

# Counterfeit Drugs

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## What are Counterfeit Drugs?

Counterfeit drugs are deliberately and fraudulently mislabeled with respect to identity and/or source. They may be contaminated or contain the wrong active ingredient, if any at all. They could have the right active ingredient but at the wrong dose.

## Are They Really a Problem?

Although difficult to truly know the incidence, the World Health Organization estimates that 10% of the global drug market is counterfeit. This activity is much more severe in developing countries. While it is thought that 30-50% of drugs used to treat serious conditions are counterfeit in some parts of the world, the incidence of counterfeit drugs in the US is substantially less than 1%.

## Can You Tell The Difference?



www.safemedicines.org

## How Safe Are Internet Pharmacies?

The National Association of Boards of Pharmacy recently conducted a study and found that 96% of the 8,000 sites surveyed did not operate in accordance with U.S. pharmacy laws. Furthermore, the World Health Organization estimates that over 50% of internet pharmacies that conceal their physical address, provide counterfeit drugs. 36 million Americans are believed to have purchased drugs from "rogue" internet sites according to CBS. Despite the rampant illegal activity with online pharmacies, some are actually safe to use. Any online pharmacy that is VIPPS accredited is a legitimate practice that provides safe medication.

## Who? What? Where? Why?

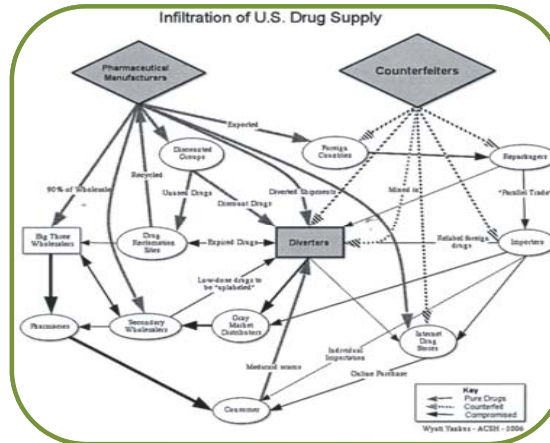
**Who:** Organized crime, corrupt government officials, wholesalers, pharmacies

**What:** Drugs that have a high market value, but for which cheap alternative ingredients are readily available. The cheap ingredients sometimes behave similar to the real drug in tests. This helps disguise the product in quality control tests and/or promotes the reputation of a legitimate manufacturer to a purchaser.

**Where:** Primarily developing countries or areas where regulatory/policing systems are weak. Countless websites on the internet are involved as well.

**Why:** The profit margins are incredible for high cost counterfeit drugs made from cheap raw materials. The market size is immense for people who do not have access to legitimate pharmacies and for those seeking more affordable medicine. Many countries have inadequate legislation, regulations, and enforcement which result in minimal punitive consequences for those found guilty of counterfeiting.

## How Do They End Up in Your Hands?



## What Is Being Done?



**INTERPOL:** The world's largest international police organization which includes 190 countries. It currently has four "operations" which have effectively shut down over 13,000 websites and has seized over 40 million pills (mostly counterfeit) since 2009.



**World Health Organization:** Created the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). This division has formed a partnership with most of the major anti-counterfeiting organizations. IMPACT works to create coordinated networks between countries to disrupt the production, trading, and selling of counterfeit drugs. It contains 5 "working groups" which address and advise IMPACT participants on specific issues relating to counterfeit drugs.



**National Association of Boards of Pharmacy:** Created Verified Internet Pharmacy Practice Sites (VIPPS). This voluntary accreditation program confirms with online customers that the site is regulated by a state board of pharmacy and has met all the necessary requirements of VIPPS, thus verifying the site is a legitimate practice. The VIPPS seal is included on all accredited sites and serves as a link to the VIPPS website which lists all accredited pharmacies.



**Food and Drug Administration:** A counterfeit drug task force was created in 2003, but has not published a report since 2006. Nevertheless, the FDA has developed a guidance for industry on anti-counterfeiting as well as standards regarding supply chain security.



**The Partnership for Safe Medicines:** an active group of not-for-profit organizations and individuals that develops informational material and programs for consumers and healthcare professionals to protect patients against counterfeit drugs. They also create policies and procedures that work as a guide for ensuring safe medicine.

## How Do I Report Counterfeit Drugs?

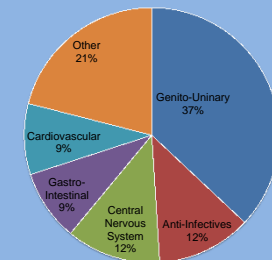
**Patients:** Contact the pharmacy where you got the medication from. If you received drugs from a site you believe is selling counterfeit drugs and your case involves:

- A life threatening situation from taking an FDA approved drug that you purchased online, call 1-866-300-4374 immediately (also contact your health care provider)
- A serious reaction or problem with an FDA-regulated product, fill out the MEDWATCH reporting form at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-332-1088 or fill out and mail the FDA form 3500.
- A report of a website that you think is involved with illegal drug activity (Counterfeiting), fill out an online form at: <http://www.accessdata.fda.gov/scripts/email/oc/buyonline/buyonlineform.cfm>
- Receiving emails from websites that you believe are involved with counterfeit drugs, follow the procedure from step (c) and forward the emails to: [webcomplaints@ora.fda.gov](mailto:webcomplaints@ora.fda.gov)

**Pharmacists:** Depending of the circumstances, follow procedures (a) or (b) as listed above. If the case does not pertain to either of the procedures, fill out the form at <http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>. Follow your company's policy on the appropriate procedures to conduct. Also, contact the manufacturer of the product in question. Finally, notify your state regulator of wholesale distributors at: <http://www.nabp.net/programs/assets/ContactVerification.pdf>

## What Should I Look Out For?

Reports of Counterfeit Medicines by Therapeutic Category



One case reflects at least one production lot, e.g. thousands of tablets, capsules, or other forms. Several cases included multiple therapeutic categories (only the most frequent category is included in the chart).  
PSI - Pharmaceutical Security Institute <http://www.psi-inc.org/index.cfm>



Pfizer

**References:**  
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Remember, counterfeit drugs are often manufactured under conditions that are not in compliance with the FDA's Good Manufacturing Practices. They are dangerous and always illegal, help spread awareness of counterfeit drugs.