

Counterfeit Injectables!

High-Value Products Draw Nefarious Interest

by Jim Rittenburg

One day five years ago, San Francisco AIDS patient Rick Roberts noticed a burning sensation while injecting Serostim, a human growth hormone that helps prevent AIDS wasting syndrome. Roberts purchased Serostim regularly from a nearby location of a national pharmacy chain. By checking with his pharmacist, he learned that counterfeit Serostim had been showing up in pharmacies in several states. Further investigation revealed that although the Serostim packaging looked real, the medicine in the vial was not. Roberts had unwittingly been injecting himself daily with the female pregnancy hormone HCG (human chronic gonadotropin), which is meant to be taken once a week. The Serostim pedigree (a record of where the drug was manufactured and its supply chain stops along the way to the pharmacy) had been falsified. That made the counterfeit Serostim appear to be an authentic drug from a reputable distributor (1).

In north Texas, US FDA agents investigating a possible case of Medicare fraud made a startling discovery as they toured a warehouse: more than 1000 vials of the Procrit injectable anemia drug that lacked the proper paperwork. Subsequent testing revealed that the vials were fakes (2).

Recently, a New York teen filed suit against several drug companies over a counterfeit version of Epogen he received from a national pharmacy chain. Timothy Fagan took injections of the drug to help speed his recovery from a liver transplant. Instead of boosting his red blood cell count, he injections caused severe cramping. After checking with his pharmacist,

Fagan discovered that he had been taking a diluted version of the drug that contained only a fraction of the listed active ingredient (3).

The trafficking of fake and altered drugs, including injectable hormones and vaccines, has reached epidemic levels in some parts of the world and is a growing problem in the United States. In the late 1990s, the FDA investigated an average five counterfeit drug cases a year. In 2003, the number of counterfeit drug investigations jumped to 30, and in 2004 it rose again to 58 (4). The problem also includes genuine drugs stolen from the supply chain. Such drugs run the risk of being mishandled, making them ineffective and potentially dangerous if they are used.

Today's counterfeit drug trade is the domain of organized crime rings that have access to sophisticated technology, including high-quality computers, scanners, and printers. Many counterfeiters zero in on the expensive and vital injectable medications used by cancer sufferers and AIDS patients. Typically, such drugs are costly and sold in very small quantities. Because of the considerable value in each small amount of product, it doesn't take much to generate large profits for the counterfeiters.

Another problem that drives counterfeiting and the diversion of injectable drugs is the black-market use of some products. Many such treatments stimulate different types of cell growth, which makes them popular with bodybuilders. For example, Serostim has a history of being diverted from the legitimate drug supply chain and sold to bodybuilders, who use it to bulk up their frames (6).



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Fake injectables began showing up in the United States drug supply in 2001, causing drug companies to seriously consider the best ways to protect their consumers — and their brands — from fake or altered products. Drug manufacturers sought help from companies such as Authentix that specialize in anticounterfeiting technology.

Key to a solid anticounterfeiting plan is a drug maker's first evaluation of its manufacturing process. Sponsors need to look at how and where their drugs are manufactured, then evaluate the way products are put together — and where the controls of related packaging components reside. That information can be used to create a strategy dictating where anticounterfeiting features should be implemented to ensure that the product supply is protected from compromise, theft, or abuse as it travels from the point of manufacture through the distribution system to various points of sale.

IDENTIFICATION

Anticounterfeiting features that can authenticate injectable drugs are both overt and covert, and they can be applied in numerous ways: on labels, onto closure seals, on cartons where vials of

injectable drugs are stored, onto the packaging, into plastic caps of individual vials, and onto the glass vial itself.

Specialized polychromatic inks (similar to those used on the new US \$20 and \$50 bills) are used on both labels and packaging. Polychromatic inks appear to be a different color depending on the angle from which they are viewed. They are difficult to manufacture and difficult for counterfeiters to duplicate. Holograms are another visible feature used for product security. Holographic elements are affixed either to the drug packaging or to the vial closure seal.

More than One Approach: Visible security features are a starting point, but drug companies need to rely on additional features to create layers of security. Counterfeiters are extremely creative and clever. Even if a visible authentication feature is hard to recreate perfectly, a counterfeiter only needs to copy it closely enough to confuse someone who just gives a package a quick glance. A good counterfeit is an excellent copy of the genuine product — so even the injectable drug's manufacturer may not be able to tell if a product is counterfeit or authentic. High-security covert features add an extra level of protection and assurance because they are difficult for counterfeiters to detect but easily verified by field inspectors who check drug authenticity.

Spectral fingerprints can be embedded into labels, closure seals, or other features of injectable drug packaging. Although such "fingerprints" are invisible to the naked eye, they can be detected using specialized handheld surface spectrophotometers. Field instruments use proprietary excitation and detection optics and pattern recognition algorithms for rapid, secure field authentication. Additional forensic layers of security are also embedded into the spectral signatures and can be confirmed through more extensive laboratory analysis.

TRACKING

Authentication of injectable drugs is only part of the solution when it

comes to curbing drug counterfeiting. It's also important to track products at various points along the supply chain. Manufacturers can keep tabs on drugs as they travel through distribution with field monitoring and barcoding.

Field monitors inspect drugs as they travel through the supply chain. For example, a field inspector might visit a drug distributor's warehouse to use a quick detector that checks for a drug's spectral profile. Absence of the proper spectral profile would immediately "raise a red flag" and act as an early warning before fake drugs could get further along through the distribution channels. In addition to actually checking for authentication features, the mere presence of inspectors acts as a deterrent. Their regular visits can discourage distributors from obtaining injectable drugs through questionable sources.

Barcodes: In the barcoding process, a company serializes individual units at the point of manufacture (giving each a unique serial number) and implements stations to read those barcodes, capture the tracking data, and drop that information into a managed database that allows authorized personnel to monitor where products go from the time they leave the manufacturing facility. You're probably most familiar with this process as it applies to shipping a package overnight, when you can track it on the Internet until it reaches its destination.

RFID Chips: Barcoding is an economical technology that is proven, easy to implement, and available today. Radio frequency identification (RFID) has recently been touted as another tracking technology that will curtail counterfeiting. Realistically, however, RFID is in its infancy. Right now the technology is better suited for overall supply chain management. When it comes to individual drug units, current RFID tags are costly and temperamental. Technical issues can affect the performance (and thus the dependability) of an RFID tag. Also, RFID read rates are easily affected by metal foil and vials containing large amounts of liquid.

AN OUNCE OF PREVENTION

Historically, drug companies have implemented anticounterfeiting strategies in response to an urgent

counterfeiting problem. Such a strategy can be put into place relatively quickly, within a matter of weeks. It is better, however, to implement a well-planned, overarching strategy that encompasses manufacturing, monitoring, and supply chain considerations before trouble arises.

As counterfeiting becomes a mounting concern, drug sponsors are to taking a proactive approach to the problem. Many companies are thinking more broadly about how to implement coordinated anticounterfeiting, antidiversion strategies across their brands and throughout different regions of the world.

Just as tamper-evident seals on bottles of pills and liquid formulations became more common due to a tampering scare in the 1980s, attitudes toward anticounterfeiting technologies are beginning to evolve now. Once viewing such measures narrowly as an "extra feature" that only "added cost" to the bottom line, drug makers are beginning to realize the importance of protecting the integrity of their brands and the most important part of the equation: protecting the safety of consumers.

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