



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

**STATEMENT
OF**

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**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”

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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.