



The Partnership for
SAFEMEDICINES

COUNTERFEIT DRUGS: **A DANGEROUS THREAT TO AMERICAN PATIENTS** **FACT PACK**





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How Big is the Counterfeit Medicine Problem?

Criminals make billions of dollars creating and selling counterfeit drugs around the world and those products make their way into the United States. They duplicate the exact packaging, look and taste of the real thing. They can be difficult to detect, but detecting them is important. Counterfeit drugs can be a death sentence for the patients who end up taking them.

Fake drugs

- ▶ deny patients treatment that can alleviate suffering and save lives
- ▶ promote drug resistant strains of diseases
- ▶ may cause reactions with undeclared drug ingredients or toxic poisoning



GLOBAL GROWTH OF COUNTERFEIT DRUG INCIDENTS

A 2010 report published by the Stimson Center cited a 90 percent increase in counterfeit drug sales between 2005 and 2010; it estimated that the trade was worth over \$70 billion globally.¹ The impact of this trade on human lives is unimaginable: **the International Policy Network estimates that 700,000 people die per year because of counterfeit malaria and tuberculosis medicines alone.**²

**COUNTERFEIT
DRUGS AFFECT
ALL KINDS
OF PATIENTS
NATIONWIDE**







IN THE U.S.: COUNTERFEITS HAVE BEEN FOUND IN EVERY THERAPEUTIC AREA



ANTIBIOTICS



CANCER DRUGS



INSULIN AND OTHER DIABETIC SUPPLIES



CARDIOVASCULAR MEDICATIONS



TREATMENTS FOR OTHER CHRONIC CONDITIONS
(HIV, ALZHEIMER'S DISEASE)



PAINKILLERS AND WEIGHT LOSS MEDICATIONS



PSYCHIATRIC MEDICATIONS

Investigators have found fake versions of these medications made with heavy metals, poison, household materials, salt or sugar pills, and with inappropriate and sometimes dangerous medications.³



MEN'S HEALTH RISKS COUNTERFEITERS EXPLOIT

THE INTERNET PROVIDES THOUSANDS OF CLICKABLE LINKS TO SOLUTIONS AND TREATMENTS FOR THE MOST COMMON MEN'S HEALTH CONCERNS, BUT HOW MANY OF THEM ARE PROVIDING AUTHENTIC, SAFE MEDICATION?

BEFORE YOU BUY MEDICATION ONLINE FOR ANY OF THESE COMMON MEN'S HEALTH ISSUES, DO SOME RESEARCH, GET A PRESCRIPTION FROM YOUR DOCTOR AND ONLY BUY FROM A **VIPPS APPROVED ONLINE PHARMACY.**



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HYPERTENSION



1:3 U.S. ADULTS HAVE
HIGH BLOOD PRESSURE



1:3 U.S. ADULTS HAVE
PREHYPERTENSION



**THEREFORE: 2:3 U.S. ADULTS ARE AT
RISK FOR HYPERTENSION**



OBESITY

IN 2000



1:4 MEN WERE OBESE

CURRENTLY



1:3 MEN ARE OBESE



CANCER

FAKE CANCER MEDICATION WITH

0 active ingredients

CAME BY WAY OF

1 illiterate Turkish trader

WHO SIGNED THE PACKING SLIP WITH AN "X".

THROUGH EXPORT BUSINESSES ACROSS

3 continents AND **6 countries**

IT MADE ITS WAY TO THE U.S. AND WAS BOUGHT IN

15 states BY **89 American doctors.**



DEPRESSION

850,000

DEATHS EVERY YEAR

#7

CAUSE OF DEATH FOR MEN





ERECTILE DYSFUNCTION (ED)

AT BEST

1^{OUT}
OF 57,915

websites that offer ED meds could be a legitimate pharmacy.

HOW DO YOU LIKE THOSE ODDS?



CHRONIC RESPIRATORY DISEASE

IN 2011 THE FDA ALERTED CONSUMERS TO FAKE ANTIBIOTICS DISTRIBUTED IN

Colorado, Delaware, Texas, Florida, California and Georgia



HAIR LOSS

WEBSITES ADVERTISING MESOTHERAPY FOR HAIR LOSS:

209,000

STUDIES THAT SHOW MESOTHERAPY GROWS HAIR:

0 (zero, zilch, nada)



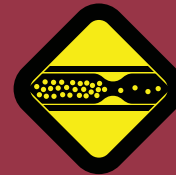
TYPE 2 DIABETES

13,000,000

AMERICAN MEN HAVE DIABETES

2,000,000

COUNTERFEIT INSULIN NEEDLES WERE FOUND IN EUROPE IN 2009



HIGH CHOLESTEROL

One of the leading factors in HEART DISEASE and STROKE.



1:6 U.S. ADULTS HAS HIGH CHOLESTEROL

COUNTERFEIT CHOLESTEROL CONTROL DRUGS ARE POPULAR ONLINE

Learn more at <http://safedrugs/top9risks>

© 2013 Partnership for Safe Medicines

The Top 9 Health Risks to Women's Health from Counterfeit Medicines

1

DISFIGURATION

has been caused by counterfeit Botox containing inauthentic ingredients such as cooking oil, which caused abscesses, scarring and kidney failure in victims.

A New Zealand woman was hospitalized for 6 weeks after being injected with an unknown substance by a friend who bought fake Botox online.

2

UTERINE INFECTION

is the likely result of counterfeit IUDs, a "nationwide problem" says the FDA. Trying to save money by purchasing fake IUDs has exposed women to unsanitary items that could cause uterine infection, complications, and unwanted pregnancy.

"Unapproved products bring a lot of unknowns into the equation," said FDA compliance officer Kathleen Anderson. "An internet ad may claim to sell IUDs made in Canada, but there's no way to be sure. They might have been made anywhere in the world and in unsanitary or undesirable conditions."

3

DIABETIC SHOCK AND COMA

can result from counterfeit insulin pen needles, fake diabetes test strips, and falsified diabetes medication. Incidents of these have all been found by government agencies. The Mayo Clinic lists diabetes as one of the top killers of women.

Resold, expired or counterfeit test strips are likely to give incorrect readings and cause treatment failure. Watch out for old test strips sold online.

4

MALARIA

is particularly deadly to pregnant mothers and their unborn children. While malaria is curable with authentic artemisinin combination therapies, fake anti-malarial drugs have become a crisis in Southeast Asia.

According to the Centers for Disease Control, malaria is at risk to re-emerge in the U.S., especially in the southern states. Counterfeit anti-malarial drugs have been found in Africa, Southeast Asia, East Asia, and the Solomon Islands.



5

CHRONIC LOWER RESPIRATORY DISEASE

is one of the top killers of women, according to the Mayo Clinic. Counterfeit antibiotics and flu vaccines, both found by investigators in fake pharmacies, can turn curable conditions into conditions like bronchitis and emphysema.

Worldwide, vaccines have been subject to counterfeiting including the inoculation of 60,000 Nigerians with fake meningitis vaccines, and 1,400 Texans injected with fake flu vaccines.

6

CANCER: Breast, Lung, Skin, and Colorectal

are the top cancers killing women, according to the Mayo Clinic. Fake cancer drugs have been found in three separate incidents in the U.S. in the past two years.

More than 50 cancer clinics in 15 states have been warned about purchasing fake cancer drugs by the FDA in just one year alone.

7

POST-PARTUM HEMORRHAGE

the leading cause of maternal mortality according to the American College of Obstetricians and Gynecologists, is treatable with Misoprostol - unless it's fake. Fake Misoprostol, available worldwide, could cost a mother's life before the mistake is discovered.

"Each year, 45 million women deliver without a skilled attendant, a situation in which the greatest number of maternal deaths occurs," say World Health Organization experts, adding that "women can safely self-administer Misoprostol orally to effectively prevent postpartum hemorrhage."

8

OSTEOPOROSIS

is treated with risedronate. A fake Canadian online pharmacy sent U.S. customers seeking to treat osteoporosis with counterfeit risedronate tablets instead of the real medication. FDA agents intercepted and tested purchases, finding them to "not contain the proper amount of active ingredients."

Not only did consumers get counterfeit medications, they also have been extorted by fake FDA agents, who demanded "fines" of \$1,300 to \$100,000 to be sent to the Dominican Republic via Western Union.

9

HEART DISEASE

is the top killer of women. Medications to prevent heart disease like smoking cessation aids, weight loss medication, and statins have all been purchased in counterfeit form online. Some fakes contained dangerous substitute ingredients that masked symptoms with the possibility of life-threatening side effects including stroke.

Buying medication from random strangers online is a great way to get a dangerous counterfeit containing controlled substances like sibutramine, which can cause high blood pressure, seizures, tachycardia, palpitations, heart attack or stroke.



Learn more at <http://safedr.org/Whlth>



HOW COUNTERFEIT DRUGS IMPACT THE HEALTH OF CHILDREN

Many children (1 in 4 in the United States) take medicine on a regular basis; many depend on prescription medication for life and health.

Counterfeit drugs inevitably make their way to children:

Texas, 2011: Austin authorities discovered counterfeit antibiotics being sold over-the-counter. Children given these supplements across the country are hospitalized after ineffective treatments.⁴

Florida, 2005: A couple who own a pharmacy concocted and sold fake medication, including inhaled drugs prescribed to children with cystic fibrosis.⁵

United Kingdom, 2011: British authorities confiscate counterfeit asthma inhalers that stop working after only a third of the doses are consumed. 1.1 million British children have asthma.⁶

Nigeria, 2009: 84 children die because their teething medication contains an industrial solvent used in antifreeze and brake fluid. This incident is just one of at least 9 mass poisonings causing hundreds of deaths worldwide over the last 20 years.⁷





5 KINDS OF POISONS FOUND IN COUNTERFEIT DRUGS

Investigators have found harmful ingredients in counterfeit drugs:

Heavy Metals are carcinogenic or toxic to central nervous system, kidneys, liver, skin, bones and teeth.

Poison can cause kidney damage, kidney failure, cancer, developmental defects.

Common household supplies (floor wax, sheet rock, paint thinner) can cause vomiting, abdominal pain, dizziness, blurred vision, respiratory difficulty, nervous system disruption, coma and death.

Inappropriate medications can cause difficulty breathing, muscle spasms or stiffness, high blood pressure and stroke.

No medicine at all. A potentially life-saving medication without an active ingredient will cause harm and could cause death.⁸

The New York Times Health | Science

OCTOBER 23, 2007, 6:34 AM

Drug-Resistant Staph: What You Need to Know

By TARA PARKER-POPE

For years health authorities have warned of the growing threat posed by drug-resistant bacteria, but most of us have been half-listening. Not anymore.

A virulent strain of bacteria that resists many antibiotics appears to be killing more people annually than AIDS, emphysema or homicide, taking an estimated 19,000 lives, the *J* recently reported in *Vit*

The New York Times Science

Published: September 3, 2012

Tuberculosis: Stubborn and Expensive to Treat, Drug-Resistant Strains Show Growth

By DONALD G. McNEIL JR.

A new study has confirmed, once again, that hard-to-cure drug-resistant tuberculosis is a growing problem.

The study, published last week by *The Lancet*, measures which antibiotics worked or did not work against

The New York Times Health

Published: March 5, 2013

Deadly Bacteria That Resist Strongest Drugs Are Spreading

By DENISE GRADY

Deadly infections with bacteria that resist even the strongest antibiotics are on the rise in hospitals in the United States, and there is only a "limited window of opportunity" to halt their spread, health officials warned Tuesday.

The bacteria, normally found in the gut, have acquired a lethal trait: they are unscathed by antibiotics, including carbapenems, a group of drugs that are generally

BBC NEWS HEALTH

11 March 2013 Last updated at 09:36 ET

Antibiotics resistance 'as big a risk as terrorism' - medical chief

By Fergus Walsh
Medical correspondent

The danger posed by growing resistance to antibiotics should be ranked along with terrorism on a list of threats to the nation, the government's chief medical officer for England has said.

Professor Dame Sally Davies described it as a "ticking time bomb".

She warned that routine operations could become

BBC NEWS HEALTH

28 May 2013 Last updated at 09:08 ET

H7N9 bird flu drug resistance concern

By James Gallagher
Health and science reporter, BBC News

Drug resistance has been detected in patients infected with the new bird flu that has emerged in China, say doctors.

The H7N9 virus became resistant to Tamiflu in three out of 14 patients treated with antiviral drugs at Shanghai Public Health Clinical Centre.

The researchers, writing in *The Lancet*, said resistance

▶ FAKE DRUGS CAUSE DRUG RESISTANT DISEASES

In 2010 malaria killed over 38,000 people, mostly pregnant women and children, in Southeast Asia. A third of the malaria medicine in the region is fake or ineffective, and these treatments have fueled the development of drug resistant malaria, which emerged in the region in 2012.⁹

Interrupted treatment and substandard counterfeit drugs have also caused a worldwide surge in drug resistant tuberculosis. In early 2013 a study of 17 countries where multi-drug resistant TB is a problem found that 9.1% of the medicines were insufficient. TB costs nearly \$5 billion each year to treat, and kills about 1.4 million people annually.¹⁰



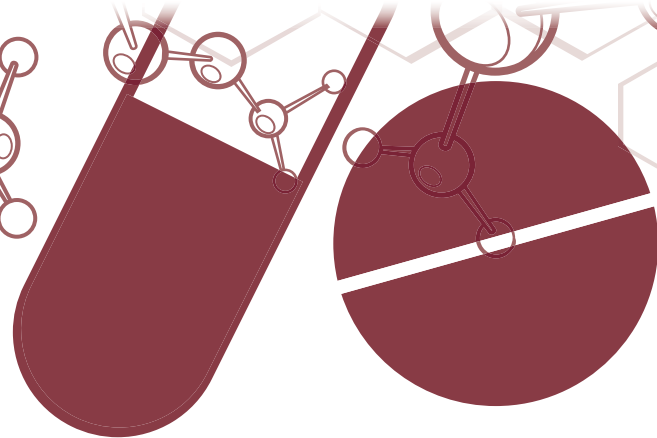
Drug resistance is also a problem here in the United States.

The CDC has identified many life threatening drug resistant strains of common illnesses, among them **MRSA, TB, Group B Strep, Gonorrhea and Bacterial Meningitis.**¹¹

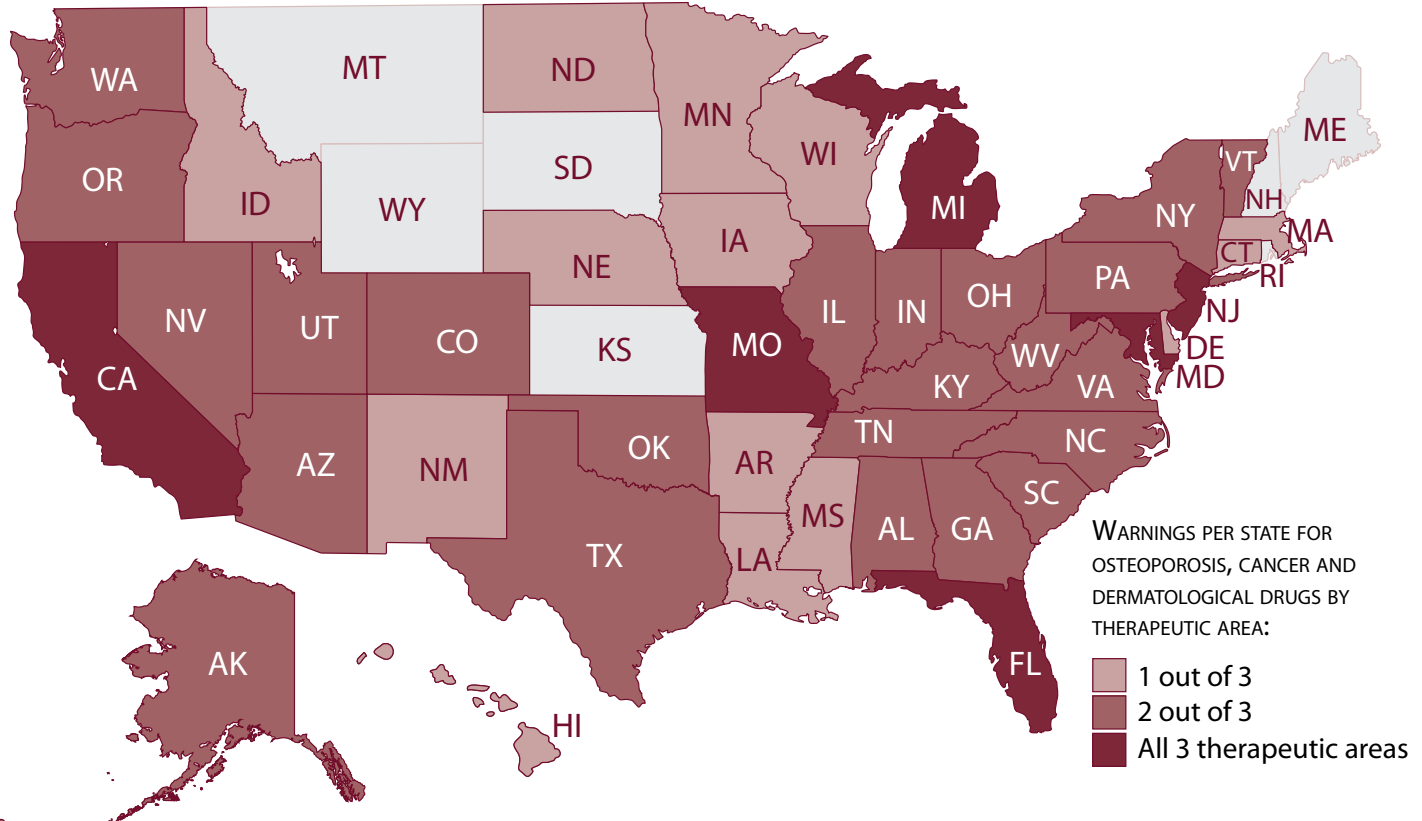
Counterfeits have fueled the development of drug resistant diseases overseas, causing needless suffering and death. A safe medicine supply can discourage drug resistant infections in the United States.

COUNTERFEIT DRUGS IN CLINICS AND MEDICAL OFFICES

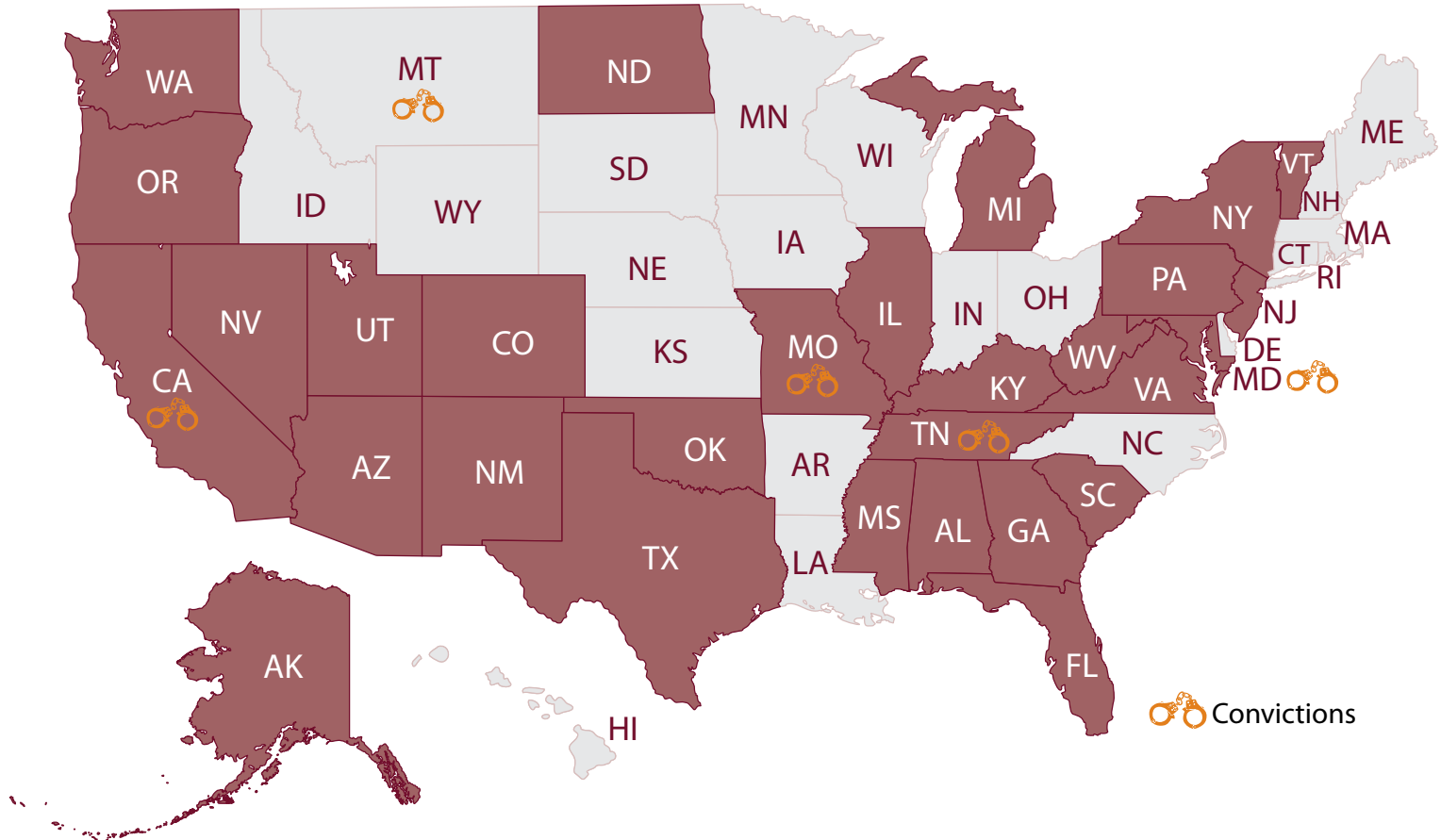
The newest threat to American patients is black market drugs being sold directly to doctors' offices and clinics. Counterfeiters are now directly targeting health care professionals with advertisements for non-FDA approved drugs from unknown sources at "too good to be true" prices.



HAVE PATIENTS IN YOUR STATE BEEN EXPOSED TO COUNTERFEIT OR UNSAFE MEDICATION?



DOCTORS WARNED ABOUT FAKE CANCER DRUGS



COUNTERFEIT DRUGS IN THE U.S.:

THE FDA FINDS FAKE CANCER DRUGS

In 2011, the FDA seized a counterfeit version of the life-saving cancer drug Avastin and found that it contained **NO ACTIVE INGREDIENT**. Since then the FDA has notified 145 medical practices in 29 states that they may have purchased a counterfeit version of the drug, which was distributed by a fake online Canadian pharmacy.

► February 14, 2012: Los Angeles, CA

Roche located foreign-supplied counterfeit Avastin with no active ingredients.

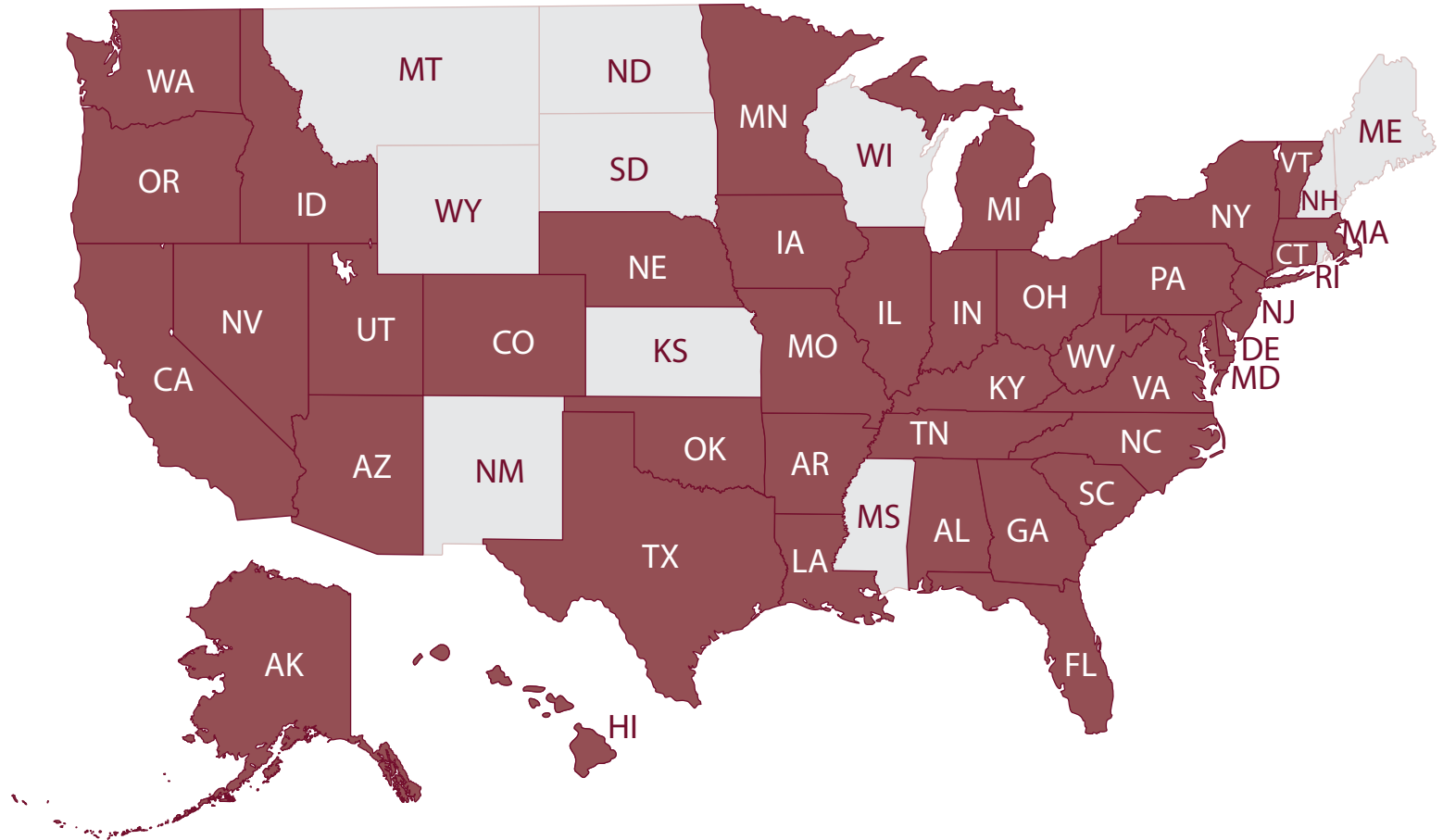
► April 12, 2012: La Jolla, CA

The FDA seized 120 vials of fake Avastin, which was shipped through the U.K. from Turkey.

► February 5, 2013: Great Neck, NY

The FDA found counterfeit Altuzan in the U.S., distributed through an unauthorized wholesaler.¹²

DOCTORS WARNED ABOUT FAKE BOTOX



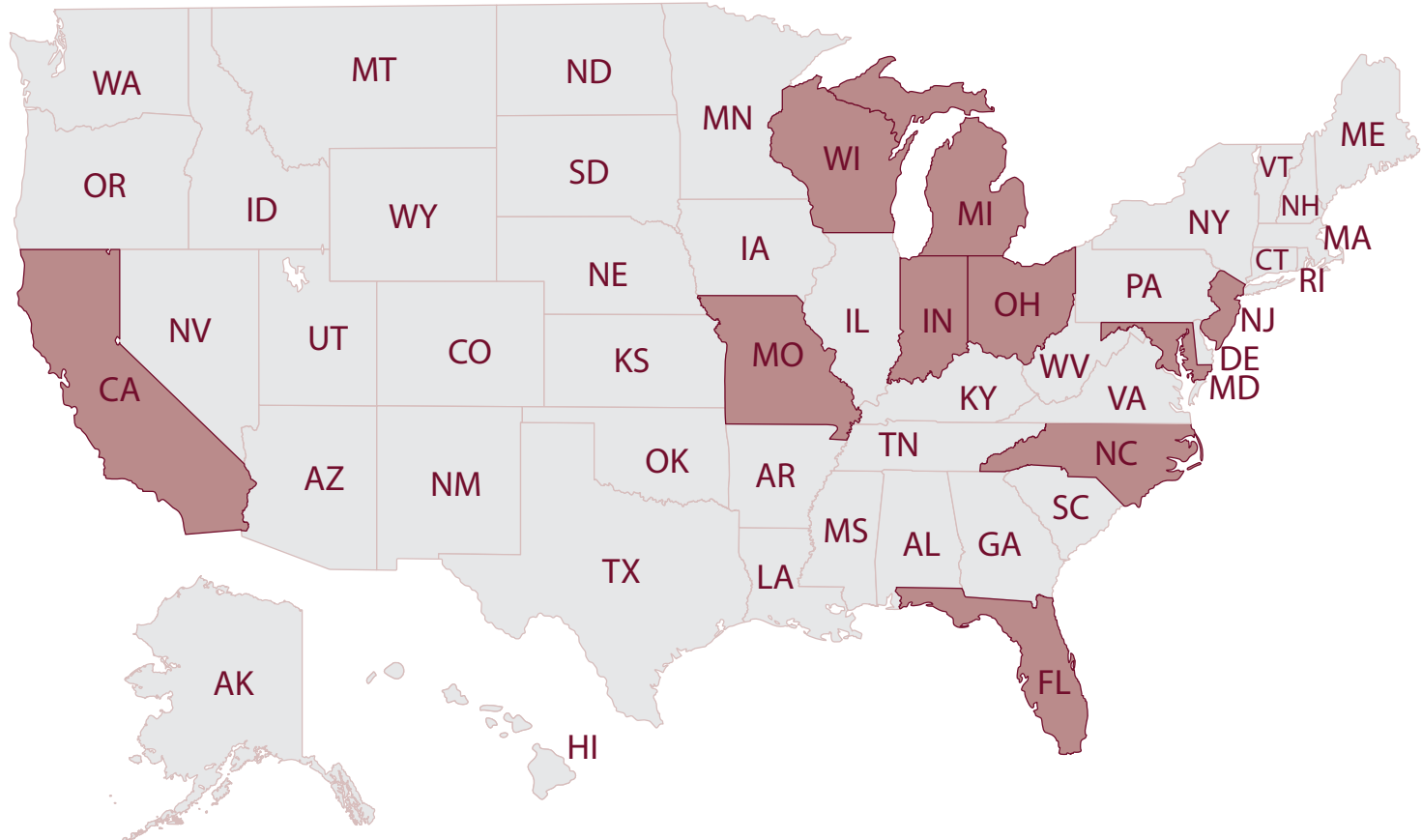
COUNTERFEIT DRUGS IN U.S.:

THE FDA WARNS DOCTORS AND HOSPITALS ABOUT FAKE BOTOX

In December 2012, the FDA sent warnings to over 350 medical offices—including a hospital in the Dallas area—across the United States asking them to stop ordering non-FDA approved Botox from unlicensed sellers. They warned that these medications may be “counterfeit, contaminated, improperly stored and transported, ineffective, and/or unsafe.”¹³

Fake Botox has been found in investigations in Los Angeles, Miami, and Kentucky since 2005. Patients receiving such treatments have suffered disfigurement, respiratory paralysis and near death.¹⁴

DOCTORS WARNED ABOUT UNSAFE OSTEOPOROSIS DRUGS



UNSAFE DRUGS IN THE U.S.:

BLACK MARKET OSTEOPOROSIS MEDICINE FROM AN UNLICENSED FOREIGN COMPANY

In September 2012, the FDA issued letters warning 23 U.S. medical practices that they may have purchased unapproved versions of the osteoporosis treatments Prolia and Aclasta from unlicensed wholesalers.¹⁵ According to Thomas Christl, Acting Director of Drug Security, Integrity and Recalls, “the Agency is very concerned that products distributed by this distributor may cause harm to patients, because they may be unsafe or ineffective.”¹⁶

UNSAFE DRUGS IN THE U.S.:

OTHER INCIDENTS

IUDs ► In August 2013, Kentucky obstetrician/gynecologist Dr. James Buck pled guilty to purchasing unapproved foreign IUDs via unlicensed online pharmacies and then **inserting them into female patients**. Black market IUDs which may be improperly engineered, sterilized and packaged can cause serious infection and even death. A second doctor, Cahn Jeff Vo, was indicted in March 2013 for the same crime.¹⁷

Flu Treatments ► In February 2013, the FDA warned consumers about fraudulent flu treatments sold over the counter and through fake online pharmacies that do not prevent or treat flu symptoms. The agency has issued over 100 enforcement letters to drug manufacturers and distributors about false flu treatments since 2001.¹⁸

Adderall ► In May 2012, the FDA warned consumers and healthcare professionals about a counterfeit version of Adderall being sold on the Internet. The circulating counterfeit contained painkillers (tramadol and acetaminophen) rather than the correct active ingredients (dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, and amphetamine sulfate).¹⁹


Weight Loss Drugs ► Between 2008 and 2010, the FDA issued a series of alerts on its website concerning tainted weight loss pills and counterfeit drugs, including the brand name drug Alli that contained sibutramine, a controlled substance that can cause high blood pressure, seizures, tachycardia, palpitations, heart attack or stroke.²⁰



▶ PATIENT DEATH:

MAXINE BLOUNT DIES AFTER FAKE ANEMIA DRUGS DELAY HER TREATMENT

When Missouri businesswoman Maxine Blount had a recurrence of breast cancer in 2001, she took Procrit to battle the anemia that was a side effect of her chemotherapy. In March 2002, nurses discovered that Maxine's medicine was one-twentieth the strength it should have been. A drug ring in Miami had sold as many as 11,000 boxes of counterfeit Procrit to legitimate wholesalers across the

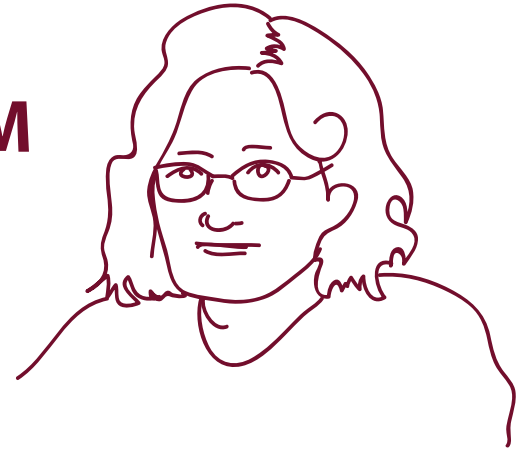


“Stronger controls would have delayed Maxine’s death, reduced her suffering, and allowed her to die with more dignity.”

country, and Maxine was unlucky enough to be a victim. Maxine died of breast cancer in October 2002. As her brother wrote in testimony before Congress in 2003, “stronger controls would have delayed Maxine’s death, reduced her suffering, and allowed her to die with more dignity.”²¹

▶ PATIENT DEATH:

MARCIA BERGERON DIES FROM HEAVY METAL POISONING FROM DRUGS BOUGHT FROM FAKE ONLINE PHARMACY



58-year-old British Columbian Marcia Bergeron was found dead in her home in 2006. Her death was a mystery until a toxicology report showed that **her liver was contaminated with heavy metals**. Investigators found that Bergeron had unknowingly been purchasing drugs from fake online pharmacies. Bergeron, like many island residents, did most of her shopping online. **She was web savvy, but didn't know about the dangers of online "pharmacies," and fell victim to greedy counterfeiters selling her contaminated drugs.**²²

▶ PATIENT DEATH:

U.K. PARAMEDIC DIES DUE TO PILLS BOUGHT FROM FAKE ONLINE PHARMACY



Lorna Lambden, a 27-year-old paramedic and master's student at the University of Hertfordshire, overdosed in her home in December 2010. Lambden had purchased amitriptyline to use as a sleep-aid, and was found with an empty glass of wine and four times the therapeutic level of the drug in her bloodstream. Amitriptyline isn't recommended in the U.K. because of the risk of overdose, especially with alcohol, but **Lambden received no counseling about the drug's dangers or advice about the correct dose. She purchased the medicine without a prescription from a fake online pharmacy.**²³

▶ PATIENT DEATH:

RYAN HAIGHT DIES FROM AN OVERDOSE OF VICODIN HE PURCHASED WITHOUT A PRESCRIPTION FROM A FAKE ONLINE PHARMACY

On February 12, 2001, Ryan Haight, a straight-A, talented high school scholar and athlete died because of an overdose of Vicodin, a powerful painkiller that he'd purchased without a prescription through an unregulated Internet seller.²⁴



Ryan's untimely death was the inspiration for **Ryan's Cause, Inc** (<http://www.ryanscause.org/>), a non-profit dedicated to "educating and providing information for parents, families and communities on issues concerning the Internet and drug abuse," and the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, which requires that no "prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription."

DRUG IMPORTATION: WHAT YOU DON'T KNOW ABOUT BUYING DRUGS FROM CANADA CAN HURT YOU

Drug importation programs—even government sponsored ones—encourage Americans to gamble with their health. Seniors and other people on fixed or limited incomes are especially vulnerable.

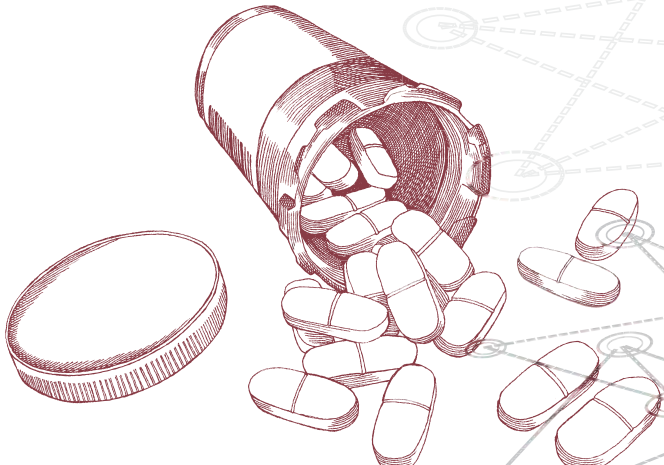
Americans who import drugs from Canada can't be sure what they're getting.

- ▶ **70% of drugs sold to Americans from Canada are made elsewhere, often from a country with fewer protections than either the U.S. or Canada.**
- ▶ **Drugs shipped through Canada are unregulated.** Health Canada does not regulate drugs unless they are prescribed to Canadian citizens and the FDA can't police Canadian drug distributors.²⁵



DRUG IMPORTATION IS ILLEGAL

- ▶ Legitimate Canadian pharmacies cannot fill prescriptions from doctors who are not Canadian.
- ▶ Importation of medicine from foreign sources violates the Food, Drug and Cosmetics Act.²⁶



**COUNTERFEIT
DRUG
CRIMINAL CASES
IN THE U.S.
SINCE 2001**



REAL DOCTORS ENDANGERING PATIENTS WITH BLACK MARKET DRUGS



When Tennessee oncologist William Kincaid purchased cancer drugs from unauthorized distributors who were hawking counterfeit drugs he made large profits for himself. Kincaid made \$500,000 by purchasing discount drugs and billing Medicare and insurers as if he had paid the full price for them.²⁷

He's not alone; doctors across many medical fields are buying drugs from outside the American supply chain and committing billing fraud for their own profit. Since 2010:

- ▶ At least 5 doctors and 2 pharmacists have pleaded guilty to illegally billing government programs for non-FDA approved drugs and pocketing the profits.²⁸
- ▶ At least 9 additional doctors are under investigation.²⁹
- ▶ 518 medical practices have been warned by the FDA that they may have purchased counterfeit or non-FDA approved Botox, Prolia, Aclasta or Avastin from foreign suppliers.³⁰

**MISSING
KEY
INGREDIENTS**

**WRONG
ACTIVE
INGREDIENTS**

**WRONG
STRENGTH**

CONTAMINANTS

**UNSAFE
METHODS**

**IMPROPER
LABELS**



HOW DO COUNTERFEIT DRUG CRIMINALS OPERATE?

Counterfeit drug criminals deliberately sell dangerous, contaminated or substandard medicines for their own profit.

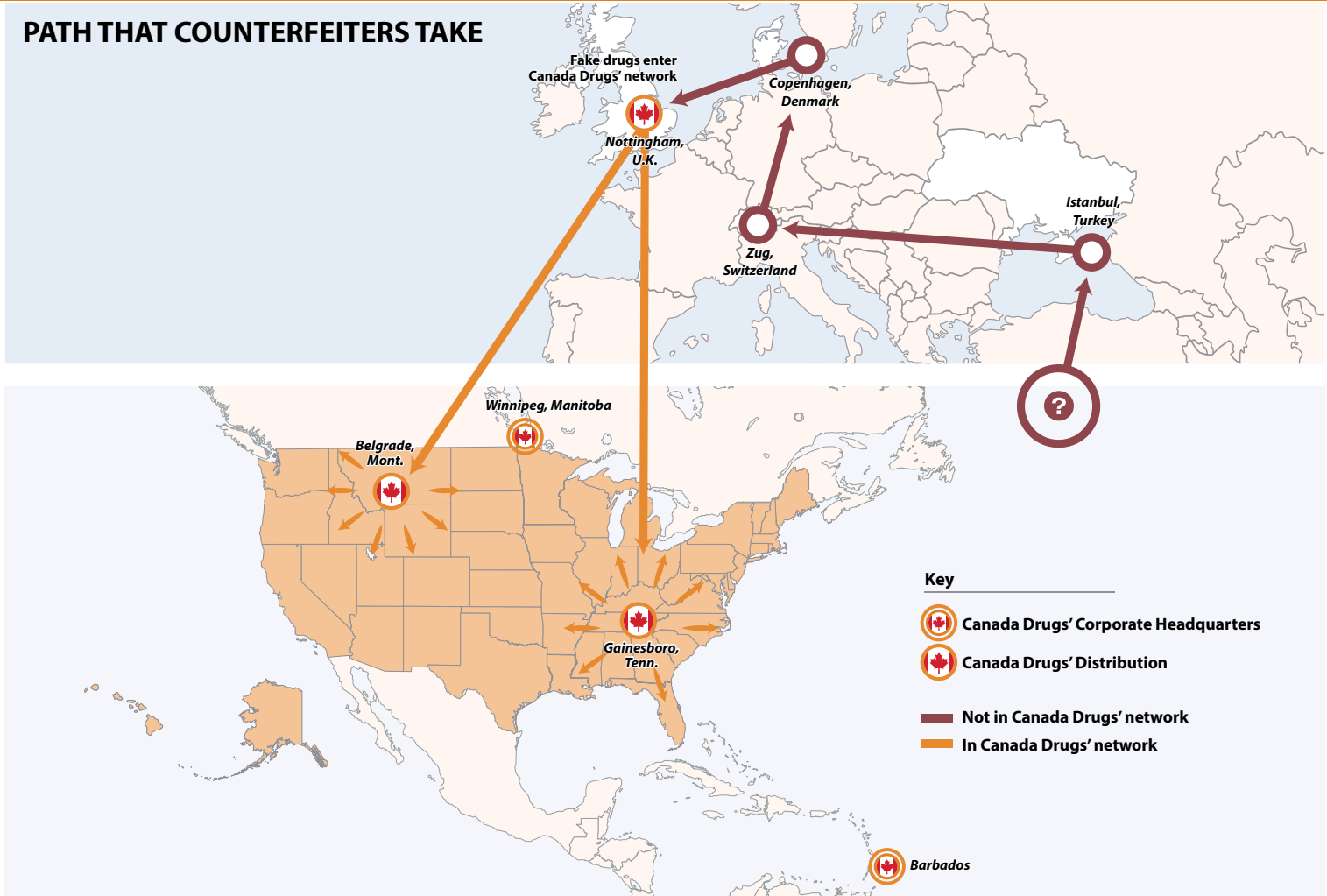
The production, distribution and trafficking of fake drugs by organized crime networks is a multi-million dollar activity that has significant impact in the United States. Between 2010 and 2012:

- ▶ The FDA opened 227 rogue Internet pharmacy investigations and convicted 219 individuals
- ▶ 138 Immigration and Customs Enforcement investigations led to 56 convictions and the seizure of nearly \$7 million
- ▶ The United States Postal Inspection Service worked on 392 investigations and arrested 560 individuals
- ▶ The IRS conducted 22 investigations and convicted 5 individuals
- ▶ The DEA seized more than \$1 million in the course of 49 investigations into rogue Internet pharmacies³¹

U.S. Customs and Border Patrol reported that in 2011 alone, it made 1,239 seizures worth \$16.8 million in counterfeit drugs bound for the American market.³²

Pills made in one country are often shipped to another, where they are packaged using forged packaging to match local specifications. Even then, fake drugs may change hands many times across many countries before reaching a victim. Fake drugs produced in China have been transported around the world, from Dubai, to London, to the Bahamas, before ending up in the United States. Unfortunately this is a common scenario.

PATH THAT COUNTERFEITERS TAKE





HOW COUNTERFEIT DRUGS ARE DISTRIBUTED IN THE U.S.: A CASE STUDY

False medicines travel through many hands to conceal who is manufacturing and repackaging them. Consumers who buy from these crime networks can never be certain what they are purchasing.

In 2011, the FDA found counterfeit versions of the cancer medication Avastin that contained

NO ACTIVE INGREDIENT.

The fake medication was injected into patients after a round-the-world journey which began in Turkey, moved through different European Union pass-through distributors, and ended up in clinicians' offices in the United States. The company that allegedly supervised the distribution of the medication according to both the FDA and the Wall Street Journal was a so-called Canadian online pharmacy, CanadaDrugs.com.³³

COUNTERFEIT DRUG CRIMES THAT THREATENED AMERICANS

A stylized illustration in the top right corner featuring a pair of handcuffs and a keychain with several keys, rendered in a light orange color.

Adulterated Cancer Medications Sold Directly to Physicians, 2008 – 2011

Through his California-based company, Ban Dune Marketing Inc., James Newcomb distributed adulterated and unapproved prescription drugs, including chemotherapy drugs such as Avastin, to as many as 60 doctors across the United States without ensuring safe handling of the medicines.³⁴

Domestic Drugs Stolen and Resold to Licensed Drug Distributors, 2007 – 2009

William Rodriguez bought medication from hijackers, black market dealers and directly from patients to resell back into the secure supply chain with forged pedigrees. Rodriguez netted \$55 million for prescription drugs he had diverted from lawful channels. The mishandled medications made their way from his co-conspirator, Altec Medical Inc., to legitimate drug distributors to retail pharmacies and on to unsuspecting patients.³⁵

At Least 160,000 Counterfeit Pills Sold by a Fake Online Pharmacy, 2009

Frances Ortiz Gonzalez shipped over 160,000 counterfeit pills made to resemble medications such as Lipitor, Xanax, Valium, Viagra and Cialis to Americans primarily in the Los Angeles area. Ortiz, a Puerto Rican citizen, was an operative for a drug ring that distributed Chinese-made counterfeit pharmaceuticals. Investigators found an additional 100,000 counterfeit pills in his home.³⁶

200,000 Boxes a Week of Counterfeit Medicines Exported to Europe and the U.S., 2001 – 2007

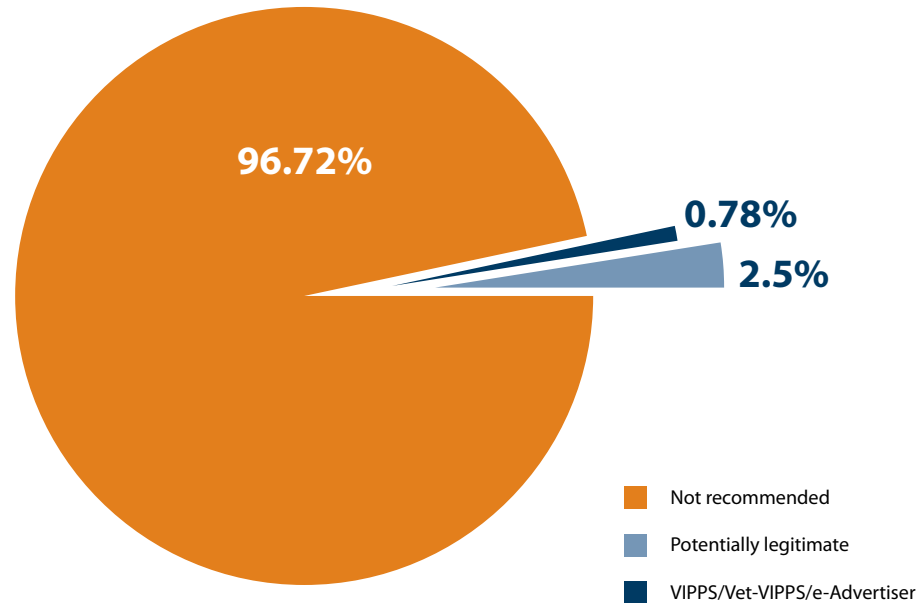
Chinese businessman Kevin Xu exported counterfeit medications to Europe, the U.K. and the U.S. at a rate of 200,000 boxes a week. Xu produced counterfeit copies of at least 25 different medicines—influenza vaccines, prostate cancer treatments, blood thinners, Alzheimer’s medication and other vital drugs. He employed devious smuggling routes from China, to Malaysia, Singapore and the U.K. For 6 years he tricked legitimate European pharmacies into buying his counterfeit medications wholesale before he tried to enter the American market.³⁷



FAKE ONLINE PHARMACIES: AN IMMEDIATE DANGER TO THE AMERICAN PUBLIC

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 “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 looking fake online pharmacy that deceives American patients.³⁸

Internet Drug Outlets Reviewed by NABP



FAKE ONLINE PHARMACIES:

97% OF ONLINE PHARMACIES ARE UNSAFE

In 2013, the National Association of Boards of Pharmacy surveyed 10,275 Internet pharmacies and found that they could not recommend 97% of the businesses. Among these pharmacies:

- ▶ 2,302 had a physical address located outside U.S. borders (if they list an address at all)
- ▶ 8,701 did not require a valid prescription (5,940 issue prescriptions per online consultation only)
- ▶ 4,839 offered foreign or non-FDA-approved drugs
- ▶ 1,588 did not have secure sites, exposing customers to identity theft and financial fraud
- ▶ 3,874 had server locations in foreign countries
- ▶ 1,121 dispensed controlled substances

257 Internet pharmacies surveyed appear to meet program criteria. Only 80 sites were accredited through NABP's Verified Internet Pharmacy Practice Sites (VIPPS) programs.³⁹

What kind of businesses are fake online pharmacies?



PIRATES, PORN AND FRAUD:

Affiliate networks have been linked to other illegal Internet-based businesses, including those that promote pornography, pirated media and fake anti-virus software.



HACKERS: Websites associated with affiliate networks have contained trojan software that will corrupt and take over your computer making your online transactions vulnerable, as well as destroying your computer.



DOPE DEALERS: Pharmacy affiliate networks have been documented selling millions of controlled pills to Americans without prescriptions.



FAKE MEDICINE PUSHERS: Purchasing drugs from affiliate online pharmacies is definitely not safe because they aren't licensed U.S. pharmacies. Even if the site purports to be American, it can really be located anywhere in the world, with potentially no regulation. Meds bought online have contained everything from heavy metals to unapproved and deadly drugs instead.



SPAMMERS: Affiliate networks are the world's largest source of spam. A police raid on one affiliate alone caused global spam volume to drop by 50 billion emails per day, a full fifth of the internet's spam traffic.

Fake pharmacies sell counterfeit medicines and controlled substances without prescriptions, but they have also been linked to **pornography, pirated media, fake anti-virus software, trojan viruses** that threaten your computer security, and a tremendous volume of **spam**.

Just 30 fake online pharmacies control tens of thousands of websites—“affiliates” represented by **54,000** unique domain names and **347 million** unique web addresses—that look different, but can be traced to the same core business. The sheer number of these fake sites make it very difficult for users to find legitimate pharmacies online.

**54,000 unique
domain names**

**347,000,000
unique web
addresses**

Is it



Safe?

Learn more about how to buy safely at online pharmacies at <http://safedr.ug/savemoneysafely>

**PROVEN
SYSTEMS for
COMBATING
COUNTERFEITS
and PROTECTING
PATIENTS**



Spot the fake? It can't be done. →



AVOIDING BREAKS in the U.S. SUPPLY CHAIN is the BEST WAY to KEEP AMERICAN PATIENTS SAFE.

In the United States, every entity involved in pharmaceuticals, from manufacturer to dispensing, is regulated to create a closed, secure drug supply. When that supply chain is broken, our FDA cannot ensure that the drugs are the real thing. Drugs bought from other countries are not FDA approved, not safety reviewed and not included in FDA safety recalls.

Many importation advocates don't realize that drugs bought from "Canadian online pharmacies" are not from Canada's legitimate drug supply, but are manufactured in less regulated markets.⁴⁰ Due to Canadian transshipping regulations, drug exporters can use Canada as a base of operations to sell ineffective and sometimes lethal products. In 2005 the FDA found that 43% of imported drugs intercepted were labeled as Canadian, but only 15% were actually Canadian. The remaining non-FDA approved drugs originated in 27 countries around the globe.⁴¹

DRUG IMPORTATION:

ARE TIER ONE COUNTRIES SAFE TO IMPORT FROM?

Online pharmacies often assure customers that their medicines come from “Tier One” countries—Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa or countries in the European Union. But the concept of a Tier One country for importation is a misreading of the regulations, confusing export countries and import countries. **The FDA has never designated any country from which it is universally safe to import medicine.**⁴²

Criminal prosecutions show that once you break the supply chain, no promise about the source of medicine can be trusted. In the Avastin case, counterfeiters bought and sold fake product repeatedly from country to country until it arrived at in the U.K.

Licensed pharmacists in countries such as the U.K. are not even allowed to fill overseas prescriptions from American doctors, so you know these businesses can't be legal pharmacies.⁴³



HOW TO SAVE MONEY SAFELY WHEN BUYING PRESCRIPTION DRUGS:

Consumer Tip: SAVING MONEY WITH GENERIC DRUGS

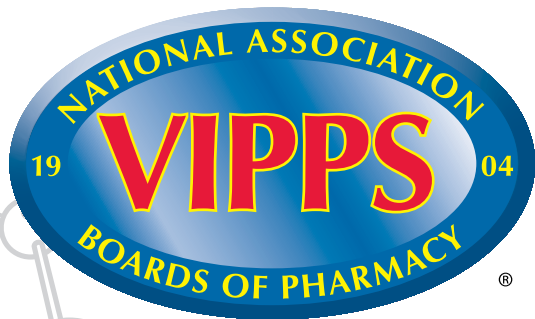
Generic drugs contain the same active ingredients in the same strength as brand-name drugs and offer a savings of 30% to 80% over brand name drugs. Patients should ask their doctor or pharmacist whether switching from a specific brand name prescription to its generic version is a good option for them.

HOW TO BUY MEDICINE ONLINE SAFELY:

Consumer Tip: COMPARISON SHOP BETWEEN LICENSED ONLINE PHARMACIES

Most consumers aren't aware of it, but drug prices differ between pharmacies and by region. Patients taking multiple prescription drugs can see real savings by comparing prices between different pharmacies in their home towns or online.

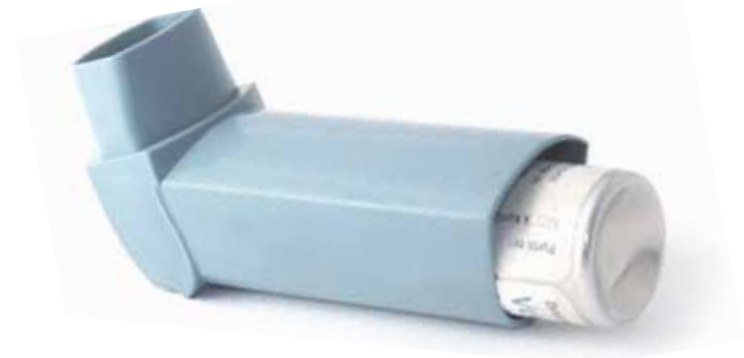
The safest way to comparison shop online is to search pharmacies listed on the Verified Internet Pharmacy Practice Sites (VIPPS) web page at www.vipps.info. VIPPS accredited Internet pharmacies must comply with state licensing where they reside and in every state where they do business. These pharmacies meet national standards of pharmacy practice, work to assure the quality of the medicines they dispense and provide real consultation between patients and pharmacists.



PATIENTS WHO COMPARE PRICES BETWEEN VIPPS PHARMACIES CAN SAVE MONEY SAFELY

ASTHMA CASE STUDY

People with asthma risk serious illness if they can't take their medications every day, and those medications can be expensive. Patients can save safely if they compare prices on VIPPS certified websites before filling their prescriptions. The Partnership for Safe Medicines staff found that common asthma medications could vary in price by up to 52%. **By shopping at VIPPS Pharmacies, for example, asthma patients prescribed Advair Diskus 500/50 can save up to \$2,160 every year.**⁴⁴



Consumer Tip: SHOP AROUND AT LOCAL PHARMACIES

Consumer Reports compared prices at more than 200 pharmacies for newly available generic drugs including diabetes drugs, antidepressants, cholesterol lowering meds and others. They found a 447% price difference between the highest- and lowest-priced stores.⁴⁵ They recommend patients:

- ▶ Consider generic versions of prescription medications.
- ▶ Request the lowest available price for your prescription and ask for a senior or student price discount.
- ▶ Fill prescriptions in rural areas, where prices are sometimes lower.
- ▶ Refill for 90 days rather than 30 to get an additional volume discount.
- ▶ Ask whether the retail price for your prescription is cheaper than your insurance copay.
- ▶ Seek out discount generic drug programs offered by major drugstore retailers, which can lower drug costs to as low as \$4 a month.

HOW TO SAVE MONEY SAFELY WHEN BUYING PRESCRIPTION DRUGS:

Consumer Tip:

PRESCRIPTION ASSISTANCE PROGRAMS



NeedyMeds is a 501(3)(c) 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.

HOW TO BUY MEDICINE ONLINE SAFELY: TIPS FOR SAFE ONLINE BUYING

Know Your Source: Buy prescription medications from a safe, reputable, licensed source. Online pharmacies with the National Association of Boards of Pharmacy's Verified Internet Pharmacy Practice Sites (VIPPS) full accreditation are the safest way to purchase prescription drugs online.

Protect Your Privacy: Don't give your social security number, credit card number, insurance information or medical history unless you are sure the website will keep your information safe and private. Look for clear and accessible privacy and security policies and make sure that the site will not share your contact information with third-parties unless you agree.



A safe online pharmacy:

- ✓ Offers an address and telephone number in the United States
- ✓ Gives users contact information that includes a licensed pharmacist
- ✓ Requires a valid prescription with your doctor's contact information
- ✓ Will accept a variety of insurance plans and payment options
- ✓ Is a licensed American pharmacy legally dispensing prescription drugs to American residents
- ✓ Will deliver your medication to your home

Fake online pharmacies:

- ✗ Offer no physical address, telephone number, or direct contact to resolve problems
- ✗ Have no licensed pharmacist available
- ✗ May not ask for a valid prescription from your doctor. May offer to sell you a prescription, or require you to fill out a questionnaire in lieu of a legitimate prescription
- ✗ Will not participate in any insurance plan, and/or require all payments by credit card
- ✗ Sell medications that are not FDA approved. These drugs have unknown authenticity, purity and safety
- ✗ Encourage you to have the drugs sent to P.O. boxes or other locations to avoid detection
- ✗ Require that you waive your rights before they send you medicine



HOW HEALTHCARE PROFESSIONALS CAN HELP





HOW YOUR ORGANIZATION CAN HELP PROTECT PATIENTS PHYSICIANS

IF YOUR COMMUNITY INCLUDES DOCTORS, CONSIDER CO-BRANDING THESE RESOURCES:

- ▶ **The L.E.A.D.E.R.S Guide for Doctors**, PSM's advice to help doctors protect patients from counterfeit drugs (http://safedr.ug/for_physicians)
- ▶ **Infographics for Physicians** (<http://safedr.ug/drinfo123>)
- ▶ **RX-360's "Protect Your Patient—Know Your Supplier"** campaign (<http://safedr.ug/18QEnF1>)
- ▶ **Safety Tips for Doctors and Patients** (<http://safedr.ug/15TqLqk>) — Tips for patients, doctors and other healthcare providers to share in newsletters, social media, and on your website
- ▶ **BeSafeRx** (www.FDA.gov/BeSafeRx) — The FDA's national campaign to raise awareness of the dangers of buying prescription medicines from fake online pharmacies



HOW YOUR ORGANIZATION CAN HELP PROTECT PATIENTS NURSES

IF YOUR COMMUNITY INCLUDES NURSES, CONSIDER CO-BRANDING THESE RESOURCES:

- ▶ **The L.E.A.D.E.R.S Guide for Nurses**, PSM's advice to help nurses protect patients from counterfeit drugs (http://safedr ug/for_nurses)
- ▶ **Consumer Materials Aimed at Patient Safety** at PSM's website (www.safemedicines.org/consumer_resources.html)
- ▶ **RX-360's "Protect Your Patient—Know Your Supplier"** campaign (<http://safedr ug/18QEnF1>)
- ▶ **5 Ideas to Share with Your Patients for Saving Money and Avoiding Counterfeit Drugs** (<http://safedr ug/5ideasforpatients>)

HOW YOUR ORGANIZATION CAN HELP PROTECT PATIENTS PHARMACISTS

IF YOUR COMMUNITY INCLUDES PHARMACISTS, CONSIDER CO-BRANDING THESE RESOURCES:

- ▶ **The L.E.A.D.E.R.S Guide for Pharmacists**, PSM's advice to help pharmacists protect patients from counterfeit drugs (http://safedr ug/for_pharmacists)
- ▶ **RX-360's "Protect Your Patient—Know Your Supplier"** campaign (<http://safedr ug/18QEnF1>)
- ▶ **What You Don't Know about Importing Drugs from Canada** — Facts about importing drugs from Canada (<http://safedr ug/ppnjWh>)
- ▶ **Safety Tips for Doctors and Patients** (<http://safedr ug/15TqLqk>) — Tips for patients, doctors and other healthcare providers to share in newsletters, social media, and on your website

HOW YOUR ORGANIZATION CAN HELP PROTECT PATIENTS OTHER HEALTHCARE PROFESSIONALS

IF YOUR COMMUNITY INCLUDES HEALTHCARE PROFESSIONALS, CONSIDER CO-BRANDING THESE RESOURCES:

- ▶ **RX-360's "Protect Your Patient—Know Your Supplier" campaign**
(<http://safedr ug/18QEnF1>)
- ▶ Consumer materials aimed at patient safety at PSM's website, including:
 - ▶ **An 8-Step Checklist for Medicine Safety** (<http://safedr ug/nrXbFZ>)
 - ▶ **Save Money Safely on Your Prescriptions from Online Pharmacies** (<http://safedr ug/stayawayfromhydra>)
 - ▶ **Safe Savings** (<http://safedr ug/acrsavings>)
 - ▶ **A Risky Proposition: How Opening the U.S. to Foreign Medicines Will Put American Children at Heightened Risk** (<http://safedr ug/nsZAht>)
 - ▶ **What You Don't Know about Importing Drugs from Canada**
(<http://safedr ug/ppnjWh>)
- ▶ **5 Ideas to Share with Your Patients for Saving Money and Avoiding Counterfeit Drugs**
(<http://safedr ug/5ideasforpatients>)

HOW YOUR ORGANIZATION CAN HELP PROTECT PATIENTS

PATIENT GROUPS

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

PSM can

- ▶ **Develop co-branded versions of “5 Steps to Saving Money and Staying Safe from Counterfeit Drugs” tailored to your members**
(<http://www.safemedicines.org/bangor5steps.html>)
- ▶ **Host educational webinars**
- ▶ **Arrange to speak at live events**
- ▶ **Produce postcards for membership mailings**
- ▶ **Design poster stand-ups and health fair materials**

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

Other Organizations Concerned with Safe Medicines

Pharmaceutical Security Institute

www.psi-inc.org

National Association of Boards of Pharmacy

www.nabp.net

The Center for Safe Internet Pharmacies

www.safemedsonline.org

Alliance for Safe Online Pharmacies

safeonlinerx.com

The Physician's Coalition for Injectable Safety

www.injectablesafety.org

The FDA's BeSafeRx: Know Your Online Pharmacy

<http://safedr.ug/BeSafeRX>

RX-360

www.rx-360.org



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