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# The New War On Drugs

## *Manufacturers vs. counterfeiters and the rise of the anti-counterfeiting technology industry*

Many successful products and services in today's market are powered by the promise of consumer convenience. An example of this is the increase in online pharmaceutical retailers. Consumers may ask themselves, "Why should I wait in a long line at the drug store when those same medications are just a few clicks away, and often at a cheaper price point? The answer: because the online sector is currently less regulated, there is a greater chance that the medications these retailers are selling are not actually the same medications. Consequently, consumers seeking the convenience of making their prescription purchases online are more open to risk as they could be getting: (1) drugs without active pharmaceutical ingredients; (2) copies of drugs made with unlicensed manufacturing processes; or (3) products with high levels of contaminants. Any of these scenarios could lead to adverse health consequences for the patient, including death. And the danger does not stop with the Internet. Sophisticated counterfeiters are often able to infiltrate legitimate supply chains as well.

Over the last ten years, pharmaceutical companies have invested millions of dollars in efforts to prevent counterfeiting, but at present, they lack any uniform or proven system for prevention. They also have insufficient guidance on the issue since legislation on the subject – both at the state and federal level – is rarely passed. If it is passed, it is seldom implemented because either (1) the measures mandated are obsolete by the time they are scheduled to take effect, or (2) they are delayed by litigation challenging their implementation. This has left some pharmaceutical manufacturers confused, and many appear to be sitting in a holding pattern. As a result, counterfeiting is more prevalent today than ever and counterfeiters seem to be more adaptable than the pharmaceutical industry.

The resulting combination of a threat to public health plus decreased market share for pharmaceutical companies, has given rise to a very specialized, and profitable market: anti-counterfeiting technology. Because counterfeiters have proven to be adaptable, the anti-counterfeiting industry has embraced the need for a continuous cycle of innovation. According to a new study conducted by Global Industry Analysts, Inc., the global market for anti-counterfeiting technologies (for both food and pharmaceuticals) could reach $82.2 billion by 2015. These companies promise manufacturers they can avoid brand-degrading lawsuits and costly media campaigns, while reclaiming critical market share and profitability lost to counterfeiters.

Here is an overview of the different kinds of anti-counterfeiting technology available:

**Direct Authentication**

This refers to a feature incorporated in the product so the pharmacist or consumer can easily discern authenticity. Examples include watermarks or holograms on the packaging, or unique shapes or designs of the drug itself. These methods are somewhat outdated today, as counterfeiters have found ways to forge such features, and intellectual property rights do little to thwart the criminal schemes. Also, since many of these features target the end-consumer, consumers must know what to look for – a factor that requires widespread public health campaigns, which are rarely feasible or desirable for manufacturers.

**Serialization and RFID**

Serialization generally refers to a unique code that is printed on the product package (e.g. a barcode) or capsule/tablet itself. It is essentially an e-pedigree used to track the product. Radio Frequency Identification, or RFID, is a more advanced form of e-pedigree, and has been touted by the FDA as the most promising technology for electronic track-and-trace across the supply chain. RFID uses electronic product codes that are "written" onto RFID tags embedded into packaging and labeling. The codes are then uploaded into a repository database that can be accessed along each stage of the supply chain.

While several pharmaceutical companies have adopted RFID, some manufacturers oppose an industry-wide RFID requirement due to unresolved concerns about privacy, cost, effectiveness and feasibility of implementation.

**Forensic Methods**

Surface analysis techniques are among the most accurate and cutting-edge technologies. These methods use unique chemical designs as part of the surface material or coating of the drug itself, or even the sub-surface material of the drug. A post-market forensic analysis can detect contaminants present on the surface, or reveal the chemical composition of the drug by analyzing ions produced from the material. These methods also tout the ability to identify whether the product was manufactured using a licensed or unlicensed process because they can detect the distribution of a specific lubricant commonly used in the manufacturing process.

A similar method getting attention involves the use of physical chemical identifiers/additives wherein the manufacturer adds inks, pigments, flavors and other identifiers to drugs in order to make them harder to falsify. Forensic testing of drugs, however, can be very expensive to administer and requires well-trained staff to conduct the testing.

**Mobile Product Authentication**

This new method is based on asymmetric encryption. Using a cell phone, customers can text message an item's unique code on the product and get an instant response confirming or denying the brand's genuineness. This technology has not been as widely tested for use in detecting counterfeit drugs as RFID, for example, but much like mobile banking or credit card authentication, could be embraced as part of the expansive trend of mobile-device reliance.

**Space Age Technology**

Most recently, a team of space research scientists from the UK revealed a new technology developed from a spectrograph that quickly detects counterfeit drugs (and other products) by comparing the characteristics of light reflecting from printed product packaging. The unique light source incorporated in the product and the selection of critical points in the packaging at which the tests are conducted provide a degree of randomness that is not known to the counterfeiter and makes it impossible to replicate.

These are representative examples of how expansive the anti-counterfeiting industry is becoming. The forms of technology emerging are not only innovative and numerous, but they are diverse across the board. Since it is not likely that a uniform system of compliance will be implemented for manufacturers any time soon – the market for anti-counterfeiting technologies has plenty of room for growth and is one to watch in the future.

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