

Pharmaceutical Counterfeiting in the US: Differentiating Dimensions of the Risk

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A-CAPPP Backgrounder

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Despite the potentially staggering economic, public safety, and health impact of product counterfeiting generally and pharmaceutical counterfeiting specifically, there are virtually no reliable, systemic data on the problem and no publicly available sources for detailed information on incidents. To address this, Michigan State University's Anti-Counterfeiting and Product Protection Program (A-CAPPP) has been gathering information to construct a database of known incidents of product counterfeiting. Built upon established tenets of problem-oriented policing and situational crime prevention, the database will serve as a foundation for developing evidence-based lessons on preventing, detecting, investigating, and responding to product counterfeiting and intellectual property violations. We developed this database through a systematic process to identify and gather open-source information on all U.S.-related counterfeiting incidents since 2000. To date, we have reviewed more than 3,100 publications from media, agency, industry and scholarly sources, and we already have identified over 800 unique, publicly reported incidents of product counterfeiting across several industries.

The information we have gathered so far on counterfeit pharmaceuticals shows that this specific form of product counterfeiting has several variations. This backgrounder highlights several important dimensions of reported incidents. Understanding how these incidents differ will help define and articulate the problem and thereby promote awareness of it

According to the World Health Organization—

A counterfeit medicine (drug) is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.

and the development of anti-counterfeit strategy.

Pharmaceutical Counterfeiting is Multi-dimensional

Incidents of pharmaceutical counterfeiting can vary by level of organization, geographic span, the number of suspects involved, and the type of medicines counterfeited.

One large-scale incident involved the counterfeiting of several kinds of prescription drugs for treating AIDS, cancer, kidney failure and high-cholesterol. At least 19 individuals across several states, working as pharmacists, medical and pharmaceutical wholesalers and distributors, and printers, colluded and made tens of millions of dollars. This highly-organized drug diversion and counterfeiting scheme involved various illicit activities, including the adulteration, re-labeling (e.g., counterfeit drug

packaging labels), theft, illegal importation and improper storage of prescription drugs.

By contrast, some incidents may involve just one suspect, location or category of drugs. One such incident involved an owner of a cosmetic-salon near Seattle convicted in 2009 on a felony and two misdemeanor counts for injecting into customers counterfeit Botox and Restylane.

Pharmaceutical Counterfeiters Vary in their Degree of Specialization

Some pharmaceutical counterfeiters appear to be “specialists” who deal only in prescription medicines. One such incident involved a Pennsylvania man indicted for his role in a larger scheme to import from China and distribute in the United States counterfeit drugs valued at more than \$350,000.

Other pharmaceutical counterfeiters appear to be “generalists” who also take part in intellectual property crime involving other industries. For example, a Rhode Island man convicted of charges that he misbranded sildenafil citrate pills (a drug marketed as Viagra), was also convicted of two counts of movie copyright infringement and had been selling computers equipped with unlicensed software that he had installed.

Counterfeiters may also engage in non-counterfeit crimes. One of the alleged ringleaders in the large-scale, multi-state pharmaceutical incident mentioned above has a diverse criminal history dating to the 1970s. He previously served three years in prison for armed robbery, was arrested for dealing in stolen property (on charges later dismissed), was given three years probation for grand theft, was ordered to participate in substance-abuse treatment, and was arrested for selling cocaine while enrolled in the treatment program. Another individual in the same incident was arrested for selling counterfeit and illegally imported Lipitor while on supervised release for a prior cocaine trafficking offense.

Some Counterfeit Pharmaceutical Incidents have Links to Terrorist Groups

Some incidents of trafficking in counterfeit pharmaceuticals have been linked to terrorist groups. For example, in 2006, a group of individuals was identified for their involvement in a multi-state racketeering enterprise in support of Hezbollah, a Lebanese terrorist organization. Altogether, the operation was active for approximately six years and generated millions of dollars and materials for Hezbollah. Some members of the illicit operation have been indicted and convicted of charges associated with trafficking contraband cigarettes, producing counterfeit cigarette tax stamps, transporting stolen property, money laundering, and trafficking counterfeit Viagra. Upon conviction, some offenders were ordered to pay millions in restitution to trademark holders, sentenced to prison, and will be deported after completing their prison sentence.

Activities Associated with Counterfeit Pharmaceuticals Occur at Legitimate and Illegitimate Locations

Pharmaceutical counterfeiting can occur at differing places. Many consumers receive counterfeit product when they purchase drugs at other-than-legitimate medical facilities. One such incident involved an individual sentenced to 48 months for trafficking in more than 38,000 counterfeit Viagra tablets who sold the pills on streets of New York. Many consumers receive counterfeit drugs from “virtual” medical facilities such as rogue online pharmacies. Consumers may also receive counterfeit drugs at legitimate medical facilities. A pharmacist in Illinois pled guilty to mislabeling with incorrect expiration dates drugs sent to nursing homes. In 2003, a New York doctor was convicted of a felony count of adulteration for flu vaccines he had diluted.

Much pharmaceutical counterfeiting occurs well before the drugs reach consumers. In many

large-scale operations, illicit wholesalers may store counterfeit drugs until illicit distributors transport them. In some incidents even individual households served as manufacturing and mailing facilities for the drugs.

Counterfeit Pharmaceuticals Cause Immediate and Delayed Harm to Consumers

In some incidents the harm caused to consumers from counterfeit pharmaceuticals is immediate and directly observable. For example, HIV patients have experienced adverse reactions (e.g., burning, welts, muscle pain, nausea and fever) upon receiving injections of counterfeit Serostim, an AIDS medication. In other incidents the harm caused to consumers is delayed and less obvious. For example, in 2002, a Kansas City pharmacist was sentenced to the maximum of 30 years in prison and ordered to pay millions of dollars in restitution for deliberately diluting two anti-cancer drugs (e.g., Gemzar and Taxol). Tests later revealed that the prescriptions contained “dangerously low concentrations,” from less than 1 to 39 percent of the proper dosage, of the drug’s active ingredient. There were no obvious signs of immediate harm to patients but over time the drugs reportedly interfered with treatment. Some accounts claimed the diluted drugs were responsible for the untimely deaths of 17 cancer patients. This led to hundreds of civil suits against the pharmacist, including more than two dozen claims of negligence and wrongful death.

Counterfeit Pharmaceutical Investigations Involve Several Agencies

Investigations of pharmaceutical counterfeiting often involve collaboration among local, state and federal agencies. The specific agencies involved vary from case to case. For example, the FDA’s Office of Criminal Investigations (OCI), the Drug Enforcement Agency (DEA) and the Valparaiso Police Department jointly investigated an incident involving the tampering of Fentanyl syringes by a nurse in Indiana. Similarly, OCI, the DEA and the Philadelphia Police Department investigated an incident of counterfeit Viagra, Cialis, and Percocet in Pennsylvania, with Immigration and Customs Enforcement and the U.S. Postal Inspection Service also participating. In May 2007, the FDA warned consumers about 24 related websites suspected of distributing counterfeit Xenical—an incident, it appears from available information, only OCI investigated.

Pharmaceutical Counterfeiting Requires Documentation and Examination

One common need for all agencies is to document incidents by type, size, and location, including characteristics of victims and suspects, for example. The A-CAPPP is continuing to do this through expansion of its database on reported incidents of pharmaceutical counterfeiting. Research and analysis on such data can provide guidance for policymakers in preventing, detecting, and responding to this crime.

About the A-CAPPP



The Michigan State University Anti-Counterfeiting and Product Protection Program (A-CAPPP) is the first and preeminent academic body focusing on the complex global issues of anti-counterfeiting and protection of all products, across all industries, and in all markets, and on strategies to effectively detect, deter, and respond to the crime. Linking industry, government, academic, and other stakeholders through interdisciplinary and translational research, education, and outreach, the A-CAPPP serves as an international hub for evidence-based anti-counterfeit strategy. For more information and opportunities to partner, contact Dr. Jeremy Wilson, Director of the A-CAPPP, at (517)353-9474 or jwilson@msu.edu. Additional information can also be found at <http://www.a-cappp.msu.edu/index.html>.

BACKGROUNDER SERIES

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