

# Buyer Beware: Counterfeit Drugs Do Exist in Marketplace

Debates about the pharmaceutical industry, and the reasons for the exorbitant prices and availability of drugs in the United States, continue to pose difficulties to consumers with spiraling health care costs. While the U.S. government, through Medicare and its responsibilities for seniors (and their numbers are growing), wrestles with the industry to set lower prices, many states are considering legislation to allow imports of lower cost medications from Canada. The latest in this effort is to actually allow importation from other countries, with the goals of stringent controls on quality and, obviously, lower prices.

Modern research in the medical sciences is exploding exponentially, creating avenues for further clinical research trials and treatment methods that just a generation ago would have seemed impossible. Preventive medicine is being practiced by more and more Americans, and they learn from the ubiquity of information technology. Doctors have become more receptive to the questions and demands of patients, and governmental regulations are easing the way for new drugs to enter the marketplace. The competition is at an all-time high, and yet the prices are inexplicably high.

More than one billion pills are sold in the U.S. every year, and the sale of counterfeit drugs in the legitimate market-



## Maintaining Your Health on Mackinac

By Yvan Silva, M.D.

place is thought to be about one percent; that still amounts to several million. Internet offers abound from sites all over the world, and it is not known how much trade really occurs and how much of that is counterfeit. There is a lag in oversight, just like in many other areas the government supervises – immigration, income taxes, banking, the stock market, and so many other areas reported daily in the media – in this era of overt dishonesty, cheating, and corruption. Clearly, when it comes to maintaining health and the result of counterfeiting is potentially life threatening, the issue is serious indeed.

The federal Food and Drug Administration (FDA), charged with this responsibility, recently reported the number of counterfeit-drug investigations has increased from five per year in the 1990s to 20 per year in 2000. Several countries that do report on this subject, such as some in Asia, Africa,

and South America, admit that 10 to 50 percent of prescription drugs there may be counterfeit. In India, counterfeit drug percentages are so high and unpredictable that the Indian parliament has been wrestling with the passage of legislation authorizing stringent penalties for drug counterfeiters.

In the United States, a scandal was caused in recent years by a Kansas pharmacist who diluted chemotherapy drugs, resulting in ineffectiveness of treatment for thousands of cancer patients whose lives, and indeed the qualities of their lives, were shamefully harmed. He has been sentenced to a long jail term. So many wonder how anyone, especially in a health care career, would ever

consider doing something like that.

Procrit (epoetin) is an important drug for cancer patients. It elevates levels of hemoglobin by the production of red blood cells in the bone marrow. It is also given to patients with other conditions compromising red blood cell production. Unbelievably, in May 2002 thousands of Procrit vials, labeled as containing 40,000 units per vial, were found to contain only 2,000 units. In another 2002 investigation, other vials of Procrit, when checked out, contained nothing but tap water from Miami. Large quantities of Lipitor (atorvastatin), one of the most popular medications

for treatment of high cholesterol, were found, in 2003, to have been counterfeited, only after some patients complained that the pills they had bought tasted bitter, and seemed larger than usual. A number of Web sites have been discovered selling counterfeit drugs; some contraceptive patches, labeled as Ortho Evra, contained no active ingredient.

tical manufacturers. The public and the physicians know very little about how drugs reach patients. Usually pharmaceuticals are shipped to wholesale dealers, who ship to hospitals and pharmacies. But there are other routes to fill understocked outlets or unload overstocked items. Multiple transactions can occur, which may help counterfeiters infiltrate the system. The Prescription Drug Marketing Act was signed into law in 1982, and amended in 1992. Enforcement of the law is impeded in a variety of ways, including inability to conduct regular inspections to ensure compliance with storage, handling, and tracking of materials. There are fewer state and federal penalties for counterfeiting drugs than other crimes. Counterfeiting the drug itself may result in three years of imprisonment, while counterfeiting the trademark on the drug may result in a 10-year sentence.

Although reports of serious adverse events have been few, actual treatment failures in the U.S. may well be more than we actually know. In some countries, where counterfeiters have sold drugs important in epidemics like malaria, cholera, and other life-threatening illnesses, there have been more serious side effects and many more deaths.

The number of available drugs and other agents related to maintenance of health and treatment of disease has become an explosive industry. The quest for cheaper drugs is on the agenda of most seniors, people on fixed incomes, those with health insurance limitations, and almost everyone else. The Internet is rampant with tempting offers. If it's too good to be true, it probably isn't, and you pay for what you get, so buyer beware.

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counterfeit drugs; some contraceptive patches, labeled as Ortho Evra, contained no active ingredient. Such incidents resulted in the recall of thousands of pills and other packaged medication, leading to costly changes in packaging and labeling to ensure authenticity, and obviously resulting in price increases.

Counterfeiters generally target high volume, expensive drugs, particularly injectables, such as psychiatric and pain medications and treatments for HIV infected patients and those with AIDS. Counterfeiters have been known to be very well funded and sophisticated to a degree that they can escape the best security experts employed by large pharmaceu-

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