



Comprised of 69 non-profit organizations, the **Partnership for Safe Medicines (PSM)** works with patient advocacy groups and consumer groups to teach them how to buy medication safely and affordably without risking their lives by dealing with unlicensed, dangerous counterfeit medication sellers.

PSM MEMBERS

Academy of Managed Care Pharmacy Alaska Pharmacists Association American Association for Homecare American College Health Association American Pharmacists Association American Society of Health System Pharmacists Arizona Pharmacy Alliance (AzPA) Association of Nurses in AIDS Care BioForward Biotechnology Innovation Organization California Life Sciences Association California Pharmacists Association California Society of Health-System Pharmacists (CSHP) Centre for Mental Health Colorado BioScience Association Community Access National Network European Federation of Pharmaceutical Industries and Associations (EFPIA) Generic Pharmaceutical Association Global Health Policy Institute

Healthcare Distribution Alliance HealthCare Institute of New Jersey Healthcare Leadership Council The Hispanic Institute Illinois Pharmacists Association Institute for Safe Medication Practices International AntiCounterfeiting Coalition International Federation of Pharmaceutical Manufacturers and Associations Kidney Cancer Association The Latino Coalition The Life Raft Group Maryland Pharmacists Association Maine Pharmacy Association Maine Society of Health-System Pharmacists (MSHP) Men's Health Network Minnesota Pharmacists Association Missouri Pharmacy Association National Alliance for Hispanic Health National Alliance On Mental Illness

National Association of Chain Drug Stores National Association of Boards of Pharmacy National Association of **Drug Diversion Investigators** National Association of Manufacturers National Alliance of **State Pharmacy Associations** National Biopharmaceutical Security Council National Community Pharmacists Association National Grange of the Order of Patrons of Husbandry NeedyMeds New York State Council of Health-system Pharmacists (NYSCHP) North Carolina Association of Pharmacists Oklahoma Pharmacists Association Parenteral Drug Association PDMA Alliance Pennsylvania Pharmacists Association

Pennsylvania Society of Health-System Pharmacists Pharmaceutical Industry Labor-Management Association (PILMA) Pharmaceutical Security Institute PhRMA RetireSafe Spina Bifida Association of America Texas Pharmacy Association Texas Society of Health-System Pharmacists United States Chamber of Commerce University of New England College of Pharmacy University of Texas at Austin College of Pharmacy Vietnam Veterans of America Virginia Pharmacists Association Vermont Pharmacists Association West Virginia Rx WomenHeart



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Overview

Abraxane Aclasta Actemra Alimta Aloxi Altuzan Anzemet Aredia Artzal Avastin Boniva Botox Doxil Dysport Eloxatin Erbitux Euflexxa Faslodex erclon Hyalgan **Every state** Juvederr cor in the U.S. Mabthera has had a counterfeit drug Menopur Me isone incident since 2000¹ Mirena Neula thovisc Perlane Perlane-L Pro Propofol Radiesse Remicade Restyla e-L Ristovi Rituxan Sandostatin-Lar Sculptra Supartz Synvise Synvise One Taxotere Triamcinalone Velcade Venofer Vidaza Xeomin Xolair Zometa

Why is Counterfeit Medicine A Problem?

It's a great scam. Counterfeiters can produce look-alike drugs and devices that contain little or no active ingredients, or the wrong ingredients, for less than the authentic medication would cost to make.

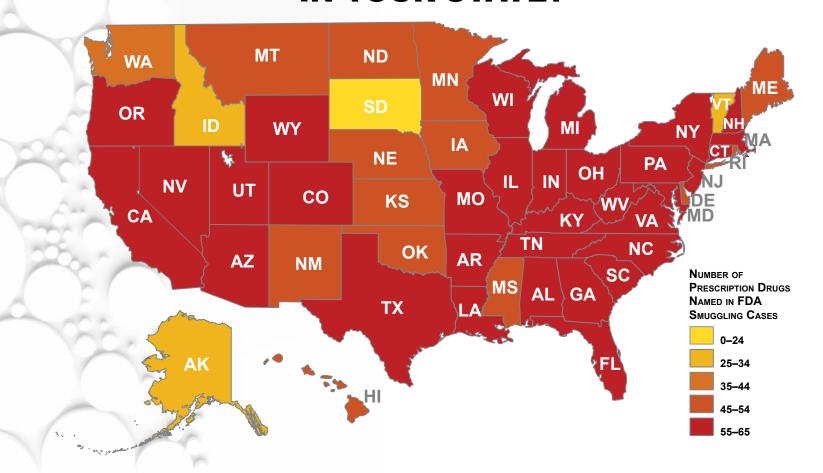
Criminals duplicate packaging, product shape, taste and feel so that it is indistinguishable from authentic medicine. Patients and doctors can't tell the difference. The patients suffer, the doctors wonder why, and no one questions the drugs' authenticity.

Fake drugs

- deny patients lifesaving treatment and relief
- promote drug resistant strains of disease
- cause suffering and death in innocent patients



HOW BROAD IS THE COUNTERFEIT DRUG TRADE IN YOUR STATE?



COUNTERFEIT MEDICINE SMUGGLERS have sold treatments for arthritis

birth control
macular degeneration
Cancer migraine
Crohn's asthma
disease infertility
anesthesia osteoporosis
cosmetic procedures

Smugglers who have been caught selling fake drugs sold up to 63 medications to over 3,000 doctors, clinics and hospitals across the U.S.²



REJECT dangerous drug importation schemes.

Overview

MEDICINE COUNTERFEITING IS A CRIME ON THE RISE

The World Health Organization estimates 10% of medicines across the world are counterfeit, and that 30% of the medicines in some areas of Asia, Africa and Latin America are fake.³ The impact of this counterfeit drug trade on human lives is unimaginable; fake drugs cost 100,000 lives a year in Africa alone.⁴

Counterfeiting medicine is a growing criminal enterprise in both variety of medicines counterfeited and in mass production. **All areas of medication are counterfeited**, with an almost **ninefold increase in the volume of fake drugs in just four years**. INTERPOL seized 2.4 million fake and illicit pills in 2011; in 2015, the total number of pills and other medications confiscated jumped to 20.7 million. 361 different pharmaceutical products were represented.⁵









In the U.S., counterfeits have been found in every therapeutic area.





Insulin and
Other Diabetic Supplies

CARDIOVASCULAR MEDICATIONS

CHRONIC CONDITION TREATMENTS (ALZHEIMER'S DISEASE, HIV)

Medical Devices
(IUDs,
Spinal Hardware,
Contact Lenses,
Bariatric Bands)

PAINKILLERS AND
WEIGHT LOSS MEDICATIONS

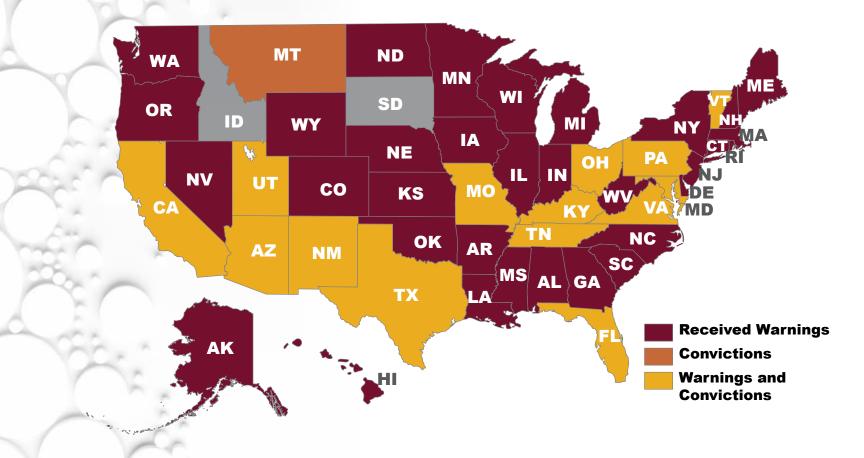
PSYCHIATRIC MEDICATIONS

Investigators have found fake versions of all of these made with heavy metals, poison, household materials, salt or sugar pills, as well as with inappropriate and sometimes dangerous medications.⁶



DOCTORS WARNED ABOUT FAKE CANCER DRUGS7

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The FDA keeps finding illegally imported counterfeit cancer medication and has notified more than 1,000 clinics across the U.S. that they may have purchased counterfeits sourced from foreign smugglers.⁸

MAY 2011: CHANDLER, ARIZONA

Cancer patient Betty Hunter had a serious reaction to an Avastin infusion given to her at Four Winds Hematology. Investigators inferred that she was treated with a counterfeit made of water and mold from the same lot of fake medicine they seized from her doctor's office.⁹

FEBRUARY 2012: LOS ANGELES, CALIFORNIA

The FDA warned health officials that unlicensed Canadian companies and their subsidiaries were selling fake Avastin cancer treatments with no active ingredients to U.S. cancer clinics.¹⁰

■ APRIL 2012: LA JOLLA, CALIFORNIA

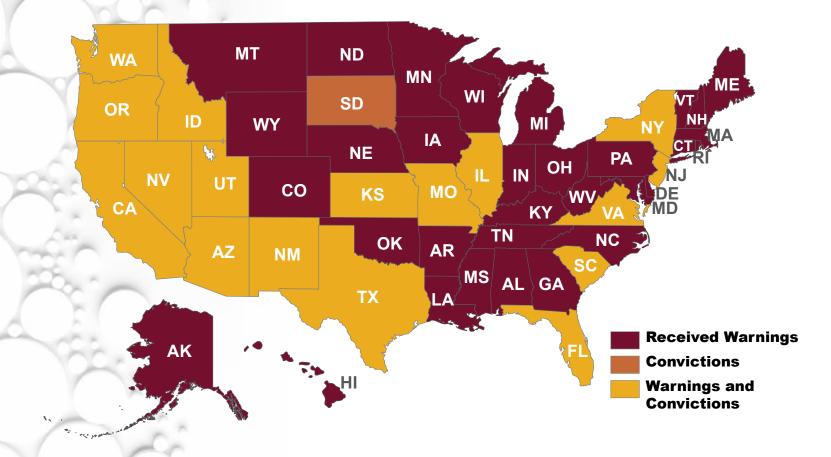
The FDA seized 120 vials of counterfeit cancer drugs with no active ingredient. The fakes were labeled "Altuzan" and imported through Turkey and the U.K. by Canada Drugs.¹¹

FEBRUARY 2013: DES MOINES, IOWA

■ The FDA found more counterfeit Altuzan distributed through an unauthorized wholesaler, Medical Device King, to an oncology practice.¹²



DOCTORS WARNED ABOUT FAKE BOTOX¹³



THE FDA WARNS ABOUT FAKE BOTOX IN 49 STATES



Since November 2012, the FDA has notified more than 2,500 American clinics—including a hospital in the Dallas area—that they have been ordering non-FDA approved Botox from unlicensed sellers. These medications, they warned, may be "counterfeit, contaminated, improperly stored and transported, ineffective, and/or unsafe." ¹⁴

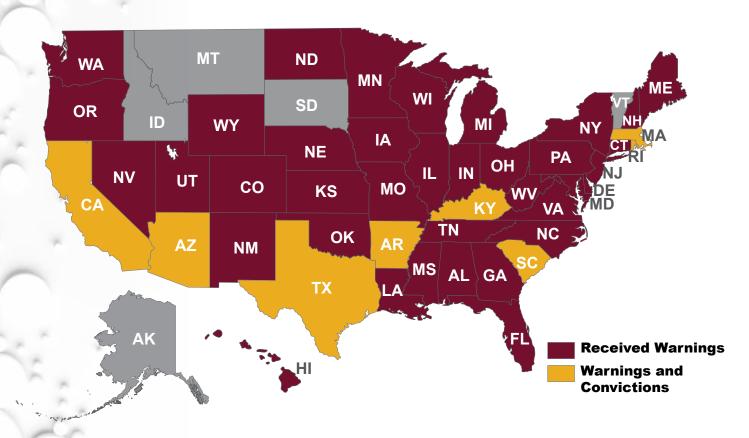
APRIL 2013

The FDA discovered counterfeit Botox purchased from unapproved foreign sources, advertised by blast faxes to medical practices, and using a false U.S. return address, even though they were mailing from overseas.¹⁵

APRIL 2015

The FDA discovered counterfeit Botox that was sold to clinics and shipped unsafely. One doctor called the supplier asking why five out of 10 clients had "side effects. Some clients went to the emergency room because the side effects were too strong." ¹⁶

BLACK MARKET IUDs IN THE U.S.¹⁷



NON-FDA APPROVED, BLACK MARKET IUDs

Unapproved intrauterine devices implanted by doctors have led to pregnancies, painful complications, and even an emergency hysterectomy. Since 2009, more than 40 individuals in 8 states have been disciplined for purchasing non-FDA approved, black market IUDs—often from unlicensed online pharmacies—and inserting them in patients. These include:

- **Dr. Paul Singh of Tehachapi, CA:** Despite multiple FDA warning letters, Dr. Singh implanted black market IUDs into his patients for years. When they complained of complications, he simply reinserted the same IUD. Many patients had to see another doctor to have them removed.¹⁸
- **Dr. Randall King of Owensboro, KY:** Dr. King was convicted of importing non-FDA approved devices from Turkey. One 22-year old patient experienced such serious complications from the IUD that an emergency surgery was scheduled, and her uterus was removed.¹⁹

In 2010, the FDA issued a letter to healthcare providers warning about the risks of black market IUDs. In 2013, the FDA issued 785 warning letters to medical practices saying they may have purchased counterfeit IUDs from known illegal importer Medical Device King.²⁰

COUNTERFEIT PILLS CONTAMINATED WITH FENTANYL ARE KILLING AMERICANS



The horror of fentanyl is not limited to heroin addicts. Laced through counterfeit prescription medications, it's killing patients who took fake pills believing that they were safe and genuine.

A lethal dose of heroin is easy to see; a lethal dose of fentanyl is barely visible to the naked eye.

Photo from New Hampshire State Police Forensic Lab, September 30, 2016.

Counterfeit medicines containing fentanyl, a synthetic opioid that is 30-50 times more potent than heroin, have been flooding into the U.S. since 2013, leaving behind a path of devastation and death. From late 2013 to late 2014, there were over 700 reported deaths related to fentanyl in the U.S. and the epidemic has only worsened since then.²¹

The counterfeit pills are made using equipment that can easily be purchased on the internet and look exactly like the legitimate medications. Only an analysis in a laboratory can detect the presence of fentanyl. **To date, counterfeit Xanax, Norco, Percocet and Vicodin have turned up in overdose deaths and drug busts in 31 states.**²² Unsuspecting individuals purchase these pills in-person or online and end up paying the ultimate price.

COUNTERFEIT MEDICAL DEVICES THREATEN PATIENTS' HEALTH



Dermal fillers: Researchers have found that illicit dermal injections can cause pneumonitis, pulmonary embolism and other serious illnesses.²³ These black market injections have included liquid paraffin, petroleum jelly, lanolin, beeswax, flax oil, linseed oil, olive oil, tire sealant, cement glue and automobile transmission fluid. Patients in Texas, Florida, Georgia and elsewhere have died after receiving these cosmetic injections.²⁴



Counterfeit and contaminated contact lenses: Tens of thousands of patients risked bacterial infection, eye injury and blindness when they purchased contact lenses from Candy Color Lenses without a valid prescription. Dmitriy Melnik of Las Vegas admitted importing bacteria-contaminated counterfeit colored contact lenses from the People's Republic of China and South Korea and selling them as "authentic" FDA-approved products. Melnik was sentenced to 46 months in prison in January 2017.²⁵



Expired weight loss surgery bands: Patients were subjected to non-sterile implants when two Florida businessmen purchased expired LAP-BAND Adjustable Gastric Banding Systems on the internet and altered their serial numbers and expiration dates so that they could be resold at a profit to Florida doctor's offices. At least seven of the bands were placed in patients.²⁶



Knock-off spine hardware: In 2013, after five years of chronic pain and infections, Derika Moses' doctor discovered that her pain was caused by an errant screw from spinal fusion surgery. After removing most of the spinal fusion hardware, investigators found that the majority of screws holding her spine together were counterfeit. Her hardware came from Spinal Solutions, a California company believed to have cut corners by hiring a local machinist to counterfeit thousands of sub-quality screws that they mixed in with the FDA-approved spinal hardware they sold to medical practices across the country. Moses is one of 106 patients who has filed a civil suit to demand redress from the hospitals that used these products.²⁷



Counterfeit surgical mesh: Patients risked infection and having their surgical mesh unravel inside their bodies when New Jersey's RAM Medical illegally imported and then sold counterfeit and contaminated surgical mesh from India and the United Arab Emirates. A lawsuit underway in 2011 suggested that as many as 150 patients may have been affected.²⁸

HIV/AIDS PATIENTS RELY ON CONSISTENT MAINTENANCE MEDICATIONS TO PRESERVE

THEIR HEALTH. Counterfeits made from secondhand and contaminated drugs undercut their treatment and expose them to poisons and illnesses like hepatitis C. America's closed, secure drug supply chain ensures the safety of these vital medicines that allow patients to live full lives without the imminent threat of death.

However, criminals exploit HIV/AIDS patients by collecting expired, partially used and illegally imported medications, repackaging them and selling them to American pharmacies and patients. In 2000, AIDS patient Rick Roberts suddenly found his HGH injections painful and the liquids in the vials were inconsistent. After 6 months of questioning and worry, Roberts was told that his lifesaving drug was a counterfeit with the wrong ingredients.²⁹



"I take over 10,000 pills a year. I depend on prescription drugs to stay alive and I need them to be safe." —counterfeit victim Rick Roberts

94 people in the U.S. have been implicated in black market HIV drug cases since 2006. As of January 2017, 69 have pleaded guilty or been convicted at trial and at least 17 cases are still in process.³⁰



AMERICAN CHILDREN are HURT by COUNTERFEIT DRUGS



One in four American children takes medicine routinely.³¹ Children depend upon prescription medication to restore health during an illness in order to become strong and healthy adults.

Counterfeiters prey on sick children and their parents:



In Austin, Texas, authorities discovered counterfeit antibiotics being sold over-the-counter. Children given these types of fake medications across the country were hospitalized for complications after ineffective treatment.³²

In Florida, a couple who owned a pharmacy concocted and sold fake medication, including inhaled drugs prescribed to children with cystic fibrosis.³³



Across the nation, the FDA has warned that internet pharmacies were selling a counterfeit version of Adderall that contained sedatives and painkillers instead of the effective active ingredients for ADHD.³⁴



Medicare for them.36

for treating patients with illegally imported osteoporosis drugs and fraudulently billing





Grandmother Betty Hunter sought treatment in 2011 for lung cancer at a Chandler, Arizona oncology clinic. Unfortunately for Hunter, that clinic was one of hundreds in the U.S. that cut corners by purchasing non-FDA approved medication. Her initial Avastin treatments had gone well, but during one chemotherapy session, she began to shake, becoming nauseous and feverish. Perplexed, the nurse discontinued the infusion.³⁹

An FDA raid of Hunter's doctor's office eventually led to the arrest and conviction of the suppliers who sold the drugs.

Lab tests revealed that the batch of medication seized was made of water and mold with no active ingredient. Hunter died of advanced stage lung cancer a few months later.⁴⁰

TENNESSEE WOMAN DIES from Counterfeit Xanax Pills





Misty Burnett, a 37-year old Tennessee mother, died in her Nashville home in January 2016 after taking fake Xanax (alprazolam). Misty's 18-year-old daughter found her dead. Shortly before she died of suspected fentanyl poisoning, she texted, "Hey, those aren't real...and I have been throwing up. I may have to go to the hospital."

Ms. Burnett's is one story in an epidemic. The FDA warns that U.S. patients who placed orders over the Internet for Xanax instead received counterfeit products containing powerful antipsychotic drugs resulting in emergency medical treatment.⁴²



San Francisco Public Health.





FAKE DERMAL FILLER INJECTIONS KILL in Florida, Georgia, and Texas



Karima Gordon, of Atlanta, Georgia died in 2012. Both Zenyasent Cisneros of Hidalgo, Texas and Suyima Torres, of Miami, Florida died in 2013. Wykesha Reid, of Dallas, Texas died in 2015. These women expected to be treated with dermal fillers made from collagen, hyaluronic acid, and other FDA-approved ingredients. Instead, they were injected with imported products made from industrial-grade silicone.⁴³

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Reid's abandoned body was found on a February morning inside a salon after a black-market silicone buttock augmentation injection went horribly wrong. A witness stated that Reid started having seizures after receiving her injections. An autopsy showed Reid died of pulmonary silicone embolization, i.e. ground glass from the injection found its way into her lungs.⁴⁴

At least 50 individuals have pleaded guilty or been convicted in court for purchasing or selling fake cosmetic injectables since 2005.⁴⁵

CHERYL WEINSTEIN DIES after taking MUSCLE RELAXANTS from a PREDATORY ONLINE PHARMACY

"911, what's your emergency?

My wife overdosed and I think she passed away. I think she's dead."



Special Agent Dan Burke told the Weinstein family's tragic story at PSM's Interchange conference in 2014. Watch it on YouTube at: http://safedr.ug/daniels911call

On March 11, 2011, Daniel Weinstein came home to find his wife dead. **55-year-old Cheryl Weinstein had overdosed in their home in Murrieta, California after taking a non-FDA approved version of carisoprodol, a muscle relaxant that she had purchased from a rogue online pharmacy.** After her death, her husband fielded predatory calls from illegitimate pharmacies who wanted Cheryl to buy more of the drug, and he found her email account flooded with hundreds of solicitations from illegal online pharmacies.⁴⁶

Online pharmacies that claim to be Canadian rarely distribute drugs from Canada, but hide behind a global distribution network. Their products appear to come from the European supply chain, but are often sourced elsewhere.

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SMUGGLERS IMPORT THEM

Drug smugglers acquire medicines at the cheapest prices, sneak them through customs and sell them for their own profit. **Alexandria, Virginia-based GALLANT PHARMACEUTICALS sold 39 non-FDA approved medications to over 300 medical practices in 34 U.S. states and D.C.** Though their address gave the impression of a legitimate company selling Canadian pharmaceuticals to the American medical market, nothing could have been further from the truth.⁴⁸

The medicine came from unreliable foreign sources and passed through transshippers in the U.K. and Canada. Drugs were shipped unsafely, and lacked patient-safety warnings.⁴⁹

To date, 12 individuals have been convicted and sentenced in connection with the case. The co-owners, Syed "Farhan" Huda and Talib Khan, were each sentenced to 36 months in prison and ordered to each pay \$3.4 million in forfeiture and restitution to victims.⁵⁰

Drugs purchased outside the safe supply chain can not be relied on to effectively treat illness. Patients taking these medicines may unknowingly be going without treatment for acute and chronic illnesses. Gallant Pharmaceuticals sold drugs that claimed to treat:

allergies, ankylosing spondylitis, brain cancer, breast cancer, cervical cancer, chronic lymphocytic, leukemia, colorectal cancer, Crohn's disease, eczema, esophageal cancer, glioblastoma inflammation, kidney cancer, lung cancer, mantle cell lymphoma, migraine, multiple myeloma, non-Hodgkin's lymphoma, osteoarthritis, ovarian cancer, Paget's disease, pancreatic cancer, plaque psoriasis, prostate cancer, rheumatoid arthritis, stomach cancer, ulcerative colitis⁴⁷

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When U.S. doctors purchased medicines from foreign supplier **TC MEDICAL GROUP/SB MEDICAL**, they were getting drugs lacking sufficient ventilation, temperature, humidity, and security. The drugs were kept in unregistered commercial mailboxes, residential backyards and porches, basement rooms, garages and kitchen refrigerators instead of drugs consistently maintained at safe temperatures and in sanitary conditions.⁵²

Excerpt from the TC Medical Group indictment:

68. On or about October 30, 2012, defendant DAVID E. BURKE and a co-

conspirator engaged in the following exchange:

Co-conspirator: 3 Orencia just arrived at the house. Ice was melted, of course, but they

weren't warm.

BURKE: did you find a cooler for yesterdays botox order?

Co-conspirator: No, but I used some insulating foil wrap and shrink wrap. Should have

been OK and looked pretty good. Sent in a white box which always

looks more medically professional too.

BURKE: perfect. thanks... have another order to go out today, sending it now.

Many commonly counterfeited medicines are temperature sensitive. If they become too hot or cold, the medication becomes ineffective. Smugglers do not care if medication arrives safely. They have stored foreign fake drugs in garages, basements and household refrigerators and sent shipments wrapped in ice, which melted. When doctors complained, they asked for the medication to be returned, put the fake vials in new boxes and sent the same drugs back to them.51

THEY FALSIFY CUSTOMS RECORDS

At trial, William Scully testified that the drugs and IUDs he sold via New York-based **MEDICAL DEVICE KING (MDK)** to U.S. doctors came from unknown "middlemen" and that he never tried to identify who they were. When the FDA tested intercepted shipments, the drugs had no active ingredient.⁵³



Doctors believed the 30 different treatments sold were FDA-approved products. Instead, MDK illegally imported counterfeit drugs from middlemen in Turkey, the U.K., Cayman Islands, Canada, UAE, Switzerland and India. Sometimes packages were seized by customs officials, sometimes customs officials were paid cash bribes to release shipments of drugs seized at the border between transshipping countries. Scully and his co-conspirator Shahrad Rodi Lameh falsified the declared value of the packages, broke packages into small quantities, and falsely labeled packages to deceive federal investigators.⁵⁴

Together, William Scully and Shahrad Rodi Lameh were found guilty of **66 felony counts**. Scully was sentenced to **five years in prison**.⁵⁵

Smugglers pose as bargain wholesalers, but their goods are made in rogue labs overseas. After they make a sale, they sneak black market medication into the U.S. using mail labeled as "gifts" and "samples." Then they repackage the drugs into counterfeit boxes and reship their fakes all over the country. In some egregious cases, they sell via telephone and ship directly from dirty labs in the third world to clinics and patients in America.

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TO OBSCURE THEIR SOURCES

TC Medical Group smuggled orthopedic injections, rheumatology infusions, cosmetic devices, ophthalmology products and oncology drugs into the U.S. from Europe, the Middle East and India. Multiple small shipments were sent to U.S. addresses using false names and falsified customs forms. Drop shippers received these packages, removed all evidence the drugs were foreign and re-shipped them to doctors and clinics in the United States with an American return address.

In addition to the five individual members of the conspiracy that pleaded guilty, TC Medical Group was fined \$45M and ordered to forfeit an additional \$30M for orchestrating a multi-year conspiracy to smuggle misbranded prescription pharmaceuticals into the United States.⁵⁶

Smugglers go to great lengths to obscure the true source of their fake medications, including lying on customs forms. They also ship to staging locations in the U.S. where they repackage drugs from unsafe countries that Americans wouldn't normally trust with fake packaging that looks like it comes from Canada, the U.K., or other countries Americans are more likely to trust.

Sometimes they disguise their products to make them look like American medicine.

TRANSSHIPPING THROUGH CANADA



Medicine smugglers use transshipping to disguise their products from customs officials. To obscure their source, packages of medicine start in one country and are shipped to Canada without passing through customs. Then they are immediately re-shipped to the U.S. without entering the Canadian drug supply.

Health Canada does not inspect packages being transshipped through Canada, but Americans who see the Canadian postmark think they've gotten a drug from the Canadian drug supply.⁵⁷

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Between 2009 and 2012, U.S. cancer patients were subject to an unknown quantity of counterfeit cancer drugs with no active ingredients when a Canadian pharmacy website sold to over 500 U.S. doctors in 45 states. In August 2015, the DOJ unsealed a 10-count indictment against eight individuals and six companies associated with CanadaDrugs.com. The indictment alleges that CanadaDrugs.com sold American medical practices \$78 million of unapproved, mislabeled and counterfeit cancer drugs between 2009–2012. Cancer drugs from the smugglers' foreign sources were tested and found to contain no active ingredients.⁵⁹

The company's complicated smuggling ring involved multiple illicit pharmaceutical distributors in Canada, the U.S., Barbados, and the U.K. LegitScript and the National Association of Boards of Pharmacy have identified CANADADRUGS.COM as a ROGUE INTERNET PHARMACY.⁶⁰



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Since 2005, at least **56 doctors have been charged with treating their patients with counterfeit or misbranded drugs**, and 51 have been pleaded guilty, been convicted, or settled the charges against them. Clinics in **CALIFORNIA**, **IOWA**, **SOUTH CAROLINA**, **TENNESSEE** and elsewhere have been prosecuted and paid fines for **defrauding Medicare** by treating their patients with deeply discounted fake or misbranded drugs. ⁶²

Some doctors have been caught buying discounted black market medication that isn't from **FDA-inspected factories** or licensed pharmacy wholesalers, treating patients with it, and then billing back insurance for significantly more than they paid. In one criminal act, they've both endangered patient safety and committed healthcare fraud.61



Among them are:







MEL E. LUCAS, DO: St. Louis-area physician Mel Lucas illegally imported Aclasta, an osteoporosis drug not approved for use in the United States, at a price that was lower than the FDA-approved equivalent, Reclast. Between 2009 and 2011 Lucas infused his unknowing patients with the unregulated Aclasta, billed Medicare and other insurance entities for the full-price Reclast, and pocketed the profits. Lucas and the clinic were sentenced to three years probation and \$185,799 in repayment to Medicare in September 2015.⁶³



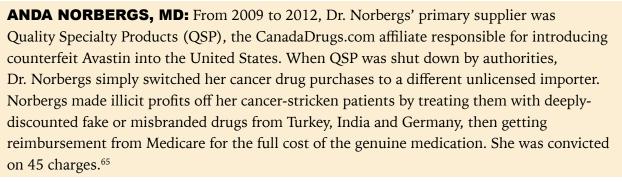
WILLIAM KINCAID, MD: Between 2007 and 2012, Tennessee oncologist William Kincaid bought imported cancer drugs from QSP, a subsidiary of CanadaDrugs.com, and billed Medicare and insurers as if he had paid the full price. When nurses raised concerns about the illegal drugs, Kincaid had the medicines shipped to a self-storage facility he owned and mixed them with the clinic's legitimate supply. He was sentenced to two years in prison and agreed to pay \$2.55 million to settle civil claims in 2013.⁶⁴

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ANOUSHIRVAN SARRAF, MD: Anoushirvan Sarraf, the owner of a cosmetic clinic in McLean, Virginia, treated his patients with black market cosmetic pharmaceuticals, but he also acted as a drop shipper for counterfeit drug sellers Gallant Pharma. Sarraf received 39 different kinds of non-FDA approved chemotherapy and cosmetic injectables at his clinic and stocked his own products from them. Between 2009 and 2013, 17,000 vials of pharmaceuticals worth more than \$10.3 million traveled through Sarraf's clinic and made their way to doctors in 34 states. Sarraf was convicted in May 2014 and sentenced in July 2014 to 18 months in prison and two years of supervised release.⁶⁶



The most common path for counterfeiters to reach Americans is through fake online pharmacies that sell directly to consumers.



Online pharmacies claim to distribute drugs approved for use in "safe" countries like Canada or the U.K., but are actually selling unapproved drugs that cannot be verified for safety or authenticity. Researchers studying consumer behavior around online pharmacies have found that it is easy to set up a convincing fake online pharmacy that deceives American patients.⁶⁷

Consumers in the U.S. mistakenly believe that Canadian pharmacies can sell them drugs from the Canadian drug supply. They are not legally allowed to do so. American patients get black market drugs marketed as Canadian, but they have not been vetted by the Canadian government.







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What they really mean: These drugs were made in a dirty lab in the third world, but we put a maple leaf on the package to make you feel better.





What they really mean: We have a special certification, but it's not by the FDA or the board of pharmacy of the state you live in. It's some guys who like cashing our checks and know how to use the Photoshop 'Chrome' and 'Lens Flare' filters for this cool seal.



What they really mean:

haven't been through the

U.S. FDA's safety trials.

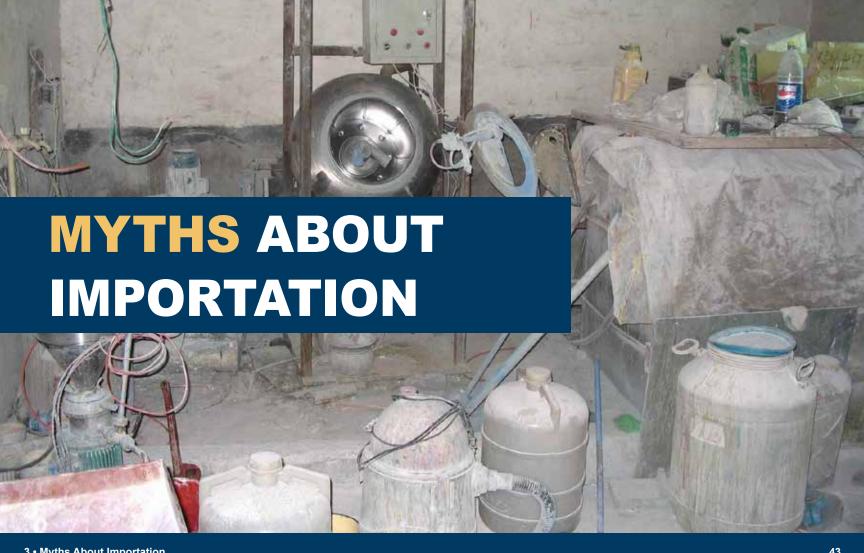
Don't be surprised if you start growing flippers or develop cardiac problems.

We offer drugs that

What they really mean: Since a Canadian pharmacist is not allowed to fill an American doctor's prescription, we can't tell you who our pharmacist is or she'd lose her license. Just trust us that she won't mix up your prescription.



What they really mean: Real doctors don't examine you via instant message and then write you a prescription for a serious lifesaving medication.



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MYTHS about BUYING DRUGS FROM CANADA

Myth: "If Canadian drugs are so dangerous, there would be more Canadian patient fatalities."

Fact: It's not legal for a Canadian pharmacist to dispense medication to an American without a Canadian doctor's prescription. What you'll get instead is a black market drug from a different foreign country, not one from the Canadian drug supply. Canadian patients don't take them.⁶⁸

Myth: "I got a package from Canada, it must be safe."

Fact: Investigators found that orders placed from so-called "Canadian websites" are often sourced from Turkey, India, or elsewhere. When you do get a package from Canada, it has likely been transshipped through Canada without passing Canadian customs. Health Canada, the Canadian version of the FDA, does not inspect transshipped packages. ⁶⁹

Myth: "Criminal penalties will deter foreign criminals from selling counterfeits to Americans."

Fact: In 2015 executives from CanadaDrugs.com were indicted for a \$78 million conspiracy to sell medications not approved by the FDA to Americans, including oncology drugs. The FDA intercepted some of their medications and lab-tested them. They were fake. These executives remain at large in Canada today, operating their fake internet pharmacy site selling to Americans.⁷⁰

Myth: "My medication is authentic because it looks just like what I buy at a U.S. pharmacy."

Fact: Not even trained pharmacists can determine whether a medication is fake without lab tests. Criminals have access to blister packs, litho printing, and even security holograms. They will use any compound from floor wax to road paint to make pills appear genuine. Some counterfeits contain a small amount of active ingredient to fool chemical screens. It is never enough to treat your disease.⁷¹

MYTH: "CANADIANS ARE HAPPY TO HAVE AMERICANS PARTICIPATE IN THEIR HEALTHCARE SYSTEM."

If Americans could guarantee that the drugs they bought from web pharmacies were coming from the Canadian pharmaceutical market, could the Canadian drug supply accommodate them?

NO. The population of the United States is nine times the population of Canada's.⁷² One patient advocate, Linda Wilhelm, noted in 2016 that drug shortages are more and more common in Canada. Opening up the Canadian drug supply to Americans will cause more shortages and endanger Canadian patients.⁷³

"We urge Americans not to raid Canada's pharmacies to try and buy cheaper medicines. Our mothers, fathers, siblings, and kids will all be further harmed by this. Furthermore many generic drugs are cheaper in America than they are in Canada."

—Linda Wilhelm, Canadian Arthritis Patient Alliance (2016)

Similar statements are available from Canadian patient advocates in the asthma, cancer, epilepsy, hemophilia, kidney, lymphoma and Parkinson's communities.

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MYTH: "WE ARE GETTING THE SAME DRUGS CANADIANS TAKE."



Testing proves they are not getting the same medicine.

They are risking ineffective and dangerous drugs from other countries.

From 2013 until 2015, Maine law allowed the importation of foreign prescription drugs from online "pharmacies" associated with licensed retail pharmacies in Canada, the U.K., Australia and New Zealand, exclusively.

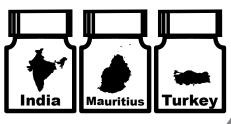
University of New England Professor Kenneth McCall tested three widely used medications from one of these pharmacy websites. He ordered drugs that are available in brand name and generic in the U.S., and received:

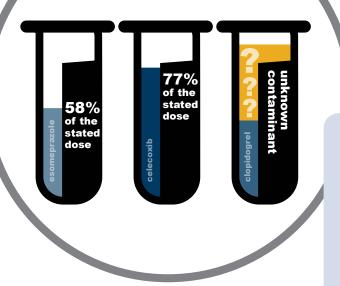
- A non-FDA approved generic of Nexium, esomeprazole (which treats acid reflux disease)
- A non-FDA approved generic of Celebrex, celecoxib (an anti-inflammatory)
- A non-FDA approved generic of Plavix, clopidogrel (a blood thinner)

The medicines McCall received came from India, Mauritius and Turkey and none of them were approved medicines in the U.S. or Canada. His tests showed: the esomeprazole was only 58% of the stated dose, the celecoxib was only 77% of the stated dose, and the clopidogrel contained an unknown contaminant.

Portland's WGME News performed the same experiment with similar results.⁷⁴







What happens if patients take black market medicine that is weaker than the stated dose? Treatment will be ineffective and potentially dangerous. Patients with chronic illnesses such as diabetes and hypertension may get sicker as doses vary between unregulated batches of medicine. Their doctors may presume that treatment is ineffective for that patient instead of realizing that their imported medication is unreliable. When patients do take medicine that is the right strength they could suffer bad side effects, overdose or death.

Because the medications come from foreign sources not supervised by the FDA, patients have no legal protection when they receive dangerous or ineffective drugs.

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EVERY HEAD of HEALTH & HUMAN SERVICES and THE FDA FOR THE LAST 15 YEARS appointed by a REPUBLICAN OR a DEMOCRAT has REFUSED TO CERTIFY the SAFETY OF DRUG IMPORTATION

APPOINTED BY A DEMOCRAT



Robert Califf, M.D.
Commissioner of the
FDA (2016–2017)

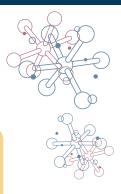
"FDA evaluation revealed that while nearly half of imported drugs claimed to be Canadian or from Canadian pharmacies, 85% of such drugs were actually from different countries."⁷⁵



Margaret A. Hamburg, M.D.

Commissioner of the FDA (2009–2015)

"Many U.S. consumers are being misled in the hopes of saving money by purchasing prescription drugs over the Internet from illegal pharmacies. Unfortunately, these drugs are often counterfeit, contaminated, unapproved products or contain an inconsistent amount of active ingredient. Taking these drugs can pose a danger to consumers."



APPOINTED BY A REPUBLICAN



Andrew C. von Eschenbach, M.D. Commissioner of the FDA (2006–2009)

"The product itself...is often coming from places other than Canada that we have absolutely no control or confidence in, or when analyzed are found to either not contain the active ingredients or to contain ingredients that are in fact harmful."



Lester Mills Crawford, D.V.M., Ph.D. Commissioner of the FDA (2005)

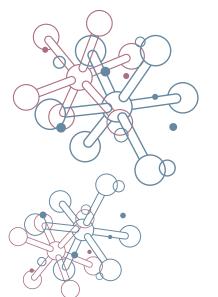


Mark Barr McClellan, M.D., Ph.D. Commissioner of the FDA (2002–2004)

APPOINTED BY A DEMOCRAT



Sylvia Mathews Burwell
Health & Human Services (HHS)
Secretary (2014–2017)



APPOINTED BY A REPUBLICAN



Michael O. Leavitt

Health & Human Services (HHS)
Secretary (2005–2009)



Kathleen Sebelius

Health & Human Services (HHS)
Secretary (2009–2014)



Tommy G. Thompson
Health & Human Services (HHS)
Secretary (2001–2005)

"It's impossible for us to certify that these drugs are safe."⁷⁹



Donna Shalala Health & Human Services (HHS) Secretary (1993–2000)

"flaws and loopholes...
make it impossible for me
to demonstrate that it
is safe and cost effective."⁷⁸

IT'S NOT A REPUBLICAN ISSUE. IT'S NOT A DEMOCRAT ISSUE. IT'S A SAFETY ISSUE.

http://safedr.ug/BiPartisan

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AFTER ALL WE'VE SEEN, CAN FOREIGN DRUG IMPORTATION WORK?

Someone who's watched it for 20 years says NO.

In the National Association of Boards of Pharmacy's nearly 20 years of experience, "U.S. consumers buying medications from Canadian online pharmacies rarely receive the Health Canada-approved products sold to Canadian customers. Instead, these Canadian pharmacy websites sell U.S. patients medicines manufactured in places where buyers would not even drink the water, e.g., India, Turkey, or Southeast Asia."⁸⁰

Since 1904, the National Association of Boards of Pharmacy (NABP) has been an independent, international, and impartial association that protects the public health by helping boards of pharmacy across the country and internationally regulate the licensing of pharmacists and pharmacies.







Patient Tip: TALK TO YOUR LOCAL PHARMACIST

Consumer Reports advises that you shop around, but then talk to your local pharmacist about price matching and keep all your medications at one pharmacy for safety. They compared prices at more than 200 pharmacies for newly available generic drugs, including diabetes drugs, antidepressants and cholesterol-lowering meds. They found "[local] pharmacists…have more flexibility to match or beat competitor's prices."81

PRESCRIPTION ASSISTANCE PROGRAMS



NeedyMeds is a 501(c)(3) non-profit that helps people who cannot afford medicine or health care costs. They administer a free drug discount program for people who do not have insurance or who cannot use their insurance to cover their medications. NeedyMeds is accepted at over 70,000 pharmacies nationwide.

Learn more at www.needymeds.org.

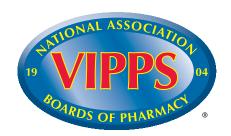


Partnership for Prescription Assistance

The Partnership for Prescription Assistance (PPA) is a free service that helps match patients who cannot afford medication to prescription assistance programs that provide free or nearly free medicines to eligible patients.

Visit www.pparx.org or call 1-888-4PPA-NOW (1-888-477-2669) for information.

Patient Tip: COMPARISON SHOP between LICENSED ONLINE PHARMACIES





Licensed online pharmacies carry the Verified Internet Pharmacy Practice Sites seal. Known as VIPPS, pharmacies that are VIPPS accredited must comply with state licensing where they reside and in every state where they do business. These pharmacies are proven to meet national standards for pharmacy practice, assure the quality of the drugs they dispense and provide real consultations with real pharmacists.

Another way to ensure that your online pharmacy is legitimate is to **look for the .pharmacy top level domain**. The National Association of Boards of Pharmacy vets the .pharmacy domain so that it contains only legitimate U.S.-licensed pharmacies.





PROTECT YOUR PRACTICE AND YOUR PATIENTS FROM COUNTERFEIT DRUGS AND DEVICES

All healthcare professionals who purchase medications or devices are familiar with unsolicited faxes from persistent direct sales companies. Though they offer below-market prices, remember that purchasing or using non-FDA approved drug products or devices exposes physicians to criminal and civil liability. Receiving and distributing counterfeit drugs or devices could be deadly for patients—and career-ending for physicians AND their staff.

FOLLOW THESE SAFETY STEPS





PHYSICIANS WERE CONVICTED OF OR PLED GUILTY TO USING UNAPPROVED ONCOLOGY DRUGS, COSMETIC INJECTABLES OR INTRAUTERINE DEVICES FROM 2009–2016.



PHYSICIANS

PAID FINES



AS LARGE AS **\$7.5** million

IN TOTAL

52 PHYSICIANS PAID \$32M IN FINES.82





Don't be fooled by fake drug sellers—verify your source. There are more than 340 MILLION FAKE ONLINE PHARMACY WEB ADDRESSES

looking for your business.83

MEDICAL OFFICE STAFF WHO PARTICIPATE IN BREAKING THE LEGAL SUPPLY CHAIN FACE HARSH PENALTIES.



THE CRIME:

An OFFICE MANAGER purchased non-FDA approved cancer drugs, mixed them in the supply of FDA approved drugs and billed back Medicare.

A COSMETIC CLINIC MANAGER made over 50 purchases of illegally imported Botox.

An oncologist and office manager purchased non-FDA approved counterfeit cancer medication that was tested by the FDA and found to lack the active ingredient for the medication.

THE PENALTY:

- HE WAS SENTENCED TO 3 YEARS OF PROBATION, 250 HOURS OF COMMUNITY SERVICE, AND A \$4,000 FINE.84
- ► HE WAS SENTENCED TO
 6 MONTHS OF HOME CONFINEMENT,
 120 HOURS OF COMMUNITY SERVICE,
 A FORFEITURE OF \$32,000 AND
 3 YEARS OF PROBATION.85
- ► THEY PAID A FINE OF \$300,000 TO SETTLE FALSE CLAIMS ACT ALLEGATIONS.86







The Partnership for Safe Medicines has Publications to Help You

FOR CONSUMERS

▶ Save Money Safely on Your Prescriptions from Online Pharmacies

♠ 6 Things You Don't Know About Canadian Web Pharmacies/

5 Ways to Save Money and Stay Safe bookmark





OUR EDUCATIONAL MATERIALS

Counterfeit Drugs in America: Victims, Crimes and Solutions, a comprehensive guide to the problem of counterfeit drugs in the U.S.

The Rogues Gallery Comic Book Series tells real-life stories of fake drug criminals and their cases.

Learn How to Decode a Fake Pharmacy Website, a poster telling your clients about the hazards of unlicensed online pharmacies.

How Healthcare Professionals Can Keep Patients Safe from Fake Drugs, a poster reminding doctors how to maintain a safe and legal drug supply.

Summaries by Therapeutic Area:

Cancer Drugs, IUDs, HIV/AIDS, Cosmetic Injectables

For additional materials, visit http://safedr.ug/psmmaterials



How Your Organization Can Help

If you are a patient advocacy group, The Partnership for Safe Medicines can help develop materials to communicate the dangers of counterfeit medicine.

- We host educational webinars for patients and law enforcement.
- We speak at conferences and other live events.
- We produce postcards for membership mailings.
- We design posters and other materials for health fairs.

Contact PSM at editors@safemedicines.org to learn more.



Alliance for Safe Online Pharmacies www.BuySafeRx.pharmacy

The FDA's BeSafeRx: Know Your Online Pharmacy safedr.ug/BeSafeRX

RX-360 www.rx-360.org

The Center for Safe Internet Pharmacies safemedsonline.org

FOOTNOTES

(for links to the materials, please consult www.safemedicines.org/factpack-2017-footnotes)

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