



# **Counterfeit Drugs: A Dangerous Threat To American Patients**

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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 U.S.
- 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 patients who end up taking them.

# How Big is the Counterfeit Medicine Problem?

- 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

# **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
- Pain Medicines and Weight Loss Medications
- Psychiatric Medications

# **Counterfeit Drugs Affect All Kinds of Patients Nationwide**

- 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.

# **How Counterfeit Drugs Impact the Health of 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.
- Florida 2005: A couple who owned a pharmacy concocted and sold fake medications, including inhaled drugs prescribed to children with cystic fibrosis.

# **Kinds of Poisons Found in Counterfeit Drugs**

- Heavy Metals are carcinogenic or toxic to the 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 and No Medicine at all



# **Drug Resistance**

## **A Problem 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.
- Counterfeits have fueled the development of drug resistant diseases overseas, causing needless suffering and death.
- A safe medicine supply chain can discourage drug resistant infections in the U.S.

# **Counterfeit Drugs in Clinics and Medical Offices**

- The newest threat to American patients is black market drugs 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.

# 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.
- February 13, 2012 Los Angeles, CA – Roche located foreign-supplied counterfeit Avastin with no active ingredient
- April 12, 2012 La Jolla, CA – FDA seized 120 vials of fake Avastin shipped through the U.K. from Turkey
- February 5, 2013 Great Neck, NY – FDA found counterfeit Altuzan distributed through an unauthorized wholesaler.

# Counterfeit Drugs in the U.S.

- December 2012 – FDA warns doctors and hospitals about fake botox – warning letters were sent to 350 medical offices “counterfeit, contaminated, improperly stored and transported, ineffective and/or unsafe”
- September 2012 – Black Market Osteoporosis Medicine from an Unlicensed Foreign Company
  - FDA issued warning letters to 23 U.S. medical practices

# **Unsafe Drugs in the U.S.**

## **Other Incidents**

- Black market IUDs , may be improperly engineered, sterilized and packaged causing serious infection and possible death
- Flu Treatments – In February 2013, the FDA warned consumers about fraudulent flu treatments sold over-the-counter and through fake on-line pharmacies that do not prevent or treat flu symptoms
- Adderall May 2012 – the FDA warned consumers and healthcare professionals about a counterfeit version of Adderall sold on the internet

# Deaths and Counterfeit Drugs

- 2001-2002 A Missouri woman, cancer patient, discovered that the Procrit she was taking to battle the anemia, a side effect of her chemo was part of 11,000 boxes of counterfeit Procrit sold by a Miami drug ring to legitimate wholesalers across the country

# Deaths and Counterfeit Drugs

- 2006 - A 58 year old British Columbian woman was found dead in her home. Her death was a mystery until a toxicology report showed that her liver was contaminated with heavy metals.
- Investigation found that she had unknowingly purchased drugs from fake online pharmacies.

# Deaths and Counterfeit Drugs

- On February 12, 2001, Ryan Haight, a straight-A, talented high school scholar and athlete died of an overdose of Vicodin that he purchased without a prescription through an unregulated internet seller.
- Ryan Haight Online Pharmacy Protection Act of 2008 requires that no prescription drug may be delivered, distributed or dispensed by means of the Internet without a valid prescription.



# **Doctors Endangering Patients with Black Market Drugs**

- A Tennessee oncologist purchased cancer drugs from unauthorized distributors who were hawking counterfeit drugs. He made \$500,000 purchasing the discount counterfeit drugs and billing Medicare and insurers as if he had paid the full price for the,.
- Other doctors across many medical fields are buying drugs from outside the U.S. supply chain and committing billing fraud for their own profit.

# How do Counterfeit Drug Criminals Operate?

- 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 a common scenario.

# **How do Counterfeit Drug Criminals Operate?**

- U.S. Customs and Border Patrol reported in 2011 alone, it made 1,239 seizures worth \$16.8 million in counterfeit drugs bound for the U.S. market
- Between 2010 and 2012 FDA OCI opened 227 rogue internet pharmacy investigations and convicted 560 individuals

# **Counterfeit Drug Crimes That Threatened Americans**

- 2008-2011 Through his California based company, Ban Dune Marketing Inc. James Newcomb distributed adulterated and unapproved prescription drugs, including chemotherapy drugs to as many as 60 doctors across the U.S. without ensuring safe handling of the medicines.

# **Counterfeit Drug Crimes That Threatened Americans**

- 2007-2009 William Rodriguez bought medications from hijackers, black market dealers and directly from patients to resell back into the supply chain with forged pedigrees. Rodriguez netted \$55 million for prescription drugs he diverted.
- The mishandled medications made their way from his co-conspirator Altec Medical to legitimate drug distributors to retail pharmacies onto unsuspecting patients.

# **Counterfeit Drug Crimes That Threatened Americans**

- 2001-2007 Chinese businessman Kevin Xu exported 200,000 boxes a week of counterfeit medicines to the U.K. and the U.S.
- Xu produced counterfeit copies of at least 25 different medicines – influenza vaccines, prostate cancer treatments, blood thinners, Alzheimer’s medication and other vital drugs

# Some Resources: How Healthcare Professionals Can Help

- 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](http://safedr ug/for_physicians)
- RX-360’s “Protect Your Patient – Know Your Supplier” campaign
  - <http://safedr ug/drinfo123>
- Safety Tips for Doctors and Patients
  - <http://safedr ug/15TqLqk>
- BeSafeRx The FDA’s national campaign
  - [www.FDA.gov/BeSafeRx](http://www.FDA.gov/BeSafeRx)



**Thank You!**

QUESTIONS?