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Legal/Regulatory

2010 Product Security Report

By: Nicholas Basta Date: 2010-10-31

More pieces for industry-wide track-and-trace are falling into place, but there's no rush to authenticate products

To amend the well-known saying about national defense, "Eternal vigilance is the price of pharmaceutical brand integrity." But while there are various efforts to tighten supply chain security in pharma distribution, especially in selected countries outside the US, the industry is still mostly sitting in anticipation of rigorous track-and-trace systems scheduled to arrive later this decade. In the meantime, manufacturers are installing serialization systems (a necessary first step to track-and-trace) selectively in production lines or for individual national markets. And a variety of cross-industry efforts are progressing to tighten the more obvious security breaches, such as Internet pharmacies. Finally, to ensure the security of individual brands as best they can, manufacturers and packagers are looking at a growing variety of covert and overt security devices or systems on containers, and making use of field-ready analytical instruments that give on-the-spot indications of counterfeit drugs.

Security and anti-counterfeiting vendors, though, have been expecting a flood of new business but have to content themselves with the trickle that's occurring now. "Manufacturers continue to question the payback of authentication," says one security-packaging vendor. "If no particular technology has ironclad protection, then they feel there's no justification."

On the other hand, the fact that there are multiple business values in better tracking of products as they move through the supply chain—a trait that goes back to the initial e-pedigree and authentication efforts in the mid-2000s—offers hope that the overall trend toward better protection is real. "I've had conversations with manufacturers who know that they are wasting tens of millions of dollars annually in bad returns; I've had other conversations where the value in tracking inventory better is understood," says another vendor, adding that "China—of all places—is moving faster on anticounterfeiting than the US. Isn't that a shame?"

Mention of China brings up the most grating point of industry inaction—the belief that counterfeiting is mostly a threat outside the US—which is true, but which requires a suspension of belief that the problems occurring abroad can't happen here. The industry keeps getting prodded by single incidents—stolen product showing up in a hospital pharmacy; pharmacists getting arrested for selling bogus product; contaminated APIs appearing in products entering regular distribution—but has yet to confront the issue in a broad, coordinated fashion.

In Washington, however, there is movement, and the question is how fast or how extensively the regulatory pressure will come into force. At an inaugural meeting of the Partnership for Safe Medicines (Washington, Oct. 8), FDA Commissioner Margaret Hamburg said that "We are organizing our efforts in fighting counterfeits, cargo theft, diversion and economically motivated adulteration into a new Drug Integrity and Security Program based in the Office of Compliance in CDER." She has also reconstituted an internal Anticounterfeiting Task Force (a group that had produced industry-organizing reports in 2004 and 2005), and reminded the audience that the agency had issued its guidance for serial numeric identifiers (SNIs) in March—"the first step for track-and-trace" to be adopted nationally.

Meanwhile, federal anticounterfeiting efforts should get a boost from the White House Intellectual Property Enforcement Coordinator (IPEC), which was brought into existence in the Bush Administration, and issued a strategic plan this summer (Pharmaceutical Commerce, July/August, p. 11). That plan calls for "mandated" track-and-trace in the pharma industry, and for coordinated efforts among law enforcement, the Commerce Dept. and other federal agencies against counterfeit pharmaceuticals.

In Congress, yet another bill, the Drug Safety and Accountability Act, was introduced by Michael Bennet (D, CO) in the summer—the latest in a list that goes back several years, but for which there has been little forward movement. The Bennet bill is focused mostly on tightening oversight of APIs, but includes FDA authorization for mandatory recalls (as opposed to the current, mostly voluntary system).

Mention of Congressional efforts reopens all the problems and complaints that were heard in 2007-2008 that California's far-reaching e-pedigree legislation was subjected to, leading to its postponement to 2015. The basic objection was that a full-fledged track-and-trace system was too expensive, had uncertain effectiveness, and was unnecessary given the relatively low level of counterfeiting or diversion going on then. Those arguments are likely to resurface as 2015 approaches.



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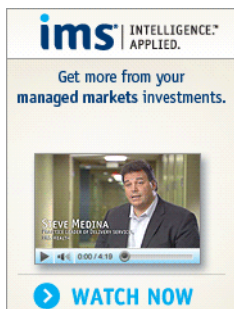
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Summarizing the mood of many anticounterfeiting and serialization vendors, Narendra Srivatsa, business development manager at Cortegra (Fairfield, NJ) says, "We continue to offer a strong portfolio of anticounterfeiting technologies, but it seems that the interest is higher outside the US than inside it for protecting brands. Industry should be asking itself, 'Do you want to know what's happening in your supply chain or not?'"

More technology offerings

While the pharma industry might be slow-footing its way to supply chain security, vendors continue to develop and offer new technologies and approaches to anticounterfeiting. Many of these technologies are in common use in document security (including currency), for consumer-goods authentication, or for various types of supply-chain tracking systems. Some are now showing up with complementary applications in marketing or customer (i.e., patient) relations.

NanoGuardian (Skokie, IL), which has been developing its NanoEncryption technology for several years, announced key collaborations in the past 12 months: one with Pfizer's Capsugel subsidiary (which provides encapsulation products and services for oral pharma products), and another with Altegrity International (Chicago), a corporate security-services firm. NanoGuardian's technology is based on nano-scale surface modification (of, for example, a pill) that can be encoded both with authentication markings and with barcodes or other data. NanoGuardian emphasizes that no physical material is added to the marking. Altegrity will help NanoGuardian build out a "Closed Loop Protection Program" that provides field verification services for clients.



Schreiner MediPharm (Blauvelt, NY), primarily a manufacturer of labels and packaging accessories, has compiled a variety of security inks, holograms and tamper-evident seals. This year, its US operation began assisting a sister division in Germany, ProSecure, in promoting its BitSecure technology in North America. That system depends on a "dissected noise pattern" image that can be printed but not easily copied into labels or package surfaces. KeySecure, a 15-digit code, can be applied to labels and then verified through a Web connection. And last month, the company introduced FluxSecure, an authentication/identification feature based on a magnetically encoded thread placed between a label and the underlying surface. The thread can be "read" from a distance by a handheld scanner.

Applied DNA Sciences (Stony Brook, NY) has partnered with two other vendors that provide services to pharma: H.W. Sands Security (Jupiter, FL) and Bilcare Technologies (Pune, India: US HQ in Phoenixville, PA). Applied DNA has a botanical-DNA-based forensic markers to authentication markets including pharmaceuticals. The marker, said to provide unique authentication of a product, can be incorporated into inks, dyes and varnishes that H.W. Sands sells for security applications; combined with magneto-optical markers for real-time field verification via hand-held scanners; or incorporated into pharma products themselves (Applied DNA Sciences says that the botanical DNA has GRAS [generally recognized as safe] status with FDA. With Bilcare Technologies, Applied DNA Sciences is incorporating its marker technology into the latter's NonClonableID solution, which combines a marker with a handheld scanner whose output can be verified via a cellular phone connection.

Last spring, Authentix (Bethlehem, PA) joined with nine organizations in Hull, UK, to pilot combined serialization and authentication on a high-speed packaging line of Reckitt-Benckhiser a technology it calls SecureTrace. According to the consortium, it's not sufficient to authenticate product via a 2D barcode; some type of forensic marker should be added to solidify the authenticity.

AlpVision (Vevey, Switzerland) has opened a US office in Chicago to help establish its Cryptoglyph technology and Krypos IT platform in US markets. Cryptoglyph is a method to apply essentially invisible markings on a package surface (but which can be read by a simple optical scan—including an office scanner); Krypos is the complementary, Web-based communication portal to upload images for authentication.

Sproxil (sproxil.com) has developed the Mobile Authentication System (MPA) expressly for infrastructure-poor nations such as Nigeria. Consumers scratch off the film covering of a numeric code on a package, text the code into a central number, and then receive simple yes/no authentication. The technology is not unimpregnable, but offers significant security in Nigeria, where counterfeits can be as much as 50% of certain drugs in circulation. The codes have been applied to 1.4 million packages there, and there is talk of expanding the system to Kenya and India.

PharmaSecure (Lebanon, NH and New Delhi, India) has commercialized a cellphone-texting system in India for authenticating pharma packages: the consumer texts a code number and receives a simple yes/no authentication in return. PharmaSecure says the system is targeted at developing countries for now, but expects to a next level of the technology to allow two-way communication between manufacturers and consumers.

TruTag Technologies (Honolulu, HI) is adapting photolithography technology used in microelectronics to produce a microscopic tag containing a spectral signal that can be read with a handheld spectral photometer. The company hopes to begin commercial-scale production of the tags in the near future.

Security plus patient connectivity

One way or another, once there is a pathway that can link the manufacturer to a customer in order to verify authenticity, the possibility of using that pathway for other communication purposes becomes possible. Thus, the growing versions of verifying codes or images via a cellphone connection also become a way to convey a marketing message, brand loyalty or enhanced medication adherence.

That's some of the thinking behind the "Media-Enhanced Packaging" (MEP) introduced last spring by Catalent Pharma Solutions (Somerset, NJ). In past years, the company's contract packaging division was one of the leaders in testing anticounterfeiting techniques and applying radio-frequency identification (RFID) to pharmaceutical cartons. Now it is pioneering a technique that could change the relationship between packaging, branding and consumer interaction.

MEP makes use of a digital watermark (licensed from Digimarc Corp.) that is added to a printed image. Viewers with an application-enabled smartphone (including Apple iPhones, or mobile phones using the Android technology of Google) capture the package image, transmit it to a central source, and then receive communications from the brand owner, such as product authentication, or a coupon or updated medication guide. Depending on how it is set up, the communication could become a direct link between the manufacturer and patient.

"We've been demonstrating this technology at many forums and before numerous manufacturers, but we've been finding that brand security managers are the least interested in adopting it, while marketing or brand managers have significant interest," says Eric Caro, product manager at Catalent. While conceding that at this point, only a little over 10% of the US population has a smartphone, he notes the intense interest in brand managers to participate in the smartphone trend. "This could be a big benefit to compliance with treatment regimens, with patients getting reminders over their cell phone, or clinical trials being run through a network."

A similar logic is at play at Covectra, where the company's Authentitrak technology can be deployed to manage serialization of products. At the receiving end, a patient or customer could text the serial number to a central location and receive verification. With the link established (via a cellphone text message, an online portal, or a smartphone app), information can begin to flow from the manufacturer to the patient, a solution Covectra calls its Brand Loyalty Information Service (BLIS).

"Besides obvious communications like coupons or patient education, this technology could also be used for managing the dispensing of controlled substances," says Steve Wood, Covectra president. "A patient could be asked to report on his inventory of a prescription, which allows for some control over when a refill is permissible." This kind of capability ties in with the industry's growing responsibility for executing Risk Evaluation and Management Strategies (REMS), which are post-marketing compliance programs that many new products now require (Pharmaceutical Commerce, May/June, p. 18).

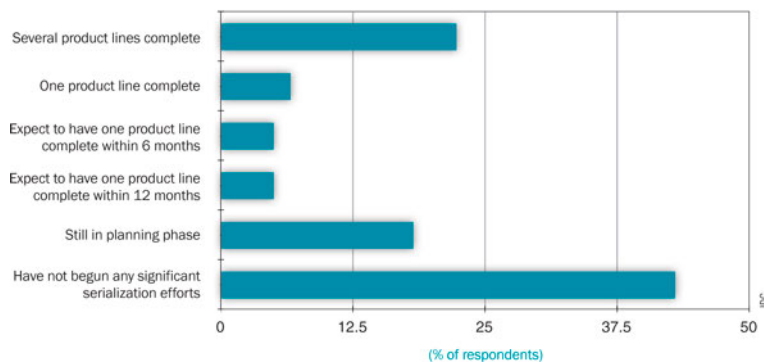
Serialize—and see what happens

Arguably, the most significant development in the past year in pharma security doesn't involve security at all: the major GPOs adopting terminology defined by the GS1 organization, and compelling manufacturers of hospital supplies (including pharmaceuticals) to use them. Most of the leading GPOs, including Amerinet, Novation, Premier and the Health Industry Group Purchasing Assn., are requiring both their member hospitals, and hospital suppliers, with the Global Location Number (GLN) defined by GS1 by December. A year later, all products supplied through these supply chains will need a GS1 GTIN (Global Trade Identification Number). For now, manufacturers simply have to include GLN documentation in their purchase orders and EDI transactions; later, the individual items will have GTINs.

The significance of this is that the GS1 standards, and structure for executing transactions and physical movements, will be established for one part of the overall healthcare system (hospitals) and from there could gradually grow out to retail pharmacy and other parts of the supply chain. If GS1 did its work right, GLN and GTIN will mesh smoothly with its more pharma-supply-chain specific parts: the Global Data Synchronization Network (GDSN) and the Electronic Product Code Information Service (EPCIS)—as well as the SNI that FDA promulgated last spring.

GS1 is actively promoting its "2015 Readiness Program" which allows supply chain participants to model their internal processes and test their IT capabilities; the organization will be holding a workshop in conjunction with the upcoming HDMA Track-and-Trace Technology Seminar.

Item-Level Product Serialization Implementation Status



According to a report from IDC Health Insights (Framingham, MA), serialization projects are moving forward, at least among some Big Pharma companies. A survey completed this summer (Table) shows that 28% of companies have at least one product line serialized; another 10% expect to reach that within the next year. "Forward-looking companies are pushing ahead with efforts to serialize because beyond enabling track and trace, there are many other benefits to be gained, both operationally and strategically" says Eric Newmark, an analyst at IDC. "This includes areas like channel optimization, inventory reduction, increased perfect order performance, better forecasting and production planning, streamlined recalls, improved analytics, and reduced revenue leakage from errors surrounding returns, chargebacks, rebates, and concealed shortages. And of course, brand equity protection from counterfeit elimination."

IT and systems integrators are pouring resources into this anticipated business. Oracle announced a "Pedigree and Serialization Manager" solution in August (Pharmaceutical Commerce, July/Aug, p. 9). Acsis has revamped its product line, branded as VisiTrak, to include ProductTrack for Life Sciences to support serialization systems. "It's all about visibility in the supply chain," says John DiPalo, CTO. He sees a critical gap to be filled between brand owners and their contract packaging organizations, and then rolling that information up with warehouse inventories and reporting the whole to enterprise

systems like SAP. Acsis is partnering with Nosco, the pharma label converter, on a packaged serialization solution.

Other vendors with offerings in this area include Systech International, which is working with package-marking vendor VideoJet on a partnered offering to meet Brazil's coming serialization rules; Axway, IBM and SAP itself. PC

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