



Pharmaceutical fakery is health care terrorism

BY PETER J. PITTS
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Around the world, millions of people are exposed to a real health threat every day - the danger of taking the wrong medication. This spreading problem has nothing to do with patients mixing up their pills. Rather, it's caused by the proliferation of counterfeit drug traffickers, who are profiting immensely from selling fake medicines.

To combat this threat, the FDA requires distributors to keep detailed records of the sources of the medications they dispense. But that's a futile undertaking. Drug counterfeiters have become so sophisticated, they can produce drugs and packaging that cannot be differentiated from the real thing without complex chemical analysis. Paper "pedigrees" are next to useless.

With huge profits, counterfeiting is increasing at a phenomenal pace. The Center for Medicine in the Public Interest estimates that counterfeit-drug commerce will grow 13 percent annually through 2010. Counterfeit sales are increasing at nearly twice the rate of legitimate pharmaceutical sales.

Illegal drugs are a money machine. In 2010, it's estimated that fake drugs will generate \$75 billion in revenues - a 92 percent increase from 2005. And the risks of detection and prosecution are low.

Authorities are concerned. The EU recently released statistics on counterfeit-drug sales in Europe. Canadian authorities have made some high-profile arrests. But overall, the results of enforcement have been marginal.

Two years ago, when the FDA claimed that counterfeit drugs were being used to fund global terrorism, politicians such as Sen. Charles E. Grassley of Iowa and Rep. Maurice D. Hinchey of New York accused the agency of being in the pocket of Big Pharma. Today, these same politicians are strangely silent. The recent news that North Korea has gone into the business of manufacturing and selling counterfeit drugs has put a muzzle on the anti-pharma gang. Trashing patents to produce generics is one thing. Manufacturing totally useless fakes is entirely different.

It's not a stretch to call it health care terrorism.

The issue is global. National borders mean nothing to these criminals. Pharmaceuticals are easily smuggled, because medical supplies are a humanitarian need. Law authorities are frequently stymied. Our FDA must work with the World Health Organization, Interpol and other international public health and law enforcement organizations. Jurisdictions overlap. Fake drugs, substituted for the real thing, move under the cover of aid efforts. And then both can be sold to double profits.

The war against prescription-drug counterfeiters is hampered by what is known

as "parallel trade." Individual drug packages - 140 million last year - are imported to the countries of the European Union. Once inside the EU, a wholesaler is allowed to repackage each one before sale.

The intent is humanitarian. But the potential for abuse - and illegal profits - is enormous. At the most basic level, drugs are mislabeled. Dosages are misstated; a label indicates tablets instead of capsules; expiration dates don't match the medication; and labels are in the wrong language or outdated.

Even when the "confusion" is unintentional, the results are dangerous. A drug purchased by a consumer from an Internet pharmacy purported to come from a British pharmacist could originate in any EU nation. In Britain, it's estimated that parallel-traded medicines account for approximately 20 percent of all prescriptions filled. No one really knows what's happening in America.

Since the EU does not require the recording of batch numbers for parallel-imported medicines, there is no way to track shipments that are recalled. If a batch of medicines originally intended for sale in Greece is recalled, tracing where the entire batch has gone (e.g. from Athens to London through Canada to Indianapolis) is impossible.

More dangerous than the lack of quality control is that such practices allow counterfeiters to integrate their products into legitimate supply chains. The WHO estimates that 8 percent to 10 percent of the global medicine supply chain is counterfeit - rising to 25 percent or higher in some countries.

The largest counterfeit market with close proximity to the EU free trade zone is Russia, where approximately 12 percent of drugs are said to be counterfeit. Now that the Baltic nations of Latvia, Lithuania, and Estonia have joined the EU, the WHO has

warned that there is increased risk of counterfeits entering the supply chain.

It's time to stop accusing the drug industry of crying wolf about counterfeit drugs. Policymakers must confront the serious business of ensuring that drugs entering our markets are legitimate and safe. It's an area where mistakes are dangerous to everyone's health.

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