

What You Should Know About Counterfeit Drugs

What is the definition of a counterfeit medication?

U.S. law defines counterfeit drugs as those sold under a product name without proper authorization. Counterfeiting can apply to both brand name and generic products, where the identity of the source is deliberately and fraudulently mislabeled in a way that suggests that it is the authentic, approved product. Counterfeit products may include products without the active ingredient, with an insufficient quantity of the active ingredient, with the wrong active ingredient, or with fake packaging.

What risks are involved with taking counterfeit medications?

An individual who receives a counterfeit medication may be at risk for a number of dangerous health consequences. Patients may experience unexpected side effects, allergic reactions, or a worsening of their medical condition. A number of counterfeits do not contain any active ingredients, and instead contain inert substances, which do not provide the patient any treatment benefit. Counterfeit medications may also contain incorrect ingredients, improper dosages of the correct ingredients, or they may contain hazardous ingredients.

What is the prevalence of counterfeit medications in the U.S.?

Counterfeiting occurs less frequently in the U.S. than in other countries due to the strict guidelines, regulations, and enforcement the FDA provides throughout the production and distribution chain. However, recently FDA has seen two highly publicized examples of counterfeit *Lipitor* and *Procrit* within the U.S. distribution system. The FDA continues to believe that the overall quality of drug products that consumers purchase from U.S. pharmacies remains high. The American public can be confident that these medications are safe and effective.

Should consumers who currently purchase medications over the Internet or import medications from other countries be concerned about counterfeits?

Consumers can be confident in the quality, safety, and efficacy of medications purchased from a U.S. state licensed pharmacy. For those consumers who purchase medications over the Internet, websites that have the Verified Internet Pharmacy Practice Sites (VIPPS) Seal are licensed pharmacies where FDA-approved medications can be purchased. These sites are identified by the VIPPS hyperlink seal displayed on their Website. Unless medications have been purchased from a U.S. state licensed pharmacy website, the safety and efficacy of these medications cannot be guaranteed.

What can consumers do to protect themselves from counterfeit drugs?

Consumers can protect themselves from the risks associated with counterfeit drugs by purchasing all prescription and over-the-counter medications from U.S. state licensed pharmacies. Consumers must be vigilant when examining their personal medications, paying attention to the presence of altered or unsealed containers or changes in the packaging of the product. Differences in the physical appearance of the product, taste, and side effects experienced should alert the patient to contact their physician, pharmacist, or other healthcare professional who is providing treatment.

The above excerpts are reprinted from the FDA document, "Counterfeit Drugs Questions and Answers" located at <http://www.fda.gov/oc/initiatives/counterfeit/qa.html>. This information was accessed February 27, 2004.

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Steps to Eliminate Counterfeit Drugs

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—See Detail-Document #190950 for a patient handout about buying medicines online—

Background

The occurrence of counterfeit drugs is fairly common in some countries. Prevalence rates can range from 10% in South-East Asian countries to as high as 50% for certain drugs in China.¹ While the problem is relatively rare in the U.S., over the last several years the FDA has investigated an increasing number of counterfeit reports (from about five per year to over 20 per year).² The most recent case being counterfeit *Ortho Evra* transdermal contraceptive patches sold via the internet.³ Counterfeit drugs can be adulterated in various ways and in many cases have the potential to pose a serious threat to patient safety. Counterfeit drugs can include those with no active ingredient (as with the contraceptive patches), incorrect ingredients (aspirin substituted for *Zyprexa* tablets), dangerous ingredients (use of nonsterile tap water in vials of *Procrit*), and subpotent doses.^{2,4}

The motivation for counterfeiters is profit. Many of the drugs targeted for this type of activity are expensive, high volume drugs² or drugs in short supply.⁵ High-risk drugs include AIDS drugs, epoetin alfa (*Epogen*, *Procrit*), somatropin (*Serostim*), filgrastim (*Neupogen*), olanzapine (*Zyprexa*), and cholesterol-lowering drugs to name just a few.^{2,5}

Entry into the U.S. Distribution System

Foreign internet pharmacies are an obvious portal of entry for counterfeit drugs coming into the U.S. But there have been reports of counterfeit drugs entering the mainstream U.S. distribution system. Recent examples of this are counterfeit *Lipitor* and *Procrit*.⁶

Approximately 90% of the prescription drugs distributed in the U.S. are handled by three primary wholesalers.² In some instances the manufacturer sells directly to the retailer, but most

often the drugs go from the manufacturer to the primary wholesaler, who in turn sells it to the retailer.¹ This scenario is probably the least likely to experience a counterfeit problem. In addition to the primary wholesalers, there are other smaller “secondary” wholesalers who often purchase drugs from wholesalers and resell to other wholesalers or pharmacies. Generally, discounted drugs are purchased by secondary wholesalers. The risk of counterfeit drugs entering the distribution channel increases when several wholesalers, and even a repackager, handle the drug before it reaches the retailer.¹

Combating Counterfeit Drugs

In an effort to limit the entry of counterfeit drugs into the U.S. distribution system, the Prescription Drug Marketing Act (PDMA) was enacted in 1988. The PDMA sought to improve the safety of prescription drug distribution in the U.S. by requiring state licensure of wholesale distributors, enacting a “pedigree” system for tracing the origin and previous sales of a drug, and prohibiting the reimportation of drugs by entities other than the manufacturer.¹ Because of limitations with technology and loop-holes in the PDMA, the current provisions for tracing the origin and previous sales of a drug is subject to fraud.

Even though counterfeit drugs are not a major problem in the U.S. at this time, the FDA has deemed it necessary to begin an aggressive campaign against this problem. In February 2004, the FDA published their recommendations for combating counterfeit drugs.⁷ Included in their report are recommendations to implement tracking and anti-tampering technology, strengthen regulations for wholesalers and distributors, improve reporting of suspected drug tampering, and educate consumers and healthcare

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professionals on what to do if a counterfeit drug is detected.⁷

Technology

- Unit of use packaging and tamper evident packaging have been proposed as being beneficial in fighting counterfeit drugs when used in conjunction with other anti-counterfeiting procedures.
- Manufacturers are being encouraged to explore the incorporation of authentication technologies (taggant, chemical marker, or other identifier) into packaging or labeling as a means to deter counterfeiting.
- Adoption of radio-frequency identification (RFID) technology to aid in the tracking and tracing of drug products (electronic pedigree). Thought to be the most promising and effective means for securing the drug supply, but won't be feasible until 2007.
- Implementation of a national list of drugs most likely to be counterfeited and/or develop a set of criteria used to identify high risk drugs. This list or criteria would aid manufacturers in choosing which products to implement the above technologies.

Regulatory Initiatives

- FDA plans to facilitate the adoption of track and trace technology by industry. This will aid in meeting the "pedigree" requirement of PDMA.
- FDA supports the adoption and enforcement of stronger state anti-counterfeiting requirements with regards to wholesale distributors.
- The FDA will work towards increasing penalties for manufacturing and distributing counterfeit drugs.

Other proposed recommendations for reducing the risk of counterfeit drugs include:

- The creation of a Counterfeit Alert Network (to improve notification of a counterfeit event).
- Encourage use of the MedWatch system by healthcare professionals to report suspect counterfeit drugs.

- Encourage secure business practices by manufacturers, wholesalers, repackagers, and retailers.
- Improve the FDA's response rate to reports of suspected counterfeit drugs.
- Educate consumers about counterfeit drugs: what to watch for, what to do if a problem is suspected, best online buying practices.
- Educate healthcare professionals about their role in minimizing exposure to, identifying, and reporting counterfeits.
- Encourage international collaboration to deter and detect counterfeit drugs worldwide.

Conclusion

While some of the FDA's proposed strategies for reducing the risk of counterfeit drugs can be implemented fairly soon, others will take a year or more to develop. There are some things that healthcare professionals can do now to help minimize their patients' exposure to counterfeit drugs.⁶ They should become familiar with those products most likely to have a counterfeit problem and know how to identify them. The National Association of Boards of Pharmacy (NABP) has compiled a list of products prone to counterfeiting. The list can be viewed at www.nabp.net. Suspect a counterfeit problem if a patient experiences an unexplained side effect or unexplained worsening of their condition. Be aware of differences in packaging or labeling of a drug. Pharmacists should avoid or limit the use of secondary wholesalers, especially those offering "a good deal," unless their good standing can be verified.⁵ Healthcare professionals should also be careful about what goes into the trash. Empty drug packages and vials can be retrieved and refilled with counterfeit drugs.⁵ If a counterfeit drug is suspected, immediately contact the manufacturer and the FDA (<http://www.fda.gov/medwatch>) or call 800-FDA-1088.⁶

Patients can also be instrumental in detecting counterfeit drugs. The *Lipitor* counterfeit problem in 2003 was first noticed when patients began to report an unusual bitter taste with their pills.⁸ Advise patients to notify you immediately if they detect changes in the appearance of their medication or of its packaging and if they notice differences in taste, side effects, or the general

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effectiveness of the drug.⁶ If patients insist on buying medications online, recommend they only use those sites that have the Verified Internet Pharmacy Practice Sites (VIPPS) Seal. The VIPPS Seal indicates the site is a licensed pharmacy with FDA-approved medications. Recently, the National Association of Pharmacy Regulatory Authorities (NAPRA) in Canada made arrangements to use a Canadian version of the VIPPS Seal to indicate websites associated with accredited Canadian pharmacies.⁹

Users of this document are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and Internet links in this article were current as of the date of publication.

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