



U.S. Immigration and Customs Enforcement

STATEMENT

OF

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**U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT
DEPARTMENT OF HOMELAND SECURITY**

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AND HUMAN RESOURCES**

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INTRODUCTION

Good afternoon Chairman Souder, Ranking Member Cummings and distinguished members of this Subcommittee. My name is Kevin Delli-Colli and I am the Deputy Assistant Director for Financial and Trade Investigations at U.S. Immigration and Customs Enforcement (ICE). I am pleased to appear before you today to speak about the ICE role in investigating individuals and groups involved in the trafficking of counterfeit pharmaceuticals. I will submit a statement for the record, and will make a brief oral statement.

In January 2004, ICE in San Diego initiated a multi-agency investigation that incorporated assets from ICE, the Food and Drug Administration (FDA), U.S. Postal Inspection Service, Internal Revenue Service and Federal Bureau of Investigation (FBI), and which targeted various websites, Internet payment networks and pharmaceutical supply chains. The targets of this investigation used more than 650 affiliated websites to distribute more than \$25 million in counterfeit or unapproved pharmaceuticals within a three-year period. The distribution network extended throughout all of North America and the source country, India, was disguised by transshipping the product through other countries. To date, this investigation has resulted in 20 indictments, 18 convictions, and the seizure of \$1.4 million. Mark Kolowich, the primary violator, was sentenced in January 2005 to 51 months imprisonment. Prosecution of other defendants is ongoing. This case highlights many of the challenges confronting U.S. law enforcement in combating the trafficking of counterfeit pharmaceuticals.

THE ICE MISSION

As the largest investigative arm of the Department of Homeland Security, ICE plays a leading role in targeting the criminal organizations responsible for producing, smuggling, and distributing counterfeit products, including counterfeit pharmaceuticals. ICE investigations focus not only on keeping these products from reaching U.S. consumers, but also on dismantling the criminal organizations that initiate, support and sustain this activity.

There are powerful new tools in the ICE arsenal of border security authorities, which were included in the recently passed reauthorization of the USA PATRIOT Act. The potential sentence for a violation of 18 USC 545 – Smuggling into the United States, was increased from five years to twenty years. That legislation also added, for the first time, an entirely new criminal charge for smuggling from the United States.

By providing ICE with the additional tools necessary to more effectively investigate and combat smuggling and other violations, Congress has simultaneously strengthened ICE's ability to combat violent criminal and terrorist organizations. The special agents who work these important economic, border, homeland and national security cases thank the Congress for this enhancement in 18 U.S.C. 545 and for its continuing strong support of ICE and our important mission.

PHARMACEUTICALS INVESTIGATIONS and ENFORCEMENT

ICE smuggling investigations have shown that the Internet has become the primary tool used by organizations engaged in the trafficking of counterfeit pharmaceuticals, whether for advertisement, direct sales or communication. Individuals who previously would have purchased controlled or prescription pharmaceuticals through an underground supplier now use the Internet to locate a source for these drugs, place orders, arrange shipments and make payments.

To date, ICE investigations have not revealed any instances in which smuggled, counterfeit pharmaceuticals were destined for the legitimate U.S. supply chain; rather, trafficking organizations have created an illicit, unregulated supply chain that is filled with counterfeit, adulterated, misbranded and unsafe drugs which are distributed directly to consumers, who in most instances are drug abusers. China and India have been the most prolific source countries for a variety of counterfeit pharmaceuticals, although Mexico, Thailand, and Brazil are also source countries. Other countries serve as transshipment points, locations for web servers, channels for payment processors, and sources for obtaining active primary ingredients.

ICE addresses the threat posed by counterfeit pharmaceuticals in several ways. ICE has a cadre of dedicated and trained special agents assigned to the 26 ICE Special Agent in Charge offices across the nation, who specialize in investigating counterfeiting violations. ICE also draws heavily upon relationships with law enforcement partners throughout the

world. ICE special agents are deployed to 56 overseas Attaché offices, which makes it possible for ICE to effectively conduct global investigations.

ICE agents in the United States and abroad also work closely with the ICE Cyber Crimes Center (C3) to combat the problem of counterfeit pharmaceutical violations over the Internet. C3 is a state-of-the-art center designed exclusively for conducting computer-based investigations and providing expertise, computer forensics and investigative tools to investigators targeting Internet violations.

ICE also hosts the National Intellectual Property Rights Coordination Center, which maintains an on-going, open dialogue with the pharmaceuticals industry to exchange information and to serve as the primary point of contact for law enforcement referrals.

Another way in which ICE combats pharmaceuticals smuggling is through targeted operations such as Operation Apothecary. ICE initiated this operation to target and dismantle organizations involved in the illegal importation of commercial quantities of illicit pharmaceuticals. This initiative concentrates on illegal foreign- and domestic-based pharmacies and organizations involved in the smuggling and distribution of counterfeit prescription drugs and controlled substances. As part of Operation Apothecary, ICE agents conduct enforcement actions, in conjunction with CBP, FDA and DEA, at international mail facilities and express courier hubs to target and examine packages containing falsely declared or undeclared pharmaceuticals. ICE uses the

information obtained from these examinations to identify and target foreign sources, domestic organizations and recipients involved in such criminal activity.

Since 2003, ICE has initiated 178 criminal investigations of pharmaceutical smuggling. To date, these investigations have led to 86 arrests, 95 indictments and 34 convictions. Millions of dosage units of counterfeit, adulterated, misbranded and unapproved pharmaceuticals have been seized. ICE also conducts parallel asset identification and removal investigations, in conjunction with criminal investigations. ICE strives not only to put the criminals in jail, but also to remove the profit incentive.

ICE also participates in the Interagency Pharmaceuticals Task Force, which is composed of CBP, ICE, FDA, the Department of Justice (including the DEA), the Office of National Drug Control Policy, and the United States Postal Service (USPS). This task force fosters mutual cooperation among the responsible agencies in the regulation and enforcement of laws governing prescription drugs that are illegally being imported via mail and courier facilities.

WORKING WITH CHINA

ICE has actively engaged the Chinese Ministry of Public Security to conduct investigations of mutual interest. This dialogue led to the first two joint U.S. - China enforcement actions ever to take place in the PRC. One of these investigations began in February 2005, when the ICE Attaché Beijing received information that Richard Cowley of Shelton, Washington, was linked to groups of individuals involved in the sale of

pharmaceuticals in the United States and Europe. This information led to the initiation of Operation "Ocean Crossing", which targeted counterfeit pharmaceuticals being distributed via the Internet. ICE special agents, acting undercover, met with Cowley and learned the identity of his supplier in the PRC. Information from this investigation was shared with Chinese authorities, who then took action against the largest counterfeit pharmaceutical operation in China. ICE special agents traveled to China to assist in the coordination of joint enforcement actions. A total of 12 Chinese nationals were arrested, and three illicit pharmaceuticals facilities were shut down during joint enforcement actions in August and September 2005. The Chinese seized finished counterfeit drugs, raw materials and production machinery worth approximately \$5 million. Cowley was arrested in the United States while the second raid was underway in China; he eventually pled guilty to importing counterfeit drugs and is awaiting sentencing. This case is an excellent example of the value of cooperation and information sharing in combating transnational pharmaceuticals trafficking. We at ICE believe that this mutual cooperation will continue to produce significant results.

CONCLUSION

ICE will continue to aggressively apply our authorities to combat the transnational organizations that traffic in counterfeit pharmaceuticals. This concludes my remarks and I would be pleased to answer your questions.

