

TRACKING & TRACING

PHARMACEUTICAL PRODUCTS



**Authenticating
Pharmaceuticals**

Spring 2011

A Counterfeit Era

How FDA and suppliers feel about counterfeiting issues and solutions.

By Marie Redding
Freelance Writer

Counterfeit drugs are a growing concern for pharmaceutical companies, suppliers, and consumers—and the multibillion-dollar black and gray markets show no signs of shrinking.

FDA announced it is reconstituting its internal Counterfeit Working Group, in an effort to “coordinate anticounterfeiting efforts across the agency,” stated FDA Commissioner Margaret A. Hamburg, M.D., at the Partnership for Safe Medicines Interchange last October.

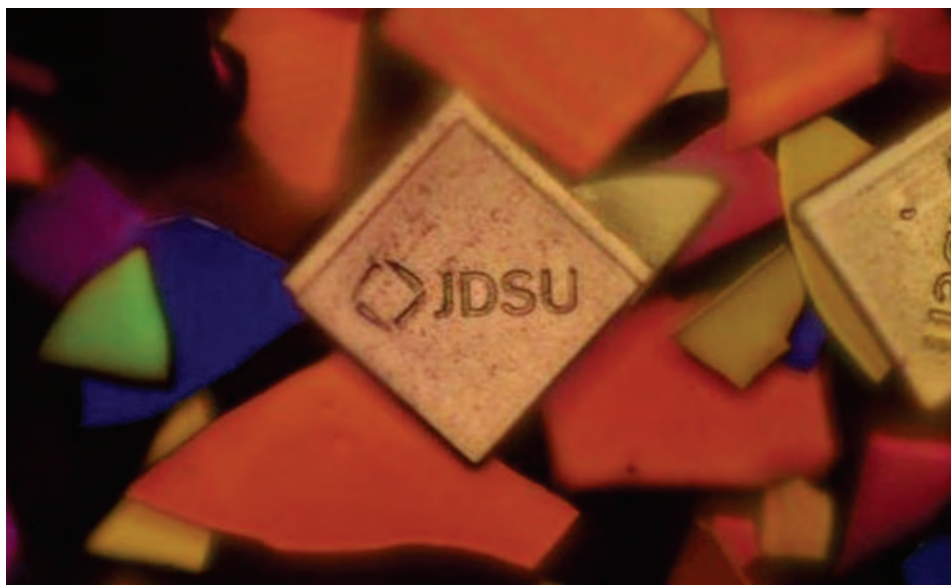
Connie Jung, senior policy advisor for pharmacy affairs, FDA, and commander in U.S. Public Health Service, further clarified by explaining, “This will be a way for the agency to share information across its different centers, so we can coordinate and develop strategies to deal with the potential risks and vulnerabilities for all FDA-regulated products. The Counterfeit Working Group can help to make sure we’re efficiently using our resources and not duplicating our efforts.”

As FDA continues with multiple efforts for combating counterfeits, it will continue to seek input from all industry and supply-chain participants, according to Jung.

How do suppliers of anticounterfeit and authentication technologies for packaging feel about FDA’s increased involvement?

“A comment like that will certainly make the pharmaceutical market continue to address issues regarding the protection of their products, and being able to authenticate them,” says Ernie Chaplin, vice president, marketing, Keller Crescent (www.kellercrescent.com/).

Ted Lithgow, chief science officer, healthcare division, MWV (www.meadwestvaco.com), emphasizes that both industry members and regulatory authorities have been working to address the global problem of counterfeiting for many years.



JDSU Charms, printable microstructured taggants that are invisible to the naked eye.

“As we deeply understand the seriousness of this issue, we have invested in new approaches to reducing a counterfeiter’s ability to be successful, including more secure and complex substrates. We, like many manufacturers, believe this is something to continue working closely with FDA on, to protect the integrity and fidelity of our nation’s medicines, diagnostics, and devices,” he says.

Troy Turley, market development director, Chesapeake Pharmaceutical & Healthcare Packaging (www.chesapeakecorp.com/pharma/) feels that more FDA regulation is needed to protect consumers.

“Counterfeiting is a huge problem for the pharmaceutical market. Access to prescription drugs outside of controlled pipelines is becoming a much larger issue, especially with the ability to obtain prescription drugs online. This is one area where there needs to be more focus to ensure consumer protection,” he explains.

PACKAGE SERIALIZATION

Regarding the issue of Standardized Numerical Identification (SNI) for packaging, FDA’s Guidance published in March 2010 recommends a serialized National Drug Code (sNDC) for most prescription drugs.

It’s not a requirement at this time, but if a company chooses to serialize, the agency has put forth its recommendation.

“FDA is working on developing standards for tracking and tracing of prescription drug packages to further secure the supply chain, and the SNI guidance was an initial step,” explains Jung. “You need to have some sort of unique identification of what you’re tracking, so a serialized number on a package would be an essential component,” she adds.

Adam Scheer, Advanced Optical Technologies division, JDSU (www.jdsu.com), says he agrees with the SNI Guidance. “We feel that using unique identifiers for tracking and tracing will help improve the security of the supply chain,” says Scheer.

Chaplin also agrees, and explains that

some of his customers are already implementing serialized data on their labels. "It will deter counterfeiters when drug companies start serializing each and every unit they sell," he says.

Lon Johnson, Colbert Packaging Corp. (www.colbertpkg.com/) feels that most pharmaceutical companies won't be asking its suppliers to print serial numbers on every pharmaceutical package anytime soon.

"I think there is an overreaction happening right now, which will die down," says Johnson. "Printing every box digitally is not practical. Pharma companies won't leave it up to printers to guarantee their track and trace security—they will handle it a different way, on their end," he adds.

Johnson says it's necessary to weigh the costs against the dangers, when choosing a security option. "There haven't been any cases where a generic drug has been counterfeited," he says.

Johnson compares serialization to the RFID issue. "Three years ago, there were a lot of people saying every package had to have two to three RFID tags, but now it's done on every 8 or 10 packages. People realized it wasn't practical, economically," he explains.

IS CONSUMER INVOLVEMENT A SOLUTION?

While there have been a number of high-profile incidents of product tampering and counterfeiting associated with high-value, low-volume products, many high-impact counterfeiting incidents target low-cost, high-volume branded products, according to Scheer.

"A number of counterfeiters piggyback off the branding efforts of large, multi-national brands, because it helps them market counterfeit products. In these cases, the consumer, unwittingly, as well as the branding of drugs, are drivers in the business of counterfeiting. FDA recommendations can do more to recognize the consumer's role," says Scheer.

Consumers are not realizing when they purchase a counterfeit drug, and need to be educated, Scheer says.

"Consumers are a part of the challenge and need to be a part of the solution. Empower them, and provide them with anti-counterfeiting tools," he says.

Scheer feels FDA can play a role in promoting a consumer awareness program that is designed to educate the public about ways to verify that a drug is real, without having to use any tools.

"Overt authentication tools can help consumers distinguish between real and fake pharmaceuticals with minimal training," he says. "These solutions can be cost-effectively integrated into existing packaging elements."

A number of these tools, such as color-shifting pigments, are used on U.S. currency.

"The U.S. Department of Treasury has an educational program to educate consumers on how to use those tools to see if notes are genuine, and it would be useful for FDA to follow that model," says Scheer.

Turley agrees. "Human-readable security features should be on cartons, and overt security features should be considered an extension of package design," he says.

Overt features are more about branding, and assuring the consumer the product is authentic. "It could be a holographic label that is applied to the packaging, high-end foils, color shifting inks, etc. But it has to be consistent for consumer recognition," Turley explains.

Turley feels that covert features are necessary as well.

"Covert features are just as important for identification, tracking, and authentication, especially when the counterfeiter has taken the pains to incorporate the overt features," he says.

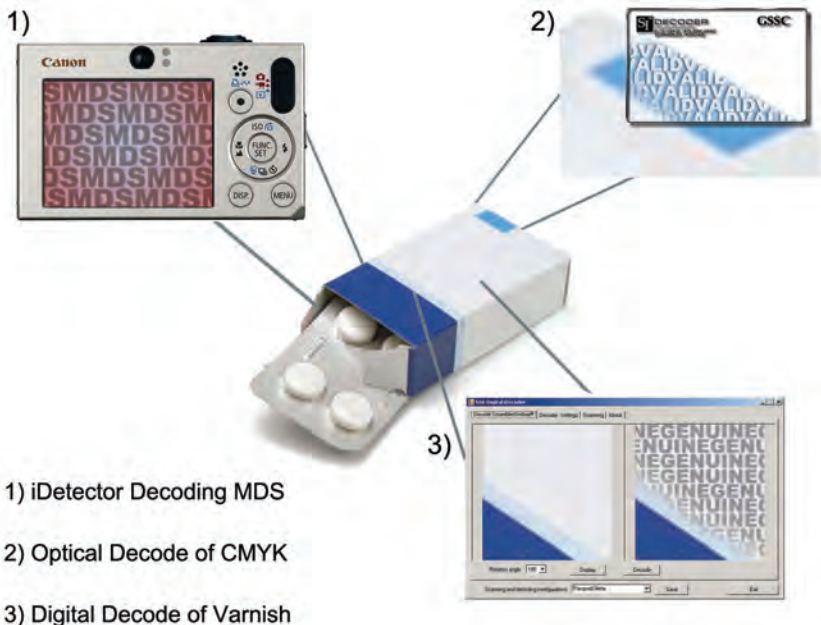
Johnson doesn't see the value of overt features when the goal is providing security.

"If everyone knew exactly what to look for, someone would be able to knock it off. A covert feature is the one critical factor that will keep you a step ahead of the counterfeiters," he says.

Jung says it has to be a balance. "If you let the public know what to look for, you're letting the counterfeiters know as well. We have seen different anti-counterfeiting technologies used on products and packaging—some that can be seen, some cannot," she says.

Scheer feels strongly about educating the public about overt features, however, he agrees they should be used in combination with other technologies.

"We recognize that there is no single technology that will solve the counterfeit



A snapshot of a digital decode using software by Graphic Security Systems. The top picture is the label and the bottom picture is the encoded images being revealed.

Feature

issue alone, which is why we offer a range of solutions. But overt identification is a large part of the solution, and we've been consistently successful with it," he says.

AN INVISIBLE OPTION

Since a counterfeiter's goal is always to maximize their profit, technologies used on packaging that require special or expensive equipment to duplicate or detect usually won't be their first choice of products to knock off.

"A counterfeiter will go after products that can be replicated the easiest, or they'll move onto the next target. Kodak Traceless is not detectable by any means unless you have our proprietary equipment, which we manufacture. It's very tough to try to duplicate what we provide on the package, because it's invisible," explains Steven Stein, technical account manager, Kodak.

"What cannot be seen cannot be counterfeited," adds Keith Cutri, Director of Business Development, Kodak.

Keller Crescent has an agreement with Kodak as a preferred licensed provider of the Traceless technology. When it comes to invisible marking technologies, Chaplin says that during the last 6 months he's seen an increase in interest in Traceless, as it pertains to track and trace.

"We currently have customers who are finding this to be an effective way of keeping their product authenticated in the market," says Chaplin.

The Kodak Traceless products include Traceless Ultra-covert authentication system, and Traceless Anti-diversion invisible track and trace system. Proprietary markers are detectable only by handheld Kodak Traceless readers. The marks can be applied to a wide range of materials, using various printing technologies, including off set, flexo, gravure, letterpress, thermal-transfer ribbon, and continuous ink jet.

"We can put Traceless on anything for pharmaceutical companies, including materials such as blisters, foils, or extruded into plastics and films," says Cutri.

Pharmaceutical products usually contain the marks on labels, or cartons, or ampoules. "Our newest product line, Traceless Anti-diversion, deploys truly invisible serialized codes through the use of continuous ink-jet printing technology. This makes



The Kodak Traceless Product Family, which uses proprietary markers that are detectable only by handheld Kodak Traceless readers. The markers can be used in materials such as inks, toners, coatings, paints, fabrics, fibers, plastics, foils, and glass.



The Kodak Traceless Anywhere System, a marking system capable of invisible authentication even on glass, and can withstand high temperatures during manufacturing processes.

life harder for diverters, who often remove overt anti-diversion codes from packaging, in order to thwart brand protection investigators," says Cutri.

Besides increased security, cost reduction is a major benefit of this technology.

"A label with holographic capabilities, which have been counterfeited in the past, can be costly. We're able to deliver

this at fractions of a penny per mark," says Stein.

POPULAR SECURITY SOLUTIONS

Over the past few years, Thoro Packaging (Corona, CA) has seen an increase in customers asking for printed authentication solutions, such as reflective coatings.

"We run special coatings that have optical

FDA's Recent Workshop

On Feb 15-16, FDA held a public workshop, "Determination of System Attributes for the Tracking and Tracing of Prescription Drugs," which was attended by manufacturers, distributors, pharmacy representatives, government groups, and suppliers of software and technology.

The workshop was intended to provide a forum for discussing potential approaches toward a track-and-trace system. Supply-chain partners discussed potential system attributes and standards that may be needed to facilitate the identification, authentication, and tracking and tracing of prescription drug packages.

"There were good discussions among the participants, and we received a lot of good input at the workshop," says Connie Jung, senior policy advisor, Pharmacy Affairs, FDA, & Commander in U.S. Public Health Service.

A summary of the discussions will be posted to FDA's web

site by the end of March.

"Overall, I think the participants felt happy to have the opportunity to provide their perspective, while also learning from other supply chain partners there," says Jung. "We would be glad to hear other concerns on this issue," she adds.

FDA is welcoming comments, which can be submitted electronically to the docket at www.regulations.gov. The docket number is FDA-2010-N-0633. Written comments can be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number. Written or electronic comments must be submitted to the docket by April 16, 2011.

Visit the Federal Registry notice here: <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM239407.pdf>.

brighteners in them, visible under a black light. We also run some security varnishes that have a tag that can be seen through a special reader," says Mike Jones, print manager, Thoro Packaging.

"A lot of our customers asking for special coatings are larger pharmaceutical companies," he says. "And, they're asking us to incorporate security into the design, and thinking about it much earlier—right from the start," says Jones.

Many suppliers are providing different types of interactive authentication solutions.

"There is a definite push in the market for this," says Turley. "Some companies are using QR codes, text messages, or variable data points. Consumers can verify a product through a link in an app or by sending a text message, and they receive a confirmation that the product is authentic," he explains.

This type of security feature encourages interaction between the brand and the consumer, while also allowing companies to track who is using the product, and where.

"Some brands are using this technology already, but it has not been to the extent we would expect, yet," says Turley. "With the growth in smart phone technology, interactive features will begin to become more prominent," he says.

Chesapeake introduced pro-tex, which offers the ability for consumers to text



The Kodak Traceless Anywhere System, capable of invisible authentication on paper, inks, toners, coatings, paints, fabrics, fibers, plastics, foils, and glass.

a variable human-readable code and receive immediate confirmation of the product's authentication. Incorrect or multi-use codes would alert the consumer of a counterfeit, uncontrolled, or potentially harmful product.

Graphic Security Systems (Lake Worth, FL) offer different types of technology as well.

"Our authentication solutions require very little training and can easily be performed using a credit-card sized optical decoding lens or a mobile smart phone," adds Dawn Sgarlata, marketing director, Graphic Security Systems.

According to Sgarlata, authentication options that are becoming more commonly used include optical decoders (a credit

Feature



Chesapeake's pro-tex, an interactive solution that uses unique identification codes to verify the authenticity of a product.

card sized optical lens), digital decoders (scan decoded images to display on a screen), and iPhone apps. Popular security features include embedding hidden text or images into artwork; or embedding variable hidden text or images into a patch.

When it comes to security features, however, the simplest solutions are often the most effective, even for the largest pharmaceutical companies, according to Lon.

Turley agrees. "In our experience, the majority of pharmaceutical companies want to keep security features simple, and

they're mainly using covert technologies right now," he says.

STAYING A STEP AHEAD

Counterfeiters have become more advanced in their abilities. Holographs, overt track and trace markings, and special inks or pigments have all been replicated in the past—even though these are expensive tools.

Combinations of security products and multilayered solutions are often used, and will offer the best protection, experts say.

"We recommend overt track-and-trace



The JDSU Phantom Authentication Label, a foil seal printed with holographic and color-changing inks.

mechanisms on packaging, along with a dual invisible marking system separate from an overt label or bar code," says Cutri.

Cutri says that a huge challenge in the industry is how far counterfeiters have come in terms of technology. "The way to address this issue is to upgrade technology within marker systems," he says.

Lithgow feels that the ability of counterfeiters often keeps pace with the development of protective technologies, underscoring the need for continued focus on new and better track and trace, and product authentication technologies.

Keeping up with advances in authentication technologies for packaging, and constantly developing new technologies, seems to be the industry's best weapon in the fight against counterfeiting. ■

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