


# Current Threats to Maintaining a Secure Pharmaceutical Supply Chain in an Online World

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## Abstract

**Background:** Maintaining integrity of the pharmaceutical supply chain is critical to providing medications that are free from adulteration (counterfeit, substandard or unapproved medications), making them safe for patient use. Purchasing pharmaceuticals through the Internet can be associated with a risk of receiving adulterated medicines. **Objective:** The objective of this study was to review the current threats to maintaining a secure pharmaceutical supply chain, specifically focused on Internet-based procurement of medications. **Methods:** A review of the literature was conducted along with collating important up to date resources and other publications that provide foundational information to understanding the risks and prevention strategies for online purchasing of pharmaceuticals. **Conclusion:** The information provided in this article helps to properly inform pharmacy leaders to the resources available to protect against the risks of on-line purchasing of pharmaceuticals.

## Keywords

pharmaceuticals, online, quality assurance, safety, counterfeiting

## Introduction

The pharmaceutical supply chain is designed to efficiently deliver legitimate medications from their original source to hospitals, dispensing pharmacies, and other providers (physician offices, clinics, surgery centers). This global complex system begins with raw materials, which are in turn processed by manufacturers and properly distributed throughout the world. The pharmaceutical supply chain includes primary and secondary wholesale distributors and packaging, and dispensers such as hospitals and community pharmacies, all ultimately leading to patients and consumers.<sup>1</sup>

The US pharmaceutical supply chain is one of the safest in the world, but also increasingly complex. External threats—importation of substandard and/or falsely labeled (SF) drugs, Internet commerce, and expanding gray markets—challenge the resiliency of safe guards. These threats result in unsafe and ineffective medication entering the US pharmaceutical supply chain.<sup>2</sup> There are growing examples of supply chain failures resulting in patient harm and death.<sup>3</sup> The Drug Supply Chain Security Act (DSCSA) was signed into law in 2013, and the resulting provisions have been implemented to limit the patient safety impact of supply chain threats. The DSCSA helps ensure supply chain safety and integrity, thus enabling pharmacists to provide patients with quality medication.<sup>1</sup>

Despite the enactment of the DSCSA, challenges to safe medications remain. Growth in e-commerce and health care consumerism introduce new dangers to safe sources of care.<sup>4</sup>

Although not intended to be a comprehensive review of all supply chain security issues, this article will highlight emerging trends and threats to maintaining a secure pharmaceutical supply chain, focusing on the intersection of the Internet and medication sales. Strategies to navigate this complex environment will also be introduced, including information that can be used to educate and support health care providers and their patients.

## Illegal Online Drug Sales

### Background

The Internet is constantly expanding, with over 1.7 billion Web sites active in March 2017.<sup>5</sup> Due to this evolving nature of the World Wide Web, there is potential for an increase in cybercrime. The US Federal Bureau of Investigation reported a cost of \$1 070 711 522 due to Internet crimes in 2015. These

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crimes ranged from corporate data breach and identity theft to health care–associated events.<sup>6</sup> Health care–related crime includes the financial impact associated with the illegal Internet pharmacy market.

An *illegal* Internet pharmacy can be described as an online-accessible outlet that is NOT:

- Licensed by the state board of pharmacy in the state in which its patients are located *and* the state from which the pharmacy dispenses drugs,
- Dispensing medication pursuant to a valid prescription based on a proper physician–patient relationship, or
- Selling only Food and Drug Administration (FDA)–approved medication, unless an approval exemption applies.

There are an estimated 30,000 to 35,000 active pharmacies online at any given point in time. Although many online pharmacies operate legally, operating in compliance with applicable state and federal law, more than 96% of online drug sellers do not.<sup>7</sup>

Pharmacists are concerned about illegal online drug sellers because research shows millions of Americans buy medication online, yet they rarely, if ever, tell their provider the source of their medication. Not only does this complicate medication management and pharmacist counseling, the medications procured online may themselves put the patient at risk. This is because illegal online drug sellers are bypassing drug safety and supply chain security laws in place to protect patient safety.

Illegal online drug sellers have been found to sell SF medications, unapproved products, or medication that are otherwise unsafe. For example, non–FDA–approved medication imported from outside the United States have been found to be contaminated or counterfeit, and to contain varying amounts of active ingredients (or none at all) or completely different ingredients than the FDA–approved product or what is noted on the prescription drug label.<sup>8</sup> To enhance profits, counterfeit drugs are often manufactured in unregulated locations, in unsanitary conditions, and then shipped by unregulated suppliers operating outside of the closed, regulated supply chain; these gray market actors may not maintain temperature or conduct other quality controls on the products as they travel through the supply chain.

This may sound like the content of crime novels, but counterfeit drug sales is big business in real life. The counterfeit drug market is estimated to be worth more than \$200 billion (USD) annually and dominates other industries of the underground economy, including prostitution, human trafficking, and illegal arms sales.<sup>9</sup>

Decisions to purchase from illegal online pharmacies may be influenced by consumer perception of risk. Current research suggests that specific socioeconomic characteristics and current health status may predispose individuals to accepting or rejecting risk. Therefore, it is important to determine these potential predictors that encourage use of online

pharmacies despite perceived risks. There are identified associations between demographic characteristics or health status and online pharmacy risk perception; for example, the acceptance of high risk in households with low income. Results also indicate that informing respondents about the risks may persuade these respondents. Overall, the potential impact that health care providers have on patient’s perception of risk creates an opportunity for intervention. Pharmacy leaders should engage with colleagues and consumer groups to understand the scope and possible impact of consumerism on their pharmacy enterprise. More education is needed to ensure these interventions alter patient risk perception and increase patient use of safe, legal online pharmacies.<sup>10</sup>

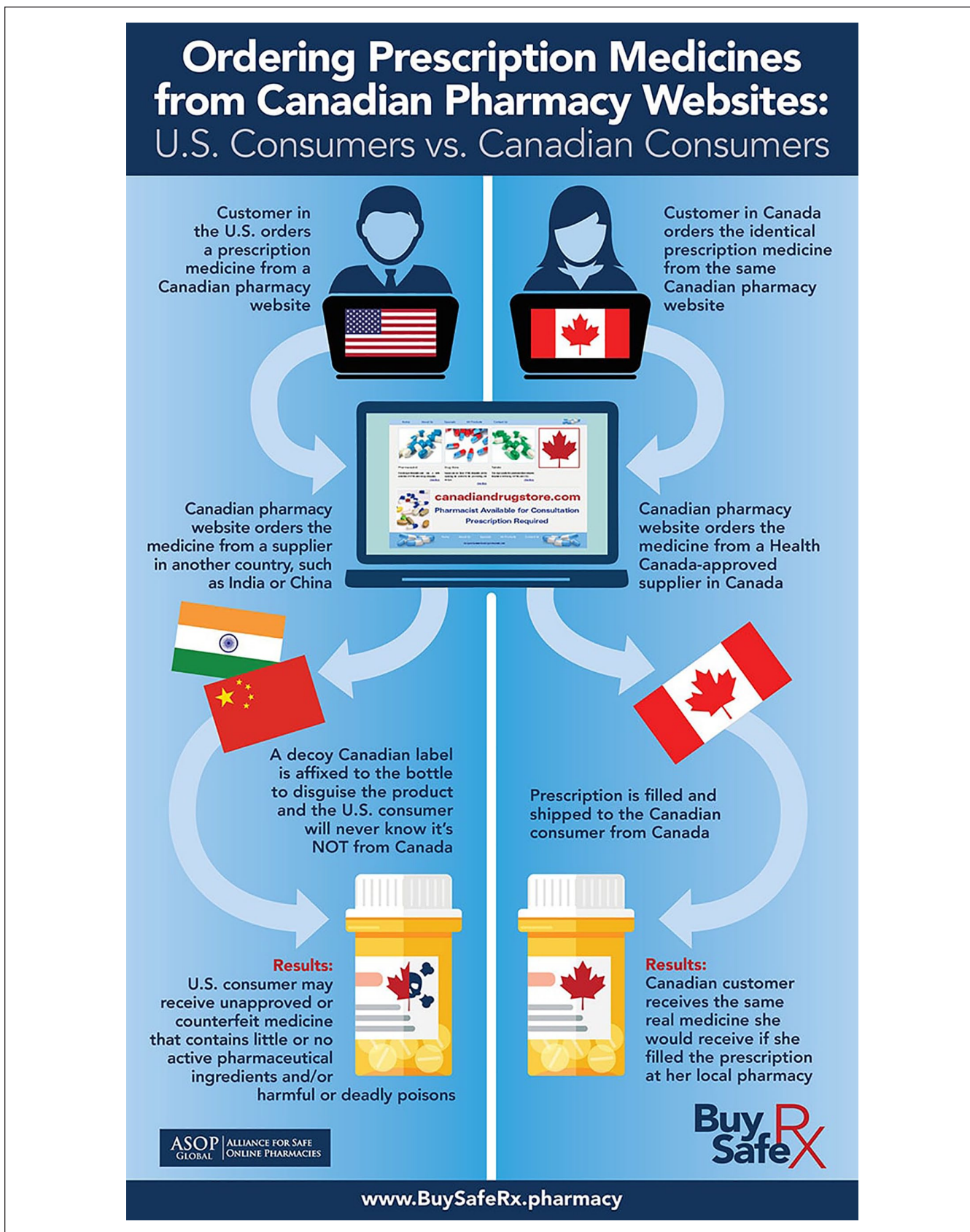
### *Online Sales of Medication From Foreign Sources*

While politicians and policymakers continue to debate the risks and potential benefits of authorizing Americans to buy medication from foreign sources, it is still currently illegal for Americans to import foreign medication. Patient safety remains a top priority, and the US FDA cannot ensure the safety of medications sourced overseas, outside of their jurisdiction and the regulated supply chain, as 4 former FDA Commissioners recently reminded Congress.<sup>11</sup> Indeed, FDA found that 85% of the medication sold online purportedly from Canada actually came from other countries. While Canada (and other countries) have legitimate pharmacies operating safely under appropriate regulations, the international and anonymous nature of the Internet allows thousands of illegal online drug sellers to evade detection. These sellers often buy medication from the cheapest source possible, transship them through a country perceived to be safe (often the United Kingdom or Canada), then use the US Postal Service to deliver the foreign products to Americans. Figure 1 illustrates this Internet-based scheme.

Despite these issues, state and federal policymakers have proposed legislation that would allow US citizens to purchase medications from Canadian online pharmacies. Proponents of this legislation maintain legal online drug importation increases competition, thus lowering drug prices and increasing access to medications in the United States. Opponents argue this represents a major threat to the US secure pharmaceutical supply chain and would endanger patient safety. No matter political or philosophical stance, pharmacy leaders should be aware of these issues, taking care to avoid unknowingly allowing patients to bring and use unverified medication in the health system.

### *Diversion and Drug Shortages*

Drug diversion takes many forms and occurs in a wide variety of settings, from individual theft to wide-scale and highly coordinated criminal activity. Internationally, diversion often occurs when large packages of medication are stolen from government warehouses or from donations/aid shipments. These medications are then sold on the private market,



**Figure 1.** Typical Internet-based schemes to distribute counterfeit and otherwise adulterated medicines. Reprinted with permission from the Alliance for Safe Online Pharmacies. [www.BuySafeRx.pharmacy](http://www.BuySafeRx.pharmacy).

typically outside the jurisdiction in which they were stolen. This is especially a problem in parts of Africa and Asia.<sup>12</sup> Diversion can be very harmful to patient populations as absence of a drug due to diversion limits access to critical therapy for vulnerable patient populations. Shortages often result from theft and can foster resistance to various therapies (ie, anti-infectives) due to treatment interruption. Furthermore, diverted drug when reintroduced to a market may not have been stored and handled appropriately, leading to quality degradation and an ineffective product.

As criminals continue to find success with diverting genuine products, counterfeit products begin to emerge. The trade routes, brokers, and smugglers that deal in stolen, legitimate, medication and counterfeit medication ultimately end up being the same enterprise. This blurring of pharmaceutical crime results in continued supply chain disruption, and patient harm.<sup>12</sup> Another significant threat to the pharmaceutical supply chain is gray markets, which often arise from drug shortages. A gray market arises when companies operate on the fringes of legitimate drug distribution channels. These markets are worth an estimated \$75 billion dollars and represent another possible entry point for SF drugs.<sup>1</sup> Gray markets are worth understanding but are not fully explored in this article; however, most experts suggest avoiding gray market pharmaceutical purchasing.

## Leadership Strategies for Prevention

Pharmacy and health care leaders must take charge of ensuring a safe and secure supply chain for patients. Previous articles, including one published in 2015, examine the role leaders must take as related to the DSCSA.<sup>1</sup> Beyond these recommendations, there are additional strategies that can be implemented to limit the possibility of harm from SF medications.

A weakness in our supply chain starts with the unassuming patient. Whether due to access, cost, or other issues, consumers and patients may go unknowingly to illegal online pharmacies for their prescription and over-the-counter medications. To curb this growing concern, pharmacy personnel should be actively engaged, both inpatient and outpatient, in educating consumers, patients, and colleagues (pharmacists, physicians, nurses, social workers) on the dangers of going online for medications without the necessary knowledge to do so safely. NABP's ".Pharmacy" initiative ensures those online pharmacies who obtain the .pharmacy top-level domain are safe, comply with the laws of the United States, and sell US FDA-approved medication. To be safe, pharmacists and pharmacy technicians can counsel patients to "look to the right of the dot"; if the consumer sees ".Pharmacy" then a safer supply chain can be assumed.

Pharmacy leaders should be directly involved in medication reconciliation and medication discharge planning processes. As part of these medication-related transitions,

policies and forms should be created that ensure health care personnel are asking patients, "Where are you getting your medication?" This essential question will help identify those individuals who may be obtaining medication from the Internet. Follow-up questions can then be asked to ascertain whether the online source of the medication is legitimate, or nefarious and potentially dangerous. Only through asking this direct and open-ended question can one hope to understand the holistic medication profile of patients. If a patient is a poor historian, cannot communicate (pediatric), then this question should be directed to the relevant caregiver. In addition, policies commonly known as "Take Home Med" should be reviewed and revised to exclude most common medications as is customary best practice. Anecdotal reports of pharmacists using identifying markings and codes on tablets and capsules to confirm the identity of a drug only to discover that drug was counterfeit exist. Codes, colors, and markings are relatively simple to recreate. Policies allowing patients to keep taking their own medications can unintentionally lead to SF medications entering our health system supply.

Access and cost continue to be a major reason why consumers seek alternate sources of medication outside of the traditional supply chain.<sup>10</sup> As such, pharmacy leaders can establish programs to assist patients in obtaining medication through safe channels. Patient assistance programs and various rebate companies can serve as important lifelines for patients struggling to afford medication. For example, GoodRx, Refillwise, and BlinkHealth all provide ways for patients to save on medications and still stay safe. Pharmacy leaders should work with other health disciplines, including social workers, to ensure patients do not struggle to obtain necessary medication. Better attention must be paid to ensure patients always have options, keeping them safe from "cheaper" and dangerous alternatives.

## Conclusions

Addressing contemporary threats to the US pharmaceutical supply chain will take a coordinated and strategic approach. Pharmacy and health care leaders are positioned to take the lead on these efforts. Although many solutions will be needed, technology will play a central role in helping secure the global pharmaceutical supply chain. Interoperability is required for the full benefit of technology to be realized. Finally, education is essential in maintaining a safe global pharmaceutical supply chain, especially with the growth of ecommerce and illegal online drug sales. Notably, consumer, patient, and health care professionals should each be uniquely targeted with messaging that introduces and reinforces the dangers associated with deviating from a secure source of medication. Safe and effective care at the bedside begins with a safe and secure supply chain.

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