DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
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STATEMENT

OF

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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

"SECURING OUR NATION'S PRESCRIPTION DRUG SUPPLY CHAIN"

APRIL 25, 2013

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman, Ranking Member Pallone and Members of the Subcommittee, I am Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss the important issue of securing the supply chain for prescription drug products.

Securing the Supply Chain for Prescription Drugs

As FDA has previously testified before this Committee, the increasingly complex drug supply chain, from raw source materials to finished products for consumers, presents multiple opportunities for the product to be contaminated, diverted, or otherwise adulterated. Our efforts to secure the supply chain include minimizing risks that arise anywhere along the supply chain continuum, from sourcing a product's ingredients through the overseeing of a 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 patients.

In addition, we continue to see counterfeit drugs threaten American consumers' health. Counterfeit drugs raise significant public health concerns, because their safety and effectiveness are unknown. A counterfeit drug could contain a substance that is toxic to patients. But even a counterfeit drug with no active ingredient could prove harmful to patients who take it, thinking that they are taking a lifesaving or life-sustaining medication, when they are not. For example, in 2003, over $20 million in illegally imported and counterfeit Lipitor (atorvastatin calcium), a popular cholesterol-lowering drug, was distributed throughout the United States. The source and

manufacturing methods of these drugs were unknown and therefore had the potential to endanger patients. As another example, in 2012, FDA learned of counterfeit versions of two controlled substances that were being sold on the Internet: Adderall (amphetamine aspartate), a drug used to treat attention deficit disorder, and Vicodin ES (acetaminophen; hydrocodone bitartrate), a drug used to treat pain. In both of these incidents, the counterfeits contained different active ingredients than the products they purported to be. Also in 2012, FDA alerted over 500 U.S. medical practices that they had purchased unapproved drugs, some of which may have included a counterfeit version of a cancer medicine. At least some of the counterfeit drugs contained no active ingredients. These examples are troubling because patients may not have received needed therapy or may have experienced harmful side effects.

Counterfeit drugs are not the only problem; stolen or diverted products also pose a threat to patients. Once products leave the legitimate supply chain, we have no idea how they are being stored or handled—or even if they have expired. When those drugs make their way back into the supply chain, they can pose a danger to patients. For example, in one case in 2009, approximately 129,000 vials of Levemir (insulin detemir) were stolen. Insulin is used to control blood sugar levels in patients with diabetes and should be stored in a refrigerator before use. A patient who received the stolen insulin had poor blood glucose control, likely as a result of it not being stored properly. In 2008, a shipment of Carbatrol (carbamazepine), a drug to treat seizures, was stolen while traveling from a company's manufacturing facility to its distribution center. The manufacturer reported that expired Carbatrol from the stolen lots made it back into the legitimate supply chain and was being returned for credit. In a case from 2011, a criminal diverted $2.7 million in prescription drugs by purchasing them from physicians who get

discounted rates, and then reselling them to wholesalers at a profit. These diverted drugs included sterile injectable drugs, which usually require special storage and handling.

While we recognize that we may not be able to eliminate all problem products from the supply chain, we take every step we can to make the supply chain more secure to keep the illegitimate products out. Implementation of a system to fully track and trace prescription drugs throughout the supply chain would help in combating incidents like these counterfeit examples. In February 2013, the Institute of Medicine issued a report entitled "Countering the Problem of Falsified and Substandard Drugs," identifying a combination of actions that could reduce counterfeit and substandard drugs domestically and globally. The report recommends implementing a mandatory drug tracking system in the United States and recognizes how knowledge of where a product is and where it has been can greatly reduce the risks introduced by product diversion and porous supply chains.

A robust track-and-trace system, in which each drug produced would be tracked as it passes through the distribution system and allows purchasers to verify its distribution history, would improve the ability to identify and detect potentially harmful products if they enter the supply chain. Another potential benefit would be to improve the efficiency of product recalls. Imagine a system that enables the distributor or pharmacist to readily determine if they have sold or now have in stock a drug that had been identified as a counterfeit or subject to a recall. They could quickly remove that product from the supply chain, keeping the patient out of harm's way. The only way this can be done effectively is if all supply chain stakeholders participate in the system and if all legitimate products have a way to be identified and tracked as they are distributed from the point of manufacture.

FDA's Current Activities

The Food and Drug Administration Amendments Act of 2007 (FDAAA; Public Law 110-85) gave FDA authority to set standards for identification, validation, authentication, and tracking and tracing of prescription drugs; but, it did not provide the Agency with explicit authority to require an effective track-and-trace system for all drug products throughout the supply chain. In March 2010, FDA issued a final guidance for industry describing the Agency's current thinking for standardized numerical identification (also known as serialization) for prescription drug packages. This guidance was the first of several steps that FDA intends to take to implement these provisions of FDAAA. We held a Track-and-Trace Public Workshop in February 2011 to obtain public input on the necessary elements to achieve effective authentication and the desirable attributes of a track-and-trace system. FDA continues to work on developing these standards.

The Food and Drug Administration Safety and Innovation Act (FDASIA; Public Law 112-144) provided the Agency with new authorities that will help to secure the safety and integrity of drugs imported into, and sold in, the United States. For example, the law includes provisions that allow FDA to refuse admission of a product to the United States if inspection of the manufacturing facility is delayed, limited, or denied; require foreign and domestic companies to provide complete information on threats to the security of the drug supply chain; and improve current registration and listing information, making sure FDA has accurate and up-to-date information about foreign and domestic manufacturers. A robust track-and-trace system would complement these new authorities to further ensure that stolen, diverted, and counterfeit drugs do not enter the supply chain or are found more quickly if they do.

Next steps

FDA has worked closely with Members of this Committee, your colleagues in the Senate, and other stakeholders to provide technical assistance in response to legislative proposals to secure the downstream pharmaceutical supply chain. Consistent with the position articulated by the President's Intellectual Property Enforcement Coordinator, FDA is focused on establishing an effective track-and-trace system. Broadly speaking, such a system should include:

- A clear path toward implementing an effective track-and-trace system to fully secure the supply chain and enhance protection of public health.
- Enforcement authority to ensure that parties adhere to implementation requirements.
- Requirements for all stakeholders to maintain the distribution history for drugs they handle, unless the system provides a way to verify a drug's authenticity and identify its complete history, when needed.
- Reasonable time frames for implementation based on what is technologically possible and what will result in the best possible outcome for public health.

CONCLUSION

An effective national track-and-trace system for all drug products throughout the supply chain would improve the security and integrity of the drug supply and ensure transparency and accountability of product distribution. Many of the challenges we have with securing the supply chain—including contamination, diversion, counterfeiting, and other adulteration—could be addressed by such a system. We look forward to continuing to work with the Committee to develop a system that meets this promise.

I appreciate the opportunity to testify before you today and would be happy to answer any questions that you may have.