

## Fighting counterfeits requires on-dose protection

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There can be no dispute that counterfeit and diverted tablets and capsules are a big problem. The Center for Medicine in the Public Interest, New York, NY, predicts that counterfeit drug sales will reach \$75 billion globally next year, nearly double the group's 2005 estimate.

According to a January 2009 report by the British newspaper *The Observer*, "Figures collated for the first time reveal that British border officials seized more than half a million counterfeit pills destined for the [National Health Service] and high-street chemists last year, an amount equal to the quantity of counterfeit drugs found in the whole of Europe in 2005" [1].

In 2006, the World Health Organization (WHO) estimated that 10 percent of the world's medicines are counterfeit and noted that the severity of the problem varies with geography [2]. In the USA and Europe, about 1 percent are counterfeit, in Russia 12 percent, in Mexico 40 percent, and in Nigeria 80 percent.

There were approximately 4.0 billion US prescriptions dispensed in 2008. Assuming 1 percent were counterfeit means that as many as 40 million prescriptions may have been filled with bogus pharmaceuticals. Today, that figure could be higher because economic hard times are forcing patients to look for cheaper medications. That could lead to a surge in demand for counterfeit and diverted products and make it that much harder to curb their spread.

The availability of drug products via the internet is also helping the growth in counterfeiting to outpace the growth of the legitimate pharmaceutical industry. According to a July 2008 report from the European Alliance for Access to Safe Medicines, "The Counterfeiting Superhighway,"



Tablets enter equipment that encrypts them with NanoCodes.

62 percent of internet medications were found to be substandard or counterfeit; 49 percent had no packaging; and 30 percent of blister packages had been tampered with or damaged [3].

Which medicines are targeted by counterfeiters and diverters could also be expanding. Typically, criminals have targeted high-value medicines (at least \$1 billion in annual sales), medicines with a high per-unit cost (greater than \$10), or lifestyle products. Yet last year, Baxter's heparin product, with annual sales of just \$35 million, had its API counterfeited. According to the FDA, there were 246 deaths blamed on contaminated heparin between January 2007 and May 31, 2008.

### Tracking the package isn't enough

The only way to fight counterfeits is to secure the supply chain. But what is the best approach to do that? The most common approaches entail overtly securing the packaging using

brand-protection technologies, such as color-shifting dyes, holograms, 2-D barcodes, tamper-evident seals, and serialization. Covert methods have also been used, including threads, taggants, and RFID. A March 2009 position paper on counterfeits issued by the Brussels-based European Federation of Pharmaceutical Industries and Associations recommended using all these and other methods. It also recommended banning the re-packaging of pharmaceuticals [4].

But counterfeiters and those who divert pharmaceuticals are adept at copying many, if not all, of these package-based protections. Besides, the original package seldom, if ever, accompanies illegally diverted products. Thus it's risky to assume that because the package is secure, the medication in the package is secure. That is often not the case. In 2005 testimony before a Congressional committee, Jim Christian, vice president for global corporate security at Novartis, said, "In

almost every case, the technology—be it a hologram, tamper-proof labels, embossing, thermo-reactive ink, RFID tags, DNA markers, and the like—enables companies to track cardboard, not product. It is not unusual to find genuine product in counterfeit packaging and counterfeit product in genuine packaging” [5].

A California-style e-pedigree track-and-trace approach also relies on links to the packaging, but stops short of protecting the actual medication within. While e-pedigree would undoubtedly increase protection, it is not a panacea since more than 90 percent of tablets and capsules dispensed at US retail pharmacies are repackaged. Nor does an e-pedigree guarantee safety once the medicine reaches the pharmacy. Indeed, pharmacists have been convicted for their involvement in schemes to sell fake, mislabeled, and stolen drug products. In addition, an e-pedigree system will require manufacturers and downstream supply-chain partners to make significant investments and will take years to implement.

### Coupling on-dose protection with random audits

For these reasons, the best approach to fighting counterfeiting and diversion is a layered security strategy that employs traditional on-package brand protection technologies, as well as overt (color manipulation, marking schemes, on-dose printing) and covert (taggants, nano-techniques) on-dose technologies.

Taggants are covert chemical or physical markers that can help authenticate tablets and capsules. They generally consist of microscopic particles, built up in many layers. Primarily used in packaging security, taggants are expanding to provide on-dose security as well. For on-dose applications, the taggant is usually a Generally Recognized As Safe, or GRAS, compound.

But the on-dose method that my company offers, called NanoEncryption, fights counterfeiting and illegal drug diversion by enabling manufacturers and law enforcement to trace and authenticate each and every



One of these two tablets carries NanoEncryption and one does not. To the naked eye, the tablets are identical.

tablet, capsule, or vial from plant to patient using a single technology. It's a technology that

- Adds nothing to the tablet or capsule
- Does not affect bioequivalence or dissolution
- Provides overt and covert, field-level authentication in the fight against counterfeiting, and
- Provides comprehensive tracing information on each and every dose via forensic-level NanoCodes [6].

These NanoCodes can be associated with an unlimited amount of data, including, but not limited to, product information (dosage strength, expiration date), manufacturing information (location, date, batch, lot number), and distribution information (country, distributor, wholesaler, chain). Since our company's on-dose protection always remains with the specific dose—even after numerous repackaging efforts—it provides brand integrity, protection, and confidence that standard, on-package, e-pedigree technologies cannot provide.

NanoEncryption is virtually impossible for counterfeiters and diverters to copy, providing long-lasting benefits to manufacturers. Last but not least, because the technology adds nothing to the existing medication, relatively little regulatory work is required for implementation.

The final step in securing the pharmaceutical supply chain is to establish a market-monitoring program that quickly notifies manufacturers when counterfeits or diverted products are detected. Our company has launched a program [7] that

combines the authentication and tracing benefits of our on-dose technology with pharmacy audits. These audits will identify counterfeit and illegally diverted pharmaceuticals that have entered the global supply chain and serve as an early warning system to manufacturers and other stakeholders.

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### References

1. “Health fears grow as fake drugs flood into Britain.” *The Observer*, January 4, 2009. Website: [www.guardian.co.uk](http://www.guardian.co.uk).
2. Website: [www.who.int](http://www.who.int).
3. Website: [www.easm.eu](http://www.easm.eu).
4. EFPIA Position Paper: “Commission’s Proposal on Counterfeit Medicinal Products.” March 2009. Website: [www.efpia.eu](http://www.efpia.eu).
5. Jim Christian testifying before the Subcommittee on Commerce, Trade and Consumer Protection, House Energy and Commerce Committee, June 15, 2005.
6. NanoCodes is a trademark of NanoGuardian, Skokie, IL.
7. Closed-Loop Protection by NanoGuardian.

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