

Shoring Up Supply Chain Security

As the saying goes, a chain is only as strong as its weakest link. From purchasing to storage and delivery, establishing supply chain integrity requires a closer look at best practices that put patient safety first.

March 2011

T BY TRUDIE MITSCHANG, staff writer, FFF Enterprises

The pharmaceutical supply chain has long been vulnerable to counterfeit products, theft and price gouging. Preventing the infiltration of counterfeit pharmaceuticals into the legitimate pharmaceutical supply chain is an important public health issue that impacts patient welfare and healthcare costs. As a result, pharmaceutical firms are under scrutiny to shore up security measures and identify areas of increased vulnerability. But where are the weakest links?

Many supply chain problems are due to criminal counterfeit activity and theft — products being stolen from distributors and manufacturers and then resold in gray markets. But when it comes to patient safety, integrity of products as they make their way through the channel is also critical. Issues of storage, shipping and tracking come into play for companies hoping to achieve impeccable safety track records. This is especially true for manufacturers and distributors of critical-care biopharmaceuticals, such as fragile plasma derivatives and other specialty products.

When these life-sustaining products are compromised, tainted products can pose a serious health threat to patients on the receiving end. Of course, most patients are unaware of the inherent risks of a compromised pharmaceutical supply chain — until it touches them personally. Just ask Denise Hasenstab.

Hasenstab is a Mission Viejo, Calif., resident who suffers from a genetic gamma globulin deficiency and multiple sclerosis — chronic conditions that have severely compromised her immune system. Over a period of six years starting in 1998, she sought treatment for her illnesses at an infusion clinic near her home, receiving pricey, twice-weekly infusions of intravenous immune globulin (IVIG). Or so she thought. When it was discovered that Hasenstab's health had deteriorated, despite the costly care, the mother of two was shocked to learn her IVIG infusions had been tampered with; instead of life-sustaining immune

globulin, she had been infused with a saline solution. Although Hasenstab has recovered from her ordeal and reached a settlement in a civil suit against the clinic, it hardly makes up for the trauma she endured.¹

“There is no dollar amount I ever could have received that could even come close to making up those lost years of my life,” she said. “Money can’t bring back that time with my children. Those years are gone.”

Re-examining Purchasing Options

Unlike other industries, pharmaceutical products are not necessarily shipped straight from the manufacturer to the customer. Often, they go through primary and sometimes secondary wholesalers to get to the customer. Within the supply chain, secondary wholesalers / distributors buy from the major drug wholesalers and each other, and then sell to the customer. According to Chris Ground, chief operating officer, FFF Enterprises, distributors for plasma proteins and critical-care products historically purchased not only from manufacturers, but also from hospitals and other distributors, leaving room for product tampering and mishandling. A lack of stringent regulations has made this an easy entry point for counterfeiting and other illegal activity.

To counter this, the Healthcare Distribution Management Association has developed a series of business practices for distributors to help address common safety concerns. One of the chief suggestions is that companies perform due diligence on wholesalers that they do business with, and verify that the wholesaler is an authorized distributor for the products in question. Another option suggested by members is for companies to deal only with manufacturers.² These suggestions have merit, and many leading companies are complying by >



making streamlined purchasing decisions. Genetech Inc., for example, currently requires distributors to certify that they will purchase the company's human growth hormone only from Genetech.³ Amgen, Ortho Biotech, Serono, Johnson & Johnson, Pfizer and others have taken similar measures with specific products.

Creating Security, Link by Link

As the nation's largest distributor of plasma products, vaccines and critical-care biopharmaceuticals, FFF Enterprises is known as a leading voice when it comes to defining the components of supply chain safety. The company has implemented several best practices designed to put patient safety first, even coining the phrase "The Eight Critical Steps to Guaranteed Channel Integrity." The eight steps in FFF's safety protocol are increasingly becoming industry-recognized standards when it comes to moving products securely through the distribution channels.

"Each of the eight steps is critical and dependent on the others to make sure patient safety is not compromised," says Patrick M. Schmidt, founder and chief executive officer of FFF Enterprises, Inc. "It is our hope that these eight steps create a standard for safety that will continue to have a positive influence on the industry as a whole."

Interestingly, the first safeguard listed among FFF's eight recommendations is one also suggested by the Healthcare Distribution Management Association — that companies purchase products only from the manufacturer. Now in its 22nd counterfeit-free year, FFF also has made the key business decision to sell to only certified healthcare providers.

Another critical step that plays an important role in pharmaceutical supply chain safety pertains to storage issues. Many pharmaceutical products are highly sensitive to temperature variations and storage facility conditions, which is why storage and transporting conditions must be tightly controlled using stringent guidelines. Best practices for distribution sites include the use of temperature-controlled warehouses with state-of-the-art monitoring systems and adequate backup generators. Stacking methods also can be modified in storage units to avoid putting pressure on fragile bottles and containers.

Product packaging is another key safety link, an especially important component for frozen or refrigerated products. While this link seems obvious, it is important to distinguish each step to see how one depends on another. Analyzing specific requirements of each product during packaging ensures that integrity is maintained during transit. Quality packaging standards may include insulation between products, gel fillers, and temp tails to indicate whether a product gets too hot or too cold during shipping.

In the pharmaceuticals distribution business, another critical step relates to product allocations to customers, which are naturally based on supply and demand. But in volatile markets, product shortages or inventory overages can create issues for patients and providers. When possible, taking a more interactive approach to allocation based on immediate rather than long-term customer needs can help create balance and minimize distribution disruptions. "Helping healthcare care is about getting products to patients when they need it, while creating a secure supply chain that is resistant to gray market tampering," explains Ground.

Delivery guidelines and methods are also important factors. Extreme weather and storms can — and should — impact shipping methods and protocols. Overnight shipping of critical-care products during times of extreme weather can ensure efficacy is maintained and that products are delivered when and where patients need them most. Another important factor can be the decision to not deliver to unlicensed facilities.

"Our own delivery guidelines are in compliance with the State Board of Pharmacy requirements. The types of products we deliver must only be transported to facilities with a DEA [Drug Enforcement Administration] license, no exceptions," adds Ground.

Verification and tracking comprise the final links in supply chain safety. The ability to verify a product's pedigree and trace exactly where it has been is critical. Companies like FFF use advanced technology to help customers take charge of shipments. FFF's system, called Verified Electronic Pedigree (VEP), allows ➤



customers to easily verify the pedigree of purchased pharmaceuticals within seconds of logging into the company's computerized system. Electronic tracking also is a helpful reassurance, matching product lot numbers to customer information.

Another important safeguard involves having a dedicated workforce to monitor manufacturer and U.S. Food and Drug Administration information sources, ensuring the timely communication of important product safety or recall notices.

Prioritizing Patient Safety

Increasing awareness is always the first step to implementing change in any segment of business. A study conducted by Marsh's Supply Chain Risk Management Practice, in conjunction with Pharmaceutical Manufacturing magazine, surveyed representatives from 66 leading life sciences organizations, and results suggested that the globalization of the industry has, in fact, undermined the security of an already vulnerable supply chain. The study went on to say that pharmaceutical manufacturers may have significantly less control over supply chain security than they think.

The report recommended that companies can contribute to supply chain safety by building in processes, standards, policies and procedures that work together to close gaps and strengthen weak links. Re-evaluating systems and best practices, while taking a closer look at each individual supply chain link, is a good first step.⁴

Mitigating the risk of counterfeit and compromised pharmaceuticals will require the creation of a pharmaceutical supply chain that is both secure and resilient. Closing security gaps and strengthening weak links will demand multilayered measures and industry-wide developments of effective partnerships. A place to begin is by seeing the bigger picture — putting patient safety first. Safeguarding the integrity of pharmaceuticals and their distribution is not only a matter of brand equity, fiscal responsibility and corporate reputation, but in some cases, a matter of life and death for patients on the receiving end.

"One of the driving values behind everything we do at FFF is that patients are always first," Schmidt explains. "It's part of our culture to recognize that at the end of every transaction, there's a patient waiting for that product."

References

1. Bennett, D. Is Your Infusion Clinic One of the Good Guys? *IG Living*, Dec/Jan 2007, pp14-15.
2. Healthcare Distribution Management Association. Recommended Guidelines for Pharmaceutical Distribution System Integrity. Accessed at www.healthcaredistribution.org/gov_affairs/pdf_anti/Guidelines_Rx_Distribution_System_Integrity_11-5-03.pdf.
3. Genetech Inc. Important Counterfeit Drug Warning. Press release, August 3, 2001. Accessed at <http://www.gene.com/gene/products/information/opportunistic/nutropin-aq/nutropin-aq-patient.pdf>.
4. Marsh Inc. Improving Pharmaceutical Supply Chain Resiliency. Accessed at http://global.marsh.com/news/articles/pharma_supply_chain.php.
Trudie Mitschang is a staff writer for BioSupply Trends Quarterly magazine.

This article was originally published in the April 2010 issue of BioSupply Trends Quarterly Magazine.

