Counterfeiting and Piracy of Pharmaceuticals

Reducing Risk in Global Supply Chains

BY ANN GRACKIN

Estimates on counterfeit trade exceed US$200 billion, and inspections across the world cost billions, yet only a very few shipments are actually inspected. This issue has particularly impacted the vital life sciences supply chain. This article discusses what solutions are at hand to reduce illicit trade and ensure a safe and secure supply of pharmaceuticals.

The past decade has seen an increase in the level of global trade and, along with it, the unintended consequences of seeking cheap labor sources and new emerging markets. Even with heightened public awareness, illicit trade has actually been increasing, resulting in grave consequences to the society and business from both physical and cybercrime. In 2006, according to the European Union (EU), more than 1.6 million counterfeit cosmetics and personal care products and 1.2 million foodstuff and beverage products were seized at the EU external border, out of a total 130 million fake objects. In addition, 2.7 million counterfeit medical products were stopped at the border. Fake medicines are reckoned to account for almost 10% of world trade in medicines.

The problem of counterfeit goods is pervasive as demonstrated by more recent headlines such as the following:

» Recall of defibrillators with 24,000 heart patients affected
» Toy recalls with over 4,000,000 units sold by various firms having lead contaminants and a price per unit of US$5–40
» Heparin contamination reportedly led to 81 deaths, 400 injured
» Food recalls and disease from seafood, eggs, chicken, and spinach, to cosmetics with contamination from animal by-products numbered in the millions
» Customs activity has never been as high as in 2006 with more than 36,000 seizure actions, an increase of around 40% compared with 2005. The number of objects seized also increased from 75 million to 130 million [1]
» National figures on fake drugs in China are unavailable, but according to a 2006 report released by London-based International Policy Network, between 200,000 to 300,000 people in China die from counterfeit or substandard medicine in China each year [2]

And of course the recent headline on CNN “My husband died from on-line drug.”

What Are the Dangers, Impacts, Costs, and Solutions to These Issues?

Estimates on counterfeit trade (excluding the domestic counterfeiting) exceed US$200 billion. In a recent testimony in front of the U.S. Congress, the Food and Drug Administration (FDA) estimated that it would cost the U.S. taxpayer an additional US$225 billion to inspect all pharmaceutical plants worldwide. The supply chains of the 21st century represent both the source (and potential solution) for many of the risks and concerns that accompany the global economy. Extended networks of interrelated trading partners contribute, inadvertently or sometimes deliberately, to the increasing elements of risk: to our society, the products we use, and the infrastructures we rely on, affecting our safety and security that cost untold billions to our economy each year. Our so-called global trading partners, in many cases, are introducing bio and cyber germs, if you will, into our products and systems. It is not just the product, but, according to the Philippine Legal, Information, and Compliance Division, there is also deliberate and fraudulent mislabeling of the products with respect to identity and/or source or with fake packaging, which is applied to both branded and generic products [3].

This article explores some of the issues associated with end-to-end supply chains today, inherent risks, as well as some new approaches and solutions to address these problems.

What Has Changed the Status Quo?

In the past decade, there has been an increase in the level of crimes, counterfeits, and piracy, leading to product integrity issues and faulty and risky products delivered from low-cost country sources and trading partners. The critical necessity of understanding each of the processes and players and ensuring universal compliance with quality, security, and product protection standards is daunting and not likely to be embraced by our newer trading partners for decades. The Pandora’s Box of open trade in many cases encourages predatory behavior, with illicit trade networks acting as a conduit for diverted and counterfeit products as well as trafficking in human beings. Sadly, both criminals and terrorists have become global masters of supply chain management and have leveraged both
information technology and logistics networks to manage global crime networks.

This affects most industries. The U.S. government is more concerned about the infrastructure, but citizens are most concerned about the human impacts: disease and death due to the importation of a virus, counterfeits, or tainted foods and pharmaceuticals and containment of the resulting human health crises.

Hence, let us look at the life sciences industry, a critical industry that consumers care about, which is also fundamental to our safe and secure society.

Although the global phenomenon of outsourcing has opened new markets as well as reduced the cost of manufacturing, it can have less than beneficial consequences for the life sciences industry. Products that were once the end product of a single-location manufacturing facility are now processed, packaged, and distributed in a series of disparate and geographically dispersed locations. In particular, the manufacture of end-of-patent or generic substitutes is increasingly taking place in far-flung locations such as South East Asia, India, China, Eastern Europe, and Latin America.

In India alone, a variety of drug categories has increased the growth of the pharmaceutical industry between 11% and 30%, with many products exported (Figure 1). Not that any nation should be denied the right to manufacture, but outsourcing does open the possibility for alien ingredients, with no real oversight, to enter our markets.

Almost daily, headlines reflect the contamination threat we face from the substitution of alternative ingredients. The final product is sold on the Internet or through legitimate channels, making its way to the supply chain’s last inch, the patient’s bedside.

A parallel threat, and one that is not universally recognized as such, is the potential contamination of the data being captured to protect this critical supply chain. Like the threat of a global pandemic, the introduction of digital germ fare into the stream of commerce is one that should not be ignored. Data corruption, data deletion, and other acts of digital sabotage should be seriously considered as an equal threat because stolen formulas, customer lists, logistics strategies, etc. enable these criminal networks to succeed at counterfeiting and piracy. In a recent Interpol investigation, fake holograms, batch numbers, etc. were found to be used to attempt to introduce counterfeits into the global market (Figure 2).

In this short article, although we do not diagnose all the factors or recommend all the solutions, we discuss some economically and technically feasible approaches to solving these problems.

![Figure 1. Increase in sales and production in the Indian pharmaceutical industry.](image1)

![Figure 2. Map showing drug counterfeiting in South East Asia.](image2)
In the EU, food traceability regulations have enabled the creation of commercial off-the-shelf software backbones for tracking and tracing the products from farm to fork.

Solutions at Hand
Solutions are at multiple levels of the life sciences value chain: government, industry, supply chain network partners, and enterprise. Each has a role to play. And solutions come from policy, process, and technology levels.

Information Technology
The good news is that information technology has kept pace with the changing face of global supply chains and beyond. A combination of wired and wireless technologies provides information about locations, state, condition, or quality, and custodianship as products move through the processes related to production, storage, and distribution. As these processes are enhanced by smart devices such as sensors, mass serialization devices, and radio frequency identification (RFID), it is now possible to create a digital audit trail via sensory networks that records the digital DNA throughout the product life cycles.

For example, in response to the increasing challenge of ensuring the safety and security of the pharmaceutical chain of custody, the FDA and state-level authorities are introducing measures and controls to track, trace, and monitor the movement of a product through its life cycle, from manufacturing through dispensing. Recent legislation in California requires that pharmaceuticals sold there include an electronic pedigree and incorporate a combination of digital signatures, mass serialization, and shared networks for authentication and control. In the EU, food traceability regulations have enabled the creation of commercial off-the-shelf software backbones for tracking and tracing the products from farm to fork.

Business Process and Sourcing Strategies
When designing supply chains, care should be taken to design transparent and controllable processes, contracts, etc. Most firms design these chains based on a cost model, the price of the commodity, or a total landed cost, rather than looking at a risk-adjusted cost. This can include quality issues, price variability, as well as the cost of increased risk management, which shows up in the overall cost of a firm but is not allocated to the specific causes such as reputation, brand, disruption, and product liabilities, which we call a total sourcing model.

Detection and Business Response
Avoidance is the first order of planning. Risk assessment, as an ongoing part of the business, should be in place with a relevant and business value-oriented compliance program. Many compliance programs become mired in bureaucracy with little relevancy to the changing business needs. These should be tested with suppliers to ensure that they genuinely address these issues and that they are usable. Many firms have manuals for testing compliance but not for testing value. Detection techniques need to be put in place across the whole supply chain from the source of raw materials, to manufacturing, logistics and border crossing, laboratories, and the provider network: doctors, clinics, pharmacies, and hospitals.

Legislation and Trade Agreements
In the United States, we seem to have a notion that legislating business activity leads to a decline in our economy. However, the life sciences industry seems to be more prosperous than others during the current economic downturn and seems to have no connection. Yet, the cost of remediation when our public safety is affected, a burden taken by our whole society, is huge. (At the time this article was written, the FDA was requesting more funding for food inspections activities, and the U.S. Congress was contemplating the FDA Food and Drug Globalization Act of 2008, which would require registration, inspection, and certification of food facilities.)

The EU can serve as a model for the United States. Its approach to food and pharmaceutical safety is extensive and global, not just the infrastructure and customs at the end of the problem but end-to-end from farm to fork. For example, the EU’s food safety program, the General Food Law, is an umbrella program of interlocking regulation and funding. The EU got rid of a U.S.-like farm-subsidy-type model (their Common Agriculture Policy) and is using these same funds to encourage better and safer farming techniques; they have food traceability laws and created a Eurowide administration (European Food Safety Authority), funding for better detection of tainted food and pharmaceutical products as well as rapidly alerting the public of problems.

In addition to the legislative policy and technology, there is a need to create both industry- and enterprise-wide cross-functional teams of stakeholders across their extended supply environment, while ensuring methods and processes that work for the industry, which also add economic value to the participant enterprises. Several activities contemplated are as follows:

- Anti-Counterfeiting Trade Agreement (ACTA), an international agreement being contemplated on intellectual property, would cover information technology and patented-type products
- World Health Organization (WHO) International Medical Products AntiCounterfeiting Task Force (IMPACT) provides recommendations on internal cooperation and education
- key nations have passed more stringent legislation such as China’s State Council special regulation, which strengthens food and drug security surveillance, passed in July 2007.

Although the source nations where the highest sourcing of counterfeits comes from have created their own version of the FDA, we have to realize that these are new and are obviously underfunded (as also the United States).

Any solution, however, will require a worldwide funding and cooperation to create legislation and information technology techniques.
Many compliance programs become mired in bureaucracy with little relevance to the changing business needs.

Obstacles Remain
All this said, there are some major obstacles to business and government addressing these needs. First, the economic investments in the process (inspection process and implementation of the process and systems) and personnel seem significant. Our findings are that many of these solutions have other business values that can be gained, but since efforts must be made to learn and delve deep enough to use these to address improved business performance and not just compliance. And, that is the rub—the commitment to learn is limited—especially as attention units are focused on the bottom-line challenges facing business.

U.S. government policies play an important role. Although there have been some efforts and some research has been done on addressing traceability, tracking, and other types of solutions to these problems, not enough has been done for legislators and administrators to understand what solutions can do, what the limitations are, and how government can be an investment partner in taking solutions to the next level. Generally, the problem is looked at nationally or in isolation, such as food safety by one department, port safety by another. In a global-supply-chain-driven world, we have virtually no borders when it comes to traded goods (imports). Hence, we have to reach out for international solutions and cooperation with other governments.

International trade agreements are very nuanced. Deals are often struck at G8 or WTO-type meetings among the wealthier nations without dealing with the causes from the sources, despite the rising net worth of the middle class around the world, and in a world where we still have more than 1 billion people in the world living on about US$1 a day. This exploitable element of society is being preyed upon by more criminal elements who can manage the illicit global supply chain.

A gnawing question also looms: who is watching the watchers? At a recent WHO IMPACT meeting in Jakarta in 2007, several international speakers as well as Interpol revealed that inspectors and lab testers falsify information, allowing seized or inspected tainted drugs to continue on their journey into the world’s drug supply. There are laws and retribution for government inspectors who take bribes, but in the case of heparin, there were FDA inspections but not through the multilayer supply chain. What legislation addresses laxness?

In Washington, the competing agendas from various power groups, some well-intended, some uninformed, stymie the kind of dialog on policy versus limits of the governments’ role in solving these problems.

Conclusions
Together with the harmonization of products and services to cater to a heterogeneous economy, it is now necessary to embrace the principles of global social responsibility. Responsibility means to create a unified approach to protection. Clearly, consumers need to get in control and push their legislators for a change in attitude. To consider the protection of the environment, societies, nations, and individual consumers, we need a deeper focus, beyond internal processes and operational activities, taking into account a global cooperation and supply chain perspective.

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