
Original Article

Promoting online drug safety: Using public–private partnerships to deter illicit online drug sales

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ABSTRACT Illicit online pharmacies selling counterfeit drugs in a global virtual marketplace remain a critical problem in global health. Yet they continue to operate with little regulation while growing numbers of consumers access the Internet for health information that may lead them to purchase dangerous drugs online. This global social problem requires immediate action to protect patient safety and public health. Public–private partnerships models represent a potentially effective way to address this issue through promoting mechanisms of collaboration and coordination of multiple stakeholders.

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INTRODUCTION

Globalization and the digital technology revolution has led to the explosive growth of an online marketplace accessible to anyone with an Internet connection. With an estimated 2 billion people using the Internet and the continued growth of mobile technology, the Internet and its services have become ubiquitous in many people's lives.¹

This growth has fueled an illicit business of selling counterfeit drugs online by Internet pharmacies. Valued at an estimated US\$11 billion,² the online pharmaceutical market shows no signs of abating, and is driven by an even larger international market of counterfeit sales valued at some \$75 billion.³

This combination of demand and ease of online sales means there is no shortage of sellers that supply fake, substandard, tainted, unapproved, misbranded or otherwise poor-quality medicines online. The underground market produces a wide spectrum of products from lifestyle drugs (such as Viagra)

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to life-saving drugs (such as anti-malarial drugs) that are extremely difficult to differentiate from authentic medicines.⁴ The consequences for global health are dire, with counterfeit medicines leading to anti-microbial resistance in disease such as malaria, HIV and tuberculosis, causing hundreds and thousands of deaths in developing countries.⁵ Collectively, these counterfeit medicines present a serious problem to the safety and validity of the global drug supply chain, with the Internet representing one of the most cost-effective and accessible ways for illegal market entry and distribution.

Added to this problem is the current global economic crisis that has left many uninsured and/or lacking resources to access needed health-care services and medicines.⁶ For these consumers, online drug purveyors may represent an option for needed therapy or viewed as an attractive alternative to traditional forms of health-care access that may be costly or inaccessible. Online drug sellers may also use deceptive marketing practices that prey on consumer preferences such as value, convenience and trust, yet may conceal the risks, benefits and safety concerns of their products.⁷ Further, online drug sellers may use targeted marketing to attract vulnerable patient populations such as seniors, adolescents, the uninsured and underinsured, handicapped persons and consumers of low socio-economic status.⁸ This includes targeted promotion using emerging technology such as social media, which has the potential to impact millions of users simultaneously.⁹

Most importantly, purchases of drugs from online pharmacies are dangerous, leading to morbidity and mortality globally. This includes tragic cases of patient deaths in the United States, which is the largest consumer of pharmaceutical products and a lucrative market for online pharmacies. Despite these known dangers to patient safety, adverse events related to online drug sales are difficult to accurately quantify through current surveillance systems.¹⁰ This can lead to underreporting, making it difficult to

adequately assess the size and scope of this growing public health problem.

The combination of these push and pull factors has created the perfect storm for supply and demand of dangerous products that can physically hurt, harm and kill unsuspecting consumers who may lack treatment options. Yet online drugs are still readily available with little regulation or oversight, necessitating further exploration of effective solutions.

CHALLENGES IN REGULATION

Global regulation and enforcement of the illegal online pharmacies is extremely challenging due to a complex and borderless global supply chain with system gaps, the underlining characteristics of web-based technology, the multitude of illicit and legal actors directly and indirectly involved, problems of detection and surveillance, and legal enforcement actions that need to be carried out across international markets. Collectively, these issues require a comprehensive solution that recognizes the individual characteristics as well as the interrelatedness of these diverse challenges.

GLOBAL TRADE GAPS

System gaps and vulnerabilities such as countries that allow parallel trade in pharmaceutical products (such as the European Union), free trade zones and repackaging and relabeling of products may enable Internet sales to occur from supply to source countries and make any kind of detection or regulation difficult.¹¹ Similarly, criminal elements may divert products by stealing or diverting medicines that have been donated or procured for specific aid programs (low-cost channels), and then reselling them at a profit (to high-cost channels).¹² Recent thefts such a US\$75 million heist involving antidepressant medicines from an Eli Lilly warehouse, which are thought to be destined for international markets, highlight concerns regarding diversion of drugs, which may make their way into online pharmacy

distribution, yet may be substandard by the time they reach consumers.¹³

THE NATURE OF THE WEB

The dynamic environment of the World Wide Web, which changes on a constant basis, makes it extremely difficult to identify the sources and business owners of rogue online pharmacies. This includes continuous recycling of online pharmacy web sites enabled by Internet technology, which allows virtually anyone to open and close a web site with little initial investment, particularly when compared with capital investment in traditional brick-and-mortar establishments. Web sites being pursued as engaging in illicit activity can be quickly shut down then reopened under a different URL or name with little chance of detection.

In addition, the anonymity of the web allows for criminals to hide behind several layers of underlining service providers, making it difficult to identify the owner of illegally operating sites. Often online pharmacies will mask their identity using registrar or listing companies and agents in their domain registrations. They may also use networks of affiliate sites linking to a master parent site that actually provides services and sales. Affiliate sites not only act to conceal identity, but also provide portals and links to more illicit forms of drug purchasing, such as for controlled substances. Hence, even if a web site is identified as acting illegally, it may be difficult to determine ownership and location of the site needed to effectuate enforcement action.

NETWORK OF ILLICIT AND LEGAL PRIVATE SECTOR ACTORS

Inherent to the complex problem of online pharmacy regulation and enforcement is the presence of a diverse mix of private sector actors across multiple industries. This includes illicit manufacturers as well as third-party facilitators and service providers that enable online drug sales.

Illicit manufacturers of counterfeit drugs often provide online pharmacies with their

products. These manufacturers vary to a high degree in quality and scale of manufacturing, and are often located in developing or emerging countries such as India and China, making enforcement extremely difficult. Without adequate enforcement efforts locally, these manufacturers continue to meet demand for this illicit activity and reap profits as wholesalers for illicit retail online sales.

In addition, though the Internet is generally accessible to anyone and relatively anonymous, the logistics of a web site involved in e-commerce cannot function without information technology services from a number of different, third party enabling providers. This includes the services provided by Internet search engines, payment processors, shipping and logistic providers, Internet services providers (ISPs) and domain registrars and other data aggregators. These providers also collect a plethora of identifying data necessary to both identify sites and enable sites to transact business.

Service providers benefit financially from illegal transactions of illicit online pharmacies. This includes the payment of search engine marketing fees for ad words, search engine optimization and sponsored web advertising, shipping and processing fees by logistic providers, payment processing fees for online payment processors as well as card services (VISA, MasterCard and so on) and other fees associated with marketing or hosting a web site online. Given that these service providers enable such activity, a broader question emerges whether service providers profiting from illicit activity need to more actively engage in surveillance, oversight and enforcement at their own cost.

Data aggregators, such as web sites that provide dubious ratings of online pharmacies (that is, www.pharmacychecker.com), and forum and membership sites that link web users to online pharmacies, are not directly engaged in online drug sales, but nevertheless facilitate illegal activity. These service providers also profit from membership fees and online advertising, yet are completely unregulated and

remain untargeted in enforcement actions. This unique set of service providers is quickly emerging as either a secondary or even primary source of information for buying all types of drugs online.

STRATEGY: PUBLIC–PRIVATE PARTNERSHIPS

Online pharmacies are enabled by gaps in the global pharmaceutical supply chain. Using public–private partnerships leveraging characteristics of Internet–based technologies and engaging private sector service providers can be the basis of a comprehensive strategy to address this global public health concern.

OPERATION PANGAEA III

In October 2010, a multi-sector public–private partnership operation shut down 290 illegally operating Internet pharmacies.¹⁴ Code named ‘Operation Pangea III’, the international operation coordinated efforts of more than 40 countries and participation of a multitude of public and private sector actors such as the World Health Organization’s International Medical Products Anti-Counterfeiting Taskforce, Interpol, the World Customs Organization, the Heads of Medicines Agencies, international law enforcement, customs agencies and pharmaceutical regulators, the pharmaceutical industry, ISPs and electronic payment processors, to combat the online sale of counterfeit and illegal medicines.

Results from the operation were promising, with 11 000 seized packages, 1 million illicit and counterfeit pills confiscated (valued at some \$2.6 million), and 76 individuals arrested for criminal acts. The operation also included a public health campaign via YouTube, which highlights the dangers of online pharmacies through case studies involving a number of different drug products and types of consumers. Hence, Operation Pangea III represents a real-life example of how coordination and cooperation among the public and private sector can lead to enforcement actions that shut down illegal Internet pharmacies,

counterfeit manufacturers/suppliers and criminals engaged in this illicit activity.

PUBLIC–PRIVATE STAKEHOLDER COORDINATION EFFORTS

The private sector has also partnered with the US government to support the formation of a nonprofit organization to target illegal online pharmacies.¹⁵ This effort, driven by calls by the intellectual property enforcement coordinator of the White House, brings together a number of private sector actors including Google, Yahoo!, MasterCard, Visa, American Express, GoDaddy.com, Neustar, Ebay and Paypal, to actively police illegal online pharmacies through private industry efforts. Such action represents an important first step in engaging the private sector in active surveillance and enforcement, yet lacks tangible support and formalized involvement from the public sector in coordinating and leading these efforts.

CONTINUING CONCERNS

Though recent actions are commendable, they fail to address key challenges of actively regulating online pharmacies. This includes engaging in efforts to prevent recycling and reopening of illegally operating online pharmacies after enforcement actions have completed, providing active surveillance to prevent web sites from becoming active, and establishing sustained coordination and cooperation vehicles of international public and private sector actors in continuous enforcement and surveillance of illegal online pharmacies. In order to accomplish these goals, a more robust public–private partnership model is required.

IMPLEMENTING A SOLUTION: A PUBLIC–PRIVATE PARTNERSHIP MODEL

In an attempt to combat some of the challenges of current efforts, a fundamental framework for use of public–private partnership models to appropriately address

online pharmacies is required. This includes the development of a centralized system leveraging the technical strengths from both the public and private sectors that focus on three key tenets: (a) surveillance, (b) enforcement and (c) prevention.

This would include engaging private sector service providers with access to information about illegal online pharmacies to provide active surveillance and reporting of illegal activity involving pharmaceutical sales online and assessing both actions of illicit online pharmacies but also other service providers who facilitate such illegal sales. Coupled with private sector partners that could immediately review and in some cases confirm such reporting, public actors can respond dynamically to threats as they emerge. This active public–private surveillance–enforcement approach could also lead to better proactive prevention measures that would ensure illegal online pharmacies were not accessible to patients and/or are permanently taken down once identified.

The benefits of engaging cooperative means between the private and public sectors are clear. They include active, real-time surveillance of illegal activity involving the online sale of pharmaceutical products, denying criminal access to vulnerable patient populations and promoting public health and welfare. The cost of such patient safety and public health systems should be shared across sectors given that this is a societal wide problem. In addition, learning from these activities can allow anticipatory actions and policies to be developed that can be uniquely implemented across the public–private spectrum of interested stakeholders. This, coupled with development of a robust regulatory pathway for legitimate online pharmacies, such as the VIPPS (Verified Internet Pharmacy Practice Site) accreditation operated by the National Association of Boards of Pharmacy, would identify legitimate online pharmacies for consumer use. This would insulate global populations from the risks of counterfeit products, misleading

marketing and poor individual choices to purchase dangerous drugs online. In combination, illicit suppliers would be reduced, whereas regulated, legitimate suppliers could increase all while dynamic and continuous public–private efforts are continued to protect the safety of the drug supply.

CONCLUSION

Anyone can open an Internet browser, enter a search for the drug of choice, and find a way to purchase a prescription drug online, often illegally without a prescription. The reality that these dangerous online counterfeit drug purveyors continue to profit from the misery and injury their products inflict on consumers should act as a call to action to develop regulatory and enforcement models that will prevent such activities from being accessible. Recent coordination between public and private sectors has shown some success in this area, but more work is needed to develop innovative public–private partnership models that actively engage in surveillance, enforcement and prevention efforts to ensure that illegal online pharmacies are no longer a mouse-click away from endangering a patient's life.

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