PODCAST
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WAR ON COUNTERFEIT DRUGS

Future Pharmaceuticals **How significant is the problem of pharmaceutical counterfeiting, and what parts of the world are affected?**

KIRK BARNES The trend is actually quite scary. In 2006 the World Health Organization estimated that the global rate of counterfeiting is about 10 percent across the globe. In developed nations, such as the United States or the European Union, that rate is about 1 to 2 percent, and in developing nations, such as Nigeria, the counterfeit rate is as high as 80 percent. In those nations, you're actually lucky to get a legitimate medication itself. To put it in perspective, people look at the U.S. or the EU and think that 1 percent isn't too bad, but consider that in 2007 there were 4 billion U.S. prescriptions dispensed, and if you take 1 percent of that, that means there were 40 million counterfeit prescriptions that were filled with fake medications here in the U.S. In fact, in the EU, in December of 2008, there was a two-month study that was conducted by the customs agents, a forum part of the EU member states, and they wanted to get a handle on how significant the counterfeiting issue was. During this study, called MEDI-FAKE, a two-month study assessed how much counterfeit pharmaceutical products were flowing into the EU borders, and they found 34 million counterfeit medicines that were received in a two-month time frame, so this was far above and beyond their expectations.

Lastly, when most people think of counterfeit medicines they think of the Internet, where there are significant emerging problems regarding counterfeit medicines. For example, in the July 2008 report from the European Alliance for Access to Safe Medicines, they found 62 percent of all medications that they were buying on the Internet were found to be counterfeit, substandard or subtherapeutic. So whether you're in a developed nation, underdeveloped nation, or you're buying your prescriptions online, it's a significant problem that is getting worse year after year.

FP What types of products are most often counterfeited?

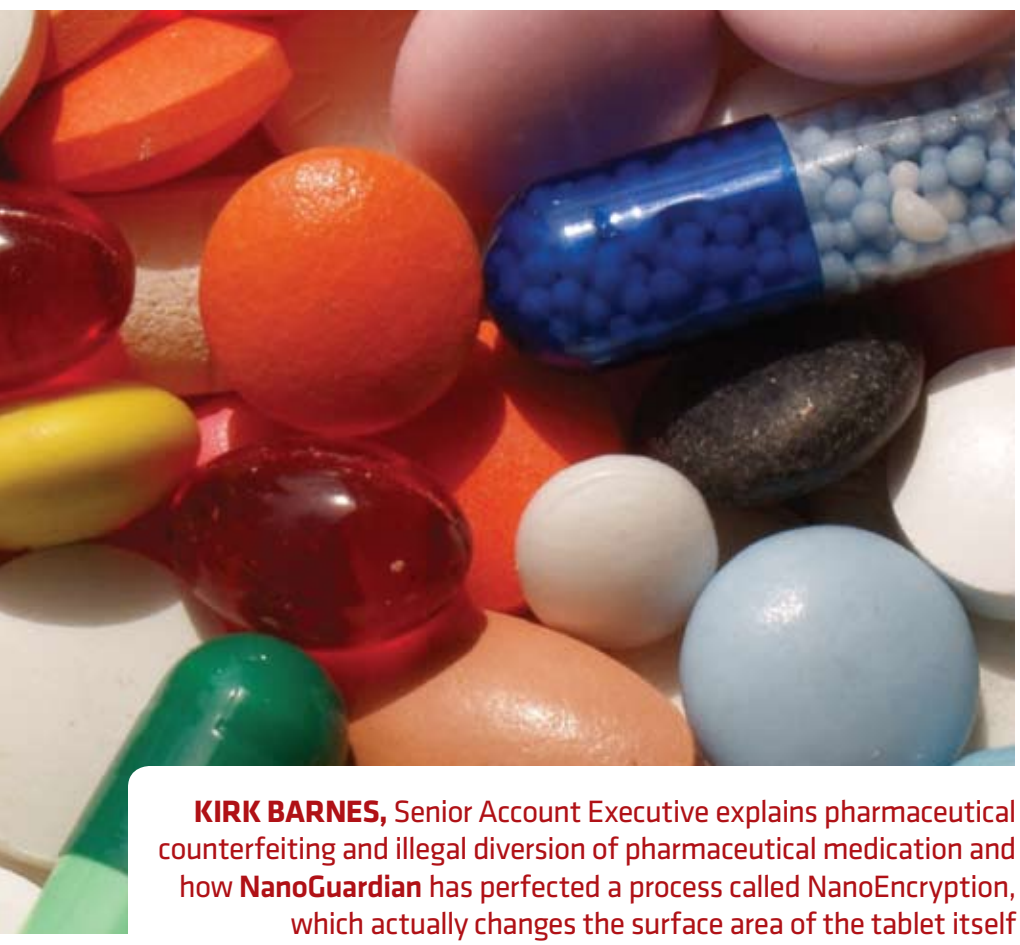
KB When most people think of counterfeit medications, especially when you look on the Internet, the ones typically most visible are

lifestyle products. However, from recent studies like MEDI-FAKE, the types of drugs that were found were not just lifestyle products but life-saving medications that people need for either chronic illnesses or life-threatening illnesses, and those therapeutic categories range from cancer, cholesterol, the swine-flu epidemic, antibiotics, diabetes medicine, and painkillers.

We used to think that if a medicine was a lifestyle drug or high-value, high-volume, high-profile drug, it would be the most likely to be counterfeited, but now we know from feedback from the law-enforcement agencies as well as regulators in the pharmaceutical manufacturers, this is not the case. All types of drugs have the ability to be counterfeited and made available to unsuspecting patients throughout the world.

FP Where do these counterfeit products originate?

KB There is a myriad of different perspectives on where these drugs come from. Mostly we hear that the drugs are manufactured in nations such as China or India, but we know that's not necessarily the case. In fact, there is a book called *Dangerous Doses* by Katherine Eban that documents multiple cases of counterfeiting taking place here in the U.S. En masse, some of the counterfeit drugs may come from nations such as India and China but that does not mean that operations are on a smaller scale here in the United States or in some of the other developing nations as well. If there is an opportunity for a criminal element to take advantage of a healthcare system and they see an opportunity to make money from counterfeiting a product and they're able to fly under the radar, that criminal element will take advantage of that opportunity, so it really doesn't matter what part of the world you're in for people to take advantage of that arbitrage opportunity.



KIRK BARNES, Senior Account Executive explains pharmaceutical counterfeiting and illegal diversion of pharmaceutical medication and how **NanoGuardian** has perfected a process called NanoEncryption, which actually changes the surface area of the tablet itself

FP What is the penalty for counterfeiting drugs, and is it a big issue that law-enforcement teams are trying to crack down on?

KB It's definitely emerging more. For example, prescription painkillers are the second most widely abused drug by teenagers in the U.S., second to marijuana. So what people are finding, in regards to the criminal element, is that they can make about the same amount of money if they were selling cocaine or marijuana by counterfeiting or illegally diverting prescription drugs and selling them in the marketplace. The people who have actually done this have been able to take advantage (unfortunately) of the legal system because our law-enforcement has be focused on fighting crime — and they've been doing a tremendous job. However, law-enforcement is not looking for fake Viagra or fake OxyContin or prescription opioids in the back of someone's truck; more likely the penalties and the searches that are being done are geared towards hardcore illegal drugs such as heroin, cocaine or marijuana.

So from that perspective, criminal elements feel they can make money by counterfeiting prescription medication or illegally diverting prescription medication and finally to launder them into the legitimate supply chain. It follows that even if they do get caught, it's very difficult for law-enforcement to decipher what is an authentic medication vs. what is a counterfeit medication. However, I think our legal system, both in the U.S. and abroad, is now getting up to speed and finding ways prosecute people that break the law.

FP What is so different about on-dose technologies vs. on-package? Does NanoEncryption replace on-packaging security features?

KB The first thing is that on-packet security

features are an absolutely necessary line of defense against counterfeiters and diverters, and there are multiple legislation initiatives across the world in regards to this. One of the things we know from feedback from law-enforcement agencies and pharmaceutical manufacturers is that if counterfeiters and illegal diverters can see and touch the technology, they can find ways to reverse-engineer it and make duplicate copies that are just as good in some cases, if not better, than the packaging that manufacturers use for their products. So we have multiple examples of where illegal diverters have copied all aspects of the packaging — from the box itself to the patient education material. Counterfeiters are very adept at being able to copy all aspects of the packaging. While packaged security features are an absolute, necessary line of defense, in some instances, they are very susceptible to being copied and reverse-engineered by counterfeiters.

So if you look at on-dose technologies, they are able to help authenticate the medicine all the way down from the manufacturer to the actual patient itself. So no matter what happens to the packaging, if you have an on-dose security feature, you're able to authenticate that medicine regardless of whether the packaging is real, counterfeit or re-packaged.

FP How does NanoGuardian's NanoEncryption work?

KB What I can tell you is that NanoGuardian has perfected a process called NanoEncryption, were we make a slight modification to the surface area of a tablet and we do so without adding any material to it. So with many articles being circulated and published regarding nano-particles or nano-tubes or nano-carbon materials, we actually add no material to any of the products that receive our NanoEncryption.

It might be better phrased in that our technology exists by leaving security features at both the micron and forensic level at the nano-level scale. So we actually are able to do this with a throughput of more than 1 million tablets in an 8-hour shift; we don't add any material to the product whatsoever, and we have three levels of security features in the way that we apply it. First is an overt feature that can be authenticated in the field without any proprietary equipment, and within that overt feature we have a customizable micron-based feature that can be customized from manufacturer to manufacturer and dose to dose, and from an authentication perspective, it can be authenticated with just a handheld loop or a microscope. Again you don't need any special proprietary equipment to authenticate that medicine. Then, from the last level of security features at the forensics scale, that's where our proprietary nano-codes exist at the nano-scale, and you actually need proprietary software and equipment to even see those nano-codes and special software to be able to decrypt all the information that can be associated with each of those nano-codes.

A manufacturer can partner with Nano-Guardian and take their particular line or their particular medicine and we can apply NanoEncryption to it and, for each pill that we apply NanoEncryption to, that pill can contain an unlimited amount of information in our nano-codes — ranging from manufacturing date, location, country of distribution, country where the product was made, and expiration. We could even associate an E-Pedigree link so that you can create a parent-child relationship between the packaging and the product itself.

In fact, one of our clients received FDA approval of the supplemental MDA to add on NanoEncryption to one of their blockbuster drugs. It's a milestone for us, because we've gone through the regulatory process and went through a very rigorous test and came out with flying colors, because we don't add any material to the product itself, which is unlike some of the other on-dosage security options that are out there right now.

FP What is the market monitoring service that NanoGuardian developed to complement its NanoEncryption?

KB NanoGuardian has developed a proactive monitoring program called Closed-Loop Protection, which acts like a Doppler radar to find out what's actually happening in the global supply chain for that manufacturer product that has been NanoEncrypted. The way it works is, after the product is in the global supply chain, NanoGuardian uses a variety of partners to random, sample pharmacies at the point of sale and acquires those prescriptions to send back to NanoGuardian's Product Integrity Center. This occurs while maintaining the chain of custody, and once we have the product we're able to provide all of the information that we decrypt from that pill and send it back to the manufacturer within a 24-hour timeframe.

That model is based upon an anticipated counterfeit rate and confidence level, and once we have those two we are able to say, "For this particular product we need to randomly sample 300 pharmacies over the course of the year." From a manufacturer's perspective, we found that this program is a great extension of the internal security team, because it's almost as if you have 300 investigations going on every month determining where in the supply chain there might be counterfeit or illegally diverted product.

FP Who are NanoGuardian's clients, and when will there be NanoEncrypted products in the global supply chain?

KB Being a brand protection company, one of the things that we keep close to us not only are the specifics of our technology but also who our clients are. What I can share with you is that over the course of the year, NanoGuardian has entered into discussions with over 15 manufacturers who are at different stages of evaluating our technology — from doing test work on pre-filled syringes to actually looking at full-scale implementation for new product launches within the forthcoming year. We anticipate that we should have at least two to three products that will be NanoEncrypted in the marketplace by the end of 2009 beginning of 2010 and we also anticipate that we will have at least one Closed-Loop Protection partner by the beginning of 2010.

For more information on NanoGuardian, our developments, and the different conferences we are attending, visit *www.NanoGuardian.net*. **FP**

KIRK BARNES possesses 15 years of experience and a distinguished track record in the pharmaceutical and biotech industry, with sales and marketing positions of increasing responsibility at AHP, J&J, and Takeda Pharmaceuticals North America. Most recently, Mr. Barnes served as a Region Sales Director at Takeda Pharmaceuticals North America, where he led a sales team of over 100 individuals in achieving sales goals in excess of $300 million. In his role as a Senior Account Executive, Mr. Barnes works with NanoGuardian clients to maximize the brand protection benefits for individual brands, companies and patients provided by NanoGuardian's NanoEncryption technology and Closed-Loop Protection offering.

LOCK IN THE DATA YOU WANT.
LOCK OUT THE PEOPLE YOU DON'T.

Lock out counterfeiters and illegal diverters with NanoGuardian,™ the cutting-edge, on-dose, product security technology. NanoGuardian locks authentication and tracing data into each and every dose, protecting your product from plant to patient. And only you have the key. Go inside at www.NanoGuardian.net.

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