

**Product/Service Review** Reprint # 46-02

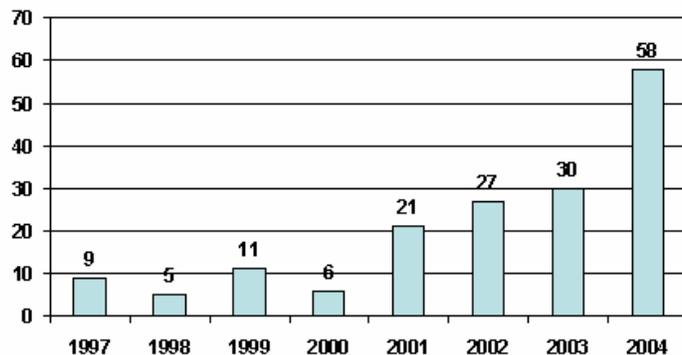
## Protecting Your Brand with Anti-Counterfeiting Solutions

By John Mack

In 2004, the office of Criminal Investigations at the Food and Drug Administration (FDA) initiated 58 counterfeit drug investigations involving hundreds of thousands of fake dosage units. These cases

lines, but they must also protect themselves from being held liable for those bogus products, according to Christopher Michie, an attorney with the law firm Dechert and an expert on the counterfeit drug trade.

Counterfeit Drug Cases Opened by FDA per Year



represent a dramatic increase from the previous year when 30 such cases were initiated (see FIGURE above). FDA estimates that counterfeit drugs account for more than 10% of the global medicines market in both industrialized and developing countries.

### Risk to Consumers and Manufacturers

It is estimated that up to 25% of the medicines consumed in poor countries are counterfeit or substandard. In the U.S. and other industrialized countries, death and serious illness have already been caused by counterfeit drugs and counterfeit pharmaceuticals contribute to higher insurance premiums.

Counterfeit drugs hurt pharmaceutical companies' bottom lines as well. An estimated \$30 billion worth of drugs are counterfeited each year and that number is expected to increase. Pharmaceutical firms, however, not only have to worry about counterfeiters taking a chunk out of their bottom

"Believe it or not, pharmaceutical and medical device manufacturers have been sued, and some judges have said, under some circumstances, they can be held liable for injuries caused by products they did not even manufacture," Michie said during an FDAnews audioconference on combating counter-feit drugs.

The liability suits are based on the alleged failure of firms to act aggressively toward the counterfeit products, Michie said. If a drugmaker has a brand, for example, and is aware that another party is misusing that brand, then the courts might be willing to impose liability on the company in certain circumstances, he said.

"A drug brand is a valuable asset that deserves protection from counterfeiting," says Renard Jackson, Executive VP Sales & Mktg. for Cardinal Health's Packaging Services business. Counterfeiting can lead to loss of brand integrity, which can hurt a manufacturer for many years and affect the image and performance of other products, said Jackson.

### Effective Anti-Counterfeiting Measures for Brand Security

There is clearly a need for effective anti-counterfeiting measures. The FDA suggests that the industry use a combination of rapidly improving track and trace technologies and product authentication technologies.

FDA identifies two types of technologies used to combat drug counterfeiting: authentication technologies and trace and track technologies.

Authentication technologies include measures such as color shifting inks, holograms, fingerprints, taggants, or chemical markers embedded in a drug

or its label. The use of one or more of these measures on drugs, starting with those considered most likely to be counterfeited, is an important part of an effective anti-counterfeiting strategy, says the FDA (see 2004 report).

## Overt, Covert, and Forensic Anti-counterfeiting Features

Several of the authentication technologies discussed in this article employ overt or covert devices.

Overt devices are visible to the eye. To ensure effectiveness, end users should be made aware of overt measures on packaging and displays or through other means.

Overt devices include:

**Optical variable devices (OVD)**—holograms make pharmaceutical packaging significantly more difficult to counterfeit

**Optical variable inks (OVI)**—provide an easy means of authentication

**Security papers**—involve the use of invisible fibers embedded into paper stock. Stocks can also employ chemical reactivity as an added anti-counterfeiting measure

**Microtext**—an effective, economical security measure

**Tamper-proof/tamper-evident techniques**—immediately alert users to products that may have been altered or contaminated

**Bar coding**—can be used as a complementary technology to identify counterfeit drugs before they're administered

Covert devices are invisible to the naked eye and are often more difficult for counterfeiters to duplicate successfully. They also have little or no effect on the design of a package.

Covert devices include:

**Ultraviolet/infrared light**—visible elements—can only be detected with special equipment

**Microscopic nanotext and hidden images**—are complex printing techniques that clearly call attention to counterfeit products. They are very difficult to replicate

**Radio-frequency identification (RFID) technology**—or electronic “track and trace” technology, provides close control of product authenticity, inventory and movement and allows rapid and effective recalls

Track & Trace technologies include bar codes and Radio-frequency Identification (RFID). These technologies are employed by other industries—e.g., consumer goods industry—to manage their supply lines, but they are just beginning to be used in the pharmaceutical industry.

### Start Close to the Product

Cardinal Health's portfolio of brand security technologies, implemented at every point along the supply chain after discovery, is a good example of what the FDA is talking about with regard to anti-counterfeiting technologies.

“Combating counterfeiting should start as close to the product as possible,” says Jackson. Delivery systems such as soft gelatin capsules and fast dissolving tablets, which are produced by manufacturing processes that are difficult to counterfeit, are examples that Jackson cites. Cardinal Health's Zydis® fast-dissolve technology is an example of the latter. Zydis is a unique, freeze-dried oral solid dosage form that can be swallowed without water, because it dissolves instantly on the tongue in less than 3 seconds.

Applying unique markings on tablets using a dry powder spray technology is another effective “close to the product” anti-counterfeit measure.

Phoqus Pharmaceuticals' UniQ™ technology make it possible to brand and manufacture solid dosage formulations with different patterns, images and color in a manner that cannot be replicated with conventional tablet-coating techniques. This offers unique opportunities for brand enhancement, brand protection and product safety (see FIGURE on next page).

### Anti-Counterfeit Packaging, Inks, and Holograms

The next closest technology to the product is the packaging, which is the paper or board used for the package inserts, cartons, and labels on bottles. Cardinal Health offers anti-counterfeiting packaging that uses security papers, security ink, and/or holograms.

Security papers have invisible fibers embedded into the paper stock. Stocks can also employ chemical reactivity as an added anti-counterfeiting measure. Papers that react to bleach or acetone, for example, can be easily detected by surveillance personnel in the field. Special papers containing trace elements detectable only by forensic analysis may also be used.

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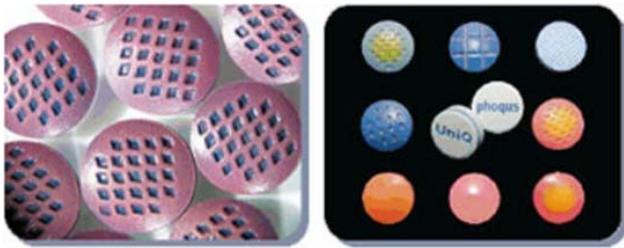


FIGURE: “On-product” branding protects every tablet against counterfeiting, and the UniQ technology can be combined with other overt or covert anti-counterfeiting solutions.

Spies, terrorists, and magicians are known to use special reactive inks to hide their messages from their enemies or to perform tricks for audiences. Ink technology, however, can also be employed to combat drug counterfeiting. Thermochromic ink, for example, changes color with temperature. By rubbing a certain area on the packaging, an image or words can be made to appear or disappear. Markers can also be added to ink so that it glows under UV or infrared light. Obviously, this technology has come a long way since when I was a kid and wrote secret messages using milk or lemon juice!

### Choose the Right Strategy

Exactly which anti-counterfeiting measure or combination of measures is appropriate for a specific product depends on the product, how likely it is to be counterfeited, regulatory considerations, and other factors.

Cardinal Health’s anti-counterfeiting team recommends the appropriate strategy based on specific needs. In some cases multiple techniques can be applied, making cartons, labels, inserts and outserts more difficult to duplicate. New technologies and methods are constantly being explored and evaluated, including proprietary Cardinal Health tactics.

Counterfeiting problems are not likely to disappear. Without investing time and energy toward effective measures to combat this critical issue, products and brands are exposed to potentially disastrous short- and long-term danger.

**Pharma Marketing News**

## RFID: Project Jumpstart

Radio-frequency identification (RFID) tracking of drugs has been all but mandated by the federal government. Last year, for instance, the FDA recommended RFID implementation in the pharmaceutical industry by 2007. And about 15 states have passed or are working on laws that require “pedigree” documentation in each step of a pharmaceutical supply chain. The industry’s consensus seems to be that RFID is the best technology for the job.

In 2004, a group of pharmaceutical manufacturers shipped bottles of prescription medications with RFID tags as part of a test nicknamed “Project Jumpstart.”

The goal was to track bottles of prescription medications from the packaging line to distribution centers to distributors, to retailers’ distribution centers, and finally to retail pharmacies.

Participating drug makers include Abbott Laboratories, Johnson & Johnson, Pfizer, and Procter & Gamble, and participating distributors include Cardinal Health and McKesson Corp. Accenture is an advisor and the U.S. Food & Drug Administration was also involved.

“RFID technology hasn’t reached the level of quality to allow us to do away completely with bar codes,” said Jackson. “Bar coding will still be used as backup.”

In the second planned Jumpstart pilot, “sequential bar coding” will be employed. Whereas standard bar codes can carry enough information to identify something as a “bottle of aspirin,” sequential bar codes can identify each bottle uniquely (e.g., “bottle of aspirin #1234”)

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