



U.S. Immigration and Customs Enforcement

STATEMENT

OF

KEVIN DELLI-COLLI

**DEPUTY ASSISTANT DIRECTOR
FINANCIAL & TRADE INVESTIGATIONS DIVISION**

OFFICE OF INVESTIGATIONS

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

BEFORE THE

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

REGARDING

**“CHINA’S IPR ENFORCEMENT; MOVEMENT OF COUNTERFEIT AND
PIRATED GOODS INTO THE U.S. AND THEIR DANGERS – A GOVERNMENT
PERSPECTIVE ON THE PHARMACEUTICAL INDUSTRY**

**WEDNESDAY, JUNE 7, 2006, 2:45 PM
WASHINGTON, D.C.**

385 RUSSELL SENATE OFFICE BUILDING

INTRODUCTION

Good afternoon Chairman Wortzel, Vice Chairman Bartholomew and distinguished members of this Commission. 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 intellectual property violations and trafficking in counterfeit pharmaceuticals. I have a statement, which I will submit for the record, and will make a brief oral statement.

- In January 2004, the ICE SAC/San Diego initiated a multi-agency investigation incorporating assets from ICE, the Food and Drug Administration, U.S. Postal Inspection Service, IRS and FBI, targeting various websites, Internet payment networks and pharmaceutical supply chains. The targets, *WorldExpressRx.com* and *MyRxForLess.com*, had in excess of 650 affiliated websites responsible for the illegal distribution via the Internet of more than \$25 million in counterfeit or unapproved pharmaceuticals in a three year period. The distribution network extended throughout the U.S., and into Mexico and Canada. The source country of the pharmaceuticals was India, and the drugs were transshipped through the Caribbean and United Kingdom to disguise their origin. To date, this investigation has resulted in 20 indictments and 18 convictions for various federal criminal charges. The primary violator, Mark Kolowich, was sentenced in January 2005 to 51 months imprisonment. More than \$1.4 million was seized. Prosecution of violators related to this investigation continues. This case

represents the scope and challenges confronting US 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 criminal organizations responsible for producing, smuggling, and distributing counterfeit products, including counterfeit pharmaceuticals. ICE investigations focus not only on keeping these products off U.S. streets, but also on dismantling the criminal organizations that initiate, support and sustain this activity.

INTELLECTUAL PROPERTY RIGHTS ENFORCEMENT

Information gleaned from numerous ICE investigations reveals that China has been a significant source of supply for a variety of counterfeit pharmaceuticals, although it is certainly not the only source country. China has also been a channel for payment processors, a source for obtaining active pharmaceutical ingredients (API), a transshipment point, and a source of gray market distribution. In some instances, web hosting companies and servers containing information of great value to investigations, such as online communications, customer lists and financial records, have been located in China, but again, China is not the only country to play such a role in these cases.

ICE addresses the threat posed by counterfeit pharmaceuticals trafficking 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 our relationships with law enforcement partners around the world. We are able to do that because of ICE's global presence. Our special agents are deployed to 56 overseas Attaché offices. This global reach and our preexisting relationships with foreign law enforcement make it possible for ICE to effectively conduct IPR investigations around the world.

Another key to our investigative efforts at ICE is the strong support provided by our partners at U.S. Customs and Border Protection (CBP). By virtue of CBP's interdiction and regulatory mission on the nation's physical borders, that agency provides the many of investigative referrals that launch ICE counterfeiting investigations.

The National Intellectual Property Rights Coordination Center (IPR Center), which is hosted by ICE, was created in 2000 and is staffed with agents and analysts from ICE and the Federal Bureau of Investigation. CBP also works closely with the IPR Center. The IPR Center coordinates the U.S. government's domestic and international law enforcement attack on IPR violations. The IPR Center serves as the primary liaison between private industry and law enforcement in targeting IPR crimes. This is very important in counterfeit pharmaceuticals cases because industry is often the first to know about these violations. ICE maintains an on-going, open dialogue with the pharmaceuticals industry to identify these cases.

ICE agents in the United States and abroad work closely with the ICE Cyber Crimes Center to combat the problem of piracy and related IPR violations over the Internet. The

Cyber Crimes Center is ICE's state-of-the-art center for computer-based investigations, providing expertise and tools to help agents target Internet piracy. The Internet has become a tool that is used by organizations engaged in trafficking counterfeit pharmaceuticals. ICE targets the illegal importation of commercial shipments of legitimate, re-directed or unapproved pharmaceuticals via the operation of rogue Internet websites and affiliates operated for the sole purpose of making money with complete disregard for the safety and health of the American Public.

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

WORKING WITH CHINA

ICE has recent investigative successes in counterfeiting investigations that were conducted in cooperation with Chinese officials:

- In September 2003, ICE Gulfport, Mississippi, began an investigation, known as "Operation Spring," which grew to include the ICE Attaché in China, the ICE Office of Investigations in Houston, the IPR Center and the Internal Revenue Service. Chinese law enforcement soon joined the investigation, turning the case into the first undercover investigation conducted jointly by U.S. and Chinese

authorities. In July 2004, with the assistance of ICE agents, Chinese officials arrested Randolph Guthrie and several co-conspirators in China. Guthrie was considered by the Motion Picture Association of America to be the largest distributor of pirated DVD movies in the world, with sales over \$2 million annually. At the time of Guthrie's arrest, Chinese officials seized approximately 160,000 counterfeit DVDs valued at approximately \$3.5 million (U.S.) and the equivalent of approximately \$200,000 in U.S. and Chinese currency. In April 2005, Guthrie was convicted in a Shanghai court on criminal charges. He was sentenced to a jail term of 30 months in China, issued a fine of 500,000 Chinese Renminbi (equivalent to \$62,500 U.S.), and ordered deported from the country upon completion of his sentence. In late September 2005, Chinese authorities expelled Guthrie to the United States where he was arrested by ICE. He pled guilty in January 2006 and forfeited more than \$800,000. In March 2006, Guthrie was sentenced to 60 months in prison and 3 years of supervised release, and was fined \$15,000.

- In February 2005, 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, the United Kingdom and other locations throughout Europe. This information led to the initiation of Operation Ocean Crossing, the second joint undercover enforcement operation with the Chinese. This operation targeted counterfeit pharmaceuticals being distributed via the Internet. In September 2005, Chinese authorities took action against the largest

counterfeit pharmaceutical operation in China and 12 Chinese nationals were arrested. Three illicit pharmaceuticals facilities were shut down. Cowley was arrested in September 2005, and in February 2006, he pled guilty to importing counterfeit drugs.

CONCLUSION

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