



U.S. Immigration and Customs Enforcement

STATEMENT

OF

LEV KUBIAK
DIRECTOR

NATIONAL INTELLECTUAL PROPERTY RIGHTS
COORDINATION CENTER

HOMELAND SECURITY INVESTIGATIONS
U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT

REGARDING A HEARING ON

“COUNTERFEIT DRUGS: FIGHTING ILLEGAL SUPPLY CHAINS”

BEFORE THE

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

Thursday, February 27, 2014 – 10:00 a.m.
2322 Rayburn House Office Building

Introduction

Chairman Murphy, Ranking Member DeGette, and distinguished members of the Subcommittee:

On behalf of the Department of Homeland Security (DHS), thank you for the opportunity to testify before you today to discuss the efforts of U.S. Immigration and Customs Enforcement (ICE) to combat the illegal importation and sale of counterfeit, unapproved, and/or adulterated pharmaceuticals.

ICE primarily consists of two operational programs: Enforcement and Removal Operations (ERO) and Homeland Security Investigations (HSI). Guided by ICE's prioritized enforcement principles, ERO identifies and apprehends criminal and other removable aliens, detains these individuals, and, removes individuals who are illegally present (or otherwise subject to removal) from the United States. HSI is responsible for a wide range of domestic and international criminal investigations arising from the illegal movement of people and goods into, within, and out of the United States, often in coordination with other federal agencies.

ICE's Role

ICE has a legacy of engagement in enforcement against intellectual property (IP) crime that spans from our past as U.S. Customs Service investigators to our present role as Homeland Security investigators. ICE is the lead agency in the investigation of intellectual property violations involving the illegal importation and exportation of counterfeit merchandise and pirated works, as well as associated money laundering violations. In coordination with U.S. Customs and Border Protection (CBP), we target and investigate counterfeit merchandise

and pirated works and we seize and forfeit goods associated with these investigations, such as those that infringe on trademarks, trade names, and copyrights. Investigating counterfeit pharmaceuticals falls within ICE's broad IP mandate.

ICE recognizes that no single U.S. law enforcement agency alone can succeed in the fight against IP crime. Rather it is essential that all relevant federal agencies work together and with IP industry partners to confront this challenge. Furthermore, law enforcement efforts alone will not fully address this growing problem. Indeed, public education, demand reduction, and global collaboration are critical to the success of this effort. To focus government efforts and to enhance efficiency, the former U.S. Customs Service, now known as ICE, formed the National Intellectual Property Rights Coordination Center (IPR Center), which combats violations of intellectual property rights, with a focus on trademark and copyright infringement.

Pursuant to the Prioritizing Resources and Organization for Intellectual Property Act of 2008 (Pro-IP Act, Public Law 110-403), U.S. government-wide intellectual property enforcement is coordinated by the White House Office of the U.S. Intellectual Property Enforcement Coordinator (IPEC), which is responsible for strategic planning and coordinating Federal efforts to address IP infringement. The IPR Center collaborates regularly with IPEC on IP policy issues.

The IPR Center

The former U.S. Customs Service established the IPR Center in 1999, but following the events of 9/11, priorities were necessarily shifted and the IPR Center could not be adequately staffed. ICE rejuvenated the IPR Center in 2008, and it now stands at the forefront of the U.S. Government's law enforcement response to global intellectual property theft.

The mission of the IPR Center is to address the theft of innovation that threatens U.S. economic stability and national security, undermines the competitiveness of U.S. industry in world markets, and places the public's health and safety at risk. The IPR Center brings together many of the key domestic and foreign investigative agencies to efficiently and effectively leverage resources, and promotes the skills and authorities to provide a comprehensive response to IP crime.

The IPR Center, located in Arlington, Virginia, operates on a task force model and is comprised of 21 relevant federal and international partners. While I serve as the Director of the IPR Center, I work with Deputy Directors from both CBP and the Federal Bureau of Investigation (FBI). The IPR Center includes embedded team members from: HSI, CBP, the Food and Drug Administration (FDA), the FBI, the U.S. Postal Inspection Service (USPIS), the Department of Commerce's International Trade Administration and U.S. Patent and Trademark Office, the Defense Criminal Investigative Service, the U.S. Consumer Product Safety Commission (CPSC), the National Aeronautics and Space Administration (NASA), the Naval Criminal Investigative Service, the Army Criminal Investigative Command Major Procurement Fraud Unit, the U.S. Air Force Office of Special Investigations, the Nuclear Regulatory Commission, the U.S. Department of State's Office of International Intellectual Property Enforcement, the Defense Logistics Agency, and the Inspector General's Office from the General Services Administration.

In 2010, the Government of Mexico and INTERPOL joined the IPR Center as our first international partners. Since then, the Royal Canadian Mounted Police and Europol have joined as partners as well. While the Department of Justice (DOJ) is not a formal partner at the IPR

Center, trial attorneys from the Computer Crime and Intellectual Property Section (CCIPS) regularly provide input on ongoing enforcement operations and policy.

Protecting Health and Safety

The illegal importation, distribution and sale of counterfeit pharmaceuticals pose a significant and growing threat to public health and safety. Working collaboratively with our law enforcement partners, the IPR Center has developed numerous initiatives and interdiction efforts to combat the infiltration of counterfeit, unapproved, and/or adulterated drugs entering the United States through a variety of means, including ports of entry, international mail facilities and express courier hubs. Our strategy is to attack the entire international supply chain, from manufacturer to distribution point and identify, disrupt, and dismantle the international criminal networks responsible for distributing counterfeit pharmaceuticals, by seizing the counterfeit product, criminal proceeds, and assets facilitating the crime, and bringing the individuals responsible for the criminal activity to the justice system to hold them accountable for their actions. This strategy requires a robust collaboration through our Attaché network with foreign counterparts where the majority of counterfeit items are made or through which they are transshipped en route to the United States and all of our trading partners worldwide.

Operation Guardian

Operation Guardian (Guardian) is the IPR Center's public health and safety initiative. Guardian was initiated in October 2007 in response to the Interagency Working Group on Import Safety and several incidents in which hazardous imports into the United States caused serious public safety concerns.

In developing Guardian, HSI, through the IPR Center, solicited the assistance of numerous law enforcement and regulatory agencies, including CBP, FDA, USPIS, DOJ CCIPS, CPSC, and the U.S. Department of Agriculture (USDA). These agencies formed a Headquarters Working Group to target high-risk commodities from foreign sources. The template we use today for surge group operations is based on the findings of this working group.

Since the inception of Guardian in fiscal year (FY) 2008, HSI has initiated 916 investigations resulting in 334 criminal arrests, obtained 419 indictments, secured 288 convictions, and worked with CBP to make more than 3,000 seizures valued at over \$195 million (based on the Manufacturers Suggested Retail Price (MSRP) for the items if genuine).

Operation Apothecary

Operation Apothecary (Apothecary), which falls under the auspices of Operation Guardian, works to combat the growing use of the Internet in illegal drug distribution. Criminals, posing as legitimate pharmaceutical providers, use the Internet to advertise purportedly FDA-approved prescription drugs, and/or less expensive unapproved foreign alternatives, all without requiring a valid prescription. The consumer purchases the pharmaceutical with the belief that the product advertised is a legitimate product, but in fact, is often purchasing a counterfeit or unapproved version of the drug manufactured under unknown conditions or not subjected to any safeguards or quality control regimes. Apothecary addresses, measures, and attacks potential vulnerabilities in the entry process to attack the smuggling of commercial quantities of counterfeit, unapproved, and/or adulterated drugs through the Internet, international mail facilities, express courier hubs, and land borders.

Through Apothecary, participants detect, seize and forfeit commercial shipments of illegally sold, shipped, and/or imported pharmaceuticals and scheduled drugs. The ultimate goal of Apothecary is to identify and dismantle domestic and foreign organizations that illegally sell, ship, import and/or distribute pharmaceuticals and scheduled drugs in the United States.

In support of the Apothecary mission, IPR Center personnel coordinated and conducted periodic enforcement surges in conjunction with ICE, CBP, FDA and USPIS at international mail facilities and express courier hubs throughout the United States. Since FY 2010, as part of Apothecary, HSI has arrested 115 individuals and obtained 112 indictments resulting in 99 convictions. There also have been 1,048 seizures worth approximately \$20 million (MSRP).

Operation Pangea

Websites offering counterfeit pharmaceuticals are a growing global phenomenon in the area of IP crime. Patients and consumers around the world are suffering from the negative side effects of counterfeit medications, which often contain unapproved, dangerous, substandard products. In response, Operation Pangea was organized by INTERPOL, with participation by ICE, CBP, FDA, and USPIS, to target the advertisement, sale, and distribution of counterfeit drugs and medical devices that threaten worldwide public health and safety.

Conducted on a yearly basis, the intent of each Pangea operation is to build upon global best practices identified from previous operations and collectively develop a collaborative worldwide approach to combat the illegal trade of counterfeit and illicit medical products, particularly products that represent a serious risk to public health. In addition to the individual countries participating in Pangea, other major international organizations have joined the effort as well, including the Universal Postal Union and the World Customs Organization (WCO).

In 2013, nearly 100 countries participated in Pangea VI, which resulted in 213 arrests worldwide and the seizure of more than 10 million potentially dangerous medicines worth approximately \$36 million. More than 13,763 websites linked to illicit online pharmacies were identified and shut down, in addition to the suspension of payment facilities of illegitimate pharmacies. Worldwide, approximately 534,562 packages were inspected by customs and regulatory authorities, of which 41,954 were seized. Among the fake medicines seized during Operation Pangea were antibiotics, cancer medication, anti-depression pills, and erectile dysfunction medication, in addition to illegal products labeled as dietary supplements.

Other Interagency Efforts

ICE shares its border security and trade mission responsibilities with its sister agency, CBP¹. Therefore, ICE and CBP work closely to target counterfeit pharmaceuticals and other illicit goods crossing the borders, including through the co-location of personnel at the first Trade Enforcement Coordination Center (TECC). In May 2012, ICE and CBP formed the first TECC in Los Angeles, which services the Ports of Long Beach and Los Angeles. The TECC enhances communication and combines resources to identify and combat trade fraud and IP crime, including counterfeit pharmaceuticals. The TECC proactively identifies, interdicts, and investigates inbound cargo that may enter the U.S. commerce in violation of U.S. customs and trade laws. TECCs ensure joint CBP and ICE oversight and prioritization of the enforcement and interdiction process in the local area, and involve ICE early in the enforcement process. The

¹ CBP has broad authority to act against imports that violate U.S. laws and is the primary federal agency responsible for securing America's borders and facilitating lawful international trade and travel.

ICE is the principal investigative arm of DHS. ICE's primary mission is to promote homeland security and public safety through the criminal and civil enforcement of federal laws governing border control, customs, trade and immigration.

TECC concept is under development to be expanded to other ports of entry, with the next in Port Elizabeth, New Jersey, which will service ICE and CBP in New York City and Newark.

ICE also collaborates closely with personnel at CBP's Centers of Excellence and Expertise (CEE), including their CEE focused on pharmaceuticals, the Commercial Targeting and Analysis Center, and through the creation of the HSI-led National Targeting Center – Investigations (NTC-I). CBP established the CEE as a central point of contact for inquiries and resolution of issues regarding pharmaceutical, health and chemical imports. By having a central point of contact for importer participants at the CEEs, CBP is able to increase uniformity of practices across ports of entry, facilitate the timely resolution of trade compliance issues nationwide, and further strengthen critical agency knowledge on key industry practices. The CTAC is a CBP facility designed to streamline and enhance federal efforts to address import safety issues by improving communication and information-sharing and reducing redundant inspection activities. The NTC-I is a CBP and HSI collaboration to enhance the current partnership with the existing CBP equities at the NTC-Passenger and NTC-Cargo and ICE's Trade Transparency Unit. The cornerstone of the NTC-I is enhance and support ongoing HSI investigations, provide quality investigative referrals and intelligence to HSI field offices, and expand current collaboration with CBP.

ICE participates in several other interagency efforts to protect the health and safety of the public, including through initiatives led by the Intellectual Property Enforcement Coordinator (IPEC). For example, ICE played a significant role in helping develop the IPEC's 2013 Joint Strategic Plan on Intellectual Property Enforcement and the Counterfeit Pharmaceutical Inter-agency Working Group Report to the Vice President and Congress, and is carrying out the pertinent recommendations in those reports. Through the IPEC, the U.S. Government is

pursuing an innovative and multi-pronged strategy to combat infringing foreign-based and foreign-controlled websites by encouraging cooperation by law enforcement, development of voluntary best practices, and international leadership. The IPR Center shares the investigative outcomes and trend information that we obtain with interagency partners and the IPEC to further inform their policy development, including strategic plans, the U.S. Trade Representative's Special 301 Process and the Administration's legislative recommendations.

ICE's International Efforts

ICE-HSI International Operations represents DHS's largest investigative law enforcement presence abroad and strongest protection beyond the border. HSI-International Operations has the broadest international footprint in DHS with 67 offices in 48 countries, which includes representatives at eight Department of Defense Unified Combatant Commands, staffed by nearly 400 personnel.

Cooperation with our international law enforcement partners is critical in combatting copyright and trademark infringement overseas and effectively protecting and enforcing American intellectual property rights holders. U.S. Government Attachés in a number of agencies, including HSI, Department of Justice, FDA, and the U.S. Patent and Trademark Office, work with international organizations and foreign law enforcement counterparts to build capacity, strengthen relationships, and conduct joint enforcement activities. ICE, as the world's largest customs investigative entity, is recognized as a worldwide subject matter expert on criminal customs matters, and holds the Chair for the Enforcement Committee within the WCO, an international organization that shares best practices among Customs officials and seeks multilateral cooperation to address emerging threats.

Our efforts to work with our international counterparts have resulted in numerous successful IP enforcement efforts. For example, in September 2013, Martin Paul Bean, III, of Boca Raton, Florida was sentenced to two years in federal custody for operating an illicit pharmaceutical scheme out of his home that sold more than \$7 million worth of unapproved and misbranded oncology drugs. The HSI and FDA investigation began in early 2010 after law enforcement authorities from the United Kingdom's Medicines and Healthcare Regulatory agency advised U.S. authorities they had intercepted a shipment of an unapproved form of an oncology drug sent from a company in Pakistan to Oberlin Medical Supply in San Diego. Bean ordered the unapproved drugs from foreign sources in Turkey, India, and Pakistan and sold the drugs to doctors in the United States at substantially discounted prices. The FBI and the U.S. Postal Service also assisted with the investigation as well.

In August 2012, the IPR Center, HSI Attaché Brazil, the Brazilian Federal Highway Police, Brazilian Customs, the Brazilian Health Agency, and local police participated in a two day IP crime training. Following the training, federal law enforcement officers in Brazil initiated a five day operation at highways connecting the Tri-border region to Sao Paulo. The operation resulted in 36 arrests, and the seizure of counterfeit goods valued at approximately \$2.4 million. The goods included counterfeit pharmaceuticals, 490 kilograms of marijuana, six guns, and 38 vehicles, and the equivalent of \$86,000 in United States currency.

The IPR Center successfully brings together members of industry, state and local partners, federal government and international counterparts to train, exchange best practices and ultimately remove counterfeit and pirated products from the marketplace and put the criminals behind them in jail.

Challenges Ahead

I am regularly asked what challenges lie ahead in IP crime enforcement -- what tools or new laws are needed. As ICE conducts multiple enforcement operations, some of which I described above, we observe trends in IP crime and we have made a number of critical observations.

Our biggest challenge is that criminals are now willing to counterfeit and market any product that will sell, regardless of whether it could result in serious and significant injury to consumers or the public. ICE has investigated cases involving counterfeit toothpaste that contained a component found in antifreeze. In May 2013, following a probe by HSI, with assistance from CBP, an Argentine man was sentenced to a year in prison for conspiracy to distribute a controlled substance, including several drugs used to treat anxiety (e.g., Lorazepam, Diazepam, and Alprazolam); Ketamine, which is used for inducing anesthesia; and Sibutramine, an anorexiant not available in the United States. When HSI searched a storage unit and apartment rented by the defendant they discovered nearly 60 boxes containing more than 700,000 prescription tablets and thousands of empty pill bottles and bottles with labels, as well as a computer containing spreadsheets documenting sales of pharmaceuticals to customers throughout the United States. CBP laboratory analysis revealed many counterfeit or unapproved drugs with and without active substances. Some subject tablets were observed to be severely under-potent or containing the incorrect drug substance.

The IPR Center recognizes that law enforcement efforts alone are not enough to succeed in the fight against intellectual property crime. Rather it is essential that all relevant federal

agencies work together with industry to confront this challenge. Furthermore, public education, demand reduction, and global collaboration are critical to the success of this effort.

To help educate consumers on emerging dangers of counterfeit products and facilitate productive partnerships with the public and private sectors, the IPR Center launched Operation Joint Venture. This effort is designed to increase support, communication, and cooperation for our ongoing IPR enforcement initiatives and our critical public health and safety efforts.

Operation Joint Venture is the IPR Center's method to provide industry with valuable information about our efforts to combat the importation of hazardous and counterfeit products, and it gives industry a point of contact they can use to provide us with leads and tips regarding efforts to compromise intellectual property rights. Also, we have developed a website, www.iprcenter.gov, where the public can obtain information on the efforts of all IPR Center partner agencies to combat IP crime and we have placed a button on the website where consumers can report allegations of counterfeit or pirated products.

Criminals' use of the Internet also poses a significant challenge to law enforcement. When a criminal never has to meet his victim face-to-face, but can hide behind what appears to be a legitimate site, consumer fraud can run rampant. Criminal networks are becoming increasingly sophisticated in conducting fraud over the Internet, which in return requires us to have sophisticated cyber investigators. Increasingly, criminal networks using multiple servers located in different countries across the world, including countries that may not be willing to cooperate with the United States on law enforcement issues, has created a challenge for criminal investigators because of the complexity of collecting electronic evidence. Approximately 250 of ICE's nearly 7,000 agents are trained and classified as Computer Forensic Agents (CFAs). These CFAs are essential to IPR Center efforts to combat counterfeit pharmaceuticals. A recent

Operation In Our Sites² enforcement action saw the deployment of five percent of ICE's CFAs on one day to secure the electronic evidence from just nine websites, and they will be heavily involved in sorting through the evidence for potential prosecutions.

Additionally, while ocean-crossing shipping containers are necessary to move bulk quantities of counterfeit items such as handbags, shoes, batteries or holiday lights, other high value items, including counterfeit pharmaceuticals, are being smuggled in smaller quantities through mail and/or express courier parcels. IP thieves are taking advantage of the lack of advance information or formal entry process at mail and courier facilities to smuggle products into the United States. ICE is working closely in tandem with CBP to improve targeting, information sharing, and adopting best practices to ensure that our limited resources are focused on finding the most egregious violators.

Finally, IP cases demand attention from criminal investigators and regulatory agencies. At a recent industry open house hosted by the IPR Center, more than 15 diverse industries were represented that collectively employ hundreds of thousands of Americans and produce substantial revenue in sales and taxes. This included pharmaceutical companies, electronics manufacturers, luxury goods corporations, software and electronic game developers, footwear and apparel producers, and entertainment conglomerates. Each of these industries makes a compelling case for government assistance in IP crime enforcement. We take our responsibility to these companies and their employees and most importantly, to the U.S. consumers very seriously. While ICE is committed to working with each of these industries and others who want

² Operation In Our Sites identifies, targets and seizes Internet domain names that defraud U.S. consumers and businesses by trafficking infringing goods, pursues assets and criminally prosecutes principals. In Operation In Our Sites, HSI and DOJ pursue the seizure and civil forfeiture of domain names under 18 U.S.C. § 981, civil forfeiture, which is the same authority used to seize tangible property or assets used in the commission of crimes.

to cooperate with us on this issue, due to limited resources, ICE's priorities in IP crime enforcement remain to protect health and safety, the military supply chain, and the American economy.

Conclusion

Thank you once again for the opportunity to appear before you today to discuss the work of ICE and the IPR Center in protecting U.S. consumers from dangerous counterfeit, unapproved, and/or adulterated pharmaceuticals. This is an issue of critical importance as it directly threatens worldwide health and safety.

I would be pleased to answer any questions that you may have at this time.