

# Pigs, Drugs, and Terrorists

Making drugs is messy. Take heparin. You raise pigs and then slaughter them. You isolate the pig intestines and cook them. Then you scrape the intestinal insides, dry them, and get them to a factory to undergo more processing (Harris, 2008).

Making drugs is also expensive. Outsourcing this messy activity to countries such as China is convenient and cheap. The hassles of oversight are vastly reduced, as are the details of getting the raw materials. So costs are minimized and profits enhanced.

Earlier this year, the case of tainted heparin from China demonstrated the vulnerability of the drug production and supply chain. Tainting the drug with undetectable deadly material that was 1/100th the cost of the legitimate active ingredient was ludicrously simple. It even came on the heels of known faulty products from China—from toys to toothpaste to pet food. With at least 81 deaths and hundreds of allergic reactions, the heparin case showed that life-saving drugs can quickly become life-threatening weapons due to loose oversight (Harris, 2008).

This is a policy problem that encompasses the globalization of drug production and distribution. But more deeply, it is a problem of how this system can be exploited to do great harm and represents a very different kind of patient safety issue.

## Domestic Oversight and Drug Production

The primary responsibility of the U.S. Food and Drug Administration is ensuring the safety of medicines in America. Domestically, it does a pretty good job. By law, domestic production facilities

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have to be inspected at least every 2 years. The FDA carries out this obligation strenuously. Surprise inspections of production facilities are the norm, and inspections can last 1 week to 1 month or longer, depending on what inspectors find. FDA officials also have the power to investigate and interview anyone they want to determine the safety of the drugs and adherence to “current Good Manufacturing Practices” (cGMP)—the primary means to ensure quality of medicines (Nielsen, 2007).

Unfortunately, most active pharmaceutical ingredients aren’t made here. Congressional committee hearings from last year painted a dismal picture. The vast majority of the active pharmaceutical ingredients in the world—including heparin—come from China. Close behind is India. These are the very countries that have been identified by international authorities as having poor regulatory oversight and being the primary sources of counterfeit drugs (Nielsen, 2007).

The fact that most drugs are sourced from high-risk countries is therefore known. So how are we doing at ensuring the safety of foreign drugs?

## Offshore Protections

The answer is disturbing: We are doing very poorly. Although there is a legal mandate for the FDA to inspect foreign factories, there are few inspections. In fact, total inspections for 2008 are slated to drop one-third from 2002 levels to only 102 worldwide for all FDA-responsible goods (not just drugs). The budget for these inspections is being whittled down from \$16.7 million in 2002 to \$16 million in 2008. Over the past several years, the number of inspections in China has actually fallen. Countries such as Germany, France, and Italy are inspected more frequently (Liang, 2008).

Second, foreign inspections haven’t been a high priority for the FDA. Congressional hearings from last year indicated that foreign factories are inspected, if at all, just once every 13 to 30 years (Nielsen, 2007). Even that number is hard to estimate because the FDA’s databases are outdated. In the heparin situation, a “clerical” error led FDA inspectors to believe that they had visited the Chinese plant making the tainted drug when they had not (Harris, 2008).

Third, there are tremendous barriers to ensuring safety. FDA inspectors have to get pre-approval to inspect through a visa or other process. This can drag out for months. Reluctant inspectors, who may not have any knowledge of the country, have to be recruited by the FDA to go to sometimes hostile or inconvenient locales. Foreign inspections are scheduled in bunches, so that inspections generally last no longer than two days. FDA inspectors often rely on foreign factories to provide translators. These factories may also

independently send samples for testing to laboratories rather than having inspectors choose samples themselves (Liang, 2008).

Consequently, offshore oversight is weak. The tools that create a safe system domestically are vitiating overseas: no dedicated, in-country inspectors; no surprise inspections; no flexibility in the time or intensity of the inspections; incomplete records often inaccessible to inspectors due to corruption and language barriers; and test samples that are not verifiably from the factory in question (Liang, 2008).

Limited oversight also exists in the exporting countries themselves. In China, the State Food and Drug Administration (SFDA), the key drug regulatory authority, claims it can't regulate pharmaceutical ingredients, since these are chemical companies. Further, the SFDA has indicated that the safety of products from China is the responsibility of the importing country (Liang, 2008).

Although the latter statement may seem callous and irresponsible, it's fairly standard internationally. The general rule is that if a drug isn't earmarked for domestic consumption, it's not subject to that country's safety laws (Liang, 2006b).

So if fake drugs from China are being transhipped through Canada for Americans, Health Canada regulations don't apply. The rationale is simple: Countries have a hard enough time taking care of their own citizens' safety; they don't want responsibility for everyone else's too. But that means in the world pharmaceutical supply chain, a fake or tainted drug can go from producer to patient without any regulation until it hits our shores.

### **Onshore Protections**

What about domestic protections? Again, the FDA is overwhelmed. The FDA has only 200 inspectors for the 300 international ports of entry. Their product lines of responsibility double every 5 years, with roughly 18 million responsible lines currently. In 2006, of the millions of drug shipments that came through our ports, only 340 had

samples taken for laboratory testing (Nielsen, 2007).

International mail facilities are also a problem. This is the main transport system for Internet sales—a highly dangerous source of medicines constituting more than 50% fake or tainted product from high-risk countries, according to the World Health Organization. But for all international mail facilities, the FDA has only 16.9 full-time inspectors to regulate the 20 million packages coming into this country annually. This figure does not include courier services such as Federal Express and UPS. Importantly, packages chosen for inspection are those declared by the sender that its contents are drugs. Even then, if the FDA doesn't inspect the package within 24 hours, it's simply given back for delivery. And even if the package does have suspect medicines, postal regulations require that the FDA return the package to its sender (Liang, 2006b).

### **Terrorism**

The drug production and distribution system is vulnerable to terrorists. Rather than our traditional patient safety focus of identifying and closing system holes to promote safety, instead, weak systems are exploited to fund criminal activities and to engage in terrorist acts.

The sale of dangerous drugs is not new in assisting terrorist activities. In the 1990s, the Irish Republican Army sold veterinary drugs to fund weapons purchases. But the globalization of drug supply and distribution is heightening its exploitation (Liang, 2006b).

We have seen recent evidence of these activities funding international crime and terrorist activities. Former illicit drug dealers have moved into the "less risky, more profitable" counterfeit drug market. For example, convicted cocaine dealers Julio Cruz and Juan Dominguez hatched a plan to sell fake Lipitor while in federal prison. They made \$10 million selling the drug online before getting caught (Liang, 2006b).

The Joint Terrorist Task Force recently issued indictments to a 19-member, 7-country criminal syndicate that was selling fake drugs and

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funneling the profits to Hezbollah (Liang, 2006a).

### **Terrorist Business Expansion**

Of course, one can easily see how such efforts can be expanded. Internet sales are an easy means of raising cash through selling fake or low quality products made in China, India, and other high-risk countries. Virtually anyone can get into this business; visit alibaba.com, where you can buy the raw material, pill presses, and labeling machines, some of which are used by the actual manufacturers.

But to really kill in mass quantities, setting up a legitimate business is the best method. Purchase a factory in China. Be a "quality" producer. Get lots of contracts. Even make money. When told to kill, simply put cyanide, arsenic, or another poison into all your supply to be sold in the United States.

In parallel, set up an online seller in Canada, the UK, or some other "trusted" country. Invite U.S. state purchasing programs to inspect you—they never come more than once or without notice. Sell real products initially. Even make money. Then, once again, when given the sign to kill, ship the tainted drugs.

Since these factories make millions of doses, the scope of harm can be large. And as the heparin case showed, detection will take time—time enough to set up for the next attack. The Internet is a great cloaking device for tainted drug sales. Once the terrorist deed is accomplished, the web sites can just be shut down and others opened for more business and terrorism.

### **Reform**

There are holes in the global drug production and supply chains. Key aspects

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of this problem are the Internet, offshore regulation, and onshore regulation; they are the primary latent failures not being addressed by healthcare policymakers.

To address the Internet problem, we should ban unregulated online sales of medicines. We already do this with other high-risk products such as tobacco, firearms, and alcohol. The FDA should also be able to destroy detected illegal drugs rather than having to send them back to a dealer (Liang, 2008).

If an online pharmacy fulfills the full requirements of the Verified Internet Pharmacy Practice Sites accreditation program of the National Association of Boards of Pharmacy, they should be allowed to sell drugs. The VIPPS program mandates accreditation inspection of online sellers, mandates them to check for valid prescriptions, requires a state pharmacy license everywhere they sell, requires a pharmacist on staff for consultation, and requires patient privacy protections. Periodic re-accreditation is required (National Association of Boards of Pharmacy, n.d.). Any system regulating online drug sales must employ a similar standard.

Offshore regulation should be as rigorous as it is domestically. FDA surprise inspections, investigative powers, American offices on foreign drug soil, multiple field offices using American employees and native speakers should be put into place. Without being on the soil with multiple field offices that have full investigative powers and the ability to inspect at will, uncooperative foreign governments will simply erect the same barriers as they have done in the past.

We should assume limited foreign cooperation. Acting domestically, however, can influence cooperation overseas. Here, we should place FDA import alerts on any products from suspect countries like China. By doing so, all drugs from China will be stopped at our borders and be subject to extensive testing and delays. This will create economic burdens on countries that do not have safety systems in place and will provide economic benefits to exporting countries that allow FDA inspectors the relevant powers to ensure patient safety. If a country, or indeed, even an individual factory, agrees to allow FDA oversight similar to that which our domestic industry faces, we could lift the import alert on its products.

The dynamic nature of and potential for terrorism requires a heightened attention to factory inspection. The FDA must have extraterritorial powers to perform these activities using dedicated investigative resources on the ground. Intelligence networks of supporting agencies like the CIA and international organizations like INTERPOL must be coordinated to include safety of the drug supply as a key concern.

Finally, diversifying supply must also be a goal. Relying on one suspect country with which we do not have strong relations is a precarious strategy at best. It is imperative that “drug diplomacy” is a concept that is taken seriously when determining where to invest resources in nation building and developing relationships. Working to ensure that international discussions regarding international security and cooperation should expressly keep safety of the drug supply on the agenda.

The worldwide drug manufacturing and distribution system is fractured and rife with vulnerability. A coordinated system must be reactive to address the risks of past system failures while also being proactive to manage newer risks. This concept is fundamental to improving patient safety in good-faith systems. But in the broader and dangerous underground systems, band-aid solutions that take into account only good faith actors—not also those who seek to

take advantage of system weaknesses—will leave us farther and farther behind those who seek to exploit these vulnerabilities. And that is a prescription for disaster. **IPSQH**

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