Counterfeit drugs have historically been associated with third world countries, where an estimated 20-30% of drugs are counterfeit products passed off as legitimate pharmaceuticals. While some counterfeits are formulated with active ingredients that mimic real medications, others have no therapeutic properties at all or, even worse, contain harmful chemicals that endanger the lives of patients. In 2008, for example, 84 children in Nigeria died after taking counterfeit teething medication composed of an industrial solvent that attacks vital organs.[1] Roger Bates of the American Enterprise Institute estimates that, conservatively, "more than 100,000 people are killed worldwide by dangerous drugs every year. And that statistic does not take into consideration the incalculable morbidity and misery caused by such products."[2]

However, counterfeit pharmaceuticals are not only a problem faced by the developing world; fake replicas are increasingly infiltrating markets in the West as well. While western nations typically have the highest drug safety standards in the world, changing economic practices and market conditions have set the stage for a rising tide of counterfeit pharmaceuticals. Supply chain vulnerabilities, such as under-regulation of drug wholesalers and repackagers, the proliferation of online pharmaceutical sales, and increased importation of medication, are allowing dangerous drugs mass produced in countries like China and India to enter the mainstream marketplace. In 2008, the EU saw an 118% percent increase in counterfeit drug seizures.[3] Meanwhile in the U.S., fraudulent imitations of several high-profile medications have led to serious health complications and fatalities, prompting the FDA and CDC to issue warnings regarding counterfeit drugs. Earlier this year, ABC News was witness to an anti-counterfeiting operation that netted "415,000 doses of illicit pharmaceutical products" in a single bust.[4]

As counterfeiting has spread, so too has the sophistication of fraudulent practices. While authorities used to rely primarily on visual inspections of drugs and suspect packaging, the refinement of counterfeit medication and packaging production, including the reproduction of anti-counterfeiting holograms, has necessitated the development of more advanced methods of detecting fraudulent pharmaceuticals. Chief among these is the deployment of spectral analysis using sophisticated spectrophotometric technologies.

Fingerprinting Drugs Using Spectral Analysis

Color is a vital component of pharmaceuticals that can deeply affect how consumers relate to medications. However, chromatic and reflectance properties of drugs also function as a fingerprint to identify pharmaceutical compounds in liquid and solid forms, acting as both a critical part of quality assurance and the patenting and trademarking process. The spectral profiles created by pharmaceutical companies to ensure proper production can also be used by anti-counterfeiting operations to detect fraudulent products. Because manufacturers of imitation pharmaceuticals often take care to mimic the visual appearance and packaging of legitimate drugs, differences between counterfeit and authentic drugs can be impossible to distinguish based on visual inspection. The precise quantification of spectral data offered by spectrophotometric analysis allows for accurate pharmaceutical fingerprinting that goes beyond the limits of human sight. The chemical and process variables of counterfeit drugs make them spectrally discrete from the drugs they are imitating and identifying these spectral differences is the basis for spectrophotometric anti-counterfeiting measures. As Randy Klimek explains:

[T]he compounding methods used by drug counterfeiters will be different than those used by legitimate pharmaceutical companies, and thus the surface geometries of their tablets will necessarily be different, which will produce altered reflectance patterns. Similarly, any additives or contaminants in a chemical will alter the product's color profile, which will alert drug enforcement agents to the counterfeit nature of the chemical.[5]

The data gained through spectral analysis can be compared to a database of legitimate drugs to quickly determine the authenticity of a particular compound. Furthermore, spectrophotometric technology removes

the need for extensive sample preparation and non-contact instrumentation allows for consistent, accurate spectral measurement without destruction of the product.

Flexible, Versatile, and Portable

Spectrophotometric instrumentation is already being incorporated in anti-counterfeiting projects around the world, from state-of-the-art operations by government bodies and pharmaceutical companies in the United States, Canada, and Europe to mobile labs in developing countries, where the majority of counterfeit drugs are both produced and distributed. The versatile nature of benchtop and portable spectrophotometers makes them ideal for use in a variety of environments, whether utilized in a dedicated laboratory or in the field. One initiative spearheaded by the National Institute for the Control of Pharmaceutical and Biological Products in China employs over 400 vans as traveling labs. Equipped with near-infrared (NIR) spectrophotometers, anti-counterfeiting agents can move throughout the country testing suspect pharmaceuticals against an existing library of NIR spectra.[6] Rather than having to seize pharmaceuticals and send them for testing at a secondary location, mobile spectral analysis allows for rapid, non-destructive detection of counterfeit pharmaceuticals, even in remote areas. The project has been replicated in several other countries as identifying and quarantining counterfeit products becomes both easier and more necessary than ever before.

Full article with photos available here:

https://www.hunterlab.com/blog/color-pharmaceuticals/spectrophotometers-and-fraud-exposure-using-spectral-analysis-to-detect-counterfeit-drugs/