

# The World's Most Counterfeited Prescription Drug

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If you guessed Viagra, you're right, although Cialis may have recently taken the top spot. Enhanced sex, along with Viagra's rise to blockbuster status, cultural phenomenon and status as a 'must have' drug have created a major health problem. Every day hundreds of guys log onto so-called 'rogue Internet mail order pharmacies' and give out personal credit card information to receive blue pills in the mail that look like Viagra. Sometimes there is enough sildenafil citrate, the active ingredient, to satisfy the purchasers but analysis by Pfizer has found blue ink, detergent, paint and other dangerous substances.

The rogue mail-order websites, usually discovered as the result of a spam solicitation or Google search, have a professional appearance with a doctor in the background and a domain name like Canadadrugs.com. While clever enough to dupe the unwary, they mask a murky underworld of secret bank accounts and underground labs.

Pfizer hires private investigators and works with law enforcement world-wide from its Groton, Connecticut research facility to combat the problem of fake drugs that includes Lipitor for cholesterol, Lybra for pain, Celebrex for arthritis and so-called 'herbal Viagra' that does not require a prescription and often contains the active ingredient for either Viagra or Cialis.

## **Pursuing the Counterfeiters**

David Woods, president of Associated Investigative Services, has handled numerous Internet investigations for pharmaceutical companies. He specializes in intellectual property and established his agency in the 1980s when product counterfeiting was escalating.

"For starters, I would deeply research the hosting domain, oftentimes finding the ownership to be masked by a proxy service or to just have blatantly false registration information designed to thwart most investigative measures," Woods said.

One typical investigation involved a website that was allegedly from Canada, but was hosted in China, registered in Russia, billed customers through Australia and shipped the counterfeit Viagra in plastic zip-lock bags from a mail forwarding company in Palatine, Illinois using a fake return address culled and mixed from their own customer list.

The investigation began with a medical questionnaire with most of the answers filled in. After completing the questionnaire, a fictitious doctor filled out the prescription. Woods was advised that the charges would appear as stpay.com on his credit card statement. Stpay.com a/k/a secureteller.net is registered in the United Kingdom but their customer service rings in Australia. The company refused to supply a contact number for their headquarters. Most interesting was a warning posted as a legal notice on their website advising visitors if 'they're investigators and retrieving information about the operators of the website, they agree to pay \$3 million dollars in damages.'

After the order was placed, the website supplied a toll free number and a direct Canadian number, both of which were never answered. Only messages could be left. The bill was nearly doubled after factoring in the cost of a doctor

consultation and shipping. No doctor's identity was ever supplied nor was Woods ever contacted by one. The prescription required product was sent through regular mail for considerably less than the amount billed. Instead of the expected branded product generic blue diamond shaped tablets that allegedly contained sildenafil citrate were sent.

"One of the sleaziest people I encountered was Dr. Robert A. Liberman who did not carry medical malpractice insurance and was referenced in the Orlando Sentinel as being 'the most sued doctor in the county,'" Woods said.

"Lieberman had eleven malpractice suits filed against him between 1980 and 1985. His medical license had been revoked in Florida and in New York. After nine years of administrative punishment for sexual misconduct with three patients, including rape, he received approval to resume a full practice in 1998."

Lieberman was writing prescriptions based on limited website supplied information. The website itself was located in Port Vila, Vanuatu which is the capitol of a small group of islands 1,500 miles north of Australia.

After making a buy from an Internet pharmacy Woods turned the fakes over to the pharmaceutical company's head of security, who had the drugs analyzed and legal action was undertaken.

Brian Donnelly, Director of Pfizer's Global Security Team North America, likens the Internet problem to the spokes of a wheel with each spoke branching out from another country. "At the top level is a lab, often in India, that's making the active pharmaceutical ingredient," says Donnelly. "Next comes the tablet or capsule manufacturing site and distribution, often from China, India and Pakistan."

According to Donnelly, the bottom rung is the Internet affiliate level, which is the computer server in one country. Once the order is placed on an affiliate website, it's shifted to a core site in another country that's often a large operation dealing in counterfeit medicines. When the order is processed it's sent to payment processing in another country, which may also be processing payments for child pornography and other illicit operations. "The customer in the United States will ultimately get his Viagra from a drop shipper in the United States," says Donnelly. "This is the result of a bulk shipment sent from overseas that wasn't seized. Those that don't get through are chalked up as a cost of doing business."

#### **Pfizer's Global Security Team North America**

Counterfeit drugs have a long history dating back to traveling salesmen hawking snake oil. Pills are an ideal product to pirate because usually the only way to detect the product is fake is through physical and chemical analysis. Some of today's counterfeits are so good it takes a team of scientists and rigorous testing to prove the counterfeits are fake. This is crucial to building a criminal case.

Pfizer's Global Security Team for North America is located at the company's Groton, Connecticut research facility. Interestingly enough, most of the major drug firms in the highly competitive pharmaceutical field have their own security operations that not only analyze fake pills but have a reciprocal arrangement amongst one another to share information.

Brian Donnelly was an FBI agent for twenty years and has a Ph.D in pharmacology and toxicology. Donnelly's counterpart at Eli Lilly also worked for the FBI. Donnelly is in charge of a forensics team of scientists that receives samples from members of the public and law enforcement and customs each week. The samples include Viagra and any other drugs that Pfizer manufacturers, including Lipitor for cholesterol, Lyrica for pain, and Celebrex for arthritis and so-called 'herbal Viagra,' which do not require a prescription and often contains sildenafil citrate or tadalafil, the active pharmaceutical ingredient in Cialis.

Pfizer's team receives investigations from three sources: One is from calls to Pfizer's complaint center. Often these are from consumers who have purchased Viagra over the Internet. They will be sent a priority mail order pouch with instructions to send it to Groton for analysis. The second is from private investigators who pursue leads from the street, Internet, Craig's list, social media, and other sources. Often they will try to meet with the counterfeiters and use other strategies to gather intelligence. The third is from law enforcement: Homeland Security, customs, and police in the United States and in other countries.

"Ninety-five percent of the products analyzed in the Groton laboratory are Viagra and 'herbal Viagra,'" says Amy Callanan, Senior Scientist on the forensics team, which documents every step taken in the scientific analysis.

Determining the pill is counterfeit is a first step. Determining the pill's composition and where it came from, if possible, are also important. It's a fascinating cat and mouse game because the counterfeits look identical and in

some instances even better than the genuine Pfizer product.

Callanan and her staff have found legitimate Pfizer products that are expired but are re-labeled, drugs used in experiments that are re-packaged. Sadly, cancer and antibiotic medicines have been sent for analysis that turned out to be medically worthless.

Every step in the analysis is rigidly documented, beginning with cataloging the weight and size and taking a digital photograph. After that comes the use of a bevy of state of the art technologies from a videometer that uses spectral imaging to test the ink used in the packaging, to a hand-held Raman spectrometer used for measuring the wavelength that makes up the pill's chemical signature, and to the use of infrared spectroscopy which involves sending an infrared beam to interact with a small sample to determine its composition. Other technologies used are: powder x-ray diffraction, high pressure liquid chromatography, and mass spectrometry.

Pfizer has two more counterfeit labs that use the same scientific technology and methodology as the North American operation. Most of the large pharmaceutical companies maintain similarly equipped security operations in the fight against the pharmaceutical counterfeiting problem that the World Health Organization now estimates at \$75 billion annually.

### **Rogue Internet Mail-Order Pharmacies**

Mail-order pharmacies have been around since the 1800s. The number of mail-order pharmacies jumped into the hundreds of thousands when the World Wide Web became main stream in the late 1990s. An early website was Drugstore.com. Launched in 1999, the website partnered with Rite Aid a few months later.

Viagra.com was launched in 1998 and Viagra was available through the website at about the same time and much later through a home delivery service after Pfizer partnered with CVS pharmacy in 2013.

Rogue pharmaceutical mail order websites quickly became a problem prompting the NABP to create the Verified Internet Pharmacy Practice Sites (VIPPS) in 1999. This is a voluntary program for domestic online pharmacies that can be identified by the VIPPS seal of authenticity.

Over the years, the Internet has assisted hundreds of thousands of consumers to safely order prescription medicines at a discount, but the downside is a staggering number of rogue mail-order websites. A man who visits one is likely to be taken in by its professional appearance, often enhanced by a background picture of a doctor and medical supplies. Ordering is easy, usually all that is required is filling out a form and the online pharmacy will write the prescription or fill the order without one. An invoice, paid with a credit card, and delivery as quick as the next day. Who could ask for more? Even worse, ordering the drug appears to be legal and consumers are surprised when they're duped.

The FDA has investigated and seized many websites that register a domain with the name of a trusted source like a pharmacy in a bid for legitimacy. For example, if you type [www.c-v-s-pharmacy.com](http://www.c-v-s-pharmacy.com) into your Internet browser, you may see an FDA notice that the domain, which was formerly controlled and hosted in Russia and the Ukraine, has been seized.

The discounted prices are enticing, much less than the actual price of the legitimate drug. Many domains use the word 'Canada.' It's no secret that Americans have been traveling to Canada for years for lower priced drugs, even though this violates the FDA's Personal Importation Policy, which prohibits most drugs from being brought into the United States from another country, even if the prescription was written by a U.S. doctor. Canadian pharmacies began online marketing in 2000. Legitimate Canadian websites are listed under the Canadian International Pharmacy Association's website [www.CIPA.com](http://www.CIPA.com).

A Food and Drug Association investigation found that nearly half of all ED drugs purchased online were fake, giving online buyers a roughly fifty-fifty chance of getting the genuine product. However, another study put the ratio at seventy-seven percent leaving buyers with a less than one in four chance of getting actual ED drugs. Many of the fakes analyzed contained dangerous substances like paint, ink or sheetrock, while others contained different medications like antibiotics.

Estimating the number of sites selling fake ED drugs is nearly impossible. According to Special Agent Daniel Burke, senior operations manager of the FDA's Cybercrimes Investigations Unit, there are 40,000 to 60,000 domain

names that could be tied to illegal pharmacies at any given time. The National Association of Boards of Pharmacy (NABP) investigated 10,000 online rogue pharmacies and found that only three percent were in compliance with pharmacy laws and practice standards.

Part of the problem is that people do so much day-to-day business on the Internet. For example, the fifteen million consumers who enrolled in the Affordable Care Act, better known as Obamacare, did so through the Internet. Most physicians today order prescriptions for their patients electronically. Although more people are ordering prescription drugs online, an FDA survey found that only a third had any idea of how to do so safely.

### **Prosecuting The Consumer**

Consumers generally won't be prosecuted for purchasing ED drugs online or bringing them over the border, especially if it is a small quantity for personal use.

"It is against the law to import most drugs purchased in another country," says Meyer of the FDA. "If the drugs are declared U.S. Customs and Border Protection will confiscate them. If purchased online, no action will be taken, although the drugs could be sent back to the country of origin. The consumer can file an appeal if they get a notice that their package has been confiscated at an international mail facility, but that rarely happens."

Viagra can be purchased in Mexico. There are hundreds of Mexican pharmacies along the border that often run radio and television advertisements state-side in an effort to lure Americans with cheaper drugs that can be purchased without the hassle of a prescription; and for those drugs that require one, there's often a pharmacist nearby or even on the premises. However, buyers should beware. One of the worst examples of fakes sold in the local market occurred in Singapore in 2008. Counterfeit ED drugs resulted in one hundred and fifty people being admitted to the hospital. Four of them died and seven suffered severe brain damage. The active ingredient in the pills included hefty doses of glyburide, used for treating diabetes.

A significant number of men who suffer from ED do not seek treatment from a physician due to embarrassment, which isn't a problem when purchasing the drug online. In one instance a doctor who worked in a hospital forged prescriptions for Viagra out of embarrassment. Dr. Mansoor Kassim, who was too embarrassed to see a doctor, drew attention from the hospital staff who became suspicious because he worked in an orthopedic unit where patients would not need Viagra (he forged a patient's name). An investigation was undertaken and eventually Dr. Kassim was taken to Court and ordered to pay for the cost of the investigation and to repay the cost of the Viagra.

### **Blockbuster Drug**

Sometimes called 'The Little Blue Pill,' Pfizer launched Viagra in 1998. The first oral medication for what was termed 'erectile dysfunction' or ED, Viagra quickly became a block buster drug and a cultural phenomenon. Sildenafil citrate, the active ingredient in Viagra, was originally developed as a cardiovascular drug to treat angina, chest pain caused by atherosclerosis or blockage of the coronary arteries from fatty deposits. The benefits of sildenafil were apparent when the test patients were reluctant to return the drug at the conclusion of the clinical trial. Instead of causing blood to rush to the heart, the drug allowed for increased blood flow in penile tissue causing an intense erection.

Viagra changed the way society looked at male impotence, which was once a taboo subject and thought to be primarily psychological. Erectile dysfunction, on the other hand, was a rarely used term until Pfizer paired it with Viagra. ED was used to describe various degrees of sexual performance and as a problem affecting tens of millions of men. The cause was largely organic and treatable with Viagra.

Viagra benefitted from the FDA's legalizing Direct To Consumer advertising shortly before the drug's launch. DTC allowed Viagra to go main stream with television advertising. The first pitchman was Presidential candidate Bob Dole who had surgery for prostate cancer. The market of potential users widened after Dole was replaced by more virile males, like NFL Hall of Fame player and coach Mike Ditka who told viewers to "stay in the game." Another advertisement had thirty-seven-year-old baseball player Rafael Palmeiro.

Many advertisements cleverly took advantage of the FDA's 'Fair Balance' rule, which requires pharmaceutical companies to list the drug's limitations and hazards in DTC advertisements. One commercial in particular amounted to a male fantasy and began with a young, attractive woman entering into a frank discussion about ED and concluded with a health warning to "see a doctor for an erection lasting more than four hours." Juxtaposing an

attractive woman with a warning about an out of control erection was almost too good to be true and seemingly offered sound advice: ED is something a man doesn't want when you're about to have sex with an attractive woman. No problem. Take a pill.

Everyone was talking about Viagra from late night talk shows to an episode of Sex In The City. Modern communication and the media informed men around the world about the new miracle drug. Doctors report overwhelming demand and writing prescriptions around the clock for Viagra, which may have contributed to a 'masculinity crisis' similar to the pressure put on athletes who use athletic enhancement drugs for maximum performance.

"Viagra raised the bar even higher in terms of sexual performance," says Meika Loe, author of *The Rise of Viagra*. "This may also inhibit men for asking their doctors about erectile dysfunction. Whereas, the Internet allows for a sense of anonymity."

ED drugs are supposed to be taken under a doctor's supervision. However, as Loe points out, the Internet offers users a choice of using it in private. The misuse of the drug can have disastrous consequences. Daniel Medforth, thirty-five years old, took thirty-five Viagra pills during a two-day drinking spree in September, 2015. He was taken to the hospital, complaining of headaches and hallucinations. He had an erection for five days. 'Herbal Viagra'

A month after Medforth was rushed to the hospital, basketball player Lamar Odom, thirty-six years old, was found in a coma at the Love Ranch brothel, located outside Las Vegas. Odom, recently divorced from Chloë Kardashian, had spent three days at the brothel taking cocaine and an estimated ten doses of so-called 'herbal Viagra.' Odom took a supplement called Reload. The FDA had issued a warning that it contained sildenafil as an undeclared ingredient in June, 2013 but had not issued an official recall, according to Meyer. Odom is also believed to have taken Libimax which contains tadalafil, the active ingredient in Cialis. However, Nature & Health, the company that manufactured the supplement, announced that it had voluntarily recalled the product in 2007.

'Herbal Viagra' is a generic term for products marketed as natural supplements that promise to increase sexual enhancement. Sexual enhancement is different than a cure for erectile dysfunction, which is a medical condition, and it is sold over the counter at gas stations department stores, food stores and other outlets. While many of these drugs are safe for consumption, others may contain unregulated versions of the drugs that require a prescription. Unlike prescription drugs, which must prove they're safe and effective before being approved by the FDA, supplements aren't tested.

According to Lyndsay Meyer, press officer with the Food and Drug Administration, supplements fall into three general categories: erectile dysfunction, weight loss and body building. The FDA sends many supplements to the lab to be tested after receiving complaints from healthcare professionals and the public, and after making undercover buys of suspicious products.

"Consumers have no way of knowing which drugs or ingredients are actually in the product just by reading the ingredients on the label," Meyer said. The FDA lab has seen hidden drug ingredients or untested chemicals in pills, coffees, chewing gum and disposable oral strips.

Consumers are advised to consult with their health care professional before taking a new supplement.

## **SIDEBAR**

### *Identifying a Legitimate Website*

- 1) Genuine websites display the Verified Internet Pharmacy Practice Sites (VIPPS). For more information visit: <http://www.nabp.net/programs/accreditation/vipps/>.
- 2) Always use a website located in the United States.
- 3) Be suspicious if the website does not offer a way to contact them by phone or sells the drug at a steep discount.
- 4) A reputable website has a licensed pharmacist available to answer your questions and requires a prescription for prescription medicines from your doctor or another health care professional who is licensed to prescribe medicines.
- 5) A reputable website provides contact information and allows you to talk to a person if you have problems or questions.

6) Takes your credit card information over a secure server.

**Bio Note:** Paul R. Paradise is an expert on trademark counterfeiting. He is the author of Trademark Counterfeiting, Product Piracy, and the Billion Dollar Threat to the U.S. Economy (Praeger Books) and he has written a novel, The Counterfeit Detective (Koehler Books), based in part on real-life private investigator David Woods who was interviewed for this article.

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“World’s Most Counterfeited Brands” accessed September 6, 2016. <http://www.msn.com/en-gb/money/news/the-world%E2%80%99s-most-counterfeited-brands/ss-BBsSfoc>;

also: Protecting Viagra: Inside Pfizer’s Fake Drug Lab, available November 24, 2016  
<https://www.youtube.com/watch?v=AVZMVsrtnC8>

Bloomberg News, May 6, 2013. “Viagra Delivery: Pfizer, CVS, to Sell Drugs Online” Accessed September 20, 2016: <https://www.youtube.com/watch?v=ip5XAUGy-sc>

WebMed. “Buying ED Drugs Online: What’s the Risk?” Accessed September 21, 2016  
<http://www.webmd.com/men/buying-ed-drugs-online#1>

Kopman, Jeffrey. “Not Tonight Dear: Most Men With Erectile Dysfunction Avoid Treatment.” EveryDay Health Online. Accessed September 22, 2016. <http://www.everydayhealth.com/sexual-health/not-tonight-dear-most-men-with-erectile-dysfunction-avoid-treatment-8397.aspx>

Cheap Canadian Pharmacies Probably A Scam. Accessed September 14, 2016. <http://fusion.net/story/4672/cheap-canadian-pharmacies-probably-a-scam/>

FDA. “Be SafeRx Surey Highlights,” Accessed September 15, 2016  
<http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/buyingmedicinesovertheinternet/be-saferxknowyouronlinepharmacy/ucm318497.htm>

“Growing Threat From Counterfeit Medicines” WHO Bulletin Accessed September 19, 2016.  
<http://www.who.int/bulletin/volumes/88/4/10-020410/en/>

Dr. Fox, Online Pharmacy and Doctor “Why You Shouldn’t Be Embarrassed By Erectile Dysfunction.” Accessed September 22, 2016. <https://www.doctorfox.co.uk/news/why-you-shouldnt-be-embarrassed-by-erectile-dysfunction/>

Loe, Meika. The Rise Of Viagra [How The Little Blue Pill Changed Sex In America. New York University Press, 2004. Pg. 47  
Ibid. pg. 18

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Lippert, Barbara. “EDS Parallel Universe” Adweek Online, May 3, 2004. Accessed September 20, 2016  
<http://www.adweek.com/news/advertising/eds-parallel-universe-72174>

Ibid at n.vii, pg. 143.

Ibid viii pg. 173

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Sims, Paul. “I Took 35 Viagra After a 2-Day Bender.” The Sun. Accessed September September 16, 2016.  
<https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&ie=UTF-8#q=daniel+medforth+viagra>

Public Notification: "Reload Contains Hidden Drug Ingredient." Accessed September 22, 2016.

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm355955.htm>

U.S. Food and Drug Administration. Firm-Press Release "Nature and Health Company Issues Voluntary Recall of Libimax, a Product Marketed as a Dietary Supplement," Accessed September 22, 2016.

"<http://www.fda.gov/Safety/Recalls/ucm143630.htm>

Szabo, Liz. "Dangers of 'Herbal Viagra': What Every Man Should Know. USA Today Online October 15, 2015.

Accessed September 19, 2016. <http://www.usatoday.com/story/news/2015/10/15/sexual-supplements-can-dangerous-especially-when-combined-cocaine/73982616/>