

According to the [World Health Organization](#), “counterfeit medicines represent an enormous public health challenge. Anyone, anywhere in the world, can come across medicines seemingly packaged in the right way, in the form of tablets or capsules that look right, but which do not contain the correct ingredients and, in the worst case scenario, may be filled with highly toxic substances. In some countries, this is a rare occurrence, in others, it is an everyday reality.”

Is the U.S. vulnerable to the worldwide counterfeit medicine epidemic?

Many other countries around the world – that have weak or open systems – are facing a daunting counterfeit medicine epidemic that the U.S., for the most part, has been shielded from because of our closed drug supply system. In the 1980’s, the U.S. drug supply system was closed by [Congress](#) after investigations into counterfeit birth control pills of foreign origin entered our prescription drug supply, causing many women to become pregnant.

While there have been attempts to open our closed drug supply system to unapproved foreign medicines, many experts, including those in the government, believe that doing so could jeopardize the safety and integrity of our drug supply and could put patients’ lives at risk.

How prevalent are rogue online pharmacy sites?

[Rogue online pharmacy sites](#) are popping up at an alarming rate. Criminal networks around the world have become increasingly sophisticated and are taking advantage of millions of patients around the globe by selling cheap counterfeit drugs on Internet sites, many of which masquerade as legitimate pharmacies and display a Canadian flag.

In fact, the Food and Drug Administration (FDA) once confiscated parcels containing pharmaceuticals from India, Israel, Costa Rica and Vanuatu — 43% of which had been ordered from Canadian Internet pharmacies. Of the drugs being promoted as Canadian, 85% actually came from 27 other countries.

The most common mechanism for counterfeit drugs to enter the U.S. drug supply is through purchases made on these illegal online sites. When buying medicines online, the government recommends that you always verify the validity of the website through the National Association of Boards of Pharmacy’s [Verified Internet Pharmacy Practice Sites](#) (VIPPS). The VIPPS accreditation program helps ensure that an online pharmacy meets state law and other VIPPS criteria.

Are countries in Europe facing the counterfeit medicine threat?

Outside of the U.S., where there is largely an open drug supply system, the counterfeit problem is growing worse by the day. In 2008, [counterfeit medicine seizures](#) rose 118 percent in the European Union (EU), and drugs to treat hypertension, osteoporosis and high cholesterol were among the drugs seized, according to a report by the European Commission. What’s more, 34 million counterfeit pills were seized at EU borders over a two month period in 2008. Among those 34 million counterfeit pills were fake cancer,

cholesterol and anti-malaria pills. In 2009, the total number of [medical product cases](#) in the EU increased compared to 2008.

Former European Union (EU) commissioner, Gunter Verheugen, once said that, ‘The number of [counterfeit medicines arriving in Europe](#)...is constantly growing. The European Commission is extremely worried...’ Commissioner Verheugen was further quoted in the German newspaper *Die Welt* stating that, ‘Every faked drug is a potential massacre. Even when a medicine only contains an ineffective substance, this can lead to people dying because they think they are fighting their illness with a real drug.’

What is the average jail time for criminals selling counterfeit drugs in the U.S.?

In most cases, criminals caught selling counterfeit medicines in the U.S. face lighter jail sentences and penalties than criminals selling illicit drugs such as heroin. For this reason, PhRMA will continue to advocate for [stricter penalties](#) for counterfeiters – the average jail time for a counterfeiting crime is 3 years but we believe that 20 years is a better fit for such a potentially deadly crime.

What are biopharmaceutical research companies doing to help ensure the safety and integrity of the U.S. drug supply?

The U.S. regulatory system – which governs the development, approval, and marketing of new drugs in the U.S. – is the most complex and comprehensive in the world.

To help ensure the integrity of our supply chain, biopharmaceutical companies must comply with the “gold standard” of quality manufacturing – referred to as the FDA’s Good Manufacturing Practices (GMP) regulations. FDA’s GMP standards require that manufacturers build quality into the design and production of prescription medicines, thereby helping to assure the quality and safety of every product.

America’s pharmaceutical research and biotechnology companies – whose lifeblood is the safety and integrity of the products they develop – are also working tirelessly with federal agencies, such as the FDA and the Department of Homeland Security, to help protect patients and prevent the proliferation of counterfeit medicines in the U.S.

The recent unprecedented and sustained wave of U.S. [government enforcement efforts](#) against counterfeit medicines is extremely important and has made great inroads into stemming the worldwide flow of counterfeit pharmaceuticals.