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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 opportunistic criminals 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

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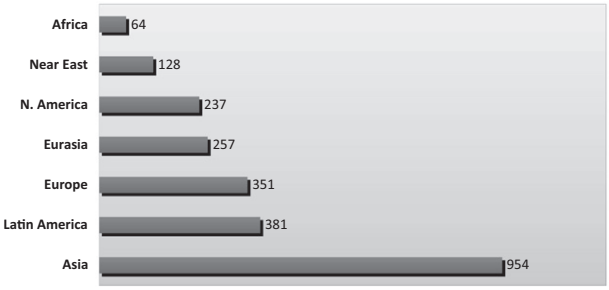
Figure 1. Pharmaceutical crime incidents - Regions of the world



Source: Adapted from the Pharmaceutical Security Institute (2012)

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