

Counterfeit Medical Products and Their Effect on Consumer Healthcare

Most people think of watches, DVDs, shoes and purses when they think of counterfeit items in the U.S. market. What about counterfeit prescription drugs, healthcare products or medical devices? Despite vigilance on the part of the U.S. Food and Drug Administration (FDA) and law enforcement, counterfeiting of healthcare products and medical devices and components has grown in recent years.¹ Using the internet as a distribution channel has made it easier for counterfeit drugs and devices to penetrate the supply chain and reach customers and end users.² And counterfeit medical products are not just a U.S. problem, they are a global problem. The World Health Organization estimates that 10 percent of the \$121.8 billion in pharmaceuticals sold globally (up to 50 percent in some countries) each year are fakes.³

Growth in counterfeiting may be spurred by the economic incentives provided by an increasing volume of high cost drugs, the development of technologies that make it easier to counterfeit drugs, and the ability to sell drugs directly to consumers without face-to-face contact through purchases over the internet. In fact, it appears that organized crime rings are becoming more involved in counterfeiting drugs and medical devices because counterfeiting is significantly more profitable and carries less risk of jail time than dealing illegal drugs.⁴

Why should the average consumer be concerned?

Counterfeiting of medical devices, drugs and healthcare products is just one component of the larger issue of healthcare fraud in the U.S. Estimates show that currently, \$250,008,288 per hour is spent on health care and of that expenditure over \$25 million per hour is lost to waste, fraud and abuse.⁵ These are not just big numbers that affect someone else. Everyone pays the price for healthcare fraud, errors and abuse, through higher insurance premiums, increased costs of medical services and equipment, and greater expenditures for Medicare and Medicaid.⁶ In fact, Blue Cross Blue Shield estimates that \$50 billion or 10% of private payer claims are attributed to health care fraud. But more importantly lives are at stake.

In January and February 2003, the U.S. Food and Drug Administration reported that counterfeit Procrit, a drug prescribed for the treatment of anemia associated with cancer and HIV was introduced into the wholesale distribution system in the U.S. and was supplied directly to hospitals and pharmacies.⁷ The counterfeit Procrit, discovered by investigators, consisted of a clear liquid that contained no medication only bacteria-tainted water posing a risk of infection in already seriously weakened patients.⁸ The U.S.

¹ <http://www.cbsnews.com/stories/2003/03/11/health/main543566.shtml>

² <http://www.sciencemag.org/cgi/content/summary/305/5683/481>

³ www.fda.gov

⁴ <http://www.medicalnewstoday.com/articles/23168.php>

⁵ Association of Certified Fraud Examiners, www.ACFE.com

⁶ The National Consumer Protection Technical Resource Center www.smpresource.org

⁷ <http://www.fda.gov/oc/initiatives/counterfeit/qa.html>

⁸ <http://www.fda.gov/oc/initiatives/counterfeit/qa.html>

Attorney for Southern District of Florida filed charges in May 2003 against three people for trafficking and unlawfully distributing counterfeit Procrit.⁹

Since the internet as a distribution channel has made it easier for counterfeit drugs and devices to penetrate the supply chain and reach consumers, in May 2007, the FDA issued warnings to consumers about obtaining counterfeit drugs from internet sellers. Counterfeit versions of popular prescription drugs such as Tamiflu, Cialis and Xenical were allegedly being sold on twenty-four websites that appeared on pharmacycall365.com.¹⁰ These are all popular drugs that require a physician's ongoing care and treatment to obtain a prescription. The FDA reported that it appeared that these websites were operated from outside of the United States.¹¹

But it's not just prescription drugs that are being counterfeited. In June 2007, a counterfeit version of Colgate toothpaste, a Colgate-Palmolive Company product, was found to be sold through discount stores in New York, New Jersey, Pennsylvania and Maryland.¹² The fake Colgate appears to have contained Diethylene Glycol rather than fluoride.¹³ The recalled toothpaste was labeled as made in South Africa, but its toxic ingredient previously has reportedly been found in Chinese-made toothpastes.¹⁴ Colgate-Palmolive pointed out the packages it had examined bore several misspellings, including "SOUTH AFRLCA."¹⁵ That suggests that even the bogus product's true origin may have been faked.¹⁶ Scott Wolfson, a spokesman for the Consumer Product Safety Commission has stated that "products made in China account for more than 60 percent of the recalls the CPSC has announced to date in 2007."¹⁷

The problem of counterfeiting extends to implantable medical devices as well. In December 2003, Ethicon, Inc. issued an alert to healthcare professionals on its Prolene polypropylene mesh product which is used in surgical repair of hernias.¹⁸ A counterfeit polypropylene mesh had entered the market and FDA tests revealed that some of the samples were not sterile creating risk of infection in patients who had the mesh implanted.¹⁹

Popular cosmetic pharmaceuticals have been counterfeited as well. In February 2005, the South Florida Sun-Sentinel reported that a couple in Palm Beach Gardens, Florida had undergone what they thought were Botox injections which were administered by a friend and business associate who also happened to be an Osteopath. But rather than receiving the FDA-approved Botox injections, which include a weak form of the botulism toxin, the couple was reportedly given a potent, raw and unapproved *botulinum* toxin that had been obtained by the doctor over the internet, according to the Sun-Sentinel. The couple was hospitalized for more than nine weeks following the injections as botulism attacked their nerve endings and caused extensive paralysis. One of the

⁹ Ibid.

¹⁰ www.fda.gov/bbs/topics/NEWS/2007/NEW01623.html

¹¹ www.fda.gov/bbs/topics/NEWS/2007/NEW01623.html

¹² Seattlepi.nwsourc.com/business/1310AP_Bogus_Imports.html

¹³ www.fda.gov/oc/po/firmrecalls/colgate06_07.html

¹⁴ Seattlepi.nwsourc.com/business/1310AP_Bogus_Imports.html

¹⁵ www.fda.gov/oc/po/firmrecalls/colgate06_07.html

¹⁶ Seattlepi.nwsourc.com/business/1310AP_Bogus_Imports.html

¹⁷ Ibid.

¹⁸ www.fda.gov/cdrh/safety/121903.html

¹⁹ Ibid.

victims required a ventilator for 22 hours a day in order to breathe. According to the couple's rehabilitation expert, "the length and extent of the couple's recovery is uncertain."²⁰

What is the FDA doing about counterfeiting?

The FDA is undertaking a major new initiative to more aggressively protect consumers from drugs that have been counterfeited. The new initiative includes creating an internal task force to explore the use of modern technologies and other measures that will make it more difficult for counterfeit drugs to get mixed up with – or deliberately substituted for – safe and effective drugs. The FDA has already increased its enforcement efforts, more than quadrupling the number of counterfeit drug cases since 2000.²¹

The FDA is working with the Bureau of Customs and Border Protection (BCBP) in conjunction with their upcoming "blitz" operations. These operations will take place this summer (2007) at International Mail Branches. BCBP scientists will work with FDA inspectors to target, examine, and test packages containing pharmaceuticals.²²

Also, the FDA is currently working with pharmaceutical manufacturers, wholesalers and retailers to identify and prevent counterfeit drugs. They have proposed that all caplets, tablets and capsules be traceable within two years.²³ This initiative demands the development and implementation of new technologies to mitigate the counterfeit risks.

How can you protect yourself?

To ensure that the medication that you take is safe, purchase all prescription and over-the-counter medication from U.S. state-licensed pharmacies. For 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.

Consult with your doctor about the tracking mechanisms and FDA registration on any medical devices that he or she prescribes. Implantable devices such as pacemakers are required to be registered upon implantation in case of a future recall or product defect that may be found.

Pharmacists, physicians and other healthcare professionals should familiarize themselves with those drugs most likely to be counterfeited and how to identify appropriate markings on these products. Healthcare professionals should suspect that a patient may have received a counterfeit drug when a patient has experienced an unexplained worsening of their medical condition or an unexpected side effect. If they suspect a counterfeit drug, the FDA should be contacted immediately.

As consumers, we need to be vigilant and know who is prescribing the medical products we use and where they are obtained.

²⁰ www.sun-sentinel.com/news/ocal/southflorida/sfl-pkaplans05feb05,06487282.story?

²¹ www.fda.gov/oc/initiatives/counterfeit/qa.html

²² Ibid.

²³ www.mdtmag.com/scripts/ShowPR.asp?PUBCODE+046&ACCT+0001028&ISSUE



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