

Pharmaceutical Fakery

Counterfeit drugs — from outright fakes to real medicines that have been adulterated — have long been a problem in many parts of the world. In fact, a recent study found that one-third of sampled malaria pills in Asia contained no medication at all. Now this epidemic is spreading to the U.S., and federal health officials are looking for ways to stop it.

Why counterfeits?

There are a variety of reasons for this growing problem. The lack of Internet drug sale regulations has left an open playing field for unscrupulous companies to sell altered or outright fake drugs. Proliferation of performance-enhancing drugs also has upped the ante for counterfeiters because blood- and muscle-boosting products are some of the most popular and expensive counterfeits. Another reason that's even harder to control is that counterfeit drugs are often less expensive than authentic versions, so people have a built-in incentive to buy them.

And though the American drug distribution system is thought to be the most secure in the world, a *Self Magazine* investigation found there is a vast unregulated market for drugs, consisting of approximately 16,000 wholesalers. Many of these wholesalers are entirely above-board. There are some, however, who take advantage of constantly fluctuating drug prices, buying at the lowest prices possible so they can sell to other wholesalers. Drugs can sometimes pass through dozens of smaller wholesalers before they reach their destinations — some of which are small retail outlets that have a lot to gain from paying less than full price. And while the drugs make their way on this largely untraceable and unregulated path, some less-than-honest companies dilute and repackage the medicine, thereby increasing their profits.

The Prescription Drug Act of 1988 was initially designed to create a paper trail that would track drug shipments and eliminate this problem. It called for a document called a pedigree paper that would detail all sales of a drug from the manufacturer to the end destination, and all stops in between. But wholesalers successfully lobbied to have this provision put on hold, claiming there would be an undue burden from the resulting paperwork. This left a gray market, controlled by the wholesalers who are being trusted to police themselves.

A search for solutions

The State of Nevada recently raised the bar for cracking down on sales by unscrupulous wholesalers, providing an example for other state agencies to emulate. The two-page form that used to be the only barrier to becoming a pharmaceutical wholesaler in Nevada has been replaced by a 20-page application and a criminal background check. They also now demand that the applicant have qualified employees, drugs on their shelves and pristine records. After the crackdown, only eight of 40 Nevada wholesalers remained. Florida intends to use the Nevada model, and it is hoped that other states will follow suit.

The FDA also has plans that will help get the problem under control. They intend to create a program that allows manufacturers, security companies and regulators to share information on which anti-counterfeiting technologies work best for each pharmaceutical product, and to search for new ways to discover counterfeit substances before they are sold. Reconnaissance International, a consulting firm that specializes in anti-counterfeiting measures, is hosting an international meeting in September 2003, where FDA, anti-counterfeiting experts and pharmaceutical companies will discuss how to address this problem.

Fortunately, there are already technological solutions in place that detect counterfeit drugs. These include tamper-evident bottles, invisible inks and drug label holograms. Another method is to add inactive ingredients as a way for scientists to determine whether a drug is authentic. Also promising is a new handheld X-ray device that can read a chemical fingerprint inside a drug container to see if it's real.

But for these technological solutions to work, there must be more cooperation between law enforcement, legislators and the pharmaceutical industry. The truth is that the solution to this problem is as complex as the problem itself. It will require the cooperation of state and local agencies, regulators, the FDA, and the use of all the technology the industry can make available. In the meantime, buyers should beware. Patients shouldn't use Web sites to circumvent a doctor's prescription, and they should let their pharmacists know if medications look different than normal.