DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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STATEMENT

OF

DARA A. CORRIGAN, J.D.

ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

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COMMITTEE ON THE JUDICIARY

U.S. HOUSE OF REPRESENTATIVES

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INTRODUCTION

Good morning, Chairman Sensenbrenner and Members of the Subcommittee. I am Dara Corrigan, Associate Commissioner for Regulatory Affairs at the Food and Drug Administration (FDA or the Agency) in the Department of Health and Human Services (HHS). Thank you for the opportunity to discuss counterfeits, cargo thefts, and the safety of the American drug supply.

FDA is responsible for protecting the public health by ensuring the safety and efficacy of medical products and the safety of foods. When FDA approves drugs based on scientific evidence and federal legal standards, the American people have every right to expect that the medicines they rely on for treatment are exactly what the packages and labels say they are—drugs that have been carefully evaluated by FDA in terms of safety, efficacy, quality, and purity. Today's testimony focuses on FDA's continuing efforts to ensure the safety of the American drug supply.

When President Franklin Delano Roosevelt established the modern FDA in 1938, the American drug supply chain was far less complicated and there were fewer opportunities for drugs to be counterfeited or stolen. For instance, at that time, the percentage of medical products imported into the United States was minimal. Today the landscape is dramatically different. Nearly 40 percent of the drugs Americans take are made elsewhere, and 80 percent of the sites that manufacture active pharmaceutical ingredients (APIs) used in FDA-approved drugs are outside our borders—from more than 150 countries, many with less sophisticated manufacturing and regulatory systems than our own. In addition to the sheer volume of imports and foreign facilities, there has been an increase in the variety of sources, shippers, methods of transportation, and supply-chain complexity of imported products, and our current authorities have not kept pace with the challenges of the current global marketplace. Combined, these

factors create great challenges to FDA and industry in ensuring that all drugs are high quality and travel safely throughout their complex supply chains.

When we refer to the drug supply chain, we are talking about the increasingly complex path that medical products travel, from raw source materials to finished products for consumers. At every stage in this process, opportunities arise for products to be contaminated, diverted, counterfeited, or otherwise adulterated. The Internet presents an additional layer of complexity by introducing more players into the system and more opportunities for criminals to reach consumers. Our efforts to secure the supply chain both in the United States and abroad include minimizing risks that arise anywhere along the supply chain continuum, from sourcing a product's ingredients through the product's manufacture, storage, transit, sale, and distribution. A breach at any point in this continuum could lead to dangerous and even deadly outcomes for consumers. Supply chain safety threats also impact manufacturers' bottom lines due to costs associated with both recalls and decreased public confidence.

As Members of this Committee well know, this threat is not purely hypothetical. Recent incidents of adulteration, counterfeiting, and cargo theft have posed serious threats to public health. The consequences, throughout the world, have been tragic. Counterfeit drugs raise significant public health concerns because their safety and effectiveness is unknown. A counterfeit drug could be made using ingredients that are toxic to patients and processed under poorly controlled and insanitary conditions. In the United States, a relatively comprehensive system of laws, regulations, and enforcement by federal and state authorities has kept drug counterfeiting relatively rare, and FDA continues to believe—and works to ensure—that Americans can have a high degree of confidence in the drugs that they obtain through legal channels. Nonetheless, with the dramatic increase in the volume and complexity of the global

supply chain, FDA and its regulatory and law enforcement partners around the world face enormous challenges regarding supply-chain security.

Those who manufacture and distribute counterfeit medical products not only defraud patients and consumers, they also prevent patients from getting the authentic safe, effective drugs they need to alleviate or end suffering and save lives. They put people at direct and indirect risk of harm from drugs that may contain too much, too little, or the wrong active ingredient—or even toxic ingredients. But even a non-toxic counterfeit drug with a substitute or no active ingredient could prove harmful to patients who think that they are taking a lifesaving or life-sustaining medication. Just last month, FDA alerted 19 medical practices in three states that they had purchased unapproved drugs—which may have included a counterfeit version of a widely used cancer drug—from a foreign supplier and distributed through a wholesaler in the United States. While the counterfeit was labeled as Avastin (bevacizumab), the imported injectable vials contained none of the product's active ingredient. This counterfeit product presents a major public health issue, because some patients may not have received needed therapy.

The Internet continues to be a major source for counterfeit, unapproved, or diverted prescription drugs. The global anonymity of the Internet provides a safe haven for illicit prescription drug sales. Many websites look like legitimate pharmacies, leading unsuspecting customers in the United States to believe the dispensing pharmacy is in the United States or Canada. One recent investigation of a website selling counterfeit drugs to U.S. customers claimed to be a "Pharmacy You Can Trust." Although the website was hosted in New York, the drugs were manufactured in clandestine laboratories in China and shipped to the United States. The U.S. customer would receive a package from a domestic address, which looked like the drugs were dispensed from a U.S. pharmacy. Our investigation showed that the payments were processed by a credit card

processor in The Netherlands and funds were transferred to Cyprus, then to Hong Kong and finally to Israel. Although the website listed a 1-800 number for customer service, the calls were routed to customer service personnel in the Philippines. The actual operators of this website were conducting operations from a wireless Internet connection onboard their yacht docked in Tel Aviv. From 2005 to 2007, the website processed over $1.8 million in sales from approximately 12,000 orders. The investigation resulted in five convictions, seven foreign arrests, and two foreign convictions.

FDA has responded to this emerging threat by strengthening its ability to prevent the introduction of counterfeit drugs into the U.S. distribution chain by facilitating the identification of counterfeit drugs working with U.S. medical product supply chain stakeholders to develop guidelines related to the integrity of our country's closed distribution system, such as the tracking and tracing of prescription drugs, in order to keep counterfeits out of this system; and by minimizing the risk and exposure of patients and consumers to falsified products through recalls, public awareness campaigns, and other steps.

As part of these efforts, FDA's Office of Criminal Investigations (OCI) expeditiously investigates reports of counterfeit products in order to protect U.S. citizens. In FY 2011, OCI initiated 59 counterfeit drug investigations. Arrests and convictions in FY 2011 for OCI counterfeit drug investigations were 30 and 38 respectively, with restitution and fines approaching $1.4 million. Restitution and fines were approximately $9.4 million in FY 2010. From OCI's 1992 inception through FY 2011, OCI initiated 580 counterfeit drug investigations, resulting in 522 arrests and 414 convictions, with fines and restitution totaling $56,943,560.

Despite these successes, the increasing number of counterfeits in the United States and global supply chain has reinforced the need for FDA, its regulatory and law enforcement partners, industry, and others to continue to take action in multiple areas to create a comprehensive system of modern protection against counterfeit drugs.

Cargo thefts of prescription drugs also pose a significant public health risk. These incidents are concerning to consumers and companies alike. Cargo thefts can put consumers at risk because the stolen drugs may not have been stored or handled properly or may have been tampered with while outside of the legitimate supply chain. They also cost drug manufacturers millions of dollars. In March of 2010, thieves broke into a warehouse and stole $75 million worth of prescription drug products, including chemotherapy drugs, antidepressants, and blood-thinners. These products have not yet been recovered, and we fear they could be distributed, in spite of public warning. In 2009, stolen insulin was reintroduced into the drug supply and caused adverse events in patients. The stolen insulin, which requires refrigeration, lost its potency and did not provide patients the needed glucose control. Approximately 129,000 vials of insulin were stolen in all.

FDA's efforts are critical to ensuring product quality and supply chain integrity. As such, we intend to further transform FDA over the next decade from a predominantly domestically focused Agency, operating in a globalized world, to an Agency fully prepared for an environment in which product safety and quality know no borders.

In June, FDA published a special report, "Pathway to Global Product Safety and Quality," our global strategy and action plan that will allow us to more effectively oversee the quality, safety, and efficacy of all products that reach U.S. consumers in the future. The Agency is developing a

new, more global operating model that relies on strengthened collaboration, improved information sharing and gathering, data-driven risk analytics, and the smart allocation of resources, leveraging the combined efforts of government, industry, and public- and private-sector third parties. Toward this goal, FDA Commissioner Margaret Hamburg created a directorate focused on grappling with the truly global nature of today's world—food and medical product production and supply, as well as the science that undergirds the products we regulate—to make response to the challenges of globalization and import safety a top priority in the years to come and to ensure that we fully integrate our domestic and international programs to best promote and protect the health of the public. This directorate includes FDA's Office of Regulatory Affairs, which I lead, and the OCI agents charged with investigating counterfeits and cargo thefts that fall within my office.

STEPS TO SECURE OUR NATION'S DRUG SUPPLY CHAIN

FDA has undertaken a wide range of activities aimed at addressing the challenges and opportunities of globalization, including efforts to harmonize scientifically rigorous standards internationally consistent with FDA's high standards for safety and effectiveness; to share scientific and technical expertise with our fellow regulators; to provide training around the world in crucial regulatory disciplines; to strengthen detection, surveillance, and assessment systems; and to design innovative risk-modeling systems.

We now have permanent FDA overseas posts in Beijing, Shanghai, and Guangzhou, China; New Delhi and Mumbai, India; San Jose, Costa Rica; Mexico City, Mexico; Santiago, Chile; Brussels, Belgium; London, England; and Parma, Italy. Last year, we opened posts in Amman, Jordan and 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 and industry in

other nations. They also conduct and facilitate inspections and other on-the-ground activities in foreign sites. We have more than 30 agreements with foreign counterpart agencies to share inspection reports and other non-public information that can help us make better decisions about the quality and safety of foreign products.

When governments collaborate to strengthen safety standards, the results are safer, higher-quality products and enhanced economic development through a productive industry and a strong, reliable export market. The arrangement is mutually beneficial. To a large extent, our success or failure in this effort will be contingent on the relationships we establish with our foreign partners. That is why we are working closely with our sister regulatory authorities, international and national organizations, and industry to leverage resources to accomplish FDA's mission. Especially in the area of good manufacturing practices for drugs, we already have agreed with major foreign counterparts on some harmonized international standards that are consistent with FDA's high standards for safety and effectiveness. By using the results of their inspections to assure us that their manufacturing plants are adhering to our agreed standard, we free up our inspectional resources to help ensure that such manufacturing practices are being followed in other, higher-risk parts of the world. This also lessens the regulatory burden on industry by allowing companies to manufacture to a common standard and undergo fewer inspections by multiple regulatory authorities. To support this effort, FDA can benefit from new legislative authorities that are, at a minimum, commensurate with those of its major global counterparts.

DRUG SAFETY AUTHORITIES

In our increasingly complex and globalized world, additional authorities could be important tools to help support FDA's efforts to protect the security of the supply chain and the health of our

citizens. As the Agency has stated in previous testimony, new regulatory authorities may help ensure that industry takes principal responsibility for the security and integrity of its supply chains and the quality control systems it uses to produce drugs for the American people. In an era of globalization, new authorities can help to level the playing field between domestic and foreign manufacturers, ensure product safety, and provide FDA with the information it needs to protect consumers. Regarding enhanced criminal and civil penalties for foreign and domestic suppliers, statutory changes could help to deter would-be criminals from targeting drug products and bring FDA's penalties in line with those for other serious federal health and safety violations.

CONCLUSION

Given the challenges and threats posed by an increasingly globalized marketplace, we must modernize our approach to drug safety. We look forward to continuing to work together to achieve our shared goal of protecting American consumers. I would be happy to answer any questions.