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IMPORT SAFETY: STATUS OF FDA'S SCREENING EFFORTS AT THE BORDER

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

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IMPORT SAFETY: STATUS OF FDA'S SCREENING EFFORTS AT THE BORDER

WEDNESDAY, APRIL 13, 2011

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

The Subcommittee met, pursuant to call, at 10:34 a.m., in room 2123 of the Rayburn House Office Building, Hon. Cliff Stearns (chairman of the subcommittee) presiding.

Members present: Representatives Stearns, Murphy, Burgess, Blackburn, Myrick, Bilbray, Gingrey, Scalise, Barton, DeGette, Schakowsky, Christensen, Dingell, and Waxman (ex officio).

Staff present: Allison Busbee, Legislative Clerk; Todd Harrison, Chief Counsel, Oversight/Investigations; Ruth Saunders, Detailee, ICE; Alan Slobodin, Deputy Chief Counsel, Oversight; Sam Spector, Counsel, Oversight; John Stone, Associate Counsel; Ali Neubauer, Democratic Investigator; Brian Cohen, Democratic Investigations Staff Director and Senior Policy Advisor; Stacia Cardille, Democratic Counsel; Rachel Sher, Democratic Counsel; Eric Flamm, Democratic FDA Detailee; and Karen Lightfoot, Democratic Senior Policy Advisor and Communications Director.

OPENING STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. STEARNS. Good morning everybody, and welcome to the Subcommittee on Oversight and Investigations hearing on Import Safety and the Status of FDA's Screening Efforts at the Border.

My colleagues, today the Subcommittee on Oversight and Investigations will examine the status of the Food and Drug Administration's efforts to ensure that Americans have access to the safest and highest quality imported food, drugs and medical products. This subcommittee has a bipartisan tradition of periodically meeting with and demanding accountability from the federal officials tasked with screening imported food and medicines that the American people increasingly rely on for their health and quality of life. As Commissioner Hamburg herself noted in February 2010, FDA-regulated products are currently imported from more than 150 countries, with more than 130,000 importers of record, and more than 300,000 foreign facilities.

This hearing marks Commissioner Hamburg's first appearance before our subcommittee since her confirmation. Since assuming her current position, the commissioner has touted a vision for FDA to serve as "a truly global public health agency." In her own words,

"The FDA faces a daunting set of tasks. Globalization has multiplied the scale of our responsibility and the challenges that we all face." I applaud the commissioner's expressed support for a number of important FDA initiatives.

Our concern this morning, however, is less with what has been promised, and more about what has been achieved in the interest of the public health. For example, in a February 2010 speech, the commissioner unveiled a new program developed over the previous decade enabling FDA, for the first time, to comprehensively and intelligently screen all food, drugs and medical products that are entering the United States. This system, known as PREDICT, which is short for Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting, is a cutting-edge, risk-based tool that could help reduce our vulnerability to poor-quality imported food, and counterfeit or otherwise prohibited pharmaceuticals.

However, despite promises to begin deploying it nationwide by late 2009 and have it fully up and running by the spring of 2010, PREDICT has only been deployed in three districts over the last 14 months. At this rate, it would take FDA over 5 years to deploy PREDICT in the remaining 16 FDA districts. FDA has informed committee staff that the technical glitches holding up PREDICT's nationwide deployment have been resolved, and that FDA anticipates deploying the system to Florida and Puerto Rico by the end of this month.

If the technical issues have been resolved, why does FDA continue to deploy PREDICT in such a piecemeal manner? I don't see any reason not to push more aggressively for its immediate deployment nationwide. I also expect to have the commissioner back here before the committee at a future time to comment on the progress of PREDICT's deployment.

Serious vulnerabilities in our import screening systems do remain. For example, millions of parcels arrive by international mail and express couriers' facilities every year. PREDICT is not deployed at any of these facilities presently, nor am I aware of any plans for PREDICT to be used in these settings. FDA must treat each and every one of these parcels just as it does imported cargo shipments, as potential carriers of dangerous, tainted foods and adulterated or counterfeit drugs. FDA cannot claim to be doing all it can to protect the American people from these threats so long as a major entry point for goods into the country remains largely unmonitored.

FDA also should not overlook the threats posed by rogue Internet pharmacies that falsely market their products as Canadian in origin. A recent 60 Minutes CBS report on counterfeit drug imports featured a senior FDA official admitting that his agency lacked the authority to destroy dangerous shipments and was forced to simply return them to the sender. This report highlighted a serious and frustrating problem with our current screening process.

We need to better protect the health and safety of all Americans. In March 2007, FDA learned that melamine-contaminated vegetable proteins imported from China and found in certain pet foods were sickening and killing cats and dogs. Also, the commissioner noted on 60 Minutes that over 80 Americans died in 2008 as a result of contaminated heparin, a blood thinner, which had also been

imported from China. The commissioner suggested earlier this year that "regrettably, another public health crisis like heparin or melamine seems inevitable" unless certain changes are made in our import screening process. We cannot and must not accept this inevitability.

PREDICT is the most promising tool we have to enhance our defenses against such a threat. Let us deploy it nationwide and without further delay.

So Commissioner, I look forward to discussing with you the possibilities of legislation or perhaps legislative report language to help provide more focus and support to the deployment of PREDICT and other improvements to FDA's import screening. Let me welcome our witness, Commissioner Hamburg.

[The prepared statement of Mr. Stearns follows:]

PREPARED STATEMENT OF HON. CLIFF STEARNS

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FDA has informed Committee staff that the technical glitches holding up PREDICT's nationwide deployment have been resolved, and that FDA anticipates deploying the system to Florida and Puerto Rico by the end of this month. If the technical issues have been resolved, why does FDA continue to deploy PREDICT in such a piecemeal manner. I don't see any reason not to push more aggressively for its immediate deployment nationwide. I also expect to have the Commissioner back here before the Committee at a future time to comment on the progress of PREDICT's deployment.

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Commissioner, I look forward to discussing with you the possibilities of legislation or legislative report language to help provide more focus and support to the deployment of PREDICT and other improvements to FDA's import screening.

Let me welcome our witness, Commissioner Hamburg. I will now yield to Ranking Member DeGette for the purposes of an opening statement.

# # #

Mr. STEARNS. I will now yield to the Ranking Member, Ms. DeGette from Colorado, for the purposes of an opening statement.

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

Ms. DEGETTE. Thank you very much, Mr. Chairman. I am very pleased that we are having a hearing today about the safety of imports regulated by the FDA.

I think that the FDA plays a vital role in protecting the health and security of Americans, and I know we will have probably many oversight hearings about this role over the next couple of years.

Although I am really happy to see Commissioner Hamburg here before us today, though, Mr. Chairman, I am dismayed that out of three of the last four hearings, the majority has denied the minority a witness, and this approach is inconsistent with the practice of all the other subcommittees on this committee and this Congress and frankly I think inconsistent with the practices of this committee in previous Congresses.

In the case of today's hearing, we requested testimony from Allan Coukell, Director of the Pew Prescription Project. Mr. Coukell is an expert on issues raised by the influx of imported drugs and other medical products, and his testimony would have enhanced our understanding of this matter. So I ask unanimous consent to put his testimony in the record, Mr. Chairman.

Mr. STEARNS. By unanimous consent, so ordered.

[The information follows:]

Testimony before the
House Committee on Energy on Commerce, Subcommittee on Oversight and Investigations
United States House of Representatives

April 13, 2011

Allan Coukell
Director, Medical Safety Portfolio, Pew Health Group
The Pew Charitable Trusts

Chairman Stearns, Ranking Member DeGette, and members of the Oversight and Investigations Subcommittee, thank you for the opportunity to submit testimony about the essential steps Congress must take to protect Americans and ensure the integrity of our drug supply.

A major focus of the Pew Health Group is identifying ways to address risks to the U.S. pharmaceutical supply chain. Last month, we hosted a two-day conference that included representatives of brand and generic pharmaceutical manufacturers, active ingredient makers, federal and state regulators, major and secondary pharmaceutical wholesalers, chain and independent pharmacies, consumer and health professional organizations and independent supply chain experts. The convening was structured around a discussion draft of a white paper entitled "After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs," which was shared with conference participants in advance.

The presenters at our meeting explained that pharmaceutical manufacturing has changed dramatically over the past decade. While the vast majority of drugs in our pharmacies and medicine cabinets are not counterfeit or adulterated, increasing globalization and reliance on outsourced manufacturing create new risks.

Heparin

The contamination of the blood thinner heparin dramatically illustrates the risks we face. In 2007, Baxter International, the major U.S. supplier of heparin, began to receive reports of unusual adverse reactions to the drug. The company informed the U.S. Food and Drug Administration (FDA) and the problem was traced to a contaminant that had been introduced during manufacture of the raw drug. The active ingredient had been sourced from a Chinese factory, which in turn relied upon a network of small suppliers. The evidence suggests that the toxic ingredient was introduced deliberately, for economic gain.[1] It was not a chemical that occurs naturally. Whoever made it likely knew that the substance would be undetected by standard tests then in use.[2] The toxic material eventually reached at least 11 countries. Based on an estimated three tons of product, this substitution has been estimated to have yielded $1 million to $3 million in gains for the individual or company that sold it.[3] The FDA received reports of deaths and serious injuries associated with use of heparin.[4]

While failure to detect the contaminant during manufacture was a key factor, the case also illustrated other systemic problems, including:[5,6,7,8]

- An absence of timely supplier audits and FDA inspections,
- Limits and errors in the FDA database of manufacturing facilities,
- The discovery of manufacturing quality issues, including poor control of incoming raw materials, and
- The fact that – even in the period after the deaths – neither the manufacturer nor the FDA was able to gain complete access to the upstream supply chain.

This incident represents a clear breach of the security of the U.S. pharmaceutical supply. To this day, no one in any country has yet been held accountable. Nor has Congress acted to update the statutes that govern drug manufacturing. Numerous experts have asserted that, absent changes to the system, another such event is inevitable.

Globalization/outsourcing

Heparin is far from the only pharmaceutical that is produced outside the U.S. for American consumers. The number of U.S. drugs and ingredients made at non-U.S. sites has doubled since 2001.[9] An estimated 80% of the active ingredients and bulk chemicals in U.S. drugs is now sourced by industry from foreign countries,[10] and up to half are purchased from plants in India and China.[11] The U.S. is the number one destination for Chinese pharmaceutical raw material exports.[12]

Despite globalization of manufacturing, FDA oversight is largely domestically focused. Current statute requires inspections of U.S. plants every two years, but specifies no inspection frequency for foreign plants.[13] The FDA lacks the resources to inspect foreign sites with any meaningful regularity.[14] The Government Accountability Office (GAO) has also found that FDA foreign inspections are shorter than inspections of U.S. plants and, unlike inspections at U.S. facilities, are pre-announced, because of cost and resource considerations.[15]

Quality/compliance

In the case of heparin, it appears that criminals deliberately sold unsafe product into the supply chain. At other times, consumers may be at risk because of failures by manufacturers to comply with quality standards. Poor adherence to quality standards has been observed both in the U.S and abroad, but the shift of manufacturing to low-cost environments with reduced oversight creates an increased risk. According to one estimate, ignoring Good Manufacturing Practices (GMPs) can save up to 25% of a factory's operating costs.[16] The expectation of inspections is an incentive for compliance with quality standards.

Compliance failures may be the result of poor performance, or they may be deliberate. One Chinese company was found to have exported heparin to the U.S. that they claimed to have made at their own factory, but was in fact made entirely at two external plants.[17] The FDA has said that some of this heparin may have contained the same contaminant associated with the deaths in 2007 and 2008.[18] Falsification of manufacturing location poses risks to patients, because regulators cannot ensure a product's quality without knowing the conditions of its manufacture.

In 2008, an Indian manufacturer was cited by the FDA for falsification of stability testing records[19] and use of active ingredients made at unapproved sites.[20] In 2010, another Indian manufacturer was found to have falsified batch manufacturing records for an anti-platelet

medicine. The falsified records were discovered in the plant's waste yard by inspectors from the European Union.[21]

In Panama in 2006, dozens of people died after taking a cough medicine that had been made with diethylene glycol, [22,23] a sweet-tasting, but poisonous solvent.[24] It had been wrongly labeled in China and passed through a series of Chinese and European brokers, who repeatedly re-labeled it without performing independent tests. The same problem has occurred with products in Africa, Haiti and India, and has been identified in consumer products in this country as recently as 2007.[25] Students of FDA history will know that diethylene glycol poisoning in the United States in 1937 was the disaster that lead directly to the enactment of the Food Drug and Cosmetic Act (FDCA).[26] It is now time to update that statute for 21st century manufacturing.

Gaps and Solutions

The Pew convening in March was structured around a discussion draft of a white paper entitled "After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs," which was shared with conference participants in advance. At the meeting, we heard from a number of industry, government, professional groups and supply chain experts that real risks exist, and that the system can – and must – be improved. We heard that serious limitations to FDA's oversight of foreign plants making drugs and ingredients for the U.S. must be remedied. Representatives from several drug manufacturing groups agreed to back new industry fees to cover additional foreign inspections.

Experts also called for industry audits of every supplier and sub-supplier. Some companies already have best practices in place, but it is important that every company have systems in place to ensure the safety and quality of its upstream supply chain.

Some steps can be taken now. The FDA has opened offices in India, China, and other countries, and pursuing changes to standards to improve supply chain oversight. The agency is also implementing a new risk-based screening system for imports to speed the clearance of low-risk shipments and increase the predictive efficacy for identifying and targeting high-risk imports. In addition, FDA has entered into 22 confidentiality agreements with regulatory bodies in different countries and shares inspectional information with the European Union and Australia.[27] Many individual companies have also taken steps. Nevertheless, additional legislative changes are now

needed to give the FDA the tools it needs to ensure that every manufacturer is held to the highest standard. Pew prioritizes the following reforms:

1. Pharmaceutical companies must have comprehensive systems in place to assess risk and ensure the quality and safety of their manufacturing supply chains. Companies must audit suppliers on-site prior to engagement and institute supplier quality agreements.[28] Company management must be held accountable for implementing these systems.

2. Overseas inspections by FDA must be significantly increased. Inspections do not guarantee quality, but the reasonable expectation of inspections is an incentive for compliance with quality standards. We can and should ensure that inspection frequencies domestically and internationally are meaningful. The FDA has recently expressed its intention to increase its reliance on third-party sources of information, particularly inspections by other regulators, to supplement FDA's own ability to conduct inspections. This is a necessary step to preserve the integrity of the U.S. drug supply.

3. FDA authority and enforcement gaps must be addressed: FDA authorities and enforcement tools are often inadequate to properly regulate the pharmaceutical industry, particularly overseas. FDA does not currently have the authority to mandate a drug recall, nor may it halt product distribution (it can do both for medical devices) and must instead go through the courts to request a seizure.[29] In addition to mandatory recall authority for drugs, the FDA needs the authority to subpoena documents and witnesses, and an improved set of enforcement tools such as civil penalties for violations of the FDCA.

4. Improve the information flow to FDA: Drug companies are not currently required to inform FDA of many types of quality or safety issues that could present risks to U.S. patients, such as suspected counterfeiting or theft. Industry whistleblowers wishing to bring information to FDA are not currently covered by specific whistleblower protections. FDA is also limited in its ability to share information protected under the trade secrets provision of the Freedom of Information Act (FOIA) with other government agencies, which can hamper international investigations, and should be given clear authority to do so.

Protect American Consumers

The public expects that FDA will ensure that the drugs they take every day are safe from contamination and, at the same time, there is increasing concern about the safety of imported drugs. A poll commissioned by The Pew Charitable Trusts found that Americans are concerned about the safety of drugs from developing countries.[30] And Americans across the political spectrum overwhelmingly support giving FDA increased authority in order to protect the domestic drug supply. For example, 86% of respondents supported inspecting foreign facilities every two years; 94% supported mandatory recall authority for the FDA.

There is broad support among industry leaders, healthcare providers and the public for reforms to ensure the safety of the drug supply. We should not await another tragedy.

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[1] Lutter, R., Deputy Commissioner for Policy, U.S. Food and Drug Administration. Addressing Challenges of Economically-Motivated Adulteration. May 1, 2009

[2] Testimony of Robert L. Parkinson, Chief Executive Officer, Baxter International Before Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives. April 29, 2008

[3] Villax, Guy, Member of the Board and Head of Globalization Task-Force, European Fine Chemicals Group, "Business of Counterfeit Heparin and its Implications". Presentation at the 3rd EFCG Pharma Business Conference. 5/29/08. Lisbon, Portugal.

[4]http://www.fda.gov/Cder/drug/infopage/heparin/adverse_events.htm.

[5] Testimony of Robert L. Parkinson, Chief Executive Officer, Baxter International Before Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives. April 29, 2008

[6] The Heparin Disaster: Chinese Counterfeits and American Failures: Hearings before the Subcommittee on Oversight and Investigations, of the House Committee on Energy and Commerce, 110th Cong., 2d Sess. (2008) (Testimony of Robert L. Parkinson, Chief Executive Officer, Baxter International).

[7] Warning Letter WL 320-08-01, April 21, 2008. To: Dr. Yan Wang, Ph.D., General Manager, Changzhou SPL Company, Ltd (a/k/a "Kaipu"). From: Food and Drug Administration, Division of Manufacturing and Product Quality Office of Compliance Center for Drug Evaluation and Research.

[8] Bogdanich, Walt, 2008 "Heparin Find May Point to Chinese Counterfeiting" *The New York Times*, March 20, 2008. Accessed 03/20/2008. www.nytimes.com.

[9] Woodcock, Janet. Director, Center for Drug Evaluation and Research, Food and Drug Administration. "The FDA's Response to Biogenerics, QA and Globalization." *Unbranding Medicines: The Politics, Promise, and Challenge of Generic Drugs.* Harvard Interfaculty Initiative on Medications and Society. December 12, 2008

[10] U.S. Government Accountability Office. (2007, November). *Drug Safety: Preliminary Findings Suggest Weakness in FDA's Program for Inspecting Foreign Drug Manufacturers.* (Publication No. GAO-08-224T)

[11] *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients.* Prepared for the United States China Economic and Security Review Commission by NSD Bio Group. April 2010.

[12] *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients.* Prepared for the United States China Economic and Security Review Commission by NSD Bio Group. April 2010. http://www.uscc.gov/researchpapers/2010/NSD_BIO_Pharma_Report--Revised_FINAL_for_PDF--14_%20April_2010.pdf accessed 4/14/2010.

[13] 21 USC §360 subsection (h)

[14] U.S. Government Accountability Office. (2007, November). *Drug Safety: Preliminary Findings Suggest Weakness in FDA's Program for Inspecting Foreign Drug Manufacturers.* (Publication No. GAO-08-224T)

[15] U.S. Government Accountability Office. (2007, November). *Drug Safety: Preliminary Findings Suggest Weakness in FDA's Program for Inspecting Foreign Drug Manufacturers.* (Publication No. GAO-08-224T)

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[17] Warning Letter WL 320-09-01, April 14, 2009,. To: Dr. Mao Jian Yi, General Manager, Shanghai No. 1 Biochemical & Pharmaceutical Co. Ltd. From: Inspections, Compliance, Enforcement, and Criminal Investigations, Food and Drug Administration, Division of Manufacturing and Product Quality, International Compliance Team

[18] Warning Letter WL 320-09-01, April 14, 2009,. To: Dr. Mao Jian Yi, General Manager, Shanghai No. 1 Biochemical & Pharmaceutical Co. Ltd. From: Inspections, Compliance, Enforcement, and Criminal Investigations, Food and Drug Administration, Division of Manufacturing and Product Quality, International Compliance Team

[19] Memorandum to Mr. Malvinder Mohan Singh, CEO & Managing Director, Ranbaxy Laboratories Limited. Food and Drug Administration, Department of Health and Human Services. February 25, 2009.
[20] Motion to Enforce Subpoenas and Points and Authorities. United States of America, petitioner, v. Ranbaxy, INC., and Parexel Consulting, respondents. United States District Court for the District of Maryland (Southern Division). 7/3/2008
[21] European Commission. Annex I: Scientific Conclusions And Ground For Amendments Of The Marketing Authorisation And Recall Of Batches Presented By The European Medicines Agency. Annex to multiple Commission Decisions of 29.3.2010: suspending the marketing and withdrawing, under Article 20 of Regulation (EC) No 726/2004 of the European Parliament and of the Council, certain batches of [multiple Clopidogrel products], a medicinal product for human use. http://ec.europa.eu/health/documents/community-register/2010/2010032978389/anx_78389_en.pdf. Accessed August 25, 2010
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Ms. DEGETTE. Thank you so much.

Over the past decade, imports of FDA-regulated products have grown at an astronomical pace. In 2004, the FDA oversaw the entry of 12 million shipments of products like food, pharmaceuticals and medical devices. In just 6 years, the number of imports nearly doubled, reaching 21 million shipments by 2010, and the number of imports is expected to grow.

Unfortunately, the FDA faces resource constraints that pose significant challenges to the agency's ability to keep the food and drug supply safe. For example, the FDA is able to physically inspect less than 2 percent of imported shipments.

In the face of such challenges, FDA has worked hard to become more efficient. One example of this is the creation of the PREDICT database system. This system enables the FDA to target higher-risk shipments for inspection, enhancing FDA's ability to ensure the safety of imported food and drugs at ports of entry into the United States. The system is currently in use in New York, Los Angeles, Seattle and San Francisco, and it will soon be implemented nationwide.

So given the increasing number of imports and the resource constraints facing the FDA, it is difficult to understand why we would be cutting FDA funding.

In H.R. 1, for example, which was the majority's opening salvo in the budget debate, the Republicans proposed cutting FDA's budget by $241 million. The Republicans' fiscal year 2012 budget, recently introduced by Representative Paul Ryan, calls for massive reductions, rolling back the agency funding to 2008 levels. In FDA's case, this would mean a budget cut of over $600 million, a nearly 20 percent reduction in the agency's total budget.

So make no mistake about it: a cut of this size would have a significant impact on the FDA's ability to keep the food and drug supply safe. We are going to be voting on this budget this week, and I am hoping that we can reconsider these devastating FDA budget cuts. Even once PREDICT is implemented nationwide, it is not going to substitute for the budget that the FDA needs to have to undertake its oversight responsibilities.

Mr. Chairman, as you so accurately noted, in the last Congress we took an important step forward regarding food safety, passing the bipartisan Food Safety Modernization Act, which gave the FDA new tools to protect the safety of the Nation's food supply. Now we have an opportunity to provide the FDA with the additional resources and authorities it so desperately needs for pharmaceuticals. Nearly 40 percent of the pharmaceuticals in this country are imported, and up to 80 percent of the active ingredients in drugs come from foreign sources.

The Drug Safety Enhancement Act, introduced yesterday by Mr. Dingell, will hold manufacturers responsible for the safety of the entire pharmaceutical supply chain, including components produced in foreign countries, and it will give FDA tools it needs to enforce these requirements. This is good legislation that deserves bipartisan support.

Mr. Chairman, there is a lot of ground to cover in today's hearing, and again, I appreciate Commissioner Hamburg coming today. I am looking forward to hearing about FDA's efforts on imports,

about the PREDICT database system, about its work implementing the new food safety law, and its views on the Drug Safety Enhancement Act. And I hope that we can work together to explain why budget cuts to the FDA right now are not the way to go in order to protect our Nation's citizens when it comes to drugs and food. Thank you.

[The prepared statement of Ms. DeGette follows:]

PREPARED STATEMENT OF HON. DIANA DEGETTE

Mr. Chairman, I am pleased that we are holding today's hearing on the safety of imports regulated by the U.S. Food and Drug Administration. FDA plays a vital role in protecting the health and security of Americans, and Congress should be vigilant in examining ways to ensure that FDA is best equipped to carry out its mission.

I am deeply disappointed, however, that for the third time in the last month, the majority has denied the minority a hearing witness. This approach is inconsistent with the practice in all other Subcommittees regarding minority witness requests and flies in the face of the bipartisan spirit we should maintain toward oversight.

In the case of today's hearing, we requested testimony from Allan Coukell, Director of the Pew Prescription Project. Mr. Coukell is an expert on issues raised by the influx of imported drugs and other medical products, and his testimony would have enhanced the Subcommittee's understanding of this matter. I ask unanimous consent that Mr. Coukell's written testimony he prepared be included in the record.

Over the past decade, imports of FDA-regulated products have grown at an astronomical pace. In 2004, FDA oversaw the entry of 12 million shipments of products like food, pharmaceuticals, and medical devices. In just six years, the number of imports nearly doubled, reaching 21 million shipments by 2010. And the number of imports is expected to grow.

Unfortunately, FDA faces resource constraints that pose significant challenges to the Agency's ability to keep the food and drug supply safe. For example, FDA is able to physically inspect less than 2% of imported shipments.

In the face of such challenges, FDA has worked hard to become more efficient. One example of this is the creation of the PREDICT database system. This system enables FDA to target higher-risk shipments for inspection, enhancing FDA's ability to ensure the safety of imported food and drugs at ports of entry into the United States.

The system is currently in use in New York, Los Angeles, Seattle, and San Francisco, and it will soon be implemented nationwide.

Given the increasing number of imports and the resource constraints facing FDA, it is difficult to understand the recent efforts by my colleagues on the other side of the aisle to cut FDA funding.

In H.R. 1, the majority's opening salvo in the budget debate, Republicans proposed cutting FDA's budget by $241 million. The Republicans' FY 2012 budget, recently introduced by Rep. Paul Ryan, calls for massive reductions, rolling back agency funding to 2008 levels. In FDA's case, this would mean a budget cut of over $600 million, a nearly 20 percent reduction in the agency's total budget.

Make no mistake—a cut of this size would have a significant impact on FDA's ability to keep the food and drug supply safe. The House will be voting on this budget this week, and I hope that my Republican colleagues will reconsider these devastating FDA budget cuts.

In the last Congress, we took an important step forward regarding food safety, passing the bipartisan Food Safety Modernization Act to give FDA new tools to protect the safety of the nation's food supply.

We now have a similar opportunity to provide FDA with the additional resources and authorities it so desperately needs for pharmaceuticals. Nearly 40% of pharmaceuticals are imported, and up to 80% of the active pharmaceutical ingredients in drugs come from foreign sources.

The Drug Safety Enhancement Act, introduced yesterday by Mr. Dingell, will hold manufacturers responsible for the safety of their entire pharmaceutical supply chain, including components produced in foreign countries. And it will give FDA tools it needs to enforce these requirements. This is good legislation that deserves bipartisan support.

There is a lot of ground to cover in today's hearing, and I appreciate Commissioner Hamburg coming today. I'm looking forward to hearing about FDA's efforts on imports, its work to implement the new food safety law, and its views on the

Drug Safety Enhancement Act. And I hope Commissioner Hamburg can help convince my Republican colleagues to reconsider their proposed cuts to the FDA budget.

Mr. STEARNS. I thank the gentlelady. I am just a little puzzled because I thought the National Journal just reported that the FDA got a $107 million increase, so maybe our figures are different, and I would also say to the gentlelady, the Hon. Hamburg is really the Administration's witness. Probably the Republicans could argue that——

Ms. DEGETTE. You know, if the gentleman would yield?

Mr. STEARNS. I would be glad to yield. I mean, we could almost request our witness because she is really more or less your witness, and as you and I discussed earlier that we want to concentrate on this PREDICT model, and she is the only one that can do it, and we just wanted one panel, and she is the top person. I yield to you. Go ahead.

Ms. DEGETTE. This was the same thing, Mr. Chairman, that you told me the last time you denied the minority a witness when you called the Administration in to testify, so I talked to our chairman emeritus, Mr. Dingell, about this, and I said, you know, when we were in the majority and we called an Administration in when the Administration was of the other party, did we allow the minority a witness, and he said yes. If someone calls a witness, it doesn't matter if they are a Democrat or Republican. The fact is, the minority retains the ability to call witnesses. In the case of the hearing today, the witness we would have wanted to call would have actually helped us understand this PREDICT system.

Mr. STEARNS. OK. I think the Hon. Dr. Hamburg seems very competent and capable of handling this all by herself.

With that, I will recognize Chairman Emeritus Mr. Barton from Texas for 2 minutes.

Mr. BARTON. Thank you. Well, I want to congratulate you and Ms. DeGette. You at least got an Administration person to come. We have a hearing upstairs where apparently everybody at EPA is on vacation. So I want to give you two credit. You have our distinguished commissioner, and I am absolutely certain that she is going to be able to handle any questions either group of us posed to her.

We do welcome you, Madam Commissioner. You have a very difficult job, and we are always glad to hear your input.

This is an important issue. It is not on the front pages right now, which is a good thing. In the last 3 to 4 years, we have had several food poisoning situations that have made the front pages, so it is good to hold a hearing in a non-crisis situation.

We all know how much of our food is being imported, how much of our medical devices, how many of our pharmaceutical finished products and precursor ingredients, so how the FDA regulates and inspects these products is extremely important. This is an area where there has been bipartisan support in the past. Chairman Dingell, Chairman Waxman, myself, Chairman Upton have all in the past 6 years worked together to improve our food system and improve the screening process.

I am going to be very interested in your comments on the PREDICT model. I know that is being used now in four locations or

four regions. I would like to know why perhaps we can't go ahead and implement it nationwide.

So Mr. Chairman and Madam Ranking Member, this is a good hearing. Hopefully it will be bipartisan in nature, and we will put the facts before the American people. With that, I yield back.

Mr. STEARNS. I thank the gentleman and recognize the gentleman from Texas, Dr. Burgess, for 2 minutes.

Mr. BURGESS. I thank the chairman for the recognition, and I will just mention to the gentlelady from Colorado, the Ranking Member of the committee, that I will support her efforts to have a full and open hearing on the heparin issue. I tried to do that when I was ranking member of the minority and then-Chairman Waxman refused those entreaties. I was fortunate enough to get a briefing by Dr. Hamburg in my office but nothing substitutes for a full and open hearing so the American people can actually hear what is going on.

Now, the Food and Drug Administration is truly at a crossroads of the issues that really impact our country today and will shape tomorrow from the food on our tables today to the cures, the drugs and devices that our Nation's doctors will offer the patients of America. The ability of tomorrow's doctors to alleviate human suffering is going to be something on a scale that none us have ever seen before if they can get through the FDA, and your agency, Commissioner, is obviously at the forefront of those battles.

This committee with its oversight of Food and Drug is responsible for maintaining an active dialog with you on the full breadth of your jurisdiction to ensure that you have the tools that you need but you are using them in a way that is beneficial for the country at large. Primarily this hearing today will focus on food safety, and I have been concerned about that for years. In 2007, I introduced legislation that would give the Secretary of Health and Human Services the power to refuse admission to a food that was strongly associated with a suspected foodborne illness. We all remember the Lou Dobbs' reports from a couple of years ago when contaminated tomatoes were quarantined in Texas, Georgia and Florida and it turned out these were peppers coming across the border. It was found on a Friday afternoon and nothing could be done until Monday because, after all, it was a weekend. We have to be able to stop that stuff when we find it. When there is a known source of contaminated food, you should be able to act without wasting time.

Now, we all knew this hearing that coming into this year that another salmonella outbreak was going to happen. We passed a food safety law last year. We have increased the FDA budget. So I am interested in, do you have the tools you need with the new legislation that you have, the budgetary allowance that you have had. Now, Dr. Sharfstein came in and said you needed no more money for drugs and devices, so I am assuming you have put a lot into food safety, and we do want to know what is going to be different this April, this May, this June than previous years when this inevitable salmonella outbreak occurs.

I thank the chairman for the recognition. I will yield back my time.

Mr. STEARNS. The gentleman yields back. The gentleman from California, Mr. Bilbray, is recognized for 1 minute.

Mr. BILBRAY. Thank you, Mr. Chairman.

Mr. Chairman, I come from a State where you can't talk about health without talking about holistic issues too and the interrelationship between components, that nothing in health is isolated. One of the things that is quite obvious that we are not going to specifically address today but I think that we all have to be aware of, that the reality of what is happening with the development of drugs and the production of drugs in this country, this issue of importation is going to grow dynamically. Literally right now, you have companies that are leaving this country in droves and going overseas to not only produce the drugs but also the research and development, and I just think this committee needs to be aware that this issue may be increasingly substantially basically because we are seeing the next generation of innovation and drug development literally leaving the country, and sadly, the fact is, is that things like drug manufacturing and research doesn't take a lot of time to leave the country and evaporate as much as, let us say, auto manufacturing. We are seeing that going. So this issue is going to grow.

The one place where it is going to probably be reduced by this crisis is the reimportation, and that is something we need to talk very openly and frankly about, the assumption that something claims to being reimported so it is not reviewed, there is no oversight. As somebody who was born and raised along the border and seeing what happens across the largest port of entry in the world, the Tijuana-San Diego port of entry, this is obviously something that is very near and dear not just to my constituents but to my family, and I think that we need to address those issues and really talk about them extensively.

But I just think that as we look at this, we have got to be aware of the crisis coming down the pike and address that with this. Thank you very much, Mr. Chairman.

Mr. STEARNS. I thank the gentleman. The gentleman from California, Mr. Waxman, the ranking member, is recognized for 3 minutes.

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

Mr. WAXMAN. Mr. Chairman, this is the fourth oversight hearing, and three out of the four, we have been denied minority witnesses. I want to join Ms. DeGette in complaining about it. Representatives of this Administration are not minority witnesses. They represent the other branch of government, and we are going to have a serious talk about this. This isn't the way this committee has operated when the Republicans controlled or when the Democrats controlled the committee in the past.

FDA's ability to protect the American public is an important topic for oversight, and our witness would have added to that understanding of this hearing. FDA is responsible for ensuring the safety of food, drugs and medical devices, and if FDA does not do its job, lives are at stake.

In the official hearing memo for today's meeting on the safety of imports, the right questions were posed: What are FDA's solutions

for enhancing the screening of imported food, drugs and medical devices? What is FDA doing to improve its IT infrastructure for risk-based screening? How can FDA better ensure the safety of imported products?

But there is an enormous disconnect between these questions and what is happening in Congress this very week. GAO told us that improving the safety of our food and drugs requires that we provide FDA with more funding and resources, yet we are doing the exact opposite.

Just last week, Representative Paul Ryan introduced the Republican budget for fiscal year 2012. The House will soon be voting on this proposal. There is not a lot of detail but there is enough to know what it would mean for FDA. Republicans propose to roll back discretionary funding for all federal agencies to fiscal year 2008 levels.

In the case of the FDA, the agency budget would be reduced by $600 million, a budget cut of almost 20 percent. This Republican budget would require a dramatic reduction in FDA's funding to keep the food and drug supply safe. The result would be the reverse of what the American people want: fewer inspections and more adulterated and dangerous food and drugs.

Mr. Chairman, there is a word now, I think part of the American language, called chutzpah. It means you have got a lot of nerve, I think the Republicans have a lot of nerve to haul the FDA commissioner up here and grill her about why FDA is not doing more to keep the food and drug supply safe while simultaneously passing a budget that takes away the resources she needs to do her job. It is chutzpah as well for the Republicans on this subcommittee to complain that FDA is not doing enough about food safety when the majority of the members on this committee voted against the Food Safety Modernization Act, which was the first expansion of FDA's food safety authorities in 70 years.

Commissioner Hamburg, we appreciate your being here. You are not here at the request of the minority. It would be ridiculous to have this hearing without you.

Mr. Chairman, I want to yield the rest of my time, 2 minutes, to Mr. Dingell, who has been instrumental in the food safety and drug and medical device safety questions and it is important that we hear from him.

[The prepared statement of Mr. Waxman follows:]

PREPARED STATEMENT OF HON. HENRY A. WAXMAN

FDA's ability to protect the American public is an important topic for oversight. The agency is responsible for ensuring the safety of food, drugs, and medical devices, and if FDA does not do its job, lives are at stake.

In the official hearing memo for today's hearing on the safety of imports, the right questions are posed. What are FDA's solutions for enhancing the screening of imported food, drugs, and medical devices? What is FDA doing to improve its IT infrastructure for risk-based screening? How can FDA better ensure the safety of imported products?

But there is an enormous disconnect between these questions and what is happening in Congress this week. GAO report after GAO report tells us that improving the safety of our food and drugs requires that we provide FDA with more funding and resources. Yet we are doing exactly the opposite.

Just last week, Rep. Paul Ryan introduced the Republican budget for Fiscal Year 2012. The House will soon be voting on this proposal. While there's not a lot of de-

tail in the budget, there is enough to know what it would mean for FDA: Republicans propose to roll back discretionary funding for all federal agencies to FY 2008 levels.

What would this mean? In the case of FDA, it would mean that the agency budget would be reduced by $600 million—a budget cut of almost 20%. This Republican budget would require a dramatic reduction in FDA's funding to keep the food and drug supply safe.

The result would be the reverse of what the American people want: fewer inspections and more adulterated and dangerous food and drugs.

Mr. Chairman, when I read the Republican budget and then look at the topic of today's hearings, I'm reminded of an old Yiddish term: chutzpah. Roughly translated, it means someone who's got a lot of nerve.

It takes chutzpah to haul the FDA Commissioner up here and grill her about why FDA is not doing more to keep the food and drug supply safe . while simultaneously passing a budget that takes away the resources she needs to do her job.

And it takes chutzpah for Republicans on this Subcommittee to complain that FDA is not doing enough about food safety when the majority of them voted against the Food Safety Modernization Act, the first expansion of FDA's food safety authorities in 70 years.

Commissioner Hamburg, I appreciate you coming today. I am looking forward to your testimony, and I look forward to working with you to ensure that FDA has the tools and the budget to continue doing its job.

Mr. STEARNS. The gentleman is recognized for 2 minutes.

Mr. WAXMAN. And I am pleased you are allowing him to give 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. I thank my good friend from California for yielding me this time. I commend you for having this hearing because it is a great opportunity for us. I think for us to spend time caviling over whether a witness is a Democratic or a Republican witness is a prodigious waste of time. This committee has a fine history of having worked together to put out good legislation and includes the food safety legislation in the last Congress, also the wonderful legislation we put together over the question of Consumer Product Safety Commission and giving it the authority.

Americans suffer from unsafe pharmaceuticals coming into this country. They have neither the personnel nor the money to do the job that we need to do to catch these things coming in. They function under inadequate law which does not enable us to seize the products coming into this country and to destroy them and rather they are turned around and sent out and come back in through another port. Americans are dying of this. They are being denied proper prescription pharmaceuticals in order to address the problems that they confront in terms of dealing with major problems like cancer, heart disease, hypertension and other things that are killing Americans.

Yesterday I introduced with my colleagues, Ranking Members Waxman, Pallone and DeGette, H.R. 1483, the Drug Safety Enhancement Act. This legislation would require manufacturers to implement improved quality and safety standards including stronger supply-chain management, a matter often the concern of my Republican colleagues. It would require manufacturers to notify FDA of counterfeits or safety concerns and to list drugs and components by the country of origin to enable us to track the movement of

these pharmaceuticals as they move through commerce. It would strengthen importers' and custom brokers' oversight. It would arm FDA with administrative detention to structure mandatory recall authorities, subpoena power and clear extraterritorial jurisdiction. It would strengthen criminal and civil penalties for crime deterrents, and it would increase foreign manufacturing inspections to be on a par with those that are suffered by American manufacturers. It would also create new funding mechanisms for FDA inspectional activities so that globalization is not going to burden American taxpayers.

I have an excellent article about the safety problems that we confront together with an analysis of the legislation, H.R. 1483. I ask unanimous consent that those be inserted into the record.

Mr. STEARNS. By unanimous consent, so ordered.

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

Mr. DINGELL. And I commend you for this, Mr. Chairman. You are leading an effort which I believe can bring great good to our people.

[The prepared statement of Mr. Dingell follows:]

PREPARED STATEMENT FROM HON. JOHN D. DINGELL

Mr. Chairman, I thank you for holding today's hearing.

For too long, Americans have suffered from unsafe pharmaceuticals coming into this country from foreign manufacturers and counterfeit drug operations. The Heparin crisis was a wake up call that the FDA needs greater authority to stop unsafe pharmaceuticals and pharmaceutical ingredients from crossing our borders.

Just yesterday I introduced with my colleagues Ranking Members Waxman, Pallone and DeGette, H.R. 1483, the Drug Safety Enhancement Act. This legislation would give FDA much-needed authorities and resources to address the safety gaps in our drug supply system.

This legislation would:

- Require manufacturers to implement improved quality and safety standards, including stronger supply chain management;
- Require manufacturers to notify FDA of counterfeits or safety concerns and to list drugs and drug components country of origin;
- Strengthen importers and customs brokers oversight;
- Arm FDA with administrative detention, destruction, and mandatory recall authorities, subpoena power, and clear extraterritorial jurisdiction;
- Strengthen criminal and civil penalties for crime deterrence;
- Increase FDA foreign manufacturing inspections to be on par with domestic facilities; and,
- Create new funding mechanisms for FDA inspectional activities, so globalization doesn't burden US taxpayers.

This last point is an important one. At the same time this Committee and Congress is asking the FDA to do more, the new Majority is cutting their funding.

The FDA serves as the watchdog for what food, drugs, devices and cosmetics are coming across our borders and they need a steady, reliable stream of funding to carry out their duties. Further, we need to address gaps in authorities that are leaving consumers vulnerable to shoddy practices overseas.

I sincerely hope my colleagues on both sides of the aisle will work with me to provide FDA with the authority it needs to improve the safety of imports coming across our border.

Mr. STEARNS. And I thank the chairman emeritus and his long serving as the former chairman of this committee. I would point out—I asked staff based on what Ms. DeGette and Mr. Waxman indicated—that last year under Democrat majority, they had a hearing with only the FDA commissioner on May 6, 2010. So I think at this point——

Mr. WAXMAN. Mr. Chairman, will you yield to me? This is kid stuff.

Mr. STEARNS. Well, no——

Mr. WAXMAN. I don't know if you requested a witness or not. If we request a witness who we think adds to it, it is going to be 5 minutes more out of your life to hear from that witness.

Mr. STEARNS. All right.

Mr. WAXMAN. I think it is very narrow and mean-spirited to try to deny us an opportunity to hear witnesses that we think could add to the hearing.

Mr. STEARNS. Well, I appreciate your sentiments. I just don't agree with you.

OK. With that, we are very pleased——

Mr. WAXMAN. We will invoke rules that require it if that is the way the chairman wishes to deal with it.

Mr. STEARNS. We welcome our witness today, the Hon. Margaret A. Hamburg, medical doctor, Commissioner of the Food and Drug Administration. If you don't mind, just turn your microphone on and move the microphone a little closer to you and that will be very helpful. I have to swear you in.

[Witness sworn.]

Mr. STEARNS. We welcome your opening statement.

TESTIMONY OF MARGARET A. HAMBURG, M.D., COMMISSIONER OF FOOD AND DRUGS; ACCOMPANIED BY DAVID ELDER, ACTING DEPUTY ASSISTANT COMMISSIONER FOR REGULATORY AFFAIRS FOR FIELD OPERATIONS

Dr. HAMBURG. Thank you very much, and good morning, Chairman Stearns, Ranking Member DeGette, members of the subcommittee. I am Dr. Margaret Hamburg, Commissioner of Food and Drugs, and joining me here is David Elder, Acting Deputy Assistant Commissioner for Regulatory Affairs for Field Operations. He has been with the agency for 23 years, 15 of which he spent in the field.

I appreciate the opportunity to be here with you to discuss our approach to import safety and the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting application, or PREDICT, and its role in our efforts to protect our Nation's supply of food and medical products in an increasingly globalized market.

When President Franklin Delano Roosevelt established the modern FDA back in 1938, the percentage of food and medical products imported into the United States was minimal. Today, the landscape, as you have already been discussing, is dramatically changed. FDA-regulated products are currently imported from more than 150 countries. This year, we expect that nearly 24 million shipments of FDA-regulated products will arrive at U.S. ports of entry. It is estimated that between 15 to 20 percent of all food now consumed in the United States originates outside our borders. Further, up to 40 percent of the drugs Americans take and up to 80 percent of the active pharmaceutical ingredients in those drugs come from foreign sources.

We face great challenges in ensuring that products are high quality and travel safely throughout their complex supply chain. As members of this committee well know, our concerns are not purely

hypothetical. The consequences of adulterated medical products throughout the world have already been noted, and they have been tragic. Pet food adulterated with the industrial chemical melamine in 2007 sickened several thousand pets here in the United States, and that same contaminant was added to infant formula in China, fatally poisoning about six babies and making 300,000 others gravely ill in that country. And members of this committee are well aware of the 2008 heparin contamination crisis in which adulterated heparin was associated with several deaths and cases of serious illness.

To address these threats and others, we need a paradigm shift in our approach to import safety where the border is no longer our primary line of defense. We must partner with industry and our global counterparts to push responsibility for safety and quality further up the supply chain and to monitor the integrity of that supply chain throughout. That is why FDA is developing a global strategy and action plan, more fully detailed in my written testimony, which will allow us to more effectively oversee the safety of all products that reach U.S. consumers in the future. While we cannot simply be guardians at the gate, border screening, surveillance and intervention must remain an important part of our comprehensive import safety program.

The task is enormous. In fiscal year 2010, FDA received a total of 21.2 million lines of FDA-regulated commodities imported from over 150 countries. FDA is currently managing 264 active import alerts, which flag potentially high-risk imports representing 3,100 types of products from over 11,000 manufacturers in 150 different countries or areas.

To help make our imports screening more efficient, FDA has developed the PREDICT application, a sophisticated information technology system which provides FDA staff on the front lines with more information regarding the many risks associated with products entering our borders and allows them to target for examination those shipments at greatest risk. PREDICT has been launched in Los Angeles, New York, Seattle and San Francisco, covering about 40 percent of all imports at the present time. Some technical difficulties, as noted, delayed our national rollout. However, I am pleased to report that we have addressed those issues and are back on track. This month, PREDICT will be implemented in our Florida and San Juan districts, expanding coverage to almost 50 percent of all imports. If successful, it will then be rolled out across the country.

PREDICT is an exciting and important innovation that harnesses advances in information science to enable us to do our job better and to improve our service to the Nation. But as I mentioned earlier, it is just one step in our efforts to fully secure the supply chain.

Congress has provided the agency with critical tools to assure the safety of imported food. New regulatory authorities for drugs similarly may help ensure that we can hold industry accountable for the security and integrity of their supply chains and the quality control systems they use to produce drugs for the American people. Those may include authorities in the areas of corporate responsi-

bility, enforcement and information sharing, which are detailed more fully in my testimony.

Thank you for the opportunity to testify this morning, and I look forward to answering your questions.

[The prepared statement of Dr. Hamburg follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

STATEMENT

OF

MARGARET A. HAMBURG, M.D.
COMMISSIONER OF FOOD AND DRUGS

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

"IMPORT SAFETY: STATUS OF FDA'S SCREENING EFFORTS AT THE BORDER"

APRIL 13, 2011

Release Only Upon Delivery

INTRODUCTION

Good morning, Chairman Stearns, Ranking Member DeGette, and Members of the Subcommittee. I am Dr. Margaret Hamburg, Commissioner of Food and Drugs at the Food and Drug Administration (FDA or the Agency), an agency of the Department of Health and Human Services. I appreciate the opportunity to be here today to discuss our approach to import safety and the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting application, or PREDICT, and its role in our efforts to protect our nation's supply of food and medical products in an increasingly globalized market.

I would like to express my gratitude to the Members of this Subcommittee and the Members of the full Committee on Energy and Commerce for your leadership in passing the FDA Food Safety Modernization Act, which provides FDA with important tools to help fulfill our mission to protect the nation's food supply in the 21st century. For the first time, FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply, and has enhanced tools to protect consumers from risks posted by both domestic and foreign food sources. As one example, the new requirement for importers to perform supplier verification activities will provide added assurances that food from abroad is as safe as domestic food. I also appreciate the efforts of Mr. Dingell and other Members of the Committee to address similar challenges we face in ensuring the safety of the supply chain for drugs.

When President Franklin Delano Roosevelt established the modern FDA in 1938, the percentage of food and medical products imported into the United States was minimal. Today the landscape is dramatically changed. FDA-regulated products are currently imported from more than 150 countries, with more than 130,000 importers of record, and from more than 300,000 foreign

facilities. This year, we expect that nearly 24 million shipments of food, devices, drugs, cosmetics, radiation-emitting products, and tobacco products will arrive at U.S. ports of entry. Just a decade ago, that number was closer to 6 million, and a decade before only a fraction of that. It is estimated that 15 to 20 percent of all food now consumed in the United States originates outside our borders. In fact, over 70 percent of seafood and about 35 percent of fresh produce consumed in the United States comes from foreign countries. Further, up to 40 percent of the drugs Americans take are manufactured outside our borders, and up to 80 percent of the active pharmaceutical ingredients in those drugs comes from foreign sources. Imported medical devices are another rapidly growing area. In addition to the sheer volume of imports and foreign facilities producing FDA-regulated commodities, there has been an increase in the variety and complexity of imported medical products. These factors combine to create great challenges to FDA and industry in ensuring that all medical products are high quality and travel safely throughout their complex supply chains. These factors also provide incentives and opportunities for criminals—those motivated for economic reasons and those who intend to harm our citizens—to introduce adulterated products into our domestic supply.

As Members of this Subcommittee well know, these situations are not purely hypothetical. In recent years, we have seen that the threat from intentional adulteration (including economically motivated adulteration) of food and medical products is real. The consequences, throughout the world, have been tragic: glycerin used in the manufacture of fever medicine and cough syrup and teething products was adulterated with the highly toxic solvent, diethylene glycol (DEG), resulting in the deaths of children in Haiti, Panama and Nigeria. In 2007, pet food adulterated with the industrial chemical melamine sickened several thousand pets in our country. That same contaminant was added to infant formula in China, fatally poisoning six babies in China and making 300,000 others gravely ill. And Members of this Committee are well aware of the 2008

heparin contamination crisis in the United States, in which adulterated heparin was associated with several deaths and cases of serious illness. FDA has seen numerous instances of drug counterfeiting over the last several years. In the first half of 2010, FDA warned consumers about a potentially harmful product represented as "Generic Tamiflu" sold over the Internet. FDA tests revealed that the product did not contain Tamiflu's active ingredient, oseltamivir, but instead contained cloxacillin, an ingredient in the same class of antibiotics as penicillin. Antibiotics are not effective against viral infections, such as influenza, the disease for which Tamiflu is indicated.

These examples demonstrate that the risk to the U.S. food and medical products supply comes from sources around the world. While FDA is able to more easily address the threat posed by domestic suppliers through the inspection of facilities and other means, it is often difficult to obtain the same level of confidence with regard to the safety of food and drugs produced thousands of miles away because FDA does not have the same level of resources on the ground. To address this issue and ensure that food and medical products from abroad are produced as safely as those made in the United States, we must partner with other federal, state, local and international regulatory and law enforcement agencies and industry to push responsibility for safety and quality further up the supply chain. That is why FDA is developing a global strategy and action plan that will allow us to more effectively oversee the safety of all products that reach U.S. consumers in the future. Specifically, the strategy includes the following components:

- FDA will work to build a global data-information system and network and proactively share data with partners.
- FDA will build additional capabilities in intelligence gathering with an increased focus on risk analytics and a transformed IT capability.

- FDA will leverage the efforts of public and private sector third parties and industry and will effectively allocate FDA resources based on risk.
- FDA, working in concert with Customs and Border Protection (CBP), will strengthen our ability to perform targeted inspections at the border.
- FDA will partner with foreign counterparts to create a global coalition of regulators focused on ensuring and improving global product safety.
    - We now have permanent FDA overseas posts in Beijing, Shanghai, and Guangzhou, China; in New Delhi and Mumbai, India; in San Jose, Costa Rica; Mexico City, Mexico; and Santiago, Chile. We will soon have a post in Amman, Jordan and a post in Pretoria, South Africa. These offices enable us to have a regional presence around the world and serve as important hubs for improved coordination with regulatory authorities in other nations and industry. They also conduct and facilitate inspections and other on-the-ground activities in foreign sites.
    - We have more than 30 additional agreements with foreign counterpart agencies to share inspection reports and other non-public information that can help us make better decisions about the safety of foreign products.
    - We are engaging in bilateral and multilateral international standards development and harmonization efforts.

It will take time to finish developing and implementing this plan; however, in the near term the Agency continues to develop innovative approaches that allow it to achieve its mission of protecting the public health in a more globalized world. Last year, FDA conducted more foreign inspections than ever before in our history and we are on track to surpass that record again this year.

IMPORT SAFETY AND FDA'S PREDICT APPLICATION

If we want to ensure that imported food and medical products are as safe as those products produced domestically, we cannot simply be "guardians at the gate," attempting to detect and weed out dangerous and contaminated products at our ports and borders. But border screening, surveillance, and intervention remain an important part of a comprehensive program—and we can and must do it in a much more meaningful way to best target our available resources. In Fiscal Year (FY) 2010, FDA received a total of 21.1 million lines of FDA-regulated commodities imported from over 150 countries or areas. Each of these lines is electronically screened. Those lines that are determined by the system to be of low risk are allowed to enter into commerce. Those that are not are reviewed by FDA staff, who determine whether a field exam or sampling is necessary or if more information should be requested or the entry should be released. In FY 2010, FDA conducted 286,339 examinations, including 159,792 field exams, 99,152 label exams, and 27,395 samples. FDA is currently managing 264 active import alerts that we have established to prevent the importation of products that have "the appearance" of being adulterated, misbranded or unapproved. The appearance is typically based on past violative samples or foreign inspections. Implementation and management of import alerts prevent potentially violative products from reaching consumers, unless and until the importer demonstrates that the product is in compliance. The 264 import alerts represent 3,100 types of products from over 11,000 manufacturers in 150 different countries or areas.

At a speech last year before the Center for Strategic and International Studies, I announced the launch of PREDICT, a sophisticated information technology system conceived and developed by FDA for use by our field staff, which provides them with more information regarding the many risks associated with products entering our borders and allows them to target for examination those shipments that pose the greatest risk.

PREDICT was first launched at the two largest FDA districts, in Los Angeles and then in New York. It has since been deployed in Seattle and San Francisco as well, covering about 40 percent of all imports. We originally planned to launch it nationwide last spring; however, some technical difficulties with our information technology hardware and systems delayed our rollout considerably. For example, users found that the software used to obtain the risk-based information from PREDICT was too slow to allow FDA entry review staff to effectively keep up with the volume of imports requiring review. After extensive investigation, technical staff determined that the delay was due to two distinct problems: data communications between our field locations and our data center, and problems with the configuration of the software at our data center. These issues required changes to settings in our field computers and to our servers at the data center, as well as modified system coding. A recent upgrade to our field network has added to the much improved performance. As a result, I am pleased to report that our nationwide rollout is back on track. This month, PREDICT will be implemented in our Florida and San Juan Districts, expanding coverage to almost 50 percent of all imports. If successful, it will then be rolled out across the country.

Currently, using risk-management strategies, FDA screens each shipment electronically to determine if the shipment meets identified criteria for physical examination or sampling and analysis, or warrants other review by FDA personnel. PREDICT represents a significant

enhancement to FDA's targeting ability by enabling the Agency to use data from a much wider range of sources to inform our entry decisions. With PREDICT, our investigators will still physically examine only a small percentage of all import shipments—a limitation that reflects resource realities—but they will have better intelligence available at their fingertips to decide which shipments to examine.

PREDICT uses a variety of assessments to rank import shipments according to risk. It considers everything from whether a product is intrinsically risky—such as fresh produce or soft cheeses—to information we have acquired from previous sample analysis, field examinations, or inspections of shippers or producers and information about the regulatory system under which the product was produced. We can even add information on factors such as floods, hot weather, or market conditions that suggest whether a particular shipment is at risk of being contaminated, spoiled, or otherwise defective. These and other factors are weighed to give a risk score in relation to other products being offered for importation. This score, along with FDA's expertise, will allow FDA field staff to target shipments that pose the highest risk to the public health.

PREDICT offers two major benefits to FDA staff as well as to importers and to the public. First, by better identifying potentially higher-risk shipments, FDA resources can be focused on those shipments more likely to contain a violative product, providing for a more efficient use of resources and allowing investigators to focus on products most likely to present a risk to the public and to prevent those found violative from entering U.S. commerce. In the four districts where it has been launched, data on examinations and sample analyses confirm the value of PREDICT's risk-scoring system for imported products. For example, in a group of 81,480 field and label exams, the likelihood of detecting a violation was 11 times greater if PREDICT had given the entry line a rank of 95 (meaning higher risk) than if it had given the entry line a rank of

5 (meaning lower risk). In addition, PREDICT automatically clears almost three times as many entry lines of lower-risk products compared to the old system. This allows entry reviewers to devote more time to targeting higher-risk products for examination. Second, by better identifying lower-risk and compliant products, we are able to expedite their entry resulting in savings to both importers and consumers, by bringing safe products into the country faster.

The success of systems such as PREDICT is linked to the quality of data that importers and entry filers submit for the entry of their products. The submission of accurate, complete data is rewarded with faster entry processing and speedier clearance of compliant, lower-risk products. FDA entry reviewers save the time which they otherwise would have spent looking up shipments in our database manually. FDA has made a substantial outreach effort to industry. Since April 2009, FDA has conducted or participated in more than 60 events for industry, explaining the PREDICT system and the mutual benefits of submitting complete, high-quality data for import entries.

PREDICT has been instrumental in the detection of violative products that might otherwise have escaped detection. For example:

- FDA's New York District received an entry of frozen fish in early 2011. PREDICT alerted the reviewer that FDA had not sampled this manufacturer's products recently and that the importer had imported violative seafood products in the past. As a result of this information the reviewer targeted the shipment and an investigator collected a sample. FDA laboratory analysis revealed the fish was contaminated with *Salmonella* bacteria. This entry has not been released by FDA into U.S. commerce and is currently under detention.

- FDA's Los Angeles District received an entry of fresh string cheese in late 2010. As a result of a PREDICT percentile rank of 100 (the highest possible rank), a reviewer targeted the shipment and an investigator collected a sample. FDA laboratory analysis revealed the cheese was contaminated with *Listeria* and *Staphylococcus* bacteria. The entry was refused entry by FDA and destroyed in early 2011.

PREDICT is an exciting innovation that harnesses advances in information science to enable us to do our job better and to improve our service to the nation. But, as I mentioned earlier, it is just one step in our efforts to fully secure the supply chain.

AGENCY AUTHORITIES TO ADDRESS GLOBALIZATION

With enactment of the FDA Food Safety Modernization Act, Congress provided the Agency with critical authorities to ensure the safety of both domestic and imported food. With regard to imported food, the new law provides FDA with tools both at the border and further up the supply chain. For example, the new law requires importers to perform risk-based verification activities of their foreign suppliers to ensure that the food is safe. The law also provides an incentive for importers to take additional food safety measures by directing FDA to establish a voluntary program through which imported food shipments may receive expedited review if the importer has taken certain measures to ensure the safety of the food. Third-party certification may be used to participate in the voluntary import program mentioned above or when FDA requires certification for certain high-risk foods. The law also charges FDA with helping to build capacity for food safety in other countries that export to the United States and with working closely with foreign governments to enhance food safety.

To further secure the drug supply chain, FDA has established a new Drug Integrity and Security Program, which specifically focuses on drug quality issues such as counterfeiting, economically motivated adulteration, cargo theft, and other supply chain threats and vulnerabilities. The program was recently launched and is currently establishing its strategic plan. These efforts may include industry guidance, regulation, inspections, collaboration, outreach, enforcement strategies, and other measures that will be effective in securing the supply chain. FDA intends to strengthen its global partnerships to effectively regulate products entering the domestic supply chain. To this effect, FDA can benefit from new legislative authorities that are, at a minimum, commensurate with those of its global counterparts.

New regulatory authorities may help ensure that we can hold industry accountable for the security and integrity of their supply chains and the quality control systems they use to produce drugs for the American people. Those authorities may include:

Corporate Responsibility

- Modernization of registration and listing – Revising these statutory provisions may improve the timeliness, completeness, and accuracy of FDA's current registration and listing information, making sure FDA has accurate and up-to-date information about foreign and domestic parties involved in medical product manufacture.
- Quality management systems – FDA currently works with industry to ensure that individual companies have effective quality management systems in place; however, additional statutory authority could place greater responsibility on manufacturers to account for the quality and provenance of the materials that go into their products.
- Track and trace – Requiring a cost-effective track-and-trace system for all products throughout the domestic and foreign supply chain would ensure transparency and

accountability of product manufacturing and distribution, whether the product is manufactured domestically or internationally.

Enforcement

- While FDA does not seek to interfere with regulatory authorities outside the United States, having express authority to address threats to U.S. consumers, wherever they may arise, is critical.
- Refusal of admission if inspection is delayed, limited, or denied – This authority is critical to providing a strong incentive for foreign firms to allow FDA to perform inspections, and to permit FDA to exclude from domestic commerce products whose foreign manufacturers are not willing to subject themselves to the same requirements as domestic manufacturers.
- Mandatory recall authority – Under current authority, in most instances industry eventually agrees to voluntarily recall products that FDA believes pose a risk; however, FDA lacks the authority to compel such recalls and critical time can be lost in negotiations between FDA and industry, leaving the public exposed to potentially serious health risks. The Agency currently has this authority for medical devices, infant formula, and now food, but not for drugs.
- Administrative detention and destruction – Absent these authorities, FDA is often forced to return violative products to their sender. Foreign products can then find their way back to U.S. ports of entry several times, wasting critical resources that could be better spent identifying new threats. This authority would level the playing field for those who produce compliant products, whether located in the United States or abroad.
- Enhanced criminal and civil penalties for foreign and domestic suppliers – Statutory changes could help to flip the cost-benefit ratio against counterfeiting pharmaceuticals,

deter would-be criminals from targeting this area, and bring FDA's penalties in line with those for other serious federal health and safety violations.

Information Sharing

- Require information upon importation – The Agency can refuse entry of an import that appears from examination of samples or otherwise to violate the Act, but FDA lacks authority to require certification or other assurance of compliance with applicable standards or requirements as a condition of importation, consistent with FDA's ability to ensure that the domestic drug supply is safe.
- Notification to FDA – This authority would permit FDA to require foreign and domestic companies to provide complete information on threats such as counterfeiting, theft, non-compliance with regulatory standards, mislabeling or misbranding, or other threats to the public health to effectively combat threats to the supply chain.
- Unique facility identifier – Absence of a system of unique facility identifiers, such as a D-U-N-S number, submitted to FDA both as a condition of registration and import, makes it difficult for FDA to properly follow threats up the supply chain, and makes it harder to get different systems, including at different agencies, to properly cross-reference.
- Authority to share non-public information with other regulatory agencies and foreign governments – This authority would allow FDA to share information that could lead to timely identification, prevention, and resolution of emerging threats.

In our increasingly complex and globalized world, these additional authorities represent important tools to help support efforts to protect the safety of imports and the health of our citizens.

CONCLUSION

Given the challenges and threats posed by an increasingly globalized marketplace, we must modernize our approach to the safety of imported products. We appreciate the Subcommittee's efforts to address this critical issue, and look forward to continuing to work together to achieve our shared goal. I would be happy to answer any questions.

Mr. STEARNS. Thank you, Commissioner Hamburg.

We have a clip we are going to show on the screen here, which is from a speech you gave in January discussing the FDA's new global challenges. If we can, play the clip and maybe just drop the lights a little bit.

[Video shown.]

Mr. STEARNS. That statement indicates that you believe the current threat is pretty serious and you have spoken repeatedly about the challenges we face in assuring the safety and quality of imported products in a global age. You mentioned that in your opening statement, and I think we can conclude that import safety is one of your top priorities, and you have promoted PREDICT as an important tool to leverage FDA's resources in responding to this global challenge.

As you mentioned in your testimony, you formally unveiled PREDICT in February 2010 in a speech and you stated that you hoped to have it up and running nationwide by the end of the spring of 2010, as we recollect. The question is, what did you do to try and accelerate the implementation of the process considering you had indicated that you thought it would be up and running by the spring of 2010.

Dr. HAMBURG. Well, as noted, PREDICT is a very important tool that will enable greater efficiencies in who we target resources, and it is very exciting to see it now in action in four of our districts and covering about 40 percent of all imports at the present time. As we rolled it out, from the very beginning it was determined that it should be done in a systematic stepwise way because very often with computer system implementations that involve extremely large databases, there are issues that emerge in the process. So we began in one location with a limited focus, expanded the focus and then began to roll it out.

In the course of that, unfortunately, some issues did emerge and we actually at a certain point decided to stop with the actual use of PREDICT in the field while we brought in experts and put together a team which examined that.

Mr. STEARNS. So really, in a sense, rather than trying to accelerate the implementation process, you really stopped it then.

Dr. HAMBURG. Well, what we did was when the problems emerged——

Mr. STEARNS. I mean, isn't that true?

Dr. HAMBURG [continuing]. In its implementation, we stopped it in order to identify what those problems were rather than keeping a system——

Mr. STEARNS. Let me get a little more specific for you. After PREDICT was deployed in the New York district in the spring of 2010, there appeared to have been a 5- to 6-month delay while a government contractor wrote a white paper on a performance assessment of PREDICT. Given that import safety is one of your top priorities, is this delay of the deployment acceptable considering how important it is? And you said earlier in your speech that this has to be enforced.

Dr. HAMBURG. Mr. Chairman, I understand your concern about an unfortunate delay that occurred in the process. However, this system is very, very important. It is critical that it work effectively

and efficiently. We had identified problems with its implementation. We stopped the full rollout while we brought in outside experts and our internal experts to identify the source of the problem. The effort that you mentioned was an effort to identify the——

Mr. STEARNS. Can I say this morning that all the technical problems have been solved?

Dr. HAMBURG. We believe that we identified the underlying problem that led to the——

Mr. STEARNS. So the answer is yes?

Dr. HAMBURG [continuing]. Inefficiencies in the system.

Mr. STEARNS. The answer is yes, that you think all the technical problems have been taken care of?

Dr. HAMBURG. It seems to be now functioning very well in the sites where it is present.

Mr. STEARNS. Can you, based upon that, make a prediction this morning that PREDICT will be fully implemented nationwide by the end of the year?

Dr. HAMBURG. That is our absolute goal but if there are problems in the implementation, we will of course examine those and correct them, but we are moving forward. We see no barriers to the further implementation of PREDICT in the two additional sites at the end of this month and extending it to 100 percent implementation by the end of the year.

Mr. STEARNS. In your opinion, wouldn't PREDICT benefit from a program focused oversight structure with executive-level involvement?

Dr. HAMBURG. I am sorry. Would it benefit from an oversight——

Mr. STEARNS. Yes, a more focused approach with more executive-level involvement. Instead of having these technical white papers, can't you just have your staff focus down on this and bring in the executives to make decisions?

Dr. HAMBURG. You know, I feel that we have been implementing this in a very responsible way with a clear program plan with internal and external experts overseeing the project. When problems emerge, we have taken the appropriate actions to remediate them. We now have the system up and running in the desired way providing benefits.

Mr. STEARNS. Well, do you think you need congressional support? Should we pass legislation specifically authorizing this program and working with the Appropriations Committee to include report language? Would that help you at all, or do you think that is not necessary?

Dr. HAMBURG. The continuing support of Congress for our efforts to support import safety is extremely welcome. I don't think we need targeted legislation or activities for the PREDICT program. As I said, I believe that it is moving forward in an appropriate and valuable way and that it was our responsibility as problems emerged to identify the source of those underlying problems, fix them and make sure that the program in place in fact was fully functional and able to do the tasks that we are asking it to do and it is proving to be of great value as we screen products today.

Mr. STEARNS. My time is expired. The gentlelady from Colorado is recognized for 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

So Dr. Hamburg, let me get this straight. It was about 14 months ago, February of last year, that the FDA announced this PREDICT program, right?

Dr. HAMBURG. In the speech that you saw the segment of we formally announced that this PREDICT was——

Ms. DEGETTE. About 14 months ago, correct?

Dr. HAMBURG [continuing]. Going to start to unfold.

Ms. DEGETTE. And then you started implementing it and you found some problems and so you had to correct those problems as the implementation went forward, correct?

Dr. HAMBURG. That is correct.

Ms. DEGETTE. And if you had just tried to implement the whole thing within 2 months, it is your view that it may not have worked because it had some problems, right?

Dr. HAMBURG. It would not have worked.

Ms. DEGETTE. Now, as of today, 14 months later, it is about 40 percent implemented, correct? You need to use words. It is about 40 percent implemented?

Dr. HAMBURG. It is implemented in four sites that cover 40 percent of the imports.

Ms. DEGETTE. And so is it the FDA's view that the major problems in the PREDICT problem have now been solved by these efforts over the last 14 months?

Dr. HAMBURG. It is our belief that through the systematic scale-up and the examination of problems as they emerge that we have been able to correct the underlying problem in code, which actually wasn't in PREDICT, it was in an interface with PREDICT.

Ms. DEGETTE. I see. OK.

Dr. HAMBURG. And that now the system, you know, is working in the sites that it is in place and we see no barriers at the present time to the full implementation in a timely manner.

Ms. DEGETTE. And the FDA believes in this program and wants to implement it as quickly as possible as well as us, right?

Dr. HAMBURG. Absolutely.

Ms. DEGETTE. So, you know, I join with Mr. Stearns in saying, you know, whatever we can do to help you implement this, we think that it is important and it should be done as soon as possible but it should also be done right.

But here is my next question. You said in your testimony, PREDICT isn't the only thing we need to do. Why is that?

Dr. HAMBURG. Because the volume of imports coming in at the borders and the number of sites of importation are so huge that the ability to really do the hands-on inspection, even with a screening tool like PREDICT, limits us in our reach. We want to reach back further, closer to where the products are actually produced and manufactured and try to build in assurances of safety and quality from the very beginning and throughout the supply chain, so working more closely with industry in terms of the standards that are expected, working with sister regulatory authorities in countries around the world so we have this harmonization of standards, sharing information with others.

Ms. DEGETTE. OK. And so let me ask you, because we passed the Food Safety Modernization Act last year. Do you think that the

FDA needs new authorities to begin to do what you are talking about and to protect the safety of the drug supply?

Dr. HAMBURG. I think the Food Safety Modernization Act has clearly given us additional authorities and a new framework for addressing food safety in this context. I think we do need to very carefully examine the opportunities on the drug side as well. We know that there are huge challenges and as was noted, they are growing. We do need additional authorities to be able to do our job and of course we need resources as well.

Mr. DEGETTE. Yes. One thing that I worked a lot on in this food safety bill that is also in the Drug Safety Enhancement Act is mandatory recall authority for the FDA for drugs. Do you believe this authority is necessary?

Dr. HAMBURG. I do believe that authority is necessary.

Ms. DEGETTE. And why is that?

Dr. HAMBURG. So that we can move swiftly when there is an imminent threat to the health of the public, to take action to make sure that a product with risks does not get out to consumers, is pulled back from shelves when it is out there. It is very vitally important, and our current authorities require us to either act through the authorities of States to embargo or pull back these products or to seek the support of the courts in taking these actions.

Ms. DEGETTE. You know, this is one thing when I worked on mandatory recall for the food safety, my constituents were shocked because they thought the FDA already had that authority, and I bet that is true with drugs too. I bet people just think the FDA has that authority with drugs.

One last question. One of the controversial areas in this new bill that we introduced calls for new registration fees on importers. I am wondering if you can talk about what the FDA opinion is on these registration fees.

Dr. HAMBURG. Well, I think it is very, very important that we recognize that the magnitude of the problem is huge and growing and outstrips available resources. Clearly, we need to bring appropriate resources to bear. Clearly, this is the responsibility that the American people care about as well as industry, and I think it is appropriate that these programs be supported with industry contributions as well, and the ability to work with industry to achieve common goals in reducing these threats to health and safety will be, I think, enhanced in this kind of an approach.

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

Mr. STEARNS. I thank the gentlelady. Dr. Burgess is recognized for 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman.

Well, they can be enhanced in that kind of approach only if we understand the problem that we had and how to deal with the problem. That of course brings me back to the heparin question, and you were kind enough to come and brief me last year in the last Congress. If I could, let me just recapitulate a couple of the things that we talked about that day. I would like to have them part of the committee's record. Can you provide to the committee a list of the people with whom you met in China, the Chinese officials with whom you met?

Dr. HAMBURG. A list of officials with whom I met while I was visiting China?

Mr. BURGESS. Yes.

Dr. HAMBURG. I could.

Mr. BURGESS. Because you met with several.

Dr. HAMBURG. For the record. I mean, I can't produce that right now.

Mr. BURGESS. Correct, and I understand that. That is why I was asking you if you could produce it for us. And did the subject of the adulterated heparin come up when you met with the Chinese officials?

Dr. HAMBURG. It did. I raised it with them to express our——

Mr. BURGESS. They didn't bring it up spontaneously? You had to raise it?

Dr. HAMBURG. I believe that I raised it.

Mr. BURGESS. OK. And what did they commit to you as far as action to investigate and uncover what happened?

Dr. HAMBURG. What was indicated to me was that they felt that there was not anything to be gained at this point by trying to continue the investigations of the underlying cause and instigators of the heparin contamination but they did recommit to working with us to ensure that this specific problem and similar problems will not occur going forward, and we do have a memorandum of understanding with the Chinese government with respect to some of the critical public health measures that need to be in place and are in place to help protect——

Mr. BURGESS. See, that whole approach is problematic to me because now we have, with all good intentions, drug safety legislation being introduced but we don't really understand what happened and how we are going to control it, and that then makes for legislative difficulties. But the heparin question is so fundamentally different from the melamine. Melamine, it can be argued, was the equivalent of a dishonest grocery putting his thumb on the scale when he weighed your produce, but the heparin, this was a molecule that was developed specifically to defeat the mass spect that was used by the manufacturer to document that in fact what they had extracted from the live specimen was the desired active pharmaceutical ingredient. So hypersulfated and chondroitin sulfate would exactly reside within the peak that normal heparin would provide one the mass spect, and only when it was done with an ultra-sensitive machine could you separate out and see, oh, there is actually two compounds here instead of one, and that compound was patented under the Chinese system. So why was it created and what possible use could it have had in a commercial application and how in the world did it find its way in to contaminate the pharmaceutical supply chain? I mean, these are some pretty critical questions that need to be answered, and to just say well, going forward we are going to be sure things are done right, I am sorry, maybe the heparin will be done right but what was the intent here? Was it simply a dishonest retailer or was there something more nefarious afoot? And we just simply don't know.

So now you have the chairman emeritus and the ranking member writing legislation which in all likelihood I could support in principle but we don't know what we are trying to fix. We don't

know how it happened in the first place. That is why we need your help. You were in China. You met with these officials. We need your help to understand how we do in fact prevent this happening in the future. Would you not agree with that?

Dr. HAMBURG. I agree that this is a very serious concern and I agree that the heparin contamination was a very sophisticated example of a broader phenomenon in fact, which you note, the economic adulteration of products, and I think it speaks to the urgency of our really strengthening the activities to ensure import safety, the importance of additional resources and authorities, the importance of stronger authorities to enable us to do investigations when there are problems outside of our——

Mr. BURGESS. Right. It almost requires that we think like the criminal because after melamine, you know, melamine, shame on us, but heparin, why didn't we see it coming.

Let me just ask you a question though because it is so important that I get this in too. We have a hearing with device manufacturers. We hear from drug manufacturers. There is a lot of complaints that the process that people have to go through with FDA to get drugs and devices approved is in fact at this point unknowable and it makes the investment community nervous and in fact it makes the investment dollars dry up, or worse yet, go overseas so these drugs and devices are developed in other markets rather than the United States so it is an outsourcing, it is an offshoring problem as well. What are you doing within the agency to ensure that those pathways can in fact be known before someone starts—so that you can actually tell people what they will need to provide and then not change the rules of the game as they go through it?

Dr. HAMBURG. You raise a really important issue, you know, for our Nation in terms of supporting innovation, critical industries, economic and global competitiveness, and FDA clearly has an important role to play. We are looking very carefully at our regulatory pathways and how we can be more transparent and predictable, also looking at how we can bring the best possible science to bear so that we have better knowledge and tools and approaches to make the regulatory pathways more effective and efficient. We are working in partnership with academic scientists and industry scientists and government scientists to really try to strengthen the underlying science because some of the problem with the regulatory pathway is in fact scientific uncertainty about how do you take a good idea and make it into a real-world product, and of course, a bit outside of the FDA's bailiwick is the important question of what are the economic incentives to help ensure investments in important candidate products that hold real promise.

Mr. BURGESS. I think we both have to agree that the timeline is a strong economic disincentive. I heard from a physician who developed a product as he watched his son being circumcised and decided there had to be a better way to do some of these things. His son is going to college and it is still tied up in the FDA.

Thank you. I yield back.

Mr. STEARNS. The gentleman's time is expired. The gentleman from Michigan, Mr. Dingell, is recognized for 5 minutes.

Mr. DINGELL. Mr. Chairman, I thank you.

Commissioner, I want to focus on the adulterated drugs that are crossing our borders. Some have said it is as much as $75 million a year. I think it is rather more. And recent scares like heparin and other matters show how much needs to be done to monitor imported drugs and pharmaceuticals. Now, having said that, in recent reports by CBS News, more than 36 million Americans have unknowingly purchased drugs on counterfeit-drug Web sites. Often these purchases are being dropped in the mail where they may not be tested either by Customs or Border Patrol. It is my understanding that under current law, if FDA recognizes counterfeit or adulterated drugs, FDA cannot detain or destroy products on site without going through a lengthy process providing notice and an opportunity for hearing so that FDA often ships these drugs back to the sender. Is that correct?

Dr. HAMBURG. That is correct.

Mr. DINGELL. So under current law, it is possible for a drug operation that is counterfeiting or adulterating drugs to put it in a package that was rejected by the FDA at one mail facility and to simply resend it through a different mail facility or again through the same fiscal year? Yes or no.

Dr. HAMBURG. Unfortunately, yes.

Mr. DINGELL. I believe I am correct in believing that if FDA had the authority to destroy drugs believed to be adulterated, misbranded or counterfeit that this would help to keep counterfeit drugs from reentering our country through alternative mail facilities or other facilities. Yes or no.

Dr. HAMBURG. That is correct.

Mr. DINGELL. Now, section 201 of the Drug Safety Enhancement Act, which I introduced yesterday with my colleagues, Mr. Waxman, Mr. Pallone and Ms. DeGette, would give FDA's officers or employees the authority to order destruction. Section 202 of the bill would authorize the destruction of any drug valued at $2,000 or less or that the Secretary deems to be a significant adverse health risk. Anything valued at more than $2,000 could not be destroyed until notice and opportunity for hearing occurred. Do you believe having this authority would discourage counterfeit drug operations from shipping their products into the United States? Yes or no.

Dr. HAMBURG. Yes.

Mr. DINGELL. Now, we know that these counterfeit and adulterated drug operations are a lucrative business. These operations make money out of the pockets of consumers who may not know that their prescriptions are either unsafe or ineffective. I believe that we must impose severe penalties at least equivalent to similar violations relating to different kinds of products so as to discourage their continued operation. The legislation introduced yesterday proposes strengthening civil and criminal penalties for any person who knowingly distributes unsafe pharmaceuticals. Do you believe that criminal and civil penalties discourage the counterfeit and adulterated drug operations? Yes or no.

Dr. HAMBURG. Yes, I believe they would.

Mr. DINGELL. Now, Commissioner, the Drug Safety Enhancement Act would also require FDA to inspect every establishment, foreign and domestic, at least once every 2 years following registration. You at FDA have been continuously and chronically underfunded.

Personnel from FDA have said publicly that FDA's resources do not keep pace with the volume of products coming into the United States. The majority proposed the 2012 budget cut $600 million from FDA in spite of the fact there are new safety authorities for food safety that you are required to implement. Would you agree that a fee system could help provide a stable funding source for drug safety activities? Yes or no.

Dr. HAMBURG. I believe we need additional resources to do the task before us.

Mr. DINGELL. Would you support such a fee system, Commissioner?

Dr. HAMBURG. Pardon me?

Mr. DINGELL. Would you support a fee system?

Dr. HAMBURG. Yes, I would.

Mr. DINGELL. Now, can you give us an appreciation of how many people you have in charge of dealing with imports of pharmaceuticals? You don't have to tell us this morning. Submit that for the record. Would you also submit to us how much that costs and would you submit to us how many people you need to do this work and how much that would cost, please?

Dr. HAMBURG. I would be delighted to put that together and submit it for the record.

Mr. DINGELL. I believe we need to know that. Now, this committee going back as far as when I was chairman of Oversight used to have people in to discuss these matters and we never got around to doing anything about it. Last year, we passed by overwhelming vote, it came unanimously out of this committee, if my memory serves me correctly, the food safety bill. Is that working well?

Dr. HAMBURG. We are still very early in the implementation but it is a huge contribution and historic shift really in how we are able to address food safety issues giving us a new——

Mr. DINGELL. It gives you lots of new and added authorities?

Dr. HAMBURG. It does.

Mr. DINGELL. And you recognize many of those authorities in the pharmaceutical safety bill introduced yesterday, do you not?

Dr. HAMBURG. I think we would like to see parallel authorities in the drug area in many key arenas.

Mr. DINGELL. Mr. Chairman, I thank you for your courtesy to me. I hope that we will be able to use this hearing as a mechanism to move forward towards safety of our people from bad pharmaceuticals as we have done with regard to bad food safety, and I would hope my colleagues would work with me in a bipartisan fashion towards this end. Thank you, Mr. Chairman.

Mr. STEARNS. I thank the gentleman. Dr. Gingrey is recognized for 5 minutes.

Mr. GINGREY. Mr. Chairman, thank you.

Mr. Hamburg, thank you for being here today and for your leadership at the helm of the FDA. I greatly appreciate your efforts and focus on efforts to encourage the FDA to adapt and improve its functions including the use of the PREDICT software at our borders and ports of entry, and we appreciate that. Going to the PREDICT model, one that is flexible and able to meet new and emerging threats to our borders and ports, in many respects I see the

FDA reform in much the same light and I think from your previous statements here, I know you do as well.

Federal initiatives to develop new drugs and diagnostics, whether in the antibiotic space or elsewhere, can be greatly supported by an FDA that is flexible, adaptable to new technologies, and understanding of the human body and genome is critical. How important of a role do you think that the regulatory science—you referenced that earlier—how important of a role do you think regulatory science can be to support the FDA in its work in the coming years and decades?

Dr. HAMBURG. You know, I think it is enormously important, and I truly appreciate your question. It is an important area of science. It is the knowledge and the tools that are needed to really effectively and efficiently evaluate a product for safety, efficacy, quality and performance, and there have been huge advances in science and technology that can be brought to bear on the regulatory process as well as on the drug development and medical product development process to make it more streamlined and more modern, and will give us tools so that we can really shorten the timeframe for the regulatory process in key ways using innovative clinical trial models, using biomarkers to help us identify early concerns like toxicity——

Mr. GINGREY. Dr. Hamburg, thank you, and I think you know I am currently working on some proposals in support of regulatory science and I am hoping that I can get your commitment that you will sit down and work with me and my staff in support of this worthy goal.

Dr. HAMBURG. I am extremely eager to work with you on that.

Mr. GINGREY. I really appreciate that. Thank you, Dr. Hamburg.

You expressed support for developing a track and trace and authentication system to help combat the counterfeit drugs. Can you update us on FDA's efforts in this area and give me your thoughts on the scope of drug counterfeiting and diversion in the United States? What else can we as a Congress do?

Dr. HAMBURG. Well, with respect to the big picture, we know that counterfeit drugs represent a very large and growing problem. It is most—the burden is most pronounced in the developing world where in some countries 30 to 50 percent of drugs for serious diseases being used in fact are not what they purport to be. It is a smaller problem in this country in large part because we have a very strong regulatory framework and we work very closely with counterpart agencies to minimize the problem but with the growing complexity of supply chains and globalization and the fact that we know that especially in the absence of strong civil and criminal penalties that counterfeiting is an increasingly attractive area for some bad guys, I am sad to say. We cannot be complacent and we need to make sure that we have the programs and policies that——

Mr. GINGREY. Well, before the hearing started, I had spoke with you briefly about the 60 Minutes clip that I am sure a lot of folks on both sides of the aisle saw recently, and the magnitude of the problem is downright scary, and certainly this is a timely hearing.

Real quickly in the last minute that I have, the events and controversy related to the approval and subsequent price increase of a drug manufactured by KV Pharmaceuticals for the prevention of

premature birth—premature labor and possibly premature birth. While not directly tied to import screening, it does involve FDA's mission to ensure the safety and efficacy of our Nation's drug supply, and it was initially thought that pharmacies would be precluded from compounding versions of this product which they had been doing for some time and selling for much less than the product marketed by KV, and because of the controversy that ensued, KV ultimately significantly lowered the price and FDA announced that it would not initiate enforcement against the compounding pharmacies. I have a couple of questions in regard to that issue. Are you aware of any safety concerns with patients taking a compounded version of this drug versus the Makena product?

Dr. HAMBURG. As far as I know, we have not had reports of adverse events associated with compounding of this particular product.

Mr. GINGREY. And then the last thing, and I realize I am a little bit over time, are any ingredients for the compounded version imported as far as you know?

Dr. HAMBURG. You know, I would have to get back to you. I honestly don't know the answer to that question.

Mr. GINGREY. And then real quickly, Mr. Chairman, I just wanted to ask you, Dr. Hamburg, in regard to Dr. Burgess's line of questioning about the heparin. Have we then abandoned the heparin investigation? Is that pretty much over and done with?

Dr. HAMBURG. In terms of the investigation of who actually instigated this economic adulteration of the heparin product, the investigations have come up dry and there are not active new leads. I think the other side of it that is important for you all to understand, for the American people to understand, is that we do have a very large number of steps in place and safeguards to protect against the importation of contaminated heparin if there were those who chose to try to begin again with this contamination of this important product.

Mr. GINGREY. Dr. Hamburg, thank you. Mr. Chairman, thank you for your indulgence. I appreciate it.

Mr. STEARNS. The gentlelady from Illinois, Ms. Schakowsky, is recognized for 5 minutes.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

Thank you, Dr. Hamburg. The job that you have taken is so expansive from baby food to medical devices in between, and I know that imports of FDA-regulated products have dramatically increased over the last 7 years. In 2004, FDA oversaw 11.8 million shipments of products like food and pharmaceuticals and medical devices, but by 2010, the importation of FDA-regulated products had nearly doubled, totaling in 2010, 21.1 million shipments. That is a lot. And so I wanted to ask you about the resources that you really have to deal with that.

The President's budget for 2012 asks for a significant increase in the FDA's budget, approximately 33 percent, which actually includes the new user fees that Mr. Dingell had mentioning, bringing it to a total of $4.3 billion, but the Republican budget as presented by Paul Ryan we understand would likely roll back FDA funding to the fiscal year 2008 funding levels, which means the agency would be cut by about $600 million. So what I am concerned about,

and my first question is, what effect would a funding cut on have the ability as specifically as possible to be able to do its job? How would that affect ordinary consumers and what would you have to do?

Dr. HAMBURG. Well, the magnitude of the cut you described, you know, would be enormously difficult for our agency to absorb without taking serious cuts in critical programs to the health and safety of the American people with respect to our ability to inspect and support the safety of the food supply, our ability to ensure the safety of the drug supply, our ability to approve new and promising medical products for the American people, our ability to protect the safety of the blood supply and other critical FDA-regulated products that people depend on every day, and it would certainly make it very, very hard for us to move forward to more fully and effectively address the challenges of import safety.

Ms. SCHAKOWSKY. And what then would be your priorities were the increases to go through, if the Congress were in fact to give you more money? For example, would we be able to—as Dr. Burgess mentioned, would there be any possibility of speeding up the permits for new pharmaceuticals or new products?

Dr. HAMBURG. We are trying to target additional resources and additional energy in the area of supporting innovation and really modernizing our regulatory pathways. Dr. Gingrey mentioned the importance of regulatory science, and investments there are making a difference in really moving our systems forward. But a lot of what matters in moving a product swiftly and surely through the regulatory pathway involves having the staff resources to work with the sponsor companies to lay out the expectations for what kinds of data and evidence they need to put forward to support the approval of their product and to work with them as they are collecting that data, analyzing that data and presenting it to us.

So if we have deep cuts, we will not be able to achieve some of what we know makes a difference in terms of the review teams and what needs to be done. We won't be able to apply advances in science and technology to modernize our regulatory pathways. And, we won't be able to do the important work every day both to ensure the safety and quality of the manufacturing and production of drugs and the important work to make sure that once those drugs are approved and they are being used by people in the real world, we continue to monitor for the safety and the efficacy of those drugs so that the American people can actually trust and depend on these important products.

Ms. SCHAKOWSKY. Thank you very much.

Mr. STEARNS. I thank the gentlelady. Ms. Myrick is recognized for 5 minutes.

Mrs. MYRICK. Thank you, Mr. Chairman, and thank you both for being here, and we do appreciate the work. I know you have got a very difficult job.

As was previously mentioned, Dr. Hamburg, you and Mr. Elder were interviewed on that 60 Minutes special regarding the threat of counterfeit imported drugs to the U.S. pharmaceutical supply. Would you mind if we just play the clip so everybody could see?

Dr. HAMBURG. OK.

[Video shown.]

Mrs. MYRICK. It is really frightening, I think, to all of us because we share your concern, and I know you have already answered the questions that you don't have the authority, etc., but in 2009 and 2010, the U.S. Customs and Border Protection seized approximately 2,000 parcels of pharmaceuticals coming through the mail. Do you have any way of knowing how many of those were screened by the FDA that were destroyed or returned to the sender? Do you have way to track any of that?

Dr. HAMBURG. The way the system works is that the products come into the mail facility. Customs and Border Protection screens. Those that look like they contain drugs or medical products get then targeted to the FDA. We work closely with CBP, of course. And then we undertake the examination of a subset of those products that have been targeted to us through Customs and Border Protection, and unfortunately, we cannot screen all of those products because of limited resources, and we do lack the authority when we find violative products to actually detain and destroy them.

Mrs. MYRICK. And when they are returned to the sender, I mean, that is kind of the majority of the work that you do. In other words, you can't destroy them so you have to return them to the sender. Is that correct?

Dr. HAMBURG. We have a couple of options. We can hold the product and seek support from the courts to destroy them.

Mrs. MYRICK. I know it would be helpful to you if you had some authority from us to be able to——

Dr. HAMBURG. Absolutely. It would make much more sense in terms of addressing important public health problems and efficient use of resources.

Mrs. MYRICK. This is a separate question. I hear a lot from patients and doctors in my area. They have really big concerns about the FDA's risk-benefit analysis. FDA threatens to remove certain drugs and devices from the market that have relatively low risk compared to a patient's risk of death without access to the drugs or devices, and in some cases we are talking about terminal illnesses, and patients are often willing in that case to take a little extra risk because it means they can live longer. So how does the FDA take these patients into account when it comes to approval and sometimes withdrawing the approval, and can the approach that you use be improved in any way, in your opinion?

Dr. HAMBURG. Well, it is such an important part of how we think about and use drugs in this country. We obviously do look at the risks and benefits in the context of a given disease and what other treatments are available, and people are willing to accept many more risks if they have a fatal disease and they have no other option.

Mrs. MYRICK. So you do take that into account?

Dr. HAMBURG. Yes. We are in the middle of a process of really trying to make this all more transparent and really systematic and lay out the criteria for weighing risks and benefits in different contexts both in terms of the understanding that our own staff have about how to think about it and the training but also so that medical product sponsors and the public including patients can under-

stand this as well, and we are doing this in an open way, getting input as we try to shape this model.

Mrs. MYRICK. I really appreciate it, because it is heartbreaking when you sit with somebody who is using a drug and it has successfully prolonged their life and they are living a normal life and then the drug is pulled or it can't be used for that particular disease. So it presents a big challenge, and it just breaks your heart. So I appreciate your looking at it. Thank you.

Mr. Chairman, I yield back.

Mr. STEARNS. The gentlelady yields back. The gentlelady from the Virgin Islands is recognized for 5 minutes.

Mr. CHRISTENSEN. Thank you, Mr. Chairman, and welcome, Dr. Hamburg. I regret that I have been in and out, and I may be repeating some of the questions, but I think it is important for us to understand the implementation of PREDICT, so I have some questions about the PREDICT database and realizing that it is a new tool that was created to enhance FDA's risk-based screening efforts at ports of entry and recognizing, of course, that FDA can't inspect every import shipment. The system enables the agency to target shipments that are more likely to violate FDA regulations.

So as I understand it, now PREDICT is fully operational for all FDA-regulated products in Los Angeles, New York, Seattle and San Francisco. Did you say San Juan as well?

Dr. HAMBURG. Not yet in San Juan. It is being implemented in a staged way and so components even aren't as fully fleshed out as they will be over time but the major components are fully operational and covering 40 percent of imports out of those four districts.

Mr. CHRISTENSEN. Thank you. And I know that the chairman asked several questions about the delay, and you said that there were problems, and if you have already specifically stated what those problems are, I apologize, but why specifically, what were the problems that caused the delay in the full deployment of PREDICT?

Dr. HAMBURG. Well, as we started to implement the system, it was operating much more slowly than people expected. It was much more cumbersome. And so questions were asked about why that would be. It was initially thought that it was an infrastructure problem that we were overlying a very large data management set of tasks onto our existing infrastructure. That was systematically looked at. It actually turned out that the problem was really most focused on a piece of software that interfaced with the PREDICT system that was slowing it down because it was doing a series of initializations underlying the entry process and that was corrected and it is now working in a very efficient way and we are seeing measurable improvements in our ability to quickly move low-risk products through and target high-risk products.

Mr. CHRISTENSEN. And then you convened a high-level group of FDA officials to identify and fix the problem. Just to clarify, did the problems that you identified with PREDICT cause any risk to the public health or food or drug safety at any time?

Dr. HAMBURG. I really appreciate that question because I should emphasize that even when we were having problems with PREDICT, we still had underlying systems that were supporting our

screening, and while not as robust and rich as PREDICT, they were still able to provide the core set of public health responsibilities that go with our import screening activities.

Mr. CHRISTENSEN. Thank you. You know, I think it is important not to make a mountain out of a molehill here. The FDA is implementing a brand-new IT system to help keep the food and drug supply safe, and it seems to me the agency is doing exactly the right thing in the right way. No IT system is implemented without problems. But the key is that when you found the problems, you acted rapidly to identify and fix them and to make sure that the public health was not harmed. So we are looking forward to the full implementation.

Let us see if I can get another question. I would like to ask you about courier fees because millions of shipments of FDA-regulated products enter the U.S. through express courier facilities like FedEx and UPS every year, and the President in his budget for 2012 proposes a new international courier fee that would be assessed. The President's budget requests a new international courier fee not to exceed $5.3 million. What activities would that fee support?

Dr. HAMBURG. It would enable us to do the kind of review and, when necessary, examination of products coming in through that mechanism. It is a growing component of imported products. It is one that operates on a 24/7 time frame. Because of our limited resources, we haven't been able to target the courier services in the way that would most benefit them and so actually this is something that I think they are very eager to work with us on in order to support greater deployment of FDA personnel.

Mr. CHRISTENSEN. So you don't expect that this fee would cause hardships for the couriers and importers, do you?

Dr. HAMBURG. I think it will benefit them because they very much are committed to very rapid transit of the materials that they are importing and this will enable FDA to be able to support their business model in terms of transit of products that are safe and low risk.

Mr. CHRISTENSEN. Thank you.

Thank you, Mr. Chairman.

Mr. STEARNS. I thank the gentlelady. The gentleman from California, Mr. Bilbray, is recognized for 5 minutes.

Mr. BILBRAY. Thank you.

Mr. Hamburg, I appreciate your being here. In the last 2 years prior to the new majority being here, how has your budget been impacted by the new Administration proportionally from the previous Administration? Has the budget been severely reduced or has it been enhanced to some degree, or what is the deal?

Dr. HAMBURG. Well, actually, beginning in the last Administration we began to see some significant increases in our budget though over the last few years we had had increases in our budget that have been very, very welcome. We do have——

Mr. BILBRAY. Do you have any idea what kind of percentages you have seen in the last 24 months?

Dr. HAMBURG. In the last 24 months?

Mr. BILBRAY. Since you have been there.

Dr. HAMBURG. Well, we have had—in the last year, it was—you know, it is a little hard to——

Mr. BILBRAY. But it has been a healthy increase?

Dr. HAMBURG. We have had significant increases in the last couple of years.

Mr. BILBRAY. OK. I appreciate that. I want to get back to this issue that we have got China demanding that research be done in China for drug development for anything sold there, so we are going to see a shift there. We will see a shift in the emphasis why manufacturing should go to China with this basic extortion game going there. You have got Europe that is really reducing their review of drugs and devices to a point way below basically it looks like much more efficient. They are getting more efficient going out. So we have got this potential of this big increase of imports coming in as we are watching our manufacturing capabilities be exported. Are you reflecting that? Are you planning on that increase in your inspection at the borders that looks which everybody in the industry is saying is basically an indication we are seeing across the board?

Dr. HAMBURG. Let me first address some misperceptions. There is a sense that we are much slower than Europe, our counterparts there, in reviewing drugs and devices. In the drug area, in fact, we went back and looked over the last couple of years and the majority of new molecular entities, new drugs that both of us approved were approved first in the United States. In fact, if you look at priority drugs, the number is actually higher.

Mr. BILBRAY. I would like to see that because the applications were made here first many times and they were basically moved on others because of the perception but the fact is that from the data we have, from the data I have received basically reflects the fact that even though you had major increases—and I think this is an issue about what do we do with the money, you know, we are looking at a 28 percent slowdown of the review of drug processing by FDA at a time your budget was expanding. So there are a lot of these institutional changes that we have to address, and just sending money across over doesn't necessarily guarantee the job is going to be done efficiently or—you know, not efficiently but basically the mindset of the bureaucracy does affect timeline and performance, does it not?

Dr. HAMBURG. Let me just assure you, we take very seriously the timeliness of our reviews, and through the user-fee program we actually negotiate with industry about timelines for performance.

Mr. BILBRAY. Doctor, let me just say, we have got industry people that we are going to have to testify about your operation behind closed screens because they are that scared of the process. But in all fairness, at a time when you had major expansion of resources to get the job done, the numbers that we have got before our committee is that 28 percent longer period for drugs, a 43 percent extension of time for devices. That means that just by giving you more money doesn't mean the system is going to run more efficiently.

Dr. HAMBURG. I don't know those numbers, and we would be delighted to sit down with you and go over the numbers, but I think

the bottom line is that we need to do better, we can do better. We are working with industry——

Mr. BILBRAY. Related to this issue, that means we have a vested interest in safety to try to make the system more efficient here as it relates to not just safety and efficiency but also the timeline because that timeline affects the decision of do you produce it in the United States or do you go overseas and then we buy our own inefficiency here, our lack of reform here in processing, we create a crisis for ourselves to have to review that much more coming in to address this issue. And I hope we have that kind of commitment by your agency showing that slowing down the process is not just an issue that makes it safe for the bureaucracy, it something that makes it more risky for everybody because it may have unintended consequences such as causing us to have to now import more drugs and have to be reviewing those.

Dr. HAMBURG. Well, I understand your concerns and we are very committed. We do take the performance timelines very seriously and we are meeting the majority of our goals. I am also systematically reaching out, listening to industry and their concerns. I just met yesterday most of the day with a group representing both device and pharmaceutical industry representatives or former representatives to hear more about some of these specific concerns and how we can identify areas to work on together to streamline the process, to help support the need to move critical products into the marketplace.

Mr. BILBRAY. OK. I would just like to ask one last question. Were you consulted about the potential of the device tax that was placed in the bill last year, the potential that device tax being an incentive to bootleg devices into this country?

Dr. HAMBURG. I was not.

Mr. BILBRAY. OK. Do you have a position on that device tax and its impact?

Dr. HAMBURG. You know, it is a complex issue and it is not within our jurisdiction.

Mr. BILBRAY. I appreciate that.

Mr. Chairman, I think before we do things like device taxes, we should be asking regulators about how it is going to impact their job. These things are all related, like I said. It is holistic. You can't do one without impacting the other. And I yield back.

Mr. STEARNS. The gentleman's time is expired. I think we will go a second round here. As the Chairman, I have the prerogative to start but I am going to let Dr. Burgess, who has to leave, if he will start on our side. So Dr. Burgess, you are recognized for 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman. And just on Mr. Bilbray's point about the devices, I can hardly go anywhere and speak to any group without someone pulling me aside so I am heartened by the fact that you are hearing some of these same things but also his point that people are afraid to come forward. When I have someone come and tell me their particular tale of woe about what they have developed and where they are in the process, and I say would you be willing to come to the committee and talk about this, and they say no, you know, I don't want to jeopardize whatever chance I might have now with the FDA, I wouldn't want

to put myself out there and jeopardize it. That is an unfortunate place for us to be.

And Mr. Bilbray is also correct, the device tax essentially zapped the research and development budget for many of these small startup companies. Also, in addition to your agency's regulations, we also have the comparative effectiveness, PCORI, the Patient-Centered Outcomes and Research Institute, that was funded in the Patient Protection and Affordable Care Act. All of these things now interplay with the bringing of new drugs and devices to market. Witness the controversy that has existed over Provenge and Avastin since the first of the year. We have certainly heard a lot about Provenge for prostate cancer and the period of time that it provides for survival, it is not cost-effective to provide it to prostate-cancer patients but I think there was recently a relaxation of that ruling, breast cancer with Avastin, some of the same considerations.

I also hear people ask me why can we not talk about surrogate endpoints. It was very effective in developing the drugs that are now useful for treating HIV/AIDS, if survivability is the only endpoint that can be used and we are not certain how reduction of viral load will affect that survivability. In the early days of that, having a surrogate endpoint actually allowed those products to move forward with a great deal more facility and provide relief to a segment of the population that previously had been denied relief.

So these are not just abstract issues that we are talking about. They are very real issues. And again, I know that because I can't go anywhere in the country without someone telling me that, you know, I was delayed 4 years with this anti-cancer drug, I am saving 2,500 people a year now so I have to assume 10,000 died while I was put on hold by a regulatory agency. I mean, that is pretty severe when we put it in those types of numbers. So I am encouraged that you are considering this, but please also understand that we don't even have the freedom to brings these folks to committee and ask them questions because they are fearful of retaliation from the FDA. Surely you have heard that before.

Dr. HAMBURG. You know, I can assure you that we make our decisions based on the best available data, not on, you know, other information. They do not need to worry about retaliation. I think what we need to focus on together, though, is to make sure that our regulatory pathways are as well defined and as predictable as possible for sponsors who are bringing new candidate products before us. We need to make sure that we are able to work with them closely so that there is clear understanding of what is expected of them and why we need to make sure that we are bringing the best possible science to bear in terms of making sure that the data that is being collected in support of a product is the right data and that, you know, things you just mentioned about surrogate endpoints, we do use surrogate endpoints, but we need to be undertaking a massive effort working with scientists and industry and government to really develop more much more innovative clinical trial models that will enable o us to get the robust scientific answers we need but with shorter times, lower costs and fewer patients and other areas where we can apply better science to both the drug and medical product development and the review.

Mr. BURGESS. And we can't move the goalpost, which again, is a frequent criticism that I am hearing.

Let me just ask you question. I was talking about heparin in the first round of questioning and the molecule, hypersulfated chondroitin sulfate. Am I correct that that was actually patented under a Chinese patent?

Dr. HAMBURG. I don't know the answer to that.

Mr. BURGESS. What is the purpose in developing a molecule like that? Does it have a use in industry?

Dr. HAMBURG. I don't know the answer to that. I would be happy to get our experts at the agency to provide you with additional information.

Mr. BURGESS. Well, it might be something that is useful to know. Again, we are talking about the committee developing legislation to prevent these products from coming into the country. We kind of need to know what was involved and why even develop such a product if it wasn't to cheat somebody who is buying heparin.

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

Mr. STEARNS. The gentlelady from Colorado is recognized in the second round for 5 minutes.

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

Mr. Hamburg, how many drug approval applications do you know offhand does the FDA get in a year? Do you know offhand?

Dr. HAMBURG. Let me see if one of my other experts knows. I don't know offhand but that is easy information for us to actually get.

Ms. DEGETTE. Well, the reason I am asking the question is because I know that the FDA is working on trying to streamline the approval process but at the same time making sure that the process for each new drug is thorough, correct?

Dr. HAMBURG. Right.

Ms. DEGETTE. If we have a large budget cut to the FDA in next year's budget, is that going to help or hurt our ability to expedite the drug approval process?

Dr. HAMBURG. Well, unfortunately, it will clearly hinder our ability, and we are talking about very large numbers, especially if you look at the drug and the device side. And as we have been talking about already, the ability to really support sponsors in their efforts to bring products before us does require—is a resource-intensive, staff-intensive activity to be able to provide the best possible and the most timely review.

Ms. DEGETTE. You know, you can streamline processes, and I assume you are doing that, but at some point it does take the resources to pay for the staff to review the applications and to do what needs to be done. Is that right?

Dr. HAMBURG. That is correct.

Ms. DEGETTE. A second question I have is, this discussion that a lot of folks have been having in this hearing about the approval process resulting in a slow and more cumbersome process than in the EU, and I hear this a lot and I have read it a lot in the media. I am wondering, I don't think you got to fully explain what the FDA found when they looked at this claim that the EU is much more fast and efficient and does a better job. I am wondering if you can just finish your answer to that question.

Dr. HAMBURG. OK. You know, we did take a very serious look at the exact numbers because we were hearing more and more questions raised in this area, and what we found was very striking. I may get the numbers slightly wrong because I didn't review them before coming to this hearing. I was more focused on the import safety issues. But I believe that between 2006 and 2010, there were about 53 or 54 new molecular entities that were approved by both the EU and the U.S. and that we were in fact significantly more rapid in approving those drugs in well over 50 percent, I think it was 43 or so of those products. If you actually look at cancer drugs, and the time frame that we looked at that was a little different, I think it was 2003 to 2010, but there were 23 new cancer drugs that were approved by both entities and we were first in approving those.

So, there clearly is a misperception that we are slower than our counterparts in the European Union, and for the priority drugs we were almost twice as fast in approving these drugs.

Ms. DEGETTE. Was this a study that you did?

Dr. HAMBURG. It was a systematic review. I mean, I fear I probably should not have even tried to give numbers——

Ms. DEGETTE. If you could supplement your testimony with that today, that would be great.

Dr. HAMBURG. OK.

Ms. DEGETTE. And I just have a couple more questions. One is, we have been talking about this terrible adulterated heparin so I guess my view would be, under this Drug Safety Enhancement Act which Mr. Dingell and some of us introduced yesterday, would that give the FDA new authorities to address issues like intentional economic adulteration like in the heparin situation?

Dr. HAMBURG. I think it could very well give us important authorities that would make a difference, additional authorities to really pursue investigations in places outside of our borders when there are public health concerns, our ability to share information with counterpart regulatory authorities so that we can get a richer understanding of potential or emerging threats. Those would certainly make a difference, and I think that enhanced civil and criminal penalties could reduce the attractiveness of pursuing some of these kinds of nefarious activities as well.

Ms. DEGETTE. Thank you, Mr. Chairman.

Dr. HAMBURG. Thank you.

Mr. STEARNS. Mr. Hamburg, I am just sort of curious about these 150 countries that export food and drugs to us. If you don't mind, if you could send us a list of those countries, that would be helpful.

Dr. HAMBURG. OK.

Mr. STEARNS. Going to your Web site, I noticed that just for this year alone it lists countries that there have been alerts on. For example, Bangladesh had 10 alerts, Cambodia had one. Indonesia, there are 27 alerts. The Ivory Coast, considering what is going on there, had three, Nicaragua had nine, Thailand had 47 and Zimbabwe had one. Do you have the authority to stop all imports when there is, shall we say, turmoil, war, a revolution, civil war that is going on over there? Do you stop imports from those countries considering the potential danger?

Dr. HAMBURG. Well, our import alerts are based on public health risks but certainly they are targeted to events in the world.

Mr. STEARNS. Do you have the authority to stop, for example, imports from Thailand where there is unrest and they had 47 alerts? Isn't that enough to say you are going to stop imports altogether?

Dr. HAMBURG. Well, I think an important and timely example is——

Mr. STEARNS. Do you have the authority to do that?

Dr. HAMBURG. We do an import alert based on——

Mr. STEARNS. Just yes or no.

Dr. HAMBURG [continuing]. A public health threat.

Mr. STEARNS. I would just like to know, yes or no, do you have the authority to stop—for example, the Ivory Coast had three alerts this year. Do you have the authority to stop all imports from Ivory Coast?

Dr. HAMBURG. No, we would have to be able to show that there was reason to believe that a product or set of products was violative.

Mr. STEARNS. But if you had three alerts in Ivory Coast and 27 in Indonesia, isn't that enough to suddenly stop imports—especially if there is a civil war?

Dr. HAMBURG. I know that for particular products where there are concerns——

Mr. STEARNS. So you don't have the authority? You have to identify the risk in detail before you do that. Otherwise you don't have the authority.

Dr. HAMBURG. Right. We don't do blanket restrictions based on circumstances within a country.

Mr. STEARNS. OK. Mr. Bilbray had talked a little bit about the budget, and I mentioned it earlier, that your budget went up by $107 million. Did you know that?

Dr. HAMBURG. We have, as I said, had, you know, very significant increases in our budget in the last couple of years. It has made a difference. I think it is important to recognize, though, that we have been underresourced for literally decades.

Mr. STEARNS. But you understand the budget has gone up for this fiscal year?

Dr. HAMBURG. I do, and I have been appreciative of that.

Mr. STEARNS. But as I understand it, when you were talking to Mr. Bilbray, you weren't sure by what percentage the budget had gone up and you weren't really clear what your budget number was. Is that correct, that you weren't quite clear on that?

Dr. HAMBURG. You know, this has been an unusual budget period. He was asking me what the budget increase was in the last, did he say 24 months?

Mr. STEARNS. Yes.

Dr. HAMBURG. But, you know, we certainly do have that information.

Mr. STEARNS. So you don't really know your budget numbers at this point. You don't know that they have gone up. Is that correct?

Dr. HAMBURG. Well, we are still looking forward to learning our budget numbers for this year.

Mr. STEARNS. OK. We have a chart here that has come from you folks, the Fiscal Year 2010 ORA Field workplan. I just want to

show you this, and staff has given it to you. If you go down to the fifth line, I know President Obama has talked about food safety being one of his top priorities, and he has indicated that it is very important for the Administration, yet when you look at imported foods in general on this line and the work plan for FTEs, which I understand to be full-time equivalents, which are not people but are just block-outs. It appears to me that in 2009 to 2010, 2009 was the Bush Administration and 2010 was the Obama Administration, it actually has gone down in terms of the work power that has actually been expended on imported foods. Is that correct? It is a little surprising considering the priorities which you have talked about, to think that the man-hours in this area have gone down, and I just want you to explain, why have they gone down?

Dr. HAMBURG. I am going to let my colleague, Mr. Elder, respond. This is a very specific question of a line. It is less than one full-time equivalent person.

Mr. STEARNS. But at the same time——

Dr. HAMBURG. But I will let him——

Mr. STEARNS. You know, the imports have increased—but the point is, with the increase of the imports, and the fact that your manpower has gone down on this is just a little puzzling.

Yes, Mr. Elder, you are welcome to take the mic. Is it turned on?

Mr. ELDER. I believe it is, Mr. Chairman. Thank you. The highlighted decrease involves one particular program within our overall foods program. It is what we call program assignment code 03819 A and B. It is import foods in general. It does reflect a 0.7 FTE decrease from the previous year. It is not the only program, however, in which we cover imported foods. You can see that imported seafood products were raised by 7 FTEs in the fiscal year. There was an overall increase of 61 FTEs——

Mr. STEARNS. But Mr. Elder, you would agree that that is the biggest program you have. When you look at all the other figures, it is multiples of all the other programs. So I think you are sort of discounting a program, which is the top program, and to see the top program actually in man-hours go down in terms of the FDA's work plan is quite startling.

Dr. HAMBURG. I think that Mr. Elder was indicating, though, that this is just one component of our overall import safety program for foods and that that program has actually expanded.

Mr. STEARNS. But wouldn't you agree, Dr. Hamburg, that all these things should have a positive, they should not have a negative?

Dr. HAMBURG. Well, I think we want to make sure that we are deploying our resources in the most responsible and efficient way possible. I don't——

Mr. STEARNS. But I would think imported foods is one of your highest priorities.

Dr. HAMBURG. But I think we also need to look at the overall program and how individuals are being deployed, and this does not mean that the overall food import program has decreased. In fact, it has increased in terms of——

Mr. STEARNS. Well, I would say that your workplan does not show an increase, rather, it shows a decrease.

My time is expired. The gentleman from Michigan is recognized for 5 minutes.

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

Mr. Hamburg, you have in response to a question from Ms. DeGette said that review times in United States and Europe vary and that FDA is faster in reviewing drugs. We have also been hearing that Europe is 2 years faster in clearing devices than our FDA. Is that statement true, and if so, why?

Dr. HAMBURG. You know, first of all, it is not a competition and we obviously have different regulatory frameworks, but when you look at the numbers in both drugs and devices, the lag times are not what have been put forward. In fact, in the drug area, as I said, in key areas we clearly have approved critical products more swiftly. The device system in Europe is quite different than that here but we are not——

Mr. DINGELL. It is a difference in what is done over there as opposed to——

Dr. HAMBURG. They have a very different approach to device review, and it is also——

Mr. DINGELL. Would you submit to us a statement as to why that is so, please, for the record?

Dr. HAMBURG. We would be happy to, the numbers that are available about comparative times.

Mr. DINGELL. Thank you, Doctor. I want to get now to some other things. I would like to come back to the new authorities given FDA in the Food Safety Modernization Act and how they are going to make the food supply and imported food safer. Is that statute working and do you have the authorities now you need? Do you need new authorities or do you need more money?

Dr. HAMBURG. We are obviously very early in the implementation of this historic piece of legislation, but we are making good progress. And we can see that it will very significantly strengthen our ability to protect the safety of the food supply to be able to really shift to a preventive approach and to work in greater partnership with our State and local partners, with foreign governments and with industry. Clearly, in terms of being able to implement all of the requirements, and there are many in that Food Safety Modernization Act, you know, we again face the resource limitation issue and we are hoping to be able to work Congress on——

Mr. DINGELL. Let me interrupt you. I remember, Doctor, that when one of your predecessors, Frank Young, for whom I had great respect and still do, used to call me up and say John, we are going to move this situation forward, we are doing a real fine job and we have a great new plan and we are going to do this without new money. And I said Frank, that is a lot of hooey. And a couple days later he would call me up and say well, John, we just can't do it because we don't have the money for this, and this brings us back to the question of registration fees.

The House bill as it came out of this committee had registration fees in it with the support of the industry, which still supports that idea. It was taken out in the Senate. So user fees in that regard both with regard to food and with regard to pharmaceuticals would ease your financial stresses and strains, would it not?

Dr. HAMBURG. We clearly cannot fully implement this bill without additional resources.

Mr. DINGELL. The other thing I remember that is very troublesome to me is, we had a movie before this subcommittee one time when I was the chairman and it showed a bunch of stuff coming into this country, mostly pharmaceuticals and things of that kind, and most of these pharmaceuticals were unsafe, misbranded, counterfeit, and some of them, believe it or not, were controlled substances, and they were just coming in through the mails. Everybody was sort of waving them as they went by. And I see you confronting the same problem, and I would be willing to bet if somebody were to put movies down there at some of the points where these things are imported, we would find the same situation is going on. Now, this situation happened to relate to the center at Miami where they would come in, and so I think that something here has to be done.

Mr. Chairman, I just want you to know that I appreciate your holding this hearing. It my hope that we can work in a bipartisan fashion with us all working together as we have done in the past. It makes great good sense. It is something that the public needs. Americans are being killed either by bad stuff coming into this country that poisons them or makes them sick or they are being killed by being denied workable and worthwhile treatments and pharmaceuticals because people are sending in things like chalk and sugar as part of the medicines that we are receiving.

So I want to commend you and thank you for the hearing and hope that as we go forward that we will be able to use this hearing as the beginning of an honest effort to work together to do something that we can do by working together, and I think it is a lot better than quibbling about whether we have got Democratic or Republican witnesses because that is not really important. I will be happy to take credit for the presence of Dr. Hamburg, and I am sure you would too, and not to quibble about whether she is a Republican or a Democratic witness.

So I commend you, Mr. Chairman, for your leadership in this matter and I thank you for your recognizing me, and I again appreciate the opportunity to start moving on something that is in the public interest.

Mr. STEARNS. I thank the distinguished chairman emeritus of the Energy and Commerce Committee and I appreciate his past leadership and his spirit of bipartisanship, that he continues to reach out. I think it is a good example for all of us to remember in this process.

Mr. Hamburg, I want to thank you very much for your forbearance and patience for this hearing.

All members have 10 days in which to submit any extraneous material they would like to, and with that, the subcommittee is adjourned.

[Whereupon, at 12:26 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Few subjects have a more direct impact on public health and the safety of the American people than our topic today, and I applaud the Chairman for convening this hearing.

The Food and Drug Administration has the daunting task of screening the millions of shipments, packages, and parcels that traverse our borders by air, ship, truck, and by land—responsible for preventing the entry of food, pharmaceuticals, and other medical products that violate our laws or pose a threat to the public health. This effort has not been made any easier by the growing number of imports we are seeing every year, as well as the increasing globalization of the supply chain.

For this reason, FDA must use its resources intelligently, and in a manner geared to most effectively target higher-risk shipments for further inspections while expediting the passage of low-risk products. Today, FDA has the tools and technologies to enhance its risk-based review of imported food and medicines without obstructing the free flow of commerce into our country.

However, I am concerned FDA may not presently be bringing all of its resources to bear in fulfilling its crucial gate-keeping responsibilities. I believe the Commissioner is serious about attaining her vision of an FDA that better assures the safety and quality of imported goods. I agree with the Commissioner that it is simply not possible, regardless of the amount of resources devoted, to inspect our way to safety. Therefore, I believe that FDA should get to work immediately on deploying all of the high-tech, intelligent, risk-based tools at its disposal. The American people deserve nothing less.

The difficult fight against counterfeit drugs

Dr. Sanjay Gupta investigates fake medications on his first assignment for "60 Minutes"

60 Minutes' nine-month investigation of counterfeit prescription drugs reveals how the dangerous and sometimes deadly fakes get into the nation's drug pipeline. Dr. Sanjay Gupta reports.

(CBS News)

There is a new front in the war on drugs, and it's not the kind of drugs you might think. We're not talking about cocaine, heroin or methamphetamines. This is about drugs that could wind up in your medicine cabinet: counterfeit prescription drugs, made with cheaper - sometimes even dangerous - ingredients such as highway paint, floor wax, and boric acid.

Criminal counterfeiters will go to any length to evade detection. We found a shadowy network of criminals with made-up names, constantly changing locations and lots and lots of money: an estimated $75 billion a year.

"60 Minutes" and CNN's Dr. Sanjay Gupta got the chance to observe a surprise early morning raid in Lima, Peru. Some 200 police in riot gear stormed an indoor market. Their target: counterfeit prescription drugs. And they found them everywhere.

There were crude packaging machines and silk screens with imprints of actual name-brand drugs. Hundreds of thousands of counterfeit medicines collected from that raid were traced back to a house. Through a back door and down a narrow hallway we found a tiny, squalid patio that was actually a fake drug factory, turning out an astonishing number of counterfeit medications.

Peruvian police were led here by someone you wouldn't expect: John Clark, from the American drug company Pfizer.

"I'm looking at this pan with these pills in it. This stuff is going to get into people's medicine cabinets around the world?" Dr. Gupta asked.

"Unfortunately, yes," Clark said.

Clark heads up a global security team assembled by Pfizer. The team includes former FBI, Homeland Security and narcotics agents who work with local police to track down criminals around the world. Counterfeit operations like these are costing drug companies millions of dollars a year.

"This has 'Pfizer' written all over it," Gupta remarked, looking at some of the counterfeit drugs.

"And it's even got the newer Pfizer emblem with the little slant on it and stuff. I mean from the packaging, you'd never know," Clark said.

In the raid, they discovered about two dozen medicines including antibiotics, seizure, blood pressure and pain medications.

"We're in the middle of this very primitive courtyard. This doesn't look like any kind of facility that you'd expect at all. Does this surprise you?" Gupta asked.

"No. No, unfortunately. The quantity of counterfeits you're seeing is phenomenal. The conditions are just abysmal. And if the consumer ever realized that products that they're putting inside their bodies come from this, from dirty water, drying out in the open under a heat lamp, insects and everything else getting into it, contaminants being, you know, brought into the equation and stuff, I think they'd be horrified," Clark said.

According to Clark, counterfeit Pfizer drugs - many from disgusting conditions like the primitive courtyard in Lima - have made their way to pharmacies and hospitals in at least 46 different countries, including England, Canada, and the United States.

"So right now, there are people around the world taking medications to save their own lives who are simply taking the wrong thing, and they don't even know it?" Gupta asked.

"Yes, absolutely," Clark said. "If you have any concerns, you should go to your doctor, should go to your pharmacist. If the pill dissolves differently, if it tastes bitter or differently."

"John, you know, I'm a doctor. I looked at these medicines today. I wouldn't be able to tell if they were fake or not. And that I'm the person they're gonna ask," Gupta remarked. "I don't know the answer. How are other people gonna know the answer?"

"Next step is every pharmaceutical company will take it back, do the test and then find out if it's counterfeit, how it got there and then try to get it off the market immediately," Clark explained.

The pills from Peru were sent to Pfizer's testing facility in Groton, Conn. Sometimes counterfeits may have a percentage of the correct active ingredients, but not when it came to a seized antibiotic or an ulcer medicine.

Instead the ulcer medicine contained sugar and chalk. Imagine taking a medication to treat a serious illness with those ingredients.

"People can die. People can be seriously injured, but people can also die," Kumar Kibble, deputy director at Immigrations and Customs Enforcement (ICE), told Gupta.

Kibble is charged with protecting our borders from illicit trafficking. Over the past few years, his attention has increasingly focused on counterfeit drugs.

"In the scheme of things, how big a threat are fake drugs?" Gupta asked.

"Fake drugs are a big threat. And it is an exploding threat you actually have traditional criminal groups that may have engaged in traditional drug trafficking. And they realize, you know, 'I can make just as much money, making, you know, tens of dollars on a pill that I manufacture for pennies,' and have very little exposure in terms of in terms of prosecution," Kibble explained.

"So, you're talking about a very low risk, very high reward, potentially tons of money," Gupta remarked.

"Yeah. Absolutely," Kibble said. "When you think about that some of these pills can be manufactured you know, for 40 cents and sold for $18 or $20, I mean, just think of that profit potential. I mean, it's insane."

Kibble tracks counterfeits from their source in clandestine labs to the United States, where they're typically sold through rogue Internet sites, often posing as legitimate pharmacies.

Thirty six million Americans are estimated to have bought their medicines from these sites, many searching for quality drugs at a better price. Some sites pretend to be from Canada because Canada is known for safe, inexpensive medicines.

Kibble caught one Israeli counterfeiter on a hidden camera admitting that very scheme.

"These are all your Internet Web sites. Is that really from Canada?" an undercover agent asked.

"Noooo!" the counterfeiter replied, laughing.

That same counterfeiter also told undercover investigators of another, decidedly low-tech, way of smuggling hundreds of thousands of pills into the United States: he simply had them dropped in the mail.

At the postal service facility at New York's JFK Airport, the sheer volume of packages of counterfeit and suspicious drugs coming into the country is staggering.

"Our resources certainly haven't kept pace with the volume of products coming into the country or the increase in volume," David Elder of the Food and Drug Administration told Gupta.

Elder told us that when they do find a fake drug, they're often forced to ship it back to the sender. On the day "60 Minutes" was there, they found pills and vials from India posing as legitimate thyroid, fertility and hypertension medication. They had to send it all back.

"That sounds crazy. Why not go after this person?" Gupta asked.

"We don't have the authority to actually destroy this on site. This product could very well come back into the country through a different mail facility. Maybe it gets through. Maybe it gets stopped," Elder said.

"But they're banking on one of these times you're gonna miss," Gupta pointed out.

"Yeah, I think they are," Elder acknowledged.

And many of these fakes are so sophisticated, even investigators at an FDA lab in Cincinnati couldn't distinguish which bottle of Zyprexa was fake with the naked eye. Using a forensic light source, they can test the ink - the label that lights up is the real one.

A fake Lipitor pill looked so authentic they had to superimpose a diagram of an actual pill to see that the number "20" on the pill did not match up.

"With the naked eye, you could not see this," a lab technician pointed out.

Balbir Bhogal was recently arrested in Madison, Wis. for allegedly trafficking counterfeit drugs.

"As they say in India, you can manufacture anything. There's no limit," he told Gupta.

Bhogal is also accused of providing millions of anti-anxiety pills from India to a Web site operator for a site with a common, seemingly harmless name.

"He was running a Internet pharmacy, which is actually, I discovered recently that its Web site, 'Easy Meds for You,'" Bhogal said. "He had lots and lots of suppliers."

Bhogal told Gupta he never met the site's operator and that it's a totally virtual operation. "Never met him and I didn't even know believe his name was real or not," he said.

Bhogal maintains his innocence and claims he was only supplying anti-anxiety medicines with the proper formulation and thought it was for the Asian market. The government says he knew the pills were illegally coming into the United States.

"Were you worried at all about these medications? Where they were gonna end up?" Gupta asked.

"Never looked at that issue at all," he replied.

Asked if he wish he had, Bhogal said, "Yes."

What is even more alarming is these counterfeit medications are not just being sold on the Internet. They are also making their way into mainstream pharmacies and hospitals. FDA Commissioner Margaret Hamburg says that while the vast majority of our drug supply is safe, there's reason for concern.

"You know, we don't really know the full dimensions of the problem. But, we do know that in certain countries somewhere between 30 and 50 percent of really important drugs for health are, in fact, counterfeit," Commissioner Hamburg said.

"How does all this increase in counterfeit drugs around the world affect the United States?" Gupta asked.

"Just consider that 40 percent of drugs taken in this country come from other countries; 80 percent of the active pharmaceutical ingredients in drugs taken in this country actually come from other countries," Hamburg said.

Even if the prescription medications are manufactured in the United States, the raw ingredients often come from overseas, through a complicated web of suppliers and distributors - and are increasingly vulnerable to counterfeiting.

That is what happened in 2008 with the blood thinner heparin, which millions of Americans rely on to prevent blood clots. Little did the manufacturer, Baxter International, know that one of the raw ingredients from China was counterfeit.

"How many people were affected by this?" Gupta asked Hamburg.

"In this country a little over 80 people actually died from contaminated heparin,"

Baxter says the number of deaths is closer to four or five, but everyone agrees it's difficult to know the exact number.

Nurse Colleen Hubley says at her dialysis center in Toledo, Ohio, she saw one patient have cardiac arrest and others with strange symptoms after receiving heparin.

"Having hypotension, diarrhea, vomiting, not feeling well, getting off treatment early. I even had another patient that stated to me, you know, 'What is going on around here?'" Hubley said.

"Had you ever seen anything like this?" Gupta asked.

"No," she replied.

And then she says she saw the same symptoms in her own family: within a few weeks, she says her husband Randy and her mother-in-law, both regular users of heparin due to chronic kidney disease, had bad reactions to the drug and died within a few days.

Baxter, which is being sued by Coleen Hubley and others, disputes that and says the serious underlying medical conditions of her family and patient "much more likely caused their deaths."

"You lost one of your patients, your mother-in-law and your husband, Randy, within a month or so," Gupta remarked.

"Gone," Hubley said.

Hubley says she never imagined heparin could be counterfeit.

"You really counted on that heparin being perfectly fine," Gupta remarked.

"Yes. We did. And I don't know if, in my nursing career, I'll ever take anything for granted again," Hubley said.

Baxter's CEO told Congress that he deeply regretted what had happened. The company told "60 Minutes" in a letter that the counterfeit ingredient so closely mimicked heparin that "it was able to evade the quality control systems and regulatory oversight of more than a dozen companies and nearly a dozen countries."

Three years later, FDA Commissioner Hamburg told us they're still struggling to get to the bottom of it.

"Do you know who perpetrated this crime, with the heparin contamination, or exactly how they did it?" Gupta asked.

"We do not know the answer to that question," she replied.

Despite what happened with heparin, most of the ingredients in our medicines today still come from other countries, including China and India, which have notoriously weak regulatory systems. The FDA only inspects about 12 percent of overseas facilities a year.

"Everyone's concerned, it's hard to regulate. It's potentially problematic. Even deadly. Why does it continue to happen?" Gupta asked.

"I think that we live in a globalized world. And components of all kinds of products are gonna come from all over the world," Hamburg said.

"It's cheaper over there. It's economics," Gupta remarked.

"It is economics, for the companies. I do believe that we can do an enormous amount to strengthen the safety of the supply chain," Hamburg said.

Drug companies say they already have their own systems in place to protect their supply chains. But they also have to worry about those clandestine labs, like the one we saw in Peru, which are popping up all around the world, according to Pfizer's John Clark.

"If there are no consequences for those doing this, then there's no disincentive not to just go back and do it again once you're caught. I mean the profit on illegal medicines is just phenomenal," he explained.

And catching them isn't easy: at the lab in Peru, police arrested a messenger, but the kingpin of the counterfeit drug operation had slipped away.

"What do you think, John, they gonna find this guy?" Gupta asked.

"They'll be lucky if they do," Clark replied.

September 29, 2010
Discussion Draft of Drug Safety Legislation
SECTION-BY-SECTION SUMMARY
Committee on Energy and Commerce

Section 1. Short Title
The short title has not yet been designated.

Section 2. Table of Contents
Section 2 provides the table of contents.

TITLE I – PREVENTION

Section 101. Registration of Producers of Drugs; Applicable Fee.

Section 101 requires excipient manufacturers to register with the Food and Drug Administration (FDA). (Excipients are substances used to dilute or carry the active pharmaceutical ingredient in a drug or to give suitable consistency or form to the drug.)

Section 101 amends section 510 of the Federal Food, Drug, and Cosmetic Act (FFDCA) with respect to a variety of registration elements. It requires drug producers to provide FDA with a qualitative and quantitative listing of each of the ingredients of a listed drug and enables FDA to change the frequency with which such information must be provided. It authorizes FDA to suspend the registration of a drug establishment for a violation of the FFDCA or for the knowing or repeated making of an inaccurate or incomplete statement or submission of information. FDA can also cancel a registration if it is not updated as required, if it contains false, incomplete, or inaccurate information, or if the registration fee is not paid within 30 days of its due date.

Section 101 requires FDA to assess and collect an annual registration fee through fiscal year 2015 to defray the costs of drug safety activities. The discussion draft leaves blank the amount of such fee.

Section 102. Drug Supply Quality and Safety.

Section 102 requires drug manufacturers to implement an effective quality system that ensures compliance with good manufacturing practices. Such system must ensure that all operations relating to manufacturing drugs, including those manufactured by others, are appropriately designed, approved, conducted, monitored, and corrected. The quality system also must include risk management procedures that ensure effective risk assessment, control, and communication.

The risk assessment procedures must address all relevant factors throughout the supply chain, including, original source materials and their origin, on-site audits, current good manufacturing practice requirements, and methods to detect or exclude potentially risky substances. In addition, manufacturers must maintain records of these procedures for at least two years and permit FDA to inspect them at any time.

Beginning two years after enactment of this Act, manufacturers must maintain, and provide in electronic form to FDA upon request, adequate information establishing where a drug and its raw materials were produced, including all information on preceding producers, manufacturers, distributors, and shippers. The information also must establish that the drug was manufactured and distributed under conditions ensuring its identity, strength, quality, and purity.

Section 103. Inspection of Producers of Drugs.
Section 103 amends section 510 of the FFDCA to require the Secretary of the Department of Health and Human Services (HHS) to inspect every establishment (domestic and foreign) engaged in the manufacture, propagation, compounding, or processing of a finished dosage form drug or of an active pharmaceutical ingredient at least once every two years subsequent to registration. The Secretary may reduce this inspection schedule to once every four years, if FDA determines, in light of the risks presented by a particular establishment, that such a reduced schedule is appropriate (based on factors the Secretary establishes through guidance). The Secretary must conduct an inspection of a facility before the drug is introduced into interstate commerce if the active ingredient is new to the drug or if the drug has undergone a major change requiring prior approval, unless the Secretary determines such inspection is not necessary based on the inspection history of the establishment.

Section 103 also amends section 510 of the FFDCA to clarify that the Secretary may inspect every establishment engaged in the manufacture, propagation, compounding, or processing of an excipient of a drug to the same extent as it can inspect establishments engaged in such processes regarding any other drug.

Section 103 requires the Secretary to submit an annual report to Congress on the funding dedicated to inspections, and on the number of establishments for which the Secretary modified the inspection schedule based on risk.

Section 103 requires the Secretary to establish information systems that can assist the Secretary in assessing risk and for conducting surveillance. The Secretary must begin the implementation of this system within 3 years of the enactment of this Act, and that same year, GAO must submit a report to Congress on the Secretary's risk-based process.

Section 104. Prohibition Against Delaying, Limiting, or Refusing Inspection.
Section 104 amends section 501 of the FFDCA to prohibit facilities from delaying, limiting, or refusing entry for inspection by an officer or employee of the Secretary.

Section 105. Clarification of Inspection Authority Related to BIMO and IRB Inspections.
Section 105 amends section 704 of the FFDCA to clarify that certain officers or employees designated by the Secretary are authorized to enter and inspect the premises of a clinical investigator, sponsor, monitor, contract research organization, site management organization, institutional review board, or other person that oversees, initiates, or conducts a clinical investigation subject to section 505(i) of the FFDCA, or a postmarket study or clinical trial subject to section 505(k) or 505(o) of the FFDCA, and any establishment associated with such clinical investigation, postmarket study, or clinical trial.

Section 106. Notification, Nondistribution, and Recall of Adulterated or Misbranded Drug Products.
Section 106 requires persons that are required to register with the Secretary to notify the Secretary as soon as practicable of the identity and location of a drug that has entered interstate commerce that the person

has reason to believe is adulterated or misbranded and may result in illness or injury to humans or animals.

Section 106 permits the Secretary to request any person who distributes a drug that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of the FFDCA to voluntarily recall such article.

Section 106 permits the Secretary to issue an order requiring any person who distributes a drug to immediately cease distribution of such drug if the Secretary has reason to believe that the use or consumption of, or exposure to, the drug may result in illness or injury to humans or animals. The person subject to the order must immediately cease distribution and provide notification as provided by the order, and may appeal the order within 24 hours of its issuance and request an informal hearing. If after providing an opportunity for an informal hearing, the Secretary determines that the order should be amended to include a recall of the drug, the Secretary must amend the order to require a recall.

If the Secretary has credible evidence or information that a drug subject to a cease distribution order presents an imminent threat of serious adverse health consequences or death to humans or animals, the Secretary may issue an emergency recall order requiring any person who distributes such drug to immediately recall such drug. An informal hearing must be granted following the issuance of such a recall.

Section 107. Notification.
Section 107 authorizes the Secretary to require that regulated persons notify the Secretary of any of the following circumstances regarding a drug:

- The use of a drug or exposure to it may result in illness or injury to humans or animals;
- A significant loss or known theft of the drug;
- A reasonable probability that a drug has been or is being counterfeited;
- A manufacturer of a component or other material used in the manufacture of a drug repeatedly failed to ensure compliance with applicable quality systems requirements;
- Any incident causing a drug to be mistaken for, or its labeling applied to, another drug;
- Any contamination or significant change or deterioration in the drug after distribution, or any failure of a distributed lot to meet an established specification; or
- Any other type of information the Secretary deems necessary to protect public health.

Section 107 defines a "regulated person" to be one who is required to register under section 510, 801(r), or 801(s) of the FFDCA, a wholesale distributor of a drug product, or any other person that distributes drugs except for retail sale.

Section 107 also authorizes the Secretary to share certain confidential information relating to a drug with any federal agency, state, local, or foreign government, but specifies that such information may not be publicly disclosed. The Secretary may, however, disclose certain confidential information to the public if the Secretary determines that such disclosure is necessary to protect the public health.

TITLE II – RESPONSE

Section 201. Administrative Detention.
Section 201 amends section 304 of the FFDCA to allow FDA officers or employees to order the detention of any drug if they have reason to believe it is in violation of any provision of this Act. Such detention

may be up to 20 days, or up to 60 days if the Secretary determines the longer period is required to institute an action. The Secretary must afford an opportunity for an informal hearing and must confirm or revoke the detention within 15 days of such hearing.

Section 202. Destruction of Adulterated, Misbranded, or Counterfeit Drugs Offered for Import.
Section 202 amends section 801 of the FFDCA to authorize the Secretary of the Treasury to destroy, upon referral by the HHS Secretary, any drug that the HHS Secretary determines to pose a reasonable probability of causing significant adverse health effect or that is valued by the Treasury Secretary at $2,000 or less. The HHS Secretary must provide for notice and an opportunity for an informal hearing with respect to such destruction. Such notice and opportunity for an informal hearing may occur after the destruction of the above-described drugs. However, for a drug that does not pose a reasonable probability of causing an adverse health effect and that is valued at more than $2,000, the notice and opportunity for hearing must occur before the destruction of the drug.

Section 203. Criminal Penalties.
Section 134 amends section 303 of the FFDCA to require any person who knowingly violates section 301 of the FFDCA with respect to a drug to be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.

Section 204. Civil Penalties.
Section 204 amends section 303 of the FFDCA to require that any person who violates a requirement of this Act that relates to drugs to be subject to a civil penalty of not more than $500,000 for each such violation, and $10 million for all such violations adjudicated in a single proceeding. Each such violation and each day during which such violation occurs is considered to be a separate offense.

Section 205. Seizure.
Section 205 amends section 304 of the FFDCA to stipulate that with respect to seizure proceedings relating to drugs, such proceedings must conform to procedures in admiralty rather than procedures for civil asset forfeiture.

Section 205 also specifies the conditions under which proceedings pending in two or more jurisdictions may be consolidated.

Section 206. Asset Forfeiture.
Section 206 amends section 303 of the FFDCA to provide for criminal and civil forfeiture of any property, real or personal, constituting or relating to the gross proceeds obtained directly or indirectly as a result of a violation, or a conspiracy to commit a violation, of section 301 of the FFDCA relating to drugs.

TITLE III – IMPORTATION AND EXPORTATION

Section 301. Documentation for Admissibility of Imports.
Section 301 authorizes the Secretary to require, as a condition of admissibility, the submission of documentation or other information for a drug that is imported or offered for import into the United States.

Section 302. Registration for Commercial Importers; Fee.
Section 302 requires all importers of drugs to register with the FDA, to pay an annual registration fee in the amount of $500, and to submit appropriate unique identifiers. (An importer that is also a registered

facility under section 101 of the Act is subject to only one such fee.) Each registered importer must comply with good importer practices, which the Secretary must establish through regulation. The Secretary may suspend an importer's registration, after notice and opportunity for an informal hearing, if the importer is found in violation of the FFDCA, or is found to have knowingly or repeatedly made inaccurate or incomplete statements or submissions of information related to the importation of drugs. The Secretary may cancel an importer's registration if, after notice, the Secretary determines that the registration was not updated correctly or otherwise contains false, incomplete, or inaccurate information. If the importer's registration is updated or corrected no later than 7 days after notice is provided, the Secretary may not cancel the importer's registration.

Section 303. Registration for Customs Brokers.
Section 303 requires all customs brokers with respect to the importation of drugs to register with the FDA in a form and manner specified by the Secretary and to submit appropriate unique identifiers as a condition of registration. The Secretary may cancel a broker's registration if, after notice, the Secretary determines that the registration was not updated correctly or otherwise contains false, incomplete, or inaccurate information. If the registration is updated or corrected no later than 7 days after notice is provided, the Secretary may not cancel the registration. Section 303 also requires customs brokers, upon request, to permit FDA to inspect their facilities.

Section 304. Exportation Certificate Program.
Section 304 authorizes the Secretary to impose a fee for the issuance of export certificates for a drug. Such fee may not exceed such amount as the Secretary determines is reasonably related to the cost of issuing certificates with respect to the export of a drug.

Section 305. Extraterritorial Jurisdiction.
Section 305 establishes extraterritorial federal jurisdiction over any violation of this Act relating to any drug intended for import into the United States or any act in furtherance of the violation that has been committed in the United States.

Section 306. Dedicated Foreign Inspectorate.
Section 306 requires the Secretary to establish and maintain inspectors dedicated to inspections of foreign drug facilities and establishments.

TITLE IV – MISCELLANEOUS

Section 401. Unique Identification Number for Establishments, Importers, and Customs Brokers.
Section 401 requires that a person required to register as a drug establishment pursuant to section 510 of the FFDCA, and importers and custom brokers required to register pursuant to section 801 of the FFDCA submit, at the time of registration, a unique identifier for the drug establishment or the principal place of business of the importer or custom broker. The Secretary is authorized to specify (through guidance) the unique numerical identifier system to be used. In developing such guidance, with respect to importers and customs brokers, the Secretary is required to consult with the Commissioner responsible for Customs and Border Protection and take into account the utilization of existing unique identification schemes and compatibility with customs automated systems. The Secretary is required to refuse admission of an imported drug into the United States for interstate commerce unless the appropriate unique identifiers are provided for such drug.

Section 402. Country of Origin Labeling.
Section 402 amends section 502 of the FFDCA to require that the website of the manufacturer of a finished dosage form drug to list both the country of origin for each active pharmaceutical ingredient in the drug and the place of manufacture of its finished dosage form.

Section 403. False or Misleading Reporting to FDA.
Section 403 amends Section 301 of the FFDCA to establish as a prohibited act, the submission of any report relating to a drug that is required by or under this Act that is false or misleading in any material respect.

Section 404. Subpoena Authority.
Section 404 grants the FDA Commissioner the power to issue subpoenas for the purpose of any hearing, investigation, or other proceeding respecting a violation of the FFDCA, the Federal Anti-Tampering Act, and the Public Health Service Act relating to a drug; or to determine if a person is in violation of a specific provision of the FFDCA, the Public Health Service Act, or the Federal Anti-Tampering Act relating to a drug. A subpoena may only be issued by a district director or an individual senior to the district director.

Section 405. Whistleblower Protections.
Section 405 grants protections for employees who refuse to violate this Act, or who disclose violations of this Act, or of the Public Health Service Act. No person who submits any information related to a drug, or any officer, employee, contractor, subcontractor, or agent may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in retaliation for assisting in any investigation regarding any conduct which the employee reasonably believes constitutes a violation of this Act that is related to a drug, or any other section of Federal law relating to the safety of a drug. Section 405 ensures an employee is entitled to all relief necessary against any retaliation by an employer.

Section 406. Rule of Construction.
Nothing in this Act or any amendment made by this Act shall be construed as affecting any authority or requirement relating to devices (as defined in section 201 of the FFDCA).

JOHN D. DINGELL
16TH DISTRICT, MICHIGAN
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COMMITTEE ON
ENERGY AND COMMERCE
CO-CHAIR
HOUSE GREAT LAKES
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April 15, 2011

The Honorable Margaret A. Hamburg, M.D.
Commissioner
The Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Commissioner Hamburg,

I write to you with additional questions following your appearance before the House Energy and Commerce Subcommittee on Oversight and Investigations hearing entitled, "Import Safety: Status of FDA's Screening efforts at the Border."

Specifically, I request further information related to the implementation, funding and personnel needs of the Food and Drug Administration (FDA) for drug safety related activities. Therefore I would respectfully request answers to the following questions:

1. How many full-time equivalent (FTE) personnel are currently dedicated to working on drug safety activities[1]?
2. What are the costs incurred by the FDA currently for drug safety activities?
3. How many FTE personnel will be needed if new authorities, such as those laid out in H.R. 1483, the Drug Safety Enhancement Act, are enacted?
4. How much funding would be needed to implement the new authorities laid out in H.R. 1483?

Thank you in advance for your assistance. I would respectfully request that you please email a response to Kimberlee Trzeciak of my Washington, DC office at kimberlee.trzeciak@mail.house.gov no later than May 6, 2011. Should you or your staff have any questions, please do not hesitate to contact me or Kimberlee Trzeciak at (202) 225-4071.

With every good wish,

Sincerely,

John D. Dingell
Member of Congress

[1] For the purposes of this letter, the term 'drug safety activities' is defined as activities relating to drugs (including research related to and the development of standards (such as performance standards and preventive controls), risk assessments, hazard analyses, inspection planning and inspections, third-party inspections, compliance review and enforcement, import review, information technology support, test development, product sampling, risk communication, and administrative detention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

The Honorable Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUN 21 2011

Dear Mr. Chairman:

Thank you for providing the opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the April 13, 2011, hearing entitled "Import Safety: Status of FDA's Screening Efforts at the Border," before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce. This letter provides responses for the record to questions posed by certain Members of the Subcommittee at the April 13, 2011 hearing as well as in your letter dated April 28, 2011. Please accept FDA's response to Congressman Bilbray's first question on European versus U.S. approvals as the Agency's response to similar questions asked by Ranking Member DeGette and Congressman Dingell during the hearing. This is a partial response. Responses to additional questions for the record from Congressman Dingell will be forthcoming. We have restated each question below in bold, followed by FDA's responses.

Thank you again for your interest in import safety. If you have further questions, please let us know.

Sincerely,

Jeanne Ireland

Jeanne Ireland
Assistant Commissioner
for Legislation

Enclosures

cc: The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Chairman Cliff Stearns

1. **Please provide a list of the 150 countries from which we import food.**

   See attached.

2. **Please describe your efforts to work with Chinese officials to educate them on the importance of quality systems and other drug regulatory controls.**

   Staff from the FDA's Center for Drug Evaluation and Research (CDER) and Office of International Programs (OIP), (including OIP staff posted in China), have provided training for key staff from China's State Food and Drug Administration (SFDA) in a number of strategic areas. The training covers standards for FDA inspections; good clinical practices (GCP), which aims to equip key Chinese staff to train other Chinese inspectors on GCPs; and current Good Manufacturing Practices (cGMP) for drugs. In addition to SFDA staff, these events have also included provincial and municipal officials, who have a primary role in monitoring and enforcing Chinese standards for drug safety.

   In addition to these targeted efforts, a number of which are ongoing, FDA meets regularly with SFDA and with officials in key provinces to communicate FDA requirements for drug safety. FDA staff posted in China have also facilitated the training of SFDA staff in the United States on key issues related to drug review, inspections, and pharmacovigilance.

3. **Have Chinese officials expressed an appreciation for the need to raise their country's drug regulatory standards?**

   China's SFDA, provincial, and municipal officials regularly express to FDA their shared desire to continue to enhance the safety of drug products exported from China, and regularly seek out new opportunities for training and collaboration with FDA to strengthen their regulatory capacity. In March 2011, China published new standards for drug GMPs, which aim to significantly raise safety standards for Chinese drugs. SFDA will oversee a phased implementation process for these new standards over the next four years.

4. **What other measures or steps can we take to help ensure that our international regulatory partners recognize and appreciate the importance of and need for strong regulatory controls in all areas, including drug manufacturing and oversight?**

   FDA is a founding member of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), which provides extensive and rigorous guidelines for regulatory authorities for the pharmaceutical industries of Europe, Japan, and the United States. These guidelines frame and facilitate discussion of scientific and technical aspects of

drug regulations, including drug manufacturing and oversight. FDA has strongly encouraged the inclusion of additional countries in the ICH process to promote use of these guidelines among more international partners.

FDA has also authored additional guidance documents that provide further recommendations to international drug regulatory authorities to enhance regulatory controls. These documents, along with other materials such as policy manuals and field guides, address numerous aspects of FDA's International Program initiatives, including multilateral arrangements and capacity building, as well as applicable laws and regulations governing imports and exports, overseas inspection policies, and fraud deterrence.[1]

5. **Given resource constraints and increased demands on the Agency, the use of risk to prioritize FDA resources seems like a logical solution to help increase inspections while ensuring they are targeted at the sites that present the highest risk. A risk-based approach has been used in a number of contexts and could help FDA efficiently target its inspection resources to those areas that present the most significant risks. Do you agree that the use of risk-based criteria can be helpful to focus and prioritize FDA inspection resources?**

FDA agrees that the use of risk-based criteria can be helpful to focus and prioritize inspection resources and has implemented a number of steps and initiatives that will enable the Agency to take a more risk-based and better-targeted approach to ensuring drug quality and to detect and prevent drugs from entering the United States. For example, annual-inspection work planning in several drug inspection programs had major emphasis on using risk-based criteria to prioritize domestic and foreign sites for inspections. Five risk-focused drug programs are either in development, being piloted, or phases of the risk-management cycle are being updated.

FDA's use of risk-focused prioritization helps to identify key data and information gaps that contribute uncertainty to risk assessments. For example, incomplete information about drug manufacturers, particularly in foreign countries, creates uncertainties in risk-focused prioritization of inspections. With the implementation of FDA's electronic drug registration and listing system (eDRLS), it is mandatory for all drug establishments shipping drugs to the United States to register with FDA electronically. The implementation of eDRLS significantly reduces lag times between receipt of registration and listing data and its electronic availability at import review operations. FDA's import entry reviewers have near real-time access to registration information, enabling more complete and timely identification of unregistered foreign firms and unlisted drugs, when offered for importation at ports and borders.

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[1] For more information, see *http://www.fda.gov/InternationalPrograms/default.htm.*

The new registration system also requires that importing firms submit more comprehensive information. As FDA fully implements the electronic registration system, reviewers will be able to quickly and easily validate information required as part of importation. As indicated at the April 13 hearing, FDA is currently testing registration- and listing-derived "risk rules" using the import operations PREDICT system. PREDICT implements expert- and data-driven analyses to focus import review resources on riskier products and manufacturers.

6. **Can you briefly describe the current recall authority the agency has for drugs? How many times has FDA requested that a drug recall be conducted and the manufacturer refused?**

FDA does not have mandatory recall authority for drugs. That means that typically, when a drug product violates federal standards for safety, effectiveness, or quality, FDA must persuade the firm to do a voluntary recall of the product. This often results in significant delays in removing potentially harmful products from the U.S. market. However if the distribution of a drug poses an imminent hazard, FDA can strongly recommend recall or take enforcement action such as seizure to have the drug removed from the market.

Firm responsiveness to a suggested recall is highly variable, often resulting in extensive delays that increase consumer and patient exposure to unsafe products. Such delays occur even in instances where the safety risk to consumers is clear and well-known, as is often the case with dietary supplements that contain undeclared prescription-strength drugs. In the event that a company initiates a recall of a drug, it is not obligated to notify FDA of the recall. FDA does not routinely track drug firm refusals to recall violative products, but it happens far too frequently. In many refusal instances, FDA has had to issue its own advisory press release, or letters to health care professionals in lieu of a recall to alert the public that there is a potentially harmful product on the market. If a company does not agree to a recall, FDA must conduct an inspection to document its findings and then issue a Warning Letter based on whatever evidence is developed from the inspection. Although FDA can establish an evidentiary case to seize the product, that action does not protect the public if the product has already been distributed through commercial channels. Even though seizure authority allows the Agency to keep products from leaving the factory, it does nothing to get already distributed products off store shelves. With recall authority, FDA could better protect the U.S. public and more efficiently utilize available resources. Congress has already given FDA similar authority for devices, biologics, and foods, and other products the Agency regulates.

7. **In a global market, FDA-regulated companies must comply with many different standards and rules. How does FDA take into account other international standards and harmonization when it creates new regulations and guidance?**

As indicated above, FDA is a founding member of the ICH. Created in 1990, ICH has generated over 60 guidelines in the area of safety, efficacy and quality that serve as the basis of a regulatory submission. Benefits of the use of these guidelines include international harmonization, which reduces time and money spent and increases international cooperation, open participation, and access to current leading thoughts on a given issue.

FDA is a strong proponent of participation in the development and use of voluntary consensus standards. The central purpose of FDA's involvement in standards is to assist the Agency in fulfilling its regulatory mission to protect and promote public health. FDA recognizes that standards serve as useful adjuncts to Agency regulations. Standards optimize the use of FDA resources, allow for international trade commitments to be met, enable cooperation between governments, encourage partnering with manufacturers, and facilitate improvement in industrial productivity by basing requirements on accepted standards.

In the *Federal Register* (FR) of November 28, 1994 (59 FR 60870), FDA published a draft policy on international harmonization of regulatory requirements and guidelines. The purpose of the draft policy was to articulate FDA's policy on the development and use of standards, with respect to international harmonization of regulatory requirements and guidelines. Specifically, the policy addresses the conditions under which FDA plans to participate with standards bodies outside of FDA, domestic or international, in the development of standards applicable to products regulated by FDA. The policy also covers the conditions under which FDA intends to use the resultant standards or other available domestic or international standards in fulfilling its statutory mandates for safeguarding the public health.

FDA's goals in participating in international harmonization are:

- to safeguard U.S. public health;
- to assure that consumer protection standards and requirements are met;
- to facilitate the availability of safe and effective products;
- to develop and utilize product standards and other requirements more effectively; and
- to minimize or eliminate inconsistent standards internationally.

8. A majority of counterfeit prescription drugs are sold through Internet pharmacies in the U.S. What is the FDA doing to address this problem and how do current and future electronic tracking systems help reduce illegal Internet pharmacy sales?

FDA uses a multilayer approach to prevent counterfeit drugs sold over the Internet from entering U.S. commerce by: (a) working with supply-chain stakeholders to secure the product, the supply chain, and distribution of the product; (b) engaging in public outreach and education; (c) coordinating action

with state and other federal agencies; (d) cooperating internationally; and (e) enhancing enforcement.

FDA is also actively involved in law-enforcement efforts with international counterparts. General partnerships and agreements with other nations contain specific provisions relating to anti-counterfeiting efforts; FDA and the World Health Organization (WHO) entered into a cooperative agreement to develop and implement a global surveillance and monitoring system. Moreover, FDA works with the U.S. Pharmacopeia (USP), an independent standards-setting authority, to revise monographs to include standards that ensure the strength, quality, and purity of drugs in the United States. These standards are included in the U.S. Pharmacopeia-National Formulary, the official compendia in the United States, and are enforced under the Federal Food, Drug and Cosmetic Act (FD&C Act or the Act), unless the label plainly states any differences from the official compendium. Additionally, FDA has established an office to focus on drug integrity and security and will specifically address counterfeit prevention and detection. FDA will continue to take a risk-based approach to identify and address importation of counterfeit drugs sold over the Internet and to review commercial drug import entries to ensure they are listed and their manufacturers registered prior to release on the U.S. market.

FDA is also developing standards for identification, tracking and tracing, and authentication of drugs to increase transparency and accountability in the supply chain. For example, in January 2009, FDA announced in the FR the launch of a voluntary pilot program (secure supply chain) to help promote the safety of drugs and active drug ingredients produced outside the United States. This program would help to prevent importation of drugs that do not comply with applicable FDA requirements by allowing the Agency to focus its resources on foreign-produced drugs that fall outside the program. This pilot program will be ongoing.

FDA will continue to develop standards to implement a track and trace and authentication system in the United States. There are several technologies that may prove helpful, including radio frequency identification (RFID) chips and taggants. For example, radio waves are used to automatically read RFID tags that are contained on items such as pharmaceutical products. These tags could have individual serial numbers on each product, thus allowing the product to be tracked and traced through the supply chain. Appropriate implementation and use of this technology can help decrease the opportunities for diversion and counterfeiting by allowing wholesale distributors and pharmacies to authenticate that the product was handled by legitimate, licensed entities in the drug-supply chain.

Drugs purchased on the Internet are often imported through express couriers and U.S. Mail. The eDRLS will allow FDA to have a manufacturer/labeler reference product label on file available to the field offices for review of imported drugs. When labeling/sampling field exams indicate initial screening for possible

counterfeit drugs, the investigator or compliance officer will be equipped with reference-drug labeling to assist in determining the possibility of counterfeiting.

9. **What is FDA's sense on when the proposed rule for Unique Device Identification (UDI) will be ready for the development of the unique device identification (UDI) system for medical devices?**

   Section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (P.L. 110-85) directs FDA to promulgate regulations establishing a UDI system for medical devices. FDA is developing proposed regulations, to issue in 2011, to establish this UDI system to strengthen and improve FDA's enforcement of other statutory authorities and improve the identification of devices through distribution and use. The system established by the rule, once finalized, would require the label of every medical device to include a UDI, except where the rule provides for alternative placement of the UDI or provides an exception for a particular device or type of device. Health care professionals and others would be able to use the UDI to rapidly and unambiguously identify a device and obtain important information concerning the device.[2]

   In conjunction with work on the draft rule, FDA is also spearheading the effort to create the UDI database (the authoritative source for all UDIs and a select list of linked attributes). FDA is planning to award the contract for creation of the database in 2011. FDA is also currently making plans to incorporate UDIs into adverse event reporting as well as into manufacturer registration and product listing. Furthermore, pilot efforts are underway to incorporate UDIs into registries early in their development.

10. **With the development of the UDI for medical devices and the serialized numeric identifier (SNI) for prescription drug packaging, please address how these emerging standards to identify products in the supply chain will harmonize and interact with the PREDICT entry review system.**

    UDI and SNI are part of initiatives to enhance the labeling and traceability of devices and drugs, respectively. The main challenge with including UDI and SNI as factors in PREDICT's screening of import entries will be in obtaining these data elements electronically. Entry filers make electronic entries to U.S. Customs and Border Protection (CBP), and CBP transmits the entries to FDA. Currently, filers are not entering electronic UDI and SNI data, so there is no data for FDA to obtain and process. CBP will need to modify their system, and entry filers will need to provide this data electronically as part of the submission process. Once they start doing so, we can modify Entry Manager and PREDICT on our side to process the data.

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[2] For more information see:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers.

11. Does FDA plan to increase the capability of field inspectors through the use of handheld and portable technologies, as CBP does?

FDA is working to increase the capability of field investigators through the use of handheld and portable technologies. FDA has identified and validated several handheld analytical tools to be used by field staff in the accomplishment of FDA operations and has begun phased deployment of some tools to the field for pilot testing. To date, FDA has deployed three handheld analytical tools. These tools are currently being field tested to validate that the tools will increase field operation capabilities and provide viable detection outcomes. The tools deployed each have individual screening capabilities for both commodities examined and detection of specific adulterants, which include: the capability to identify potentially counterfeit drug products; screen food and drug products for the presence of heavy metals; and the capability to screen for the presence of the prescription drugs sibutramine and fluoxetine in herbal and "natural" products. These tools will allow FDA investigators to screen a commodity on site, returning an analytical screening result within minutes. From that screening result, investigators will have better scientifically based data to determine whether the product should be sampled and submitted to an FDA field laboratory for further analytical determination of the presence and levels of adulterants or if the product can be released into U.S. commerce.

FDA is also working to identify and establish an internal system that will allow for the use of remote access technologies for the completion of day-to-day field operations. These remote access tools will be used to carry out import activities, as well as domestic and foreign inspections. While the Agency is still in the preliminary stages of identifying system requirements and working to establish an internal information technology system to support the use of these devices, this effort continues to remain a priority for the Agency.

12. Is FDA developing any field-based interdiction models to support the PREDICT and OASIS programs?

FDA has trained all employees on conducting the entry review process that will effectively interdict imported products using OASIS. As the Agency transitions from OASIS to PREDICT, it is currently developing and will be issuing guidance to the field for the interdiction of imported products to reflect the risk-based enhancements that PREDICT can provide.

13. Recent actions at FDA could have the unintended consequence of restricting access to treatments that appear to be effective in a subset of patients – women with Stage 4 Breast Cancer – because they are not effective for a larger group of patients, or cause side effects in a group of patients. I am aware of that for certain women Avastin is effective for treatment of metastatic breast cancer. Has the FDA considered the ramifications of removing the Avastin breast cancer indication to these patients?

FDA is responsible for protecting the public health by ensuring that drugs and biologics are safe and effective. In determining whether a product should be labeled for a particular indication, we take seriously our obligation to carefully weigh the risks and benefits for the patient. Specifically, the Agency considers whether the benefits of the drug, including the magnitude of those benefits, outweigh the product's toxicities for the indicated use.

The metastatic breast cancer MBC indication for Avastin (bevacizumab) was approved in 2008 under the accelerated approval regulations (21 CFR part 601, subpart E). Accelerated approval provides earlier patient access to promising new drugs for treatment of patients with serious and life-threatening diseases, while confirmatory clinical trials are being conducted to verify that the drugs are effective. If those trials fail to confirm clinical benefit to patients, or if the company does not pursue the required confirmatory trials with due diligence, FDA can withdraw approval through an expedited withdrawal procedure (21 CFR 601.43).

On December 16, 2010, FDA's CDER announced the recommendation to remove the breast cancer indication from the label for Avastin because the drug has not been shown to be safe and effective for that use. CDER is responsible for the review and approval of drugs and most therapeutic biologic products. CDER made this recommendation after reviewing the results of four clinical studies of Avastin in women with breast cancer and determining that the studies do not provide adequate evidence that the drug prolongs overall survival in breast cancer patients or provides a sufficient benefit in slowing disease progression, to outweigh the significant risk to patients. As stated in the approved labeling for this drug, these risks include severe or fatal bleeding and hemorrhage; the development of gastrointestinal perforations (or "holes"), and other serious and sometimes fatal consequences of use of this drug.

We know that many patients believe that Avastin works for them. Unfortunately, outside of controlled clinical trials, it is often difficult to interpret anecdotal reports of patient benefit from any drug. It is particularly difficult with drugs like Avastin, which are always used in conjunction with chemotherapy. If Genentech wishes to pursue studies to demonstrate that there is a subset of women who may benefit from Avastin, FDA will work with the company on the design of any such trials.

The decision whether to remove the breast cancer indication from the Avastin label will be made at the end of a process and CDER's recommendation was the first step. The drug itself would not be removed from the market and the December 16, 2010, action will not have any immediate impact on its use in treating breast cancer. Any final action taken would not affect the approvals for colon, kidney, brain, and lung cancers. CDER is recommending that oncologists currently treating patients with Avastin for MBC use their medical judgment

when deciding whether a patient should continue treatment with the drug or consider other therapeutic options.

On December 23, 2010, Genentech submitted a request for an FDA hearing on CDER's proposal to withdraw Avastin's MBC indication. Genentech also submitted information to the docket (Docket No. FDA-2010-N-0621) dated January 17, 2011, to support its request for a hearing. On February 23, 2011, FDA notified Genentech that their request for a hearing was granted. In that hearing, to be held on June 28-29, 2011, Genentech and CDER will present opposing views and evidence on the scientific questions that are relevant to this decision. An expert advisory committee will consider those views and evidence and provide its advice and recommendations to the Commissioner. Ultimately, upon consideration of that advice, and the advice and recommendations of the presiding officer, the Commissioner will make a final decision.

Congressman Michael Burgess

1. **Please provide a list of Chinese officials with whom you met on your visit to China in August 2010.**

   See attached.

2. **Was the molecule "oversulfated chondroitin sulfate" (OSCS) patented in China?**

   Shandong University filed a Chinese patent application for oversulfated chrondroitin sulfate under the title "Poly-sulfated chondroitin sulfate and preparation method thereof" (Application Number 200510045393, filed December 20, 2005, published June 21, 2006). According to the patent application abstract, "The polysulfated chondroitin sulfate possesses appreciable action of resisting tumour breeding, inhibiting tumour transferring and inhibiting mastocyte pulling-off granule, and etc., the anticoagulating potency ≤ 10IU/mg, and also possesses strong antiphlogistic and analgesic action." This patent was deemed withdrawn as of June 17, 2009.

3. **Why would someone develop OSCS?**

   We are unaware if OSCS has a "legitimate" application and use outside of the United States. OSCS is a modified form of chondroitin sulfate. In its natural form, chondroitin sulfate, which is made from animal cartilage, is used as a natural dietary supplement for the relief of osteoarthritis. OSCS is man-made and does not occur naturally. OSCS mimics heparin's qualities and therefore appears to be heparin when subjected to standard tests.

OSCS is easy to make and less expensive than biologically sourced heparin. Its use became prevalent in 2006-2008, when the cost of heparin rose due to an outbreak in China of the deadly infection known as blue-ear pig disease. FDA officials believe that the contamination of heparin was an instance of economically motivated adulteration.

Congressman Marsha Blackburn

1. **How many people do you employ at FDA?**

   FDA currently employs approximately 11,500 people.

2. **How many people are responsible for PREDICT?**

   FDA has one full time employee dedicated to management of the PREDICT project. FDA has multiple personnel and contractors engaged in the PREDICT project on a part-time basis. The management, operational, policy, technical and subject matter experts who contribute varying amounts of their time to the project are critical to the overall success of the project. These people include import entry reviewers and supervisors from district offices, representatives from Center compliance offices, management and staff from FDA's Office of Regulatory Affairs (ORA), and FDA information technology staff. FDA does not have a system for tracking the contributions of these part-time contributors, since they only provide a relatively small part of their time to this particular initiative.

Congressman Phil Gingrey

1. **Are any ingredients in the compounded version of a drug manufactured by KV Pharmaceuticals (for the prevention of preterm labor) imported?**

   The active ingredient used in Makena is hydroxyprogesterone caproate, which is manufactured overseas. Makena also contains inactive ingredients which are manufactured in the United States.

Congressman Brian Bilbray

1. **Please provide results of any internal analysis you conducted looking into review times and approvals of drugs and devices in the United States versus in Europe.**

   For drugs, applications received in FY 2010, as of March 31, 2011, FDA has met the Prescription Drug User Fee Act (PDUFA) goals negotiated with industry 100 percent of the time for priority applications and 97 percent of the time for

standard applications, with 5 percent of priority applications and 25 percent of standard applications still pending FDA review, all within their PDUFA goal.[3]

The European Medicines Agency (EMA) and FDA premarket review processes for drugs feature a number of differences, although the Agencies often work in parallel and communicate with one another. For example, a drug sponsor may elect to undergo EMA overall review or seek approval on a country-by-country basis. The majority of drugs that reach the market in the United States are concordant across the Atlantic. In some cases the timing differs, usually by a matter of months, but these differences are dependant on many factors including the different systems in place for review and, more importantly, when applications are submitted by sponsors to the different regulatory bodies (they are usually within six months of each other).

As noted above, the variations in drugs that are submitted in the European Union (EU) versus the United States, combined with differences in regulatory review processes make direct comparisons somewhat difficult. However, FDA recently examined the time to approval for novel drugs approved by both authorities. In this analysis FDA compared marketing approval of 57 novel drugs approved by both FDA and EU regulators between 2006 and 2010. Of these, 43 were approved first in the United States and 14 were approved first by the EU. Twenty-seven of these 57 drugs were FDA-designated priority review drugs that provide a therapeutic advance, and all but three of the 27 were approved first by FDA. The median time from marketing submission to FDA approval was 183 days for priority review products and 396 days for standard review products. In the EU, those times were 403 days and 449 days, respectively.

A recent article published by *Health Affairs*[4] examined 35 oncology products approved by either FDA or EMA for the period 2003-2010. Of the 35 products considered, FDA approved 32. For this subset, the median time from FDA-receipt date to approval was 182 days. EMA approved 26 of the 35 products. For the approved subset, the median time from EMA-receipt date to the issuance of the Committee of Medical Products for Human Use (CHMP) approval letter was 350 days. Twenty-three of the 35 oncology products were approved by both FDA and EMA. For these 23 products, median FDA review time was 182 days. For the same products, median EMA scientific review time was 349 days. The median difference in the length of the scientific reviews was 123 days in favor of FDA. FDA completed its review (using the FDA Approval Date) before EMA completed its review (using the CHMP Date) for 21 of the 23 products. For the

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[3] See 2010 PDUFA Performance Report:
http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/PDUFA/ucm243357.htm.

[4] See "Despite criticism of the FDA review process, new cancer drugs reach patients sooner in the United States than in Europe," Health Affairs, July 2011, Roberts et al.:
http://content.healthaffairs.org/content/early/2011/06/14/hlthaff.2011.0231.abstract.

21 products approved in the United States before EMA completed its review, the median delay was 217 days.

For devices, FDA has not conducted nor are we aware of any comprehensive comparison of device review or approval times in the United States versus Europe. Two factors make comparisons difficult. First, the European model for device review has a different approval standard and other important limitations. Unlike the United States, the EU does not require that a device be shown to be effective. Moreover, the decision to approve a device in the EU is made by private companies, of which there are over 70, from which a manufacturer can select and to whom it pays a fee. These private companies, called Notified Bodies, are subject to variable amounts of oversight and the information on which they make an approval decision is not made available to the public. Second, it is difficult to compare the United States and EU systems because, unlike in the United States, the EU does not have a centralized, publicly available database of review performance, summaries of approval decisions, or important measures of safety, such as adverse event reports. The European Commission has recognized that the EU model does not always offer a uniform level of protection of public health and that its system has been criticized as being too fragmented and fraught with national variation.

Recent publications have highlighted these concerns. The European Society of Cardiology (ESC) recently issued a "case for reform" of the European medical device regulatory system, and their recommendations included creating a unified system, stronger clinical data requirements, and more accountability for notified bodies.[5] The ESC cites examples of many different cardiovascular technologies that were implanted in patients in the EU that were then proven to be unsafe and/or ineffective through clinical trials required under the U.S. system and removed from the European market. Recent articles in the *British Medical Journal* discuss the opacity of the European medical device regulatory system, with regard to access to decisions regarding device clearances.[6] The articles cite the FDA system's transparency as helping physicians to make informed decisions on which devices to use and giving patients access to information on devices that will be used on them. One of the articles looked at the UK system and found that the number of recalls had increased over 1,200 percent over a recent five-year period.

A recent industry-sponsored study[7] compared approval dates between the United States and the EU. Although the study is highly flawed, it does note that devices

[5] See "Clinical evaluation of cardiovascular devices: principles, problems, and proposals for European regulatory reform," Fraser, et al., European Heart Journal, May 2011.
[6] See "Medical-device recalls in the UK and the device-regulation process: retrospective review of safety notices and alerts," Heneghan, et al., British Medical Journal, May 2011.
[7] See "Competitiveness and Regulation: The FDA and the Future of America's Biomedical Industry," California Healthcare Institute and Boston Consulting Group, February 2011. *http://chi.org/uploadedFiles/Industry_at_a_glance/Competitiveness_and_Regulation_The_Future_of_America's_Biomedical_Industry.pdf.*

subject to a 510(k) without clinical data tended to come on the market first as often or more often in the United States than in the EU. Note that these types of devices represent about 90 percent of all 510(k)s and over 80 percent of all devices approved or cleared in the United States each year. Additionally, it is important to note that the Agency is meeting or exceeding its Medical Device User Fee Act (MDUFA) performance goals for over 95 percent of the submissions we review. Ninety-five percent of the more than 4,000 annual device applications subject to performance goals are reviewed within the timeframes FDA and the device industry agreed upon. This includes reviewing 90 percent of all 510(k)s within 90 days. Further, 98 percent of 510(k)s are reviewed in 150 days.

2. **When U.S. companies import FDA approved pharmaceutical products made abroad, assuming the paperwork matches up, FDA knows exactly what they're importing – FDA certified products made with FDA approved processes in, generally, FDA inspected plants. In fact, FDA only rarely physically examines these shipments and less rarely samples any pharmaceutical. Once a shipment arrives, FDA inspectors, when they have time, verify that the paperwork on the shipment matches with FDA data files, placing a hold on the shipment if they don't exactly match up. Sometimes, FDA databases at the ports and at headquarters are not synchronized, causing these mismatches. This process is, in fact, an exercise in paperwork verification. FDA should implement an alternative approach: a voluntary program in which highly compliant importers submit their internal processes and controls to rigorous FDA examination to verify that applicant companies have strong internal controls for manufacturing processes, product safety, supply chain integrity, and trade compliance that demonstrate the safety and security of their imported products. Once FDA certifies a company as a "trusted importer," imports from that company could be released by FDA immediately upon their arrival, with relevant paperwork and certification maintained on an ongoing basis. Could FDA implement such a program?**

   FDA is currently working to implement the Secure Supply Chain Pilot Program (SSCPP). This program would expedite the entry of specific finished drug products and active pharmaceutical ingredients (APIs) for applicants in the program. FDA has worked closely with CBP to include verification that participants meet certain requirements of CBP's Customs-Trade Partnership Against Terrorism (CTPAT) program. If the pilot proves to be beneficial to both the Agency and the industry, the program will be evaluated, changes will be made, and it will continue after the pilot ends. The goal of the pilot is to allow FDA to determine the practicality of developing a secure supply chain program that would assist the Agency in its efforts to prevent the importation of drugs that do not comply with applicable FDA requirements, allowing the Agency to focus its resources on foreign-produced drugs that fall outside the program and that may

not be compliant. It should be noted that although a facilities' track record will be a factor in this pilot program, the pilot will not establish an expedited entry process for all drug commodities for any participating pharmaceutical importer.

Additionally, under provisions of the new FDA Food Safety Modernization Act (FSMA) (P.L. 111-353), FDA will be establishing a Voluntary Qualified Importer Program (VQIP). Importers accepted into this program will receive expedited entry review when they have systems and controls in place that will help ensure the safety of the products they intend to import. Once established, this program could serve as a model for other products that the Agency regulates.

3. **Many companies import the exact same FDA certified product from the exact same facility abroad, sometimes at the exact same time each month. For several months these shipments are cleared quickly and sent on their way, but then, randomly the FDA will decide to place a shipment on hold. What percentage of shipments that FDA places holds on are repetitive shipments, i.e. shipments that arrive on a regular schedule containing the same merchandise, from the same importer, from the same manufacturing facility? On what grounds does FDA detain these shipments? How many – what percentage – are released without negative finding? What would you estimate these fruitless exercises cost the government?**

   FDA does not collect data on "repetitive shipments" and detentions of those shipments; however there are several reasons why the Agency would detain a shipment to protect public health. Those reasons include: routine surveillance examination/analysis to ensure continued compliance with FDA regulations; new evidence or data leading the Agency to identify a product for detention without physical examination (DWPE); or recent information indicating public health safety concerns with a specific product area which would require increased sampling of the those commodities to ensure products are not injurious to health.

4. **How many inspector-hours does FDA spend in the process of detaining FDA-approved products from companies that have averaged less than one refusal over the past three years?**

   FDA does not collect data on detentions of products from companies that have averaged less than one refusal. As a general matter, FDA personnel in Fiscal Year (FY) 2010 spent more than 20,000 hours reviewing entry declarations for all pharmaceutical shipments offered for entry into the United States via commercial entries, courier facilities, and international mail facilities.

5. **Partnership programs can help agencies focus on truly dangerous imports and make supply chains more dependable, but the programs need to balance the more stringent requirements with tangible incentives for participants, or else neither government nor industry will be satisfied. Agencies need to coordinate so that these programs complement each other. If an importer**

interfaces with three agencies at the border, but only two agencies have partnership programs, then the importer may not clear its shipments any faster. Please report back on steps FDA and CBP have taken to implement partnership programs that will reduce oversight costs and facilitate trade.

FDA agrees that trusted partnership programs (TPP) can provide assurance that products being imported from verified supply chains pose less of a risk than unverified supply chains. Because these are known entities with processes that have been verified, the entry admissibility process can be expedited, freeing up resources towards unverified entities and processes. SSCPP, discussed above, is one such program which will allow FDA to assess entities involved in a repetitive-type pharmaceutical import chain, and expedite the entry admissibility process. If successful, FDA will explore expansion to other FDA-regulated commodities. FDA also agrees that partnering with other government agencies can be a good means of leveraging resources and knowledge sets. However, not every agency's TPP will satisfy another agency's mission; an agency's program will invariably be focused on that agency's mission and priorities. For example, CBP's CTPAT does a good job of addressing security concerns in the shipment and handling of cargo. However, it does not address the conditions of a facility's manufacturing that produced such cargo, which is of key importance to FDA in assuring those products are free from adulteration, like microbiological or chemical contaminants. Where possible, the Agency leverages other agencies' TPP. For example, participation in CBP's CTPAT is a prerequisite for participation in FDA's SSCPP. In this way the Agency leverages CBP's security-based TPP with our own importer/foreign supplier-based TPP.

FSMA provides FDA with additional capabilities to develop and leverage TPPs, by requiring FDA to establish a VQIP for expedited review and importation of food and to issue guidance related to participation in, revocation of such participation in, reinstatement in, and compliance with, such program.

6. **Commissioner Hamburg, I understand you met with CBP Commissioner Bersin in October 2010 to discuss ways to improve the import process. What steps have you taken with Commissioner Bersin since then?**

In October of 2010, CBP Commissioner Bersin, Consumer Product Safety Commission (CPSC) Chairman Tenebaum, and FDA Commissioner Hamburg hosted the first Interagency Safety Conference. The meeting brought together agency heads and other senior leaders from 10 agencies to focus efforts to protect the health and safety of the American consumer from unsafe products. From this meeting, the Border Interagency Executive Council (BIEC) was formed. Since the October meeting, the BIEC has met on several occasions and created a charter, developed guidelines for the Interagency Policy Committee, which will provide policy oversight for the BIEC, and identified three initiatives related to information sharing, document imaging, and partnership programs, for which FDA is a working member. Through this council, FDA will continue to work

with CBP and the other federal agencies to identify opportunities to improve the import process.

Commissioner Hamburg also met with Commissioner Bersin at the National Targeting Center to view CBP and FDA co-located operations and discuss issues related to import security and safety. During that meeting, the agencies identified several opportunities to improve data sharing, operational procedures, and communications. Both commissioners remain committed to working together to address these issues.

7. By how much has FDA's budget increased during Commissioner Hamburg's tenure?[8]

Commissioner Hamburg was confirmed on May 18, 2009. As shown in the following table, the FDA budget year-to-year change for FY 2010 and FY 2011 is $0.324 billion and $0.572 billion, respectively.

Food and Drug Administration
Program Level Budget
FY 2009 - 2011
(dollars in billions)

Fiscal Year	Budget Authority	User Fees	Total	Change from the Prior Year
2009 Actual	$2.196	$0.598	$2.794	
2010 Actual	$2.369	$0.748	$3.118	$0.324
2011 Enacted	$2.457	$1.233	$3.690	$0.572

[8] This question was not submitted in writing, but was asked during the hearing.

Countries or areas[9] that imported FDA-regulated products in FY 2010

Afghanistan
Albania
Algeria
American Samoa
Andorra
Angola
Anguilla
Antigua & Barbuda
Argentina
Armenia
Aruba
Australia
Austria
Azerbaijan
Bahamas
Bahrain
Bangladesh
Barbados
Belarus
Belgium
Belize
Benin
Bermuda
Bhutan
Bolivia
Bosnia-Hercegovina
Botswana
Brazil
British Indian Ocean Territory
British Virgin Islands
Brunei Darussalam
Bulgaria
Burkina Faso
Burma (Myanmar)
Burundi
Cameroon
Canada
Cape Verde
Cayman Islands
Central African Republic
Chad
Chile

[9] FDA does not track imports solely by country, but rather by defined areas, as established in consultation with our U.S. regulatory counterparts, such as the U.S. Department of State.

China
Christmas Island (Indian Ocean)
Cocos Islands
Colombia
Comoros
Congo (Brazzaville)
Congo, Dem Rep of (Kinshasa)
Cook Islands
Costa Rica
Croatia
Cuba
Cyprus
Czech Republic
Denmark
Djibouti
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Estonia
Ethiopia
Falkland Islands
Faroe Islands
Fiji
Finland
France
French Guiana
French Polynesia
French Southern Antarctic
Gabon
Gambia, The
Georgia
Germany
Ghana
Gibraltar
Greece
Greenland
Grenada
Guadeloupe
Guam
Guatemala
Guinea
Guinea-Bissau

Guyana
Haiti
Heard & McDonald Islands
Honduras
Hong Kong SAR
Hungary
Iceland
India
Indonesia
Iran
Iraq
Ireland
Israel
Italy
Ivory Coast
Jamaica
Japan
Jordan
Kampuchea
Kazakhstan
Kenya
Kiribati
Korea, Democratic Peoples Republic
Korea, Republic Of (South)
Kosovo
Kuwait
Kyrgyzstan
Lao Peoples Democratic Republic
Latvia
Lebanon
Lesotho
Liberia
Libya
Liechtenstein
Lithuania
Luxembourg
Macau SAR
Macedonia
Madagascar
Malawi
Malaysia
Maldives
Mali
Malta & Gozo
Marshall Islands
Martinique

Mauritania
Mauritius
Mexico
Micronesia, Federated State Of
Moldova
Monaco
Mongolia
Montenegro
Montserrat
Morocco
Mozambique
Namibia
Nauru
Nepal
Netherlands
Netherlands Antilles
New Caledonia
New Zealand
Nicaragua
Niger
Nigeria
Northern Mariana Islands
Norway
Oman
Pakistan
Palau
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Pitcairn Island
Poland
Portugal
Puerto Rico
Qatar
Reunion
Romania
Russia
Rwanda
Saint Christopher & Nevis
Saint Helena
Saint Lucia
Saint Pierre & Miquelon
San Marino
Sao Tome & Principe

Saudi Arabia
Senegal
Serbia
Seychelles
Sierra Leone
Singapore
Slovakia
Slovenia
Solomon Islands
Somalia
South Africa
Spain
Sri Lanka
St. Vincent & The Grenadines
Sudan
Surinam
Swaziland
Sweden
Switzerland
Syrian Arab Republic
Taiwan
Tajikistan
Tanzania, United Republic Of
Thailand
Timor Leste
Togo
Tokelau Islands
Tonga
Trinidad & Tobago
Tunisia
Turkey
Turkmenistan
Turks & Caicos Island
Uganda
Ukraine
United Arab Emirates
United Kingdom
United States Outlying Islands
Uruguay
Uzbekistan
Vanuatu
Vatican City State
Venezuela
Vietnam
Virgin Islands Of The U.S.
West Bank

Western Sahara
Western Samoa
Yemen
Yemen, Democratic (South)
Yugoslavia
Zambia
Zimbabwe

Chinese officials with whom Commissioner Hamburg met in August 2010

August 10, 2010
Beijing, China
Meeting with Changcheng Pu, Vice Minister, China General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)
Purpose: To review the progress of FDA's work with AQSIQ, and discuss key challenges in the area of food safety.

August 11, 2010
Beijing, China
Meeting with Mingli Shao, Commissioner, China State Food and Drug Administration (SFDA)
Purpose: To review the progress of FDA's work with SFDA, convey FDA's ongoing concerns related to heparin.

August 12, 2010
Shanghai, China
Meeting with Jinji Xu, Director-General, Shanghai Entry-Exit Inspection and Quarantine Bureau (Shanghai CIQ)
Purpose: To affirm and strengthen FDA's relationship with Shanghai CIQ and discuss issues related to food safety and Shanghai CIQ's laboratory testing system.

August 13, 2010
Shanghai, China
Meeting with Longxing Wang, Director-General, Shanghai Municipal Food and Drug Administration (Shanghai FDA)
Purpose: To affirm and strengthen FDA's relationship with Shanghai FDA, and to visit Shanghai FDA laboratories.

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