



Pharmaceutical Product Security

Technology Advances Anticounterfeiting Options

Hallie Forcinio

As pharmaceutical counterfeiting gains a foothold in the United States, technology steps in on the side of manufacturers.

Worldwide, the practice of counterfeiting brand-name products is a multibillion-dollar problem. In the United States, this problem costs consumers \$200 billion annually, according to figures from the International Anti-Counterfeiting Coalition (IACC, Washington, DC).

In some countries, more than one-half of the branded products in the marketplace are imitations. By stealing sales from legitimate manufacturers, counterfeiting reduces product sales, depresses prices, and damages the reputation of a product and its maker. Additionally, counterfeit products can pose a hazard to consumers as well as create or increase product liability issues for the manufacturer.

The World Health Organization (Geneva, Switzerland) estimates that counterfeit products constitute 10% of worldwide pharmaceutical sales.

Percentages are much higher in areas where specific medications such as antimalarials are in demand.

The prevalence of fraudulent drug products has been less of an issue in the United States than in other countries, but the American marketplace hardly is immune. "Counterfeiters have become highly organized and very sophisticated," says Jay Parker, PhD, director of technology at Westvaco Brand Security, Inc. (Stamford, CT). Worldwide, counterfeiters benefit from factors such as computer technology that makes product replication easier than ever and the difficulties law enforcement has obtaining evidence that disappears as the product is consumed.

Counterfeit drugs are a bigger problem than commonly known, in part because "no pharmaceutical company wants to admit it has a problem," says Ralph Dillon, director of quality engineering, GS API BioPharma QA at Pharmacia (Kalamazoo, MI). In reality, the consequences of pharmaceutical counterfeiting are real and diverse. Consumers might fail to improve or control a health condition, resulting in a more serious illness or even death. Legitimate drug manufacturers could

lose both the trust of consumers and brand reputation could be irreparably damaged. Furthermore, in our litigious society, consumers harmed by a counterfeit drug have been known to file suit against the maker of the authentic product on the grounds the manufacturer should have been more vigilant in its protection efforts. Finally, counterfeiting operations often exist to fund organized crime and terrorist activities.

Ensuring authenticity

Counterfeiters gravitate toward potential profit opportunities and tend to duplicate high-demand, relatively expensive, yet more easily replicated products. If a product is too well protected, however, the counterfeiter moves on to something else.

To fend off the efforts of fraudulent manufacturers, anticounterfeiting experts recommend a multilayer solution. "Multiple features make it harder to copy," says Gregg Metcalf, national accounts representative, security products, for Kurz Transfer Products, L.P. (Charlotte, NC), a supplier of optically variable devices (OVDs) for product authentication. Some of the same authentication methods also can help prevent diversion and provide tamper evidence.

Security solutions don't have to be expensive; simple techniques can add a layer of protection. "Industry is missing some obvious things that are almost free," says Dillon. "A lot of packs have cut codes. [Using] a unique font [to produce a cut code] is a simple way to provide some protection," he says. Other options include special inks, blind

Definitions

Counterfeiting refers to the theft of a product or brand by reproducing and substituting a similar product.

Diversion occurs when a product does not reach its rightful destination but is sold elsewhere. Often this practice is a pricing scheme involving shipping a product from one country to another, repackaging the product, and then reshipping it to the country of origin.

Tampering involves changing packaging or goods in place of the original item.

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tubes with a piercing closure, or blow-fill-seal containers that cannot be refilled.

Techniques for preventing counterfeiting and diversion can be overt or covert (see "Security measures" sidebar). Overt devices are visible and include holograms, microtext, and line-screen printing. Because overt devices generally are authenticated by the end user, consumers must be trained to identify them. This informa-

tion may be noted on the package itself, included in point-of-sale information, or discussed on the brand owner's Web site. Covert devices are invisible to the naked eye and include ultraviolet or infrared light-visible elements, microscopic nanotext, hidden images, and intentional errors. Many overt devices also can include covert features.

Security measures

Overt Security Measures

Hologram
Microtext
Line-Screen Printing

Covert Security Measures

Ultraviolet- or Infrared-Sensitive Elements
Nanotext
Hidden Images

Covert features are not readily visible and thus are less likely to be successfully duplicated by a counterfeiter. Such features also are appealing to marketing managers because of their minimal effect on a package's graphic design.

The obvious goal is to incorporate security devices that are easily verified by the appropriate party such as the shipper, retailer, regulatory official, or consumer while also challenging illegal duplication efforts. However, to reach that goal, drug manufacturers first must determine whether they are trying to prevent diversion, counterfeiting, tampering, or a combination (see "Definitions" sidebar). Some security tools are effective against more than one problem, and others address a single challenge. Combatting diversion, for example, generally requires variable printing features such as sequential bar codes.

Parker recommends the following four-step process for choosing a security tool:

- recognize the value of the brand
- understand that counterfeiters are competitors, albeit nontraditional and generally unknown
- develop a strategy for brand protection
- implement the strategy.

This process should begin as early as possible during the product development phase or during preparation for a relaunch.

Protection options

Several firms provide anticounterfeiting solutions, and in recent years some major companies have established separate business units to focus solely on brand security. Kurz Transfer Products, L.P., part of Germany's Kurz Group, has been making hot-stamping foil for 110 years. For the past 25 years, the company also has been active in Europe providing high-security protection for applications such as passports and currency, including the Euro. More recently, Kurz has commercialized anticounterfeiting solutions for pharmaceuticals, liquor, and entertainment media based on OVDs. Its latest offering, TrustSeal, is a



Magnified view of demetallicized, first-opening guarantee label.

proprietary, patented technology that is based on diffractive optics and is available as a hot-stamp foil, first-opening guarantee label, or cap seal in metallized, partially metallized, or transparent materials.

Options from Kurz also include two-dimensional (2D), three-dimensional (3D), combination 2D–3D, and dot-matrix holograms; hot-stamping foil with a continuous or registered-image design; embossed label stock; serial numbering; partial demetallization; nanotext with type heights ranging from 25 to 75 μm ; hidden images; and machine verification–readability. A sample carton shown at Interphex 2002 included a TrustSeal on the primary panel, microprinted borders at the top and bottom, a message revealed by rubbing with a coin, and an UV light–visible area.

Protective devices can be incorporated into primary labels, tamper-evident seals, blister cards, foils, and lidstock. A new type of syringe label self-destructs if removed, thereby disrupting graphics and leaving a sticky residue. All materials are produced in-house to maintain control of them. Kurz also supplies hot-stamping equipment.

A long-time supplier of holograms, American Bank Note Holographics, Inc. (Elmsford, NY), offers a range of security products, including HoloCap holographic induction seals and tamper-evident HoloSeal holographic labels, which may be specified with micro-demetalization to create a diffractive OVD image. The newest member of the protective packaging family is HoloSleeve, a holographic shrink band/label that can be produced in various sizes. Covert features such as machine-readable, latent images; tiny micro text or logos; or tinier nano text or logos can be

incorporated into the sleeve. Various holographic images also are available.

During 2001, Westvaco (now Mead-Westvaco, Stamford, CT) set up Westvaco Brand Security (WBS) to provide security solutions for brand managers. WBS's offerings include incorporating UV-sensitive fibers into paperboard folding cartons and corrugated shipping cases; patterned lines that cannot be scanned for accurate color reproduction; microtext; intentional errors; microtaggants, which fingerprint ink or other material; and holograms. A variety of techniques rely on special inks such as UV-sensitive, pen-reactive, and thermochromic, which change color at a predetermined temperature.

Another new business group devoted to brand security is DuPont Authentication Systems (Bridgeport, CT). Its total-response authentication program offers various security tools for use with labels, transparent and opaque laminates, seals, cards, and tags. The centerpiece of the program is the DuPont photopolymer hologram. The result of a 10-year development effort, the hologram relies on DuPont's patented photopolymer film and laser light to create multilevel, high-resolution images. A vertically integrated supply chain made possible by last year's acquisition of Label Systems Inc. ensures DuPont's control of the materials. Available in clear and dark backgrounds, the photopolymer holograms also may incorporate elements visible under UV, IR, or laser light. Currently, the photopolymer holograms are being used by at least two pharmaceutical customers in Asia, where conventional holograms have been known to be duplicated by counterfeiters within a month of product launch.

Blister packaging security concerns are being addressed by Hueck Folien, the Ger-



KURZ TRANSFER PRODUCTS

Magnified view of nanotext, an embedded brand- and product-verification security technology.

man parent company of Hueck Foils LLC (Wall, NJ). Introduced in 2001, Hueck Folien's Protecco security foil lidstock incorporates as many as six different security elements: conventional and 3D-animated OVD holograms, mathematically derived guilloche patterns, UV-visible features, rainbow gradations, and microprinting.

Working with covert technologies, Nordson Deutschland GmbH (Erkrath, Germany) has developed Secutag color-coded particles and dispensing equipment to apply the particles as a UV-cured lacquer or dot to the product's surface. When exposed to an IR light, a product-specific color code is revealed. Because the microscopic color particles are incorporated into the surface of the product, the "fingerprint" cannot be copied. The color parti-

cles can be incorporated into various solid, pasty, or powdery materials or applied to the product by various printing processes, brush, sprayer or coating machine, or by hot-melt transfer.

A range of holographic effects is available from HoloWebs, LLC (San Diego, CA). Possibilities include 2D, 3D, and combination 2D-3D. The company also offers colorgrams that are created from a photographic image as well as 2D-3D multichannels that provide animation. Yet another style, Holomatrix, relies on microdots embossed with a laser beam to create the image. Variations include Holomatrix 2D-3D, which generates a more complex pattern. The company also offers various stock background patterns.

To address supply-chain security, Savi Technology, Inc. (Sunnyvale, CA) combines its Savi SmartChain software platform, Savi SmartSeal electronic seal for shipping containers and air cargo unit-loading devices (ULDs), and recently acquired CanTRACK software. The combined systems enable air freight carriers, shippers, supply-chain asset

Product security standards

- High technological entrance barriers
- Exclusive features — efficient and reliable to verify
- Modular structure with overt or covert security features
- Nonseparable combination of product and security element

Reference: "Protecco — Hard Times for Product Pirates," presentation by Angela Roggenhofer at Interphex 2002, New York, NY.

providers, and third-party logistics companies to automatically manage, monitor, and ensure the security of cargo containers and contents. This improved tracking and tracing capability should not only reduce losses, but also improve on-time ULD delivery beyond the current 10% level.

Being prepared

"We can make a difference by working on

[counterfeiting deterrence]," says Dillon. "Precautions in place put us in a lot better position to protect the food and drug supply," he adds (see "Product security standards" sidebar).

To help industry in its efforts to improve product security, Reconnaissance International (Greenwood Village, CO) has published the 200-page book, *Protecting Medicines & Pharmaceuticals: A Manual of Anticounterfeiting Solutions*. Edited by Magali LeParc and containing chapters by numerous industry experts, the book describes the counterfeit problem and its consequences, risk assessment, possible solutions, future technologies, and protection strategies. The text also includes a glossary and lists of information sources, suppliers, solution providers, and international organizations.

Another source of current information about counterfeiting and deterrence methods is the Global Forum on Pharmaceutical Anticounterfeiting, scheduled to be held 22–25 September 2002 in Geneva, Switzerland, in association with the World Health Organization and Reconnaissance International. Conference topics include understanding the problem, detection and enforcement, protecting and enforcing supply chain and distribution integrity, monitoring and policing Internet pharmacies, technologies for identification and authentication, and designing and implementing corporate anticounterfeiting strategies.

Conferences also are held by the IACC, usually in the fall and spring. The next scheduled conference is 16–18 October 2002 at the Loews Hotel South Beach (Miami, FL).

As noted by Dillon, "Right now there's a lot of trust between the pharmaceutical industry and the consumer." However, that trust could evaporate if measures aren't taken within the pharmaceutical industry to block counterfeit products. If Levi Strauss and Co. (San Francisco, CA) can incorporate more than a dozen security features into its blue jeans, comparable security technology should be effectively applied to consumable products such as drugs and nutraceuticals. **PT**