



# Strategies to Secure the Pharma Supply Chain

By Dean Hart at  
NanoGuardian

Several factors are coming together to create the equivalent of 'the perfect storm' for counterfeiters and illegal diverters of prescription drugs; it is the responsibility of pharmaceutical manufacturers to secure their brands by implementing comprehensive protective strategies to defend the reputation of their products.

Pharmaceutical manufacturers, the pharmaceutical supply chain and unsuspecting patients are all under attack by sophisticated and well-funded criminal elements who seek to profit from counterfeit and illegally diverted medications. Unfortunately, the counterfeiters and diverters seem to be winning many of the battles – if not the war. A perfect example is the theft of \$75 million in drugs from Eli Lilly & Co in March 2010 in one of the biggest pharmaceutical heists ever.

The US-based Centre for Medicines in the Public Interest has estimated that counterfeit drug commerce is growing by 13 per cent annually – which is nearly twice the rate of legitimate pharmaceuticals – and this growth in counterfeit medications will generate \$75 billion in revenues – a 92 per cent increase from 2005.

## CONTRIBUTORY FACTORS

The global economic downturn has played an important role in the recent escalation in counterfeiting and illegal diversion of pharmaceuticals. According to the latest estimates from the US Department of Labor, there are almost 15 million Americans without a job. The US is not alone in its economic pain as virtually every part of the world is undergoing a period of economic uncertainty. Those that are experiencing the most economic pain are evaluating the spend of every dollar, and are cutting back on non-essential needs such as hobbies, leisure activities and vacations. Additionally, the need to continue taking medicines to maintain health and well-being for these unemployed individuals and their family members has created a concerning situation where patients feel no choice but to search for more economical sources to obtain their medications.

The availability of pharmaceutical products via the internet is also helping the growth in counterfeiting. An April 2008 Congressional press release supported concerns about counterfeit drugs and the internet by stating that up to 360,000 packages containing counterfeit drugs enter

US international mail facilities each day – that is up to 10 million packages a month and 130 million counterfeit drug packages in a year. Additionally, according to a July 2008 report from the European Alliance for Access to Safe Medicines entitled *The Counterfeiting Superhighway*, 62 per cent of internet medications were found to be substandard or counterfeit; 49 per cent had no packaging; and 30 per cent of blister packages had been tampered with or damaged.

At the same time, the delays in government-driven and supported brand protection initiatives – such as California's ePedigree legislation, which has been pushed back at least eight years – negatively affect the focus and commitment that will be required by governments, manufacturers, and virtually all members of the supply chain to meet the goal of a globally secure pharmaceutical supply chain.

Combined, these factors – economic hardship, a lack of coordinated global intervention and the ease of obtaining perceived legitimate product via the internet – create what equates to a 'perfect storm' for counterfeiters and illegal diverters. There has perhaps never been a more opportunistic environment in the pharmaceutical industry for counterfeiters and diverters.

## BRAND PROTECTION TECHNOLOGIES

Ultimately, it is the health and wellbeing of patients that is most at risk. And while pharmaceutical manufacturers have worked hard to raise the pharmaceutical supply chain to a higher level of integrity, they must fully realise that if they are to stem the tide of counterfeiting and illegal diversion, they must supplement traditional methods of brand protection with state-of-the-art technologies that protect the integrity and therapeutic benefit of each and every dose.

The best approach in the fight against counterfeiting and diversion is a brand security strategy that includes a

combination of on-package and on-dose tactics. On-dose technologies are typically grouped into overt (visible with the naked eye) and covert (special detection tools required) technologies. Colour schemes, on-dose printing and special marking schemes are common overt on-dose brand protection tactics. Unfortunately, while useful, counterfeiters are adept at mimicking any aspects of the dosage form that they can see – including security features.

One overt on-dose brand protective weapon available to manufacturers is taggants; these are chemical or physical markers that can aid in the authentication of a medication. They generally consist of microscopic particles, built up in many layers. Primarily used as an on-package security tactic, taggants are expanding into the on-dose security area. For on-dose applications, the taggant used is usually a 'generally recognised as safe' or GRAS compound.

### **NANOENCRYPTION**

NanoEncryption technology is an on-dose brand protection weapon that can be implemented immediately by manufacturers to protect brands and patients, as it does not require an investment by downstream supply partners to be effective. Developed by NanoGuardian, NanoEncryption enables manufacturers to trace and authenticate every single dosage from plant to patient. NanoEncryption technology adds no additional chemicals or materials to the dose, and is achieved by making purposeful manipulations in the coatings and gelatine used in the manufacture of tablets and capsules.

The overt and covert NanoEncrypted features allow in-field authentication of every dose (tablet, capsule, single-use vial cap or pre-filled syringe) at any point in the supply chain, while the forensic-level, nano-sized NanoCodes provide comprehensive tracing information on each and every dose.

NanoCodes can be associated with an unlimited amount of data including – but not limited to – product information (strength, expiration date), manufacturing information (location, date, batch, lot number) and distribution information (country, distributor,

wholesaler). Given their nano-scale size – 350 NanoCodes fit into the width of a human hair – the reading of the NanoCodes requires specialised equipment and software housed at NanoGuardian's Product Integrity Center, the first of which is located at our office in Skokie, Ill, US. The process to decrypt the NanoCodes is non-destructive and can be completed within minutes – yielding a wealth of dose-level tracing data for the manufacturer.

As such, NanoEncryption provides manufacturers with a single weapon that they can use in the fight against both counterfeiting and illegal diversion.

### **A STRONG OFFENCE**

It has been said that the key to a good defence is a strong offence – and the same is true when approaching the war against counterfeiting and diversion. Manufacturers must take the fight to those who mean to harm them and their patients by aggressively defending their IP and proactively monitoring the supply chain for intrusions of counterfeit or diverted product. One approach to supply chain auditing is data mining of ordering patterns by manufacturers, wholesalers, distributors and retail pharmacies to find discrepancies.

At NanoGuardian, we have launched a programme that is directed specifically at the medication being dispensed to patients; our Closed-Loop Protection Program works hand-in-hand with NanoEncryption technology and utilises statistical modelling with randomised pharmacy auditing in an effort to identify counterfeit or illegally diverted pharmaceuticals on pharmacies' shelves awaiting distribution to patients. The mission of the Closed-Loop Protection Program is to provide early detection of counterfeit and illegally diverted products, helping to reduce the risk to patients, brands and companies.

### **TAKING THE UPPER HAND**

In an environment of global economic hardship, a lack of coordinated global intervention, and the ease of obtaining perceived legitimate product via the internet, criminals are reaping huge profits by deceiving law enforcement and – most importantly – innocent and unsuspecting patients. Pharmaceutical manufacturers must continue their commitment, and focus on securing their brands by implementing comprehensive protective strategies that have an immediate impact. By doing so, manufacturers can take an upper hand in the war against counterfeiting and illegal diversion, protect the reputation of the safe and efficacious products that they have worked so hard to achieve and ensure that patients continue to receive the authentic medicinal benefits that positively add to their health and wellbeing.



**Dean Hart** joined NanoGuardian in February 2008 as Executive Vice President. He possesses more than 25 years of sales and marketing experience in the pharmaceutical marketplace. He began his pharmaceutical career at Bristol-Myers Squibb and then served as National Sales Director for Eisai, Inc. Most recently, he served as Senior Vice President of Sales at Takeda Pharmaceuticals North America. Dean holds a Bachelor of Science in Business Management from Indiana University (US) and a Master of Business Administration from the Kellogg School of Management at Northwestern University (IL, US). Email: [dhart@nanoinc.net](mailto:dhart@nanoinc.net)