part of the solution to the agency's funding crisis – and supported the recent passage of drug safety legislation that dramatically increased such user fees – BIO strongly believes that the imbalance between user fees and appropriated funds within the agency's budget has become too great, hence the need for a much larger appropriation. BIO would urge this Subcommittee to ensure that, if new user fees are created, that the amount and use of any new user fees are set forth clearly in any new legislation, to ensure both transparency and accountability. It also is essential that any new inspection user fees paid by BIO members are not duplicative of existing registration and establishment fees, and are specifically allocated to inspections of their facilities, not used to subsidize the inspections of other regulated parties' establishments. We believe that such fees should be collected fairly from all regulated parties under this proposed legislation, commensurate with the additional inspectional resources needed for purposes of inspecting such parties' establishments.

Second, any new legislation in this area should recognize the significant differences between biologics and small molecule drugs, as well as between and among different types of biologics. This is particularly relevant with respect to the type of testing that may be required to ensure safety and purity. Biologics are

complex products, derived from living organisms. In some cases, the active substance may be poorly characterized; in other cases, it may be characterized, but not easily separable from other components of the product, using current scientific methods. Of course, all biologics, like all other drugs, are regularly tested for purity and to ensure that they continue to meet their approved regulatory standards. But it is important that Congress not seek to create "one-size-fits-all" testing specifications because, frankly, a "one-size-fits-all" approach will not work for all safe, pure and potent biologics. Rather, FDA must have the responsibility and the discretion to ensure appropriate testing based on each particular product.

Third, there currently exists a highly detailed regulatory framework governing approval and post-approval manufacturing of drugs and biologics, including requirements for ensuring the consistent manufacture of a safe and effective product in accord with its FDA approval package. If the Congress is to enact new requirements or programs in this area, it is critical that they build upon and strengthen this established foundation and avoid imposing confusing, duplicative, or vague new mandates.

Fourth, any new legislation should ensure that the FDA has the time, resources, and direction to implement new requirements and programs in a way that will not result in shortages or disruptions to the supply chain of life-saving and life-enhancing medicines. It is important to recognize that the current "closed" regulatory system has been successful overall, and improvements to this system should not occur at the expense of patient access to needed therapies.

Finally, it bears emphasis that this "closed" regulatory system for imported drugs and drug products is an essential element in ensuring drug safety here in the United States. As we seek to strengthen this "closed" system together, we must keep in mind that efforts to broaden permissible importation of drugs will only

undermine such efforts and add to the FDA's already heavy burden.

I want to thank the Subcommittee in advance for the consideration of these views.

Mr. PALLONE. Thank you, Congressman.

Next is Ms. Mundkur recognized for 5 minutes.

**STATEMENT OF CHRISTINE MUNDKUR, CHIEF EXECUTIVE OFFICER, BARR LABORATORIES, INC.**

Ms. MUNDKUR. Thank you for the opportunity to present today. I am Christine Mundkur, the CEO of Barr Laboratories, a global generic pharmaceutical company.

Prior to being CEO, I spent about 15 years at Barr Laboratories in the areas of quality, regulatory, and safety, and most recently I have served as the executive vice president of Global Quality, overseeing our manufacturing facilities located in the Czech Republic, Poland, Croatia, as well as the United States, and as well as ensuring the distribution of high-quality generic pharmaceuticals in over 30 markets.

I am proud to be here today on behalf of GPHA, which represents both domestic as well as multinational companies that manufacture 90 percent of the FDA-approved generic pharmaceuticals dispensed in the United States. We are committed to work with Congress, the Committee and FDA to ensure that adequate oversight of the Nation's drug supply is in place to ensure the availability of safe and high-quality products. We are pleased today to support the overall goals and the fundamental provisions of the draft FDA Globalization Act of 2008, and we continue to support HHS's Import Safety Action Plan.

While we have stringent regulations on all drugs approved by FDA, as you are aware, we have drugs today in the United States that do not have FDA approval and are not regulated. We know these to be counterfeit drugs. The safety of our supply chain is only as strong as the weakest link. We continue to encourage this committee to place a high priority on the prevention of these counterfeit drugs.

Also, while we support your efforts to enhance the foreign inspections, we encourage this committee to recognize the need to carefully balance the competing demands of FDA resources to prevent the increased emphasis on foreign inspections from unintentionally or negatively impacting the timely availability of U.S. generic pharmaceuticals, which already have a significant backlog in the review and approval times.

As Dr. Woodcock stated, quality cannot be tested in nor can we inspect our way to safety. FDA has acknowledged as well as the industry has acknowledged these statements through the implementation of risk-based approaches. Risk-based approaches don't take away from the necessary need of human resources as well as additional capital, but allows us to prioritize the needs of what we need for GMPs. In addition, FDA and the industry continues to work in the area of improving our quality systems. As Dr. Woodcock stated, GMPs and the quality of our product are really based on the quality systems that we manufacture, produce, and distribute our products by, and these have also taken on a global nature through our ICH initiatives and the quality area, including quality risk management, quality systems, and GMP for API suppliers.

The pharmaceutical industry has continuously improved its quality systems, both the branded side as well as the generic side. I think it is important to understand that we all operate under the same laws whether you a branded company or a generic company, and many of our quality systems actually go beyond what is written in the law. As similar to what Lori stated, our quality starts from the design and development of our products and it continues through very robust quality organizations utilizing robust and complicated quality systems. For example, in the area of third parties, we have very defined systems for our vendor qualification programs, how we source APIs, making sure that we have long-term relationships with our API suppliers through quality agreements and our vendor audit programs.

One of the challenges that we have had, as you heard, is that as the pharmaceutical industry has become more global, many additional challenges have hit both the industry as well as FDA's responsibilities for ensuring that there is quality and safe supply of pharmaceutical products coming to the United States. As we have heard, one of the areas that has probably been most challenging is in the area of foreign inspections, and we support the establishment of one uniform high-quality inspection program for all facilities. Today what we have is, we have a domestic inspection program and a foreign inspection program and they are not necessarily linked as one. We support the idea of having one inspection program that will serve as both the domestic as well as the foreign manufacturers. We also believe that all foreign inspections should be comparable in frequency and duration to those of their domestic counterparts. We do understand that FDA must have the resources, both human and capital, necessary to conduct both domestic and foreign inspections equally across all manufacturers for both APIs as well as for finished products. These resources need to be supported by additional agency appropriations and also by the establishment or the registration fees by manufacturers.

It is our position that the current agency appropriations should be adequate to support the domestic facility inspections. However, we believe that the registration and establishment fees should be allocated solely to the support of the foreign inspection program for both GMP as well as pre-approval. We support a fee structure tied to facility inspections, that is, what do I mean by that? That the fee is actually due upon the completion of the inspection, which has a very similar model in the EU system.

We further support and continue to encourage FDA's use of a risk-based approach for the inspection program that would prioritize the need of inspections based on the compliance history of the company, the compliance history of the facility, as well as the products that that facility manufactures, such as OTCs versus sterile products.

In addition, we believe that it is necessary to establish a foreign inspection cadre that may also include the establishment of FDA inspection offices in various regions worldwide and we commend the FDA in looking at the idea of putting FDA offices in China and India and other regions where it may be necessary.

With regard to third-party inspections, we understand that additional work is necessary in crafting the final language, and we are

committed to working with you on that language. However, we believe that there are opportunities for FDA to collaborate with third parties, and most specifically with other international regulatory authorities through such programs as——

Mr. PALLONE. I am going to mention again you are a minute over so if you could wrap up.

Ms. MUNDKUR. So in closing, I do believe that we strongly have the—the United States enjoys the world's safest supply of pharmaceutical products, and as an industry we are committed to supporting both Congress and FDA in strengthening the foreign inspection program.

[The prepared statement of Ms. Mundkur follows:]

## STATEMENT OF CHRISTINE MUNDKUR

Good morning Chairman Pallone, Ranking Member Deal, and Members of the House Energy and Commerce Committee Subcommittee on Health. Thank you for asking me to participate in this very timely and important hearing.

I am Christine Mundkur, Chief Executive Officer of Barr Laboratories, Inc., the global generic pharmaceuticals business unit of Barr Pharmaceuticals, a leading global manufacturer of generic and brand name prescription drugs, and over-the-counter medicines. Barr currently operates in more than 30 countries, with manufacturing and packaging operations of finished dosage form products in multiple sites in the United States, and manufacturing of active pharmaceutical ingredients and finished dosage form products in Croatia, Poland, and the Czech Republic.

Prior to being named CEO of Barr Laboratories in March of this year, I held a variety of legal, regulatory, quality, and safety management positions since joining the company in 1993. I am also a regulatory attorney. Most recently, I served as Executive Vice President, Global Quality, Safety and Regulatory Affairs, and had responsibility for leading the Company's global quality, safety, regulatory affairs and pharmacokinetics/bioequivalence (PK/BE) operations. Following Barr's acquisition in 2006 of PLIVA, a leading European pharmaceutical company based in Croatia, I had the opportunity to relocate to our European headquarters in Zagreb, Croatia. In this position, I worked to harmonize the quality, safety, regulatory, and manufacturing processes across the global operation and gained valuable experience and knowledge working with the European drug regulatory system.

I have worked extensively over the past 15 years with FDA in all aspects of product review, approval, and the regulation of manufacturing and quality standards, and actively managed our relationships with suppliers of active and inactive pharmaceutical ingredients in our products.

In addition, I am proud to speak on behalf of the Generic Pharmaceutical Association, which represents domestic and multinational companies that manufacture 90% of the FDA-approved generic pharmaceuticals dispensed in the United States, as well as active ingredient suppliers for this market.

### OVERVIEW OF TESTIMONY

I would like to make two brief points in my testimony today, before commenting in some detail on the proposed Food and Drug Administration Globalization Act, and in particular Title II of the Act, which addresses drug and device safety.

First, we applaud the work of this subcommittee, and the commitment of Congress to ensure the safety of America's drug supply—brand and generic. For nearly a quarter of a century America's generic drug industry has been developing, manufacturing, and marketing generic versions of brand-name prescription drugs. Last year, approximately 65% of the 3.6 billion new and renewal prescriptions dispensed in the U.S. were filled with generics, saving patients and consumers literally billions of dollars. We are committed to doing everything possible to work with Congress and the FDA to ensure that adequate oversight of the Nation's drug supply is in place to ensure our safety.

Second, I want to make clear that the generic pharmaceutical industry is among the most highly regulated in the world. FDA promulgates strict rules governing the development, manufacture, approval, packaging, marketing, and post-marketing surveillance of prescription drugs. And to ensure the highest purity and quality, FDA has in place rigorous inspection standards for facilities that manufacture and supply prescription drugs.

These stringent regulations apply equally to all brand, generic, and biological prescription drugs approved by the FDA. However, as you are aware, there are drugs being sold in the U.S. today that do not have FDA's approval. I am speaking primarily of counterfeit drugs, which are sold over the Internet and on the black market. We do not want to lose sight of this untenable situation and the grave risk these unapproved and unregulated products carry for U.S. consumers. Our drug safety system is only as strong as its weakest link, and we encourage this committee to continue to place high priority on preventing counterfeit medicines from reaching consumers.

While we support your efforts to enhance foreign inspections, we encourage the subcommittee to recognize the need to carefully balance competing demands for FDA resources to prevent the increased emphasis on foreign inspections from unintentionally and negatively impacting the timely availability of U.S. generic pharmaceuticals. Generic applications already are backlogged at the FDA, with the average review and approval time for Abbreviated New Drug Applications (ANDAs) now approaching 20 months, according to the Office of Generic Drugs. This is a delay of more than a year longer than the 6-month statutory approval period specified by the Hatch-Waxman Act. Action related to enhancing foreign inspections cannot be permitted to further delay FDA's timely approval of generic drug applications.

Now, I would like to spend my remaining time outlining the generic industry's position regarding modifications to the Foreign Inspection process.

## CONSUMER SAFETY IS PARAMOUNT

The Government Accountability Office (GAO) reported to Congress in November that FDA's effectiveness in managing its foreign drug inspection program continues to be hindered by weaknesses, and that fundamental flaws in the program identified a decade ago continue to persist. The GAO report, coupled with the recent recall of heparin containing foreign-made active ingredients, has served to amplify the call for revamping the FDA's foreign drug inspection program to ensure the safety and quality of imported pharmaceutical products.

The generic industry applauds the diligent efforts of Chairman Dingell and Members of the Energy and Commerce Committee who, for more than a year, have been working on initiatives aimed at protecting American consumers from substandard and unsafe medicines. Product safety and efficacy must always be paramount, and our industry has long supported measures to strengthen regulations that assure that all medicines—whether manufactured here or overseas—meet the highest standards for quality and safety.

We agree with Chairman Dingell that we cannot "inspect our way to safety." FDA must have the resources to enforce programs designed to prevent drug safety problems before they occur. And when prevention fails, the Agency must have the authority to impose appropriate penalties. That is why we are pleased to support the overall goals and fundamental provisions of the FDA Globalization Act.

Our industry has long supported measures to strengthen safety standards across the board and to deal with the problems posed by insufficient current Good Manufacturing Practices (cGMP) inspections. The key to addressing these issues is to provide FDA the resources it needs to do the job.

First, the generic industry realizes that FDA needs additional funding to defray the costs of sustaining an adequate inspection. Therefore, we support, in principle, Section 201 and the need for annual registration fees applicable to producers of drugs. However, the draft legislation proposes that these fees be allocated to support inspections of both domestic and foreign facilities. It is the position of the generic industry that current agency appropriations already are adequate to support domestic facility inspections. Thus, our position is that annual registration fees proposed in Section 201 be allocated solely to support the inspection of foreign facilities, where there is an immediate and significant need for resources to address the larger issues that are providing the momentum for this legislation.

The generic industry advocates a "flat fee" structure that would cover both cGMP and pre-approval inspections, and would also have provisions to incorporate re-inspections. We support a fee structure that is tied to facility inspections, very similar to the system currently in place in the European Union. Under this fee model, payment of the inspection fee is due upon completion of the inspection. However, regardless of whether fees are registration-based or inspection-based, the fee structure should be tiered, with one rate for API manufacturers and another rate for finished dosage suppliers.

In conjunction with generating the funds needed to achieve a successful inspection program, the fee system should require that the FDA adhere to certain performance metrics and adequate reporting to Congress to monitor program effectiveness and

help ensure inspection goals are being met. Such performance-based metrics should help maintain a system under which manufacturers have product entry assurances that are tied to timely pre-approval inspection. In this way, the program would to a certain degree parallel the goals and assurances that are fundamental to the PDUFA user fee program for new drug applications.

It also is critical that fees collected are "locked in" for their intended purpose, namely defraying the costs of foreign inspections. We would not be inclined to support a program that permitted fees to be comingled into other accounts that do not support foreign inspections.

The inspection program must ensure a fair and level playing field between foreign and domestic manufacturers. The generic industry urges the establishment of one uniform, high quality inspection standard for all facilities, with foreign inspection as inclusive and robust as the strictly controlled processes that FDA requires of domestic manufacturers. This would include assurances that products are made in facilities that have the proper core competencies, laboratories, and operational infrastructures, and that inspections are conducted with the same frequency, whether the facility is domestic or based overseas.

We further support a "risk-based" model for the inspection program that would prioritize the allocation of inspection resources according to a company's safety and compliance track record. This system would ensure that questionable or problematic facilities receive a comprehensive review and evaluation. At the same time, companies with strong records of compliance and positive inspections could be permitted to proceed to market with their products based upon this track record, without delays resulting from waiting for FDA pre-approval or surveillance inspections on every product. By no means would a risk-based approach exempt companies with solid compliance from FDA inspections, but rather it would put them further down on the inspection schedule, allowing the Agency to focus its immediate attention on companies that have compliance needs.

We also support Section 202, which would require an initial inspection before the introduction or delivery for introduction into interstate commerce of any drug or active pharmaceutical ingredient. We particularly endorse the provision in this Section that would require both domestic and foreign drug facilities to be inspected at the same frequency. Again, we urge the drafters of this legislation to ensure that implementation of this biennial inspection does not unnecessarily inhibit the introduction of new products from company's that have and continue to meet the highest standards of FDA cGMPs.

In talking with committee staff, we understand that there is more work needed in crafting final language relative to third-party inspections, which is covered in more depth in the Food section of the Act, but also comes into play in the Drug and Device section. We agree that additional language needs to be incorporated that ensures that third-party inspections, including other foreign regulatory authorities, are performed using consistent standards and that third parties involved in inspections meet the highest levels of conflict of interest standards.

In the matter of testing for drug purity and identity, addressed in Section 205, generic manufacturers currently test their finished products and the active ingredients they contain for purity. However, prior to providing full support for this section, we would like to work with the Committee to ensure the appropriate testing practices are in place.

Section 206 of the Act addresses country of origin labeling. While our product labels currently specify the country in which the finish dose is made, there would be significant practical problems associated with indicating countries of origin for every component of a finished product. Therefore, we request clarification of the Committee's intent in this Section—whether the country of origin labeling applies only to finish dose, the active ingredient, or all components of a product.

It should be noted that country of origin information for the components of the finished dosage are already contained within ANDAs, and such information is updated annually and submitted to FDA. Because of the complexity of this issue and the myriad of technicalities involved in adding to labels the country of origin information for every component of a finished dose product—which could include all inactive ingredients, color agents, capsules or tablet coating materials, etc.—we believe that this section of the Act needs to be further examined in light of the practical issues related to its implementation if all inclusive.

There has been some talk about drug tracking, so-called pedigree, as part of the drug safety initiative. The generic industry believes this bill could be an appropriate vehicle to implement a federal pedigree program that would ensure a uniform and strong national safety regime. We advocate adoption of a federal pedigree system, with uniform standards across all states, as opposed to a patchwork of more state-

enforced regulations. The challenge will be to ensure that the technology is reasonable and feasible in light of numerous economic, technical and logistical factors.

To address potential quality concerns with inactive ingredients, we recommend that the GMP requirements as currently provided in the pharmacopeias, USP, EP, and JP, be further clarified and revised as deemed appropriate.

Lastly, we support those sections of the discussion draft dealing with the destruction of adulterated, misbranded or counterfeit drugs offered for import; providing civil money penalties for violations; and granting the Secretary the same authority for detention of drugs as is currently available for devices.

SUMMARY

Our Foreign Inspection Process is only as strong as its weakest link. Failure to infuse adequate resources and implement reform measures will perpetuate a system where there is one standard for domestic FDA-approved prescription drug manufacturers and a lesser standard for foreign manufacturers.

In conclusion, Mr. Chairman, while we strongly believe the U.S. enjoys the world's safest pharmaceutical supply chain, we know from recent and unfortunate events that there still is room for improvement through enforcement of more rigorous standards. As an industry, we stand ready to support Congress and the FDA in strengthening the foreign inspection program to ensure we continue to lead the world in safety.

Thank you. I would be happy to address any questions of the Committee.

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Mr. PALLONE. Thank you.

Mr. Bone.

## STATEMENT OF RON BONE, SENIOR VICE PRESIDENT, DISTRIBUTION SUPPORT, MCKESSON CORPORATION

Mr. BONE. Mr. Chairman and members of the Committee, I thank you for the opportunity to testify today. I am Ron Bone, senior vice president of distribution support for McKesson Corporation, the largest pharmaceutical distributor in North America. I have worked for McKesson for 36 years with senior-level management positions in distribution, sales, finance, and independent pharmacy management. I am responsible for overseeing McKesson's electronic tracking systems for pharmaceuticals and I am a member of the leadership team of GS1 Healthcare on track-and-trace standards internationally and in the United States.

I am testifying today on behalf of Healthcare Distribution Management Association (HDMA), a national association representing primary pharmaceutical distributors. HDMA members are responsible for storing, managing, and delivering 80 percent of the prescription medicines sold in the United States. I am here today to express HDMA's support for H.R. 5839, the Safeguarding America's Pharmaceuticals Act, introduced by Representatives Buyer and Matheson.

Pharmaceutical distributors play a critical role in the delivery of medicines in the United States. HDMA members purchase medicines from more than 700 manufacturers. Each day we deliver 13 million prescription drugs to more than 144,000 pharmacies, hospitals and other healthcare settings in the United States. Our customers order electronically every evening. We pick the order that night and it is delivered the next morning.

Critical public health functions are performed with tremendous efficiency and save the Nation's healthcare system $34 billion each year. The U.S. pharmaceutical supply chain is extremely secure, providing an effective system for safe and efficient delivery of medicines to patients nationwide. Recognizing emerging threats from so-

phisticated criminal elements, the distribution industry is consistently developing innovative ways to preserve the integrity and the security of the network. The industry has promoted legislation in multiple States to tighten licensure requirements and to increase the criminal penalties for those who counterfeit and divert medicines. HDMA members also have a record of supporting current and emerging track-and-trace technologies such as those required in California.

In 2006, HDMA established Rx Safe Track, an industry task force of manufacturers, distributors, and pharmacies dedicated to identifying the operational and technical requirements for track-and-trace implementation.

There are three critical reasons our industry supports this bill.

First, the bill provides for a uniform electronic pedigree standard that the national supply chain can implement. The current patchwork of State pedigree laws causes confusion, erodes efficiency, and disrupts the availability of medicines. These conflicting requirements slow the development and adoption of uniform approaches to pedigree implementation.

Second, the bill allows the industry to focus on and invest in uniform technology to track-and-trace pharmaceuticals across the supply chain. One standard for the country, rather than 50 potential State requirements, will be more efficient and less costly.

Third, the world is moving towards a unique identifier for each prescription drug. This bill builds upon the standard numerical identifier provisions of the FDA Amendments Act. These standards, mandated by Congress, are under development by the FDA.

As pharmaceutical distributors, our greatest priority is the security of the supply chain. Uniform pedigree requirements will support the existing national pharmaceutical inventory and enables the safe, reliable, and efficient distribution of critical medicines and facilitates our rapid response in times of emergency. This legislation strikes the right balance by providing the FDA with the authority to establish federal standards while preserving the critically important roles of States to license, regulate and enforce.

With a net industry profit margin of approximately 1 percent, HDMA members have every incentive to ensure the technology is right the first time. Pharmacies and hospitals will look to their distributors for assistance in implementing track-and-trace technologies. The distribution industry has pioneered innovative electronic ordering and other inventory management systems in the past and we will continue to support and ensure our customers' success.

We urge the Committee to consider this important legislation, which we believe will successfully reduce the threat of counterfeit and diverted medicines in the legitimate pharmaceutical supply chain.

Thank you for your consideration, and I would be pleased to answer any questions.

[The prepared statement of Mr. Bone follows:]

## STATEMENT OF RON BONE

Mr. Chairman, thank you for the opportunity to testify before the House Energy and Commerce Subcommittee on Health about the safety and security of the U.S.

pharmaceutical supply chain. My name is Ron Bone and I am Senior Vice President of Distribution Support for McKesson Corporation, the largest pharmaceutical distributor in North America. I have worked for McKesson for 36 years with senior management positions in distribution, sales, finance, and independent pharmacy management. Currently, I am responsible for overseeing McKesson's electronic tracking systems for pharmaceuticals and serve as a member of the leadership team of GS1 Healthcare, which is developing track-and-trace standards internationally and here in the U.S.

I am testifying on behalf of the Healthcare Distribution Management Association (HDMA), the national trade association representing primary pharmaceutical distributors. HDMA's member companies are responsible for storing, managing, and delivering 80 percent of prescription medicines sold in the U.S.

Today, I am here to express HDMA's support for HR 5839, the "Safeguarding America's Pharmaceuticals Act," as introduced by Representatives Buyer and Matheson.

This comprehensive bipartisan legislation would establish a uniform, national requirement for the tracking-and-tracing of prescription medicines from the manufacturer, through the distributor, to the pharmacy.

ROLE OF DISTRIBUTORS IN U.S. PHARMACEUTICAL SUPPLY CHAIN

HDMA's pharmaceutical distributor members typically purchase prescription medicines from more than 700 different manufacturers. We safely store these medicines in state-of-the-art distribution centers across the country and make daily deliveries to the Nation's 144,000 pharmacies, hospitals, nursing homes, physician offices, and other healthcare providers. Each day, HDMA member companies deliver 13 million prescription medicines and other healthcare products. This critical public health function is performed with tremendous efficiency, saving the Nation's healthcare system nearly $34 billion each year.

INDUSTRY EFFORTS TO FURTHER SECURE THE U.S. PHARMACEUTICAL SUPPLY CHAIN

The U.S. pharmaceutical supply chain is extremely secure, providing an effective system for the safe and efficient delivery of medicines to patients nationwide. Manufacturers, distributors, and pharmacies together share a responsibility to continuously monitor, protect, and enhance this secure system against increasingly sophisticated criminals who may try to introduce counterfeit or diverted drugs into the legitimate supply chain.

HDMA members have a long history of working with Congress, the FDA, state legislatures and regulators, law enforcement, and supply chain partners to identify business, policy, and technology improvements that can be made to enhance patient safety.

The industry has promoted legislation in multiple states to tighten licensure requirements and to increase the criminal penalties for those who counterfeit or divert medicine. HDMA members also have a record of supporting current and emerging track-and-trace technologies such as those required in California.

In 2006, HDMA established Rx SafeTrack, an industry task force of manufacturers, distributors, and pharmacies dedicated to identifying the operational and technical requirements for track-and-trace implementation. In addition, HDMA has led the development of track-and-trace research and education, as well as technical guidelines.

We are pleased the "Safeguarding America's Pharmaceuticals Act" includes provisions that build upon these innovations, as well as the work already underway in many states.

INDUSTRY SUPPORT FOR THE "SAFEGUARDING AMERICA'S PHARMACEUTICALS ACT"

HDMA members support this bill for three primary reasons.

First, the bill provides for a uniform, federal electronic pedigree standard that the national supply chain can implement. Today's pharmaceutical supply chain is regulated at both the Federal and State levels of government. Federal law establishes minimum licensing and pedigree requirements as a baseline, while each State can enact additional requirements. The variability of these state requirements creates a patchwork of regulations that causes confusion, erodes efficiencies, and disrupts the just-in-time availability of prescription medicines. These conflicting requirements slow the development and adoption of uniform approaches to pedigree implementation.

Second, this bill will allow the industry to focus on and invest in interoperable technologies to track-and-trace pharmaceuticals across the supply chain. One stand-

ard for the country, rather than 50 potentially conflicting State requirements, will be more efficient and less costly. The development of end-to-end systems based on the unique identification and tracking of individual prescription drugs will achieve true, long-term safety benefits for all Americans.

Third, the world is moving toward a unique identifier for each prescription drug. This legislation builds upon the standardized numerical identifier provisions of last year's Food and Drug Administration Amendments Act (FDAAA). These standards, mandated by Congress, are under development by the FDA.

CONCLUSION

As pharmaceutical distributors, our greatest priority is the security of the supply chain.

National, uniform pedigree requirements will support the existing national pharmaceutical inventory that enables the safe, reliable and efficient distribution of critical medicines and facilitates our rapid response in times of emergency.

This legislation strikes the right balance by providing the FDA with the authority to establish Federal standards, while preserving a critically important role for states to license, regulate, and enforce.

With a net industry profit margin of approximately one percent, HDMA member companies have every incentive to ensure the technology is right the first time. Pharmacies and hospitals will look to their distributors for assistance in implementing track-and-trace requirements. The distribution industry has pioneered innovative electronic ordering and other inventory management systems in the past, and we will continue to help ensure the success of our supply chain partners.

We urge the Committee to consider this important legislation, which we believe will successfully reduce the threat of counterfeit and diverted medicines in the legitimate pharmaceutical supply chain.

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Mr. PALLONE. Thank you, Mr. Bone.

We have four votes on the Floor, one 15-minute followed by three 5-minute votes. I am going to try to get through the last two panelists before we break, and we will be breaking for about a half an hour and then we will come back with the questions.

Mr. Nicholson, you are recognized.

**STATEMENT OF KEVIN NICHOLSON, R.PH.D., J.D., VICE PRESIDENT, PHARMACY REGULATORY AFFAIRS, NATIONAL ASSOCIATION OF CHAIN DRUG STORES**

Mr. NICHOLSON. Thank you. Mr. Chairman and members of the Health Subcommittee, thank you for the opportunity to testify. I am Kevin Nicholson, a pharmacist and an attorney, and vice president of pharmacy regulatory affairs for the National Association of Chain Drug Stores.

Chairman Pallone, NACDS first reiterates our thanks for your leadership in sponsoring H.R. 3700, the Fair Medicaid Drug Payment Act. This bill would mitigate reimbursement cuts that could force 20 percent of all U.S. pharmacies to close, including those serving our most vulnerable low-income patients

Now onto drug safety. Our industry is committed to assuring that we purchase and dispense only safe and high-quality pharmaceuticals. We take a back seat to no one in our commitment to the health and well-being of our patients. The U.S. drug supply chain is among the safest in the world, if not the safest. Both the FDA and the World Health Organization agree that prescription drug counterfeiting is rare in the United States. Still, we are committed to working with you to maintain and strengthen this highly reliable system.

We commend the work of Members of Congress to assure the quality and safety of drugs provided to patients. We especially com-

mend the leadership of this committee, Chairmen Dingell, Pallone, and Stupak, for developing a strong and thoughtful food and drug safety discussion draft. It contains several important measures that would bolster existing safeguards and provide new programs to further protect the drug distribution system.

However, we do have concerns regarding the bill's provisions on country-of-origin labeling. These concerns are detailed in my written statement.

Now onto track-and-trace legislation. As the Committee is aware, Representatives Buyer and Matheson have introduced H.R. 5839, mentioned by my colleagues, which contains a specific requirement for the tracking-and-tracing of prescription drugs. This is a mandate we do not support. We appreciate that the Committee draft does not contain this provision. We want to state our strong concerns with this approach and urge the Committee to resist any attempt to add a track-and-trace mandate.

The sponsors of H.R. 5839 share our goal of enhancing the security of the drug supply chain. In fact, the bill does contain certain promising concepts. For example, the bill would allow the destruction of adulterated and misbranded drugs. This is an idea we support. It would also strengthen the requirements for licensure of wholesale drug distributors, another idea we support. And the bill creates a study to determine the threats to the domestic prescription drug supply chain, which could yield very important information. However, we cannot support this or any legislation that would mandate a track-and-trace system. Such a proposal is fraught with technical difficulties and formidable costs and would not live up to safety expectations at this time.

First, track-and-trace systems are many years away from full development. They have not been fully tested and lack uniform standards and patient privacy safeguards. This was recently acknowledged by the State of California, which has delayed its mandate twice, recognizing that the distribution chain is not ready. Second, track-and-trace systems could be hugely disruptive to the efficient delivery of prescription drugs and patient care. Pharmacies face special challenges implementing such technologies since we are the only members of the pharmaceutical supply chain that have direct patient care responsibilities. Requiring pharmacies to adopt nascent technologies will take away resources from providing care to our patients. And finally, track-and-trace could cost as much as $30,000 per individual pharmacy location. With 55,000 pharmacies nationwide, this could cost the industry $1.65 billion, a devastating blow when also facing billions in reimbursement cuts under Medicaid.

Some proponents of track-and-trace reference this year's recall of contaminated heparin. The related deaths are tragic and heart-wrenching. Our condolences go out to anyone injured or harmed by this incident. But track-and-trace would not have prevented this situation. Four key points are crucial to understanding this. The heparin incident was caused by contamination in China of the active ingredient used to manufacture the product. Tracking-and-tracing the finished product would not have prevented the contamination of the active ingredient. The FDA recall process was immediate, robust, and effective. Track-and-trace would not replace the

need for the FDA recall process and a thorough and effective FDA investigation. Bottom line, drug tracking addresses drug distribution, not production, and would not have prevented the events resulting in this incident.

Although we strongly believe the domestic supply chain is safe, we have developed a set of principles that we believe will lead to a stronger and more secure system. One: Create strong uniform federal requirements for state licensure of wholesale drug distributors. Two: Create an FDA-administered certification program for manufacturers, distributors, and pharmacies assuring adherence to secure drug distribution supply chain practices. Three: Require chain of custody pedigrees for distribution by uncertified supply chain entities. We believe this approach is more feasible than disruptive and costly changes contemplated under track-and-trace proposals.

Mr. Chairman, Chain Pharmacy has taken a leadership role to ensure the integrity of the products we dispense. We pledge to work with Congress to help further strengthen drug chain security. I will be happy to answer any questions.

[The prepared statement of Mr. Nicholson follows:]

Statement

Of

The National Association of Chain Drug Stores

On

Drug and Device Provisions of the Food and Drug Administration Globalization Act Discussion Draft Legislation

To

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

May 1, 2008
10:00a.m.
2322 Rayburn House Office Building

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National Association of Chain Drug Stores (NACDS)
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www.nacds.org

NACDS thanks the Committee for the opportunity to submit a statement on the drug and device provisions of the Food and Drug Administration Globalization Act Discussion Draft Legislation. The National Association of Chain Drug Stores (NACDS) represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. Chain pharmacies operate more than 37,000 pharmacies, employ 114,000 pharmacists, and fill more than 2.3 billion prescriptions yearly. Other members include more than 1,000 suppliers of products and services to the chain drug industry.

On behalf of the National Association of Chain Drug Stores (NACDS), it is my pleasure to present testimony to the Energy and Commerce Subcommittee on Health regarding the drug and device provisions of the Food and Drug Administration Globalization Act Discussion Draft Legislation. My name is Kevin Nicholson, and I hold the position of Vice President, Pharmacy Regulatory Affairs.

***IMPROVEMENTS CAN BE MADE, BUT THE CURRENT U.S. DRUG DISTRIBUTION SYSTEM IS SAFE***

Chain pharmacy supports efforts to enhance the safety of the drugs dispensed by chain pharmacies to their patients. We recognize the efforts of the Committee to increase safety and security through the provisions in this discussion draft and we support many of the provisions. Our members have and continue to work diligently to undertake efforts to secure the pharmaceutical supply chain from counterfeit drugs. Our industry takes a back seat to no one in its commitment to the safety of the drug distribution system and the health and well being of our patients and customers. We are supportive of the Committee's efforts and appreciate the opportunity to work with you in this process.

However, we believe it is important for lawmakers to remember that while not perfect, the United States prescription drug distribution system is one of the safest in the world, if not the safest. The Food and Drug Administration (FDA) attributes this fact to an

extensive array of federal and state regulations and proactive safety measures in the private sector. In fact, both the FDA[1] and the World Health Organization[2] agree that prescription drug counterfeiting is rare in the United States. Still, we understand the need to maintain and strengthen the integrity of this highly reliable system and are committed to working with lawmakers to improve existing safeguards.

***RECENT ACTIONS HAVE HELPED STRENGTHEN THE SUPPLY CHAIN***

We are proud of the systems and initiatives that our members have developed with other industry stakeholders to improve U.S. drug supply chain security. Chain pharmacy has taken a leadership role to further ensure the integrity of the products they dispense. For example, many pharmacies have made changes in their purchasing practices, such as requiring their wholesale distributors to purchase prescription drug products directly from manufacturers. Our industry has supported state-level legislation requiring enhanced wholesale distributor licensure requirements and chain of custody "pedigrees" for drug distributions outside the recognized and safe "normal distribution channel." More than 60% of the states have enacted laws and regulations to strengthen the security for the drug distribution supply chain. We have also supported increased fines and penalties for violations of these state laws. Our members have seen marked improvements in the drug distribution supply chain since the adoption of these initiatives and state laws earlier this decade. While there were several incidents drug counterfeiting in the early 2000's, we are not aware of notices from the FDA of drug counterfeiting in the U.S. normal distribution supply chain since that time. It appears that these initiatives and stricter requirements have removed the bad actors from operating within the legitimate drug supply chain.

Drug manufacturers and the wholesale distribution industry have also taken significant steps to further ensure the integrity of the products they distribute. Many wholesale distributors, including the nation's three largest wholesale distributors, have indicated they would no longer trade with secondary wholesalers. This practice was historically a

[1] *FDA Counterfeit Drug Task Force Report: 2006 Update, June 8, 2006, p.1*
[2] *World Health Organization, Fact Sheet No. 275, "Counterfeit Medicines," Revised 14 November 2006*

potential entry point for counterfeit products and contributed heavily toward drug diversion. The elimination of this practice creates a direct flow of product from the manufacturer, to the wholesale distributor, to the pharmacy, and finally to the patient.

Finally, Congress acted just last year to help further secure the drug supply chain by passing the Food and Drug Administration Amendments Act (FDAAA), which requires FDA to "expand and enhance" its resources to secure the drug supply chain against counterfeit drugs.

***DRUG AND DEVICE SAFETY PROVISIONS IN THE DISCUSSION DRAFT***

*Provisions NACDS Supports*

While these actions have helped increase the security of the system, we recognize the need to help further secure the drug distribution system against potential future breaches. We applaud the Committee's commitment to stimulate discussion among stakeholders on the need to increase funding and authority for FDA to ensure the safety of the nation's supply of drugs and medical devices. The discussion draft outlines the following meaningful steps to meet this goal: annual registration and FDA inspections of drug and device producers and importers; restrictions on the entry of importation of drugs lacking assurance of identity, safety and purity; requirements for manufacturers of drugs to test their ingredients for safety; allowing FDA to issue fines for violations of drug safety requirements; extending FDA's recall authority to drugs, and extending FDA's enforcement authority to destroy counterfeit or adulterated commercial imports; requiring drug manufacturers to identify the source of the active pharmaceutical ingredient and its place of manufacture upon FDA's request; and prohibiting false or misleading statements to the FDA. We are encouraged by these common sense improvements included in the proposal that may help prevent unsafe products from entering the market in the first place. We also applaud the Committee's efforts to ensure a robust inspection program by creating a dedicated foreign inspectorate and requiring the FDA to keep its field laboratories and district offices open.

*Provisions with Which NACDS Has Concerns*

*Country of origin labeling:* While we understand they are well intentioned, NACDS has concerns with the country of origin labeling requirements for drugs and food products under the proposed bill. Many of our members offer high quality and affordable "private label" products to meet the needs of the American consumers. Such products include, among other things, over the counter (OTC) drugs, vitamins and dietary supplements. Ingredients and manufacturing locations of these products may change frequently to accommodate availability, market forces and consumer behavior. Requiring labels to be updated each time the source of an ingredient or the place of processing changes could discourage proper purchasing or processing practices, and limit retailers' ability to respond to market changes, product availability or perceived threats. Further, we are not aware of any basis to suggest that consumers will find this information useful. In fact, requiring country of origin labeling may cause consumer confusion as the labeling of a product purchased today may be different than the labeling of the same product purchased tomorrow. We believe that such situations are likely under the current proposal.

In addition, further regulation of such items as dietary supplements and vitamins would be superfluous in light of the steps the FDA has taken in recent years to ensure safety of these products. In 2007, the FDA issued a final good manufacturing practices (GMP) rule related to supplements which addressed safety concerns related to their manufacturing, processing, packaging and holding. We believe that the FDA should be allowed to pursue its current approach to dietary supplement and vitamin safety without imposing onerous labeling requirements. A consumer taking a supplement properly manufactured using the FDA's GMP process in an FDA inspected and monitored facility will not care if the ingredient is from Montreal, San Francisco or Sao Paulo (for example) so long as the product meets the FDA's standards and their personal needs. We are aware of no evidence that these products pose high risk to consumer safety. FDA's efforts, including the recent GMPs, appear to be working very well.

Similarly, requiring country of origin information on drugs, including OTC drugs, may be confusing to consumers as the source of the active ingredient may change often because of market forces and other reasons. As a result, different packages of the same product on a retail shelf may contain the names of multiple countries. Consumers will have no meaningful way to resolve whether a particular package of a given product is safer than the next based on the differences of their country of origin, and are not likely to find such information meaningful or necessary for their needs.

The FDA should be equipped with proper tools to ensure safety of consumer products instead of a labeling requirement that does not appear to provide any further value. As the draft legislation aptly proposes, FDA should be provided with additional resources and authority to execute meaningful inspection and monitoring plan that will allow the FDA, with confidence, to conduct inspections and surveillance of manufacturing processes to ensure the safety of drugs before they are introduced into the market. This will maintain the trust and confidence of the American public and retailers.

Therefore, we urge Congress to move cautiously with careful deliberation before requiring country of origin labeling on drugs and other products sold in chain pharmacies. We believe further study is needed before we have an understanding of whether these requirements will actually achieve the goal of enhancing drug safety. Finally, the FDA should be adequately funded to provide for proper inspection process to maintain a high level of confidence with the American consumer.

*Concerns with Tracking and Tracing for Prescription Drugs:* As the Committee may be aware, legislation has been introduced [H.R. 5839] that includes a mandate for tracking and tracing of prescription drugs. While we appreciate that the Committee draft does not contain these provisions, we believe it necessary to state our strong concerns with this approach. First, however, let us clarify that we understand and appreciate that the sponsors of the bill share our goal of helping secure the drug supply chain and we know that their bill is a well intentioned effort to achieve that goal. While we cannot support H.R. 5839 as currently drafted, it does contain certain provisions that we could support. For example, the bill contains provisions that would allow the destruction of adulterated

and misbranded drugs, would increase the requirements for licensure of wholesale drug distributors, and would require a study on threats to the domestic prescription drug supply chain.

Despite these sensible provisions, our overriding concern with the bill relates to its mandate that all prescription drug containers be tagged with "track and trace" technologies. Although emerging technologies (e.g. 2D barcodes, radio frequency identification (RFID) tags) to track and trace the distribution of prescription drugs may provide promise as future safeguards, significant industry-wide challenges must be addressed and overcome before these technologies can be determined to be an integral, reliable, and effective means for drug supply chain security. Simply stated, these technologies need to be properly "road tested" and the "bugs" worked out before any statutory mandates for their use.

We are concerned with mandating use of any technology that is under development and premature. While these technology mandates may sound simple, their adoption would be extremely complex and costly for the health care system, and most importantly there are many issues and concerns regarding their use and operation that remain unresolved. Chain pharmacy is directly aware of these concerns from participation in pilot programs. Chain pharmacy has participated in pilots to test the feasibility of RFID technology, determine its ability to meet the needs of the supply chain, and it's utility to detect and thwart counterfeit product from entering the supply chain. The results identified many issues and areas where improvement was needed and many unresolved issues and concerns. The pilots have shown that they are many years away from being proven reliable, scalable, operational, and effective.

*Mandates for Prescription Drug Tracking and Tracing are Costly:* In addition, our members have serious and legitimate concerns with the considerable costs that track and trace systems would impose. Some estimate the cost associated with purchasing and installing all the necessary hardware and software related to track and trace could be as much as $30,000 per pharmacy location. With 55,000 pharmacies nationwide, this could cost the pharmacy industry $1.65 billion – a devastating blow to an industry facing

billions in cuts from Medicaid "AMP" payment reductions. Moreover, the costs of these mandates will not be limited to retail pharmacies. Our understanding of these proposals is that track and trace systems will also be required wherever prescription drugs are dispensed, such as hospitals and clinics. To be clear, pharmacy is not averse to making investments to secure the safety of the supply chain. To the contrary, our members make significant investments every year to ensure that the products they provide our patients and customers are safe and effective. Their reputations and the health of their patients are on the line. However, our industry cannot support an unfunded mandate of billions of dollars for systems that are still unproven and that could cause serious disruptions in our ability to efficiently provide prescription drugs to our patients.

***DRUG TRACKING AND TRACING SHOULD NOT BE MANDATED DUE TO SERIOUS CONCERNS FOR PHARMACIES AND DELIVERY OF HEALTHCARE***

Although emerging technologies such as electronic pedigrees and technologies (such as RFID tags) to track and trace the distribution of prescription drugs may be promising as future safeguards, this has not been proven. Significant industry-wide issues must be addressed and evaluated before any such mandates should even be considered, and these technologies have been determined to be an appropriate and cost-effective means to secure the drug distribution system.

Pharmacies face particularly difficult challenges with implementing such technologies. Concerns at the pharmacy level are more sensitive than for manufacturers and wholesalers, as pharmacies are the only members of the pharmaceutical supply chain that would have to balance their resources between electronic tracking compliance and direct patient care. Requiring pharmacies to adopt immature technologies will cause pharmacists and pharmacy personnel to be distracted with complex compliance issues, thus taking time away from providing pharmacy services to their patients.

As the last link in the supply chain, pharmacies would be responsible for enforcing the tracking and tracing compliance of previous possessors of that product including researching discrepancies and malfunctions of upstream systems. This research would

take precious time from already busy pharmacists and pharmacy personnel, allowing less time for professional pharmacy responsibilities, such as patient counseling and prescription processing. As we stated above, any tracking technologies must be extensively tested before we can even consider mandating their use by pharmacies.

Under existing proposals, pharmacies could receive many different types of track and trace systems creating burdensome and unworkable requirements that would add formidable costs and disrupt the delivery of pharmacist patient care services. The cost burden for implementing these as yet unproven technologies will be very high across the health care system and would likely raise the prices of drugs with resulting negative effects for the delivery of healthcare. Therefore as discussed previously, we are of the opinion that our proposed measures to prevent counterfeiting provide optimal cost and security benefits for the health care system. We propose a three-pronged approach to fight counterfeiters as discussed below.

***TRACK AND TRACE TECHNOLOGY WOULD NOT HAVE PREVENTED THE HEPARIN INCIDENT OR ENHANCE THE DRUG RECALL PROCESS***

Some proponents of mandatory track and trace systems cite this year's recall of contaminated heparin to build support for their proposals. While the deaths associated with this incident are tragic and heart wrenching and we extend our condolences to anyone affected by this incident, we believe that track and trace technologies would have done little to prevent or improve that unfortunate situation. Four key points are crucial to this understanding: (1) the heparin incident was caused by *contamination* in China of the *active ingredient* used to manufacture the finished heparin product ; (2) tracking and tracing the finished heparin product would not have prevented the *contamination of the active ingredient used in the heparin*; (3) the FDA recall process for the contaminated heparin was immediate, robust, and effective; and (4) the tracking and tracing technologies would not replace the need for the FDA recall process, and a thorough FDA inspection and investigation. A significant point is that the tracking and tracing technologies have no ability to replace the FDA manufacturing inspection process or the FDA mandates and inspections for compliance with good manufacturing practices. We

fear the technologies could provide a false sense of security because they would be applied to the finished product.

It is essential to understand that the FDA investigation shows that the heparin contamination incident relates to events in the manufacturing of the active ingredient, and not to the post-manufacturing drug distribution of the finished labeled prescription product in the U.S. drug distribution system that would be subject to the tracking and tracing technologies. As such, tracking and tracing of the finished drug product through the U.S. distribution system would not have prevented the heparin contamination incident. FDA has indicated that the heparin incident was caused by a "heparin-like" contaminant found in the *active ingredient* used to make the heparin prepared at Chinese facilities. The contaminant was not detected during the routine required testing process that occurs before manufacturing of the finished product. FDA is investigating how the contamination occurred.

For those concerned about whether tracking and tracing is necessary for the recall of products such as the recent contaminated heparin, FDA already has an efficient, extensive, and quick recall process, and *one that includes effectiveness checks on all of the company's actions to determine that the recall is complete*. When FDA orders a recall, notices are immediately sent out to wholesalers and pharmacies to instantly pull the affected product from their inventory. As a result, we have hundreds of thousands of hands at the drug manufacturers, wholesalers and pharmacies working immediately to pull recalled products from the entire U.S. distribution system. Handling drug recalls by scanning tracking tags would not hasten the recall process. The recent heparin contamination is evidence of the effectiveness.

- On January 9, 2008, FDA learned of the adverse events related to heparin from CDC investigators.
- On January 16, 2008, FDA initiated inspection of the drug manufacturer's manufacturing plant and the drug manufacturer initiated the heparin recall.
- On January 17, 2008, FDA initiated notice of the recall. In addition, FDA launched and is continuing an extensive in-depth investigation.

Finally, it is far from clear that these technologies would improve the existing robust and time-tested recall process significantly, if at all. An efficient, robust and quick FDA recall process already exists, and it has worked very well in the past and in the current heparin incident. Even if these technologies would enhance any facet of the recall process marginally, a point which has not been established, these technologies are not ready for implementation and cannot play a role in ensuring product safety.

## ***NACDS SUPPORTS A THREE-PRONGED PROACTIVE APPROACH TO ENHANCE SECURITY OF THE DRUG DISTRIBUTION SUPPLY CHAIN***

While today's emerging drug tracking technologies, such as RFID, show promise in providing future improvements to the drug supply chain integrity, significant time will be required to fully develop and standardize these technologies and understand their capabilities. In the meantime, we offer a proposal that provides practical and immediate initiatives to enhance the security of the drug supply chain. We are of the opinion that our proposal is the optimal approach to secure the U.S. drug distribution system from counterfeit and adulterated prescription drug products and for the safety of consumers.

The measures proposed until now to secure the U.S. drug distribution supply chain from counterfeit prescription drug products have been technological in nature from identification and tagging, such as RFID and 2D bar-coding. However, the investment costs across the supply chain required to implement these technologies is formidable for drug manufacturers, wholesale drug distributors, and pharmacies. Because criminal behavior is the basic component of counterfeiting and adulteration, it is doubtful that technological measures are likely to stop these wrongful acts.

Unlike proposals for tracking prescription drugs, we believe that our proposal is workable and would prevent the introduction of counterfeit drugs in the first place. A system of tracking prescription drugs would only be helpful after the fact when a counterfeit incident occurs, not with preventing the introduction of counterfeit drugs. A tracking system would only be secure until counterfeiters figured out ways to exploit the system for their gain. We frequently hear about breaches of supposedly secure systems. Our

proposal does not rely on undeveloped technology that may be exploited at some point in the future.

Since these technologies are directed at authenticating genuine drug products, we support measures to prevent counterfeiting through the strict controls of a certification process of all partners in the U.S. drug distribution system. Our opinion is that certification of all partners in the U.S. drug distribution channel is the optimal means to prevent counterfeiting by providing a sustainable and cost-effective solution.

Our three-pronged proposal would prevent the introduction of counterfeit drugs into the prescription drug supply chain by proactive steps that would raise the security for drug distribution across the nation. All drug distribution supply chain participants would be required to meet strict standards. Our proposal would do the following: (1) require uniform comprehensive standards for state licensure of wholesale distributors across all 50 states rather than allowing differing state requirements; (2) require all drug distribution supply chain stakeholders at the company level (e.g. drug manufacturers, wholesale distributors, and pharmacies) to be certified periodically through a Food and Drug Administration program for compliance with "secure drug distribution practices" ("SDDPs"); and (3) require uncertified entities to provide prescription drug pedigrees. Our proposal is discussed in more detail below.

*Uniform National Enhanced Wholesale Distributor Licensure Requirements*

Chain pharmacy's proposal would amend federal law to require states to establish enhanced requirements for licensure of wholesale distributors and to establish uniformity of these strong and secure wholesale distributor licensure requirements for all states. It would set comprehensive stringent requirements rather than federal law's current "minimum" requirements. By providing national uniformity, it would benefit the drug distribution system and provide wholesale distributors (where many operate in a number of different states) with similar requirements in each state. The increased licensure provisions would add extensive requirements. These include comprehensive licensure information to obtain or renew a license as a wholesale distributor. This will allow state licensing authorities to have adequate and necessary information when granting licenses.

Examples of minimum information include complete business information, owner information, and lists of other licenses. In addition, wholesale distributors would be required to have a designated representative for each wholesale distributor facility who would be responsible for ensuring that the operations are in compliance with applicable requirements. The designated representative would be required to meet certain requirements, such as age and experience, and would be required to provide a personal information statement under oath concerning the representative's history, such as residences, occupations, and any misdemeanors or felonies related to drug distribution. These requirements will assure that the person is suited to manage the facility.

Other requirements include: (1) a security bond to be posted by the licensure applicant of at least $100,000 or similar security that will ensure that the state licensing agency can collect assessed penalties for any violations. A publicly-traded company that files a form 10K with the Security and Exchange Commission would be exempt; (2) mandatory physical inspections of wholesale distribution facilities for initial licensure and periodically thereafter, to ensure that the facilities are legitimate, and have adequate resources and a proper environment to serve as a wholesale distributor of drugs; (3) criminal background checks of designated persons to ensure legitimacy of persons seeking to operate wholesale distribution facilities; and (4) a license for each facility operated by the applicant. The state licensing agency would have the ability to restrict, suspend, or revoke the license.

The proposal would preempt state laws and regulations that are different from the federal requirements. This will foster a uniform system of wholesale distributor licensure that will best serve the interests of the public in providing a safe and secure drug distribution supply chain through uniformly high standards for licensure.

*FDA Certification Program for Drug Distribution Participants to Assure Security of the Drug Distribution System*

Our proposal would amend federal law to add a new requirement for drug distributors to be certified in accordance with FDA developed "secure drug distribution practices" ("SDDP"). It would replace the authorized distributor of record system with a more

secure system that would require all participants in the drug supply chain to be certified for compliance with secure distribution practices. These requirements would assure a safe drug distribution supply chain through compliance with safe secure distribution practices, such as purchasing directly from the manufacturer, or from a wholesale distributor that purchases directly from a manufacturer or from other certified distributors.

The proposal would establish an FDA administered certification program requiring drug manufacturers, wholesale drug distributors, pharmacies, and other participants in the drug distribution system to certify compliance with the safe and secure drug distribution practices. A business entity as a whole would apply for certification, not each individual location.

Certification would provide a safe and secure drug distribution supply chain to prevent counterfeit, adulterated, misbranded, expired, and recalled drugs from entering the drug distribution system. Certified entities would be required to provide proof of certification to upstream and downstream entities upon request and to provide evidence of certification through a certified statement on any documentation that accompanies, or provides advance notice of, any distribution. The provision would also contain a preemption provision in relation to state laws. The preemption clause would be required to establish a national uniform system to certify compliance with secure drug distribution practices.

*Pedigrees Required for Drug Distributions by Uncertified Lacking FDA Certification of Compliance with Secure Drug Distribution Practices (SDDPs)*

Chain pharmacy's proposal would amend current Prescription Drug Marketing Act provisions to remove the exemption for manufacturers and Authorized Distributors of Record from passing a pedigree. This proposal would provide numerous benefits to secure the drug distribution supply chain. It would eliminate the concerns with the current law in which pedigrees are not required from manufacturers and ADRs and replace it with a secure system that would require that any distributor of a drug that is not certified by the FDA for compliance with secure distribution practices would be required to provide a "pedigree" (i.e. a statement of distribution history back to the drug

manufacturer or to the certified entity that purchased the drug directly from the manufacturer).

The ADR and manufacturer exemptions would be removed so that there is a uniform certification system for all participants in the drug distribution supply chain. It would create a certification system that allows for easy and certain recognition of drug distribution participants that have met FDA established standards, and thereby foster a safe secure distribution system. This change would assure that drug products are distributed in accordance with secure distribution practices, and if not, the drug must be accompanied by a pedigree showing the distribution history back to the drug manufacturer.

This would also preempt state laws that are different from the federal law to establish a uniform national security system for the drug distribution supply chain. A uniform national system would avoid a patchwork of different pedigree laws across the supply chain and provide certainty to regulators to know when a pedigree is required.

We believe that our three-pronged proposal offers an effective, practical, efficient, and timely solution to prevent counterfeit drugs from the U.S. drug distribution supply chain. It would establish a reliable and operational check on the drug distribution supply chain with both immediate and long standing benefits for the safety and security of the drug distribution supply chain. Furthermore, it is not contingent on technologies that will require years to develop, standardize, test, and evaluate, and need further investigation. In addition, it is not yet known whether these technologies will ever be a reliable, scalable, practical and cost-effective solution for guarding the drug supply chain.

***CONCLUSION***

NACDS thanks the Committee for consideration of our and allowing us to share both our concerns about the problem of counterfeit drugs as well as our comments on chain pharmacy's proposal for a proactive 3-pronged approach to enhance the security of the pharmaceutical drug supply chain.

***Attachment***

***Executive Summary***

The United States prescription drug distribution system is one of the safest in the world, if not the safest. Chain pharmacy is committed to working with lawmakers to maintain the integrity of this reliable and safe system. We are proud of the systems and initiatives that our members have undertaken to maintain and improve the security including changes in purchasing practices and working with their wholesale distributor partners to require purchasing directly from drug manufacturers.

Chain pharmacy supports the Committee's efforts through this discussion draft to increase the safety and security of U.S. drugs and devices. We particularly want to highlight the provision in the discussion draft that calls for a certification program for foreign and domestic food facilities that aligns with NACDS' proposal. NACDS is offering a proposal for enhancing the safety of the drug distribution supply chain through certification of supply chain partners in the U.S. drug distribution supply chain.

NACDS offers a three-pronged approach to prevent introduction of counterfeit drugs by proactive steps that would raise the security of the drug distribution supply chain across the nation. Our proposal would do the following: (1) require uniform comprehensive standards for state licensure of wholesale distributors across all 50 states rather than differing state requirements; (2) require all drug distribution supply chain stakeholders at the company level (e.g. drug manufacturers, wholesale distributors, and pharmacies) to be certified periodically through a Food and Drug Administration program for compliance with "secure drug distribution practices" ("SDDPs"); and (3) require uncertified entities to provide prescription drug pedigrees.

NACDS is concerned with legislative mandates for unproven and immature prescription drug tracking and tracing technologies. Their adoption would be extremely complex and costly for the health care system and many issues and concerns regarding their use and operation remain unresolved. Chain pharmacy is directly aware of these concerns from participation in pilot programs. Such technologies are many years away and present a number of challenges that have yet to be address and resolved.

Pharmacies face a number of particularly difficult challenges with implementing such technologies. Pharmacies are frontline health care providers and would have to balance their resources between compliance with drug tracking and tracing and providing medications to patients. As health care providers, pharmacies would be responsible for enforcing and clearing up problems if the technology did not operate as intended. As a result, patients may experience delays in obtaining their prescription medications. These activities would take precious time away from pharmacists in providing patient care such as patient counseling, medication therapy management, and prescription dispensing. Additionally, as the technologies are immature, pharmacies would receive many different types of track and trace systems and likely face constantly changing systems.

Track and trace systems would not have prevented the contaminated heparin incident. The heparin incident was caused by contamination in China of the *active ingredient* (derived from pig intestines) used to manufacture the finished heparin product. Tracking and tracing the finished heparin product would not have prevented this contamination. The FDA recall process for the contaminated heparin was immediate and robust. A significant point is that the tracking and tracing technologies have no ability to replace the FDA manufacturing inspection process or the FDA mandates and inspections for compliance with good manufacturing practices.

We urge Congress to carefully examine all proposals and not prematurely mandate technologies that are still under development. Efforts to enhance the security of the drug supply chain must be feasible, practical, reliable, and cost-effective. We further urge Congress not to include proposals that would interject drug identification and tracking requirements into this bill. Lawmakers should proceed cautiously before imposing additional requirements on the drug distribution supply chain and consider the impact on the health care system. Issues of such great importance to the health care system deserve significant deliberation.

Requiring country of origin labeling on drugs and food products will provide no additional value in ensuring their safety. In fact, consumers are likely to be confused by such information. Instead, the FDA should embark upon a thorough inspection and

surveillance of manufacturing processes and controls to ensure that harmful products never enter the market in the first place. Finally, we applaud the Committee's recognition of the need to increase the FDA's funding and inspection authority to ensure the safety of regulated products.

Mr. PALLONE. Thank you, Mr. Nicholson.

Ms. Gadhia, I think I am going to wait until we come back for you because there is only about 6 or 7 minutes left. So we will take a break, I am not going to say exactly but approximately half-an-hour for all the votes, and then we will come back, finish with Ms. Gadhia, and take questions. So the subcommittee stands in recess.

[Recess.]

Mr. PALLONE. The subcommittee hearing will reconvene, and we left off with Ms. Gadhia, who is recognized for 5 minutes.

**STATEMENT OF AMI GADHIA, POLICY COUNSEL, CONSUMERS UNION**

Ms. GADHIA. Good morning, Subcommittee Chairman, Subcommittee Ranking Member, my name is Ami Gadhia and I am policy counsel with Consumers Union, the nonprofit publisher of Consumer Reports magazine. I am here today to testify about the drug, device, and cosmetic safety provisions of the discussion draft of the FDA Globalization Act. Consumers Union commends Chairman Dingell, the subcommittee chairman, the ranking members of the Committee and subcommittee and the members of the Committee for Chairman Dingell's leadership on the proposed legislation and the members of the Energy and Commerce Committee for holding today's hearing on this critical consumer safety issue.

The call for a major overhaul of the FDA has now become a roar. A November 2007 GAO report put the problem in stark relief. Of all foreign plants, at most only 7 percent of them are inspected in a year. Some of the more high-profile failures of our regulatory system are well known at this point. The import of contaminated heparin, which is suspected to have been involved in the deaths of over 80 people, the 2006 recall of 183,000 packages of contact lens solution manufactured in China because of bacterial contamination, and a June 2007 import alert about toothpaste made in China that contained the very dangerous chemical diethylene glycol, which is used in antifreeze and as a solvent.

There have been lots of mentions today about counterfeit drugs, but we would just like to mention that largely what has brought us here today has been not counterfeit drugs but unsafe drugs, devices and cosmetics that are properly sold under their brand names.

Consumers Union believes that the discussion draft of the FDA globalization bill contains a number of strong provisions that will help make consumers safer. First, the bill would require mandatory inspection of both domestic and foreign drug and device facilities every 2 years. Consumers Union would respectfully recommend that this inspection occur annually, and more frequently if there are problems, given the host of serious public health risks that have emerged.

Second, the discussion draft would require destruction of adulterated, misbranded, or counterfeit drugs that accompany attempts to import into the United States. This provision is necessary to prevent importers from shopping until they find a U.S. port that will admit entry for their products. We would also recommend that the bill provide for a similar destruction of unsafe medical devices.

Third, the discussion draft would give the FDA the authority to recall seriously unsafe drugs, an authority that the Agency currently has for dangerous devices but which has been lacking for drugs.

We also applaud members of the Committee for including in this draft a provision requiring a label with the country of origin of APIs and biologics and a label with the country of manufacture for devices. We believe that consumers and their healthcare professionals are better served by more information rather than less.

We are also glad that the bill includes provisions addressing the safety of cosmetics. It is not sufficient for FDA's inspection resources to stay at their current, extremely inadequate level with regard to imported cosmetics. Creating a fee requirement for importers of cosmetics is one step towards addressing this problem.

There are, however, some implementation time frames in the discussion draft that Consumers Union would urge the Committee to consider shortening. It appears that the effective dates of a number of the bill's provisions are too far out in the future, sometimes 2 or 3 years out. These should be shortened.

We support the discussion draft's provision creating a user fees regime for various new FDA functions. However, we urge the Committee to ensure that the user fees do not turn into a pay-for-play scenario. We would not want to see regulated entities have the ability through the user fee program to exert undue influence over the FDA in its decisionmaking or other functions. In addition, like the user fees for food safety importation, the drug and device importer fees should be indexed for inflation.

Consumers Union also believes the civil money penalties for violations are set too low. For a large manufacturer, producer or other multinational, a penalty of $100,000 could simply be a cost of doing business or perhaps a few hours worth of profit. For the penalties to serve as a true deterrent against unsafe or illegal actions, they should be set higher.

FDA must also have the ability to perform unannounced inspections of foreign facilities. Because of advanced warning, foreign manufacturers, unlike domestic companies, are able to clean up to ensure that they past inspection, even if they are not in compliance every other day of the year.

We wholeheartedly support providing FDA with new authorities and resources. We are pleased that this discussion draft gives FDA a number of new and very necessary additional powers to better ensure the safety of our drugs, devices, and cosmetics. We also urge that manufacturers and others who profit from the sale of such products to American consumers fairly shoulder their full responsibility for improving the safety and quality of the products they sell.

I thank the Committee for the opportunity to testify today, and we at Consumers Union look forward to working with the Committee to help move forward on the strongest FDA reform bill possible. Thank you.

[The prepared statement of Ms. Gadhia follows:]

**Statement of Ami Gadhia**

**Concerning Discussion Draft of "FDA Globalization Act"**

**Subcommittee on Health, Energy & Commerce Committee**

**U.S. House of Representatives**

**May 1, 2008**

Good morning, Chairman Dingell, Ranking Member Barton, Subcommittee Chairman Pallone, Subcommittee Ranking Member Deal, and members of the Subcommittee. My name is Ami Gadhia, and I am Policy Counsel with Consumers Union[1], the non-profit publisher of *Consumer Reports* magazine. I am here today to testify about the Drug, Device, and Cosmetic Safety provisions of the Discussion Draft of the Food and Drug Administration (FDA) Globalization Act. Consumers Union commends the Chairman for his leadership on the proposed legislation, and commends members of the Energy and Commerce Committee for holding today's hearing on this critical consumer safety issue.

## I. FDA IS AN AGENCY IN DIRE NEED OF MAJOR REFORM

The FDA is the federal agency responsible for the regulation of myriad foods, drugs, devices, and cosmetics. The products regulated by this one agency represent about 25 cents of every consumer dollar spent, and are among the most intimate and important ones in our lives, including the drugs we take when we are sick and the medical devices implanted in our bodies to improve our lives. However, serious safety scares over the past few years have cast major doubt upon the ability of this beleaguered agency to adequately protect American consumers.

The call for a major overhaul of the FDA has now become a roar. According to a 1998 study by the Government Accountability Office (GAO), *ten years ago*, as much as

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* and its other publications and websites have a total subscription of approximately 8.6 million. *Consumer Reports* regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

80 percent of the bulk drug substances used by U.S. drug manufacturers was imported. No doubt this number has increased in the past ten years. A more recent GAO report, issued in November 2007, put the problem in stark relief: of all foreign plants, at most only seven percent of them are inspected in a year.[2] Of those that are inspected, these inspections are all announced to the plant owners in advance, despite FDA policy guidelines requiring that inspections be conducted without prior notification. In recent years we have seen a slide towards lax oversight and neglect of safety of imported products at the FDA. According to an April 2008 *New England Journal of Medicine* article, ". . .the evidence suggests that inspection needs have overwhelmed the agency's capacity."[3]

Some of the more high-profile failures of our drug, device, and cosmetics regulatory system are well known at this point: the import of contaminated heparin, a blood-thinning drug whose active pharmaceutical ingredient (API) was manufactured in China, and which is suspected to have been involved in the deaths of over 60 people; the 2006 recall of 183,000 packages of contact lens solution, manufactured in China, because of bacterial contamination; and a June 2007 import alert about toothpaste made in China that contained the very dangerous chemical Diethylene Glycol, which is used in antifreeze and as a solvent.

A September 2004 FDA report on the risk-based method of choosing foreign facilities for inspection indicated that the number of "registered human drug establishments" had increased by more than 400 percent during the previous 25 years, whereas the number of Good Manufacturing Practices inspections conducted dropped by more than 60 percent during that same time period. As FDA itself stated in that report,

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[2] GAO, Drug Safety: Preliminary Findings Suggest Weaknesses in FDA's Program for Inspecting Foreign Drug Manufacturers, GAO-08-224T (Washington, D.C.: Nov. 1, 2007).
[3] Stuart O. Schweitzer, "Trying Times at the FDA – The Challenge of Ensuring the Safety of Imported Pharmaceuticals, *The New England Journal of Medicine*, April 24, 2008, p. 1776.

"it is impossible for FDA to achieve uniformly intensive [Current Good Manufacturing Practices] inspectional coverage for all registered drug facilities."[4]

## II. PROVISIONS IN THE DISCUSSION DRAFT SUPPORTED BY CONSUMERS UNION

Consumers Union believes that the Discussion Draft of the FDA Globalization bill contains a number of strong provisions that will help make consumers safer. First, the bill would require mandatory inspection of both domestic and foreign drug and device facilities every two years. This inspection provision – if implemented with protections against conflicts of interest – should help improve compliance with existing FDA safety regulations. Consumers Union would respectfully recommend that this inspection occur annually (and more frequently, if there are problems), given the host of serious public health risks that have emerged from foreign facilities in particular. However, recognizing the time and resources involved in inspections, the annual inspection requirement could be modified to include a graduated inspection schedule depending on the category of product (e.g., tongue depressor facilities may be inspected less frequently than an establishment that manufactures heart medications).

Second, the Discussion Draft would require destruction of adulterated, misbranded, or counterfeit drugs that a company attempts to import into the United States. This provision is necessary to prevent importers from "shopping" until they find a port that will admit entry for their products, and will therefore keep dangerous products out of the U.S. The destruction of these unsafe drugs will also prevent importers from simply "dumping" them on the citizens of other countries – particularly those with lax

[4] "Risk-Based Method for Prioritizing CGMP Inspections of Pharmaceutical Manufacturing Sites – A Pilot Risk Ranking Model," Dept. of Health and Human Services, U.S. Food and Drug Administration, September 2004, pg. 4.

regulation. We would also recommend that the bill provide for a similar destruction of unsafe medical devices.

Third, the Discussion Draft would give the FDA the authority to recall seriously unsafe drugs – an authority that the agency currently has for dangerous devices, but which has been sorely lacking with regards to drugs. We strongly support this provision.

We also applaud members of the Committee for including in this Draft a provision requiring a label with the country of origin of active pharmaceutical ingredients and biologics, and a label with the country of manufacture for devices, known as Country of Origin Labeling (COOL). We believe that consumers and their health care professionals are better served by more information, rather than less. In addition, the draft bill would keep FDA from closing any of its 13 labs without Congressional review of its reorganization plan, which we support. (FDA originally indicated it would close 7 of the 13 labs, but has suspended that decision.)

We are also glad that the bill includes provisions addressing the safety of cosmetics. As mentioned above, in June 2007, FDA issued an import alert against imported toothpaste that contained Diethylene Glycol. Other cosmetics may also contain this or other harmful chemicals. It is not sufficient for FDA's inspection resources to stay at their current extremely inadequate level with regard to imported cosmetics. Creating a fee requirement for importers of cosmetics is one step towards addressing this problem.

There are, however, some provisions in the Discussion Draft that Consumers Union would urge the Committee to consider shortening the timeframes for implementation. It appears that the effective dates of a number of the bill's provisions are too far out into the future. For example: there is a two-year delay after enactment of

the Act before foreign producers are required to undergo inspection of their facilities as a pre-condition to importation, and a similar delay in the implementation of the COOL provisions. There is a *three*-year delay after the enactment of the Act before importers are required to produce documentation demonstrating compliance with drug and device safety requirements as a pre-condition of entry. These implementation dates, particularly the three-year delay in the requirement to produce documentation, should be shortened.

## III. AREAS OF CONCERN

We support the Discussion draft's provision creating a "user fees" regime for various new FDA functions such as registration, certification, and inspection as a reasonable way to pay for the numerous new functions that FDA must incorporate. However, we urge the Committee to ensure that the user fees do not turn into a "pay-for-play" scenario. That is, we would not want to see regulated entities have the ability, through the user fee program, to exert undue influence over the FDA in its decision-making or other functions.

We are also concerned that the fees for registration of importers as established by Section 401(c) of the Draft are not indexed for inflation. Like the user fees for food safety importation, the drug and device importer fees should be indexed.

Consumers Union also believes the civil money penalties for violations of the bill, in Section 210, are set too low. For a large manufacturer, producer, or other multi-national, a penalty of $100,000 is simply a cost of doing business. The drug and device industry is a multi-billion dollar industry, and a $100,000 fine may simply be a few hours' worth of profit for some companies. For the penalties to serve as a true deterrent against unsafe or illegal actions, they should be set higher.

We also urge inclusion of one particular GAO recommendation from its November 2007 report that is not currently in the Discussion Draft: FDA must have the ability to perform unannounced inspections of foreign facilities. Currently, since FDA gives foreign manufacturers advanced warning of inspections, these manufacturers – unlike domestic companies – are able to "clean up" to ensure they pass inspection, even if they are not in compliance every other day of the year. A dedicated foreign inspectorate (which the bill provides for) and regular FDA presence overseas, as well as adequate resources to staff these overseas offices, may be the best way to ensure random inspections.

Finally, any provisions in the final bill that permit FDA to outsource inspection, certification, registration, or any other agency tasks to a third party should include protections against such tasks being performed by entities with a conflict of interest. That is, any third party entities engaged by FDA to conduct safety and quality tasks should not be in any way connected with, related to, or otherwise influenced by any company within the supply chain.

## IV. CONCLUSION

We wholeheartedly support providing FDA with new authorities and resources. We are pleased that this Discussion Draft gives FDA a number of new – and very necessary – additional powers to better ensure the safety of our drugs, devices, and cosmetics. We also urge that manufacturers and others who profit off of the sale of drugs, medical devices, and cosmetics to American consumers fairly shoulder their full responsibility for improving the safety and quality of the products they sell.

I thank the Committee for the opportunity to testify today, and we at Consumers Union look forward to working with the Committee to help move forward on the strongest FDA reform bill possible.

Mr. PALLONE. Thank you, Ms. Gadhia, and thank you all the panel. We will start taking questions and I will recognize myself for 5 minutes for questions.

I wanted to start with Mr. Hubbard. In your testimony, you mentioned the heparin incident. Obviously that is of grave concern to us and should never—obviously we don't want it to happen again. In some of the meetings we have had with pharmaceutical manufacturers, they have pointed out that regardless of increased inspection, we currently do not have the technological capabilities to actually prevent similar incidents as the heparin case, and actually in her testimony on Tuesday, Dr. Woodcock pointed out that, and I quote, "Conventional laboratory testing did not identify the contaminant" and that the Agency had to develop a new test but they had to know that they were looking for something that shouldn't have been there.

So basically the way I understand it, Mr. Hubbard, the industry is saying that they can't test for unknowns that are unknown. They have got to have some idea what they are looking for. So it possible to screen drugs and biologics for unknown contaminants, and if not, what else can be done to ensure that the drugs sold to the American people are truly pure and safe?

Mr. HUBBARD. Well, it is certainly difficult to look for something that shouldn't be there and we saw that with melamine last year, but I think this case points up the fact that we have got to find a way because if people can do this kind of contamination so easily, save so much money and get it into our system without being caught, there has to be a way. If widespread use of capillary electrophoresis or these other sophisticated technologies are going to be difficult, it may have to be so be it, but I would hope that you would have a magnitude of scale that if you had more testing along these lines, that you would be able to have some cost savings, plus if FDA is regulating more and enforcing its GMPs, you are going to presumably raise the standards generally and deter these folks anyway and so you are going to have a secure supply chain where whoever put that chondroitin in at some point will know that there are more people looking, there is more testing, there is more overall quality assurance. So I think you have got the two pieces. You have a stronger system and perhaps some testing. And maybe you don't need to test everything but I think that some testing is probably going to have to be necessary.

Mr. PALLONE. No, I understand what you're saying, which is that, you know, we have to try to check things through the chain and set up standards. It is not just a question of a test at the end, but at the same time, we have to try to maybe invest in new testing methods too, just can't give up.

Let me ask Ms. Gadhia, I wanted to ask you a question about the country-of-origin labeling. You mentioned it, and of course a number of the other panelists voiced their concerns about country-of-origin labeling. The most common argument we have heard is that knowing what country the drug was made in or where the ingredients came from would only make consumers more worried and confused about the products they are purchasing. Is this country-of-origin labeling important, and why, and what would you say about the industry's concerns?

Ms. GADHIA. Well, I understand, and I have heard those concerns and generally speaking, the approach that we take is that consumers are better served by more information rather than less, and in fact, we think that the internal customers within the supply chain system would also be served by the internal information on a packaging or on what have you, letting them know where the product is from. The way that things like heparin, for example, work, it is not something that the consumer takes off the shelf themselves. It is something that a purchasing manager within a hospital would buy, or something like that, and we would like to see the awareness of potential red flags for danger or safety issues to go to those consumers, so to speak, as well. So we think that everyone across the board would be better served by that kind of information.

Mr. PALLONE. I wanted to ask Mr. Bone one more question here. You said that McKesson, I guess, has the electronic tracking system, right? You mentioned that. And you mentioned in your testimony the need for interoperable technologies to track-and-trace pharmaceuticals across the supply chain. We have heard today about concerns with respect to technology, at least in its current state, to be able to actually accomplish what is set forth in the bill that we have, and I know that the term "interoperability" is used often with respect to health information technology and EHRs, yet really doesn't mean that the systems truly are interoperable. So I guess what I wanted to ask you, I know that even like in hospitals, because I visit them all the time, they struggle to connect with other providers in the region or the Nation and a lot of times the technologies don't work the way they are supposed to. There are significant concerns about radio frequency identification, and in your opinion, is the technology there yet and are you confident that if each pharmacy purchased a different system, your suppliers will be able to integrate seamlessly with each other? Just basically tell me what McKesson is doing to ensure that their systems are truly able to connect seamlessly with all other technology manufacturers out there. You should know, we are probably going to deal with a larger HIT bill in the subcommittee too in the next few weeks so obviously this is of concern. If you want to just comment, if you will?

Mr. BONE. So what is happening in the industry, and I do serve on two leadership groups that are working on the standard for track-and-trace, both domestically and internationally. We are building the backbone for those standards. They are not specific in saying that you have to do it precisely this way, meaning you have to use RFID. There are other ways that you can communicate that information, and one of those is using a barcode. We have a barcode that is more robust. It is a 2–D barcode that a number of manufacturers are looking at. In the work that we have done so far in the standard setting, we recommend unit level packages that have RFID chips backed up with a 2–D barcode. That means that you would have an alternative method, for those who say I am not technologically sophisticated enough to read RFID chips. And quite frankly, I think reader costs are going to come down in price dramatically in the coming years. Those people could say that at this juncture reader costs are too high; however, they would have some-

thing more akin to what they are using today, which is a linear barcode. Now, a 2–D barcode is a barcode kind of on steroids. A 2–D barcode is a more sophisticated barcode because it can store more information on it. There are manufacturers that are experimenting with this system. We have actually been moving RFID product for over 2 years now, almost 3 years, where we have been testing with some manufacturers on that piece. So there is more work to be done. That is why I like the timing of this bill because it does give us the time to complete the standards work that we are doing, which we intend to get done later on in this year, first part of next year, which fits in the timing that you have here. And we are also trying to do it on an international basis, because many of the manufacturers are international based. We feel that it is important to expand that scope. But for us, what is most important is one standard for the Nation.

Mr. PALLONE. Do you think you can—I mean, I just want to restate the question. You think that with respect to the technology you will be able to actually accomplish what is set forth in the bill? I am talking about the Buyer-Matheson bill obviously.

Mr. BONE. That is correct. Yes, we do.

Mr. PALLONE. OK. Thank you.

Mr. Buyer.

Mr. BUYER. Thank you.

This will be a yes or no question and I am going to go right down the line. Do you see a value and a necessity and therefore support a one uniform national pedigree standard as opposed to 50 separate State pedigree standards? Mr. Hubbard?

Mr. HUBBARD. Absolutely.

Mr. BUYER. Ms. Reilly?

Ms. REILLY. Yes.

Mr. BUYER. Congressman Greenwood?

Mr. GREENWOOD. I certainly do.

Mr. BUYER. Ms. Mundkur?

Ms. MUNDKUR. Yes.

Mr. BUYER. Mr. Bone?

Mr. BONE. Yes.

Mr. BUYER. Mr. Nicholson?

Mr. NICHOLSON. Well, it is difficult——

Mr. BUYER. "Well" is not a yes or no response.

Mr. NICHOLSON. I do have difficulty answering that as a yes or no response.

Mr. BUYER. All right. Thank you.

Ms. Gadhia?

Ms. GADHIA. No.

Mr. BUYER. The next question I have, Mr. Greenwood, in H.R. 5839, there is a provision on page 23 which would exempt drugs from being required to have an identifier such as 2–D barcode, RFID chip or other technology. So if a manufacturer can demonstrate that the identifier would adversely affect the safety, effectiveness, purity or potency of the drug or would not be technically feasible, do you believe that this provision that we have in the Buyer-Matheson bill would be important for you to ensure that any new technologies do not affect biologics, which are known to be highly sensitive drugs?

Mr. GREENWOOD. I believe the answer to that is yes. I would like to reserve the opportunity to give you an answer in writing after I check with some of our technical staff.

Mr. BUYER. All right. Thank you.

Mr. Bone, first, on a personal note, let me thank you for your service as a Vietnam veteran. You state in your testimony that a track-and-trace system will create efficiencies and decreased costs. Can you explain just a little further?

Mr. BONE. Yes, and this is particularly relative to the uniform pedigree standard that is in your bill. We are focused on making sure the same serialized pedigree system is used, which means serialization when we start that product, and the receipt of that item in any one of our facilities throughout the distribution network, and as we pass that on to our customers, is the same system. What we have demonstrated over time, once we have that in place, and there are provisions in this bill to incrementally bring people on, so at the early stages I would say that is not going to happen but as we have the entire network in place, what we will do is, we will determine those places that we can improve inventory, recalls, returns processing, and the knowledge that we are going to have of those products and the quickness with which we will be able to handle those products will give us those savings.

Mr. BUYER. Thank you, Mr. Bone.

Now, Mr. Nicholson, I have got a series of inconsistencies that I want to give you the opportunity to clarify. One would be, you in your testimony, you use a $30,000 figure as a cost per pharmacy, and yet one of your own board members, the former CEO and chairman of Walgreen's, used a $20,000 figure. I would like to know if you are familiar with his May 2007 comment. The chairman and CEO of Walgreen's was quoted as stating, "Working together through our recently formed coalition within independent pharmacies, I am convinced that we can take hundreds of millions of dollars out of the pipeline by fully exploiting potential RFID in pharmacy. Even more promising is the vast improvements in data management networks over the last decade are justification for tremendous optimism." When he broke down the cost savings of an RFID technology for pharmacy, $7,250 per store for improved productivity, $2,000 per store per year in reduced labor costs on cycle counts, $2,500 per store in reduced returns and recalls, $4,000 per store per year in improved shrinkage, $24,000 per store per year in better inventory forecasting, improved out of stock positions and improved pharmacy workflow. Have you seen this analysis?

Mr. NICHOLSON. Yes, I have.

Mr. BUYER. Can you reconcile?

Mr. NICHOLSON. Well, Mr. Buyer, yes, I have. What I can tell you is that our members have—as Mr. Bone has indicated, our members have participated in track-and-trace pilot programs and the numbers that I spoke of today are the numbers that they have developed as part of the participation in the pilot programs. The costs that I spoke of today are—we do have a very diverse membership and for some members the costs may be greater than for others but these are the costs, this is the average cost that our members have indicated they would have to put out, that they would have to

spend in order to adopt a track-and-trace system at this point in time.

Mr. BUYER. Do you recognize that there have been decreased costs in track-and-trace technology in recent years? Do you acknowledge that?

Mr. NICHOLSON. I don't have that personal knowledge, and I——

Mr. BUYER. Would it surprise you if I were to tell you that industry analysis has found that for one identification system, which is the RFID, prices have fallen by 70 percent by year 2005? Would that surprise you?

Mr. NICHOLSON. No, that would not surprise me.

Mr. BUYER. OK. With regard to your ambivalence to a yes or no question, would you acknowledge that your organization, that there would be considerable costs to pharmacies for you to comply with 50 State separate pedigree requirements as opposed to one uniform standard?

Mr. NICHOLSON. We do prefer, as an association that represents large companies that operate in many States, we generally do support the harmonization of State requirements and we actually have been working in the States to harmonize the pedigree requirements among the States. More than half the States have passed legislation requiring pedigrees for distributions outside the normal distribution channel, so we feel that this has been an adequate way of addressing that situation.

Mr. BUYER. Mr. Chairman, I appreciate your indulgence. I have one last question.

Mr. Nicholson, you state that you cannot support legislation which would mandate a track-and-trace system.

Mr. NICHOLSON. At this point in time.

Mr. BUYER. However, your own lobbyist testified in California on April 7 that your organization supports the California legislation currently in the California Senate, which is a track-and-trace system. So I note their system, we have worked with them, mirrors a lot of our own provisions. How do you reconcile your testimony of April 7 supporting the California position, yet stand here and say emphatically that you do not now support a track-and-trace system?

Mr. NICHOLSON. Mr. Buyer, let me address that also. Our position in California is that pharmacies would need 2 years after the supply chain changes required to implement that changes are required for us to proceed. We have not endorsed track-and-trace in California. The legislation currently moving in the California legislature would amend current statutory requirements for track-and-trace. We are working with the Board of Pharmacy. We are working with stakeholders in California and so we are not supporting track-and-trace in California.

Mr. BUYER. You are not supporting? So you disavow the testimony that occurred in California on April 7?

Mr. NICHOLSON. Our testimony in California was not a support of track-and-trace.

Mr. PALLONE. We have to move on here. Let us go to Mr. Matheson. Maybe he can follow up on this. You don't have to. I recognize the gentleman from Utah.

Mr. MATHESON. Thank you, Mr. Chairman.

Mr. PALLONE. You are welcome.

Mr. MATHESON. I have a whole bunch of questions. Mr. Nicholson, in your testimony you mentioned that advocates of the Buyer-Matheson legislation are somehow implying that it would have stopped the heparin issue that took place. I just want to make a statement. We are not naive. We don't think our legislation deals with tainted drug supply and I don't think we have ever said it deals with stopping tainted drug supply and to set up an argument in your testimony to criticize legislation, it is a false argument. It is a straw man that you were able to knock back down but we have never said that and that hasn't been part of why we have justified this legislation. So just for the record, I don't think that part of your testimony really is germane to our bill. We would stipulate that our bill would not have prevented the heparin situation.

I have a whole bunch of questions and again, I know you didn't like the yes or no before, but in terms of on page 7 of your testimony where you mentioned the organization's concern with mandating use of any technology that is under development and premature. Let us try some yes-no questions on that. Are you aware of the provisions in H.R. 5839 which require the development of identifier and track-and-trace standards before anyone in the industry would be required to buy technology with such standards?

Mr. NICHOLSON. Yes, sir.

Mr. MATHESON. Are you also aware that the bill provides 18 months for identifiers to be placed on pharmaceuticals and at least 18 months for the supply chain to adopt track-and-trace after the standards are announced by the FDA?

Mr. NICHOLSON. Yes.

Mr. MATHESON. Additionally, are you aware of the comment period currently underway at the FDA as FDA develops standards for a unique identifier to be applied on all drug units?

Mr. NICHOLSON. Yes, we are providing comments to FDA.

Mr. MATHESON. Are you aware of the rulemaking process written into the bill for stakeholders to provide input to the FDA as it forms standards for the track-and-trace system?

Mr. NICHOLSON. We do support FDA's initiative.

Mr. MATHESON. It seems to me that the bill allows for pretty sufficient time for the supply chain as the FDA creates its standards for the track-and-trace system.

Mr. NICHOLSON. Well——

Mr. MATHESON. I understand——

Mr. NICHOLSON. My response to that would be is that we have been talking about track-and-trace for many years now and, you know, various stakeholders had promised the State of Florida track-and-trace. Back in 2003 they promised we would have track-and-trace in 2006. We didn't. California was promised track-and-trace in 2007.

Mr. MATHESON. What I am going to tell you, Mr. Nicholson, is our legislation puts in a buffer and it gives the FDA the time to develop these standards. We are not mandating specific dates in this legislation, and you imply that we are trying to push premature technology, and what I am telling you is, our legislation sets up a process by which the FDA through a rulemaking process with input from stakeholders is going to come up with those stand-

ards. So you can talk about Florida in 2003 all you want. That is not what our legislation does. We are not setting a date certain where it has to happen.

Let me move on. I understand that actually NACDS has been at the forefront of promoting use of track-and-trace technology. You sponsored annual summits right here in Washington for several years to promote the use of track-and-trace technology. According to Drug Store News, on December 10, 2007, your summit in 2007 drew nearly 500 attendees that came together to learn on how RFID and track-and-trace can be tightened for pharmaceutical supply chain security and enhance business processes. I also read an article in the 2007 RFID track-and-trace healthcare industry adoption summit, which was hosted by your organization, that Walgreen's CEO, David Bernauer, and I think Mr. Buyer mentioned this, he called on supply chain executives to adopt a comprehensive uniform system of RFID and track-and-trace technology and he further stated that RFID or other track-and-trace technologies could usher in a far more efficient supply chain, reducing shrink, out-of-stocks and returns of outdated product and would improve order accuracy and reduce costly inventory levels. Does your organization recognize those comments by one of your member companies at the summit that happened just last fall?

Mr. NICHOLSON. Yes, sir. Yes, Mr. Matheson, we do recognize that. We do support the—as you will notice in our testimony, we do not say that RFID or track-and-trace technology is bad. We say that it has much promise, that it should continue to be reviewed and to be researched, that it does have much promise for creating efficiencies in the supply chain. However, we are not comfortable with any legislation that mandates track-and-trace technology.

Mr. MATHESON. Did you know he noted in your 2005 summit you hosted that while it may mean supply chain improvements and heightened patient safety, the related benefits associated with the implementation of the new technology also includes increased customer retention? He thinks it is going to increase sales. That is what the chairman of Walgreens said. Did you note these benefits in your testimony? I don't think you did actually. You talked about the costs with the $30,000 amount, which Mr. Buyer has already brought into question, but one of your own member companies, one of your significant ones, has acknowledged that track-and-trace technology actually creates a lot of business opportunity and benefits for your industry as well.

Mr. NICHOLSON. We don't dispute that.

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

Mr. PALLONE. I am going to start dreaming track-and-trace here tonight with all the track-and-trace back and forth.

Thank you all. We certainly appreciate your testimony and obviously this is the second—we are actually going to have another hearing on this bill, I think, next week dealing with the cosmetics and the medical devices, but all of your testimony has been very helpful.

Let me mention that the members can submit additional questions for the record to be answered by you, and basically we get those questions submitted to the clerk within the next 10 days, so within 10 days or so, the clerk will notify your offices that you may

have written questions and we would certainly ask you to respond to those.

Mr. BUYER. Mr. Chairman, I would like to thank you for your courtesy today, not only to do your draft bill but to take into consideration Mr. Matheson's and my bill. I appreciate it.

Mr. PALLONE. You are welcome. It is very important and I am glad that we have a good discussion about it.

So thank you again, and without objection, the meeting of the subcommittee is adjourned.

[Whereupon, at 1:45 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

1 **SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CON-**
2 **TENTS.**

3 (a) SHORT TITLE.—This Act may be cited as the
4 "Food and Drug Administration Globalization Act of
5 2008".

6 (b) REFERENCES TO THE FEDERAL FOOD, DRUG,
7 AND COSMETIC ACT.—Except as otherwise specified,
8 whenever in this Act an amendment is expressed in terms
9 of an amendment to a section or other provision, the ref-
10 erence shall be considered to be made to a section or other
11 provision of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 301 et seq.).

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

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

TITLE I—FOOD SAFETY

Subtitle A—Prevention

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

Subtitle B—Intervention

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

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

Subtitle C—Response

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

Subtitle D—Miscellaneous

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

TITLE II—DRUG AND DEVICE SAFETY

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

TITLE III—COSMETIC SAFETY

Sec. 301. Registration of cosmetic facilities.

TITLE IV—MISCELLANEOUS

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

# TITLE I—FOOD SAFETY

## Subtitle A—Prevention

**SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILITIES.**

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

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

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

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

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

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

1 (2) REGISTRATION FEE.—Chapter VII (21
2 U.S.C. 371 et seq.) is amended—
3 (A) by redesignating sections 741 and 742
4 as sections 744 and 745, respectively; and
5 (B) by adding at the end of subchapter C
6 the following:

7 **"PART 3—FEES RELATING TO FOOD**

8 **"SEC. 741. FACILITY REGISTRATION FEE.**

9 "(a) IN GENERAL.—The Secretary shall assess and
10 collect a fee for a facility registration under section 415
11 for food safety activities under this Act.
12 "(b) AMOUNT OF FEE.—
13 "(1) IN GENERAL.—Subject to paragraph (2),
14 the amount of the fee under this section shall be
15 $2,000 for the initial registration and each rereg-
16 istration under section 415 of each facility operated
17 by the registrant.
18 "(2) ANNUAL INCREASE.—
19 "(A) IN GENERAL.—Subject to the limita-
20 tion specified in subparagraph (B), the amount
21 of the fee under this section for registrations
22 and re-registrations for a fiscal year after 2009
23 shall be the amount of such fee under this sec-
24 tion for the previous fiscal year increased by the
25 same percentage as the percentage inflation ad-

1 justment described in section 736(c)(1) for the
2 fiscal year.
3 "(B) LIMITATION.—An increase in the
4 amount of the fee under this paragraph shall
5 not be made under this section for any fiscal
6 year unless—
7 "(i) the amount appropriated for sala-
8 ries and expenses of the Center for Food
9 Safety and Applied Nutrition within Food
10 and Drug Administration for such fiscal
11 year is equal to or greater than the
12 amount appropriated for salaries and ex-
13 penses of such Center for fiscal year 2008
14 multiplied by the adjustment factor appli-
15 cable to the fiscal year involved under sec-
16 tion 736(c); and
17 "(ii) the amount appropriated for sal-
18 aries and expenses of the Food and Drug
19 Administration for such fiscal year is equal
20 to or greater than the amount appro-
21 priated for salaries and expenses of such
22 Administration for fiscal year 2008 multi-
23 plied by the adjustment factor applicable
24 to the fiscal year involved under section
25 736(c); and, except that in making deter-

1 minations under this subparagraph for the
2 fiscal year involved there shall be excluded
3 the amounts of fees collected under this
4 part, section 736, section 738, and section
5 740.
6 In applying clauses (i) and (ii) there shall not
7 be taken into account salaries or expenses that
8 are paid from fees, including those collected
9 under subsection (a), section 736, 738, 740,
10 741B, and 741D.".
11 (c) CONTENTS OF REGISTRATION.—Paragraph (2) of
12 section 415(a) (21 U.S.C. 350d(a)) is amended by striking
13 "containing information" and all that follows and insert-
14 ing the following: "containing information that identifies
15 the following:
16 "(A) The name, address, and emergency
17 contact information of each facility engaged in
18 manufacturing, processing, packing, or holding
19 food for consumption in the United States that
20 the registrant operates.
21 "(B) The primary purpose and business
22 activity of each such facility, including the dates
23 of operation if the facility is seasonal.
24 "(C) The general food category (as listed
25 under section 170.3(n) of title 21, Code of Fed-

1 eral Regulations, or as the Secretary may other-
2 wise designate for purposes of evaluating poten-
3 tial threats to food protection) of any food man-
4 ufactured, processed, packed, or held at each
5 such facility.
6 "(D) All trade names under which each
7 such facility conducts business related to food.
8 "(E) The name, address, and 24-hour
9 emergency contact information of the United
10 States distribution agent for each such facility,
11 which agent shall maintain information on the
12 wholesale and retail distribution of food.
13 Such registration shall also include an assurance
14 that the registrant will notify the Secretary of any
15 change in the products, function, or legal status of
16 each such facility (including cessation of business ac-
17 tivities) not later than 30 days after the date of such
18 change.".
19 (d) SUSPENSION AUTHORITY.—Such section is fur-
20 ther amended by adding at the end the following:
21 "(6) SUSPENSION OF REGISTRATION.—
22 "(A) IN GENERAL.—The Secretary may
23 suspend the registration of any facility reg-
24 istered under this section, including the facility
25 of an importer—

1 "(i) for violation of this Act that could
2 result in serious adverse health con-
3 sequences or death to humans or animals;
4 or
5 "(ii) if the facility, or employee of the
6 facility, delays, limits, or denies an inspec-
7 tion by the Secretary under this Act.
8 "(B) NOTICE AND OPPORTUNITY FOR
9 HEARING.—Before suspending the registration
10 of a facility under this paragraph, the Secretary
11 shall provide notice to a registrant of an intent
12 to suspend the registration and provide the reg-
13 istrant with an opportunity for an informal
14 hearing. The Secretary may issue a written
15 order of suspension following the hearing, if the
16 Secretary finds that a violation described in
17 subparagraph (A) has occurred.
18 "(C) REINSTATEMENT.—A registration
19 that is suspended under this section may be re-
20 instated pursuant to criteria published by the
21 Secretary in the Federal Register and on a pub-
22 lic website of the Food and Drug Administra-
23 tion.
24 "(D) APPEAL.—Any registrant whose reg-
25 istration is suspended under this section may

1 appeal that action in any appropriate district
2 court of the United States.".
3 (e) EFFECTIVE DATE.—
4 (1) MODIFICATION OF REGISTRATION FORM.—
5 Not later than 30 days after the date of the enact-
6 ment of this Act, the Secretary of Health and
7 Human Services shall modify the registration form
8 under section 415 of the Federal Food, Drug, and
9 Cosmetic Act to comply with the amendments made
10 by subsection (c).
11 (2) APPLICATION.—The amendments made by
12 this section, other than by subsection (c), shall take
13 effect on the date that is 30 days after the date on
14 which such modified registration form takes effect,
15 but not later than 60 days after the date of the en-
16 actment of this Act.
17 **SEC. 102. FOOD SAFETY PLAN; PROCESS CONTROLS; AND**
18 **PERFORMANCE STANDARDS.**
19 (a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et
20 seq.) is amended by adding at the end the following:
21 **"SEC. 418. FOOD SAFETY PLAN; PROCESS CONTROLS; AND**
22 **PERFORMANCE STANDARDS.**
23 "(a) IMPLEMENTATION OF FOOD SAFETY PLAN.—
24 "(1) IN GENERAL.—Before a facility (as de-
25 fined in section 415(b)) introduces or delivers for in-

1 troduction into interstate commerce any shipment of
2 food, the owner, operator, or agent in charge of the
3 facility shall develop and implement a written food
4 safety plan (in this section referred to as a 'food
5 safety plan') that is based on an analysis of—
6 "(A) the specific practices for—
7 "(i) obtaining and ensuring the safety
8 of raw materials and ingredients for food
9 produced, manufactured, processed,
10 packed, or held at a facility;
11 "(ii) producing, manufacturing, proc-
12 essing, packing, and holding food at the fa-
13 cility; and
14 "(iii) transporting food to and from
15 the facility; and
16 "(B) any hazard that has been present in
17 or on, or is reasonably likely to be present in
18 or on, any food that is manufactured, proc-
19 essed, packed, or held at the facility.
20 "(2) CONTENTS.—The food safety plan shall in-
21 clude each of the following elements:
22 "(A) A description of the preventive con-
23 trols being implemented that are reasonably ap-
24 propriate to control or limit identified hazards
25 and to comply with applicable hazard-specific

1 performance standards and other food safety
2 regulatory requirements.
3 "(B) Validation that such preventive con-
4 trols are effective to reduce, control, or elimi-
5 nate such hazard.
6 "(C) A description of monitoring of such
7 preventive controls being implemented, includ-
8 ing sampling and testing relating to the control
9 of hazards where appropriate to verify that the
10 controls are effective.
11 "(D) A description of the recordkeeping
12 being conducted, including evidence of correc-
13 tive actions, sampling and testing records, mon-
14 itoring and verification records, and validation
15 records.
16 "(E) A description of established proce-
17 dures for the recall of such articles of food,
18 whether voluntarily or when required under sec-
19 tion 423.
20 "(b) FOOD SAFETY PLAN REVISIONS.—
21 "(1) IN GENERAL.—The food safety plan shall
22 be revised—
23 "(A) when major changes have been made
24 by the owner facility; and

1 "(B) as deemed appropriate by the Sec-
2 retary.
3 "(2) INCLUSION OF SPECIFIC HAZARD CON-
4 TROLS.—The Secretary may require that a food
5 safety plan for a facility include specific hazard con-
6 trols, if such controls are needed to ensure the pro-
7 tection of the public health including to prevent in-
8 tentional adulteration of food.
9 "(c) INSPECTION OF FOOD SAFETY PLAN IN COURSE
10 OF FACILITY INSPECTION.—In the course of a facility in-
11 spection under section 704A, the Secretary shall conduct
12 a review of the food safety plan to ensure the plan—
13 "(1) is based on a thorough hazard analysis
14 and is adequate to protect the public health;
15 "(2) meets relevant regulatory and food safety
16 standards; and
17 "(3) limits the presence and growth of contami-
18 nants in food prepared in a facility to meet perform-
19 ance standards of subsection (d).
20 "(d) PERFORMANCE STANDARDS.—
21 "(1) IN GENERAL.—To protect the public
22 health, the Secretary may establish by regulation
23 and enforce performance standards that define, with
24 respect to specific foods and contaminants in food,

1 the level of food safety performance that a facility
2 shall meet.
3 "(2) CONSULTATION.—In establishing perform-
4 ance standards under this subsection, the Secretary
5 shall consult with the Centers for Disease Control
6 and Prevention and infectious disease experts out-
7 side the federal government, and hold public meet-
8 ings for the purpose of receiving public input and
9 comment.".
10 (b) EFFECTIVE DATE.—The amendment made by
11 subsection (a) shall apply to food shipments introduced
12 or delivered for introduction into interstate commerce on
13 and after the date that is 2 years after the date of the
14 enactment of this Act.
15 **SEC. 103. SAFETY STANDARDS FOR FRESH PRODUCE.**
16 Chapter IV (21 U.S.C. 341 et seq.), as amended by
17 section 102(a), is further amended by adding at the end
18 the following:
19 **"SEC. 419. SAFETY STANDARDS FOR FRESH PRODUCE.**
20 "(a) IN GENERAL.—Section 418 (relating to food
21 safety plan; process controls; and performance standards)
22 shall apply with respect to the production of a type of
23 fresh produce for consumption in the United States 1 year
24 after the date on which the Secretary by regulation de-

1 scribes how a producer of such type of fresh produce may
2 comply with such section.
3 "(b) LOCAL GROWING CONDITIONS.—The Secretary
4 shall assist a State or foreign country in identifying how,
5 considering local growing conditions, producers in such
6 State or foreign country may comply with section 418, as
7 applied under subsection (a).
8 "(c) VARIANCES.—If the Secretary issues a regula-
9 tion under subsection (a) with respect to the production
10 of a type of fresh produce, the Secretary shall provide for
11 a variance from such a regulation for producers in a State
12 or foreign country if the State or foreign country deter-
13 mines, and the Secretary concurs, that the variance—
14 "(1) is necessary in light of local growing condi-
15 tions; and
16 "(2) will be at least as effective in controlling
17 hazards as if the variance had not been provided.
18 "(d) FRESH PRODUCE DEFINED.—In this section,
19 the term 'fresh produce' means any fruit or vegetable that
20 is intended to be sold to the consumer—
21 "(1) in its unpeeled, natural form; or
22 "(2) with minimal processing (such as peeling,
23 chopping, or trimming).".

1 **SEC. 104. PERIODIC INSPECTIONS OF FOOD FACILITIES.**

2 (a) IN GENERAL.—Chapter VII is amended by add-
3 ing after section 704 the following:

4 **"SEC. 704A. PERIODIC INSPECTIONS OF FOOD FACILITIES.**

5 "(a) NATURE OF INSPECTIONS.—

6 "(1) IN GENERAL.—The Secretary shall provide
7 for an inspection system for the conduct of unan-
8 nounced inspections of facilities (as defined in sec-
9 tion 415(b)) to determine whether such facilities are
10 operating in compliance with this Act and with good
11 manufacturing practices, including the requirements
12 of section 419. Inspections shall include review of
13 records and sampling of food products.

14 "(2) TIMING OF INSPECTIONS.—

15 "(A) IN GENERAL.—Subject to subpara-
16 graph (B), inspections of facilities shall be con-
17 ducted every 4 years.

18 "(B) NONCERTIFIED FACILITIES.—Inspec-
19 tions of facilities that are not certified under
20 section 418 shall be conducted every 2 years.

21 "(3) SANCTION FOR INTERFERENCE WITH IN-
22 SPECTIONS.—If a facility or employee of a facility
23 delays, limits, or denies an inspection of the facility
24 under this section, the Secretary shall make a deter-
25 mination that may result in the facility losing its
26 registration under section 415.

1 "(b) CONDUCT OF INSPECTIONS.—

2 "(1) SCOPE.—An inspection under subsection
3 (a) of any facility shall extend to all things therein
4 that bear on whether food products are in compli-
5 ance with this Act. Access to records may include
6 the copying of such records.

7 "(2) AUTHORITY.—In conducting such inspec-
8 tions, officers or employees duly designated by the
9 Secretary, upon presenting appropriate credentials
10 to the owner, operator, or agent in charge, are au-
11 thorized—

12 "(A) to enter at reasonable times any facil-
13 ity in or to enter any vehicle being used to
14 transport or hold such food products;

15 "(B) to inspect in a reasonable manner
16 such facility or vehicle and all pertinent equip-
17 ment, finished and unfinished materials, con-
18 tainers, labeling, processes, controls, and prem-
19 ises;

20 "(C) to collect and retain samples of food
21 products or ingredients or of any other items
22 found during an inspection that may contribute
23 to a finding of whether such food products are
24 unsafe for human consumption or adulterated
25 or misbranded under this Act;

1 "(D) to review food safety plan established
2 under section 418; and
3 "(E) may take photographs and such pho-
4 tographs shall be treated as documents subject
5 to section 301(j).
6 "(3) WRITTEN REPORT.—Within 24 hours after
7 completion of inspection, the Secretary or certifying
8 agent making the inspection shall give to the owner,
9 operator, or agent in charge a report in writing set-
10 ting forth any conditions or practices observed which
11 indicate that either processing controls are inad-
12 equate to prevent or minimize food safety hazards or
13 that any food from such facility is unsafe for human
14 consumption, or adulterated or misbranded under
15 this Act.
16 "(c) PRODUCT DETENTION AND CONDEMNATION.—
17 "(1) ORDERS.—If, during an inspection con-
18 ducted under this section, the Secretary or certifying
19 agent has reason to believe that a food product is
20 unsafe for human or animal consumption, or adul-
21 terated or misbranded under this Act, the Secretary
22 may order the food product segregated, impounded,
23 and if objection is not made within 48 hours, con-
24 demned. If objection is made, such food products
25 that are in perishable form may be processed to the

1 extent necessary to prevent spoilage, and a hearing
2 shall be commenced expeditiously.
3 "(2) RELABELING.—If the Secretary deter-
4 mines that, through re-labeling or other action, such
5 food products can be brought into compliance with
6 this Act , the food may be released following a deter-
7 mination by the Secretary that such re-labeling or
8 other action as specified by the Secretary has been
9 performed.
10 "(3) DESTRUCTION OF CONDEMNED FOOD.—
11 Any food product condemned without objection, or
12 after an informal hearing, shall be destroyed under
13 supervision of the Secretary.".
14 (b) CONFORMING AMENDMENTS.—
15 (1) Section 415(a) (21 U.S.C. 350d(a)), as
16 amended by section 101(b), is amended by adding at
17 the end the following:
18 "(7) INSPECTION.—Every facility that is reg-
19 istered under this section shall be subject to inspec-
20 tion pursuant to section 704A.".
21 (2) OTHER INSPECTION RIGHTS AND DUTIES.—
22 Section 704 (21 U.S.C. 374) is amended by adding
23 at the end the following new subsection:
24 "(h) The rights and duties under this section of duly
25 designated officers and employees and of other persons

1 shall apply to the exercise of authority under section
2 704A.".

3 **SEC. 105. REINSPECTION FEE APPLICABLE TO FACILITIES.**

4 (a) IN GENERAL.—Part 3 of chapter VII (21 U.S.C.
5 371 et seq.), as added by section 101(b)(2), is further
6 amended by adding at the end the following:

7 **"SEC. 741A. REINSPECTION FEE APPLICABLE TO FACILI-**
8 **TIES.**

9 "(a) IN GENERAL.—The Secretary shall assess and
10 collect fees from each facility (as defined in section
11 415(b)) that—

12 "(1) during such fiscal year, commits a viola-
13 tion of any requirement of this Act relating to food,
14 including any such requirement relating to good
15 manufacturing practices; and

16 "(2) because of such violation, undergoes addi-
17 tional inspection by the Food and Drug Administra-
18 tion.

19 "(b) AMOUNT OF FEES.—The Secretary shall set the
20 amount of the fees under this section to fully defray the
21 costs of conducting the additional inspections referred to
22 in subsection (a)(2).

23 "(c) USE OF FEES.—The Secretary shall make all
24 of the fees collected pursuant to this section available sole-

1 ly to pay for the costs of additional inspections referred
2 to in subsection (a)(2).".
3 (b) EFFECTIVE DATE.—The amendment made by
4 subsection (a) shall apply to additional inspections occur-
5 ring after the date of the enactment of this Act.
6 **SEC. 106. FOOD FACILITY CERTIFICATION PROGRAM.**
7 (a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et
8 seq.), as amended by sections 102(a) and 103, is amended
9 by adding at the end the following:
10 **"SEC. 420. FOOD FACILITY CERTIFICATION PROGRAM.**
11 "(a) IN GENERAL.—
12 "(1) CERTIFICATION.—The Secretary shall es-
13 tablish a program for the certification of a facility
14 as being in compliance with the applicable require-
15 ments of this Act. Such program shall provide for—
16 "(A) direct certification by the Secretary;
17 or
18 "(B) certification by a certifying agent
19 that has been accredited under subsection (b).
20 "(2) VOLUNTARY CERTIFICATION.—Any facility
21 may apply to be certified to the Secretary under this
22 section.
23 "(3) FACILITY DEFINED.—For purposes of this
24 section, the term 'facility' has the meaning given

1 such term in section 415(b), and includes both for-
2 eign and domestic facilities.
3 "(4) CERTIFIED FACILITY DEFINED.—For pur-
4 poses of this chapter, the term 'certified facility'
5 means a facility that has been certified under the
6 program established under this subsection.
7 "(b) LISTING AND NOTICES.—
8 "(1) PUBLIC LISTING OF CERTIFIED FACILI-
9 TIES.—The Secretary shall make available to the
10 public through the Internet Web Site of the Food
11 and Drug Administration a list of each facility that
12 is certified under this section and the date on which
13 such certification will no longer be in effect.
14 "(2) DURATION OF CERTIFICATION.—The cer-
15 tification for a facility under this section shall be in
16 effect for 2 years from the date the Secretary or cer-
17 tifying agent approves the application for such cer-
18 tification of the facility.
19 "(3) REQUIRED INSPECTION.—No facility shall
20 be certified without having been inspected by the
21 Secretary or a certifying agent.
22 "(4) NOTICES OF VIOLATIONS.—
23 "(A) IN GENERAL.—If a certifying agent
24 in the process of inspecting a facility for certifi-
25 cation determines that the facility's food safety

1 plan is in violation of this Act and that the fa-
2 cility has failed to take corrective action within
3 30 days, the agent shall notify the Secretary of
4 such violation and such failure.
5 "(B) IMMEDIATE NOTICE.—A certifying
6 agent shall notify the Secretary immediately
7 during inspection of a facility if the food at the
8 facility appears to be unsafe for human or ani-
9 mal consumption or adulterated or misbranded
10 "(5) SUSPENSION OF CERTIFICATION.—The
11 Secretary may suspend the certification of a facility
12 under this section if, after opportunity for an infor-
13 mal hearing, the Secretary finds that—
14 "(A) the food safety plan of the facility
15 fails to comply with requirements of section
16 418; or
17 "(B) the facility is found on inspection not
18 to be in compliance with other applicable re-
19 quirements of this Act.
20 "(c) ACCREDITATION OF FOREIGN GOVERNMENTS
21 AND CERTIFYING AGENTS.—
22 "(1) IN GENERAL.—Beginning not later than 2
23 years after the date of enactment of this section, the
24 Secretary shall establish and implement an accredi-
25 tation system under which a foreign government, a

1 State or regional food authority, a foreign or domes-
2 tic cooperative that aggregates the products of grow-
3 ers or processors, or any other third party that the
4 Secretary determines appropriate, may request per-
5 mission to certify that facilities meet the applicable
6 requirements of this Act.

7 "(2) REQUEST BY FOREIGN GOVERNMENT.—
8 Prior to accrediting a foreign government as a certi-
9 fying agent under this paragraph (1)(A), the Sec-
10 retary shall perform such reviews and audits of food
11 safety programs, systems, and standards of the gov-
12 ernment (including all statutes, regulations, and in-
13 spection authority) as the Secretary deems necessary
14 to determine that they are adequate to ensure that
15 facilities certified by such government meet the re-
16 quirements of this Act with respect to food manufac-
17 tured, processed, packed, or held for import to the
18 United States.

19 "(3) REQUEST BY OTHER THIRD PARTY.—Prior
20 to accrediting a third party under paragraph (1)(B),
21 the Secretary shall perform such reviews and audits
22 of the training and qualifications of inspectors used
23 by the agent and conduct such reviews of internal
24 systems and such other investigation of the party as
25 the Secretary deems necessary to determine that

1 each facility certified by the party has systems and
2 standards in use to ensure that such facility meets
3 the requirements of this Act.
4 "(d) IMPORTATION.—As condition of accrediting
5 such government or certifying agent, the government or
6 certifying agent shall agree to issue a written and elec-
7 tronic certification to accompany each food shipment made
8 for import from a facility certified by such government or
9 certifying agent, subject to requirements set forth by the
10 Secretary.
11 "(e) MONITORING.—Following any accreditation of a
12 certifying agent under subsection (b), the Secretary may
13 at any time—
14 "(1) conduct an on-site audit of any facility cer-
15 tified by the agent, with or without the certifying
16 agent present; or
17 "(2) require the agent to submit to the Sec-
18 retary, for any facility certified by the agent, an on-
19 site inspection report and such other reports or doc-
20 uments the agent requires as part of the audit proc-
21 ess, including for a facility located outside the
22 United States documentation that the facility is in
23 compliance with registration requirements and prior
24 notice requirements for food imported to the United
25 States.

1 "(f) DEFINITIONS.—For purposes of this section:

2 "(1) CERTIFYING AGENT.—The term 'certifying
3 agent' means a foreign government or other third
4 party that conducts certification of facilities.

5 "(2) INSPECTOR.—The term 'inspector' means
6 a person who has completed training as required by
7 the Secretary in the conduct of food safety inspec-
8 tions.

9 "(g) LIMITATION.—

10 "(1) TO SPECIFIED FOOD PRODUCTS.—The
11 Secretary may limit the accreditation of a foreign
12 government or a third party under this section to
13 the certification of facilities for the import to the
14 United States only of specified food products (or
15 specified categories of food products), as determined
16 by the Secretary.

17 "(2) TO AVOID CONFLICTS OF INTEREST WITH
18 CERTIFYING AGENTS.—The Secretary shall promul-
19 gate regulations to ensure that there are adequate
20 protections against conflicts of interest between a
21 certifying agent and the facility to be certified by
22 such agent.

23 "(h) WITHDRAWAL OF ACCREDITATION.—The Sec-
24 retary may withdraw accreditation from a certifying agent
25 under subsection (b)—

1 "(1) if food from facilities certified by such
2 agent is linked to an outbreak of human or animal
3 illness;
4 "(2) following an investigation and finding by
5 the Secretary that the agent no longer meet the re-
6 quirements of subsection (b) for accreditation; or
7 "(3) following a refusal to allow United States
8 officials to conduct such audits and investigations as
9 may be necessary to ensure continued compliance
10 with the requirements set forth in this section.
11 "(i) RENEWAL OF ACCREDITATION.—The Secretary
12 shall audit accredited certifying agents whenever needed,
13 but no less than once every three years, to ensure the con-
14 tinued compliance with the requirements set forth in this
15 section. Renewal of accreditation shall occur following
16 each satisfactory audit.".
17 (b) FEE.—Part 3 of chapter VII, as added by section
18 101(b) and amended by section 105(a), is amended by
19 adding at the end the following:
20 **"SEC. 741B. CERTIFYING AGENT FEE.**
21 "(a) IN GENERAL.—The Secretary shall assess and
22 collect a fee for the accreditation of a foreign government
23 or third party as a certifying agent under section 420 for
24 the purpose of defraying the costs of the implementation

1 of the accreditation programs required to carry out such
2 section.
3 "(b) AMOUNT OF FEE.—The amount of a fee under
4 this section shall be as determined by the Secretary.".

5 **SEC. 107. TESTING OF FOOD SHIPMENTS; ACCREDITED LAB-**
6 **ORATORIES.**

7 (a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331)
8 is amended by adding at the end the following:
9 "(oo) The introduction or delivery for introduction
10 into interstate commerce by facility that is not certified
11 under section 420 of any shipment of food before arrang-
12 ing for sampling and testing of such shipment and submit-
13 ting the results of such sampling and testing to the Sec-
14 retary in accordance with section 421.".
15 (b) TESTING OF FOOD SHIPMENTS; ACCREDITED
16 LABORATORIES.—Chapter IV (21 U.S.C. 341 et seq.),
17 amended by sections 102(a), 103, and 106(a), is further
18 amended by adding at the end the following:

19 **"SEC. 421. TESTING OF FOOD SHIPMENTS; ACCREDITED**
20 **LABORATORIES.**

21 "(a) TESTING IN NON-CERTIFIED FACILITIES.—Be-
22 fore introducing or delivering for introduction into inter-
23 state commerce any shipment of food, a facility (as defined
24 in section 415(b)) that is engaged in manufacturing, proc-
25 essing, packaging, or holding such food and that is not

1 certified under section 420 with respect to such food shall
2 arrange for a laboratory accredited under subsection (c)—
3 "(1) to conduct sampling and testing of such
4 shipment to ensure compliance with applicable food
5 safety standards; and
6 "(2) to simultaneously submit electronically the
7 results of such sampling and testing to the Secretary
8 and to the owner of such facility.
9 "(b) TESTING IN CERTIFIED FACILITIES.—A facility
10 certified under section 420 that is engaged with manufac-
11 turing, processing, packaging, or holding food shall ar-
12 range for a laboratory accredited under subsection (c)—
13 "(1) to conduct, on a periodic basis specified by
14 the Secretary, sampling and testing of shipments of
15 food being introduced or delivered for introduction
16 into interstate commerce to ensure compliance with
17 applicable food safety standards; and
18 "(2) to submit electronically the results of such
19 sampling and testing to the Secretary and to the
20 owner of such facility.
21 "(c) ACCREDITATION OF LABORATORIES.—
22 "(1) IN GENERAL.—The Secretary shall ac-
23 credit laboratories for the purpose of conducting
24 sampling and testing under subsections (a) and (b).

1 "(2) STANDARDS.—Not later than 1 year after
2 the date of the enactment of this section, the Sec-
3 retary shall establish and publish in the Federal
4 Register standards to accredit or deny accreditation
5 to laboratories under this subsection. A laboratory
6 shall not be accredited unless it has paid the accredi-
7 tation fee required under section 741C.
8 "(3) AUDITS.—To ensure that laboratories ac-
9 credited under this subsection continue to meet the
10 standards of accreditation, the Secretary shall—
11 "(A) make onsite visits on an annual basis
12 to each accredited laboratory to audit the per-
13 formance of such laboratory; and
14 "(B) take such additional measures as the
15 Secretary determines to be appropriate.".
16 (c) ACCREDITATION FEE.—Part 3 of chapter VII, as
17 added by section 101(b) and amended by sections 105(a)
18 and 106(b), is amended by adding at the end the fol-
19 lowing:
20 **"SEC. 741C. LABORATORY ACCREDITATION FEE.**
21 "The Secretary shall assess and collect an annual fee,
22 specified by the Secretary, for accreditation under section
23 421(c) for the purpose of defraying the costs of the accred-
24 itation activities under such section.".

1 (d) EFFECTIVE DATE.—Sections 301(oo) and 421(a)
2 of the Federal Food, Drug, and Cosmetic Act, as added
3 by subsections (a) and (b), shall apply to shipments of
4 food introduced or delivered for introduction into inter-
5 state commerce on or after such date, not later than 3
6 years after the date of the enactment of this Act, as the
7 Secretary of Health and Human Services shall specify.

8 **SEC. 108. SAFE AND SECURE FOOD IMPORTATION PRO-**
9 **GRAM.**

10 Chapter VIII (21 U.S.C. 381 et seq.) is amended by
11 adding at the end the following:

12 **"SEC. 805. SAFE AND SECURE FOOD IMPORTATION PRO-**
13 **GRAM.**

14 "(a) IN GENERAL.—Beginning not later than 2 years
15 after the date of the enactment of this section, the Sec-
16 retary shall establish by regulation and carry out a pro-
17 gram under which the Secretary expedites the movement
18 of food through the importation process under this Act
19 if each facility involved in the production, manufacture,
20 processing, packaging, and holding of the food—

21 "(1) is certified under section 420; and

22 "(2) has agreed to abide by, and has been de-
23 termined by the Secretary to be in compliance with,
24 the food safety and security guidelines developed
25 under subsection (b) with respect to such food.

1 "(b) GUIDELINES.—

2 "(1) DEVELOPMENT.—For purposes of the pro-
3 gram established under subsection (a), the Secretary
4 shall develop safety and security guidelines applica-
5 ble to the importation of food.

6 "(2) FACTORS.—Such guidelines shall take into
7 account the following factors:

8 "(A) The personnel of the person import-
9 ing the food.

10 "(B) The physical and procedural safety
11 and security of such person's food supply chain.

12 "(C) The sufficiency of access controls for
13 food and ingredients purchased by such person.

14 "(D) The need for tracking and maintain-
15 ing records on food and ingredients purchased
16 by such person or moved through the supply
17 chain.

18 "(E) Documentation processing through
19 such person's supply chain.

20 "(F) Access by the Secretary to such per-
21 son's business records for review.

22 "(G) Vendor and supplier information.

23 "(H) Such other factors as the Secretary
24 determines necessary.".

1 **Subtitle B—Intervention**

2 **SEC. 111. IMPORTS AND COMMERCIAL FOOD IMPORTATION**
3 **THROUGH SPECIFIC PORTS OF ENTRY.**

4 Chapter IV (21 U.S.C. 341 et seq.), as amended by
5 sections 102(a), 103, 106(a), and 107(b), is further
6 amended by adding at the end the following:

7 **"SEC. 422. IMPORTS AND COMMERCIAL FOOD IMPORTA-**
8 **TION THROUGH SPECIFIC PORTS OF ENTRY.**

9 "Beginning on a date (not later than 5 years after
10 the date of enactment of this section) specified by the Sec-
11 retary, food shall only enter the United States, other than
12 only for personal use, through a port of entry that is lo-
13 cated in a metropolitan area with a federal laboratory, un-
14 less each facility (as defined in section 415(b)) that has
15 manufactured, processed, packed, and held the food is cer-
16 tified under section 420.".

17 **SEC. 112. RESEARCH ON TESTING TECHNIQUES FOR USE IN**
18 **INSPECTIONS OF IMPORTED FOOD SAFETY;**
19 **PRIORITY REGARDING DETECTION OF INTEN-**
20 **TIONAL ADULTERATION.**

21 Section 801 (21 U.S.C. 381) is amended by adding
22 at the end the following: "

23 "(p) RESEARCH ON TESTING TECHNIQUES FOR USE
24 IN INSPECTIONS OF IMPORTED FOOD SAFETY.—

1 "(1) IN GENERAL.—The Secretary shall (di-
2 rectly or through grants or contracts) provide for re-
3 search on the development of tests and sampling
4 methodologies, for use in inspections of food under
5 this section—
6 "(A) whose purpose is to determine wheth-
7 er food is adulterated by reason of being con-
8 taminated with microorganisms, chemical tox-
9 ins, or pesticide chemicals or related residues;
10 and
11 "(B) whose results are available not later
12 than approximately 60 minutes after the ad-
13 ministration of the tests.
14 "(2) PRIORITY.—
15 "(A) IN GENERAL.—In providing for re-
16 search under paragraph (1), the Secretary shall
17 give priority to conducting research on the de-
18 velopment of tests that are suitable for inspec-
19 tions of food at ports of entry into the United
20 States, with the greatest priority given to the
21 development of such tests that the Secretary de-
22 termines would be useful in detecting the inten-
23 tional adulteration of food.
24 "(B) SPECIFIC PRIORITIES.— In providing
25 for such research, the Secretary shall give pri-

1 ority under this paragraph to conducting re-
2 search on the development of tests and sam-
3 pling methodology for detecting the presence in
4 or on food of—
5 "(i) pathogens, including Escherichia
6 coli (STEC) 0157, salmonella, cyclospora,
7 cryptosporidium, hepatitis A, Clostridium
8 botulinum, or listeria;
9 "(ii) pesticide chemicals and related
10 residues;
11 "(iii) chemical toxins; and
12 "(iv) such other pathogens or sub-
13 stances as the Secretary determines to be
14 appropriate, including any pathogen or
15 substance that the Secretary determines is
16 a candidate for use to intentionally adul-
17 terate food.
18 "(C) GOAL.—The Secretary shall establish
19 the goal of developing, by the expiration of the
20 3-year period beginning on the date of the en-
21 actment of this subsection, tests and methodolo-
22 gies under paragraph (1) for each of the patho-
23 gens and substances receiving priority under
24 this paragraph.
25 "(3) PERIODIC REPORTS.—

1 "(A) IN GENERAL.—The Secretary shall
2 submit to the Congress periodic reports describ-
3 ing the progress that has been made toward the
4 goal referred to in paragraph (1)(C) and de-
5 scribing plans for future research toward the
6 goal.
7 "(B) CONTENTS.— Each of the reports
8 shall provide an estimate by the Secretary of
9 the amount of funds needed to meet such goal,
10 and shall provide a determination by the Sec-
11 retary of whether there is a need for further re-
12 search under this subsection.
13 "(C) DEADLINES.— The first report under
14 this paragraph shall be submitted not later
15 than 2 years after the date of the enactment of
16 this subsection. Subsequent reports shall be
17 submitted annually until such goal is met.
18 "(4) CONSULTATION.—The Secretary shall
19 carry out the program of research under paragraph
20 (1) in consultation with the Director of the Centers
21 for Disease Control and Prevention, the Director of
22 the National Institutes of Health, and the Admini-
23 trator of the Environmental Protection Agency. The
24 Secretary shall with respect to such research coordi-
25 nate the activities of the Department of Health and

1 Human Services. The Secretary shall in addition
2 consult with the Secretary of Agriculture (acting
3 through the Food Safety and Inspection Service of
4 the Department of Agriculture) in carrying out the
5 program.".

6 **SEC. 113. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
7 **OF ADULTERATED OR MISBRANDED ARTI-**
8 **CLES OF FOOD.**

9 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.
10 331), as amended by section 107(a), is amended by adding
11 at the end the following:

12 "(pp)(1) The failure to notify the Secretary in viola-
13 tion of section 423(a).

14 "(2) The failure to comply with—

15 "(A) an order issued under section 423(b) fol-
16 lowing any hearing requested under section 423(c);
17 or

18 "(B) an amended order issued under section
19 423(d)(1).".

20 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL
21 OF ADULTERATED OR MISBRANDED ARTICLES OF
22 FOOD.—Chapter IV (21 U.S.C. 341 et seq.), as amended
23 by sections 102(a), 103, 106(a), 107(b), and 111, is fur-
24 ther amended by adding at the end the following:

1 **"SEC. 423. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
2 **OF ADULTERATED OR MISBRANDED ARTI-**
3 **CLES OF FOOD.**
4 "(a) NOTIFICATION TO SECRETARY OF VIOLATION.—
5 "(1) IN GENERAL.—A person (other than a
6 household consumer or other individual who is the
7 intended consumer of an article of food) that has
8 reason to believe that an article of food when intro-
9 duced into or while in interstate commerce, or while
10 held for sale (regardless of whether the first sale)
11 after shipment in interstate commerce, is adulter-
12 ated or misbranded in a manner that, if consumed,
13 may result in illness or injury shall, as soon as prac-
14 ticable, notify the Secretary of the identity and loca-
15 tion of the article.
16 "(2) MANNER OF NOTIFICATION.—Notification
17 under paragraph (1) shall be made in such manner
18 and by such means as the Secretary may require by
19 regulation.
20 "(b) RECALL AND CONSUMER NOTIFICATION.—
21 "(1) VOLUNTARY ACTIONS.—On receiving noti-
22 fication under subsection (a) or by other means of
23 a suspected adulteration or misbranding of food, if
24 the Secretary finds that an article of food when in-
25 troduced into or while in interstate commerce, or
26 while held for sale (regardless of whether the first

1 sale) after shipment in interstate commerce, is adul-
2 terated or misbranded in a manner that, if con-
3 sumed, may result in illness or injury (as determined
4 by the Secretary), the Secretary shall provide all ap-
5 propriate persons (including the manufacturer, im-
6 porter, distributor, or retailer of the article) with an
7 opportunity (as determined by the Secretary)—
8 "(A) to cease distribution of the article;
9 "(B) to notify all persons—
10 "(i) that produce, manufacture, pack,
11 process, prepare, treat, package, distribute,
12 or hold the article, to cease immediately
13 those activities with respect to the article;
14 or
15 "(ii) to which the article has been dis-
16 tributed, transported, or sold, to cease im-
17 mediately distribution of the article;
18 "(C) to recall the article;
19 "(D) in consultation with the Secretary, to
20 provide notice of the finding of the Secretary to
21 all consumers to which the article was, or may
22 have been, distributed and to appropriate State
23 and local health officials; and
24 "(E) to notify State and local public health
25 officials.

1 "(2) MANDATORY ACTIONS.—If the appropriate
2 person referred to in paragraph (1) does not carry
3 out the actions described in that paragraph with re-
4 spect to an article within the time period and in the
5 manner prescribed by the Secretary, the Secretary—
6 "(A) shall issue an order requiring the per-
7 son—
8 "(i) to immediately cease distribution
9 of the article; and
10 "(ii) to immediately make the notifica-
11 tion described in paragraph (1)(B); and
12 "(B) may take control or possession of the
13 article.
14 "(3) NOTICE TO CONSUMERS AND HEALTH OF-
15 FICIALS.—The Secretary shall, as the Secretary de-
16 termines to be necessary, provide notice of the find-
17 ing of the Secretary under paragraph (1) to con-
18 sumers to which the article was, or may have been,
19 distributed and to appropriate State and local health
20 officials.
21 "(c) HEARINGS ON ORDERS.—
22 "(1) IN GENERAL.—The Secretary shall provide
23 a person subject to an order under subsection (b)(2)
24 with an opportunity for a hearing on—
25 "(A) the actions required by the order; and

1 "(B) any reasons why the article of food
2 that is the subject of the order should not be
3 recalled.
4 "(2) TIMING OF HEARINGS.—If a hearing is re-
5 quested under paragraph (1) with respect to an
6 order, the Secretary shall hold the hearing as soon
7 as practicable, but not later than 2 business days,
8 after the date of issuance of the order.
9 "(d) POST-HEARING RECALL ORDERS.—
10 "(1) AMENDMENT OF ORDERS.—If, after pro-
11 viding an opportunity for a hearing (and a hearing
12 if requested) under subsection (c), the Secretary de-
13 termines that an article of food when introduced into
14 or while in interstate commerce, or while held for
15 sale (regardless of whether the first sale) after ship-
16 ment in interstate commerce, is adulterated or mis-
17 branded in a manner that, if consumed, may result
18 in illness or injury, the Secretary may, as the Sec-
19 retary determines to be necessary—
20 "(A) amend the order under subsection
21 (b)(2)—
22 "(i) to require recall of the article or
23 other appropriate action; and
24 "(ii) to specify a timetable during
25 which the recall shall occur;

1 "(B) require periodic reports to the Sec-
2 retary describing the progress of any such re-
3 call; and
4 "(C) provide notice of such a recall to con-
5 sumers to which the article was, or may have
6 been, distributed.
7 "(2) VACATION OF ORDERS.—If, after providing
8 an opportunity for a hearing (and a hearing if re-
9 quested) under subsection (c), the Secretary deter-
10 mines that adequate grounds do not exist to con-
11 tinue the actions required by the order, the Sec-
12 retary shall vacate the order.
13 "(e) REMEDIES NOT EXCLUSIVE.—The remedies au-
14 thorized by this section shall be in addition to any other
15 remedies that may be available.".
16 (c) EFFECTIVE DATE.—Sections 301(pp)(1) and
17 423(a) of the Federal Food, Drug, and Cosmetic Act, as
18 added by subsections (a) and (b), shall apply with respect
19 to articles of food as of such date, not later than 1 year
20 after the date of the enactment of this Act, as the Sec-
21 retary of Health and Human Services shall specify.

22 **Subtitle C—Response**

23 **SEC. 121. CIVIL PENALTIES RELATING TO FOOD.**

24 (a) IN GENERAL.—Chapter III (21 U.S.C. 331 et
25 seq.) is amended by adding after section 303 the following:

1 **"SEC. 303A. CIVIL PENALTIES RELATING TO FOODS.**

2 "(a) IN GENERAL.—

3 "(1) ASSESSMENT.—The Secretary may assess
4 against a person that commits an act prohibited by
5 section 301 with respect to an article of food a civil
6 penalty for each such act of not more than—

7 "(A) $100,000, in the case of an indi-
8 vidual; and

9 "(B) $500,000, in the case of any other
10 person.

11 "(2) SEPARATE OFFENSES.—Each prohibited
12 act described in paragraph (1) and each day during
13 which the act continues shall be considered to be a
14 separate offense.

15 "(3) NOTICE AND OPPORTUNITY FOR HEAR-
16 ING.—The Secretary shall not assess a civil penalty
17 under this section against a person unless the person
18 is given notice and opportunity for a hearing on the
19 record before the Secretary in accordance with sec-
20 tions 554 and 556 of title 5, United States Code.

21 "(4) DETERMINATION OF CIVIL PENALTY
22 AMOUNT.—The amount of a civil penalty under this
23 section—

24 "(A) shall be assessed by the Secretary by
25 written order, taking into account—

26 "(i) the gravity of the violation;

1 "(ii) the degree of culpability of the
2 person;
3 "(iii) the size and type of the business
4 of the person; and
5 "(iv) any history of prior offenses by
6 the person; and
7 "(B) shall be reviewed only in accordance
8 with subsection (b).
9 "(b) JUDICIAL REVIEW.—
10 "(1) IN GENERAL.—An order assessing a civil
11 penalty against a person under subsection (a) shall
12 be final unless the person—
13 "(A) not later than 30 days after the effec-
14 tive date of the order, files a petition for judi-
15 cial review of the order in—
16 "(i) the United States court of ap-
17 peals for the circuit in which the person re-
18 sides or has its principal place of business;
19 or
20 "(ii) the United States Court of Ap-
21 peals for the District of Columbia Circuit;
22 and
23 "(B) simultaneously sends a copy of the
24 petition by certified mail to the Secretary.

1 "(2) FILING OF COPY OF RECORD.—The Sec-
2 retary shall promptly file in the court a certified
3 copy of the record on which the order was issued.
4 "(3) STANDARD OF REVIEW.—The findings of
5 the Secretary relating to the order shall be set aside
6 only if the findings are found to be unsupported by
7 substantial evidence on the record as a whole.
8 "(c) COLLECTION ACTIONS FOR FAILURE TO PAY
9 ASSESSMENT.—
10 "(1) REFERRAL TO ATTORNEY GENERAL.—If a
11 person fails to pay a civil penalty assessed under
12 subsection (a) after the order assessing the civil pen-
13 alty has become a final order, or after the court of
14 appeals has entered final judgment in favor of the
15 Secretary, the Secretary may refer the matter to the
16 Attorney General.
17 "(2) ACTION BY ATTORNEY GENERAL.—The
18 Attorney General shall bring a civil action to recover
19 the amount of the civil penalty in United States dis-
20 trict court.
21 "(3) SCOPE OF REVIEW.—In a civil action
22 under paragraph (2), the validity and appropriate-
23 ness of the order of the Secretary assessing the civil
24 penalty shall not be subject to review.

1 "(d) PENALTIES DEPOSITED IN TREASURY.—All
2 amounts collected as civil penalties under this section shall
3 be deposited in the Treasury of the United States and
4 shall be available to cover costs of the Administration in
5 carrying out food safety activities under this Act.
6 "(e) PENALTIES IN LIEU OF OTHER ACTIONS.—
7 Nothing in this Act requires the Secretary to report for
8 prosecution, or for the commencement of any libel or in-
9 junction proceeding, any violation of this Act in any case
10 in which the Secretary believes that the public interest will
11 be adequately served by the assessment of a civil penalty
12 under this section.
13 "(f) REMEDIES NOT EXCLUSIVE.—The remedies au-
14 thorized by this section shall be in addition to any other
15 remedies that may be available.".
16 (b) EFFECTIVE DATE.—The amendment made by
17 subsection (a) shall apply to prohibited acts committed on
18 or after the date of the enactment of this Act .
19 **SEC. 122. ENFORCEMENT AND RECALL.**
20 Section 801 (21 U.S.C. 381), as amended by section
21 112, is further amended by adding at the end the fol-
22 lowing:
23 "(q)(1) The Secretary may deny importation of food,
24 other than only for personal use, from any foreign country,
25 or which is manufactured, processed, packed, or held by

1 a facility (as defined in section 415), if the government
2 of such country, or such facility, respectively, does not
3 timely consent to an investigation by the Administration
4 when food from that country or facility is linked to a food-
5 borne illness outbreak or is otherwise found to be adulter-
6 ated or mislabeled. Any food imported for consumption in
7 the United States may be detained and condemned pursu-
8 ant to section 704A(c) or recalled pursuant to section
9 423.".

## 10 Subtitle D—Miscellaneous

### 11 SEC. 131. LABELING REQUIREMENT FOR MEAT, POULTRY 12 PRODUCTS, AND SEAFOOD THAT CONTAIN 13 CARBON MONOXIDE.

14 (a) LABELING REQUIREMENT.—
15 (1) IN GENERAL.—Paragraph (t) of section 201
16 (21 U.S.C. 321) is amended by adding at the end
17 the following:
18 "(4) In the case of food that is meat within the mean-
19 ing of the Federal Meat Inspection Act, a poultry product
20 within the meaning of the Poultry Products Inspection
21 Act, or seafood (including all fresh or saltwater fish,
22 molluscan shellfish, crustaceans, and other forms of
23 aquatic animal life) intended for human consumption as
24 food within the meaning of section 201(f) (referred to col-
25 lectively in this paragraph as 'seafood'), the term 'color

1 additive' shall include carbon monoxide under conditions
2 of use that may impart, maintain, preserve, stabilize, fix,
3 or otherwise affect the color of fresh meat, poultry prod-
4 ucts, or seafood, unless the label of such food bears,
5 prominently and conspicuously in such place and in such
6 manner as to render it likely to be read and understood
7 by the ordinary person, the following statement to prevent
8 consumer deception and serious risks to the public health:
9 'CONSUMER NOTICE: Carbon monoxide has been used
10 to preserve the color of this product. Do not rely on color
11 or the "use or freeze by" date alone to judge the freshness
12 of the product.' ".

13 (2) EFFECTIVE DATE.—The amendment made
14 by this subsection shall apply to food labeled on or
15 after the date that is 30 days after the date of the
16 enactment of this Act.

17 (b) DISCRETIONARY AUTHORITY.—If, not earlier
18 than 5 years after the effective date described in sub-
19 section (a)(2), the Secretary of Health and Human Serv-
20 ices finds, based on competent and reliable scientific evi-
21 dence, that the statement prescribed in section 201(t)(4)
22 of the Federal Food, Drug, and Cosmetic Act is no longer
23 required to prevent consumer deception and other harms,
24 then the Secretary is authorized to issue regulations estab-
25 lishing alternative labeling requirements that are shown

1 to be adequate and effective in preventing consumer de-
2 ception and other harms related to the conditions of use
3 of carbon monoxide, including with respect to preventing
4 any consumer deception or other harm that may result
5 from the actual conditions of carbon monoxide use and
6 its potential to impart a persistent color to meat, poultry
7 products, or seafood described in such section through a
8 reaction with natural pigment.

9 **SEC. 132. FOOD SUBSTANCES GENERALLY RECOGNIZED AS**
10 **SAFE.**

11 Section 409 (21 U.S.C. 348) is amended by adding
12 at the end the following:

13 "Substances Generally Recognized as Safe

14 "(k)(1) Not later than 60 days after the date of re-
15 ceipt by the Secretary after the date of the enactment of
16 this subsection of a request for a substance to be deter-
17 mined by the Secretary to be a GRAS food substance, the
18 Secretary shall publish such notice in the Federal Reg-
19 ister.

20 "(2) Not later than 90 days after the date of publica-
21 tion of a notice concerning a GRAS food substance, the
22 Secretary shall determine whether the substance is consid-
23 ered generally recognized as safe.

24 "(3) In this subsection, the term 'GRAS food sub-
25 stance' means a substance excluded from the definition of

1 the term 'food additive' in section 201(s) because such
2 substance is generally recognized, among experts qualified
3 by scientific training and experience to evaluate its safety,
4 as having been adequately shown through scientific proce-
5 dures (or, in the case of a substances used in food prior
6 to January 1, 1958, through either scientific procedures
7 or experience based on common use in food) to be safe
8 under the conditions of its intended use.

9 "(4) A determination whether a substance is gen-
10 erally recognized as safe by the Secretary shall be pub-
11 lished in the Federal Register.".

12 **SEC. 133. COUNTRY OF ORIGIN LABELING; DISCLOSURE OF**
13 **SOURCE OF INGREDIENTS.**

14 (a) FOOD.—Section 403 (21 U.S.C. 343) is amended
15 by adding at the end the following:

16 "(z) In the case of a processed food if—

17 "(1) the labeling of the food fails to identify the
18 country in which the final processing of the food oc-
19 curs; and

20 "(2) the website for the manufacturer of the
21 food fails to identify the country (or countries) of or-
22 igin for each ingredient in the food.

23 "(aa) In the case of non-processed food if—

24 "(1) the labeling of the food fails to identify the
25 country of origin of the food; and

1 "(2) the website for the original packer of the
2 food fails to identify the country of origin for the
3 food.".
4 (b) REGULATIONS.—Not later than 180 days after
5 the date of the enactment of this Act, the Secretary of
6 Health and Human Services shall promulgate final regula-
7 tions to carry out the paragraphs (z) and (aa) of section
8 403(z) of the Federal Food, Drug, and Cosmetic Act, as
9 added by subsection (a).
10 (c) EFFECTIVE DATE.—The requirements of para-
11 graphs (z) and (aa) of section 403 of the Federal Food,
12 Drug, and Cosmetic Act, as added by subsection (a), takes
13 effect on the date that is 2 years after the date of the
14 enactment of this Act.

15 **SEC. 134. NEW FOOD AND ANIMAL FEED EXPORT CERTIFI-**
16 **CATION FEE TO IMPROVE THE ABILITY OF**
17 **UNITED STATES FIRMS TO EXPORT THEIR**
18 **PRODUCTS.**

19 Part 3 of chapter VII (21 U.S.C. 371 et seq.), , as
20 added by section 101(b) and amended by sections 105(a),
21 106(b), and 107(c), is further amended by adding at the
22 end the following:

1 **"SEC. 741D. NEW FOOD AND ANIMAL FEED EXPORT CER-**
2 **TIFICATION FEE TO IMPROVE THE ABILITY**
3 **OF UNITED STATES FIRMS TO EXPORT THEIR**
4 **PRODUCTS.**

5 "(a) IN GENERAL.—If the Secretary provides for the
6 issuance of export certificates for foods and animal feeds
7 in cases where exportation is restricted without such a cer-
8 tificate, the Secretary may impose a fee for the issuance
9 of such a certificate.

10 "(b) AMOUNT.—The amount of the fee under this
11 section shall be an amount that is reasonably related to
12 the cost of issuing such certificates.

13 "(c) USE OF FEES.—The Secretary shall make all
14 of the fees collected pursuant to this section available sole-
15 ly to pay for the costs of issuance of such certificates.".

16 **TITLE II—DRUG AND DEVICE**
17 **SAFETY**

18 **SEC. 201. REGISTRATION FEE APPLICABLE TO PRODUCERS**
19 **OF DRUGS AND DEVICES.**

20 (a) PROHIBITED ACT.—Subsection (p) of section 301
21 (21 U.S.C. 331), as amended by section 101(a), is amend-
22 ed by striking "501(k);" and inserting "501(k), the failure
23 to pay an annual registration fee in violation of 736C,".

24 (b) REGISTRATION FEE.—Part 2 of subchapter C of
25 chapter VII is amended by adding at the end the following:

1 **"SEC. 736C. REGISTRATION FEE.**

2 "(a) IN GENERAL.—The Secretary shall assess and
3 collect an annual fee for registration under subsection (b),
4 (c), (d), or (i) of section 510 for the purpose of defraying
5 the costs of inspecting establishments registered under
6 such subsection to ensure that such establishments are in
7 compliance with the requirements of this Act relating to
8 drugs and devices.

9 "(b) AMOUNT OF FEE.—The amount of a fee under
10 this section shall be—

11 "(1) such amount as the Secretary determines
12 for establishments with respect to drugs; and

13 "(2) such amount as the Secretary determines
14 for establishments with respect to devices.".

15 (c) EFFECTIVE DATE.—The Secretary of Health and
16 Human Services shall first impose the fee established
17 under section 736C of the Federal Food, Drug, and Cos-
18 metic Act, as added by subsection (b), for fiscal years be-
19 ginning with fiscal year 2009.

20 **SEC. 202. INSPECTION OF PRODUCERS OF DRUGS, ACTIVE**
21 **PHARMACEUTICAL INGREDIENTS, DEVICES,**
22 **AND DEVICE PARTS.**

23 (a) PROHIBITED ACT.—Subsection (p) of section 301
24 (21 U.S.C. 331), as amended by sections 101(a) and
25 201(a), is amended by inserting before "or the failure to
26 provide a notice required by section 510(j)(2)" the fol-

1 lowing: "the introduction or delivery for introduction into
2 interstate commerce of any drug, any active pharma-
3 ceutical ingredient, any class II or III device, or device
4 part to such a device, as determined by the Secretary, be-
5 fore an initial inspection is complete in violation of section
6 510(h)(2),".

7 (b) INSPECTION.—Subsection (h) of section 510 (21
8 U.S.C. 351) is amended—

9 (1) by striking "(h)" and inserting "(h)(1)";

10 (2) by striking "Every establishment in any
11 State registered with the Secretary pursuant to this
12 section" and inserting "Every establishment reg-
13 istered with the Secretary pursuant to subsection
14 (b), (c), (d), or (i)"; and

15 (3) by adding at the end the following:

16 "(2) Upon receipt of an initial registration under sub-
17 section (b), (c), (d), or (i) for an establishment, the Sec-
18 retary shall ensure that such establishment is promptly
19 inspected pursuant to section 704. Until such initial in-
20 spection is complete, any drug (including any active phar-
21 maceutical ingredient) or class II or III device or any de-
22 vice part of such a device (as determined by the Secretary
23 that is manufactured, prepared, propagated, compounded,
24 or processed by such establishment shall not be introduced
25 or delivered for introduction into interstate commerce.

1 There shall be a new initial inspection of a drug or device
2 establishment when the establishment begins to manufac-
3 ture, prepare, propagate, compound, or process a drug, ac-
4 tive pharmaceutical ingredient, class II or III device, or
5 a part of such a device (as determined by the Secretary)
6 before its introduction or delivery into interstate commerce
7 unless the product constitutes only a minor modification
8 to a product previously manufactured, prepared, propa-
9 gated, compounded, or processed at the establishment..
10 "(3) A drug or device establishment, or employee of
11 such an establishment, that delays, limits, or denies an
12 inspection under this Act is subject to suspension of reg-
13 istration under section 510. If the Secretary determines
14 that such an establishment delays, limits, or denies such
15 an inspection, the establishment shall not place into inter-
16 state commerce any drug or device it manufactures, pre-
17 pares, propagates, compounds, or processes.".
18 (c) EFFECTIVE DATE.—
19 (1) IN GENERAL.—The amendments made by
20 this section shall apply to drugs introduced or deliv-
21 ered for introduction into interstate commerce on or
22 after the date that is 2 years after the date of the
23 enactment of this Act
24 (2) ESTABLISHMENTS ALREADY REGISTERED,
25 BUT NOT INSPECTED.—In the case of any establish-

1 ment that is registered under subsection (b), (c),
2 (d), or (i) of section 510 of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 351) as of the effective
4 date specified in paragraph (1) but has not been in-
5 spected pursuant to section 704 of such Act (21
6 U.S.C. 374) as of such date, such amendments shall
7 not apply until 2 years after such effective date.

8 **SEC. 203. DOCUMENTATION FOR ADMISSIBILITY OF DRUG**
9 **IMPORTS.**

10 Section 801 (21 U.S.C. 381), as amended by sections
11 112 and 122, is amended by adding at the end the fol-
12 lowing:

13 "(r) Beginning 3 years after the date of enactment
14 of this subsection, a drug shall only enter the United
15 States, other than only for personal use, through a port
16 of entry that is located in a metropolitan area with a fed-
17 eral testing laboratory, unless the party offering that drug
18 for import provides the Secretary, at the time of offering
19 the drug for import, documentation demonstrating compli-
20 ance with applicable requirements pertaining to identity,
21 strength, quality, purity, approval, listing, labeling, and
22 registration. The Secretary may require that such docu-
23 mentation include verification of compliance by an accred-
24 ited third party or by the Secretary during an inspection
25 within the past two years, and such other information as

1 the Secretary determines is necessary for protection of the
2 public health.".

3 **SEC. 204. ORIGIN OF INGREDIENTS.**

4 (a) IN GENERAL.—Section 501(a)(2) (21 U.S.C.
5 351(a)(2)) is amended by inserting after "; or" at the end
6 the following: "or (D) if it is a drug and it bears, contains,
7 or consists of an active or inactive ingredient and the man-
8 ufacturer of that ingredient and of each drug that contains
9 that ingredient does not have, and provide to the Secretary
10 upon request, adequate documentation to establish where
11 the ingredient was made, including all previous producers
12 and manufacturers, that the ingredient is not adulterated
13 or misbranded, that the ingredient will perform in accord-
14 ance with specifications, is not contaminated, and does not
15 have any undisclosed additives, and that the ingredient
16 was manufactured, distributed, shipped, warehoused,
17 processed, brokered, imported, and conveyed under condi-
18 tions that ensure the identity, strength, quality, and purity
19 of the drug; or".

20 (b) EFFECTIVE DATE.—The amendment made by
21 subsection (a) shall take effect on a date, specified by the
22 Secretary of Health and Human Services, not later than
23 3 years after the date of the enactment of this Act.

1 **SEC. 205. TESTING FOR DRUG PURITY AND IDENTITY.**

2 (a) IN GENERAL.—Section 501(a)(2) (21 U.S.C.
3 351(a)(2)), as amended section 204(a), is amended by in-
4 serting after "; or" at the end the following: "or (E) if
5 it is a drug, unless each manufacturer of the finished dos-
6 age form, active ingredients, and inactive ingredients con-
7 tained in or consisting of that drug verifies its product's
8 purity and identity using scientifically sound and appro-
9 priate methods of sufficient analytical precision and speci-
10 ficity to detect and quantify the product separate from
11 contaminants, impurities, and adulterants; or (F) if it is
12 a drug, unless each manufacturer of an active pharma-
13 ceutical ingredient contained in or consisting of that drug
14 periodically evaluates its ingredient's impurity profile to
15 verify that it remains substantially similar to or better
16 than the profile of the lot (or lots) used in the clinical
17 studies and/or toxicological evaluation. If no clinical stud-
18 ies or toxicological evaluation was conducted, then the im-
19 purity profile shall determined according to standards to
20 be established by the Secretary; or".

21 (b) EFFECTIVE DATE.—The amendment made by
22 subsection (a) shall take effect on a date, specified by the
23 Secretary of Health and Human Services, not later than
24 3 years after the date of the enactment of this Act.

1 **SEC. 206. COUNTRY OF ORIGIN LABELING.**

2 (a) DRUGS AND DEVICES.—Section 502 (21 U.S.C.
3 352) is amended by adding at the end the following:

4 "(y) If it is a drug or device and—

5 "(1) its labeling fails to identify the country (or
6 countries) which is the source of the active pharma-
7 ceutical ingredient in whole or in part and of its
8 place of manufacture in the case of a drug, or the
9 country of manufacture in the case of a device; or

10 "(2) in the case of a drug the website of the
11 manufacturer of the drug does not list the country
12 of origin for any drug ingredient of such drug.".

13 (b) REGULATIONS.—Not later than 180 days after
14 the date of the enactment of this Act, the Secretary shall
15 promulgate final regulations to carry out section 502(y)
16 of the Federal Food, Drug, and Cosmetic Act, as added
17 by subsection (a).

18 (c) EFFECTIVE DATE.—The requirement of section
19 502(y) of the Federal Food, Drug, and Cosmetic Act, as
20 added by subsection (a), takes effect 2 years after the date
21 of the enactment of this Act.

22 **SEC. 207. RECALL AUTHORITY FOR DRUGS.**

23 Subchapter E of chapter V is amended by adding at
24 the end the following:

1 **"SEC. 568. RECALL AUTHORITY FOR DRUGS.**

2 "The Secretary shall have the same authority with
3 respect to drugs as the Secretary has with respect to de-
4 vices under section 518(e). In applying the previous sen-
5 tence, any reference in such section to a device shall be
6 deemed a reference to a drug.".

7 **SEC. 208. DESTRUCTION OF ADULTERATED, MISBRANDED**
8 **OR COUNTERFEIT DRUGS OFFERED FOR IM-**
9 **PORT.**

10 (a) IN GENERAL.—The fifth sentence of section
11 801(a) (21 U.S.C. 381(a)) is amended by inserting before
12 the period at the end the following: ", except that any
13 product that is refused admission may, at the discretion
14 of the Secretary, be destroyed and not exported if (1) it
15 appears to pose a risk of injury or death, or (2) has a
16 value of less than $2,000, as determined by the Sec-
17 retary".

18 (b) EFFECTIVE DATE.—The amendment made by
19 subsection (a) shall take effect the date of the enactment
20 of this Act, regardless of when the product may have been
21 refused admission.

22 **SEC. 209. ADMINISTRATIVE DETENTION OF DRUGS THAT**
23 **APPEAR TO VIOLATE THE LAW.**

24 (a) IN GENERAL.—Section 304(g) (21 U.S.C.
25 334(g)) is amended—

1 (1) by inserting "drug or" before "device" each
2 place it appears; and
3 (2) in paragraph (1), by inserting after "adul-
4 terated or misbranded" the following: "or, in the
5 case of a drug, which in the determination of the of-
6 ficer or employee making the inspection appears to
7 be in violation of section 505,".
8 (b) EFFECTIVE DATE.—The amendments made by
9 subsection (a) shall take effect on a date, specified by the
10 Secretary of Health and Human Services, not later than
11 1 year after the date of the enactment of this Act.
12 (c) TRANSITION.—Until such time as the Food and
13 Drug Administration issues regulations to carry out the
14 amendments made by subsection (a), the regulations ap-
15 plicable under section 304(g) of the Federal Food, Drug,
16 and Cosmetic Act shall apply to drugs, as included by the
17 amendment made by such amendments.
18 **SEC. 210. CIVIL MONEY PENALTIES FOR VIOLATIVE DRUGS**
19 **AND DEVICES AND IMPROPER IMPORT**
20 **ENTRY FILINGS.**
21 (a) IN GENERAL.—Section 303 (21 U.S.C. 333) is
22 amended by adding at the end the following:
23 "(h)(1) Any person who violates a requirement of this
24 Act that relates to drugs and devices for human use shall
25 be liable to the United States for a civil penalty not to

1 exceed $100,000 per violation. Each day during which a
2 violation continues shall be considered a separate viola-
3 tion.

4 "(2) Any person, including a manufacturer, dis-
5 tributor, importer, broker, or filer, who knowingly reports
6 or enters false data on documents related to the introduc-
7 tion of drugs and devices in interstate commerce shall be
8 liable to the United States for a civil penalty not to exceed
9 $150,000. Each act of reporting or entering false data
10 shall be considered a separate violation.

11 "(3) The provisions of paragraphs (2), (5), (6), and
12 (7) of subsection (g) shall apply to a civil money penalty
13 under paragraph (1) or (2) of this subsection in the same
14 manner as they apply to a civil money penalty under sub-
15 section (g)(1).".

16 (b) EFFECTIVE DATE.—The amendment made by
17 subsection (a) shall apply to violations occurring on or
18 after the date of the enactment of this Act.

# 19 TITLE III—COSMETIC SAFETY

20 **SEC. 301. REGISTRATION OF COSMETIC FACILITIES.**

21 (a) IN GENERAL.—Chapter VI is amended by adding
22 at the end the following new section:

23 **"SEC. 604. REGISTRATION OF FACILITIES.**

24 "(a) IN GENERAL.—The Secretary shall by regula-
25 tion require that any facility engaged in manufacturing,

1 processing, packing, or holding of cosmetics in the United
2 States or for import to the United States be registered
3 with the Secretary.

4 "(b) APPLICATION OF FOOD REGISTRATION RULES
5 AND REGISTRATION FEE.—Except as provided in this sec-
6 tion, the provisions of section 415 and section 741 shall
7 apply to registration of cosmetic facilities under subsection
8 (a) in the same manner as they apply to registration of
9 facilities (as defined in section 415(b)) under such respec-
10 tive section, except that, with respect to registration fees
11 imposed under this subsection, any reference in section
12 741 to 'food' is deemed a reference to 'cosmetics'. Each
13 facility shall list in the registration the cosmetic products
14 it manufactures, processes, packs, or holds and, in the
15 case of a manufacturing facility, a list of the ingredients
16 for each product so listed that it manufactures.

17 "(c) ADVERSE EVENT REGISTRY.—The Secretary
18 shall by regulation require a facility that manufactures
19 cosmetics to report to the Secretary all anticipated and
20 unanticipated serious adverse events relating to the use
21 of cosmetics it has manufactured.

22 "(d) GOOD MANUFACTURING PRACTICES.—The Sec-
23 retary shall by regulation require that the methods used
24 in, and the facilities and controls used for the manufac-
25 ture, process, packing, or holding of a cosmetic conform

1 to good manufacturing practices as prescribed in such reg-
2 ulations.".
3 (b) EFFECTIVE DATES.—
4 (1) REGISTRATION AND FEES.—Cosmetic facili-
5 ties shall be required to register (and pay registra-
6 tion fees) under subsections (a) and (b) of section
7 604 of the Federal Food, Drug, and Cosmetic Act,
8 as added by subsection (a), beginning 6 months
9 after the date of the enactment of this Act.
10 (2) ADVERSE EVENT REGISTRY AND GOOD MAN-
11 UFACTURING PRACTICES.—The Secretary of Health
12 and Human Services shall establish the adverse
13 event registry and the good manufacturing practices
14 under the amendment made by subsection (a) not
15 later than 18 months after the date of the enact-
16 ment of this Act.

17 **TITLE IV—MISCELLANEOUS**

18 **SEC. 401. REGISTRATION AND FEE FOR COMMERCIAL IM-**
19 **PORTERS OF FOOD, DRUGS, DEVICES, AND**
20 **COSMETICS.**

21 (a) PROHIBITIONS.—Section 301 (21 U.S.C. 331), as
22 amended by sections 107(a) and 113(a), is further amend-
23 ed by adding at the end the following:
24 "(qq) The importation of food, drugs, devices, or cos-
25 metics other than only for personal use by an importer

1 that is not registered with respect to such food, drugs,
2 devices, or cosmetics under section 415, 510, or 604, re-
3 spectively, unless the importer is registered under section
4 801(s).".

5 (b) REGISTRATION.—Section 801, as amended by
6 sections 112, 122, and 203, is amended by adding at the
7 end the following:

8 "(s) The Secretary shall by regulation require that
9 an importer of food, drugs, devices, or cosmetics, other
10 than only for personal use, that is not registered with re-
11 spect to such food, drugs, devices, or cosmetics under sec-
12 tion 415, 510, or 604, respectively, shall be registered with
13 the Secretary in a form and manner specified by the Sec-
14 retary. The Secretary shall assign a unique identification
15 number to each importer so registered.".

16 (c) FEE.—Subchapter C of chapter VII is amended
17 by adding at the end the following:

18 **"PART 6—IMPORTERS OF FOOD, DRUGS,**
19 **DEVICES, AND COSMETICS**

20 **"SEC. 742. IMPORTERS OF FOOD, DRUGS, DEVICES, AND**
21 **COSMETICS.**

22 "(a) IN GENERAL.—The Secretary shall assess and
23 collect an annual fee for the registration of an importer
24 of food, drugs, devices, or cosmetics under section 801(s).

1 "(b) AMOUNT OF FEE.—The amount of the fee under
2 this section shall be $10,000.".
3 (d) EFFECTIVE DATE.—
4 (1) REGISTRATION.—Not later than 1 year
5 after the date of the enactment of this Act, the Sec-
6 retary of Health and Human Services shall establish
7 procedures for the registration of importers under
8 section 801(s) of the Federal Food, Drug, and Cos-
9 metic Act, as added by subsection (a).
10 (2) REGISTRATION.—The amendments made by
11 this section shall first apply not later than 1 year
12 after the date of the enactment of this Act.
13 **SEC. 402. UNIQUE IDENTIFICATION NUMBER FOR FOOD,**
14 **DRUG, AND DEVICE FACILITIES AND ESTAB-**
15 **LISHMENTS.**
16 (a) FOOD AND COSMETICS.—Section 415(a)(3) (21
17 U.S.C. 350d(a)(3)) is amended by adding at the end the
18 following: "Such a registration number shall be a unique
19 identification number for each such facility that may be
20 used for purposes other than registration under this sub-
21 section.".
22 (b) DRUGS AND DEVICES.—Section 510(e) (21
23 U.S.C. 360(e)) is amended by adding after the first sen-
24 tence the following: "Such a registration number shall be
25 a unique identification number for each such establish-

1 ment that may be used for purposes other than registra-
2 tion under this subsection.".
3 (c) APPLICATION TO COSMETICS.—The amendment
4 made by subsection (a) applies to cosmetics through the
5 operation of section 604 of the Federal Food, Drug, and
6 Cosmetic Act, as added by section 301(a).
7 (d) APPLICATION TO IMPORTERS.—See section
8 402(b) of this Act for the requirement for a unique identi-
9 fication number for importers that are registered.
10 (e) EFFECTIVE DATE.—The Secretary of Health and
11 Human Services shall implement the amendments made
12 by this section not later than 1 year after the date of the
13 enactment of this Act.
14 **SEC. 403. DEDICATED FOREIGN INSPECTORATE.**
15 Section 704 (21 U.S.C. 374) is amended by adding
16 at the end the following:
17 "(h) The Secretary shall establish and maintain a
18 corps of inspectors dedicated to inspections of foreign
19 food, drug, device, and cosmetics facilities and establish-
20 ments. This corps shall be staffed and funded by the Sec-
21 retary at a level sufficient to allow it to conduct inspec-
22 tions of foreign food, drug, device and cosmetic facilities
23 and establishments at a frequency at least equivalent to
24 the inspection rate of domestic food, drug, device, and cos-
25 metic facilities and establishments.".

1 **SEC. 404. CONTINUED OPERATION OF FIELD LABORA-**
2 **TORIES.**
3 (a) IN GENERAL.—Subject to subsections (b) and
4 (d), the Secretary of Health and Human Services (in this
5 section referred to as the "Secretary") shall not—
6 (1) terminate any of the 13 field laboratories
7 that were operated by the Office of Regulatory Af-
8 fairs of the Food and Drug Administration as of
9 January 1, 2007;
10 (2) consolidate any such laboratory with any
11 other laboratory;
12 (3) terminate any of the 20 district offices or
13 any of the inspection or compliance functions of any
14 of the 20 district offices of the Food and Drug Ad-
15 ministration functioning as of January 1, 2007; or
16 (4) consolidate—
17 (A) any such district office with an office
18 in any other district; or
19 (B) transfer any of the compliance or in-
20 spection functions of any such district office to
21 any other district.
22 (b) REPORT BY SECRETARY.—
23 (1) SUBMISSION.—The Secretary shall submit a
24 reorganization plan involving the termination or con-
25 solidation of the laboratories, the district offices, or
26 the functions of such district offices specified in sub-

1 section (a) to the Comptroller General of the United
2 States, the Committee on Energy and Commerce of
3 the House of Representatives, and the Committee on
4 Health, Education, Labor, and Pensions of the Sen-
5 ate.
6 (2) CONSULTATION.—In preparing the reorga-
7 nization plan described in paragraph (1), the Sec-
8 retary shall consult with personnel and unions to be
9 affected by the plan.
10 (c) REPORT BY GAO.—The Comptroller General
11 shall study the cost effectiveness of the reorganization
12 plan described in subsection (b) and its impact on the
13 safety of food, drug, and other products regulated under
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
15 et seq.) and the Public Health Service Act (42 U.S.C. 201
16 et seq.) and report to the Committee on Energy and Com-
17 merce of the House of Representatives and the Committee
18 on Health, Education, Labor, and Pensions of the Senate.
19 (d) REORGANIZATION.—
20 (1) CONGRESSIONAL REVIEW.—The reorganiza-
21 tion plan described in subsection (b) is deemed to be
22 a major rule (as defined in section 804(2) of title 5,
23 United States Code) for purposes of chapter 8 of
24 such title.

1 (2) EFFECTIVE DATE.—Notwithstanding sec-
2 tion 801(a)(3) of title 5, United States Code, the re-
3 organization plan described in subsection (b) shall
4 take effect (unless disapproved under section 802 of
5 such title) on the date that is specified in such plan,
6 but not earlier than 180 days after the date on
7 which the Comptroller General submits the report
8 required by subsection (c).

9 **SEC. 405. FALSE OR MISLEADING REPORTING TO FDA.**

10 (a) IN GENERAL.—Section 301(q)(2) (21 U.S.C.
11 331(q)(2)) is amended by inserting after "device" the fol-
12 lowing: "food, drug, or biological product".

13 (b) EFFECTIVE DATE.— The amendment made by
14 subsection (a) shall apply to submissions made on or after
15 the date of the enactment of this Act.

16 **SEC. 406. APPLICATION TO BIOLOGICAL PRODUCTS.**

17 Under section 351(j) of the Public Health Service Act
18 (42 U.S.C. 262(j)), the amendments made to the Federal
19 Food, Drug, and Cosmetic Act by this Act shall also apply
20 to biological products.

21 **SEC. 407. LIMITATION TO COMMERCIAL IMPORTATION.**

22 Nothing in this Act, or the amendments made by this
23 Act, shall be construed as applying to importation other
24 than commercial (and not personal) importation.

## WILLIAM K. HUBBARD, ANSWERS TO SUBMITTED QUESTIONS

### QUESTION SUBMITTED BY HON. JOHN D. DINGELL:

**1. Mr. Hubbard, the discussion draft would require a unique identification number for registered facilities and importers so FDA can more effectively track facilities in case of emergencies. There has been talk from various groups of using a Dunn and Bradstreet Number as a unique identifier. What would be the advantage of using that number specifically? Are there any disadvantages to using that number?**

A: It is clear from the findings by the Committee and the GAO that the current registration system for foreign facilities has not been successful, as demonstrated by the inaccurate and changing information about which foreign drug manufacturers are registered and sending drugs to the United States. Therefore, unique identification # is needed, and FDA officials now recognize that need. The advantage of using the Dunn and Bradstreet (DUNS) system is that it is a well established one that has worked well in the past, and does not require FDA to create a new system from "scratch." I do not know of any disadvantages to using the DUNS system.

### QUESTIONS SUBMITTED BY HON. STEVE BUYER:

**1. During your time at the FDA, why was FDA unable to destroy counterfeit, adulterated, and misbranded pharmaceuticals coming through our international mail system? Do you think FDA should have the ability to destroy these unregulated drugs?**

A: Under current law, FDA is required to go through certain legal processes, such as notifying the intended recipient of the drug that it may be in violation of law, hold the drug while the recipient considers that notification, and permit the recipient to have a hearing on the drug's detention. FDA has little storage capacity at border points, and does not have the staff to detain and notify the thousands of such drug shipments that arrive via the mail each week. The agency has requested the authority to destroy such shipments, much as the Drug Enforcement Administration can for controlled substances under its purview, but Congress has not acted on that request. If FDA did have such authority, it could deter the purchases over the internet of drugs from unknown and unsafe sources, and thus provide a significant deterrent to the sale in the US of counterfeit and otherwise dangerous drug imports.

**2. Do you support a uniform national pedigree system and do you think a track-and-trace system will help to secure our Nation's pharmaceutical supply chain from counterfeiting and diversion?**

A: Yes, a uniform national pedigree system, allied with an effective trace and trace system for monitoring the movement of drugs, is, in my opinion, the single most effective strategy that the United States can adopt to deter the counterfeiting and diversion of pharmaceuticals. The technology exists for doing so, and should be mandated as soon as possible, with a reasonable period of time for manufacturers, wholesalers and others in the supply chain to implement.

**3. Do you believe drug counterfeiting and drug diversion are problems in the United States?**

A: Yes. Not only are drug counterfeiting and diversion a problem today in this country, it is a growing problem that increasingly threatens the safety of our citizens. The counterfeiters are seeking more and more each year to sell their dangerous products in the United States, as they currently do commonly in many countries around the world. FDA is unable, with current resources and authority, to effectively stop this trend, and I urge Congress to strengthen the Agency's capability to do so.

### QUESTION SUBMITTED BY HON. DIANA DEGETTE

**1. Counterfeiting is becoming increasingly more common worldwide, and I believe that it is vital for FDA and border control agents to have tools at their disposal that will enable them to appropriately deal with adulterated or counterfeit drugs at the point of entry.**

I want to make sure that there will be sufficient technology, resources, and authority available to border control agents to ensure the continued safety of our Nation's drug supply. Could you please comment on what you believe is necessary at the border in order to safeguard our pharmaceutical supply?

A: FDA needs a range of new tools to effectively deter counterfeit drugs that are imported from other countries. First, the Agency needs sufficient resources. The

agency has only 450 import inspectors to cover more than 400 ports of entry, so that effort is clearly massively underfunded. And the Agency has inspectors to conduct only a handful of surveillance inspections in foreign countries each year (where most of our drug ingredients are now produced).

Second, FDA needs to be able to require state-of-the-art technology for tracking-and-tracing pharmaceuticals, using a universal pedigree for each drug. Such technologies are available today and have been demonstrated to be an effective deterrence against counterfeiters, who are essentially prevented from introducing their dangerous products into the US market.

Third, border inspectors need changes in their current authority over drugs that are found at the border. Currently, inspectors must go through such complicated procedures to detain suspect imported drugs that they must let most go through unimpeded. Those procedures were created in an earlier day in which few drug imports arrived at border points, and the border inspectors are now overwhelmed by the volume of drug imports. Specifically, border inspectors need the authority to either immediately refuse entry or destroy imported drugs that violate US law, without going through the cumbersome notice procedures required by current law.

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## LORI M. REILLY, ANSWERS TO SUBMITTED QUESTIONS

Dear Chairman Dingell and Rep. Buyer:

Thank you for your letter dated June 9, 2008, which sets out additional questions from Rep. Steve Buyer. For your convenience, I have reproduced your questions below, followed by answers on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $44.5 billion in 2007 in discovering and developing new medicines. Industry-wide research and investment reached an estimated record $58.8 billion in 2007.

## QUESTIONS SUBMITTED BY HON. STEVE BUYER

**1. Do you see value in one, uniform national pedigree standard as opposed to 50 separate state pedigree standards?**

PhRMA sees great value in the establishment of a single, national pedigree standard. In fact, several states have adopted pedigree and electronic track-and-trace requirements. In addition, many other states are considering pedigree and electronic track-and-trace legislation. Because of the complexity of these systems and the need for coordination among many different trading partners, there should be one uniform national pedigree and/or electronic track-and-trace system, not multiple and potentially inconsistent state requirements. This would provide national uniformity of all pedigree and track-and-trace laws, and will help encourage the adoption and use of anti-counterfeiting technologies rather than promoting multiple and potentially inconsistent state requirements.

**2. What have your member companies done in terms of moving toward track-and-trace systems?**

Based on discussions intended to inform PhRMA's advocacy with Congress, the Food and Drug Administration (FDA), and state legislators and regulators, we can confirm that numerous manufacturers are working towards implementing electronic pedigrees. The increase in activity compared to just a few years ago demonstrates manufacturers' ongoing commitment to assuring a safe supply chain that will enhance patient safety. We view electronic pedigree as a key approach to meeting the mandate of the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 913 of FDAAA directs the FDA to, among other things: "develop a standardized numerical identifier (which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier) to be applied to a prescription drug at the point of manufacturing and repackaging . . . . at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking-and-tracing of the prescription drug." [1] Neither Section 913 of the FDAAA nor FDA's Federal Register notice defines the term "standardized numerical identifier." The FDA has begun the process to collect information as directed under

[1] Public Law No. 110-85 (Sept. 27, 2007).

FDAAA, and PhRMA will continue to work closely with the Agency and relevant stakeholders as the FDA progresses.

Additionally, in October 2007, as requested by the California Board of Pharmacy Enforcement Committee, and to help inform our advocacy, PhRMA conducted a confidential survey of its member companies on their activities and mechanisms to track the distribution of pharmaceutical products in the supply chain. Twenty-one members of PhRMA responded to the survey. U.S. antitrust laws prevent disclosure of the identity of companies responding to the survey; that information has not been shared with PhRMA staff or member companies. Company-specific information has been aggregated to protect its confidential nature.

E-PEDIGREE WITHOUT SERIALIZATION

PhRMA's survey results revealed that more than 2/3 of our member companies were in the planning phase for non-serialized electronic pedigree, or e-pedigree, as of last fall. Of the remaining respondents, the majority are currently conducting e-pedigree pilots. A small number of companies, less than 10% of the respondents, have implemented non-serialized e-pedigree for all of their products in commercial distribution.

PhRMA's members report that, based on their pilot studies, pharmacy involvement in non-serialized e-pedigree pilots is extremely limited; wholesaler participation is greater but still limited.

SERIALIZATION

The PhRMA survey results reveal that the research-based pharmaceutical manufacturers' experiences with serialization pilots are in the preliminary stages. Multiple companies are conducing serialization pilots at the case, pallet and item level, and the majority of these pilots involve limited product tagging. The majority of respondents conducting serialization pilots at the item level are using 2–D barcode technology. The majority of serialization pilots involving tagging at the case or pallet level are using UHF/RFID technology. Eighty-two percent of the serialization pilots involving wholesalers and/or pharmacies affect no more than 25% of the volume of that product in the commercial marketplace.

The PhRMA survey results reveal that planning and conducting serialization pilots is a time and resource-intensive process. The majority of the pilots our member companies are involved in are taking 12–18 months to plan and implement, and the majority have an expected duration of 12–18 months. Thus, a serialization pilot at the case, pallet or item level takes approximately 3 years from planning to completion. The cost to conduct these pilots ranges from approximately $200,000 for a limited scope serialization pilot to anywhere from $1 million to $15 million for one pilot.

PhRMA's survey indicates that the impact of item-level serialization for manufacturers would be significant. Based on our survey, more than 2000 medicines of the research-based prescription drug industry are affected, with each manufacturer having an average of 113 affected products. A total of 431 packaging lines in 162 plants are impacted, with an average of 25 packaging lines in 8.5 different plants impacted. Our manufacturers estimate that nearly 900 internal company personnel would be involved in any commercial serialization, with an average of 53 people per company.

PhRMA's survey results also reveal that each implementation is unique. Taking into account the significant time and resources necessary to plan and conduct pilots, it is clear that each implementation of item-level serialization will be time-consuming and resource-intensive, and could face unexpected challenges and delays at any time. Survey estimates of the time to serialize all products range from approximately 1 year per product to 5–7 years to serialize all products. Moreover, PhRMA's survey results suggest that the costs to serialize all medicines of the research-based pharmaceutical companies in commercial distribution range between, at the low end, $5–$10 million for a company all the way up to $200 million for a single company. PhRMA's best estimate of the initial investment to implement serialization at the smallest unit shipped by the manufacturer, for all innovator human prescription drugs sold in the United States, is $4.5 billion, based on our survey results.

**3. What other steps have manufacturers taken to help secure the prescription drug supply chain?**

PhRMA believes there is no technological "silver bullet" to protect against counterfeits. PhRMA member companies currently employ and routinely enhance a variety of anti-counterfeiting technologies, including covert and overt features on the packaging of high-risk prescription drugs. They have also adopted a range of business processes to better secure the supply chain and help facilitate the early detec-

tion of criminal counterfeiting activity. These are additional tools to help strengthen the security of the pharmaceutical supply chain.

PhRMA member companies have a strong interest in ensuring that the supply chain that moves drugs from the manufacturer to the patient is safe and secure. Our companies manufacture these products following exacting standards and use 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 breakdowns in the distribution system, such as diversion and counterfeiting. America's pharmaceutical research companies are committed to embracing new technologies as a means of protecting the integrity of the American drug supply. PhRMA has also collaborated with other members of the supply chain to explore a variety of approaches to help assure American patients that the drugs they get are not counterfeit.

Manufacturers of pharmaceuticals sold legally in the U.S. must comply with the "gold standard" of quality manufacturing—FDA's GMP regulations. The GMP regulations are applicable to all pharmaceuticals sold in the U.S., wherever they are made, and extend to all components of a finished drug product, including active pharmaceutical ingredients (APIs), without regard to where those ingredients are sourced. These regulations are extensive and thorough and require manufacturers to build quality into the design and production of pharmaceuticals, thereby helping to assure the safety, integrity and quality of every product approved and sold in the U.S. from the outset. FDA's GMP regulations are based on the fundamental quality assurance principle that quality, safety and effectiveness "cannot be inspected or tested into a finished product," but instead must be designed and built into a product. GMPs represent a comprehensive, systems-based approach that requires a company to build quality directly into the entire manufacturing operation, in order to ensure that the process itself is under control and therefore will consistently produce a drug product that meets designated specifications. Pharmaceutical manufacturers employ extensive quality systems and take extraordinary measures to secure the supply chain throughout the life cycle of the product since any loophole or breakdown in the pharmaceutical distribution system may provide an opportunity for diversion or counterfeiting to occur. Thus, in our view, the most effective way to combat counterfeiting is to adopt a multi-pronged strategy that addresses weaknesses throughout the distribution system.

**4. Does PhRMA see a problem with thousands of unregulated pharmaceutical packages coming through our Nation's international mail system every day?**

While the current system has been effective in the U.S. for protecting public health, it faces increased threats with the proliferation of Internet drug sellers outside the U.S. and outside the jurisdiction of the FDA. The safety concerns that exist today are many and include concerns over the introduction of unsafe or counterfeit drugs into the U.S. stream of commerce as well as concerns about individuals using the Internet as a means to avoid getting a prescription for their medicine. Both pose considerable safety concerns.

Experts agree that buying prescription medicine from unknown Internet drug sellers poses inherent risks to patients. FDA estimates that counterfeits make up 10 percent of the global medicines market.[2] The World Health Organization (WHO) has found that 50% of prescription medicines from rogue Internet sites are counterfeit. According to the WHO, ".the message for now is: do not take the risk of buying your medicines from unknown sources, such as the Internet. If you must buy from the Internet, ensure that the Web site is that of a pharmacy you know and trust."[3] According to counterfeit expert Tom Kubic, Executive Director of the Pharmaceutical Security Institute (PSI), "Counterfeit drugs are posing increasing risk to U.S. consumers, especially when shopping online.Except [for] a few legitimate U.S. Internet pharmacies, there is little or no effective control over drugs purchased over the Internet."[4]

According to a recent National Public Radio report, the Internet and the growth in international commerce, as well as easy access to sophisticated technology has facilitated the rise of counterfeit medicines in the marketplace. Recently, the FDA's Director of Pharmacy Affairs Ilisa Bernstein noted that there are "counterfeiters circulating all over the world" and it is difficult to "tell how many there are because

[2] FDA, "Counterfeit Drugs Questions and Answers," available at: http://www.fda.gov/oc/initiatives/counterfeit/qa.

[3] World Health Organization, "WHO and partners accelerate fight against counterfeit medicines; Up to 50% of medicines sold through rogue web sites are fake," November 15, 2006.

[4] ABC News, "Dateline's Bitter Pill Investigation Highlights Need for Consumer Awareness of Counterfeit Drugs," June 6, 2006.

the counterfeiters are just so good at what they do." According to Bernstein, the FDA is unable to inspect "millions and millions and millions" of packages coming in making it "very difficult to find and catch all of these drugs that are coming in."[5] And, according to Dr. Valerio Reggi, head of the WHO's Anti-Counterfeiting Task Force, inspections may not be successful in finding all counterfeit drugs. According to Reggi, "no counterfeiter would manufacture one pill or even container of pills.for every drug that you find, it means at least one batch. And one batch usually is between 30,000 and 60,000 tablets."[6]

A recent example illustrates the real safety concerns that exist. In February 2007, the FDA alerted consumers to "unsafe, misrepresented drugs purchased over the Internet." According to FDA, patients recently ordering drugs online for depression and insomnia instead received schizophrenia medication that caused them to seek emergency medical treatment for breathing problems. Side effects ranged from muscle spasms to difficulty breathing.[7]

The FDA has conducted a number of investigations and analyses that illustrate that consumers may be misled into believing that the drugs they have ordered online came from locations such as Canada, when in fact, they may have come from anywhere in the world. In late 2005, an FDA investigation revealed that many drugs being promoted as "Canadian" products really originated from other countries and a number of the products were counterfeit. FDA's operation confiscated parcels containing pharmaceuticals from India, Israel, Costa Rica and Vanuatu—43 percent of which had been ordered from Canadian Internet pharmacies. Of the drugs being promoted as "Canadian", 85 percent actually came from 27 countries around the globe. According to the FDA commissioner, "These results make clear there are Internet sites that claim to be Canadian that in fact are peddling drugs of dubious origin, safety and efficacy."[8]

According to FDA, "In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs have been of unknown quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA."[9] An FDA analysis of three commonly prescribed drugs purchased from a Web site advertised as Canadian showed that so-called "Canadian Generics" bought from the Web site were fake, substandard and potentially dangerous. One was a controlled substance. According to FDA, "This firm shipped drugs that were the wrong strength, including some that were substantially super-potent and that pose real health risks as a result, drugs that didn't dissolve properly, drugs that contained contaminants, and drugs that should not have been given because of potentially dangerous drug interactions."[10]

Even many pharmacies based in Canada are admittedly purchasing drugs from all over the world to fill their Internet orders. According to Dean Jorgensen, founder of Winnipeg-based Canadameds.com, "We're filling 50 percent of our prescriptions [from international pharmacies.]" Jorgensen's website boasts, "Not just from Canada anymore! Choose your country and your savings."[11] The president and owner of CanadaRx.net, Harvey Organ, also confirmed that the medicines his web site sells are not coming only from Canada. According to Organ, "I can get drugs from all over the world."[12] A Bloomberg news article reported that CanaRx Services Inc. "has joined other Canadian Internet pharmacies in finding sources of drugs from partners in the U.K., Continental Europe, Israel, Australia and India."[13] This is particularly troubling since according to a study by the Temple University for Pharmaceutical Health Services Research, India is a worldwide leader in the production of

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[5] Allan Dodds Frank, "Illegal Viagra Leads 24% Jump in Counterfeit Medicine Seizures," Bloomberg News, June 10, 2008.

[6] National Public Radio, "Counterfeit Drug Cases on the Rise," May 22, 2008.

[7] Gregory Lopes, "Patients Get Wrong Drugs Online; Anti-Psychotics Substituted for Depression, Insomnia Medicine," The Washington Times, February 17, 2007.

[8] FDA News, "FDA Operation Reveals Many Drugs Promoted as 'Canadian' Products Really Originate From Other Countries," December 16, 2005.

[9] Letter from FDA to Robert P. Lombardi, Esq. of The Kullman Firm: February 12, 2003, available at: <http://www.fda.gov/ora/import/kullman.htm>.

[10] FDA Test Results of Prescription Drugs from Bogus Canadian Website Shows All Products are Fake and Substandard, FDA Press Release, P04-65, July 13, 2004.

[11] Leonard Zehr, "Internet Pharmacies Aim Overseas," Globe and Mail, February 6, 2005.

[12] Christopher Rowland, "Drugs from Anywhere; As Importation Networks Spread, Concerns for Consumer Safety Grow," The Boston Globe, December 16, 2004.

[13] "FDA Seizes Drugs Imported Under States' Program, Supplier Says," Bloomberg, March 9, 2005.

counterfeit drugs with as much as 35 percent of the world's drug counterfeiting originating in that country.[14]

Of added concern is recent news from the FDA that many Americans are buying drugs over the Internet from foreign countries in an apparent effort to avoid the need for a prescription. The Agency conducted a yearlong investigation of imported drugs and according to Randall Lutter, the FDA's deputy commissioner for policy, "The data leads us to believe that many people are buying drugs online not to save money but to bypass the need for a prescription from their doctor, since these Web sites typically do not require the purchaser to have a prescription." The FDA's investigation confirms the finding of a survey conducted by PhRMA last year. The PhRMA survey found that a significant number of American adults have recently purchased medicines from a foreign country. Half of those surveyed said they are buying drugs in another country because they lack a doctor's prescription. The survey found that antibiotics and pain relief medicines are, in most cases, the typical medications consumers seek from other countries. Other key findings include: one in five Americans purchasing drugs online earn more than $100,000 annually; they are more likely to be under the age of 35; and 85 percent have insurance with prescription drug coverage.

**5. In your testimony, you state that any legislative or regulatory requirements to authenticate products and pass pedigree information should be uniform, should apply to all parties in the pharmaceutical supply chain, and should recognize the recent Federal requirement for a standardized numerical identifier. You state that H.R. 5839 meets these criteria. Does this mean that PhRMA believes that everyone in the supply chain should pass pedigrees—manufacturers, wholesalers, and pharmacies?**

Commercial technologies, such as electronic pedigree, Advance Ship Notices (ASNs), and emerging product serialization technologies, offer new tools to help combat counterfeiting of drugs. The use of an electronic pedigree with an e-signature or an ASN without an e-signature are currently viable measures to help further secure the supply chain. PhRMA has supported the mandatory use of non-serialized electronic pedigree by all parties in the pharmaceutical supply chain as a viable near-term solution to help enhance patient safety and to provide additional supply chain security.

Use of lot-level numbers is required of manufacturers by FDA's GMPs, and has been used for years to support business processes such as product recalls and lot reconciliation. A manufacturer-initiated e-pedigree or similar requirement would provide a formal means to associate this lot information with customer shipments and pass this information forward in the supply chain. Requiring the extended supply chain to account for product movement at the lot level would provide additional security, with added benefits to patient safety and resulting public health impact. For example, implementation of an electronic pedigree that contains lot number information would establish the documented change of ownership for products based on specific customer shipments and would help facilitate recall of products. Additionally, implementation of an electronic pedigree or similar mechanism will continue to help facilitate investigation and prosecution of potential counterfeit cases, and thus could have a deterrent effect.

**6. Do you agree that H.R. 5839 is technology neutral and allows FDA the flexibility to work with the supply chain to determine the proper technologies for an identification and track-and-trace system?**

Section 5 of H.R. 5839 directs FDA to develop, no later than 18 months after enactment, a report "evaluating the feasibility and operational efficiencies of adopting . . . security technologies including barcodes, Radio-Frequency Identification Tags, nanotechnology, or other promising track-and-trace technology throughout the prescription drug supply chain." FDA is directed to consider these report findings when it develops a standard numerical identifier under FDAAA. Section 5 does not mandate a particular type of technology, but rather directs FDA to consider the report findings on efficiencies of adopting a variety of technologies.

Further, section 6 of the bill sets out a process for FDA to issue regulations to establish a drug identification and tracking system. In developing such regulations, FDA shall "consider the technical feasibility of compliance" by manufacturers, repackagers, wholesale distributors, and dispensers, and for different types of drugs. These provisions direct FDA to consider technical issues related to a drug identification and tracking system, but are silent with respect to the particular technical aspects of such a system.

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[14] "Pharmacists React to CanaRx Exploring Importation of Drugs from India, Bloomberg Article Reveals Canadian Internet Pharmacy is Considering Use of Drugs From Country Associated with Counterfeits," Yahoo, March 16, 2005.

**7. You reference contaminated Heparin that recently entered the U.S. While the Heparin incident dealt with our Nation's legitimate supply chain, do you recognize the overall increasing problem of counterfeit pharmaceuticals entering our Nation through regulated and unregulated means?**

America's patients trust that the drugs they and their loved ones take meet the high standards set by the FDA for safety and efficacy and are not substandard or counterfeit, and they rely on our complex and comprehensive regulatory system to ensure that is the case. Patients also depend on a secure pharmaceutical supply chain, and this is a responsibility our companies share with the FDA. The lifeblood of America's research-based pharmaceutical companies is dependent on a safe, secure prescription drug supply chain.

The regulatory system that governs the development, approval, marketing, and surveillance of new drugs in the United States is the most complex and comprehensive in the world. To ensure that Americans have the safest drug supply in the world, it has become increasingly comprehensive and robust over time. For example, the Prescription Drug Marketing Act of 1987 (PDMA), authored principally by Chairman Dingell and Rep. Waxman, was passed following an investigation of incidents of counterfeit drugs reaching American consumers. This landmark legislation closed the U.S. prescription drug supply to products that have circulated overseas, beyond the jurisdiction of FDA and outside the control of the manufacturer. The PDMA, coupled with exacting FDA regulatory requirements such as GMPs, has helped significantly minimize the possibility that a U.S. consumer receives a counterfeit drug.

However, the growth in a global marketplace, rise of the Internet and easy access to sophisticated technology has helped facilitate the rise of counterfeit medicines around the world. According to recent data from PSI, counterfeit medicine seizures rose 24% in 2007. Among the $3 billion worth of counterfeit medicine seized in 99 countries were versions of 403 different prescription medicines, including copies of 19 of the world's 25-best selling drugs.[17] A 2006 counterfeiting report by the Royal Canadian Mounted Policy (RCMP) found a "dramatic increase in the amount, sophistication and type of counterfeit products which are being sold across the country." The report found that counterfeit pharmaceuticals are being sold to consumers in Canada in "alarming amounts." The report continued to state that, "The goods are no longer only being offered for sale by 'mom and pop' operators but are being controlled by large sophisticated organizations including traditional and non-traditional organized crime groups." According to RCMP Commissioner Zaccardelli, "The face of crime is being facilitated by the Internet and counterfeit goods are threatening the health and safety of Canadians."[18]

The WHO has estimated that tens of thousands may be dying due to counterfeit malaria, HIV/AIDs, diabetes, and tropical disease medicines. And, the problem is expected to continue to grow in the future. According to a report by the Center for Medicines in the Public Interest, counterfeit drug sales are expected to reach $75 billion in 2010, a shocking 92% increase from 2005.[19]

According to the European Commission, counterfeit medicine seizures rose 51% in 2007 in the European Union (EU). Last year, 4.1 million counterfeit pharmaceuticals were seized by EU customs officials.[20] The Financial Times reported that medicines to treat hypertension, osteoporosis, and high cholesterol were among the counterfeits seized. Laszlo Kovacs, the EU's taxation and customs commissioner noted that the 2007 figures showed "some new and alarming tendencies" given the increase in counterfeit seizures in medicine and personal care products that could pose dangers to consumers.[21] A January 2007 report in the The Independent found, "Counterfeit drugs are flooding into Europe from across the world. Customs seizures published in November listed them as a separate category for the first time, in an indication of the growing trade."[22] According to a report by the School of Pharmacy at the University of London, "the UK is the most vulnerable country in Europe to counterfeiting owing to the high level of 'parallel importing' drugs sold to a foreign

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[17] Allan Dodds Frank, "Illegal Viagra Leads 24% Jump in Counterfeit Medicine Seizures," Bloomberg News, June 10, 2008.

[18] Royal Canadian Mounted Police, "The Counterfeit Report," 2006.

[19] PR Newswire, "New Report Says Counterfeit Drug Sales to Reach $75 Billion in 2010, up 92% From 2005," September 13, 2005.

[20] European Commission, Report on Community Customs Activities on Counterfeit and Piracy: Results of the European Border—2007.

[21] Nikki Tait, "Surge in European Seizures of Fake Drugs," Financial Times, May 20, 2008.

[22] Jeremy Laurance, "Why Britain is a Good Target for the Counterfeiters," The Independent, January 2, 2007.

country and then imported into Britain and the fact that English is an international language."[23]

Of notable concern is the evidence that counterfeiters are increasingly targeting chronic care and life-saving medicines. According to a report by the European Commission, the trend in counterfeiting medicines is increasingly moving towards counterfeit life-saving medicines, rather than "lifestyle" medicines, including "medicines to treat cancer and heart disease, psychiatric disorders, and infections." In the past four years, the UK's Medicines and Health Regulatory Agency (MHRA) has issued nine recalls of medicines including heart and cancer treatments that reached pharmacists and patients.[24] On five other occasions, the MHRA discovered counterfeit drugs at the wholesale level before they reached patients. A recent paper from the EU notes the "criminals increasingly target life-saving medicines, including medicines to treat cancer and heart disease, psychiatric disorders, and infections." The EU believes that this "trend may increase as the main driving factor is high value, high turnover and total disrespect for patient health."[25]

The European Commission has identified other factors that are driving the increased presence of counterfeit drugs. According to the report by the Commission, "the licensed distribution chain, including authorized wholesalers, parallel traders and pharmacies are being increasingly targeted by counterfeiters."[26] Similarly, a Council of Europe report found, "The existence of a significant level of parallel trade in the EU, and the absence of adequate controls on repackaging and relabeling, provides an opportunity for the inadvertent entry of counterfeit medicines into the market.Furthermore, parallel trade means that any counterfeit product within the legitimate distribution chain in one MS [Member State] can easily contaminate other MSs."[27]

While the U.S. has arguably the safest system in the world with one of the lowest percentages of counterfeit drugs in the market, no system is perfect and the proliferation of Internet drug sellers and the ease of ordering medicine online, without even a prescription in many cases, have introduced new threats that cause concern. At a time when we, and others around the globe, are struggling to combat counterfeit drugs and tighten security at our borders, we should be searching for ways to close existing loopholes in the drug distribution chain, not creating new ones. Maintaining a closed system is one way to ensure that U.S. consumers are protected against counterfeit medicines.

**8. In your testimony, you note that domestic challenges to our Nation's closed distribution system remain great and that counterfeit and tainted products do surface even with all of our regulatory controls. Can you explain where the weaknesses exist in our regulated supply chain?**

While the current supply chain in the U.S. for prescription medicines is arguably the best in the world, it is not perfect and weaknesses exist. As mentioned above, the proliferation of Internet drug sellers has created a weakness in our current supply chain since they have been responsible for introducing unsafe and counterfeit medicines into the supply chain and into the hands of consumers.

In our opinion other weak spots in the supply chain exist but could be addressed in future legislation. For example:

1. Increase Requirements for Repackagers. Repackaging has been an identified 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 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 appro-

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[23] Id.

[24] MHRA, <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/Counterfeitmedicinesanddevices/index.htm> (Accessed on April 23, 2008).

[25] European Commission. 'Public Consultation in preparation of a legal proposal to combat counterfeit medicines for human use" < http://ec.europa.eu/taxation—customs/resources/documents/customs/customs—controls/counterfeit—piracy/statistics/counterf—comm—2006—en.pdf> (Accessed 29 May 2008)

[26] European Commission, "Public Consultation in Preparation of a Legal Proposal to Combat Coutnerfeit Medicines for Human Use," March 11, 2008.

[27] Jonathan Harper, MB, ChB, BSc (honors), MBA, "Harmonised provisions for legislative and administrative procedures applicable to counterfeit medicines in the Council of Europe Member States," January 2005.

priate, 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 is supportive of efforts to strengthen the licensure requirements for wholesalers and distributors. Recent investigations, such as 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 states to prevent diverters and counterfeiters from re-locating to states without strong licensure requirements. This can be accomplished through revisions to 21 U.S.C. §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 3 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 therefore 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.

Thank you very much for the opportunity to further elaborate on my testimony of May 1, 2008. Should you have additional questions, please feel free to contact me.

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

James C. Greenwood
President & CEO

June 13, 2008

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Dingell:

Thank you for the opportunity to provide additional information and answer questions in response to the May 1st Subcommittee on Health hearing on "Discussion Draft of the 'Food and Drug Administration Globalization Act' Legislation: Drug Safety." Protection of the public is a priority for BIO and all of the pharmaceutical and biologic manufacturers we represent, and BIO commends the Committee for its commitment to securing America's drug supply against counterfeit drugs and biologics. BIO supports the Committee's efforts to further secure the pharmaceutical supply chain by establishing a uniform national standard for biopharmaceutical product pedigrees and track-and-trace to help facilitate product authentication and to combat criminal counterfeiting.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. In particular, many of our members are involved in the research and development of life-saving therapies and play a critical role in delivering treatments that both prolong life and reduce the burden of disease for patients worldwide.

1. **Is BIO concerned about the threat of counterfeit pharmaceuticals to our regulated drug supplies?**

   Patient safety is of paramount concern to BIO and its members throughout the entire lifecycle of a product – from research & development to product manufacturing to distribution and to final dispensing - and combating criminal counterfeiting of biopharmaceutical products is a priority for BIO and our member companies. Pharmaceutical counterfeiting, adulteration, and diversion remain a persistent threat in the global marketplace and the presence of any amount of fake, adulterated, sub-potent, or super-potent drugs in the American pharmaceutical distribution system

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poses a threat to the public health. Counterfeiting of biological products, which must be injected or infused directly into a patient's bloodstream, can place patients at extraordinary risk and BIO member companies remain concerned and vigilant. The actual prevalence of criminal counterfeiting is difficult to quantify, but the World Health Organization estimates that less than 1% of sales in developed countries and more than 10% in developing countries are counterfeit or adulterated. America's closed drug distribution system has helped to limit the prevalence of counterfeit products in the domestic market, but biopharmaceutical companies understand that as long as there are counterfeits in the world, there can be counterfeits anywhere. Strong protections are necessary to ensure patient confidence in the integrity of the drug supply. This includes strong federal laws that do not allow unfettered entrance into the U.S. market of products whose origins we cannot confirm and whose pathway into our market we cannot substantiate.

2. **In H.R. 5839, there is a provision on page 23, which would exempt drugs from being required to have an identifier-such as a 2D barcode, RFID chip, or other technology-if a manufacturer can demonstrate that the identifier would adversely affect the safety, effectiveness, purity, or potency of the drug or would not be technologically feasible.**

    a. **Do you believe this provision is important to ensure that any new technologies do not affect biologics, which are known to be highly sensitive drugs?**

The biotechnology industry brings a unique perspective toward efforts to improve the pharmaceutical supply chain. Biologics are complex medicines that are manufactured using living organisms. These drugs are different and far more complicated than most small molecule chemical drugs. Due to their complexity, biologics require special handling and care and are often shipped through "specialty" distribution channels or direct drop shipments to the provider with additional precautions such as preserving the cold chain. These additional precautions ensure the safety and efficacy of the product, but also pose challenges when establishing a uniform national distribution practices. For that reason, BIO supports interoperable, standards-based approaches to track-and-trace that are technology neutral, thereby allowing manufacturers to deploy product appropriate solutions. Indeed, manufacturers are the most knowledgeable about their products, packaging, and distribution and are best suited to determine the appropriate anti-counterfeiting technology or data carrier for that particular product. Anti-counterfeiting technologies continuously evolve and change in response to the constantly changing threat of counterfeiting and the technological sophistication of counterfeiters, and consistent with FDA regulations, manufacturers should continue to decide which anti-counterfeiting measures should be applied to the product to ensure patient safety.

Two of the most commonly discussed data carriers for product serialization are 2-D barcode and Radio Frequency Identification Tags (RFID). Both technologies can

carry adequate data to validate a product's transaction history and enhance inventory management. However, at this time it is uncertain how the radio emissions emitted by RFID readers impact the molecular stability of therapeutic proteins and biologics. To date, there has been limited scientific testing and development of testing protocols to ensure that RFID will not negatively impact the stability of biologics. Indeed, due to the uncertainty regarding RFID impact on protein products, FDA's RFID Compliance Policy Guide discourages piloting of RFID on biologics.

For those reasons, BIO is pleased that H.R. 5839 establishes a process to implement an interoperable, standards-based track-and-trace system that does not specifically mandate any particular technology or data carrier. Additionally, the legislation appropriately provides FDA with the discretion to exempt any product classes from serialization and track-and-traces requirements if it would not be technically feasible or would adversely affect the safety, effectiveness, purity, or potency of the drug.

**3. What have BIO member companies done to protect their products, and what have they done to move toward an identification and track-and-trace system?**

BIO member companies recognize that there is no one technological "silver bullet" that can overcome criminal counterfeiting, and that a comprehensive anti-counterfeiting and supply chain management approach is necessary. Counterfeiters have become increasingly sophisticated at mimicking pharmaceutical packaging and labels as well as overt and covert anti-counterfeiting technologies. Pharmaceutical supply experts are in a technological "arms race" to stay a step ahead of counterfeiters and the industry has taken productive steps to secure drug and biologic products with holograms, color shifting dyes, and numerous other anti-counterfeiting technologies. In addition to these product-based security features, many companies have put in place integrated programs to protect their medicines. These processes often include:

- Full-time, dedicated staff to ensure company-wide vigilance in the fight against counterfeiting.
- Contractual requirements for distributors to buy directly and only from the manufacturer, and to report any evidence of product diversion or counterfeiting.
- The use of secure distribution practices to prevent a drug shipment from being stolen, tampered with, or otherwise interfered with in transit.
- Investigation of all complaints received from patients, health care providers, and others in the chain of distribution and use.

However, there is an opportunity for industry to do more to address the problems and secure the drug supply to ensure continued patient safety. BIO recognizes that there are vulnerabilities within certain parts of the supply chain that could be remedied through the use of ePedigree technology. Implementation of electronic track-and-trace technology would help create transparency, disclosing the origin and distribution history of drug and biologic products. BIO supports its use within the drug distribution system in a responsible manner. BIO believes that fully

implemented electronic tracking from the manufacturer to the pharmacist will reduce any gaps in the supply chain which could lead to opportunities for counterfeit medicines entering the distribution system. If products carry serialized machine-readable tags, their authenticity can be verified through the electronic pedigree at every level of distribution. Indeed, such serialized machine-readable tags could also be used effectively to authenticate the drugs being dispensed at the pharmacy or clinic, thereby protecting patients with a single-system, negating the need to create a complex interoperability matrix.

In November 2007, BIO and the California Healthcare Institute (CHI) conducted a joint survey of our collective members to ascertain timelines and milestones toward compliance with the California ePedigree laws[1]. Overall the results revealed that the manufacturers we represent are working diligently toward implementing the changes in business practice that will be required to bring them into compliance with the ePedigree mandate. It should be noted that the creation and implementation of new electronic technologies to track the distribution of drug and biologic products is a tremendous undertaking for large pharmaceutical companies and small biotech companies alike. These changes in business practice will have profound consequences for the highly complex operations of manufacturing facilities, packaging lines, distribution centers, and the operations of third-party partners and logistics providers. With so many business components directly affected by the adoption of an electronic track-and-trace system, great care and deliberation must be employed to ensure that a safe, appropriate, and cohesive structure is put in place.

Our survey results show that the manufacturers we represent are actively engaged in the process of working toward the development of an interoperable track-and-trace system that will benefit the industry, the supply chain, and consumers of drug and biologic products. There is no quick or simple solution to addressing this problem. Companies responding to our survey indicated diverse levels of readiness. Most of our surveyed companies have indicated that they are currently in the planning phase, testing various technology applications internally. Only a small percentage of our responding companies indicated that they are currently implementing track-and-trace technology for all or a limited number of product lines. There are many technological and production hurdles for manufacturers to overcome before any system can be implemented. However, companies continue to develop, deploy, and adopt standards that will serve as the basis for a new supply chain and ensure safe, secure, and reliable pharmaceutical distribution.

**4. What is BIO's position on the California identification and track-and-trace system?**

BIO has been constructively engaging the California Board of Pharmacy and other supply chain stakeholders to ensure that the California ePedigree legislation is

[1] The results of this survey were presented to the California Board of Pharmacy Enforcement Committee on December 5, 2007.

implemented in a responsible manner under reasonable timeframes that will not result in a disruption to the supply of drug and biologics in California. However, in early January 2008, it become clear that it was not possible to create an interoperable track-and-trace system that can ensure effective delivery of medicine to patients by January 1, 2009 and BIO requested that the Board of Pharmacy exercise its authority to extend the date for compliance to a new date of January 1, 2011. In March 2008, the Board of Pharmacy announced a delay of the effective date of the California law to 2011. In the mean time, the biotechnology industry continues to work with all segments of the supply chain to implement the law, ensuring that the standards, distribution processes and technologies employed will further protect the California public.

However, BIO believes that it is appropriate for Congress to exercise its authority to preempt state law and establish a uniform national pedigree and track-and-trace standard. Without federal leadership in this area, biologics manufacturers could be subject to up to 50 separate and potentially inconsistent statutory schemes which would introduce significant inefficiencies into the national drug distribution system, erect barriers to interstate commerce and create confusion which counterfeiters may seize upon. Indeed, a heterogeneous system of state-by-state pedigree laws will encourage counterfeiters to establish criminal enterprises in those states with the most lenient pedigree standards. This has been a problem in the past with respect to paper pedigrees.

If supply chain stakeholders can work towards the implementation of a single uniform national standard for product serialization, they will be able to more efficiently and effectively establish new track-and-trace systems that can serve as a cornerstone of a uniform federal track-and-trace program. BIO believes that such a program should in turn be implemented using a risk based approach that is part of an overall risk based anti-counterfeiting strategy. Through a more focused implementation effort, there will be greater assurance that the complexities of such a program can be addressed. This will ultimately serve to ensure the success of track-and-trace implementation.

Thank you again for the opportunity to respond to these questions. Should you have additional questions, please do not hesitate to contact me.

Sincerely,

James C. Greenwood
President & CEO

**ADDITIONAL INFORMATION:**

More information on BIO's position on e-pedigree and track-and-trace can be found at the following links:

- **Submission Regarding Implementation Date of California e-Pedigree Laws** (January 9, 2008), BIO letter to the California State Board Pharmacy, http://bio.org/local/healthcare/20080109.pdf
- **Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments** (May 19, 2008), BIO's comments to the FDA, http://bio.org/reg/20080519_standard_numerical_id.pdf
- **Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information** (May 19, 2008), BIO's comments to the FDA, http://bio.org/reg/20080519_tracktrace.pdf

## CHRISTINE MUNDKUR, ANSWERS TO SUBMITTED QUESTIONS

Dear Congressman Buyer:

I am writing to answer the questions submitted to me after my May 1, 2008 testimony before the Committee on Energy and Commerce on behalf of Barr Pharmaceuticals and the Generic Pharmaceutical Association, GPhA. I have set forth the answers to the best of my ability to each of the questions, which are repeated below for ease of reference.

## QUESTIONS SUBMITTED BY HON. STEVE BUYER

**What is the value of preemption and one Federal pedigree standard?**

A Federal Pedigree, preempting state initiatives, would provide a single standard and directive aligning the entire pharmaceutical supply chain into a single focused initiative. The risk of different standards, arising from multiple states and segments within the industry, carries a significant cost to the entire pharmaceutical supply chain. Multiple disjointed initiatives would potentially involve multiple system driven implementations and multiple serialization solutions, ultimately costing the entire industry unnecessary and additional time and resources to implement. Simplifying the process to a single Federal initiative would provide focus and provide the momentum necessary to drive a single solution throughout the industry. We also recommend that strong enforcement of the normal chain of distribution be the foundation for a Federal resolution, and requirements for pedigree requirements be limited to product supply that has been outside the normal supply chain.

**What is Barr's position on the California identification and track-and-trace system currently on the books?**

While Barr fully appreciates the CA legislature's efforts to combat counterfeiting within the Pharmaceutical industry, the legislation in CA requiring electronic pedigree and unit level serialization for all pharmaceutical products by January of 2011 represents an approach, which may negatively impact the ability for Californians to have access to affordable medicines and inherently raise healthcare costs with little commensurate benefit to the general public. Many manufacturers simply won't be able to meet the requirements by the given deadline, resulting in fewer manufacturers operating within this market segment potentially causing opportunities for less competition (and therefore higher costs) and product availability concerns. The most reasonable approach to improving the security of the drug supply chain is to focus on areas of vulnerability, such as the internet and secondary wholesaler markets, and products which are most likely to be targeted by counterfeiters. The Generic industry provides significant savings in healthcare costs by providing affordable medicines, and the resources required to implement serialized electronic pedigrees will significantly affect the affordability of generic medicines, when in reality, generic medicines are the least likely candidates for counterfeiting due to their inherent lower profitability. Enforcement of the normal chain of distribution combined with a risk based pedigree approach, focusing on high risk product supply outside the normal chain of distribution would provide a more commensurate benefit to the public without negatively impacting supplies or increasing healthcare costs.

**Does Barr support Senate Bill 1307 in the California Senate?**

Barr does not support SB1307. This bill requires specific percentages of products to be serialized/pedigreed within a fixed time schedule without consideration to alternative solutions such as strong enforcement of the normal chain of distribution, and if required, a risk based approach to drugs that are being introduced by parties outside the normal chain of distribution or deemed to be at high risk of counterfeiting. However, Barr does support the current proposal from the California Governor's office and CA State and Consumer Services Agency that establishes an "accredited distribution chain" model to meet the common goals of ensuring the safety and efficacy of drugs provided to consumers.

Please do not hesitate if I can provide any further assistance.

June 23, 2008

The Honorable John Dingell
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Attn: Melissa Sidman, Legislative Clerk/Public Health

Dear Chairman Dingell:

I am writing to you on behalf of the Healthcare Distribution Management Association (HDMA) in response to your June 9, 2008 letter requesting information from Ron Bone, McKesson Corporation.

Mr. Bone testified on behalf of HDMA during the Subcommittee on health hearing on May 1, 2008 entitled, "Discussion Draft of the 'Food and Drug Administration Globalization Act' Legislation: Drug Safety." Following the hearing, Mr. Bone received a series of questions for the record from Congressman Steve Buyer. I have attached HDMA's response to those questions for the record.

Please contact me at 703-885-0235 or jtrauger@hdmanet.org if you have any further questions.

Sincerely,

Joe Trauger
Senior Director, Federal Government Affairs

CC: Congressman Steve Buyer

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**HDMA Response to Questions from the May 1, 2008 House Energy and Commerce Subcommittee on Health Hearing**
**June 23, 2008**

**1. What are the current threats facing our nation's pharmaceutical supply chain?**

We believe internet pharmacy and the importation of pharmaceuticals from other countries are the most critical threats to the U.S. supply chain. The link below from the FDA also highlights this growing concern.
http://www.fda.gov/bbs/topics/news/2007/new01623.html

Although the U.S. medicine supply remains among the safest in the world, counterfeit drugs continue to threaten the health and safety of the American public. That is why manufacturers, distributors, pharmacies, government, regulators and law enforcement must work together to further secure the supply chain against this backdrop of increasingly sophisticated criminals. These entities share a responsibility to continuously monitor, protect and enhance our nation's secure supply chain system and to work together to prevent counterfeit or diverted drugs from entering the legitimate chain.

Counterfeits can originate domestically or from abroad and are very hard to distinguish from genuine products. The World Health Organization (WHO) estimates that many countries in Africa, Latin America and parts of Asia have areas where more than 30 percent of the medicines on sale may be counterfeit; in many of the former Soviet republics, the proportion is 20 percent.

Developed markets, such as in Europe, have seen an increase in reported counterfeit cases, too. For example, the European Commission announced that its customs department had seized 2.7 million fake tablets in 2006, most of them originating in India (Source: *Indian Journal of Pharmacology* 39, no. 4 (August 2007): 206–7).

Although rare in the United States, HDMA and our primary healthcare distributor members have zero tolerance for criminal counterfeiting, diversion, adulteration and misbranding of prescription medicines. There is no one solution to prevent counterfeiting; it requires ongoing efforts to explore, test and implement the best business, government and law enforcement solutions by all partners in the healthcare supply chain. HDMA believes that ongoing education and the use of innovative new technologies are part of a multi-layered battle plan to combat criminal activity and further ensure patient safety.

**2. Why do you think a serialized electronic track-and-trace system will help secure our nation's pharmaceutical supply chain?**

HDMA believes that technologies that can track and trace individual units of medication from the beginning to the end of the supply chain hold the most promise to further advance supply chain security. Such technologies can link each unique package of medicine to electronic information, effectively documenting chain of custody information

throughout the supply chain. Linking the physical product using a unique identifier with electronic information creates added levels of visibility and accountability that will help prevent counterfeit and diverted product from entering the supply chain and will help identify potential entry points for counterfeit drugs.

A unique serial number for each product would result in the following benefits:

i. Traces its possession back to the manufacturer
ii. Enables the creation of a history of every owner of the product from the time of manufacture to the point of dispensing or destruction
iii. Provides a history of products that are being processed for return
iv. Makes it difficult for a counterfeiter to insert counterfeit product into the legitimate supply chain

**3. Why are uniform Federal requirements necessary?**

Patient safety is enhanced with national, uniform pedigree standards and requirements. Uniformity is needed both to further secure our national supply chain and also to support ongoing efforts to deploy compatible and interoperable track-and-trace technologies in a systematic way across all 50 states. A confusing and potentially conflicting patchwork of state laws and regulations has negatively affected efforts to research and implement the use of item-level serialization with track and trace, as supply chain partners are forced to create unique systems on a state-by-state basis. This patchwork of state laws and regulations could be exploited by criminal elements to introduce compromised products into the supply chain. HDMA supports a national standard for item serialization and track and trace to clarify implementation requirements and focus industry attention and resources on a single path. Additional reasons for Federal requirements include:

a. Uniform pedigree requirements will support the existing national distribution network that enables the safe, reliable and efficient distribution of critical medicines and facilitates our rapid response in times of emergency.
b. The current patchwork of state pedigree laws (over two dozen) causes confusion, erodes efficiencies and disrupts the availability of medicines. These conflicting requirements slow the development and adoption of uniform approaches to pedigree implementation.
c. Two states (Florida and California) have enacted significantly different laws than any other state. In Florida, there have been situations where a distributor was not able to supply products from the distribution center located in the state and was unable to ship the needed product from a distribution center in another state. California is still in the process of working with industry on implementation of its law.
d. With additional states implementing unique pedigree laws, the distribution network has experienced inefficiencies and disruptions in attempting to comply with the different laws. Unfortunately, this slows the delivery of prescription medicines to patients and adds unnecessary costs to the system.
e. A federal requirement/standard would allow the industry to focus on and invest in uniform technology to track-and-trace pharmaceuticals across the supply chain. One

standard for the country, rather than 50 potentially conflicting state requirements, will be more efficient and less costly.

**4. You state in your testimony that a track-and-trace system will create efficiencies and decrease cost. Can you explain this?**

To effectively track and trace items in the supply chain, each item must be uniquely identified at the lowest saleable unit. Without the ability to uniquely differentiate individual packages within the same lot or batch number, it is impossible to verify with any certainty the track-and-trace history. HDMA believes that in addition to the safety benefits, track-and-trace systems also hold the most promise for increasing efficiencies, streamlining operations and enhancing value and eliminating waste, which may offset some of the costs of deployment. One standard for the country, rather than 50 potentially conflicting state requirements, will be more efficient and less costly.

a. While there is not a significant amount of data currently to demonstrate a return on investment, we believe there are intuitive efficiencies that will be gained from a track-and-trace system (detailed under item b below) that ultimately will decrease certain costs. Most importantly, we believe the greatest benefit will be in ensuring that patients/consumers receive the right prescription medicines, when and where they need them.
b. Distributors and other partners would realize the following efficiencies from such a system:
    i. Optimized receiving
    ii. Reduced inventory
    iii. Increased productivity
    iv. Improved product recall
    v. Improved shelf management
        1. Expiry management
        2. Returns
    vi. Improved service levels/fill rate for customers
    vii. Improved benchmarking
    viii. Management of supply cost
c. A track-and-trace system would offer significant public health benefits in the event of a local, state or national emergency. This system would enable us to provide more timely and accurate identification of the location of a critically needed product. Additionally, the system could pinpoint the source of tainted product in a far timelier manner.
d. At the heart of track-and-trace technology is a unique serial number applied to the product by the manufacturer. The serial number could be applied using RFID or 2D barcode.
    i. RFID (non line-of-sight)
        1. With non line-of-sight RFID, the processes of receiving, picking and returns will have to be 100% accurate. Many

products will be able to be scanned without having to individually scan the contents of cases, pallets or totes.

2. Inventory accuracy will be enhanced as every unit of product in the inventory is unique. Cycle counting product to confirm inventory quantities will be 100% accurate and will be accomplished without removing product from their cases.
3. RFID uses encryption technology and makes counterfeiting and diversion of product virtually impossible.

ii. 2D Barcodes (line-of-sight)

1. 2D barcodes are a line-of-sight technology which requires a manual process to scan each case, pallet or item. 2D barcodes can be a viable alternative to RFID because they store and transmit information specific to each pharmaceutical product as it moves through the supply chain. Some distributors prefer the use of RFID for logistical and security reasons. However, we understand that 2D barcodes are preferable to many of the branded, generic and biotech manufacturing suppliers. Branded and generic manufacturers are concerned about the costs associated with RFID, a relatively new technology; biotech manufacturers have expressed concerns that RFID might compromise the integrity of certain products.
2. Line-of-sight scanning is used today in many warehouse applications but only on the NDC number, which provides information about the drug and not unique information about the specific unit.
3. Inference is required to allow 2D barcodes to provide a close proximity to the efficiency of RFID. All segments of the supply chain have a compelling need for inference. Industry has worked with the global standards setting organization, GS1, to create the following definitions:
    a. Work Group Definition: Inference assumes that the serialized number is based on information provided by the upstream supply chain, reasonable inspection of the product and application of the Serialized Inference Rule by the Shipping and Receiving partners.
    b. Serialized Inference Rule: The process a supply chain partner uses to ensure there is enough evidence to infer the serialized number without physically reading ALL serialized numbers. A Serialized Inference Rule should be defined for each packaging unit (e.g., pallet, case, item, etc.) for the key process steps of Commission/Aggregation, Ship, and Receipt.

5. **Some say the standards for a track-and-trace program are not ready. You have been an active participant with several global and U.S. Standard setting bodies- what standards have been developed, to date, and what is still being debated?**

GS1 is the standards group that industry and regulators are relying on to develop these standards. GS1 Healthcare and EPCglobal are the two groups within GS1 that are developing worldwide standards for track and trace. GS1 is developing the international standard for unique identification and traceability. EPCglobal is developing the standard for the use of RFID based on the GS1 standards. HDMA believes the NDC should be included in the unique item identifier where appropriate. Please see Attachment A, which delineates GS1/EPCglobal standards.

6. **In your testimony, you stated that the world is moving toward a unique identifier for each prescription drug. Can you expand on this?**

GS1 is an entity with members in 108 countries. GS1 has developed the Global Trade Item Numbers (GTIN) for pharmaceutical products and medical devices which are detailed in Attachment A. Information is available on their website at www.epcglobalinc.org/standards/sdp.

In the U.S., the industry advocates two components to the standard identifier: product identity, i.e., the National Drug Code (NDC), and serial number to uniquely identify the item. No other intelligence should be built into the serial number portion of the identifier. The NDC uniquely identifies the product and is ingrained in many systems across the supply chain. Existing GTIN standards allow for the encoding of NDC. The serialized GTIN standard with the NDC encoded in the GTIN should be used as the unique identifier. Lot/batch numbers, expiration dates, pedigree history and other data elements can be exchanged electronically between trading partners as part of a track-and-trace system. This information is not meant to be part of the identifier. The unique identifier is a reference number to data records that contain information about the product and its transaction history, enabling companies to track and trace products. Some countries and companies would like the unique identifier to exclude the NDC. The impact of excluding the NDC in GTIN for use in track and trace in the U.S. is going to be studied by GS1.

7. **Do you know how many States have taken action to implement pedigree regulations or laws?**

a. At least 38 states have taken action to implement unique pedigree legislation/regulations.
b. No two states have the exact same pedigree law. This variability creates confusion and waste in the system and causes unneeded disruptions to the prescription medicine supply chain.
c. Attachment B provides an updated HDMA state pedigree map which reflects the legislative/regulatory actions in all states.

**8. What have you learned from various pilot programs McKesson has been involved in?**

a. The distribution industry, including McKesson, has partnered with manufacturers and pharmacies over the past three years to better understand the challenges with tracking and tracing pharmaceutical products.
b. Jump Start and On Track are two of the implementation workgroups in which we have participated.
c. Learnings:
    i. People and process changes pose as many challenges as the technology.
    ii. The technology is still in its infancy, particularly RFID.
    iii. 2D DataMatrix has limitations due to the need to read the barcodes on every piece of product
    iv. The back end systems to support serialization, track and trace and pedigree need radical changes to adapt to tracking product at the unit level.
    v. The Jump Start program, which started in October 2003, lasted through September 2004 and during that time tagged nearly 13,500 units of 10 different products. The project achieved its objective to assess the potential for RFID/EPC technology to provide business value in an end-to-end supply chain context and help to establish facets of an industry operating model. Although the work revealed areas in need of more development, it was clear that RFID/EPC will deliver on its potential. Please reference Attachment C: "High Performance Enabled Through Radio Frequency Identification – The Cure for the Common Pharmaceutical Supply Chain."
    vi. Our most recent experience reading RFID labeled cases on a pallet has provided us with 99.5 percent read rates. This is a significant improvement over the rates we had in the Jump Start pilot mentioned above.

**9. What is the value of item-level serialization?**

a. It ensures that pharmaceuticals can be uniquely identified.
b. It enables track-and-trace items to be serialized at the selling unit level.
c. Information on where a product has been is essential to knowing the product's chain of custody.
d. The returns process, using item-level serialization, provides a clear history of where a product has been before it is returned to the distributor.
e. Expiry management could be greatly improved if the individual item could be linked to additional transaction data. This improved inventory management system would reduce waste in the supply chain.
f. Recalls can be accomplished at the unit level in the future. Notices of recall can be sent to specific members of the supply chain that received the product. Today, manufacturers blanket every member of the supply chain that could have received the

recalled product. This means many recall notifications are sent to supply chain partners that have not possessed the product, thereby diluting the effectiveness of the notification.

g. Current pedigree systems rely on lot numbers, which is wholly inadequate to track-and-trace a pharmaceutical through the supply chain. Manufacturers produce thousands of individual bottles of medicine with the exact same lot number/expiration, which are then distributed to dozens of distributors and, ultimately, hundreds of pharmacies. If a patient receives a compromised medicine, a pedigree system based on lot numbers will not provide a definitive way to trace the product back through the supply chain.

**10. Does the legislation provide adequate time for the supply chain to implement its provisions?**

a. HR 5839 includes a phase-in for implementation of track-and-trace standards. This provides a timetable for development of a track-and-trace system for high risk products, eventually incorporating more and more products as designated by the Secretary.

b. An industry-wide group has been working with the state of California on implementation for similar California legislation. This work group has been discussing a longer phase-in than stipulated by HR 5839 and has also considered that many segments of the supply chain need to be ready to implement the technology.

**Attachment A - GS1/EPCglobal standards**

**Item Level**

*RFID – PRIMARY Carrier*

UHF Gen 2 with a SGTIN-96 encoded EPC value per the EPCglobal Tag Data Standards V1.3, Section 3.5, with NDC.

- HF Generation 2 will be supported when standards are completed.

*Bar Code – BACK-UP Carrier*

- 2D ECC Data Matrix encoding AI(01) GTIN + AI(21) serial number. The GTIN should include the NDC.

**Case Level – Homogenous Product**

*RFID – PRIMARY Carrier*

- UHF Gen 2 with a SGTIN-96 encoded EPC value per the EPCglobal Tag Data Standards V1.3, Section 3.5. The SGTIN should have the NDC encoded.

*Bar Code – BACK-UP Carrier*

- Linear GS1 Code 128 encoding concatenated AI (01) GTIN + AI (21) serial number – for cases large enough to have linear bar codes. The GTIN should have the NDC encoded.
- 2D data matrix (ECC200) encoding concatenated AI (01) GTIN + AI (21) serial number should be used for cases too small to have a linear bar code. The GTIN should have the NDC encoded.

**Case Level – Mixed Product**

*RFID – PRIMARY Carrier*

- UHF Gen 2 with a SSCC-96 encoded EPC value

*Bar Code – BACK UP Carrier*

- Linear GS1 Code 128 encoding AI(00) SSCC-18

**Pallet Level**

*RFID – PRIMARY Carrier*

- UHF Gen 2 with a SSCC-96 encoded EPC value

*Bar Code – BACK UP Carrier*

- Linear GS1 Code 128 encoding AI(00) SSCC-18

Traceability in Healthcare Work Team

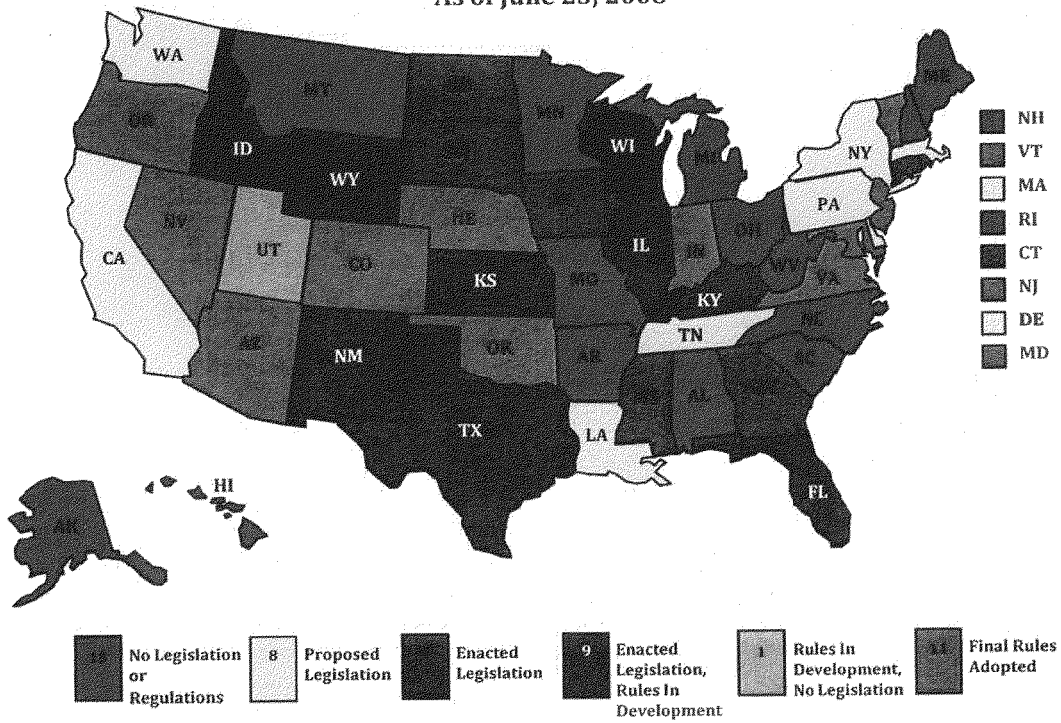
This GS 1 team is defining the global requirements for traceability in healthcare to ensure that the business needs of the sector are fulfilled, including ensuring global traceability in an efficient, secure and reliable way, addressing legal requirements and achieving cross-industry interoperability. This work is scheduled to be completed by the end of 2008.
http://www.gs1.org/sectors/healthcare/about/workteams.html

The information that appears here is from the publicly available GS1 Web site.
http://www.epcglobalinc.org/standards/sdp/

Attachment B

# HDMA Map of State Pedigree Legislation/Regulations

As of June 23, 2008



**Attachment C**



# High Performance Enabled Through Radio Frequency Identification – The Cure for the Common Pharmaceutical Supply Chain

*a report by*
**James Hintlian, Stephen Proud,** *and* **Bonni Kirkwood**

*Partner, Associate Partner, and Senior Manager, Accenture*

Accenture's on-going research and client experience has found that high-performance businesses have the ability to harness technology to their advantage. In addition to teaming with companies across many industries to leverage radio frequency identification (RFID) and electronic product code (EPC) technologies to achieve high performance, Accenture joined forces with a pioneering group of industry concerns to determine the real business value of these technologies. Led by Accenture, the group sought to evaluate how the technology could indeed deliver a safe and secure supply chain, streamline reverse logistics, and increase the accuracy and efficiency of distribution and pharmacy operations. The result of the collaboration: evidence that RFID/EPC can enable higher performance levels across the pharmaceutical value chain.

According to a report by the US Food and Drug Administration (FDA), drug counterfeiting is growing in both developed and developing countries.[1] The FDA has uncovered some level of counterfeit drug production in virtually every country across the globe; in some regions, as much as 50% of drug types are counterfeit. To combat this burgeoning problem, the FDA's anti-counterfeiting task force examined new technologies, including RFID/EPC.

RFID/EPC technologies enable manufacturers to establish a safe and secure supply chain by tracking items at the unit level to ensure their authenticity. According to the FDA, "RFID tagging of products by manufacturers, wholesalers, and retailers appears to be the most promising approach to reliable tracking and tracing."[2]

Ensuring that supply chains are safe and secure is no longer optional for the industry. Major retailers are looking to their suppliers to implement RFID/EPC capabilities with many deadlines hitting as soon as 2005. In addition, legislative initiatives are also pointing to adoption of the technology. One example is Florida's Pharmaceutical Pedigree Papers Act, which requires paper-based histories of all drugs sold. The problem is that these paper trails can be easier to counterfeit than the drugs themselves. With an industry-wide adoption of RFID/EPC, more secure and accurate pedigrees will result. By establishing an RFID/EPC approach to meet Florida's requirements, a model can be set for other states that are on the brink of establishing their own pedigree requirements (see *Figure 1*).

## RFID/EPC – The Future is Now for Pharmaceuticals

To get a jump-start on the inevitability that is RFID/EPC, a group of manufacturers, wholesale distributors, retail pharmacies, and industry associations joined forces to realize the future benefits of the technology today. Abbott Laboratories, Barr Pharmaceuticals, Inc., Cardinal Health, CVS/pharmacy, Johnson & Johnson, McKesson Corp., Pfizer, Procter & Gamble, Rite Aid, the Healthcare Distribution Management Association (HDMA), and the National Association of Chain Drug Stores (NACDS) were among the participants in this pioneering group. In addition to these industry players, the project coordinated closely with the FDA, keeping the governmental organization involved in important developments. The group's efforts began by developing a model that illustrates how the industry will tackle the issues surrounding RFID/EPC adoption (see *Figure 2*). The main objective was to assess whether RFID/EPC could be used to help create a safe and secure supply chain, streamline reverse logistics, and increase the accuracy and efficiency of distribution and pharmacy operations in an end-to-end supply chain context. Another important goal of the group was to work towards establishing an operating model for the use of RFID/EPC in the pharmaceutical industry.

It is by now conventional wisdom that the greatest pay-off of RFID/EPC will occur when the technology stretches across the value chain, creating a seamless flow of information and communication from manufacturer to supplier to end consumer. According to a study on RFID/EPC, 86% of manufacturers surveyed report that the greatest benefits would come across multiple organizations. Recognizing this, the project extended

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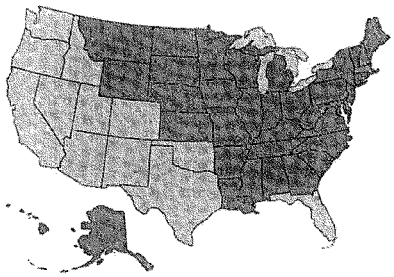
Stephen Proud is an Associate Partner in the Accenture Supply Chain Management service line; he specializes in product life-cycle management. Based in London, he leads the company's Manufacturing and Design practice in the UK.

Bonni Kirkwood is a Senior Manager in the Accenture Health and Life Sciences Supply Chain Management practice. Based in Boston, she has worked with pharma supply chain and retail clients to develop strategies, construct business cases, and launch pilots supporting the use of radio frequency identification (RFID) in their businesses.

1. *"Combating Counterfeit Drugs," released by the FDA in February 2004.*
2. *Quote taken from "Combating Counterfeit Drugs," report by the FDA.*

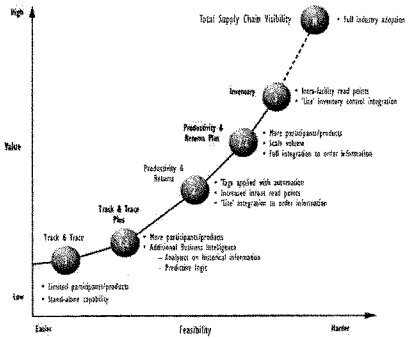
Figure 2



The states in blue are close to – or are already – implementing pedigree laws. By embracing RFID/EPC industry-wide, companies can avoid multiple filings.

Source: http://www.mdn.net/newsletter/0404/pedigree.htm

*Figure 2: Accenture Developed a Roadmap for the Adoption of RFID/EPC Industry-wide that Addresses Critical Business Concerns*




across the supply chain to test the performance of RFID/EPC "beyond the four walls" of any one organization. To minimize complexity and cost, the initial effort did not integrate RFID/EPC with existing systems, and no modifications were made in packaging or production processes.

The project ran from October 2003 through September 2004 and, during that time, the participant companies tagged nearly 13,500 units of 10 different products. Tagged items were shipped, received, handled, tracked, and traced through the project's system (see *Figure 3*).

## The Collaboration's Findings

It is important to note that the efforts of the group were conducted in a controlled environment with limited scope. Many processes that would in reality be automated were handled manually for the sake of controlling project scope. Although there are many issues yet to be addressed and much more work that remains to be done before RFID/EPC is ready for industry-wide adoption, important insights were evident from the project, including:

- Tags need to be cheaper and better – to reach industry scale, the cost of tags will have to decrease dramatically. While costs need to fall, the stability of tag functioning needs to rise: right now there are too many problems with defective tags. Tags must also work effectively with all types of products, packaging, and environments: liquids, biologics, metals/foils, and cold chain products, as well as in mixed-item shipments.

- Internal efforts must be cross-functional – to achieve maximum value from RFID/EPC, cross-functional work teams all need input into the design and processes surrounding supporting systems. Teams should include personnel from packaging, quality assurance, logistics, information technology, regulatory affairs, public relations, and operations for manufacturing, distribution, and stores.

- Companies should not "go it alone" – it is unlikely that any single member of the group could have gone as far as the collaborative effort did – or at the level of cost – without the shared knowledge, experience, and assets of the combined resources.

- Third-party oversight participation was essential – the presence of an independent third party was important to facilitate collaboration, reach deadlines, and coordinate cross-organizational communications. Coordination from a technical perspective was also important. Many different organizations and individuals (data center administrators, virtual private network (VPN) engineers, facility engineers, network specialists, security specialists, etc.) needed to move in concert to complete the design, deployment, and support activities.

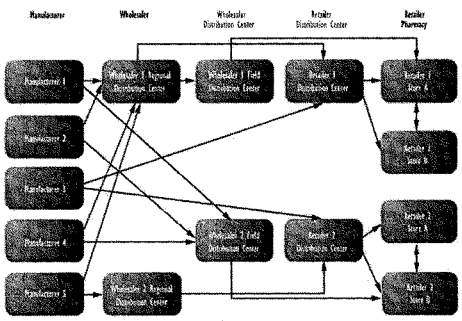
- Integration is key – the efforts of the project were stand-alone and were not integrated with core operational systems. To realize the benefits of the technology, this integration piece needs to improve significantly; intra-industry information systems must be built before mandates can be satisfied.

- Standards development is critical – federal and state regulatory agencies, standards-setting organizations, and industry trade associations need to get involved in projects like this to create consistent standards. It will also be critical to mutually establish timetables that reflect the state and effectiveness of RFID/EPC technology and associated processes, and the pharmaceutical industry's experience in leveraging them.

## High Performance Through RFID/EPC

This pioneering project achieved its stated objectives – to assess the potential for RFID/EPC technology to provide business value in an end-to-end supply chain context, and help to establish facets of an industry operating model. Although the work revealed areas in need of more development, it was clear that RFID/EPC will deliver on its potential.

Figure 3: A Limited Amount of Product was Tagged and Processed from Manufacturers to Retail Pharmacy




Perhaps the most important outcome of the collaboration was that the group's efforts established a forum for the industry to ask tough questions and transfer knowledge of RFID/EPC applications to other companies. Industry enthusiasm for the group's initial efforts has only grown. A second group of companies, comprised of some new and some initial group participants, is testing the technology using different products and processes.

Plans are also underway to launch an entirely new release of the initiative beginning in 2005. In contrast to the stand-alone approach from the first release, release two will focus on using RFID/EPC technology in an existing environment (not one that is controlled) and will tackle the challenges uncovered in the initial effort. One outcome of the second release will be a definitive industry adoption plan to guide organizations through the maze of opportunities and options. The team will also tackle systems integration and develop a solution that satisfies regulatory requirements, such as the Florida pedigree legislation, as well as lot and returns management.

Through this groundbreaking work, these organizations will define the best RFID/EPC implementation path, and uncover the technology's greatest potential. It is the beginning of a revolutionary change that will further transform the value chain and help pharmaceutical companies become high-performance businesses.

### Accenture – High performance. Delivered.

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Accenture is a pioneer in the area of RFID and electronic product codes: It is a member of EPCglobal (formerly the Auto-ID Center), the group that is setting the standards for this technology around the world. For almost a decade, the Accenture Technology Labs have been immersed in RFID and electronic product code research and development. Accenture offers high-performance solutions that help its clients across varied industries to seize the opportunities this technology offers – from efficiency and profitability to complete value chain transformation. It is recognized by analysts and the media as the leader in RFID and electronic product code technology and its impact on business environments. For more information on Accenture and its innovative research in this area, please visit www.accenture.com/silentcommerce

June 23, 2008

The Honorable Steve Buyer
U.S. House of Representatives
2230 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Buyer:

Thank you for the opportunity to respond to your questions from our testimony before the Subcommittee on Health on May 1, 2008, at the hearing entitled "Discussion Draft of the 'Food and Drug Administration Globalization Act' Legislation: Drug Safety." The questions articulated in your correspondence of June 9, 2008, and our responses are provided below.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

The National Association of Chain Drug Stores (NACDS) represents traditional drug stores, supermarkets and mass merchandisers with pharmacies. Its approximately 200 chain member companies include regional chains with a minimum of four stores to national companies. NACDS members also include approximately 1,000 suppliers of pharmacy and front-end products, and approximately 100 international members representing more than 30 countries. Chains operate more than 39,000 pharmacies, and employ a total of more than 2.7 million employees, including 118,000 pharmacists. They fill nearly 2.5 billion prescriptions yearly, and have annual sales of over $750 billion. For more information about NACDS, visit www.NACDS.org.

We have provided the text of your questions below, followed by our responses in *italics*:

1. On page 7 of your testimony, you state that NACDS is concerned with mandating use of any technology that is under development and premature. I have a series of questions for you and would appreciate yes or no answers. Are you aware of the provisions in H.R. 5839, which would require the development of identifier and track-and-trace standards before anyone in the industry would be required to buy technology with such standards? *NACDS: We have concerns with legislative mandates for track and trace systems.*

    a. Are you also aware that the bill provides for sufficient time AFTER the FDA announces these standards before the supply chain would have to employ the standards? *NACDS: Although this may be true for other supply chain entities, and we cannot comment on their readiness, we do not believe this to be true for pharmacies. At this time, we are unconvinced of the value of track and trace at the pharmacy level, considering the high costs of implementation and maintenance.*

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b. Additionally, are you aware of the comment period currently underway at the FDA as FDA develops standards for a unique identifier to be applied on drug units? *NACDS: Yes*

c. Are you aware of the rulemaking process written into the bill for stakeholders to provide input to the FDA as it forms standards for the track-and-trace system? *NACDS: Yes*

2. There are significant costs associated with not securing our drug supply chain. However, I recognize that there are also costs of implementing a track-and-trace system for the pharmaceutical supply chain. In your testimony, you state that your members have serious concerns about these potential costs. You note a surprisingly high number - $30,000 per pharmacy cost. Yet, in 2005, David Bernauer who has served on your board gave a cost estimate of $20,000 per pharmacy.

   a. How did you determine the $30,000 figure? Can you provide me with the data that you used to calculate these costs? *NACDS: NACDS did not determine that figure. It was provided in testimony to the California Board of Pharmacy. We do not have the data to calculate these costs. However, a recent study released by Accenture indicates that the costs of a track and trace system and e-pedigree if implemented by retail pharmacy would be significant. Accenture developed a model to examine the expected costs, with approaches constructed to represent the typical large, medium, and small chain pharmacy, and independent pharmacies. Based on the analysis by Accenture, the projected cost of this approach would range from about $84,000 to over $110,000 in the first year alone for pharmacies depending on the size of the pharmacy plus additional costs for pharmacy data centers to manage the track and trace data and for pharmacy distribution facilities. This represents on average about 2 percent of retail pharmacy's total annual sales for pharmacy and almost 3% of independent pharmacy's total annual sales.*

   b. Has NACDS considered any cost savings that will arise from track-and-trace technology? *NACDS: At this time, it is not possible to construct a methodology to calculate a potential, reliable cost saving, as there are too many unknown factors and considerations.*

   c. If not, are you familiar with a May 2007 comment from David Bernauer – the Chairman and CEO of Walgreens – who was quoted as stating – "Working together through our recently formed coalition [with independent pharmacy], I'm convinced we can… take hundreds of millions of dollars out of the pipeline by fully exploiting the potential of RFID in the pharmacy…Even more promising: the vast improvements in data management and networks over the last decade are justification for tremendous optimism." Mr. Bernauer broke down cost savings from RFID per pharmacy per year:

i. $7250 per store per year in improved receiving productivity
ii. $2000 per store per year in reduced labor on cycle counts
iii. $2500 per store per year in reduced returns and recalls
iv. $4000 per store per year in improved shrink
v. $24000 per store per year in better inventory forecasting, improved out-of-stock positions and improved pharmacy work flow.

Have you seen this analysis? Can you offer the Committee any information regarding why these cost savings numbers would be erroneous or should not be taken into consideration when addressing the problem of counterfeit drugs? *NACDS: We do not have any more detail about this information than provided above in the text of the question.*

d. Yes or No: Do NACDS members operate in numerous States? NACDS: Yes Has NACDS considered the cost to pharmacies of complying with 50 separate State pedigree requirements? *NACDS: No. We are not aware of 50 separate State pedigree requirements. However, 19 states have adopted requirements for pedigrees to be distributed outside of the recognized and secure normal distribution channel. We are hopeful that additional states will adopt this provision, thus creating a de facto national standard.*

e. Does NACDS agree that the cost of complying with 50 separate State pedigree requirements would be exponentially higher than the cost of complying with one Federal pedigree standards? *NACDS: Please see response under letter d above.*

f. Has NACDS analyzed what costs to its member companies would be to comply with 50 separate pedigree standards? Can you please provide us with this analysis if so? *NACDS: Please see response under letter d above.*

g. Is NACDS aware of the cost to the pharmaceutical industry of counterfeit pharmaceuticals? *NACDS: We do not have that information. A recent report from Accenture indicates no incidents of counterfeit prescription drugs in the US pharmaceutical distribution system since 2005.*

h. Has NACDS noted the decrease in costs for track-and-trace technology in recent years? *NACDS: Although the cost of hardware may have decreased, the costs of overhead, infrastructure, labor, operations, hardware and software are significant, according to a recent study released by Accenture. For the study, Accenture developed a model to examine the expected costs, with approaches constructed to represent the typical large, medium, and small chain pharmacy, and independent pharmacies. Based on the analysis by Accenture, the projected cost of this approach would range from about $84,000 to over $110,000 in the first year alone for pharmacies depending on the size of the pharmacy plus additional costs for pharmacy data centers to manage the track and trace data and for pharmacy distribution facilities.*

3. On page 8 of your testimony, you state that "requiring pharmacies to adopt immature technologies will cause pharmacists and pharmacy personnel to be distracted with complex compliance issues, thus taking time away from providing pharmacy services to their patients." Does NACDS see any benefits to track-and-trace technology? *NACDS: A number of our members have participated in pilot programs. The pharmacy industry is still determining the potential benefits of track-and-trace technology.*

4. Is there currently any authentication of medicines at pharmacies to ensure that the drugs are legitimate drugs? *NACDS: Yes, pharmacists and pharmacy personnel draw upon their experience and professional judgment when providing prescription drugs to patients. If a pharmacist or pharmacy employee has reason to believe that a prescription drug is not legitimate, they investigate according to the pharmacy's policies and procedures.*

5. On page 3 of your testimony you state that while there were several incidents of drug counterfeiting in the early 2000's, you are not aware of notices from the FDA of drug counterfeiting in the U.S. normal distribution supply chain since that time. As I understand it, the "normal distribution chain" means that a product flows from manufacture to wholesaler to dispenser. Is this what you mean by normal distribution chain? *NACDS: Yes, that is a general description of the normal distribution chain.*

6. On page 4, you commend the passage of the Food and Drug Administration Amendments Act (FDAAA) which was passed last year. Additionally in a written statement last week, NACDS supported the FDAAA provisions, which called for the development of "standards for the identification, validation, authentication, and tracking and tracing of prescription drugs." Does NACDS support these provisions? *NACDS: Yes, we support the development of uniform standards.*

    a. Why would NACDS support development of standards for an identification and track-and-trace system for pharmaceuticals, but oppose implementation of systems using these standards AFTER the standards are developed? *NACDS: We support the development of voluntary standards, not a mandate to use such standards.*

7. On page 3 of your testimony, you state that your industry has supported State-level legislation requiring chain of custody "pedigrees" for drug distributions outside of the recognized and safe "normal distribution channel."

    a. What State legislation has NACDS supported? *NACDS: We have supported legislation in a number of states that includes the requirement for pedigrees for prescription drug wholesale distributions outside the recognized and safe normal distribution channel, including the following states: Oregon, Idaho, Arizona, Wyoming, Colorado, Texas, Oklahoma, Nebraska, South Dakota, North Dakota, Wisconsin, Illinois, Mississippi, Louisiana, Indiana, Kentucky, Florida, Georgia, Virginia, Maryland, and Delaware.*

b. Does NACDS support California's identification and track-and-trace (pedigree) system created under the 2004 California legislation? *NACDS: We did not support this 2004 California legislation*

c. Does NACDS support Senate Bill 1307 currently being considered in the California legislature? *NACDS: At the time of this writing, our position currently is "support if amended." However, our position may change in light of recent developments initiated by the Schwarzenegger administration that recognize that pedigrees are not necessary for distributions within a secure chain of distribution.*

d. Are you aware of testimony giving by NACDS's lobbyist in the California Legislation on April 7, 2008, in which your colleague states that NACDS supports "if amended" California's pedigree system? *NACDS: Yes. However, we did not support the 2004 legislation that mandated track and trace in California. We are supportive of amendments to this mandate.*

e. Would NACDS agree that the law on the books in California allows for the creation of an identification and track-and-trace system in which all supply chain members NOT JUST THOSE OUTSIDE OF THE NORMAL DISTRIBUTION CHANNEL would be required to pass chain of custody "pedigrees"? *NACDS: Yes, that is currently in California statute.*

f. If the answer to 7(e) is yes, then I understand that NACDS does, in fact, support a pedigree system passed by all supply chain members…in contrast with your comments on page 3 of your testimony. Is this correct? *NACDS: No. Please see our responses under questions 7c and 7d above.*

8. According to testimony given to by your organization's lobbyist in the California Legislature, Jennifer Snyder, NACDS is fully supportive of the California legislation currently before the California Senate. Does NACDS support that pending legislation? *NACDS: Please see our responses under questions 7c and 7d above.*

   a. Can you explain to me why NACDS would support the pending California legislation with many of the exact same intentions and similar provisions of H.R. 5839, but would campaign strongly against H.R. 5839? *NACDS: Please see our responses under question 7c and 7d above.*

   b. Can you explain why NACDS supports California's track-and-trace system and opposes the track-and-trace system in H.R. 5839? *NACDS: Please see our responses under question 7c and 7d above.*

9. I understand that NACDS has been at the forefront of promoting the use of track-and-trace technology such as RFID technology. NACDS has sponsored annual summits right here in Washington for the past several years to highlight and promote the use of RFID technology by the drug supply chain. Is that correct? *NACDS: NACDS has*

*hosted an annual RFID Conference with HDMA. As a trade association, we provide programs to help our members understand new and emerging technologies that they may use on a voluntary basis.*

10. I read an article that at the 2007 RFID/Track and Trace Health Care Industry Adoption Summit – which was hosted by NACDS – that Walgreens CEO David Bernauer called on supply chain executives to adopt a comprehensive, uniform system of RFID and track-and-trace technology and further stated that RFID or other track-and-trace technologies could usher in a far more efficient supply chain, reducing shrink, out-of-stocks, and returns of out-of-date product and would improve order accuracy and reduce costly inventory levels.

    a. Does NACDS recognize these comments by one of its member companies at this summit that the organization hosted just last fall? *NACDS: We recognize these statements as advice to encourage the voluntary adoption of this technology.*

    b. Mr. Bernauer also noted at the 2005 summit hosted by NACDS that while RFID means supply chain improvements and heightened patient safety; the related benefits associated with implementation of the new technology also include increased customer retention and even sales." Has NACDS noted these benefits? *NACDS: We have noted this information.*

    c. Do you agree that while there will be costs in implementing identification and track-and-trace technologies; there is a significant cost-benefit to be realized by this same technology? *NACDS: NACDS itself has not conducted such an analysis. At this time, it is not possible to construct a methodology to calculate a potential, reliable cost saving, as there are too many unknown factors and considerations.*

11. On page 8 of your testimony you highlight that drug tracking and tracing should not be mandated. However, are you aware of statements made by the FDA acting associate commissioner, Randall Lutter, where he stated that "Supply chain stakeholders assured us (the FDA) that there would be considerable movement toward implementation of RFID and that widespread adoption could be done by 2007…We (the FDA) believe at that time, regulatory intervention might stifle innovation and progress in adopting this emerging technology. Yet, from out vantage point today, it appears a voluntary approach may not be enough.

    a. Do you disagree with FDA's assessment that regulatory action is needed to move the supply chain toward adoption of track-and-trace technology? *NACDS: We are not confident that either voluntary or mandatory widespread RFID adoption is feasible.*

12. In your testimony, you continue to highlight NACDS' opposition to a Government mandate for track-and-trace technology. However, Walgreens Chair and CEO David

Bernauer stated in May 2004, "This is probably the first time in my life I think we need government intervention. I support the idea that the FDA should set some time limits because there are some huge technical issues here." Do you disagree with your Member company's statement? *NACDS: We interpret this to mean that FDA must set its own time limits for the development of voluntary standards.*

13. On page 11 of your testimony, you state, "because criminal behavior is the basic component of counterfeiting and adulteration, it is doubtful that technological measures are likely to stop these wrongful acts." However, Walgreens Chair and CEO David Bernauer stated in May 2004 that RFID technology is "just too compelling in terms of safety issues, controlling counterfeits, reducing returns and making sure that you're not stuck with outdated product." Do you disagree with your Member company's statement? *NACDS: We note that Mr. Bernauer has not called for an RFID mandate.*

14. I have seen NACDS' counter proposal to the Buyer-Matheson legislation. Under this proposal, NACDS would preempt State pedigree with a certification system. Can you explain this system? *NACDS: Entities not certified by FDA would be required to create and/or pass pedigrees for the distribution of prescription drugs.*

    a. Am I correct that the NACDS proposal would only allow for a pedigree to be created if products are passed by entities that are not certified? *NACDS: The proposal requires entities that are not certified in accord with requirements set by FDA to pass pedigrees. Others may create or pass them if they so desire.*

    b. Am I correct that the proposal would make it illegal for entities to pass drugs if they are not certified by the FDA? *NACDS: No, it would be illegal for entities to pass drugs without a pedigree if they are not certified by FDA.*

    c. So, what I understand is that under the NACDS proposal, the only entities passing a pedigree would be those folks that are acting illegally? *NACDS: Details of pedigree requirements would be determined in the rulemaking process.*

    d. And, for those entities that are certified, we would have no record of the flow of pharmaceuticals through these entities. Is this correct? *NACDS: No, manufacturers, wholesale drug distributors, and pharmacies are required to maintain records pursuant to federal and state laws and regulations to maintain and provide records such as advance shipping notices, invoices, and packing slips.*

15. On page 9 of your testimony you state that "some proponents of mandatory track and trace systems cite this year's recall of contaminated heparin to build support for their proposals." Which proposals are you referring to with this statement? *NACDS: Proposals for track and trace mandates in the domestic supply chain.*

16. On page 10 of your testimony you state that "for those concerned about whether tracking and tracing is necessary for the recall of products such as the recent contaminated heparin, FDA already has an efficient, extensive, and quick recall process." Do you disagree with the argument that recalls could be improved with serialization and track-and-trace technology? *NACDS: An efficient, robust and quick FDA recall process already exists. Even with this type of technology, the recall of products will require pharmacy staff to respond to and handle drug recalls. Moreover, even if these technologies would enhance any facet of the recall process marginally, a point which has not been established, these technologies are not ready for implementation and cannot play a role in ensuring product safety at the current time.*

17. In a memorandum circulated by NACDS, you state "despite the lack of evidence to support that track-and-trace systems are actually needed or would be effective, several recent legislative proposals would call for unproven and immature technologies to maintain supply chain integrity. Proposals to mandate serializations, RFID, track and trace systems, etc., do not consider the complexities technical difficulties, and formidable costs for all drug supply chain stakeholders." I also note that in the same place you note that the lack of uniform standards must be resolved.

    a. Are you aware that H.R. 5839 calls for FDA to establish such uniform standards before implementing any identification and trace-and-trace system? *NACDS: Yes.*

18. NACDS has been circulating a proposal. As I understand this proposal, you would create a certification system which would require drug manufactures, wholesale drug distributors, pharmacies, and other participants in the drug distribution system to go through a certification program developed by the FDA.

    a. Under this proposal, certified entities would not be passing pedigree. Is this correct? *NACDS: Entities certified in accord with FDA requirements would not be required to pass a pedigree.*

    b. Additionally, you have a provision for a pedigree which would be required for drug distributions for uncertified distributors. Is this correct? *NACDS: Yes*

    c. So, as I understand it, the NACDS proposal would get rid of our Nation's current pedigree system, the system which Chainman Dingell authored in 1988 with his Prescription Drug Marketing Act. And, the only time that a pedigree would be created is when uncertified entities distribute prescription drugs? Is this correct? *NACDS: No. Our proposal would enhance Chairman Dingell's leadership on the security of drug distribution supply chain by adding additional security of certification within the drug distribution supply*

*chain through compliance with FDA requirements.*

d. Under your proposal, it would be a violation of Federal law if you were distributing drugs without certification. Is this correct? *NACDS: No, that is not correct. Some of the details of our proposal would be determined in the rulemaking process.*

e. Following this line of reasoning, under the NACDS proposal, only distributors acting in violation of Federal law would be passing a pedigree? *NACDS: No, please see above.*

19. Following up on the NACDS proposal, I want to clarify that NACDS would preempt State pedigree laws. Is this correct? *NACDS: If they conflict with or are different from the proposal in accord with FDA requirements.*

a. And, because NACDS gets rid of a pedigree system, we would no longer have pedigree in our nation and would not be able to track the flow of pharmaceuticals in our Nation. Is this correct? *NACDS: No, the proposal does not eliminate the pedigree system. Please see responses above.*

b. I understand that NACDS believes that if everyone is buying and selling from "certified" entities, there is no room for drug diversion. Is there any requirement on entities buying drugs to authenticate that they are buying from an FDA-certified entity? *NACDS: This is a detail that would have to be worked out in rule making.*

c. Should a person make their way into the drug distribution system, dilute or adulterate a product, we would have no way of catching where the problem occurred or which certified entities even touched that drug. Is this correct? *NACDS: No, it is expected that the FDA certification process would include FDA established requirements to be applied to supply chain distribution practices and recordkeeping requirements.*

Again, Mr. Buyer, we thank you for the opportunity to provide answers to your questions about our testimony. We hope that we have been able to convey our concerns and perspectives to you, as well as answer your questions to your satisfaction.

Sincerely,

Kevin N. Nicholson, R.Ph., J.D.
Vice President, Pharmacy Regulatory Affairs

cc: The Honorable Frank Pallone, Chairman, Health Subcommittee

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