



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
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**STATEMENT
OF
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POLICY**

**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**

“COUNTERFEIT DRUGS: FIGHTING ILLEGAL SUPPLY CHAINS”

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INTRODUCTION

Mr. Chairman, Ranking Member DeGette, and Members of the Subcommittee, I am Howard Sklamberg, Deputy Commissioner for Global Regulatory Operations and Policy 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 counterfeit drugs.

Recent incidents of counterfeiting and adulteration have caused serious threats to public health. The consequences around 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 unsanitary conditions. Substandard drugs are also a major public health concern, especially regarding infectious disease drugs, such as anti-HIV and anti-malarial drugs. In the United States, a relatively comprehensive system of laws, regulations, and enforcement by Federal and state authorities has kept drug counterfeiting incidents in the United States 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 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 safe, effective drugs that can improve health, alleviate suffering, and possibly save their lives. They put people at risk of harm from drugs that may contain too much or too little active ingredient, the wrong active ingredient, or even toxic ingredients. But even a counterfeit drug with no active ingredient could prove harmful to patients who think they are taking a lifesaving or life-sustaining medication.

FDA is not alone in its effort to address the problem of counterfeit drugs. FDA works closely with the White House's Intellectual Property Enforcement Coordinator (IPEC) to develop and coordinate the U.S. Government's strategy to address counterfeit pharmaceuticals.¹ I also want to note the efforts of our colleagues in the National Intellectual Property Rights Coordination Center—in which FDA participates and is a full partner—and other domestic and foreign regulatory and law enforcement partners working to help secure the supply chain. The State Department and the U.S. Agency for International Development (USAID) have also served as key partners, ensuring that the issues of drug quality and supply chain security are raised in our diplomatic and development efforts. I also want to thank the Government Accountability Office (GAO) and the Institute of Medicine (IOM) for their reports drawing attention to illegal online pharmacies and global challenges with substandard, counterfeit, and falsified products. In addition, industry partners have made valuable contributions to address supply chain issues. These collaborative efforts are imperative to bring counterfeiters and traffickers to justice and to protect consumers from counterfeit or substandard products. A counterfeit or substandard drug with too little active ingredient could cause a patient to develop drug resistance and

¹ See *Administration's 2013 Joint Strategic Plan on Intellectual Property Enforcement*
<http://www.whitehouse.gov/sites/default/files/omb/IPEC/2013-us-ipecc-joint-strategic-plan.pdf>.

potentially spread that resistant strain to the community, eroding our arsenal of effective medicines.

Challenges of Protecting the Supply Chain

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 the source of 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 can also affect manufacturers' bottom lines due to costs associated with both recalls and decreased public confidence.

Nearly 40 percent of the drugs Americans take are made elsewhere, and about 80 percent of manufacturing sites of active pharmaceutical ingredients (APIs) used in drugs manufactured in the United States are located outside our borders—in 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 products. Combined, these factors create great challenges to FDA and industry in ensuring that all drugs and drug components are high quality and travel safely throughout their complex supply chains. These factors also provide opportunities for criminals to adulterate drugs for economic or other malevolent reasons.

Growth in counterfeiting may be spurred by the economic incentives provided by an increasing volume of drugs, longer (often international) supply chains, the development of technologies that make it easier to counterfeit drugs, the involvement of international organized crime, and the ability to sell drugs directly to consumers through the Internet, without face-to-face contact. This growth also is exacerbated by the relatively low criminal penalties for distribution of adulterated, unapproved, or misbranded drugs provided under the Federal Food, Drug, and Cosmetic Act (FD&C Act), compared to other types of crimes.

The Internet presents an additional layer of complexity by introducing more players into the system and more opportunities for criminals to reach consumers, and as a result, it continues to be a major source for counterfeit and unapproved prescription drugs, many of which are dispensed without prescriptions. The global anonymity of the Internet can provide 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.

FDA's Efforts to Protect the Supply Chain

FDA has responded to this threat by working to protect and further strengthen the integrity of our country's closed drug distribution system in multiple ways. We have made it a priority to investigate reports of counterfeit products. FDA also has worked with U.S. drug supply chain stakeholders to improve our ability to prevent, detect, and respond to threats of counterfeit and substandard drugs. We are developing standards for tracking and tracing prescription drugs. In addition, we are educating consumers and the health care community about the risks of, and

minimizing exposure to, counterfeit and substandard drug products through recalls, public awareness campaigns, and other steps.

As part of these efforts, FDA's Office of Criminal Investigations (OCI) aggressively investigates reports of counterfeit products in order to protect U.S. citizens. A number of these investigations involve sales of foreign unapproved drugs, many of which we suspect are portals for counterfeiters. Because of OCI's focus on protecting the medical product supply chain, and the good communication within FDA between the regulatory and criminal investigative functions, we have had some notable successes.

For example, when FDA discovered that foreign, unapproved, and counterfeit versions of the cancer drug Avastin had entered the U.S. supply chain, we mobilized our resources to counter the threat. We expanded an existing investigation, which thus far resulted in the conviction of the foreign source of supply, wholesalers, middlemen in Canada and the United States who bought and sold these sophisticated drugs, and physicians who knowingly put their patients' well-being at risk in order to turn a profit by buying drugs at a discount. As part of the investigation, we recently arrested two Turkish nationals as the source of supply of counterfeit and unapproved cancer medications. These drugs, the indictment alleges, were shipped to the United States with false customs declarations. Moreover, the defendants are alleged to have shipped some prescription drugs requiring constant cold temperatures to maintain their stability and effectiveness in shipping boxes without useful or effective insulation or temperature protection. Given the length of time required to ship products from Turkey to the United States, it is alleged that defendants were aware that on many occasions their packages of prescription

drugs arrived in the United States at temperatures outside the constant cold temperature range discussed on the drugs' labeling.² FDA was also able to arrest the United-Kingdom-based distributor of counterfeit and unapproved cancer drugs, who was ultimately sentenced to 18 months imprisonment.³ We have investigated this black market supply chain, including wholesalers based in the United States,⁴ and U.S. pharmacies peddling unapproved foreign and potentially counterfeit drugs, leading to a number of arrests and convictions.⁵ We also investigated and arrested a number of health care providers who knowingly put their patients' health at risk by buying foreign, unapproved cancer medications at a discount, but billing government health care insurance at full price. This included a California oncologist who purchased over \$3.4 million in foreign unapproved cancer drugs,⁶ a Tennessee physician purchasing over \$3 million in foreign unapproved drugs,⁷ seven Ohio physicians purchasing and administering over \$2.6 million in unapproved cancer medications,⁸ a Texas-based oncologist administering over \$1 million in unapproved drugs,⁹ and others.¹⁰

As part of a coordinated effort alongside the criminal investigation, our Center for Drug Evaluation and Research (CDER) issued alerts to the medical community and public at large

² <http://www.fda.gov/ICECI/CriminalInvestigations/ucm383001.htm>

³ <http://www.fda.gov/ICECI/CriminalInvestigations/ucm360652.htm>

⁴ <http://www.fda.gov/ICECI/CriminalInvestigations/ucm360948.htm>
<http://www.justice.gov/usao/cas/press/2012/cas12-0928-BeanandIdrissPR.pdf>

http://www.justice.gov/usao/moe/news/2012/june/behe_sandra.html

<http://www.fda.gov/ICECI/CriminalInvestigations/ucm316986.htm>

<http://www.fda.gov/ICECI/CriminalInvestigations/ucm338637.htm>

<http://www.fda.gov/ICECI/CriminalInvestigations/ucm363279.htm>

<http://www.fda.gov/ICECI/CriminalInvestigations/ucm377434.htm>

⁵ <http://www.fda.gov/ICECI/CriminalInvestigations/ucm378038.htm>

<http://www.fda.gov/ICECI/CriminalInvestigations/ucm380566.htm>

⁶ <http://www.fda.gov/ICECI/CriminalInvestigations/ucm359636.htm>

⁷ <http://www.fda.gov/ICECI/CriminalInvestigations/ucm379431.htm>

⁸ <http://www.justice.gov/usao/ohn/news/2014/29jancan.html>

⁹ <http://www.fda.gov/ICECI/CriminalInvestigations/ucm380564.htm>

¹⁰ <http://www.fda.gov/ICECI/CriminalInvestigations/ucm332118.htm>

<http://www.fda.gov/ICECI/CriminalInvestigations/ucm294706.htm>

<http://www.fda.gov/ICECI/CriminalInvestigations/ucm267356.htm>

about the potential for harm. When we first learned of the issue, we issued a general alert.¹¹ Later, as the scope of the illegitimate distribution chain became more known, we alerted over 1,500 medical practices in the United States that they had purchased or received unapproved drugs—which may have included counterfeit drugs—from foreign suppliers, some of which used wholesalers in the United States to distribute the products. We were also able to alert the medical community about specific wholesalers that the criminal investigation had determined had been selling foreign unapproved drugs.¹² The specialization and coordination between the criminal and regulatory functions of FDA enabled us to respond in an integrated manner to emerging public health threats.

While we recognize that we may not be able to eliminate all problem products from the supply chain, we are committed to making the drug supply chain more secure, keeping illegitimate products out of the U.S. drug supply chain, and tackling the roots of the problem globally.¹³ FDA is reaching beyond our U.S. borders and working with our foreign counterparts to identify global supply chain vulnerabilities as well as identify and implement realistic solutions, nationally and internationally.

FDA has also been working with industry and international partners to develop new methods to address the problem of counterfeit drugs. FDA scientists have developed and have been testing a counterfeit detection device, CD-3, at U.S. ports of entry and elsewhere for use by FDA investigators to check for suspected counterfeit products. CD-3 is a battery-operated, hand-held

¹¹ <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf>

¹² <http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm>;

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/ucm338283.htm>

¹³ In February 2013, IOM issued a report entitled “Countering the Problem of Falsified and Substandard Drugs,” identifying a combination of actions for regulators, industry, and other stakeholders that could reduce counterfeit and substandard drugs domestically and globally.

and inexpensive tool that costs a fraction of the price of existing laboratory-based and field-deployable technologies. It works much like a high-powered flashlight, and does not require special scientific or technical training to operate effectively. Moreover, extensive tests have shown it to be effective in identifying counterfeit products and packaging. The tool has successfully helped to detect counterfeit goods and has been helpful in discovering product tampering and checking questionable documents. FDA is working with Corning Incorporated to refine and improve the tool for eventual manufacturing on a larger scale. Partners in the CD-3 effort include the Skoll Global Threats Fund, U.S. Pharmacopeia (USP), National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the multi-agency President's Malaria Initiative (PMI), led by USAID.

To address threats posed by illegitimate pharmacies operating over the Internet, FDA participates in the annual International Internet Week of Action (IIWA), or Operation Pangea, a global cooperative effort in partnership with international regulatory and law enforcement agencies, to combat the online sale and distribution of potentially counterfeit and illegal medical products. INTERPOL reports that as part of the 2013 annual effort (Operation Pangea VI), the partnership took action against more than 13,700 websites illegally selling potentially dangerous, unapproved prescription medicines to consumers. These actions included the issuance of regulatory warnings and the seizure of offending websites and over \$36 million worth of illegal medicines worldwide.¹⁴ OCI, in coordination with the U.S. Attorney's Office for the District of Colorado, seized and shut down 1,677 illegal pharmacy websites. OCI conducted a number of undercover purchases from these websites, all of which advertised themselves as selling Canadian drugs. The agents, who were able to purchase prescription drugs without a

¹⁴ <http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea>

prescription, received drugs directly from India and Singapore. The drugs were not approved for use in the United States, contained no directions for use, and were often in unfamiliar dosage forms and of unknown quality and purity. None of the drugs, as far as the investigation could tell, ever came through Canada or were subject to Canadian regulation.

GAO recently noted the substantial challenges in the criminal investigation of rogue Internet pharmacy operators, including the increasingly complex nature of the criminal organizations and the difficulties in pursuing investigations and prosecutions of conduct that occur mainly overseas and often span several foreign countries.¹⁵

Nevertheless, OCI has had success in investigating Internet pharmacies. For example, we were able to successfully investigate Andrew Strempler, who ran a website under the RxNorth.com banner. Strempler falsely represented that RxNorth was selling safe prescription drugs in compliance with regulations in Canada, the United Kingdom, and the United States. In fact, he obtained the prescription drugs from various other source countries without properly ensuring the safety or authenticity of the drugs. Some of the drugs sold by Strempler included counterfeit drugs.¹⁶ Another example, the case of Manuel Calvelo, illustrates the inherently international, and thus difficult-to-prosecute nature of Internet pharmacy investigations. Calvelo was a Belgian citizen operating a global Internet pharmacy, with a call center in the Philippines, and a credit card processor in The Netherlands. Calvelo's websites offered for sale more than 40 prescription drugs, including brand names such as Viagra, Depakote, Glucophage, Zoloft, Lipitor, Cialis, Xanax, Ativan and Klonopin. Note that Xanax, Ativan, and Klonopin are

¹⁵ <http://www.gao.gov/assets/660/655751.pdf>, at 19-22.

¹⁶ <http://www.fda.gov/ICECI/CriminalInvestigations/ucm323949.htm>

controlled substances. OCI was able to arrest Calvelo in Costa Rica and extradite him to the United States after an extended undercover operation, in which OCI agents posed as pharmaceutical wholesalers seeking to do business with him.¹⁷

One other investigation, in which we worked with U.S. Immigration and Customs Enforcement, Homeland Security Investigations, involved the selling of counterfeit drugs to U.S. customers by a website that 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, shipped to the United States (via packages whose contents were falsely represented on Customs forms to be something other than pharmaceuticals), and received by U.S.-based confederates, known as drop shippers, who would break down the shipments and then send the U.S. customer a package from a domestic address, giving the appearance that 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 using 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.¹⁸

To further its success in this area, in March 2013, FDA formed a new Cyber Crimes Investigation Unit, a special team within OCI, devoted to combating rogue Internet pharmacies.

¹⁷ <http://www.fda.gov/ICECI/CriminalInvestigations/ucm257945.htm>

¹⁸ <http://www.fda.gov/ICECI/CriminalInvestigations/ucm301685.htm>

This unit works with other domestic and international agencies to track down the operators and suppliers of websites that illegally sell prescription drugs. The agents' methods include high-tech detection in which they follow the cyber-trail of these pharmacies and go undercover to infiltrate the criminal world.

Because of the difficulties in criminal investigation and prosecution, public education is very important as a first-line defense against counterfeit drugs. Health care practitioners who expose patients to unapproved or counterfeit drugs are risking their patients' health. Therefore, the Agency is conducting proactive educational outreach to the medical community and other stakeholders to ensure they have an understanding of how to purchase drugs both legally and safely. It is crucial that they understand why they should not circumvent the safeguards that Federal and state authorities have in place to ensure the purchase of safe and effective prescription drugs. In September 2012, FDA launched a national campaign targeted at patients and health care professionals to raise public awareness about the prevalence of fraudulent Internet pharmacies, called BeSafeRx – Know Your Online Pharmacy. BeSafeRx provides resources for patients and caregivers who might purchase prescription drugs online to enable them to better understand who they are buying from and to help ensure that the drug they buy matches what their doctor prescribed. The campaign provides information about the dangers of purchasing drugs from fraudulent Internet pharmacies, as well as how to identify such pharmacies and how to find legitimate Internet pharmacies.

New Authorities

Recognizing the potential threats posed by the increasingly complex global supply chain, Congress has recently enacted legislation to help address some of the risks posed by counterfeit drugs and other substandard drugs. 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 provides FDA with the authority to administratively detain drugs believed to be adulterated or misbranded, and the authority to destroy certain adulterated, misbranded, or counterfeit drugs offered for import. The law also requires foreign and domestic companies to provide complete information on threats to the security of the drug supply chain and to improve current registration and listing information, making sure FDA has accurate and up-to-date information about foreign and domestic manufacturers.

The recently enacted Drug Quality and Security Act (DQSA) outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.¹⁹ Drug manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) will be called on to work in cooperation with FDA to develop the new system over the next 10 years. Within 10 years after enactment, the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain. The new system will: enable verification of the legitimacy of the drug product identifier down to the package level; enhance detection and notification of illegitimate

¹⁹ In the *Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations*, March 2011, at p. 2 ("White Paper"), the Administration recommended legislation to adopt a track-and-trace system for pharmaceuticals and related products. See http://www.whitehouse.gov/sites/default/files/ip_white_paper.pdf.

product in the drug supply chain; and facilitate more efficient recalls of drug products.²⁰

Manufacturers, wholesale distributors, repackagers, and pharmacies will immediately quarantine and promptly investigate drug products deemed suspect or illegitimate for potentially being counterfeit, unapproved, or dangerous, such as a recalled drug product; they will alert FDA to these findings. The system will improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

Remaining Challenges

Despite recent successes, the continued threat of counterfeits in the United States and the 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 to better protect against counterfeit drugs.

While the new authorities under DQSA and FDASIA help address some of the risks posed by counterfeit drugs, they will not prevent all types of illegal diversion or distribution schemes that FDA has discovered in recent years. For example, FDA has uncovered numerous instances of medical practitioners deliberately obtaining unapproved drugs—some which have been counterfeits—directly from foreign sources for administering to patients. These laws would not prevent situations where consumers purchase drugs from rogue Internet websites or where a pharmacy purchases product from outside the legitimate supply chain and dispenses directly to a patient.

²⁰ Under current law, recalls are voluntary as FDA does not have the authority to issue mandatory recalls of drug products.

Given the high profit potential of trafficking in counterfeit and unapproved drugs and the relatively low penalties for non-compliance, bad actors still have incentives to find ways to circumvent the new requirements. The reality is that the criminal penalty for the risky and inherently dangerous practice of importing unapproved foreign drugs is simply not sufficient to deter the criminal element. The penalty for such conduct, which generally falls under the “misbranding” and “unapproved new drugs” provisions of the FD&C Act, is three years imprisonment, and only if the Government can show that there was a specific intent to defraud or mislead. Otherwise, it is a misdemeanor, punishable only by a maximum of one year imprisonment.

The penalties for health and safety violations for distributing unapproved or misbranded drugs have not been revised in decades and are substantially less severe than penalties for violations relating to intellectual property or economic loss. Title 18 Counterfeiting, designed to protect the trademark holder, carries with it a 20-year maximum penalty for counterfeit pharmaceuticals. However, risky conduct such as trafficking in foreign unapproved or adulterated drugs, carrying with it the same risk to the public health, is subject to a one- or three-year penalty—same risk to public health, dramatically different results.²¹

For example, this summer, a Utah man was convicted of trafficking in Internet sales of various pharmaceuticals unapproved for distribution in the United States. He obtained these drugs from a variety of international sources, with no idea as to whether the medicines were counterfeit or substandard or how they were stored. Because of the nature of the investigation, we had no way

²¹ See *White Paper*, at 2, recommending an increase in the statutory maxima under the FD&C Act. See also, *Administration’s Counterfeit Pharmaceutical Inter-Agency Working Group Report to the Vice President of the United States and the Congress*, at 17. http://www.whitehouse.gov/sites/default/files/ip_white_paper.pdf, and Inter-Agency Working Group Report.

of proving whether the drugs were counterfeit or adulterated, because they had already been distributed to unsuspecting American consumers, but the sketchy supply chain and the high-value nature of the drugs dramatically increased the odds that they were. This man shipped over \$5 million of unapproved drugs, but because of the restrictive nature of the statutory scheme, received only a one-year sentence.²² There is some evidence that increasing penalties can have an important and beneficial impact. The GAO noted that the Ryan Haight Act, which substantially increased penalties for online distribution of controlled substances, has significantly reduced the extent to which controlled substances are sold online.²³

There are additional lessons that can be learned from law enforcement's experiences with the Ryan Haight Act. In addition to its penalty provisions, the Ryan Haight Act was also important because it set forth, for the first time under Federal law, the definition of a "valid prescription" with regard to controlled substances. Many online pharmacies sell prescription drugs that are not controlled substances under Federal law. These drug sales are regulated under the FD&C Act and require a valid prescription, but the FD&C Act does not define what constitutes a valid prescription. In the online pharmacy context, where numerous doctors and their respective customers are often located in different states, this can complicate criminal prosecution under the FD&C Act.²⁴

CONCLUSION

Given the challenges and threats posed by an increasingly globalized marketplace, it is important that

²² <http://www.fda.gov/ICECI/CriminalInvestigations/ucm363279.htm>

²³ <http://www.gao.gov/assets/660/655751.pdf>, at 30.

²⁴ In the Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations, the Administration recommended extending the Ryan Haight Act's definition of a "valid prescription" to the FD&C Act. See White Paper, at 13, http://www.whitehouse.gov/sites/default/files/ip_white_paper.pdf.

FDA, regulatory and law enforcement partners, and industry continue to work together to address the problem and threat of counterfeit drugs, and that we continue to ensure authorities keep pace with the complex system that counterfeiters and traffickers take advantage of. 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.