

A BITTER PILL: Exploring the Realm of Drug Counterfeiting

The rising scourge of pharmaceutical counterfeiting—and what pharmaceutical companies can do to protect their products, safeguard their brand, and ensure the health and safety of consumers.

In 2015, the total number of counterfeit pills and other medications seized by Interpol's Pangea pharmaceutical investigation team reached 20.7 million—a drastic increase over the 2.4 million seized by the same team in 2011. In May 2014 alone, a single Interpol operation led to the seizure of 9.6 million counterfeit medications—a haul of fraudulent goods worth an estimated \$32 million—and resulted in 434 arrests and 11,800 counterfeit websites being shut down.

While these results are impressive, the eye-opening numbers tell us less about the efficacy of the solution and more about the scale of the problem: the rapid and troubling growth of the counterfeit pharmaceutical market. The World Health Organization estimates that approximately 10 percent of all medications are counterfeit. This shocking number elicits even more concern because it may be too conservative of an estimate.

Criminals see counterfeit drugs as a low-risk high-reward opportunity, and that, along with regulatory confusion, comparatively modest legal penalties, the vulnerabilities inherent to an increasingly complex global marketplace (and the ease and anonymity with which websites can become digital storefronts or pop-up “e-pharmacies” that are difficult to trace) makes producing and distributing

counterfeit pharmaceuticals an extremely attractive proposition for those that operate outside of the law.

For the pharmaceutical industry, the growing problem of counterfeit medications is extremely troubling. Not only are counterfeit pharmaceuticals a direct threat to public health and safety, they can do significant and sustained economic damage to brands and businesses. Patient/consumer wellbeing is clearly paramount—and health and safety concerns remain the single most important factor motivating the pharmaceutical industry.

Counterfeit medications are often mislabeled and frequently contain dangerous or unregulated ingredients. Consumption of these fraudulent products can be extremely dangerous, and unwitting consumers who ingest them may become sick or even die. That is a dark irony for an industry that manufactures products designed to improve health, and the negative associations that can result from poor outcomes or products that are now perceived as unreliable can result in long-term damage to even the most

iconic of pharmaceutical brands. The resulting hit to the bottom line can be dramatic—even crippling.

As a result, understanding the contours of the global counterfeit drug trade—including the growing threat of counterfeit medications around the world, the different ways in which criminals are able to create counterfeits and sell them to unsuspecting consumers, and the strategies that pharmaceutical companies can use to protect their products from being counterfeited—is a critically important part of the professional equation for any pharmaceutical company.

A Global Problem

The challenges of effectively regulating and monitoring today's global pharmaceutical have increased over the course of the last 10-15 years. One of the biggest reasons for that is the degree to which international operators have emerged in new markets around the world.

The complexity of international supply chains affords new opportunities for bad actors to identify and exploit weak

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links in those chains. Today, a large portion of international counterfeiting begins in China and other parts of Asia, where many counterfeiters manufacture facsimiles of drugs that they have reverse engineered. While China used to have a thriving counterfeit marketplace, that market has tightened somewhat: today much of the fraudulent product that originates in China is shipped overseas to the Middle East.

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While virtually any part of the world is susceptible to counterfeit pharmaceuticals, places where there is a decentralized regulatory authority and/or ineffective or inefficient enforcement mechanisms are particularly vulnerable. Today, large amounts of counterfeit pharmaceuticals are making their way to Africa, the Philippines and Iran (by way of Turkey and Russia).

Enforcement Challenges

The task of identifying, tracking and policing the production and sale of counterfeit drugs seems to get more difficult with each passing year. Counterfeiters are becoming more sophisticated, not only with structural and operational details (such as shell companies), but also with respect to understanding the relevant laws and penalties in different countries. Many have become “experts” in trafficking in amounts of material that just barely stay under the total required to trigger more serious penalties. Consequently, even when they are caught, many are able to get away with little more than a slap on the wrist.

The regulatory and law enforcement challenges with respect to business conducted online can be significant, and in-

consistent international laws (some that require notifying a suspect organization before conducting a raid or searching for counterfeit products) can hamstring enforcement efforts.

But even in the face of these challenges, the industry is generally doing a better job of collaborating with legislators and security/enforcement agencies. Companies and countries are starting to appreciate the full scope of the problem—and

many have responded in constructive ways. In some cases, strict new regulatory guidelines and tough new laws (with steeper fines and longer prison sentences) are either in place or under discussion.

New agencies and organizations specifically tasked with reducing counterfeit pharmaceuticals are having a positive impact. Pangea, the Interpol anti-counterfeiting organization responsible for the high-profile successes mentioned earlier, was founded in 2008 and is active today in over 100 countries. Approximately 200 different agencies participate in the Pangea initiative, which has been particularly successful going after the internet service providers behind illegal online pharmacies.

But there is only so much that even the most sophisticated law enforcement organization can do. It is incumbent upon individual manufacturers and producers to do their part to combat pharmaceutical counterfeiters.

Strategies and Tactics

Pharmaceutical companies looking to bolster their security posture and reduce their exposure to counterfeiting should begin by reviewing the following list of best practices and security strategies:

Coordinate

Coordinating with local agencies and taking advantage of resources on the ground in different parts of the world is critically important. In some cases, customs officials can be an invaluable tool, willing and able to help look for specific products and substances when alerted to a potential problem.

Partner

Remarkably, some of the biggest pharmaceutical brands in the world are still relying on mom and pop operations to handle security and anti-counterfeiting efforts. When a problem exists on a global scale, half measures are unlikely to yield positive results. If possible, work with a professional partner that understands the law and is flexible and capable enough to seize critical digital evidence as easily as conducting a warehouse raid.

Resources

Your security partner should have global reach and insight into any market where a pharmaceutical company is conducting business. The right company will have the resources to do test purchases all over the world. In an environment where even a small delay can be costly, the ability to move quickly and sometimes conduct simultaneous raids is essential. Counterfeiters like to go for the low-hanging fruit and will always take the path of least resistance. If you have a product that is heavily policed, monitored and enforced, you can greatly reduce your exposure to counterfeiting.

Invest

Stick with it. Building a strong anti-counterfeiting program can take time, and the payoff is not always immediate. Big seizures and big victories can happen, but so can high-profile misses. Pharmaceutical companies need to understand that they are making a long-term investment, and should structure their security program and protocols accordingly.

Brand Protection

A company's brand protection efforts are far more effective and efficient when centralized through a global security department or brand protection department (rather than through legal counsel). Security and brand protection professionals have a better sense of the global challenges and can usually be nimbler and more proactive than attorneys. Any brand protection program also has to be multifaceted and all-encompassing: including online efforts, street-level operations, market surveys and more.

Technology

Counterfeiters are taking full advantage of technology to achieve their goals, and there is no reason why pharmaceutical companies and their security partners cannot do the same. From tracking products and materials to locating counterfeiters and identifying suspicious patterns or potential problems early, new software and new devices (such as handheld detection devices that can instantly authenticate or flag materials) can be key weapons in the anti-counterfeiting arsenal.

Vigilance

Pharmaceutical companies must practice "proactive enforcement". That includes measures like monitoring consumer behavior and purchasing patterns, listening carefully to complaints or concerns, and providing comprehensive anti-counterfeiting education and training for all employees. Vigilance also means monitoring and securing your supply chain, and understanding that internal reporting tends to underreport cargo theft.

Conduct regular reviews of facilities and procedures looking for potential vulnerabilities. The lack of a consistent secu-

rity policy often results in facility managers or other leaders operating without any formal training or security background.

If the pharmaceutical industry can respond to the growing threat of counterfeit medications with vigor and vigilance, coordinating and collaborating with law enforcement agencies and international health and welfare organizations, and adopting simple and straightforward security measures within their own operation, they will be doing their part to keep their products secure, their customers safe, and their brand and bottom line healthy—in every sense of the word. ■

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