



## U.S. Immigration and Customs Enforcement

# Fact Sheet

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### **ICE EFFORTS TO COMBAT COUNTERFEIT PHARMACEUTICALS**

As the largest investigative arm of the Department of Homeland Security, U.S. Immigration and Customs Enforcement (ICE) plays a leading role in targeting criminal organizations that produce, smuggle and distribute counterfeit pharmaceuticals. ICE investigations are designed to keep these products from reaching U.S. consumers and to dismantle the criminal organizations that perpetuate this illegal activity.

#### **The Threat:**

ICE investigations have demonstrated that, in recent years, the Internet has become the primary tool for criminal organizations to advertise, communicate and conduct sales of counterfeit pharmaceuticals. The Internet has also become the primary mechanism for consumers to find, order and make payments for counterfeit pharmaceuticals.

To date, ICE investigations have not revealed any instances in which smuggled counterfeit pharmaceuticals were intended for the legitimate U.S. supply chain. Instead, trafficking organizations have created an illicit, unregulated supply chain of counterfeit, adulterated, misbranded, and unsafe drugs that are distributed directly to consumers in the United States and elsewhere.

In recent years, China and India have emerged as the most prolific sources of supply for a variety of counterfeit pharmaceuticals, although Mexico, Thailand, and Brazil are also source countries. ICE investigations have identified other nations that serve as transshipment points, locations for web servers, channels for payment processors and sources for obtaining active primary ingredients.

#### **The ICE Response:**

ICE addresses the threat posed by counterfeit pharmaceuticals in several ways. ICE has a cadre of agents assigned to its 26 domestic Special Agent-in-Charge offices who specialize in investigating counterfeiting violations. ICE also draws heavily on law enforcement partners around the world. ICE has agents assigned to 56 Attaché offices in foreign nations, making it possible for ICE to conduct global Intellectual Property Rights (IPR) investigations in conjunction with its overseas law enforcement partners.

ICE agents combat the importation and distribution of counterfeit, misbranded and adulterated pharmaceuticals through complex investigations with the Food and Drug Administration (FDA), the Internal Revenue Service (IRS), the U.S. Postal Inspection Service (USPIS) and the FBI. ICE enhances these

investigations with assistance from the ICE Financial and Trade Investigations Division and U.S. Customs and Border Protection (CBP).

ICE agents at home and abroad routinely use the ICE Cyber Crimes Center or (C3) in their investigations of counterfeit pharmaceuticals sold or distributed via the Internet. The C3 is a state-of-the-art facility in Virginia designed exclusively for conducting computer-based investigations. The center provides computer-related forensic support and other investigative tools to help agents target Internet violators. ICE also hosts the National Intellectual Property Rights Coordination Center, which serves as the primary point of contact between the pharmaceutical industry and ICE. Through the National IPR Coordination Center, ICE maintains strong partnerships and ongoing dialogue with representatives of the pharmaceutical industry.

ICE is also using powerful new legal tools to combat the scourge of counterfeit pharmaceuticals. The recently-passed reauthorization of the USA Patriot Act increased the potential criminal sentence for a violation of 18 USC Section 545 (Smuggling into the United States) from five years to 20 years incarceration. The legislation also added, for the first time, a new criminal charge for smuggling from the United States.

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. As part of these investigations, millions of dosage units of counterfeit, adulterated, misbranded, and unapproved pharmaceuticals have been seized. ICE also conducts parallel asset identification and removal investigations to target the ill-gotten assets of criminal organizations engaged in counterfeit pharmaceutical smuggling and distribution.

Finally, ICE participates in the Interagency Pharmaceuticals Task Force, which is comprised of US Customs & Border Protection, ICE, the Drug Enforcement Administration, the Department of Justice, the Office of National Drug Control Policy, and the United States Postal Service. This task force fosters cooperation among those agencies involved in the regulation and enforcement of laws governing prescription drugs illegally imported via mail and courier facilities.

#### **Major ICE case examples:**

- **WorldExpressRx.com / MyRxForLess.com / Kolowich et. al.** -- In January 2004, ICE agents in San Diego launched a multi-agency investigation with the Food & Drug Administration, U.S. Postal Inspection Service, Internal Revenue Service, and the FBI, which targeted various websites, Internet payment networks and pharmaceutical supply chains. The targets of this investigation used more than 650 affiliated websites, including *PharmFast.com*, *WorldExpressRx.com* and *MyRxForLess.com*, to distribute more than \$25 million in counterfeit or unapproved pharmaceuticals from Mexico and other nations to U.S. and foreign customers within a three-year period. The distribution network extended throughout North America, while the source country, India, was disguised by the transshipment of products through other nations. To date, 20 conspirators have been indicted, including a practicing pharmacist in California and a practicing pharmacist in Mexico. Eighteen individuals have pleaded guilty to federal smuggling and/or money laundering charges related to the investigation. Search and seizure warrants have resulted in the seizure of more than \$1.4 million in illicit proceeds, more than 1.4 million units of various controlled and non-controlled pharmaceuticals that, if sold properly in the U.S., required valid prescriptions. The primary violator, Mark Kolowich, was sentenced in January 2005 in San Diego to 51 months imprisonment.

- **Operation Ocean Crossing** – This ICE investigation began in February 2005, when the ICE Attaché in China received information that a U.S.-based individual, Richard Cowley, and other members of a China-based criminal organization were involved in the sale of counterfeit pharmaceuticals in the United States, the United Kingdom, and other locations throughout Europe. In April 2005, ICE conducted undercover meetings with Cowley and identified his main source of pharmaceuticals in China. Based on this ICE information, Chinese authorities arrested three Chinese nationals in Tianjin province in August 2005 and seized approximately 55,500 blister packs of counterfeit Viagra and Cialis, roughly 75 kilograms of loose pills, an induction-sealing machine, a large quantity of Viagra trademark labels and other pharmaceutical packing materials. In September 2005, Chinese authorities took additional action against three associated facilities in Henan province that were producing and distributing larger quantities of counterfeit pharmaceuticals. Chinese officials arrested eight Chinese nationals, seized approximately 222,300 tablets of counterfeit Viagra and Cialis, 70,000 loose pills, 260 kilograms of raw materials, 580,000 counterfeit Viagra trademark labels, and 13 pieces of equipment used to produce counterfeit drugs. On the same date, ICE agents arrested Cowley in Washington state as the U.S. distributor for the China-based conspiracy. In February 2006, Cowley pled guilty to the importation of counterfeit pharmaceuticals. His sentencing for this crime is pending.
- **Operation Rock of Gibraltar** – A joint investigation by ICE agents in San Jose, California, the ICE Cyber Crimes Center, the FDA, and Postal Inspection Service targeted several foreign Internet websites involved in the smuggling and distribution of controlled substances and prescription drugs into the United States. In this investigation, ICE discovered thousands of Americans who spent more than \$20 million during a 24-30 month period, for the purchase of drugs online from foreign websites. To date, ICE agents have seized more than 500,000 units of controlled substances and prescription drugs, secured indictments on a number of individuals and companies, and seized approximately \$700,000.00 in monetary funds. The investigation revealed that many customers knew their online purchases were illegal and that valid prescriptions were necessary to purchase them legally in the US or abroad. Many specifically ordered from the foreign websites because they did not require prescriptions, medical history, doctor's information, or medical examinations. Several customers had no valid medical reasons for ordering the drugs, and admitted to long time drug use and addiction. Many foreign websites provided re-shipments or refunds for drugs seized by U.S. authorities and advertised various smuggling techniques to ensure delivery.
- **Vinci-Online.com** -- This case was a joint ICE and FDA Las Vegas criminal investigation into the illegal activities of *Vinci-Online.com* and associated companies CFF Pharma Consult GmbH of Bergkirchen, Germany, the principle supplier of pharmaceuticals, and Vinci American Ltd of Las Vegas. *Vinci-Online.com* sold more than 420,000 units of various controlled and non-controlled pharmaceuticals that, if sold properly in the US, required valid prescriptions. *Vinci-Online.com* used forged and fraudulent supporting correspondence, claiming a federal endorsement for *Vinci-Online.com* and CFF Pharma Consult to provide drugs to US citizens. One defendant pleaded guilty and was sentenced to 37 months federal custody. Another was convicted in a jury trial of 17 felony counts, including conspiracy, money laundering, and operating an Internet business engaged in the unlawful sale of prescription drugs and controlled substances.
- **Olinepillbox.com** – This case was a joint investigation by ICE, FDA, DEA, Postal Inspection Service and Texas Department of Public Safety into the activities of Richard Willhite and *Olinepillbox.com*, an Internet website he operated offering various controlled substances, including Ritalin, Codeine and Valium, for sale and delivery without a prescription to US customers via the U.S. and foreign mail.

During the investigation, ICE agents in Houston determined that Willhite did not require customers to submit valid prescriptions for their purchases. He processed thousands of orders filled with unapproved pharmaceuticals from Thailand, the Philippines and Mexico. Willhite generated more than \$400,000 in proceeds to pay the overseas suppliers. He was convicted of federal conspiracy charges, sentenced to 37 months custody and ordered to pay a fine in the amount of \$1.29 million.

# ICE #

*U.S. Immigration and Customs Enforcement (ICE) was established in March 2003 as the largest investigative arm of the Department of Homeland Security. ICE is comprised of four integrated divisions that form a 21st century law enforcement agency with broad responsibilities for a number of key homeland security priorities.*