

KEY DATA ABOUT ONLINE SALES OF PRESCRIPTION MEDICINES

- There are believed to be between 35,000-50,000 active online drug sellers in operation. Often, these companies sell medicine without requiring a doctor's evaluation.
- 96% of online drug sellers worldwide do not comply with applicable laws and standards put in place to protect patients.
- According to the World Health Organization, 50% of the prescription medicines sold online by websites that hide their physical address are counterfeit.
- Counterfeiting pharmaceutical drugs is a global public safety threat estimated to be worth \$75 billion.
- Patients have been harmed and in some cases killed by unsafe medicines purchased from illegitimate sources on the Internet.
- Online pharmacies have increased their market footprint, growing to an estimated \$11 billion in sales in 2009. It is estimated that some illegal online drug sellers are capable of generating profits of \$1 million to \$2.5 million per month.
- A US study found that 85% of the 159 websites surveyed that offer controlled substances did not require a prescription.
- According to a 2015 study completed by Dr. Timothy Mackey from the University of California, San Diego, over a 2 week period, there were more than 2.4 million tweets that mentioned the non-medical use of prescription medications (by both generic and street names). Drugs offered varied from Valium and Xanax to Adderall and Ritalin to OxyContin and Oxycodone.
- While 29% of Americans are unsure of how to purchase legitimate medications online, 20% of shoppers will purchase medications online (with that number only expected to grow).

International Facts from ASOP-sponsored Studies

- Japan: While only 1 online pharmacy (<0.1%) complies with Japanese FDA/MHLW regulations, three large criminal networks control 44% of all Internet pharmacies targeting Japan.
- China: China continues to top charts regarding the number of 'counterfeit incidents' while seeing consistent increases in total revenue from online pharmaceutical sales (topping 6 billion yuan).
- EU: At any one time, in excess of 30,000 illegal pharmacy websites are accessible by the European population; EU Customs has reported a doubling of shipments stopped with detentions with traffic up 82% (69% of the articles detained were medicines).

EXAMPLES OF PATIENTS HARMED BY MEDICATIONS PURCHASED ONLINE

These are just a few illustrations, in chronological order, of the serious and growing global problem of illegal online drug sellers.

1. On April 12, 2015, Eloise Parry died after consuming “diet pills” that she purchased over the Internet. The police are investigating the case and believe the pills contain the highly toxic substance, dinitrophenol or DNP.¹
2. Emily-Sue Thomas, 18, became violently ill after taking a weight-loss pill that she purchased online. Thomas said she became interested in the drug after viewing an advertisement on her Facebook page claiming that the drug was popular with celebrities.²
3. Michael Thompson, a Nova Scotia man, died on March 18, 2015, of an accidental overdose. Thompson was addicted to prescription drugs and his family received an alarming package in the mail just two days after his death. The envelope was from reChem Labs and contained what they thought was the drug equivalent to Avitan, an anti-anxiety medicine. After analysis it was found to be Etizolam, a drug 10 times more potent than Valium. Etizolam is not approved for sale in either the U.S. or Canada.³
4. On January, 3, 2015, Kelly Best, a 19-year-old man, died after taking counterfeit OxyContin that contained a high dose of a different drug. Best is the third person in Saskatoon to be killed by the pills within 6 months according to Canadian police.⁴
5. In November 2014, Aidan Karpenko, 19, was found dead just hours after taking a single Etizolam pill that was purchased by his friend on the Internet. Etizolam is a medication used to treat anxiety, insomnia and panic attacks. The drug is not licensed or regulated in the UK; however it is licensed in Japan and India.⁵
6. On April 23, 2013, Sarah Houston, a 23-year old medical student in the United Kingdom obsessed with her weight, purchased DNP, a deadly diet pill, through an online drug seller. The pill, sold as a weight loss aid through many illicit online pharmacies, is actually a pesticide with lethal consequences to humans. Ms. Houston died the day after a bout of breathlessness, icteric sclera and hyperthermia, symptoms she had previously experienced.⁶
7. On April 4, 2012, a mother and son in Los Angeles were looking for cold medication. They purchased and fell victim to a counterfeit drug "vitamin injection." The victim's heart rate

¹ “Warnings after student ‘diet-pills’ death” Yahoo! News (April 21, 2015); available at <https://uk.news.yahoo.com/warnings-student-diet-pills-death-092436702.html#RFWMuwe>

² “Health professionals urge the public to steer clear of ‘dangerous’ online slimming pills” Wales Online (March 26, 2015); available at <http://www.walesonline.co.uk/news/health/health-professionals-urge-public-steer-8926003>

³ “Research chemicals’ making their way into illicit drug markets, police say” Yahoo! News (October 1, 2015); available at <https://ca.news.yahoo.com/research-chemicals-making-way-illicit-090000428.html>

⁴ “Counterfeit OxyContin claims another life in Canada” Securing Industry (January 12, 2015); available at <http://www.securindustry.com/pharmaceuticals/counterfeit-oxycontin-claims-another-life-in-canada/s40/a2233/#.VoBtZVJmo-x>

⁵ “One pill can kill’ warning after death of popular Chesterfield teen” Derbyshire Times (November 27, 2014); available at <http://www.derbyshiretimes.co.uk/news/grassroots/one-pill-can-kill-warning-after-death-of-popular-chesterfield-teen-1-6973111>

⁶ “Banned slimming drug kills medical student: Coroner attacks online dealers who target the vulnerable” The Daily Mail, United Kingdom (April 22, 2013); available at <http://www.dailymail.co.uk/health/article-2312986/Sarah-Houston-Banned-slimming-drug-DNP-kills-medical-student-coroner-attacks-online-dealers-target-vulnerable.html> This medicine was misused. The patient took both anti-depressants and a pill marketed as a weight loss aid containing lethal ingredients.

increased rapidly, experienced severe headaches, dramatic weight loss, pass-outs and numbness in lips. The victim was eventually hospitalized.⁷

8. On June 3, 2011, an emergency room doctor, from Texas, suffered a stroke from ingesting counterfeit Alli from www.2daydiets.com. The counterfeit Alli was produced using the controlled substance sibutramine, rather than the approved ingredient orlistat, and then shipped to the US for redistribution. Two individuals operated the site. The first is a Chinese citizen who has been sentenced to 7 years in federal prison, \$504,815.39 in restitution to victims, and deportation following his sentence. The second US citizen received 3 years probation.⁸
9. In January of 2010, 150 patients were admitted to hospitals in Singapore after taking counterfeit Tadalafil and herbal preparations that claimed to cure erectile dysfunction. Seven (7) of the patients were comatose and four (4) subsequently died from the online drugs which contained powerful ingredients used to treat diabetes.⁹
10. Steven Kovacs was a 22-year old aspiring psychologist in New York when he started buying medication online after first being prescribed Adderall, used to treat attention-deficit hyperactivity disorder, and Xanax, used to treat anxiety. Steven died of a prescription drug overdose on July 8, 2009 after mixing, Adderall, Xanax and OxyContin.¹⁰
11. On May 22, 2008, a man from Wichita, Kansas died from an accidental overdose of muscle relaxants he received from an online pharmacy. He obtained these drugs without ever visiting a doctor. The man's wife described her husband as "an addict --and that the Internet sites that sold him the drugs were his pushers."¹¹
12. Marcia Bergeron, a Canadian resident and US citizen, died in 2006 from heavy metal poisoning caused by the contaminated prescription medications she had purchased from an illicit online pharmacy. Otherwise healthy, the coroner determined that Bergeron died of cardiac arrhythmia caused by metal toxicity from counterfeit medication. According to the coroner, the website where Marcia bought her medicines looked reputable as did the box of pills, but the drugs were actually shipped from overseas and had high levels of lead, titanium, and arsenic, which caused her death.¹²
13. On December 17, 2006, Craig Schmidt, a 30-year-old plastics salesman, purchased Xanax (an anxiety drug) and Ultram (a painkiller) from an online drug seller without seeing or speaking to the doctor that prescribed the medications. After taking the drugs, he nearly died and has been

⁷ "Cracking Down on Counterfeit Drugs" San Diego Union-Tribune (April 4, 2012); available at

<http://www.utsandiego.com/news/2012/apr/04/cracking-down-counterfeit-drugs/?page=1#article> This medicine was contaminated.

⁸ "June 3, 2011: Chinese National Sentenced to Federal Prison for Trafficking Counterfeit Pharmaceutical Weight Loss Drug" U.S. Department of Justice (June 3, 2011); available at <http://www.fda.gov/ICECI/CriminalInvestigations/ucm257912.htm>

This medicine was contaminated with significantly high levels of metal. The patient suffered a stroke after ingesting the medication.

⁹ "Counterfeit Internet Drugs Pose Significant Risks and Discourage Vital Health Checks," Science Daily (January 20, 2010). This contaminated medicine, claimed to cure erectile dysfunction contained a powerful drug used to treat diabetes.

<http://www.sciencedaily.com/releases/2010/01/100120085348.htm>

¹⁰ "Mom, Schumer urge Web Pharmacy Crackdown," Newsday, United States (July 10, 2011); available at <http://www.newsday.com/long-island/mom-schumer-urge-web-pharmacy-crackdown-1.3016581> This medicine was obtained without a prescription and was abused because online prescription drugs were easily accessible.

¹¹ "Widow: My Husband Died from Online Drugs" CNN (May 22, 2008); available at

<http://www.cnn.com/2008/HEALTH/05/21/online.drugs/index.html?ref=allsearch> This drug was misused and abused. The medicine was purchased online without a doctor's visit or a prescription.

¹² "Counterfeit Pills Bought Online Leads to Death, Coroner Confirms," The Times Colonist (July 6, 2007); available

at <http://www.canada.com/victoriatimescolonist/news/story.html?id=05142ca2-9796-4868-bf42-76e939915fa5&k=29039> This medicine was contaminated with significantly high levels of metal.

left permanently impaired with brain damage that inhibits him from driving or even walking without stumbling.¹³

14. On February 12, 2001, U.S. citizen Ryan Haight died from adverse reactions to painkillers that he purchased over the Internet. He was only required to fill out a questionnaire that was “examined” by a doctor who had never met him.¹⁴

RECENT LAW ENFORCEMENT ACTIONS INVOLVING ILLEGAL ONLINE DRUG SELLERS

A few examples of recent law enforcement actions involving online drug sales, in chronological order:

1. On October 29, 2015, Daniel Sanchez, 40, was sentenced to 21 months in prison and then be deported for his role in smuggling counterfeit drugs into the U.S. Sanchez arranged to have misbranded Viagra, painkillers and other prescription drugs imported from India to two re-shippers in the U.S.: Neil Russell of Pittsburgh, PA, and Manuel Pena of Houston, TX. Both re-shippers are under indictment along with Paridhi Sharma, who is identified as being the Indian shipper.¹⁵
2. On October 7, 2015, an investigation led by the United States Food and Drug Administration, Office of Criminal Investigations (FDA-OCI) in conjunction with the Puerto Rico Police Department, Guayama Municipal Police, and the Puerto Rico Treasury Department resulted in an indictment against Jorge L. Pagán Kortright and his companies. The indictment is for charges of introducing misbranded drugs into interstate commerce, conspiracy to commit wire fraud, wire fraud, and mail fraud. If found guilty, the defendant could face up to 30 years in prison for mail fraud and wire fraud charges.¹⁶
3. In August of 2015, an indictment filed in the US District Court in Montana charged Canada Drugs and affiliates in the UK and Barbados with smuggling, money laundering and conspiracy. The online pharmacy sold \$78 million worth of unapproved, mislabeled and in some cases, counterfeit cancer drugs to doctors in the U.S. over a three-year period. All but one of the 14 companies and individuals named as defendants are located outside of the U.S. and will force prosecutors to undertake the extradition process.¹⁷
4. From June 9-16, 2015, 236 agencies from 115 different countries came together to thwart online sales of counterfeit medicines through Operation Pangea VIII. The week-long operation resulted in the seizure of 20.7 fake and/or illicit medicines worth an estimated \$81 million. During the operation, 156 individuals were arrested in connection to these crimes.¹⁸

¹³ “Online Extra: The Deadly Side Effects of Net Pharmacies” Bloomberg Businessweek (December 18, 2006); available at <http://www.businessweek.com/stories/2006-12-17/online-extra-the-deadly-side-effects-of-net-pharmacies>

¹⁴ “Don’t underestimate the danger of drugs from abroad” San Diego Union-Tribune (February 25, 2011); available at <http://www.signonsandiego.com/news/2011/feb/25/dont-underestimate-the-danger-of-drugs-from-abroad/> This medicine was misused. The patient, without a prescription, purchased pain medications over the Internet. He had a serious reaction and died. The patient was only required to fill out a questionnaire that he was “examined” by a doctor who had never met him.

¹⁵ “Counterfeit-drug smugglers, under indictment in Pittsburgh, headed to prison” Pittsburgh Post-Gazette (October 30, 2015); available at <http://www.post-gazette.com/local/city/2015/10/30/Counterfeit-drug-smuggler-under-indictment-in-Pittsburgh-headed-to-prison/stories/201510300160>

¹⁶ “Businessman Arrested For Introducing Misbranded Drugs Into Interstate Commerce, Conspiracy, Wire And Mail Fraud” US FDA (October 8, 2015); available at <http://www.fda.gov/oc/criminalinvestigations/ucm466310.htm>

¹⁷ “US charges Canadian company with smuggling, money laundering” Yahoo! News (August 10, 2015); available at http://news.yahoo.com/us-charges-canadian-company-smuggling-money-laundering-024150984.html;_ylt=AwrT6Vl3cNtV0u4A6xinnlIQ;_ylu=X3oDMTE0ODE1M2RiBGNvbG8DZ3ExBHBvcwMxBHZ0aWQODUFEQkNLMV8x-BHNIYwNzYw--

¹⁸ <http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea>

5. Chinese police detained over 20 people in a crackdown on the production and online trading of fake drugs. Police seized at least 20,000 boxes of fake drugs and several tons of raw materials in the operation that lasted for more than three months. The drugs were sold to nearly 30 provinces and municipalities across China and the total selling price topped 100 million yuan (16.11 million US dollars).¹⁹
6. The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) seized over £3 million of illegally traded medicines during 2014. Additionally, over 1,600 websites involved in the illicit selling and advertising of counterfeit or unlicensed medicines were shut down by the agency. The MHRA is now targeting social media by working with YouTube, Amazon, and eBay to combat these criminal efforts, and as a result, almost 19,000 online videos have been removed in the past year.²⁰
7. On May 22, 2014, the U.S. FDA reported on the 7th annual International Internet Week of Action (IIWA) also known as Operation Pangea VII. During the event, May 13 to May 20, 2014, law enforcement, customs, and regulatory authorities from 111 countries collaborated to target illegal online pharmacies. Within the U.S. the FDA along with Customs and Border Protection (CBP) inspected packages at various mail facilities resulting in the seizure of 583 shipments. The FDA notified Internet service providers of the 1,975 websites in violation of U.S. law.²¹
8. In May of 2014, the San Diego County Sheriff's Department made 19 arrests and seized drugs and \$25,000 in U.S. and Mexican currency after a five-month undercover investigation called Operation.com. Undercover deputies made 41 buys upon easily finding drugs available on sites like Facebook and Craigslist. Seized were quantities of heroin, methamphetamine, LSD, cocaine, Ecstasy and prescription drugs.²²
9. In a March 2014 raid, India's FDA officials seized more than 4,000 strips of prescription drugs including addictive anti-depressants, anti-hypertensives and Viagra, worth over Rs 4,000,000, before the shipments could be illegally exported. All of the drugs had been ordered online, and the raid came just before the consignment was about to be smuggled to various countries like the US, UK, Australia, Japan, and Dubai.²³
10. On June 27, 2013, the U.S. FDA reported the successful execution of Operation Pangea VI, a law enforcement initiative resulting in the elimination of 1,677 websites selling illegal prescription drugs. The partnership included individuals from the US Department of Justice, FDA Office of Criminal Investigations, Interpol, and authorities from nearly 100 countries. The members of Operation Pangea VI took action against 9,600 websites and included the seizure of dangerous drugs valued at \$41 million.²⁴
11. On March 27, 2013, three men and one woman were sentenced in relation to the illegal online supply of prescription-only and counterfeit medicines. This follows an undercover operation by

¹⁹ "At least 20 detained in China fake drug crackdown" China Daily (July 20, 2015); available at http://www.chinadaily.com.cn/china/2015-07/20/content_21328169.htm

²⁰ "Illicit vendors using YouTube to advertise fake drugs, says MHRA" In-Pharma Technologist (January 8, 2015); available at <http://www.in-pharmatechnologist.com/Regulatory-Safety/Illicit-vendors-using-YouTube-to-advertise-fake-drugs-says-MHRA>

²¹ "FDA targets illegal online pharmacies in globally coordinated action" U.S. Food and Drug Administration (May 22, 2014); available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm398499.htm>

²² "San Diego County deputies bust Internet sales of illegal drugs" Los Angeles Times (May 11, 2014); available at <http://www.latimes.com/local/lanow/la-me-ln-drugs-internet20140511-story.html>

²³ "FDA halts illegal export of drugs worth Rs40 lakh" Mumbai Mirror (March 24, 2014); available at

<http://www.mumbaiirror.com/mumbai/others/FDA-halts-illegal-export-of-drugs-worth-Rs40-lakh/articleshow/32591533.cms>

²⁴ "International operation targets online sale of illicit medicines" Interpol (June 27, 2013); available at <http://www.interpol.int/News-and-media/News-media-releases/2013/PR077>

the Medicines and Healthcare Products Regulatory Agency (MHRA). Searches of the homes of those involved uncovered stashes of counterfeit medication and generic prescription-only medicine. The seizure included Viagra, Cialis, diazepam and methadone. A study of a computer also showed email traffic between Andrew Luxton, Samantha Steed, Carl Willis and others indicating the previous supply of illegitimate medicine.²⁵

12. On March 27, 2013, nine defendants were sentenced for their roles in illegally distributing controlled substances to customers who bought the drugs from illicit Internet pharmacies. The defendants were also collectively ordered to forfeit more than \$94 million in illegal proceeds. Drug Enforcement Administration Acting Special Agent in Charge Bruce C. Balzano stated, "prescription drug abuse has risen to alarming levels, often times leaving a trail of devastation behind and negatively impacting our communities. The individuals sentenced this week were involved in online pharmacy schemes that were illegally distributing controlled substances."²⁶
13. On March 13, 2013, Edmond Paolucci, 54, of Coventry, Rhode Island and Patrick Cunningham, 44, of Cranston, Rhode Island, admitted to the court that they participated in a conspiracy to repackage illegal drugs and sell them under various names and labels to consumers who placed orders via the Internet. A significant portion of the profits realized from the sale of the illegal drugs was laundered back to individuals in Israel.²⁷
14. On August 9, 2012, a Puerto Rican man faced up to 10 years in prison after being found guilty by a jury on U.S. federal charges stemming from his role as a key operative for a drug ring that distributed large quantities of Chinese-made counterfeit pharmaceuticals throughout the United States and worldwide. Special agents with U.S. Immigration and Customs Enforcement's (ICE) Homeland Security found more than 100,000 pills made to resemble a variety of popular prescription medications, including Viagra, Cialis, Valium, Xanax and Lipitor.²⁸
15. On August 5, 2012, Chinese government officials seized "more than \$182 million of counterfeit pharmaceuticals ...in the latest attempt to clean up a food and drug market that has been flooded with fakes." Chinese police arrested more than 2,000 individuals and destroy 1,100 production facilities for producing counterfeit drugs.²⁹
16. On April 24, 2012, two men pleaded guilty and were sentenced for smuggling counterfeit and misbranded pharmaceuticals into the U.S. Both men operated an Internet business in Israel that used multiple websites to illegally sell large amounts of prescription drugs to U.S. purchasers. In total, they sent approximately 9,000 separate drug shipments to U.S. purchasers, generating over \$1.4 million in gross profit. Ultimately, one man received 10 months in federal prison, was fined \$30,000 and forfeited \$50,000. The other man received one year of probation, was fined \$15,000 and forfeited \$15,000.³⁰

²⁵ "Three men and one woman sentenced in counterfeit medicines case" MHRA (March 27, 2013); available at <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON254851>

²⁶ "Nine Sentenced For Illegally Distributing Controlled Substances Over The Internet" Department of Justice (March 27, 2013) available at http://www.justice.gov/usao/can/news/2013/2013_03_27_nine_sentenced_press.html

²⁷ "Two Plead Guilty to Participation in International Conspiracy to Import and Distribute Prescription Drugs and Anabolic Steroids" Department of Justice (March 13, 2013). <http://www.justice.gov/usao/ri/news/2013/mar2013/steroids.html>

²⁸ "Man convicted for role in international counterfeit drug distribution scheme Search continues for organization's ringleader" U.S. Department of Homeland Security, ICE (August 9, 2012); available at <http://www.ice.gov/news/releases/1208/120809losangeles.htm>

²⁹ "China Arrest 2,000 Individuals and Destroys 1,100 Production Facilities for Making Counterfeit Drugs" Rx-360 (August 5, 2012) available at http://hosted-p0.vresp.com/427409/59c2b9af06/ARCHIVE***#>

³⁰ "2 Israeli men sentenced for smuggling counterfeit and misbranded pharmaceuticals into the United States" U.S. Department of Homeland Security (April 24, 2013); available at <http://www.ice.gov/news/releases/1204/120424stlouis.htm>

17. In December of 2012, the State of Oregon fined Hayden Hamilton, founder of ProgressiveRx.com, \$50,000 for operating without an Oregon pharmacy license. The 35-year-old Portland businessman has shipped medicine from India and other countries to customers in the United States and around the world.³¹
18. In the summer of 2011, U.S. federal agents identified a 41-year-old, Shane Lance on suspicion of illegal online drug sales. Agents arrested Lance and indicted him on multiple counts, including conspiracy to traffic counterfeit drugs. Last spring, he pleaded guilty to one count of conspiracy to traffic and one count of trafficking, and in November he received his sentence: 10 months in prison and a \$5,100 fine to be paid to Pfizer.³²

³¹ "State fines online pharmacy with Portland ties; Oregon shipments blocked" U.S. Department of Homeland Security (December 21, 2012); available at http://www.oregonlive.com/health/index.ssf/2012/12/state_fines_online_pharmacy_wi.html

³² "Inside Pfizer's Fight Against Counterfeit Drugs" Bloomberg Businessweek (January 17, 2013); available at <http://www.businessweek.com/articles/2013-01-17/inside-pfizers-fight-against-counterfeit-drugs>