

Counterfeit Drug Prevention Issue Brief

Defining Counterfeit Drugs

A counterfeit medication can be any medication product that is contaminated, contains the wrong or no active ingredient, or contains an improper amount of an active ingredient. There are two types of counterfeit drugs:

1. **Substandard drugs** contain the labeled product but have either gone through poor manufacturing techniques or contain substandard raw materials. This type of counterfeiting often occurs because of outsourcing or comes from a manufacturer that is not authorized to make the specific product.
2. **Total fraud**, in which no attempt was made to provide the appropriate drug or go through normal supply channels (i.e. vials are pulled from the garbage and filled with tap water, inexpensive drugs re-labeled as expensive drugs, or outdated medications are relabeled for use). This can also include potency issues with illegally imported drugs, which can be damaged because they were not stored or handled appropriately.

Drug Quality and Security Act (DQSA) of 2013

HOPA fully supports the DQSA and was pleased to see Congress and the Administration take action to prevent drug counterfeiting. DQSA established a national electronic tracking system for prescription drugs. Over its ten-year implementation, DQSA will require manufacturers to use product identifiers on every prescription drug package they produce and wholesalers will only be allowed to distribute those drugs that have the product identifier included. The FDA will begin implementing the tracking system in late 2014, with stakeholder implementation scheduled for 2015 through 2017.

As with any sweeping new law, implementation will not be immediate, making it essential for health care providers and manufacturers to take extra precautions to ensure that patients are not exposed to dangerous (and sometimes deadly) counterfeit drugs. **The FDA alone cannot solve drug counterfeiting—an increased prevalence of overseas manufacturing of active ingredients and certain drugs makes regulation challenging and the need for patient and provider education even more important.**

Background on Drug Counterfeiting

Both generic and brand name drugs are at risk for counterfeiting. The most commonly counterfeited drugs are tablets for performance enhancement and chronic disease maintenance (cholesterol lowering and anxiety management). However, all categories are susceptible to counterfeiting and drugs that are hard to find, including injectable and life-saving drugs, are the fastest-growing segment of the counterfeit market. Rough estimates suggest that 20 percent of the international drug supply is counterfeit, but it is impossible to know the true scope of the problem.¹ Once manufactured, these drugs go through several levels of distributors and wholesalers before they are purchased by providers or pharmacies for distribution to patients. This complex web of drug distribution leaves much vulnerability. Several problem areas include:

- The Internet – unauthorized distributors use websites, emails, faxes, and sales reps to offer discounted, counterfeit, and illegally imported drugs
- Pricing – due to the high costs of drugs in the U.S., people often search across international boundaries to find lower cost options, which can create lucrative markets for counterfeiting
- Drug shortages – when drugs are in short supply, counterfeiters see an opportunity to create a fake “surplus” of a drug in high demand

¹ Pharmaceutical Security Institute, Counterfeit situation: <http://www.psi-inc.org/incidentTrends.cfm>

Scope of the Problem and Patient Safety

Despite a regulatory framework governing the production and distribution of drug products, instances of counterfeiting still occur:

- In 2007-08, 149 Americans died from a contaminated “blood thinner” called heparin that was legally imported into the U.S., but contained a counterfeit ingredient
- In 2012, vials of the cancer medicine Avastin™ (bevacizumab) were found to contain no active ingredient, leaving many cancer patients to believe they were receiving an active drug when they were not
- In 2012, there was a 48 percent increase in counterfeit cytotoxic drugs commonly used to treat cancer²

If a physician or pharmacist does not know a drug is counterfeited, they may stop (or alter) the patient’s therapy because they observe that it is not effective, when in fact the drug is actually fake or contains harmful substances. In the Avastin™ (bevacizumab) case, there were reports of patients shaking during infusions and experiencing other side effects that warranted the patients to discontinue therapy. It is often difficult to prove if adverse reactions are drug-related (or counterfeit-related) or if they are disease-related.

Counterfeit drugs have a large economic impact. Some providers knowingly purchase cheaper drugs outside of the normal distribution channels to increase their profit margins. In one case, a cancer center purchased over \$2 million in misbranded, unapproved drugs and billed Medicare and other government health programs about \$2.5 million.³ The estimated economic impact of counterfeiting in the U.S. is over \$200 billion annually,⁴ compared to an annual U.S. prescription drug spend of \$330 billion and a global drug spend of \$1 trillion.

Recommendations

Development of provider education and sound regulatory policy is critical to protecting patients from the serious consequences of counterfeit drugs. To this end, HOPA recommends the following actions:

- Educate providers to not utilize suppliers outside of FDA regulation
- Educate patients and consumers about the dangers of ordering from internet pharmacies—patients should look for the VIPPS logo (Verified Internet Pharmacy Practice Sites) on all internet pharmacy sites
- Educate patients to report any changes in response to their medication after obtaining a new supply (including a lack of response, excessive response, or side effects) immediately to their provider
- Encourage providers to consider that a patient’s lack of response, excessive response, or side effect to therapy may serve as an indicator for a potential counterfeit drug and educate them how/where to report these observations
- Educate pharmacists and their staff to recognize signs of counterfeit drugs or tampering, such as different containers, labeling differences, changes in solubility, and how/where to report these observations
- Ensure the FDA has quality checks in place for approval of all raw materials prior to use in manufacturing of new products—both in the U.S. and abroad for drugs that will be distributed in the U.S.
- Support the implementation of the DQSA—require importers and manufacturers to notify the FDA when they discover counterfeit drugs; require distributors to provide verification of the source of the product; and require manufacturers be able to provide quality records including the source of their raw materials for each lot number of drug
- Encourage more severe penalties for health care professionals who willingly and knowingly aid and abet the distribution of counterfeit products
- Enforce drug importation laws to stop individual states from allowing consumers to purchase prescription drugs over the internet that are not regulated by a U.S. entity
- Establish a national drug surveillance program to better understand incidence and prevalence of drug counterfeiting and the scope and magnitude of harm to patients because of drug counterfeiting

² Pharmaceutical Security Institute, Counterfeit situation: <http://www.psi-inc.org/incidentTrends.cfm>

³ CBS News, <http://www.cbsnews.com/news/us-doctors-buying-unapproved-drugs/>

⁴ Organization for Economic Co-operation and Development (2007), the Economic impact of counterfeiting and piracy: <http://www.oecd.org/industry/ind/38707619.pdf>