

The World Health Organization (WHO) in 2012 estimated that the global market for counterfeit pharmaceuticals generated \$431 billion in gross annual revenues¹ for purveyors of those fake products. Since then, WHO has stopped estimating the counterfeit industry's revenues because of the difficulties in tracking fake prescription drugs. WHO is quick to note that the counterfeit pharmaceutical problem is not confined to developing countries with lax regulations. In 2014, the U.S. Food and Drug Administration (FDA) seized more than \$73 million worth of counterfeit drugs, and since 2010, the FDA has tracked and recorded more than 1,400 incidents of adverse reactions caused by counterfeit drugs².



Counterfeit pharmaceutical products run rampant through internet pharmacies. Image Credit: Flickr User [Carlos Lowry](#) (CC BY 2.0)

The prevalence of internet pharmacies has elevated the problem to near epic proportions. WHO estimates that more than half of all pharmaceuticals sold over the Internet are counterfeit³. Consumers that buy cheap drugs online, even when their purchases are made from internet pharmacies that appear in every respect to be legitimate, are taking great risks with their own health and safety. Counterfeit pharmaceuticals might be compounded from ingredients that range from inert to harmful or adulterated. Consumers cannot be faulted for attempting to save money on prescription drugs, but they are ill-equipped to detect counterfeit products and inevitably they rely on manufacturers and regulatory authorities to keep the fakes off of the market.

At an extreme, regulators and pharmaceutical companies can implement plans to test batches of pharmaceuticals at various stages of the global supply chain with gas chromatography and other sophisticated technologies⁴. These technologies will distinguish genuine products from knockoffs, but their broad implementation is expensive and impractical. Moreover, local regulatory agencies and shipping inspectors will not have the resources or access to complex analytical tools to implement the kind of widespread screenings that are required to snag every counterfeit

pharmaceutical product. A more practical option is to use portable spectrophotometers for rapid early screening of both the pharmaceuticals and their packaging as the first line of defense against counterfeit drugs.



Pharmaceutical companies can impede counterfeiters by publishing precise color profiles of their labels. Image Credit: Flickr User [Austin Kirk](#) (CC BY 2.0)

Color and Pharmaceutical Packaging

Legitimate pharmaceutical manufacturers use advanced packaging with holograms, bar codes, and other features to confirm that the enclosed products are real. Packaging color is as critical an indicator of legitimacy as these advanced features.

Consumers generally avoid products with inconsistent or dubious packaging⁵, but consumers that purchase pharmaceuticals from internet pharmacies do not have the luxury of picking and choosing. Counterfeiters might take advantage of this by using cheaper printing and packaging materials. This leaves an opening for a legitimate manufacturer to publish a color profile for its own packaging. Screeners and regulators can then use portable spectrophotometers to measure a pharmaceutical product's packaging for comparison against a manufacturer's standard color profile. Any differences

will be a first marker of counterfeiting that the regulator can then use to flag a batch for more advanced testing and verification.

Drug Color Consistency

Counterfeiters are becoming more adept at replicating the appearance of legitimate drugs, but subtle color differences between real and fake drugs are still a strong indication of a counterfeit product. Strict FDA standards on drug production result in products that have identical colors and appearances from batch to batch. Even more so than with pharmaceutical packaging, manufacturers can create color profiles for each of their products. They can then use portable spectrophotometers for quality control and assurance during a manufacturing process. Regulators can also use these devices to sample drug products in supply chains in order to weed out any products that are outside of that profile. Without their own spectrophotometers, counterfeiters will be unable to precisely match the exact profiles of the drugs they are emulating. Certain spectrophotometers can detect differences on UV wavelengths, which would be invisible to the naked eye. This makes color profiles even more difficult to fake without instrumental aid.

Using HunterLab's Devices to Detect Counterfeit Drugs

HunterLab has long been at the forefront of providing appearance and color testing instrumentation to the [pharmaceutical industry](#). To measure both opaque substances at UV wavelengths, regulators can use the UltraScan Vis or Pro.

To learn more about which instrument would be ideal for your production process, [contact our friendly, professional sales force today](#).

1. "Deadly fake Viagra: Online pharmacies suspected of selling counterfeit drugs," 2015, <http://www.cnn.com/2015/08/31/health/counterfeit-medications/>
2. "Counterfeit Drugs Are Flooding the Nation's Pharmacies And Hospitals," 2016, <http://www.aarp.org/health/drugs-supplements/info-2016/counterfeit-prescription-drugs-rx.html>
3. "Rise in online pharmacies sees counterfeit drugs go global," 2015, [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(15\)00394-3/fulltext?rss%3Dyes](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)00394-3/fulltext?rss%3Dyes)
4. "Countering the Problem of Falsified and Substandard Drugs," <https://www.ncbi.nlm.nih.gov/books/NBK202524/>

5. "Combat counterfeiting with packaging design and color consistency,"
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