The challenge of curbing counterfeit prescription drug growth: Preventing the perfect storm

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Abstract The recent case of fake Avastin® brought the problem of counterfeit pharmaceuticals to the forefront of illicit trade. Drug counterfeiters are opportunistically motivated by the windfall profits that are realized from selling fake pharmaceuticals with limited legal penalties. This article describes the interrelated trends that may trigger a catastrophic situation of counterfeit drugs infiltrating the global pharmaceutical supply chain—a ‘perfect storm.’ We discuss the failure of policymakers to note the early warning signs and the ease of penetrating the pharmaceutical supply chain—both physically and virtually—by an array of illicit traders, ranging from small cottage operations to full-scale manufacturing facilities; the recent U.S. legislation enacted to curb growth in counterfeit pharmaceuticals; and the proliferation of national, multilateral, and industry-led agencies to protect the prescription drug supply chain. Finally, we conclude with an analysis of anti-counterfeiting tactics (e.g., consumer education campaigns, authentication technology) developed by various stakeholders.

1. Predicting the size of the storm: An elusive task

Ronald Noble, secretary-general of INTERPOL (international police organization), stated: “The Avastin case was a watershed moment for law enforcement to recognize that this is not a problem restricted to one part of the world. . . . It let the U.S. know it’s not immune to [counterfeit drugs]” (Weaver & Whalen, 2012). The World Health Organization (2012) defines counterfeit pharmaceuticals as “medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source.” Almost 15 years ago, in his book, Bitter Pills: Inside the Hazardous World of Legal Drugs, Stephen Fried (1998) estimated that 10% of the world drug supply was counterfeit. In a report published by the U.S. Customs and Border Protection, the domestic value of counterfeit drug seizures in 2011 was $16.68 million, an increase of 200% from 2010 to 2011 (CBP Office of International Trade, n.d.). The top three source countries based on
the domestic value and volume of counterfeit goods seized in 2011 were China (62%), Hong Kong (18%), and India (3%) (CBP Office of International Trade, n.d.). Since U.S. Customs searches a very small percentage of all products entering the United States, this data significantly underestimates the problem (Chaudhry & Zimmerman, 2009).

As illustrated in Figure 1, the Pharmaceutical Security Institute (2012) provides insight regarding the number of pharmaceutical crime incidents by region, yet recognizes the fact that many counterfeit medications remain undetected in the legitimate supply chain. Importantly, use of counterfeit pharmaceuticals can kill. The think tank, International Policy Network, estimated that 700,000 annual deaths can be attributed to counterfeit drugs to treat or prevent malaria and tuberculosis (Harris, Stevens, & Morris, 2009).

In April 2012, Ron Guido, Vice President of Global Brand Protection at Johnson & Johnson, in his presentation at the International Quality and Productivity Center (IQPC) conference, summarized that counterfeiting and diversion of pharmaceuticals is a result of many factors including: free trade agreements; growth and capitalization of emerging markets; Asia becoming the ‘world’s factory’; the Internet, due to lack of regulations and knowledge of supply; illicit traders who are well-funded and technologically advanced, and who have a high reward-to-risk ratio; under-resourced regulatory and enforcement agencies; lack of protection for intellectual property (IP) in some countries; liberal legislation governing cross-border trade; and lack of control and visibility of supply chain activities (Guido, 2012). In the upcoming sections, our discussion centers on the ease of penetrating the pharmaceutical supply chain by an array of illicit traders, ranging from small cottage operations to full-scale manufacturing facilities and fake online pharmacies, and the recent proliferation of agencies and U.S. legislation designed to curb the problem.

2. Early warning signs of a storm brewing were marginalized

Katherine Eban’s (2005) provocative reporting in her book, Dangerous Doses, attempted to raise awareness surrounding the ease of unscrupulous counterfeiters entering this market. One year later, Moisés Naim (2006) discussed an array of illicit trade in various sectors, including fake pharmaceuticals, in Illicit: How Smugglers, Traffickers, and Copycats are Hijacking the Global Economy. In 2009, our work on consumer complicity to obtain illicit pharmaceuticals in Brazil, Russia, India, China, and the United States was reported in The Wall Street Journal such that business managers might better understand why consumers seek them (Chaudhry & Stumpf, 2009). Roger Bate (2012) raises the health issue in his book, Phake: The Deadly World of Falsified and Substandard Medicines, focusing on the illicit trade in Africa, India, China, and the Middle East.

Extensive media coverage of fake Avastin®, a drug used in the treatment of cancer, was breaking news in 2012. In The Wall Street Journal, Jeanne Whalen (2012) initially reported the fake pharmaceutical in the U.S. supply chain as allegedly coming from an Egyptian supplier. Just one month later, Weaver, Whalen, and Faucon (2012) claimed that Avastin® was distributed through online Canadian pharmacies, with an overall trade route that:

[I]llustrated the circuitous path that pharmaceuticals can take before reaching consumers. Wherever the counterfeit Avastin was manufactured—possibly China—investigators are examining a zigzagging route that may have taken the product through Turkey and Egypt before it was sold to Swiss and Danish wholesalers and then to Mr. Haughton’s [a Canadian citizen] UK wholesaler, River East Supplies Ltd.

Finally, in July 2012, the ‘path of fake Avastin®’ was highlighted by Weaver and Whalen (2012) in The Wall Street Journal as an interactive learning tool, to better help readers comprehend the global distribution channel. While it is difficult to know the full extent of the problem, reports on counterfeit drugs increase dramatically every year; Table 1 illustrates a few recent cases.

3. Major stakeholders in the tempest

To better understand the actors in the U.S. pharmaceutical marketplace, we now present a succinct description of the market served by both manufacturers and wholesalers, including a discussion of
illicit traders and how they supply fake pharmaceuticals—especially by way of rogue online pharmacies.

### 3.1. The legitimate manufacturers

In its annual report on the U.S. pharmaceutical industry, Datamonitor (2011) estimated revenues in this sector at $265.7 billion in 2010, with market growth of 5.5% for the 2010-2015 time frame to $346.7 billion. Four firms control almost 30% of the U.S. marketplace: Pfizer (10.9%), Merck & Co. (6.1%), GlaxoSmithKline PLC (5.7%), and Johnson & Johnson (4.7%). Concurrently, 72.5% of the market is served by other manufacturers. Lennard and Matlis (2011) summarize the six principal threat concerns of pharmaceutical industry professionals regarding their supply chain as:

1. Contaminated/non-conforming raw materials (61%);
2. Impact on product safety, efficacy, and effectiveness (51%);
3. Our product being counterfeited (44%);
4. Lack of ability to trace products (43%);
5. Cost of complying with additional regulatory burdens (42%); and
6. Our product being diverted (35%).

Several of these threats are interrelated to the continued growth of counterfeit trade, such as inability to track products.

### 3.2. The market dominance of three big wholesalers

Fein (2011) illustrated the market dominance of three companies controlling 85% of the U.S. wholesale pharmaceutical market in 2010, with almost $300 billion in annual revenue shared between AmerisourceBergen Corporation ($80.7 billion); Cardinal Health, Inc. ($97.4 billion); and McKesson Corporation ($113.5 billion). The remaining 15% of the market is fragmented by a variety of smaller players, such as Morris & Dickson ($3.7 billion) and H.D. Smith ($3.4 billion). Overall, there are hundreds of secondary wholesalers and re-packagers that can handle prescription drugs before the product reaches the consumer’s mailbox or retail pharmacy. These extra layers in the distribution network create a porous system which limits visibility, leaving opportunities for counterfeit drugs to enter the supply chain (Health Strategies Consultancy LLC, 2005). Eban’s (2005) reporting in Dangerous Doses clearly illustrates illicit traders infiltrating the ‘Big Three’ U.S. wholesalers and other distribution channels with their lower prices. Of the U.S. supply chain, the journalist said (Eban, 2005, p. 130):

> Everybody bought from everybody. The biggest, most established wholesalers, including Cardinal and Amerisource, vetted their vendors in

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**Table 1. Recent examples of counterfeit pharmaceuticals**

<table>
<thead>
<tr>
<th>SFFC medicine</th>
<th>Country/Year</th>
<th>Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avista (cancer treatment)</td>
<td>United States of America, 2012</td>
<td>Affected 19 medical practices in the U.S.A. The drug lacked active ingredient.</td>
</tr>
<tr>
<td>Viagra and Cialis (erectile dysfunction)</td>
<td>United Kingdom, 2012</td>
<td>Smuggled into the UK. Contained undeclared active ingredients with possible serious health risks to the consumer.</td>
</tr>
<tr>
<td>Zidolam-N (HIV/AIDS)</td>
<td>Kenya, 2011</td>
<td>Nearly 3,000 patients affected by falsified batch of their antiretroviral therapy</td>
</tr>
<tr>
<td>Alli (weight-loss)</td>
<td>United States of America, 2010</td>
<td>Smuggled into the U.S.A. Contained undeclared active ingredients with possible serious health risks to the consumer.</td>
</tr>
<tr>
<td>Anti-diabetic traditional medicine (to lower blood sugar)</td>
<td>China, 2009</td>
<td>Contained six times the normal dose of glibenclamide. Two people died, nine people were hospitalized.</td>
</tr>
<tr>
<td>Metakelfin (antimalarial)</td>
<td>United Republic of Tanzania, 2009</td>
<td>Discovered in 40 pharmacies. The drug lacked sufficient active ingredient.</td>
</tr>
</tbody>
</table>

advance. After that, price was the guiding criterion—the lower, the better. Once suspect medicine entered the Big Three’s warehouses, it became intermingled with—and inseparable from—medicine purchased directly from manufacturers.

3.3. The virtual sea of fake online pharmacies

Various stakeholders have described the purchase of prescription drugs as a major issue fueling the aforementioned ‘perfect storm.’ The distribution of fake drugs online represents a labyrinth of illicit traders who deceive consumers about the legitimacy of their websites and products. In July 2012, the National Association of Boards of Pharmacy (NABP)—the governing body for state agencies that license pharmacies—reported that 97% of the 10,065 online pharmacies were illegitimate. The NABP describes the situation as follows (Internet Drug Outlet Identification Program, 2012):

When counterfeit medicines emerge, as they have repeatedly in the last year, it is difficult to trace their origin, the point in the supply chain at which they were introduced, who perpetuated the illegal transaction, and which parties knew about it and enabled it in any way. Because Internet commerce transcends geographical and jurisdictional borders, protecting the public health requires the coordinated efforts of multiple, international public and private entities to diminish the threat that counterfeiters and rogue sellers pose.

In September 2012, the Food and Drug Administration (FDA) launched its BeSafeRx (2012) campaign to educate consumers about the menace of counterfeits available via fake online pharmacies. This campaign centers on three distinct messages:

1. Know the Risks (e.g., you could receive counterfeit or substandard drugs);
2. Know the Signs (e.g., beware of deep discounts/cheap prices); and
3. Know your Online Pharmacy (provides a web link for the consumer to authenticate his/her pharmacy).

In 2011, The Center for Safe Internet Pharmacies (CSIP) was created to represent a dozen of the top Internet payment processors and e-commerce firms, jointly working together to curtail fake drugs sourced online. CSIP founding members include payment facilitators (e.g., American Express, Discover, PayPal), search engines (e.g., Google, Yahoo!), and domain name registrars (e.g., Go Daddy). The NABP is also currently working on securing a top-level domain name, dot.pharmacy, for use in identifying genuine online pharmacies.

3.4. Illicit suppliers range from cottage industries to full-scale manufacturing facilities

The profit potential of selling counterfeit pharmaceuticals lures an array of opportunistic criminals into the squall of the storm. In the journal Science News, Ehrenberg (2011) estimated that a $1,000 investment in illegitimate prescription drugs can yield a $30,000 return—10 times the profit rate of trafficking heroin! Illicit pharmaceuticals dealers stand to earn windfall gains due to potential sky-high profits, relatively low barriers to entry, and the limited legal recourse that exists against engaging in this dark side of counterfeit trade. Attempting to describe these unscrupulous players is an elusive task; it is illicit trade, and narratives of these criminals must be drawn from a multitude of sources (Chaudhry & Zimmerman, 2012). For example, the array of reports on illicit traders ranges from profiling a person—such as Michael Carlow, leader of a group that sold millions in fake drugs in Florida (Eban, 2005)—to profiling operations, such as full-scale manufacturing facilities in China (United Nations Office on Drugs and Crime, 2010). Michael Carlow specialized in the sale of counterfeit cancer, HIV, and cholesterol drugs such as Lipitor, and received a 9-year sentence in 2010. The value of his trafficking of just one fake version of Lipitor was estimated at $43 million (LaMendola, 2010).

A 60 Minutes exposé by Sanjay Gupta (2011) reports the counterfeit pharmaceutical drug trade as a $75 billion annual global industry. The news segment shows footage of a sting operation in Peru that led to uncovering the production of counterfeit goods in the basement of a house in Lima. This lucrative illicit trade can be relatively uncomplicated, yet may also be much more than a cottage industry. A recent report of the United Nations Office on Drugs and Crime (2010)—or UNODC—describes the gamut these operations can run (p. 8):

The production of counterfeit pharmaceuticals can be as simple as producing alternative packaging materials using a laser printer or as complicated as the production of the original product. In general, counterfeit production in China appears to be more sophisticated than in India. In China, counterfeit drug producers are
often chemical companies that are not licensed to produce pharmaceuticals, or licensed companies that produce both legitimate and bogus drugs.

In August 2012, The Wall Street Journal reported that over 2,000 individuals were arrested in China for the trafficking of fake pharmaceuticals worth $182 million (Burkitt, 2012). By contrast, the United Nations Office on Drugs and Crime (2010, p. 8) classifies illicit traders in India as “unlicensed manufacturers who operate out of small cottage factories, licensed manufacturers who secretly make fake drugs alongside their legitimate products, and importers who bring in drugs from China and then fraudulently repackage them.”

The overarching problem on the supply side is that the barriers to entry for making fakes have been lowered by the ease of buying pharmaceutical machinery on Internet auction sites and the proliferation of printing technology that makes any unskilled trader able to duplicate pharmaceutical packaging (Chaudhry & Zimmerman, 2012). Figure 2 illustrates how difficult it would be for a consumer to discern between real versus fake Tamiflu simply based on packaging. The necessary equipment and materials to set up production for illicit drugs are just a click away on the Web. For example, Figure 3 is a screen shot of a recent search for a ‘pill making machine’ at the Internet auction site Alibaba.com; there were 913 results for this type of machinery. Another query, ‘packaging pharmaceutical’ yielded 73,663 hits for various packaging materials, such as blister packs from suppliers around the globe—primarily China.

4. The proliferation of agencies designed to stifle the storm

Patricia Van Arnum (2012), senior editor of Pharmaceutical Technology, highlights that cooperation between regulatory bodies, standard-setting organizations, and industry is needed to address the illicit trade of counterfeit pharmaceuticals and safeguard the supply chain of ingredients. The Institute of Research Against Counterfeit Medicines (IRACM)
illustrates the need for global harmonization of legislation and sanctions that apply to the trafficking of fake drugs, since courts will garner redress through violation of the protective laws of intellectual property; crime of deceit and falsification; misleading or fallacious information and advertising; violation of rules regarding dispensation; import and distribution of products without marketing authorization; and illegal practice of the pharmacist profession (“Tracking and Condemning,” 2012). At the international level, several agencies—such as the World Health Organization’s International Medical Product Anti-Counterfeiting Taskforce (WHO IMPACT), Interpol’s Medical Products Counterfeiting and Pharmaceutical Crime (MPCPC), the Institute of Research Against Counterfeit Medicines (IRACM), and the Permanent Forum on International Pharmaceutical Crime—are addressing the problem. Other multilateral agencies, such as the World Customs Organization (WCO) and World Intellectual Property Organization (WIPO), are involved with the over-arching problem of counterfeit trade in a variety of products. Figure 4 portrays a summary of selected agencies that are currently working on the problem.

In the United States, key organizations to consult are the FDA; the Office of the Intellectual Property Enforcement Coordinator (IPEC); Customs and Border Protection (CBP); Immigration and Customs Enforcement (ICE); the Departments of Justice, State, and Commerce; and the Agency for International Development. In fact, all of these agencies represented the Counterfeit Pharmaceutical Inter-Agency Working Group in a March 2011 report to the Vice-President and U.S. Congress on counterfeit medicines. Each has its own hierarchy, with select alliances with one another (see Figure 5).

5. U.S. legislative actions center on penalties and drug distribution to diffuse the storm

In the U.S. legislative pipeline, two proposed changes center on sentencing guidelines and drug
distribution. H.R. 3468: Counterfeit Drug Penalty Enhancement Act of 2011 is a bill with the aim to increase penalties and prison sentences for traffickers of fake pharmaceuticals. Table 2 illustrates how this bill would amend the current sentencing guidelines found in Section 2320(a) of title 18, United States Code. H.R. 3026: Safeguarding America’s Pharmaceuticals Act of 2011 is meant to amend the Food, Drug, and Cosmetic Act, and improve the safety of the country’s drug supply. If passed, the bill will introduce measures to track the supply chain of the wholesale distribution of pharmaceuticals and includes provisions that allow for the destruction of counterfeit pharmaceuticals offered for import into the United States. This bill includes tracking measures—such as standard numerical identifiers—for pharmaceuticals and would establish a regulatory system for various entities in the supply chain (e.g., drug manufacturers, re-packagers, wholesalers) to authenticate the ‘history’ of the drug, and create a new system for licensing pharmaceutical wholesalers. The status of enacting these bills in the U.S. Congress can be tracked at www.govtrack.us.

6. Recent tactics to suppress the bluster of the storm

Various stakeholders have provided myriad recommendations aimed at diffusing the storm, ranging from novel authentication technology to public education via consumer awareness campaigns. Next, we highlight some of the more recent anti-counterfeiting tactics for illustrative purposes only.

6.1. Raising consumer awareness through government and agency-led initiatives

The NABP website attempts to educate consumers regarding how to validate real versus fake pharmaceuticals as follows (“Why Should I Be Concerned,” n.d.):

- Packaging — Does the packaging look as though it has been compromised?
- Labeling — Is the label on crooked? Is it different than the label the prescription drug had before?

| Table 2. Proposed change in sentencing guidelines for trafficking counterfeit drugs |
|-------------------------------|-------------------------------------------------|---------------------------------|
|                               | Counterfeit Drug Penalty Enhancement Act of 2011 (H.R. 3468) | 18 USC 2320: Trafficking in Counterfeit Goods or Services |
| Maximum fine for an individual/prison term | $4 million Life imprisonment or for any terms of years | $2 million 10 years |
| Maximum fine for entities (e.g., company) | $10 million | $5 million |
| Repeat individual offender/prison term | $8 million Life imprisonment or for any terms of years | $5 million 20 years |
| Repeat entity offender | $20 million | $15 million |
Figure 6. Authentication technology designed for pharmaceutical packaging

- Pill Appearance — Are the pills cracked or chipped? Has the pill color changed? Does it appear a shade different from earlier prescriptions?

- Pill Taste — Does the drug taste different?

- Side Effects — Did you experience any adverse effects?

A variety of public awareness messages have recently been developed to address fake pharmaceuticals, including the CSIP ‘Be Safe. Buy Smart,’ INTERPOL ‘Proud to Be,’ and FDA ‘BeSafeRx’ campaigns. The challenge lies in waiting to see if this type of education ultimately alters buyer behavior. Will consumers heed the warnings and take a closer look at their pharmaceuticals, distributed both in physical and virtual marketplaces?

6.2. Educating consumers via company-led social media initiatives

Pfizer, manufacturer of the heavily counterfeited erectile dysfunction drug Viagra, used social marketing to leverage its ‘Counterfeiters are Smart. You can be Smarter’ campaign. The firm employed Google search ads, ‘Counterfeit Pills Can Be Dangerous,’ to link up to video content on YouTube at [http://www.youtube.com/viagra](http://www.youtube.com/viagra) (Kaye, 2012). The current corporate YouTube channel contains 11 distinct video segments on various topics, allowing the firm to present consumers with information about illicit pharmaceutical trade via digital material. Pfizer is at the forefront of enlisting YouTube, Twitter, SlideShare, and LinkedIn to spread awareness of the problem.

Another anti-counterfeiting tactic entails empowering consumers at the point of purchase, allowing verification of the drug through a text or code. Pharmaceutical firms can use a labeling technique, such as IT’S TRUE® ([www.its-true.com](http://www.its-true.com)), for consumers to determine whether they have obtained legitimate product (see Figure 6). The manufacturer simply affixes a packaging label that contains a concealed code, which the customer can validate by way of smartphone or text message (“Counterfeit Drugs,” 2012).

6.3. Using authentication technology: Empowering IP enforcement officials

In our opinion, consumer identification of real versus fake is an elusive task (see Chaudhry & Zimmerman, 2009, 2012). As discussed previously, illicit pharmaceuticals traders are concentrating their efforts on imitation and easy access to the printing technology that is necessary in developing copycat packaging. Thus, we feel that detecting fake pharmaceuticals should be further up the supply chain, focusing especially on ports of entry and international mail. Toward this end, the FDA recently unveiled a new tool that will be helpful in this area: the hand-held Counterfeit Detection Device #3, or CD3. The CD3 emits light waves and, when aimed at counterfeit drug products, shows differences in color or shade as compared to the authentic article. As it is easy to use, relatively inexpensive ($1,000 per device), and completely portable, the CD3 will enable international mail inspectors and customs and border protection officers at various U.S. ports of entry to authenticate pharmaceuticals in ‘real time’ (“FDA Unveils,” 2012).

References


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