

Pharmaceutical Counterfeiting:

Endangering Public Health, Society and the Economy

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Executive summary

The presence of counterfeit medicines in international commerce was initially identified as a problem in 1985 at the World Health Organization Conference of Experts on Rational Drug Use. Prior to this event, the dangers and challenges of pharmaceutical counterfeiting were primarily limited to developing countries. The global picture, however, has starkly changed. Pharmaceutical counterfeiting now spans every continent and no medicine is immune.

Masquerading as curative medicines, counterfeit pharmaceuticals are increasingly prevalent and profitable. Moreover, there is anecdotal evidence that the trade is being used to fund criminal organizations and terrorism. In addressing the threat of counterfeit drugs, there is obvious scope for benefiting consumers, government health programs, and international pharmaceutical firms.

Pharmaceutical counterfeiters have no shame, no boundaries, and no limits. Accordingly, counterfeiters produce spurious versions of all types of medicines: branded drugs, generic drugs, over-the-counter drugs, and herbal remedies. These drugs may contain no active ingredient, harmful ingredients, the wrong drug, the wrong concentration, the wrong dose, or drugs past their expiry dates. All of these put patients at risk for treatment failure, harmful side effects, and dangerous drug interactions.

The most obvious and significant appeal of pharmaceutical counterfeiting is the profitability of the trade. A 2017 article notes that counterfeiting prescription drugs can be ten times as profitable as trafficking heroin. While anecdotal evidence of the link between counterfeiting targets and profit is quite plentiful, the clandestine nature of the business as well as the secrecy maintained by law enforcement make it virtually impossible to completely understand or measure the extent of the trade.

The OECD estimates that counterfeit goods accounted for 2.5% of the global pharmaceutical trade in 2013. According to a 2015 report, worldwide pharmaceutical sales reached US\$1.1 trillion in 2015. Moreover, if the counterfeit pharmaceutical industry is worth as much as \$200 billion annually, this is only slightly less than the \$246 billion illicit drug trade.

While Canada maintains a safe drug supply chain, recent incidents point to the presence of counterfeit pharmaceuticals in Canada in both the

legitimate supply chain as well as in the illicit drug trade and in illegal internet pharmacies. The challenges surrounding counterfeit pharmaceuticals are largely, though not exclusively, based in online or internet pharmacies. Nevertheless, there are documented cases in which counterfeit medicines made their way into licensed brick-and-mortar pharmacies.

Pharmaceutical counterfeiting in Canada is facilitated by factors that are universal and others that are unique to the Canadian market. The forces at play include demand-side factors, supply-side factors, inadequate regulation, enforcement, and sanctions, as well as quality sourcing issues and loopholes within the regulatory architecture. These factors are compounded by the insufficient criminal penalties currently in place.

This study makes several recommendations to limit the growth of pharmaceutical counterfeiting and protect patients, providers, and manufacturers: Raise public awareness, improve regulatory oversight, regulate pharmaceutical transshipments, increase criminal sanctions, implement global harmonization, and pursue an international treaty.

Pharmaceutical counterfeiting is a growing priority internationally and has consequently attracted the attention of international policymakers. Considering the more public and more aggressive campaign against counterfeiting, it is important to examine the extent of the problem, what is known about counterfeit production and distribution, links to organized crime, and appropriate policy responses. This paper reviews each of these in turn in the Canadian context, as well as providing a set of recommendations for safeguarding the Canadian drug supply and the health of Canadian patients.

1. Introduction

Counterfeiting has been termed the “second oldest profession”. An expansive literature documents the dangers associated with falsified goods ranging from toys to perfumes to airline components.¹ Indeed, consumers were cautioned about the dangers of adulterated medicines as early as the fourth century BC (WHO, 1999). The presence of counterfeit medicines in international commerce was initially identified as a problem in 1985 at the World Health Organization Conference of Experts on Rational Drug Use (WHO, 2002). Prior to this event, the dangers and challenges of pharmaceutical counterfeiting were primarily limited to developing countries, the world’s least profitable markets, and constituted a regrettably low priority for the industry. Fundamentally, it was too difficult and too expensive to address the complicated challenge of pharmaceutical counterfeiting in the developing world. The global picture, however, has starkly changed. Pharmaceutical counterfeiting now spans every continent and no medicine is immune (Lybecker, 2007, 2016; Clark, 2015).

Responding to concerns in governments and the business community, the OECD recently produced a report on the risks and economic consequences of illicit trade in pharmaceuticals. The dangers surrounding counterfeit medicines are growing and increasingly impact industrialized nations, even those with sophisticated supply chains such as Canada. Masquerading as curative medicines, counterfeit pharmaceuticals are increasingly prevalent and profitable. Moreover, there is anecdotal evidence that the trade is being used to fund criminal organizations and terrorism. In addressing the threat of counterfeit drugs, there is obvious scope for benefiting consumers, government health programs, and international pharmaceutical firms. While Canada maintains a safe drug supply chain, several recent incidents point to the presence of counterfeit pharmaceuticals in Canada as well as the involvement of criminal entities.

1. Excellent overviews of the problems of counterfeit goods are presented by the United Nations Office on Drugs and Crime (2015, n.d.).

Consider a recent report on *Notorious Markets* which identifies particular online markets in which pirated or counterfeit products are reportedly available. The report highlights Rebel, a Canada-based domain name registrar that “allegedly knowingly licenses domain names to a disproportionate number of illegal online pharmacies.” Specifically, “Rebel maintains less than 0.05 percent of the total domain name market but reportedly more than 17 percent of the entire illegal online pharmacy market. One submission estimated that Rebel sells domain name registration services to 4,850 illegal online drug sellers” (Office of the US Trade Representative, 2015).

Pharmaceutical counterfeiting is a growing priority internationally and has consequently attracted the attention of international policymakers. Considering the more public and more aggressive campaign against counterfeiting, it is important to examine the extent of the problem, what is known about counterfeit production and distribution, links to organized crime, and appropriate policy responses. This paper reviews each of these in turn in the Canadian context, as well as providing a set of recommendations for safeguarding the Canadian drug supply and the health of Canadian patients.

2. Pharmaceutical counterfeiting: Definition

"Despite increasing awareness of the fraudulent drug epidemic, efforts to quantify and stop this peril have been stymied by multiple obstacles, not the least of which is agreement on definitions."

Nayyar et al. (2015)

As with many things, a precise definition of the phenomenon of pharmaceutical counterfeiting is essential to effective debate and progress in overcoming the problem. Unfortunately, the lack of clarity and the fact that the phrase "counterfeit pharmaceuticals" conflates many terms are problematic (Mackey et al., 2015; Ossala, 2015). The legal debate, which has unfolded on the global stage, over an exacting definition of counterfeit medicines and the appropriate terminology has thwarted progress in combating counterfeiting and improving the security of the global supply chain and the quality of available medicines.²

2. "One of the biggest hurdles to stemming the global tide of counterfeit medicines is disagreement over the term itself, which drug companies are accused of hijacking for commercial rather than public health reasons. But international agreement over how to deal with fake medicines has been elusive, with discussions getting bogged down over exactly what kinds of drugs should be targeted. The problem is that the phrase normally used in the debate—'counterfeit medicines'—can refer to far more than chalk pills with forged labels. 'Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.' Yet pharmaceutical companies consider even safe, efficacious drugs 'counterfeit' when their expensively developed and patented formulas are copied without their permission, or even when their own drugs, licensed and packaged for sale in one country, are diverted, repackaged and sold elsewhere at a higher price" (IRIN, 2013). Fundamentally, the debate boils down to the question of whether efficacious therapies that are produced in violation of global intellectual property rights regimes constitute "counterfeit" drugs or not. Patent holders (and the governments of many industrialized countries) argue that they are, while the producers (and the governments of India, Brazil, and China) of these effective, patent-violating products argue that they are not. This debate is evident in the terminology described in the Appendices of this article, and is beyond the scope of this article.

Attaran, Bate, and Kendall (2011) note that the World Health Organization correctly observes that “the definitions used in ... different countries differ enough to create problems in the ... implementation of measures to combat counterfeit drugs.” According to the World Health Organization, the lack of a universally accepted definition undeniably inhibited progress toward understanding the extent of the problem and facilitating the exchange of information between countries. To rectify this, the World Health Organization developed the following definition: “A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging” (WHO, 2015). The Organization has since revised its definition and terminology, adopting a new definition in January 2016 of “substandard, spurious, falsely labelled, falsified, and counterfeit (SSFFC) medical products.” Appendix A provides the revised, current definition. The World Health Organization further clarified the definition of substandard and falsified (SF) medical products in May 2017, noting explicitly that it does not cover the protection of intellectual property rights. Appendix B provides that updated definition of SSFFC medical products.

While this is certainly the most widely-cited definition and as close as we can come to an agreed-upon definition, the definitions utilized by individual countries and agencies do vary. Moreover, it is important to note that many of the terms utilized in discussions of SSFFC have official, specific definitions developed by either regulatory authorities or legislative bodies in many countries throughout the world, while in other countries there are no official definitions of the terms (PSI, 2017a). Finally, Appendix C provides Health Canada’s definition of a counterfeit health product and Appendix D describes Canada’s current intellectual property (IP) protections for pharmaceuticals.

In the context of the debate over terminology and the nuances surrounding intellectual property rights and quality issues, it is instructive to be explicit about the difference between falsified and substandard medicines. Due to the link between intellectual property considerations and the term “counterfeit,” there is a trend toward using the term “falsified.” As described by Paul Newton (2015), the Head of the Wellcome Trust-Mahosot Hospital-Oxford Tropical Medicine Research Collaboration, falsified medicines are deliberately fraudulently produced and frequently, though not always, lack the active pharmaceutical ingredients. In contrast, substandard medicines are legitimately produced by the authorized manufacturer, but “do not meet national pharmacopeial standards because of errors in the quality or quantity of raw materials or in manufacturing” (Newton, 2015). The distinction goes beyond splitting hairs and is one of particular importance since the origins and solutions are radically different for counterfeit and substandard

medicines. In the first case, this is a deliberate criminal attempt to deceive, while the latter case results from poor or inadequate quality control.

This paper adopts the definition and terminology used by the World Health Organization in the 2015 definition. While the word “counterfeiting” is utilized, it is critical to recognize this goes beyond the issue of intellectual property theft; it is a purposeful and fraudulent act. Fundamentally, counterfeit medicines are neither regulated nor quality-controlled and should therefore be expected to be substandard as they move outside the safety of established, regulated supply chains (Lybecker, 2016).

3. Pharmaceutical counterfeiting: Contributing factors

Types of pharmaceutical counterfeiting

Pharmaceutical counterfeiters have no shame, no boundaries, and no limits. Accordingly, counterfeiters produce spurious versions of all types of medicines: branded drugs, generic drugs, over-the-counter drugs, and herbal remedies.³ These drugs may contain no active ingredient, harmful ingredients, the wrong drug, the wrong concentration, the wrong dose, or drugs past their expiry dates (Lybecker, 2016; Blackstone et al., 2014; Ossola, 2015; Canada, 2012). All of these put patients at risk for treatment failure, harmful side effects, and dangerous drug interactions.

Moreover, the problem of counterfeit and substandard products is not just limited to drugs. “Cases of counterfeit medical devices such as contact lenses, condoms, surgical mesh and diagnostic strips used by diabetics have all been uncovered” (Redpath, 2012). Counterfeit breast implants containing industrial-grade silicone have been discovered, which may be linked to 400,000 cases of cancer worldwide (Redpath, 2012). According to a report by the World Health Organization, “medical devices and medical-related products have also been counterfeited, including blood glucose test strips, contact lenses, surgical instruments, and even condoms” (Toscano, 2011). Notably, “[o]ne of the leading counterfeited items is actually ChapStick” (Health Research Fund, 2014: 2).

3. The problem of counterfeit medicine extends to both innovative branded and generic versions of prescription drugs, as well as to over-the-counter (OTC) medicines. Former Deputy Criminal Chief for the US Department of Justice Samuel Louis described the first US investigations into OTC drug fraud in a 2014 interview, stating “in the last six months there have been two instances of counterfeit OTC sites being investigated, one in New York and one in Texas. We hadn’t seen this before, but it seems to be on the rise.” Louis described an individual with ties to China who was manufacturing large quantities of medicines including OTC in an upscale Texas neighborhood. He notes that local manufacturing, and the unlikelihood of consumers to report failed treatment “due to the placebo effect of the less serious nature of an OTC drug not working,” handicap the battle against pharmaceutical counterfeiting (Stanton, 2014).

The quality of a medical product, and the difficulties in establishing said quality, are at the heart of the challenges surrounding pharmaceutical counterfeiting. It is undeniably difficult to establish quality and a variety of qualities are provided to consumers (Redpath, 2012; Ossola, 2015).

The trouble for the authorities is knowing where to start. Some fakes are probably not even that dangerous. They may be out-of-hours runs in established manufacturing facilities, produced by criminals who are keen to generate repeat business and therefore try to maintain quality standards. If they have been produced to correct formulae in hygienic conditions and shipped correctly, they may pose a commercial threat to the pharmaceutical industry but not a health threat to the consumer. Most fakes, however, are produced to incorrect formulae in unhygienic conditions and may contain dangerous contaminants. For the criminal gang, it is not the contents of the package that are important in avoiding detection, it is the package itself. As Roger Bate points out, "... most counterfeiters are most interested in the packaging – the product must look the part, whether it's a Louis Vuitton purse, a Rolex watch or an antibiotic." (Redpath, 2012: 8)

What is undeniable is that all these versions and methods of counterfeiting endanger patient health. "As noted by Roger Bate, 'Drugs can kill directly, if they have heavy metal, bacterial, fungal or other contamination. Drugs without active ingredients allow people to die from otherwise treatable infections. And drugs with some active ingredient may accelerate the process of natural selection of more robust microbes to previously effective drugs'" (Redpath, 2012).

The majority of counterfeit drugs are not lethal. "As [Peter] Pitts of the Center for Medicine in the Public Interest points out, 'It's generally bad business to kill your consumer, and it's not in the interest of counterfeiters to hurt you outright.' Counterfeiters are more likely to produce drugs containing inert substances" (Toscano, 2011). Accordingly, counterfeiters are inclined to produce drugs with inactive ingredients or to include a small fraction of the active ingredient.

Facilitating factors

According to Pfizer Global Security, "[a] number of factors have contributed to the rise in pharmaceutical counterfeiting. Included among them are the growing involvement in the drug supply chain of under-regulated wholesalers and repackagers, the proliferation of Internet pharmacies, advancements in technology that make it easier for criminals to make counterfeit drugs, and the increased importation of medicines from Canada and other countries" (Pfizer, 2007: 2).

Wyld (2008: 1) provides a concise list of the factors that contribute to the growing trade in counterfeit pharmaceuticals, including:

- ◆ the profitability of the activity;
- ◆ its relative ease;⁴
- ◆ the demand for drug products;
- ◆ the cost of prescription drugs;
- ◆ the web of country-specific regulations;
- ◆ the vast cost disparities between countries on the same products;
- ◆ the ease of transporting pharmaceuticals;
- ◆ the practice of relabeling, repackaging, and reimporting controlled substances;
- ◆ the low prospect of being caught once the counterfeit pharmaceuticals are integrated into the drug supply.

Elaborating on a few of these elements illuminates the factors that facilitate pharmaceutical counterfeiting. This section describes the profitability of counterfeiting, the minimal criminal sanctions, a lack of regulation, the convoluted supply chain, internet commerce, and the involvement of organized crime as important elements in the global emergence of pharmaceutical counterfeiting.

The profit motive

The most obvious and significant appeal of pharmaceutical counterfeiting is its profitability. A 2017 article notes that counterfeiting prescription drugs can be ten times as profitable as trafficking heroin (Riley, 2017). “One source reported that selling counterfeit sildenafil [Viagra] ‘can be as much as 2000 times more profitable’ than selling cocaine” (Bingham, 2009; Riley, 2017). Additional evidence comes from Redpath (2012): “British security software firm, Sophos, which intercepted hundreds of millions of fake pharmaceutical adverts and websites during that time, said it was possible to earn an average of \$16,000 per day working on one network that operated out of Russia. ‘But the criminals can be members of more than one affiliate network, and some have boasted of earning more than \$100,000 per day,’ it said.”

Links to transnational organized crime

Pharmaceutical counterfeiting is linked to numerous forms of organized crime: drug trafficking, money laundering, and terrorism (Lybecker, 2016;

4. While the barriers to entry for counterfeit pharmaceutical manufacturing are quite low, the risks associated with such production are very high, effectively limiting entry. Accordingly, while this is a highly lucrative activity and entry is cheap and easy, the risks and criminal penalties associated with the trade serve to restrict the extent of the practice.

Pfizer, 2007; Redpath, 2012; Criminal Intelligence Service Canada, 2006; UNODC, 2017). As reported by Redpath (2012: 7), “not only have groups such as the Russian mafia, Colombian drug cartels, Chinese triads and Mexican drug gangs all become heavily involved in producing and trafficking counterfeit drugs over the past decade, but mounting evidence also points to the direct involvement of Hezbollah and al Qaeda.” Given the profitability of the endeavor, it is not surprising that pharmaceutical counterfeiting is increasingly a source of funding for terrorist groups (Lybecker, 2016; Pfizer, 2007; Redpath, 2012).

Moreover, by their very nature, organized criminal operations are well suited to the intricacies of pharmaceutical counterfeiting. “Criminal organisations have the advantage of huge resources, international networks and skilled labour. They can move with a speed that often confounds the authorities. Counterfeit versions of the antiviral drug Tamiflu were available on fake internet pharmacy sites, like the one posing as the ‘Canadian Pharmacy,’ within weeks of the [World Health Organization] declaration of H1N1 as a pandemic” (Redpath 2012: 8).

While anecdotal evidence of the link is quite plentiful, the clandestine nature of the business as well as the secrecy maintained by law enforcement make it virtually impossible to either completely understand or measure the extent of the trade. A 2014 INTERPOL study provides perspective on pharmaceutical crime and organized criminal groups. INTERPOL’s Medical Product Counterfeiting and Pharmaceutical Crime Sub-Directorate has prepared an analysis of available data, dating from 2008 to 2014, to establish the extent of organized criminal groups (OCGs) activity in the realm of pharmaceutical crime (INTERPOL, 2014).⁵ According to the report, a recent Europol threat assessment concludes that there are “a wide variety of actors, operating within the pharmaceutical crime arena, encompassing both OCGs and individual criminals, both of which are involved at any point in the supply chain.” The report points to the involvement of both traditionally structured hierarchical crime groups in addition to highly organized, yet generally informal, networks of illicit online pharmacies and finally, small groups of three to ten members.

The INTERPOL study, as well as those from other agencies, provides some perspective on the involvement of organized criminal groups in Canada.

5. Three primary sources of information were utilized in the creation of the INTERPOL report: questionnaire responses, INTERPOL’s database system (ICIS), and open source media articles. The questionnaire was provided to all 190 of INTERPOL’s Member Countries in addition to the Permanent Forum on International Pharmaceutical Crime (PFIPC), the Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO), the Pharmaceutical Security Institute (PSI), and multinational pharmaceutical firms. A total of eight pharmaceutical companies responded to the questionnaire. Admittedly this represents limited participation by manufacturers.

- ◆ Numerous investigations in the US, Canada, and Sweden have linked the Hell's Angels to the production and distribution of counterfeit medicines, in particular ED medications and steroids (INTERPOL, 2014).
- ◆ Fake oxycontin pills containing fentanyl were responsible for more than 50 deaths in Alberta in 2015. The counterfeit pills are also responsible for three deaths in Saskatchewan (Partnership for Safe Medicines, 2015b).
- ◆ In November 2013, Canadian authorities began an organized crime investigation named "Project Forseti," targeting the Hells Angels and the Fallen Saints (Customs Today Report, 2015). In January of 2015, police in Saskatchewan and Alberta, Canada seized guns and drugs, including significant amounts of counterfeit oxycontin.

A United Nations Interregional Crime and Justice Research Institute (UNICRI) study suggests that criminal networks use routes and methods to transport counterfeit medicines that are similar to those used to traffic in drugs, firearms, and people (UNICRI, 2012). Evidence suggests that organized criminal gangs involved in the production of synthetic drugs are able to easily access the materials and expertise needed to also produce counterfeit medicines. In both Europe and Southeast Asia, authorities cite evidence of "criminal manufacturers of amphetamine-type substances [that] have been involved in the production and distribution of counterfeit medicines" (INTERPOL, 2014).

Lack of regulations and criminal sanctions

Fundamentally, many nations rely extensively, if not exclusively, on limited existing legislation to combat the trade in counterfeit medicines. This most frequently amounts to a reliance on criminal laws and intellectual property rights laws. Regrettably, this is woefully inadequate.

While legislative tools are limited, so too are the regulatory measures that nations have put in place. As described by the *Lancet*, "there is no global system for the mandatory reporting, assessment, and dissemination of information on suspicious medicines. ... It is extraordinary that, in 2014, such systems are widely in place for suspicious aircraft parts but not for suspicious medicines" (Newton et al., 2014).

"Rather than examining pharmaceutical crime as a specific type of crime requiring specialized legislation, many countries continue to place it under the category of intellectual property crime or use existing criminal law on narcotics or fraud. As a result, [a significant proportion of experts believe that] countries do not possess the necessary legal apparatus to effectively target the issue, while others argued that penalties were far too low for the offences committed."

INTERPOL (2014)

Globally, we have been slow to respond and slow to catch on to the magnitude and subtleties of pharmaceutical counterfeiting. “Though public health officials have known about falsified pharmaceuticals for decades, they didn’t understand the extent of the catastrophe until they started collecting data in the early 2000s. Interpol’s pharmaceutical crime unit wasn’t even founded until 2005” (Ossola, 2015). Accordingly, the punishment has rarely fit the crime. “These falsifiers are in fact murderers—they are causing death,” says Jim Herrington, executive director of the Gillings Global Gateway at the University of North Carolina’s Gillings School of Public Health. “And you’re more likely to get prosecuted for counterfeiting a Gucci purse than a drug” (Ossola, 2015). Across the globe, economies seldom have sufficient criminal sanctions in place (Eaton, 2016; Ossola, 2015; Attaran et al., 2011).

A national-scale approach to criminalization and enforcement also means that enforcement and penalties for counterfeiting vary widely. On the one hand, in some countries medicine counterfeiting simply is not a crime, though governments may hasten to enact a law after the problem manifests itself, as Syria recently did. Other countries, such as China, propound draconian penalties including the death penalty, but often as a facade for selective and inconsistent enforcement. Too few countries adopt a flexible approach, with judicial discretion as to imprisonment and monetary fines. ... Such sharp differences in the criminal law treatment between countries create difficulties in transnational enforcement. Extradition laws often contain a requirement of double (or dual) criminality, meaning that a person is only extraditable from country ‘A’ at the request of country ‘B’ if the act for which he or she is accused is criminalized in substantially identical terms and with comparable penalties in both countries. By not even agreeing on the basic fact that counterfeiting is a crime, countries afford criminals the basis to resist or avoid extradition. (Attaran et al., 2011: 5–6)

In many nations this is compounded by a lack of regulatory authority. As reported by Riley (2017), fully 30% of all countries do not have a functional regulatory authority. In particular, it is the international nature of the spurious drug trade that makes it such a complicated problem and so difficult to manage. “Very few of the 196 countries in the world have a specific dedicated service to deal with pharmaceuticals,” says Aline Plançon, the assistant director of Interpol’s program fighting counterfeit medical products and pharmaceutical crime. “Others can’t enforce their laws because they don’t have the capacity or budget” (Ossola, 2015).⁶

6. This raises the issue of how much counterfeiting is done in venues that would be inspected by regulators if such authorities were in place versus how much counterfeiting is done in clandestine locations. While a significant proportion of counterfeit manufacture is done in venues beyond regulatory inspection, the ease with which this product infiltrates the supply chain could be foiled by the inspections of regulatory authorities.

Internet commerce

Pharmaceuticals purchased over the Internet comprise a significant and growing source of counterfeit medicines. This is a particular threat to patients seeking less expensive drugs or unauthorized treatments, and for those individuals who want to avoid a consultation with a doctor (Pfizer, 2007; Beard, 2013; Blackstone et al., 2014). More on the threat of illegal internet pharmacies is included in a later section.

The convoluted supply chain

The pharmaceutical supply chain is inherently complicated and global in nature, which further obscures the source and origin of ingredients and finished products (Lybecker, 2016; Blackstone et al., 2014). As evidence of this, in the United States, “nearly 40% of drugs are made overseas and approximately 80% of the active medicinal components of drugs are imported” (Blackstone et al., 2014). These sentiments are echoed by Riley (2017) who notes that pharmaceutical products are characterized by “high value and high utilization, and ... the complex development process means large amounts of chemicals cross borders.”

In particular, it is worth pointing out that “[c]ounterfeit drugs are available through the legitimate supply chain, which also includes a small percentage of online pharmacies. The legitimate supply chain has many stages in which counterfeits can enter, starting with providing ingredients for manufacturing of the drug. Subsequent stages for infiltration include storage, transportation, and finally distribution” (Blackstone et al., 2014: 218). Moreover, secondary wholesalers are not in direct contact with drug manufacturers. In essence, they buy and sell drugs in response to market shortages and surpluses. More distressingly, secondary wholesalers package and repackage the drugs, providing an opportunity for counterfeits to enter the market (Blackstone et al., 2014).

Globally, this is further complicated by international arbitrage and production opportunities. Riley (2017) provides a notable example: that a drug may sell for \$20 per vial in Brazil but \$10 a vial in Argentina, which creates incentives for third-party traders to divert drugs to Brazil. On the production side, given that “cheap-labor countries now [account] for an estimated 80% of raw materials for the industry, it makes regulation and enforcement many times more challenging” (Palmer, 2012).

Drug shortages

Drug shortages are also a critical component, as consumers and health-care providers look beyond the secure supply chain to obtain medicines.⁷

7. The causes of drug shortages, particularly in the Canadian context, are discussed in Section 5.

Numerous reports document the role played by reliable drug supplies, and the ways in which drug shortages contribute to pharmaceutical counterfeiting.

‘We’ve seen it happen regularly—if a shortage occurs, hospitals and clinics will step outside the normal supply chain, and the [criminals] exploit the situation,’ says Michael Deats, a group lead for the [World Health Organization’s] Department of Essential Medicines and Health Products. (Ossola, 2015: 5)

For drugs in short supply, hospitals and other providers search beyond normal sources to obtain the drugs, increasing the ability of inserting the counterfeits into the market. ‘Shortages of key medicines in the US and Europe have created new opportunities for illicit traders, while ever-longer manufacturer supply chains open the door to diversion and theft.’ (Blackstone et al., 2014: 219).

Drug shortages lead to increased prices for a legitimate drug and increase the opportunity and ability for unscrupulous people to make financial gains by introducing counterfeit drugs into the market. Counterfeiters are able to take advantage of the drug shortage and charge exorbitant prices. Cost markups (presumably compared with standard prices) on drugs associated with shortages during a 2-week period in the beginning of 2011 averaged 650%. (Blackstone et al., 2014: 219).

According to Owen Adams of the Canadian Medical Association (CMA), “[i]n a survey of physicians conducted by the CMA in September 2012, two thirds of respondents said the shortage of drugs was a significant issue in terms of its impact on patient care and outcomes” (Senate, 2014: 32).

Adverse consequences

The damaging consequences of pharmaceutical counterfeiting are principally experienced by the consumer who ingests the spurious drugs as well as the pharmaceutical manufacturers, both innovative branded and generic firms. This points to the fact that counterfeiting encompasses virtually every class, category, and type of medicine: innovative originator drugs, generic, those requiring a prescription, and over-the-counter treatments.

Squandered health resources

Given that counterfeiters divert resources away from genuine treatment, in essence stealing scarce resources from the health budgets of individuals and

government, counterfeit medicines result in squandered health resources. Spurious drugs both reduce access to efficacious treatments and endanger legitimate drug supplies. The reduced prices of counterfeit versions encourage purchases by both consumers and health providers. This is exacerbated by drug shortages and limited supplies. The potential wasted expenditures are a significant burden for families and the increased burden of additional treatment can impose even greater economic hardship (Cameron et al., 2008). For health plans, a serious issue is “the potential negative effects from patients obtaining and using counterfeit medications without getting the clinical benefit of the drugs. The risks for disease progression, side effects, or the need to change the treatment approach because of a poor response all present issues for the health plan, and can lead to poor patient outcomes and increased costs” (Kenney, 2014: 224).

Consequences to the patient

“More than 120,000 people a year die in Africa as a result of fake anti-malarial drugs alone, says the World Health Organization, either because the drugs were substandard or simply contained no active ingredients at all.”

Wall (2016: 2)

Evidence that counterfeit pharmaceuticals are increasingly prevalent and pose a serious and growing threat to public health has been established in a large body of work. Counterfeit drugs provide little to no medicinal value and frequently result in therapeutic failure.⁸ Lost confidence in the value of medicines is a critical component of this, as is the potential for antimicrobial resistance. The severity of the health risk associated with counterfeit medicines varies in severity, from inconvenience to unwanted pregnancies to fatality. Tracing illness and death to counterfeit drugs is obviously very difficult, but even the limited evidence available suggests that the scope of the problem is considerable. Ossola (2015) suggests that “anywhere from 100,000 to a million people die every year due to falsified drugs.”

Unfortunately, the scope and cost of the impact of counterfeit drugs on patient health and safety is seemingly impossible to quantify and measure. Individuals who ingest counterfeit drugs may suffer prolonged illness, disability, death, and treatment failure, as well as the potential for additional complications depending on the composition of the falsified medicine.

8. This discussion of the social costs of counterfeiting focuses on counterfeit drugs that do not contain the correct ingredients or are otherwise degraded, so that they do not help or do actual harm to the patient. Appendix E provides a justification for this assumption and briefly examines the case in which counterfeit drugs are cheaper, effective versions produced in violation of the relevant intellectual property protections.

According to C. Legris, as cited by UNICRI:

Side effects can be classified into six main categories with respect to the presence or not—and if so, to what degree—of APIs (for example, under-dosed antibiotics present bigger chances for the consumers to develop drug resistance with serious repercussions while total absence of APIs increases the mortality incidence due to complete therapeutic failure); composition-related problems (difference between the APIs contained in the drug and the one illustrated on the package which will undoubtedly lead to under- or over-dose as the type, combination and/or quantity of the substance indicated on the package does not reflect the reality); the presence of toxic, chemical or completely inappropriate microbiological substances that are dangerous for the human organism; stability-related problems that are related to the abusive extension of the expiration date of a medicine which can lead to highly toxic products or to products with considerably decreased therapeutic capacity; excipients' bioavailability-related problems due to an inefficient control of fabrication or miscalculation of the effects of the mixture of the excipients with the APIs; and finally, problems generated by the interaction between the medicines and its container because of the inferior quality of the latter. (UNICRI, 2012)

Moreover, patients who take counterfeit medicines may also experience lost income due to absenteeism from work due to worsening clinical condition or disability.

As with many of the calculations in this paper, accurate estimates are difficult to come by. However, anecdotal evidence of the harm done to patients by counterfeit medicines is plentiful and may be found in virtually every country. The following examples provide a glimpse of the problem:.

- ◆ Based on 10% estimates of substandard and falsified medicines, the University of Edinburgh estimates that 72,000 to 169,000 children may die each year from pneumonia due to substandard and falsified antibiotics. (WHO, 2017a)
- ◆ Fake Oxycontin pills containing fentanyl were responsible for more than 50 deaths in Alberta in 2015. The counterfeit pills are also responsible for three deaths in Saskatchewan. (Partnership for Safe Medicines, 2015b)
- ◆ CanadaDrugs, an online Canadian pharmacy, sold US\$78 million worth of unapproved, mislabeled, and counterfeit cancer drugs to US physicians and clinics. (Horton, 2015)

- ◆ Customs officials in the port of Le Havre, France discovered more than 2.4 million units of counterfeit drugs in February of 2014. The seizure, the largest counterfeit drug haul discovered to be destined for the European Union, included fake aspirin and anti-diarrheal medicines containing sugar in place of active pharmaceutical ingredients (API). (Stanton, 2014)
- ◆ While no research to date quantifies the share of child deaths attributable to falsified and substandard medicines, a recent report from the Institutes of Medicine includes a table linking the most common causes of child death to verified reports of substandard medicines. The list includes pneumonia, diarrheal diseases, and malaria. (Institute of Medicine, 2013)
- ◆ In 2012, the Centers for Disease Control and Prevention (CDC) was notified by the Tennessee Department of Health of an outbreak of meningitis caused by fungal infection through a contaminated epidural steroid injection from the New England Compounding Pharmacy Center in Framingham, Massachusetts. Ultimately, the CDC traced 693 illnesses and 45 deaths in 19 states to the contaminated drug.⁹ (Institute of Medicine, 2013)
- ◆ In 2008, a counterfeit version of heparin, a blood thinner, was discovered in the United States. The counterfeit version lacked the active ingredient and instead contained a cheaper substance that generated an adverse reaction in patients. As a result, a nationwide recall of heparin was initiated. The medication, whose counterfeit active ingredient came from China, is suspected as the cause of as many as 81 deaths. (Toscano, 2011)
- ◆ In 2011, Pakistan discovered counterfeit heart medication was given to up to 40,000 patients in Lahore. The result was the rapid depletion of white blood cells and platelets, leading to the deaths of more than 100 patients. (BBC News, 2012)
- ◆ In 2010, Pennsylvanian authorities discovered the illegal importation and distribution of four million fake diet pills, containing unapproved drugs and carcinogens. The fake diet pills caused “significant side effects in some individuals, including nausea, vomiting, elevated blood pressure, heart attacks, and strokes”. (Partnership for Safe Medicines, 2010)

9. Ultimately, 14 people were charged in connection with the meningitis outbreak. These individuals face charges including fraud, criminal contempt, misleading regulators, falsifying records, preparing drugs in unsanitary conditions, and shipping mislabeled drugs and prescriptions with fake patient names. In addition, the company filed for bankruptcy at the end of 2012 following the filing of hundreds of lawsuits (Enwemeka, 2017).

- ◆ A counterfeit cough syrup resulted in the deaths of more than 500 children around the world. The product was tainted with ethylene glycol, an industrial solvent, in place of propylene glycol in pediatric paracetamol formulations. (Liang, 2006)
- ◆ In 2005, eleven people died in Ontario after being prescribed a counterfeit version of Norvasc, a Pfizer heart medication, containing only talcum powder. (Partnership for Safe Medicine, 2005)
- ◆ In 2002, Florida investigators discovered up to 110,000 bottles of low-dose Epogen, an anemia drug, relabeled to create counterfeit high-dose Epogen and Procrit. Accordingly, patients received insufficient levels of life-preserving therapy and suffered painful side effects. (Pew Charitable Trusts, 2014)
- ◆ In the midst of a meningitis epidemic in Niger in 1995, more than 50,000 people were vaccinated with counterfeit medicine, resulting in 2,500 deaths. (WHO, 2003)
- ◆ The Royal Pharmaceutical Society notes that internet sales of counterfeit medicines are characterized by an informational health risk as well. “[T]he user has no information about the ingredients, dosage instructions, or potential side effects, so patients would not be receiving proper healthcare advice.” (Wise, 2013)

Consequences to the government

Not surprisingly, national governments also bear the costs of pharmaceutical counterfeiting. These take primarily three forms: the loss of tax revenues, the increased regulatory and enforcement cost of securing the supply chain, and the higher cost of healthcare due to the adverse effects of fake drugs. Again, it is impossible to calculate the extent of lost tax revenues, though given the extent of the trade, the losses can be assumed to be significant.

Regulatory and enforcement costs

As in the case of measuring the extent of pharmaceutical counterfeiting or the economic consequences, regulatory and enforcement costs are difficult to quantify. Most frequently, the expenses associated with the regulation and enforcement of counterfeit pharmaceutical are included in the overarching budget of the regulatory and enforcement entities. Some costs may be separable, such as the forensic chemistry assays described below; however, in most cases it is impossible to identify the costs specific to counterfeit goods in general, and to counterfeit medicines in particular. Scientific advances now enable immensely powerful and expensive forensic chemistry techniques

which provide investigators information on the unique fingerprints manufacturers leave on their products and packaging. These techniques may also provide the evidence prosecutors need to tie falsified drugs to particular sources. Forensic chemistry assays cost US\$5,000 to \$15,000 per test on average. While extremely sensitive and accurate, these tests are impractical for routine product quality market surveillance (Institute of Medicine, 2013).

Increased healthcare costs

Another concern to governments is that counterfeit medicines may generate higher healthcare costs, as patients may require additional treatment due to the potential adverse effects of falsified medicines. This is exemplified in the case of a patient who, given a liver transplant, required injections for anemia. Following two months of injections, the patient failed to respond to treatment. The patient's physicians then discovered that the medicine used was counterfeit. In most cases, healthcare providers rarely suspect counterfeit or substandard drugs as the source of a patient's poor therapeutic response. Accordingly, they most frequently respond by ordering more tests or repeating the course of treatment (Institute of Medicine, 2006).

Consequences to the pharmaceutical industry

Lost sales and revenues

While the most pressing issue for the pharmaceutical industry is the harm counterfeiters do to patient health and well-being, the damage generates economic cost as well. Simply put, counterfeiters most directly threaten product sales and revenues. Again, precise calculations of the losses are very difficult to come by, but the World Health Organization estimates counterfeiting costs the pharma industry \$75 billion a year (Palmer, 2012).¹⁰ This estimate is echoed by the Criminal Intelligence Service Canada (2006: 4): "[m]ost estimates range in the billions annually for global losses."

Some perspective on the extent of the problem may be gleaned from anecdotal evidence from around the world. While these countries obviously face a much more serious problem than Canada, the examples do point to the enormity of the problem for the pharmaceutical industry.

- ◆ *China:* "[A] flood of unauthorized copies of a drug produced by an international pharmaceutical company caused a drop in annual sales in China to about US\$242,000. After counterfeiting was halted, sales reportedly climbed to US\$1.2 million." (Beach, 2001)

¹⁰. Given the global pharmaceutical market is estimated to be US\$1 trillion, this number may be perceived as rather modest. However, taken in the context of the damage done, even a 1% market share takes a significant toll on human health and life.

- ◆ *India*: The estimated annual turnover of India's pharmaceutical industry was approximately US\$4.2 billion in 2003, but counterfeiters rob legitimate producers of close to US\$1 billion annually. (BBC News, 2003)
- ◆ *El Salvador*: INQUIFAR, the association of pharmaceutical companies, has denounced the extensive availability of counterfeit drugs in the domestic market. According to a local manufacturer, counterfeit medicines currently generate economic losses of around US\$40 million per year to the country's pharmaceutical industry. (WHO, 2006)
- ◆ *Indonesia*: The International Pharmaceutical Manufacturers Group (IPMG) estimates that pirated drugs constitute 25% of Indonesia's \$2 billion pharmaceutical market. "According to IPMG's vice chairman, those fake drugs hit foreign pharmaceutical companies' bottom lines and pose a potential serious public health threat." (WHO, 2006)
- ◆ *Colombia*: ASINFAR, the Association of Colombian Pharmaceutical Industries, estimates that close to 5% (US\$60 million) of an annual total US\$1,300 million stems from contraband, counterfeiting, or adulteration. (WHO, Organization 2006)

It is important to recognize that it is impossible to measure the extent of economic damage done by pharmaceutical counterfeiters. Since counterfeit medicines are often sold at prices much lower than genuine medicines, additional information about the price sensitivity of consumers is necessary before one can determine whether each purchase of a counterfeit drug would have been a legitimate sale under other circumstances. In like manner, an accurate estimate of lost revenue is also impossible to calculate.

Additional costs of securing the supply chain and anti-counterfeiting technology

Counterfeiting also increases the costs of legitimate pharmaceutical manufacturers by forcing them to incorporate anti-counterfeiting technologies into their products and packaging. Firms will incorporate overt, covert, and forensic technologies as necessitated by the risk and sophistication of counterfeiters (Lybecker, 2016; Riley, 2017). Available technologies are frequently layered to protect products, creating overlapping security (Riley, 2017). Innovative pharmaceutical firms also monitor their products in the markets of counterfeit-prone countries and conduct their own investigations

"Eli Lilly has invested \$110 million into stamping unique codes and serial numbers on every drug package that it sells around the world so they can be effectively tracked."

Health Research Fund (2014: 2)

into reported counterfeiting incidents. “Pfizer’s own investigative work into counterfeit drugs leads to about 50 or 60 convictions each year. ... The issue is so extensive that Pfizer reports sending 2 or 3 cases for law enforcement investigation weekly after they’ve conducted their own internal investigation” (Health Research Fund, 2014: 2, 4). A recent report by the Institute of Medicine noted that multinational pharmaceutical companies have invested in security departments that cooperate globally with regulators and law enforcement agencies. These departments collect 80% of the evidence used in criminal prosecution (Institute of Medicine, 2013). Consider that a tip from Pfizer led to an investigation in China that dismantled a counterfeiting operation that extended over eleven economies including Britain, the United States, and Israel (Sommerville, 2005).

Reputational damage and liability

Beyond reduced revenues and increased costs, innovative pharmaceutical firms risk unquantifiable damage to brand and reputation from counterfeiters. This amounts to an externality associated with counterfeiting that is borne by the pharmaceutical firm that others in the supply chain do not account for. While it is the case that no single entity “owns” the problem of pharmaceutical counterfeiting, fake medicines put the firm’s reputation for safety and quality at risk (Smith-Anthony and Whymark, 2013).

Moreover, the practice subjects them to potential liability if consumers are harmed by counterfeit versions of their drugs. “Legal scholars have begun to suggest that manufacturers may have an obligation under civil tort law to take steps to prevent counterfeiting. ... [Further, they] may be held liable for injuries suffered by innocent purchasers of the defective product imitations if certain conditions are met” (Kontrnik, 1998). These conditions would include: if the counterfeiting and injury were foreseeable; if the firm had a role in creating the risk; and if it failed to take reasonable action to reduce that risk (LePark, 2002). This further encourages the monitoring, described above, done by innovative pharmaceutical firms.

Decrease in innovation

The prevalence of counterfeit medicine also impacts pharmaceutical innovation. Notably, smaller revenues and increased costs reduce the resources available for the research and development of new treatments and cures. Recent estimates place the fixed costs of drug development at more than US\$2.6 billion (Tufts Center for the Study of Drug Development, 2014). Admittedly, this number is highly controversial, but even at half that amount, the investment is undeniably significant. Given that the development of a new drug is an inherently risky and expensive venture, when the potential returns on this investment are diminished by counterfeiting, the incentives to invest are also reduced.

Consequences to global health

Antibacterial resistance

Counterfeit pharmaceuticals containing a greatly reduced dose of the active constituent unarguably contribute to global microbial resistance and more virulent forms of disease, undermining the fight against infectious diseases (Lybecker 2016, 2017a; Blackstone et al., 2014; Beard, 2013). “Counterfeit medicines have contributed to antibiotic-resistant forms of shigella, cholera, salmonella and tuberculosis” (Criminal Intelligence Service Canada, 2006: 4). The dangers of actual microbial resistance are compounded by false reports of drug resistance.

Anti-infective medicines containing only minimal or inadequate amounts of the established active ingredient will engender drug resistance. When pathogens are exposed to sub-therapeutic amounts of the stated active ingredient, the more resistant pathogens will multiply while the susceptible pathogens are eliminated (Lybecker, 2016). Accordingly, future patients are more likely to be infected with pathogens that are resistant to the active ingredient. In the case of diseases treated with combination drug therapies—examples include HIV, TB, and malaria—when one active ingredient is present in inadequate concentrations, the pathogens also risk becoming co-resistant to the partner drugs (Newton, 2012).

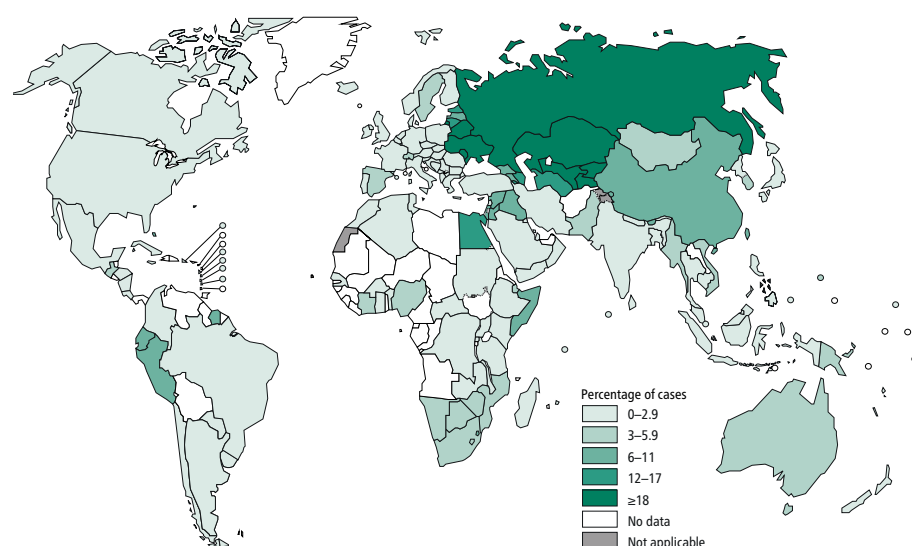
For anti-malarials, the evidence “strongly suggests that under-dosing is an important contributor to resistance. Therefore, if patients consume co-circulating falsified and substandard medicines sequentially, so that heavy parasite burdens encounter low drug concentrations, the risks of engendering resistance are high” (Newton et al., 2014). Moreover, the use of counterfeit and substandard anti-malarials, and the resulting failure of patients to improve, have generated false reports of drug resistant strains of malaria (Newton, 2006a). While artemisinin derivative-based combination therapies (ACTs) for malaria once showed great promise for controlling malaria in Africa, poor-quality versions are already widespread on the continent (Newton, 2006a, 2006b; Bate, 2008). It is believed that the wide use of monotherapy, substandard artesunate, and fake artesunate containing sub-therapeutic quantities of artemisinin and artesunate in South-East Asia have probably contributed to the *plasmodium falciparum* artesunate resistance (Newton, 2008).

Consider too the case of HIV. In 2007, the US Center for Disease Control reported that HIV surveillance sites found that one in six newly diagnosed infections were drug-resistant (Dahl, 2014). In the case of tuberculosis (TB), poor quality TB drugs are clearly correlated with the increasing burden of TB drug resistance (Liang, 2004).¹¹

11. Unfortunately, it is impossible to tease out how much of the increase in TB drug resistance is due to counterfeit drugs relative to the overuse of prescribed (and legal) drugs.

Figure 1 depicts how worrying this truly is. The figure shows the increasing prevalence of multidrug-resistant tuberculosis. The Extremely Drug Resistant Tuberculosis (XDR-TB) strain is now confirmed in 49 countries (Harris et al., 2009). According to the World Health Organization, between 2003 and 2007, an estimated 5% of new tuberculosis infections were resistant to multiple drugs, with the rate as high as 35% in some countries (WHO, 2008).

Figure 1
Increasing incidence of multidrug-resistant tuberculosis (MDR-TB)



Source: WHO, 2017c.

Environmental damage

While the legitimate pharmaceutical industry collaborates with local, state, and federal agencies to comply with environmental laws and regulations and to reduce the environmental footprint of the research and manufacturing process for new medicines, counterfeit manufacturers do not embrace the same practices. While the legitimate industry embraces environmental regulations, counterfeiters reap the financial benefits of dirty production, taking every environmental shortcut imaginable. During the manufacturing process, counterfeiters disregard the impact that chemical compounds may have on the environment, disposing of toxic dyes and chemicals without regulatory oversight and ignoring the treatment of wastewater streams. The increasing volume of seized counterfeit goods constitutes an additional environmental challenge since destruction may be a costly, waste-generating process (OECD, 2007). It is particularly difficult to dispose of seized counterfeit electronic goods and counterfeit chemicals and pharmaceuticals in an environmentally

friendly manner (Soentgen, 2012; UNOCD, 2015). The experience of the European Union is illustrative. In 2011 alone, customs authorities seized more than 115 million counterfeit items, a 15% increase in goods seized over 2010. More than 75% of the seizures were destroyed, evidence of the difficulties of disposing of counterfeit goods (Soentgen, 2012).

4. Global dimensions, issues, and magnitude

The OECD estimates that counterfeit goods accounted for 2.5% of global trade in 2013, and that this “misappropriated revenue stream totaled \$461 billion” (Wu, 2016: 1). In its most recent report on the problem, the World Health Organization notes that since 2013 it has received 1,500 reports of cases of substandard or falsified products (WHO, 2017a). In terms of the market for counterfeit pharmaceuticals specifically, precise estimates are impossible to come by, but it is believed to be valued at US\$75–\$200 billion, and in some countries the share of counterfeit drugs on the market may be as high as 50% (Riley, 2017; Smith-Anthony and Whymark, 2013; Eaton, 2016; Miller and Duggan, 2017; Beard, 2013). Counterfeit drugs have been discovered in 124 countries and across all continents (Clark, 2015). Globally, it is estimated that counterfeit drugs represent between 8% and 15% of all medicines (Riley, 2017), with most experts placing the number around 10% (Blackstone, Fuhr, and Pociask, 2014; Criminal Intelligence Service Canada, 2006). It is undeniably a large, and growing, market.

According to Peter Pitts, President of the Center for Medicine in the Public Interest and former US FDA Associate Commissioner, the sale of counterfeit drugs is growing at twice the rate of legitimate pharmaceuticals (Redpath, 2012: 6) and is expected to grow by 20% annually in coming years (Toscano, 2011: 1). This growth is reflected in recent seizure statistics. Consider the reports by Operation Pangea, an international week of action tackling the online sale of counterfeit and illicit medicines coordinated by INTERPOL.¹² In 2011, Operation Pangea reported that it seized 2.4 million fake and illicit pills, while in 2015, the total number of seized medications increased to 20.7 million (Riley, 2017; Ossola, 2015). Further evidence may be gleaned from US Customs and Border Protection seizures. In 2017, the agency

12. “The annual operation brings together customs, health regulators, national police and the private sector from countries around the world. Activities target the three principal components used by illegal websites to conduct their trade—the Internet Service Provider (ISP), payment systems and the delivery service” (INTERPOL, 2017).

reports seizing pill presses—the equipment used to manufacture counterfeit medicines—at a rate 19 times higher than in 2011. Strikingly, some presses can generate 170,000 pills per minute (Ganim, 2017). In like manner, another measure of the pharmaceutical counterfeiting problem is the size of the global counterfeit drug detection devices market. In 2016, the global counterfeit drug detection devices market was valued at US\$904.5, and it is expected to reach US\$1,368.5 million by 2021 (Globe Newswire, 2017).

To put this number in perspective, consider that, according to a 2015 report, worldwide pharmaceutical sales reached US\$1.1 trillion in 2015 (Riley, 2017). Moreover, if the counterfeit pharmaceutical industry is worth as much as \$200 billion annually, this is only slightly less than the \$246 billion illicit drug trade (Peasgood, 2015). Notably, the counterfeit medicines market is more lucrative than the narcotics business (Miller and Duggan, 2017).

With some concept of the magnitude of the global problem, it is important to consider the sources. “Ninety-seven percent of all counterfeit pharmaceuticals seized at the US border in Fiscal Year 2015 were shipped from four economies: China, Hong Kong, India, and Singapore” (Brennan, 2016). When considering the global problem, the most significant actors are the same. “The Regulatory Affairs Professional Society cites Brazil, China, Guatemala, India, Indonesia, Lebanon, Peru and Russia as countries that are major players in producing, selling and distributing counterfeit drugs. In 2015, 90 percent of all counterfeit medicines were shipped from China, Hong Kong and Singapore” (Riley, 2017). The largest players on the global stage are sophisticated operations based in countries with rapidly developing pharmaceutical manufacturing capacities. Counterfeit drug manufacturing frequently grows in tandem with legitimate drug manufacturing in these countries:

Dubbed the ‘pharmerging countries,’ the BRIC nations of Brazil, Russia, India and China are expected to see the fastest pace in pharmaceutical growth over the next few years, according to an IMS health study. China alone is predicted to grow at 2,527 percent, which will make it the world’s third-largest pharmaceutical market by 2013. As they develop their own internal manufacturing capabilities, with less regulation in place than is generally found in the West, these countries are also becoming the largest producers of fake medicines. (Redpath, 2012: 7)

While counterfeit drugs may enter a nation’s supply chain and pervade “brick-and-mortar” pharmacies, it is undeniable that the dangers of counterfeit drugs have grown with the rise of Internet commerce. The World Health Organization estimates that 50% of the drugs for sale on the internet are fake (Clark, 2015). While online dispensaries may have the appearance of a legitimate purveyor, a survey of 10,000 of them by America’s National

Association of Boards of Pharmacy (NABP) found that 9,938 did not comply with NABP patient safety and pharmacy practice standards, and 97% of those examined were not compliant with either US federal or state laws (Clark, 2015; Blackstone, Fuhr, and Pociask, 2014). According to a 2010 World Health Organization Bulletin, close to 50% of all counterfeit drugs sold on the internet “were for weight loss, with fake versions of erectile dysfunction drugs such as Cialis and Viagra also forming a ‘key market for counterfeits in Europe and Asia.’ However, increasingly there is a concerning trend for counterfeiting of other mainstream prescription-only products used to treat serious health conditions” (Smith-Anthony and Whymark, 2013: 2).¹³

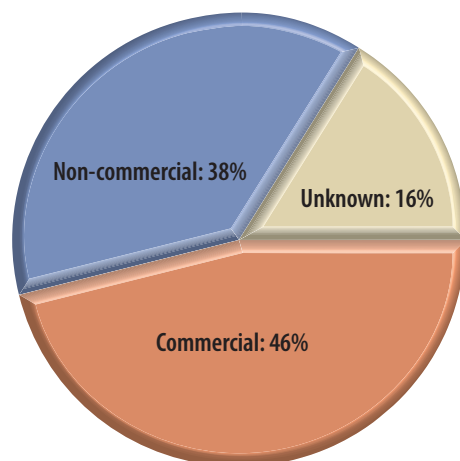
Unfortunately, counterfeit medicines often go undetected, even in the nations with the most sophisticated and secure supply chains. Given this, incidents will go largely underreported (WHO, 2017a; Eaton, 2016; Criminal Intelligence Service Canada, 2006). “Since 2010, nearly 1,400 adverse reactions related to counterfeit drugs have been reported to the [US] FDA ... [yet] the reports don’t reflect the true size of the problem. Most people who use counterfeit or compromised medications never find out about it” (Eaton, 2016: 3). Moreover, it is essential to recognize that the regions that are most frequently linked to counterfeiting incidents are not necessarily those with weak enforcement and inspection programs. “Rather, countries in these regions are effectively identifying pharmaceutical crime through law enforcement activity and inspections by drug regulatory agencies ... Due to competing law enforcement priorities, lack of funding or inadequate regulatory structures, in certain regions of the world, counterfeit medicines often go undetected” (PSI, 2017e: 1). That is, when considering the nations where counterfeit drugs are most frequently discovered, one must distinguish between whether this is because the problem is more extensive, or because detection is more effective.

Admittedly, accurate data on the magnitude and extent of pharmaceutical counterfeiting are virtually impossible to come by. Perhaps the best information available comes from the Pharmaceutical Security Institute (PSI), an organization dedicated to protecting public health by sharing information on the counterfeiting of pharmaceuticals, and initiating enforcement actions through the appropriate authorities (PSI, 2017f). The following figures come from PSI, and incorporate the best information available on the global scope of the problem.

13. It is worth pointing out that shame and embarrassment surround the conditions treated by the majority of counterfeit drugs sold over the internet (50% are for weight loss or erectile dysfunction). Clearly, the anonymity sought through online purchases is a contributing factor to the sale of counterfeit drugs. However, it is also critical to recognize that the sale of counterfeit drugs is not limited to online transactions, nor limited to treatments for just these two conditions. Indeed, pharmaceutical counterfeiters target everything from Aspirin to Zyprexa. Unfortunately, pharmaceutical counterfeiting is not limited to a particular disease condition or type of drug.

The PSI categorizes counterfeiting seizures according to whether they are commercial or non-commercial incidents. Seizures of more than 1,000 dosage units were classified as commercial incidents, while incidents involving less than 1,000 dosage units were classified as non-commercial (PSI, 2017b). **Figure 2** depicts the distribution of counterfeiting seizures in calendar year 2016.

Figure 2
Worldwide counterfeit seizures by type, 2016



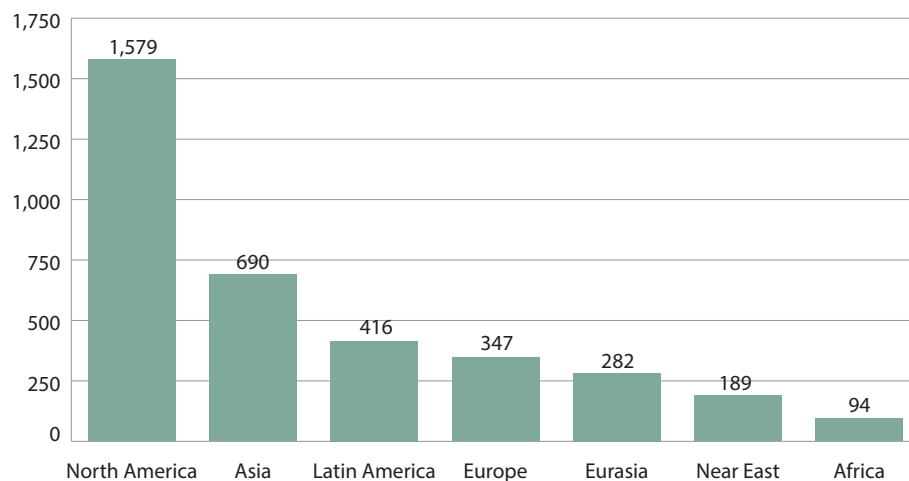
Source: Pharmaceutical Security Institute, 2017b.

Counterfeiting incidents may be further examined in the context of geographic location,¹⁴ total numbers over time, and therapeutic categories. **Figures 3, 4, and 5** provide this information.¹⁵

14. It is worth clarifying that multiple regions can be linked to a single incident.

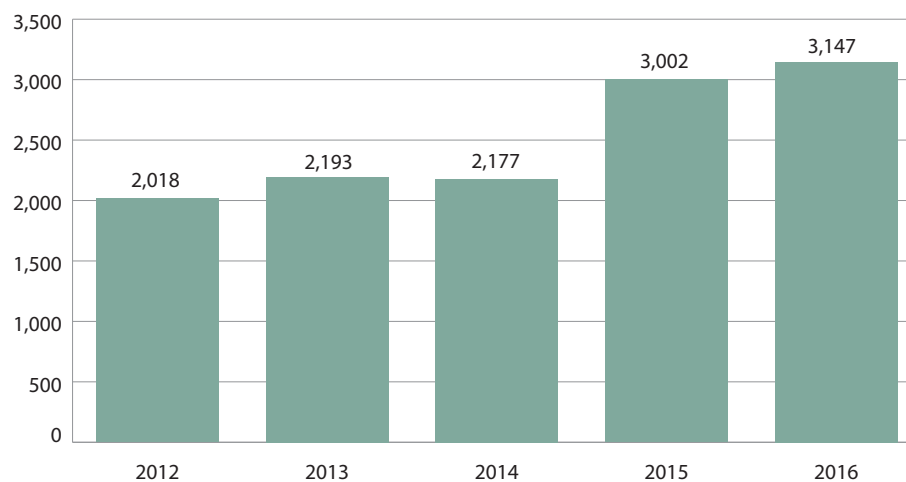
15. The number of incidents in North America is more than four times the number of incidents in Europe, regions with approximately the same populations. This is likely due to the fact that pharmaceutical prices in the United States are free of price controls and therefore the market is more profitable and more attractive to counterfeiters. Please see the discussion of contributing factors in Section 3.

Figure 3
Counterfeiting incidents by regions of the world, 2016



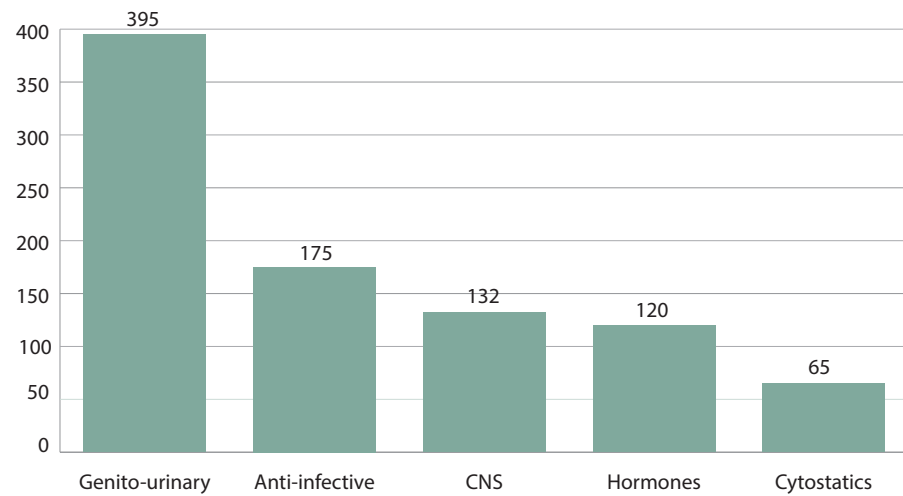
Source: Pharmaceutical Security Institute, 2017e.

Figure 4
Total number of counterfeiting incidents, 2012 to 2016



Source: Pharmaceutical Security Institute, 2017b.

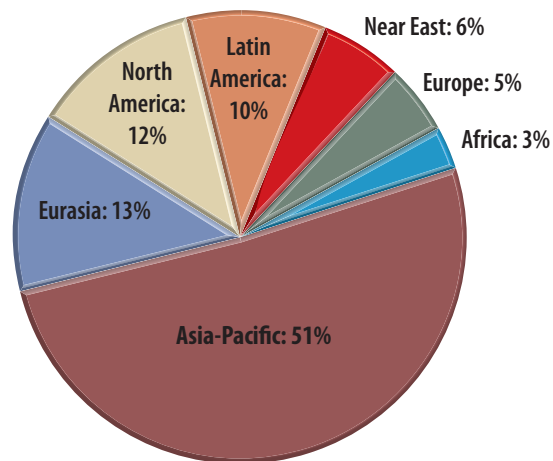
Figure 5
Counterfeiting incidents by top five therapeutic categories, 2016



Source: Pharmaceutical Security Institute, 2017d.

PSI collects information on arrests as one indicator of a government's commitment to addressing pharmaceutical counterfeiting. Reviewing the numbers for 2016, PSI found that 1,258 persons were arrested for “counterfeiting, illegally diverting, or stealing pharmaceuticals,” though the number of arrests fell by 9% relative to global arrests in 2015 (PSI, 2017c). **Figure 6** categorizes these arrests by region.

Figure 6
Arrests by region, 2016



Source: Pharmaceutical Security Institute, 2017c.

The Pharmaceutical Security Institute has collected data on counterfeiting, illegal diversion, and theft incidents for fourteen consecutive years, providing them with perhaps the best and most accurate perspective on the pharmaceutical counterfeiting problem over time. A 2016 analysis of 3,147 incidents revealed the following (PSI, 2017b, d, e):

- ◆ Relative to 2015, the 2016 numbers represent a 5% increase in the worldwide incident total, an all-time high.
- ◆ Over the past five years, incidents have increased by 56%.
- ◆ Criminals targeted pharmaceuticals in every therapeutic category.
- ◆ 127 countries were impacted by pharmaceutical crime.
- ◆ Incidents in the North American region increased by over 100%, surpassing one thousand incidents.
- ◆ 1,258 different drugs and medicines were involved in these incidents.
- ◆ Relative to 2015, the 2016 numbers represented a 15% increase in different types of drugs.
- ◆ As many as sixty-four different medicines were discovered in a single incident.

Pharmaceutical counterfeiting is a pervasive problem, impacting nations of every size and income level, and drugs of every class and description. Since pharmaceutical treatments and cures are very high value products relative to their bulk, and demand is mostly price-inelastic over a wide price range,¹⁶ pharmaceutical counterfeiting has assumed enormous proportions (Obi-Eyisi and Wertheimer, 2000; Lybecker, 2007; Fulda, Lyles, and Wertheimer, 2016). The immense size of the global pharmaceutical market and the margin between manufacturing costs and market price create a substantial economic incentive (Lybecker, 2007). According to Christophe Zimmerman, the anti-counterfeiting and piracy coordinator of the 176-nation World Customs Organization (WCO), “[w]e now have more fakes than real drugs in the market. In 2007–2008 alone, it rose 596 percent” (Irish, 2010). In the WCO’s 2013 report, there were 24,092 reports of seizures of IP-offending goods and more than half of these were related to illegal pharmaceuticals (WCO, 2014).

¹⁶ Demand for pharmaceuticals is inelastic, meaning that the quantity demanded does not significantly change with changes in price. Consumer purchases are relatively unresponsive to changes in price. This makes the sale of pharmaceutical products very lucrative and attractive to counterfeiting.

5. Pharmaceutical counterfeiting in Canada

Infiltration of the Canadian market

As is the case with global estimates, it is very difficult to calculate the extent and magnitude of the counterfeit pharmaceutical problem in Canada. Nevertheless, several incidents demonstrate that Canada is far from immune from the problem. In particular, consider the following examples:

- ◆ Results from INTERPOL, as well as from other agencies, provide some perspective on the involvement of organized criminal groups in counterfeit trade. Numerous investigations in the United States, Canada, and Sweden have linked biker gangs to the production and distribution of counterfeit medicines, in particular erectile dysfunction medications and steroids. (Interpol, 2014a)
- ◆ “In June 2005—following the discovery that an accredited pharmacy in Canada had dispensed counterfeit Norvasc, Pfizer’s popular blood pressure medicine—11 reported deaths were examined for a link to the fakes. The regional coroner reported that of the 11 deaths, the counterfeit medicine could not be ruled out as a cause for four of them.” (Pfizer, 2007: 3)

Some perspective on the scope of the problem in Canada comes from the Pharmaceutical Security Institute. According to their calculations, recent Canadian participation in Operation Pangea provides clear evidence of a significant, and growing, problem. In addition, there are good reasons to believe that these calculations may underestimate the problem and that the extent of counterfeiting in Canada exceeds these conservative estimates.

Here in Canada, approximately 3,700 packages originating from 21 countries were inspected. Of these, almost 90% were either refused or seized as they contained counterfeit and/or unlicensed health

products, such as prescription drugs. The total street value is approximately \$850,000 CAD. (RCMP, 2015)

*8 days = 3,700 packages * 90% refused = 3,330;*

If 8 days equaled 3,330 packages, then 365 days could yield 151,931 packages

If 8 days equaled \$850,000 CAD, then 365 days could yield \$38,781,250 CAD as the value of medicines. (Kubic, 2017)¹⁷

In Canada, inspections at mail processing centers and border crossings resulted in the assessment of 4,227 parcels. Of those inspected, 91% were either refused or seized, because they contained counterfeit and/or unlicensed health products, such as illegal prescription drugs. The street value of the total amount seized and refused is estimated to be \$2.51 million CAD. (RCMP, 2016)

*9 days = 4227 packages * 91% refused = 3,847;*

If 9 days equaled 3,847 packages, then 365 days could yield 156,017 packages

If 9 days equaled \$2.1 M CAD, then 365 days could yield \$85,166,666 CAD as the value of medicines. (Kubic, 2017)

Importantly, “counterfeit drugs within licensed pharmacies in Canada are a rare occurrence” (Criminal Intelligence Service Canada, 2006). The challenges surrounding counterfeit pharmaceuticals are largely, though not exclusively, based in online or internet pharmacies, where most of the products are fake and most are not from Canada. Moreover, most websites do not even originate in Canada. Nevertheless, there are documented cases in which counterfeit medicines made their way into licensed brick-and-mortar pharmacies. These sentiments are echoed by Declan Hamill, Vice President of Legal, Regulatory Affairs and Compliance for Innovative Medicines Canada. Hamill (2017) describes the traditional supply chain as secure, noting that it is characterized by a finite number of players who are well established, with significant due diligence measures in place. He contrasts this with drugs on the internet, where none of these characteristics apply.

While counterfeiting incidents within the country’s licensed pharmaceutical system are rare, counterfeit drugs infiltrate the illegal drug supply chain as well. Individuals seeking to misuse prescription drugs, and who aim to purchase these drugs outside the legitimate supply chain, may also obtain counterfeit versions. Counterfeit OxyContin containing lethal doses of fentanyl has led to a spike in deaths and overdoses in recent years.

¹⁷ While RCMP utilizes the term “parcel” and Kubic uses the term “package”, the terms are interchangeable and reference the same unit.

The Partnership for Safe Medicines describes the following incidents:

- ◆ "In May, CBC News reported that a pair of British Columbia middle-schoolers had died of fentanyl poisoning after taking counterfeit pills.
- ◆ In March, Ottawa investigators confirmed that 14-year-old Chloe Kotval had died as the result of taking a counterfeit Percocet pill that instead contained a lethal dose of fentanyl. ...
- ◆ Counterfeit Percocet made instead with fentanyl has also been found in Newfoundland & Labrador ... CTV News reports that there were two deaths and 14 overdoses in the region due to these fake pills.
- ◆ Radio Canada International has reported that counterfeit pills laced with fentanyl have even reached Prince Edward Island. Police there report seizures of three types of fentanyl-laced pills. ...
- ◆ The Star is reporting that 25% of all organs transplanted in British Columbia this year have come from people who had been poisoned by fentanyl."

(Partnership for Safe Medicines, 2017b)

In 2012, the Government of Canada removed the prescription opioid OxyContin from the legitimate market, resulting in a sharp increase in overdoses and deaths stemming from the use of fentanyl. Between 2009 and 2014, there were at least 1,019 fentanyl-related drug poisoning deaths in Canada, with more than half occurring during 2013 and 2014. Canadian officials advise that this is likely an underestimate. In Canada, fentanyls are mixed with or disguised as heroin and pressed into counterfeit prescription pills. Traffickers import fentanyls into Canada directly from China; however, Canadian officials have also seized fully functional fentanyl synthesis and pill-producing clandestine laboratories. While pill presses and tableting machines are not currently regulated by Canada's federal government, the Province of Alberta passed legislation to regulate these devices effective January 1, 2017. In addition, efforts are underway to draft similar legislation for at least one more Canadian province (US DEA, 2016: 7).

Beyond counterfeit drugs infiltrating the licensed supply chain and the illegal drug supply chain, the third, and most prominent, source of counterfeit drugs is through internet commerce. The World Health Organization (2010) reports that 50% of the medicines purchased over the internet from illegal sites that conceal their physical addresses are counterfeit. A 2008 report by researchers from the European Alliance for Access to Safe Medicines concluded that more than 60% of the drugs sold by online pharmacies are counterfeit or substandard. The challenge of regulating online pharmacies is immense. According to the National Association of Boards of Pharmacy (2014), at any one time there are approximately 40,000–50,000 active online drug sellers. Moreover, researchers at the University of California San Diego

estimate that the largest illegal online drug sellers generate between US\$1 million and US\$2.5 million in sales every month (PhRMA, 2012).

Illegal internet pharmacies frequently claim to be Canadian in order to defraud consumers across the globe. However, some really are Canadian, specifically targeting Canadian consumers and patients.

Winnipeg pharmacist Daren Jorgenson questions the slack regulation of internet pharmacies in Canada and warns that the medicines coming from Canadian internet pharmacies are unsafe. ‘Is Canada a safe haven for online counterfeit pharmacists shipping into the US? Do we want to be known as that?’ he asked. He abandoned the internet pharmacy business, the CBC reports, because the drug supply chain was not secure and safe. ‘Basically, all my competition started selling drugs they were sourcing overseas from, in my opinion, unsafe countries and marketing them as Canadian. I couldn’t compete with that.’ (Partnership for Safe Medicines, 2017a)

Online pharmacy sites open and close easily, change their names with tremendous frequency, and often operate from servers based in other countries (Criminal Intelligence Service Canada, 2006). Estimates indicate that 90% of drugs purchased online come from a different country than the one purported in the claims made on the website (Riley, 2017; Ossola, 2015). The World Health Organization echoes these sentiments and warns, “Be especially careful of company websites stating they are ‘Canadian’ because the FDA found 85% of the drugs being promoted as ‘Canadian’ came from 27 other countries, and many products were counterfeit” (Peasgood, 2015). Importantly, Canadians use these websites also. “Some Canadians use illegal Internet pharmacies to obtain a variety of drugs for which they do not have a prescription and wish to purchase in relative anonymity. The illegal websites also supply some Canadians abusing or addicted to prescription drugs or seeking experimental or unapproved medications” (Criminal Intelligence Service Canada, 2006).

Contributing factors

Pharmaceutical counterfeiting in Canada is facilitated both by factors that are universal and factors that are unique to the Canadian market. The forces at play include demand-side factors, supply-side factors, inadequate regulation, enforcement and sanctions, and quality-sourcing issues and loopholes within the regulatory architecture. Many of the factors described in Section 3 apply to the Canadian market. Factors especially relevant or specific to Canada are enumerated here.

The demand for counterfeit pharmaceuticals is exacerbated by the misuse of prescription drugs. Individuals who seek to misuse prescription drugs may seek to purchase them without a prescription, through channels outside of the regulated supply chain.¹⁸ “Prescription drugs are the third most common substance misused by Canadian youth (after alcohol and cannabis). In 2016, over 80,000 Canadian teenagers used prescription drugs to get high. Youth may also use counterfeit drugs, knowingly or unknowingly. These drugs can contain additional unknown contents that can lead to serious harm” (Government of Canada, 2017: 1). While the extent of the problem among Canadian youth is striking, the phenomenon is a significant problem among adults as well.

Supply factors also facilitate the trade in counterfeit pharmaceuticals. As described earlier, drug shortages are an important contributing factor, and Canada suffers from significant shortages.¹⁹ “Canada, like many other countries, for the past ten years has been experiencing significant drug shortages, brought about by a number of factors including manufacturing issues and market pressures. In fact, for some conditions, the inability to source certain necessary medicines has reached a critical point with devastating impacts on patient care. Currently, over 750 products are posted on the Canadian drug shortage registry including epilepsy drugs, chemotherapy drugs, supportive treatments for cancer, painkillers, anesthetics, anti-inflammatory drugs, antibiotics and hormones” (Partnership for Safe Medicines, 2016b). Drug shortages are a particularly salient factor given US Senator Bernie Sanders proposed bill which would allow US citizens to purchase prescription drugs from Canada (Downs, 2017; Senate, 2014). The Canadian market is not equipped to meet US demand and such a policy would almost certainly exacerbate drug shortages (Rawson and Binder, 2017; Shepherd, 2017(a); Shepherd, 2017b).

In a recent study, Shepherd (2017a) examines the impact of proposed US drug importation on the Canadian drug supply.²⁰ Drawing on 2015

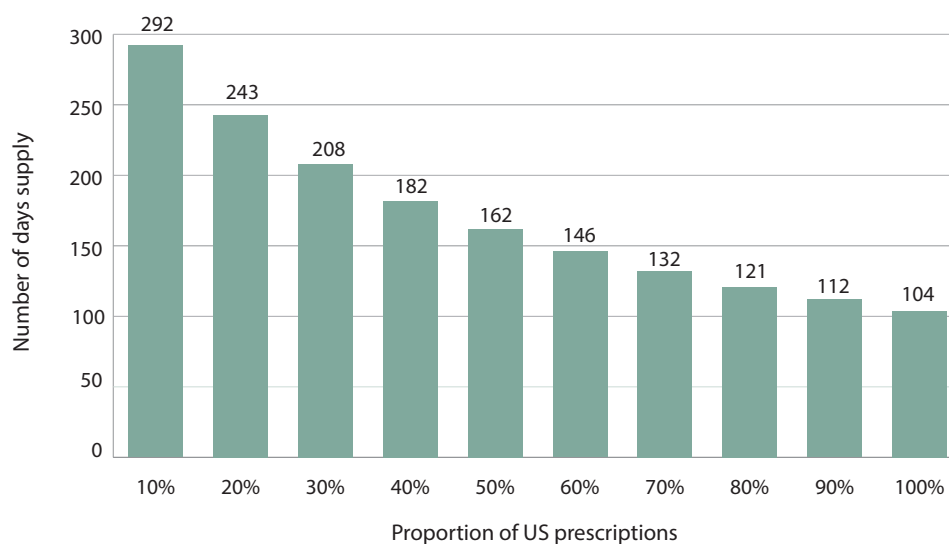
18. It has been documented that shame and embarrassment motivate some individuals to seek prescriptions for erectile dysfunction drugs outside of the legitimate supply chain. This is also true of individuals who develop an addiction to prescription opioids and seek to obtain them without the recommendation of a physician or a prescription.

19. The 2012 production stoppage at the facility that produced the majority of generic injectable drugs in Canada starkly illustrates the supply chain’s vulnerability (Rawson and Binder, 2017). As described by Health Canada (2017), “[i]n response to direct calls for action from the Minister of Health, industry associations launched in 2012 www.drug-shortages.ca—a publicly available website providing notification and information on drug shortages, drug discontinuances, and therapeutic alternatives” (Health Canada, 2017).

20. Shepherd (2017a) employs a forecasting model drawing on “baseline numbers from the number of Canadian and US prescriptions dispensed in 2015. Two models were employed: one for all prescriptions and one for brand name prescriptions dispensed. Based on these results, the number of days to exhaust the Canadian prescription drug supply was estimated by varying the proportion of US prescriptions demanded from Canada based on average prescription dose per person.”

prescribing data, the study finds that if a mere 20% of all US prescriptions were filled using Canadian prescription drug sources, the result would be the exhaustion of the Canadian drug supply in 183 days. Isolating the effect for brand name drugs reveals that a 20% demand from the US for patented drugs would result in the exhaustion of the Canadian brand name drug supply in 201 days. **Figure 7** depicts the number of days before the supply of brand name Canadian drugs would be exhausted, relative to the proportion of brand name US prescriptions demanded. If 20% of US brand name prescriptions were sourced in Canada, the Canadian supply would be exhausted in approximately eight months. At 40% and 80% demand, the supply would be exhausted in six months and four months respectively.

Figure 7
Number of days supply for Canadian brand name prescription drugs by proportion of US prescriptions demanded



Source: Shepherd, 2017a.

Beyond market conditions, inadequate regulatory oversight, insufficient enforcement, and deficient criminal penalties also play a significant role in facilitating pharmaceutical counterfeiting in Canada. This is particularly true in the case of the illegal activity centered around online pharmacies. Regulation of the Canadian pharmaceutical supply chain and responsibility for detecting counterfeit products and identifying the companies that produce them is a shared endeavor across Health Canada, the Royal Canadian Mounted Police (RCMP), and the Canada Border Services Agency (CBSA). Specifically, “Health Canada may have reason to alert the enforcement agencies to shipments from a particular vendor, while CBSA can inspect suspect packages at the border and the RCMP conducts investigations of counterfeit products” (Senate, 2014: 10).

Unfortunately, tremendous room for improvement exists. Consider that the Canadian International Pharmacy Association, which certifies Canadian online pharmacies, is run, in part, by CanadaDrugs, a Canadian online pharmacy that has faced legal issues. In a 2015 federal indictment, the US Department of Justice²¹ charged CanadaDrugs with money laundering, customs forms falsifications, and conspiracy to sell fake cancer medicines to unsuspecting doctors and clinics (Horton, 2015; Vogel, 2017). “CIPA ‘certifies’ Canadian pharmacies shipping to US residents as legitimate. ... Its seal is relied upon by millions. But it is not an independent certification organization: according to the Canadian corporation database, its six directors include Brock Gunter Smith, the Chief Business Development Officer for CanadaDrugs. Five out of six of the other CIPA board members work for a similar online pharmacy that is CIPA-approved, meaning that CIPA is bootstrapped—run by the very online pharmacies it purports to certify” (Horton, 2015).

While online pharmacies are a significant component of the problem, it is important to recognize that regulatory inadequacies extend to brick-and-mortar pharmacies as well. The majority of drugs consumed by Canadians are generic versions and a large proportion of these are produced—in whole or in part—in nations with which Canada has not entered into a Mutual Recognition Agreement (MRA). An MRA may be established with a nation that Canada considers to have equivalent Good Manufacturing Practices Compliance Programs for pharmaceutical production. An MRA covers the drugs produced in that country as well as those imported into it which are sent on to Canada (Senate, 2014). As reported by the Senate of Canada (2014), “[w]ith the exception of the United States, these countries are often those with developing economies and drug regulatory frameworks that do not meet the same high standards as those of Canada, the United States, Australia and the European Union. Of such countries, India and China manufacture and export to Canada a significant quantity of drugs. The committee feels that it is essential that Health Canada place additional focus on regulating these imports.”

In a recent report, the Senate of Canada (2014) pointed to Health Canada’s “poor record of inspecting foreign sites and its inconsistency in adopting measures taken by its MRA partners.” Notably, of the countries lacking a Mutual Recognition Agreement, India and China produce and export a significant quantity of drugs to Canada. Disturbingly, while Health Canada relies extensively on the information gathered by MRA partner nations on drug manufacturing facilities in non-MRA countries, the process is shockingly inadequate. Despite “Canada’s MRA partners banning the sale of products made by Indian-based drug manufacturer Ranbaxy because the company

21. In the US, criminal penalties result from the violation of US Code Title 18, section 2320 and US Code Title 21, section 333, as well as many state statutes.

had confessed to fabricating data, Health Canada took no action on this issue. A Health Canada representative assured members [of the Senate of Canada] that the department has many communication options to address any safety issues that may arise, including Foreign Product Alerts” (Senate, 2014).²² Nevertheless, Health Canada has issued no communications regarding ongoing problems with Ranbaxy and numerous products from the company remain for sale in Canada (Senate, 2014).

More troubling still is the fact that Health Canada is woefully unprepared to provide country-of-origin information for the drugs and medicines authorized for sale in Canada. The Senate of Canada (2014) points out that Health Canada “could only provide country-of-origin information ... for just over half of the almost 16,000 drugs currently authorized for sale in this country.” Health Canada relies on MRAs to ensure Good Manufacturing Practices compliance in industrialized nations. But “Health Canada indicated that 50% of foreign sites from which Canada imports medicines are located in MRA countries. Of the remaining 50%, half are in the United States and the remainder of the foreign sites are in non-MRA countries such as India and China” (Senate, 2014). That is, fully 25% of Canada’s foreign-sourced medicines come from countries with whom Canada has not entered into a Mutual Recognition Agreement.

In terms of the number of drugs imported from foreign sites, Health Canada provided country of origin information to the committee for only 54% of the 15,868 pharmaceuticals currently authorized for sale in Canada, or 8,554 drugs. Of these drugs, 51.6% are domestically produced, 22% are from the United States, 4.6% from India, 4.1% from Germany, 3.3% from the United Kingdom, and 3.1% from France. Amir Attaran, holder of the Canada Research Chair in Public Health and Global Development Policy at the University of Ottawa, stated that the proportion of imported pharmaceuticals in Canada is not known. Regardless of the proportion of Canada’s drug being manufactured in non-MRA countries, the committee heard that Health Canada does not focus any inspection programs at facilities in these countries. Unlike the United States Food and Drug Administration that conducts

22. “The committee was told that in several instances drug manufacturing sites in non-MRA countries, particularly India, have been identified by drug regulators in other countries to be non-compliant with GMP requirements. Of particular concern to the committee was the issue of the generic drug manufacturer Ranbaxy Laboratories Limited, which has a number of facilities in India. Under whistle-blower protection legislation in the United States a former executive with Ranbaxy informed the Food and Drug Administration in 2008 that the drug maker had been deliberately falsifying its records and fabricating data about the medicines it produced. There are still unresolved issues with this company today resulting in bans of its products from certain facilities in the European Union as well as the United States. To date, there has been no action by Health Canada with respect to Ranbaxy which is authorized to market about 160 medicines in this country” (Senate, 2014: 11-12).

hundreds of inspections at sites outside of the US each year, Canada conducted only three foreign inspections in 2011. A Health Canada official indicated that this number had increased to 14 foreign site inspections in 2013/14 (Senate, 2014).

All of these factors are compounded by the insufficient criminal penalties currently in place. “Officials from Health Canada stated that the penalties provided for under the Food and Drugs Act are not substantial and the [Senate of Canada] was told that no prosecutions have occurred under that Act. The committee notes that the Food and Drugs Act provides for a maximum penalty of no more than three years imprisonment or a fine not exceeding \$5,000, or both” (Senate, 2014).

Ironically, Canada relies on MRAs to cover “the drugs produced in that country *as well as those imported into it and which are sent on to Canada*” (Senate, 2014, emphasis added), while Canada makes no such allowances for drugs that are imported into Canada and sent on to other nations. Canada specifically exempts products for export from Health Canada oversight. While products sourced from Canada are perceived to be safe, in reality those destined for export are exempt from quality standards. The fact that drugs come from Canada does not mean that the manufacturer adhered to Canadian safety standards. This issue was raised recently by former Industry Minister James Moore, who told a Senate committee, “[t]he idea Canada would act as a customs agent for the United States is, frankly, not something that’s on the table. ... The scope of this is protecting Canadians and the Canadian domestic market.” Minister Moore was addressing Bill C-8, the Combating Counterfeit Products Act, which aims to stop the estimated \$38 million worth of fake goods annually flowing into Canada, by increasing the powers border agents have to stop them. Unfortunately, the law only allows border agents to intercept parcels intended for sale or distribution in Canada—not those being transshipped through Canada to another nation (Wyld, 2014). The scope reflects a missed opportunity and a short-sighted view of the challenges surrounding the battle against counterfeit goods.

Transshipment is particularly concerning. As described by Declan Hamill, Vice President of Legal, Regulatory Affairs & Compliance for Innovative Medicines Canada, there are no regulations in place to deal with trans-shipments of medicines that are located in Canada only while in transit from one supplier country to another destination country.

This is worrisome since most counterfeit product is imported into Canada in the postal and courier streams (Senate, 2014). Notably, within the former Harper Government’s Combating Counterfeit Products Act, Health Canada is explicitly omitted from regulating transshipped medicines as they are not destined for use in Canada. (Smith, 2017). Counterfeiters frequently present themselves as licensed facilities operating in nations with highly regulated supply chains, while in reality, the primary source of counterfeit drugs is

Southeast Asia (Senate, 2014). While “there have been no successful prosecutions to date in Canada of illegal online pharmacies, several Canadians have been successfully prosecuted in the United States for operating such websites and selling counterfeit products” (Senate, 2014). The incidents described below reflect those efforts and the steps taken by US authorities to halt the counterfeit medicines trade.

- ◆ *Ram Kamath ... is one of eight people indicted by the US Justice Department for allegedly participating in a conspiracy to distribute \$78 million worth of non-FDA approved and counterfeit cancer medications into US doctors' offices. ... In February 2012, the FDA informed doctors and the public that counterfeit Avastin had been discovered in US doctors' offices. Ultimately, the FDA sent warning letters to over 100 doctors in 28 states. (Partnership for Safe Medicine, 2015a)*
- ◆ *A Federal Court in Virginia has accepted the guilty plea of SB Medical Inc. and TC Medical Group on charges that they indulged in a multi-year conspiracy to smuggle and sell misbranded prescription pharmaceuticals in the United States and unlicensed wholesaling of prescription drugs. SB Medical Inc. was based in Toronto, Canada, and TC Medical Group was based in Barbados. SB Medical Inc. and TC Medical Group used false names to sell pharmaceutical products to doctors and clinics throughout the United States. Large shipments were broken down into multiple small shipments for shipping across the border. Those shipments were then sent to various US addresses to be shipped out to customers with a US return address. The non-FDA approved prescription medications were sourced from other foreign countries including, India, Turkey, France, Italy, and other countries. (Partnership for Safe Medicine, 2015c)²³*
- ◆ *When US doctors purchased medicines from foreign supplier TC Medical Group/SB Medical, they were getting drugs lacking sufficient ventilation, temperature, humidity, and security. The drugs were kept in unregistered commercial mailboxes, residential backyards and porches, basement rooms, garages and kitchen refrigerators instead of drugs consistently maintained at safe temperatures and in sanitary conditions. ... [The US Department of Justice] press release at the time of sentencing reported that the Toronto, Canada business was fined \$45 million, and required to pay an additional \$30 million for selling their misbranded medications to over 1,000 U.S. doctors and medical clinics between 2011 and 2014. (Partnership for Safe Medicines, 2017d)*

²³. It is important to recognize that these doctors and clinics were not knowingly purchasing counterfeit drugs. Both cost factors as well as available supplies may have made the drugs attractive to the purchasing physicians.

- ◆ *Hazim Gaber, 22, of Edmonton, Canada, was sentenced today in Phoenix by US District Court Judge James A. Teilborg to 33 months in prison for selling counterfeit cancer drugs using the Internet, announced Assistant Attorney General Lanny A. Breuer of the Criminal Division, US Attorney Dennis Burke for the District of Arizona and FBI Special Agent in Charge of the Phoenix Field Office Nathan T. Gray. Judge Teilborg also ordered Gaber to pay a \$75,000 fine, as well as \$53,724 in restitution, and to serve three years of supervised release following his prison term. Gaber was indicted by a federal grand jury in Phoenix on June 30, 2009, on five counts of wire fraud for selling counterfeit cancer drugs through the website DCAdvice.com. Gaber was arrested on July 25, 2009, in Frankfurt, Germany, and was extradited to the United States on Dec. 18, 2009. At his plea hearing in May 2010, Gaber admitted selling what he falsely claimed was the experimental cancer drug sodium dichloroacetate, also known as DCA, to at least 65 victims in the United States, **Canada**, the United Kingdom, Belgium and the Netherlands between October and November 2007. Gaber also admitted to selling more than 800 pirated copies of business software between February 2007 and December 2008. As part of the plea agreement, Gaber agreed to forfeit or cancel any website, domain name or Internet services account related to this fraud scheme. (US Department of Justice 2010, emphasis added)*

Finally, a significant gap in Canadian law provides a loophole for pharmaceutical counterfeiters. This underscores the lack of enforcement and the seemingly laissez-faire attitude surrounding the threat of spurious drugs. Specifically, even in the face of numerous administrative actions in Canada, online pharmacies may simply move, change their name, and continue their operations. Consider the case of Global Pharmacy Plus (previously Global Pharmacy Canada). The operation has been around for more than a dozen years, with a target market of US citizens. Operating an international mail order center and a call center out of Ontario, the company was subject to a 2013 injunction for operating without accreditation, and ordered to shut down. With the name change, they continue to operate. Global Pharmacy Plus claims to be a middleman. “We act as your agent to deal with pharmacies located around the world; the company says on its website. ‘The pharmacies we deal with source most of their generic medications from India, the world’s largest manufacturer of generic medications’” (Gallagher, 2016). So, consumers are forced to rely on India for quality control. This is particularly troubling because “India currently lacks regulatory oversight and exhibits legal weaknesses that encourage substandard drug producers to flourish ... Furthermore, some Indian producers seem to be consistently and intentionally making poorer-quality products” (Bate, 2017). Global Pharmacy Canada argued that “it was only arranging the shipment of drugs from India

to Americans, so it didn't need a license. Global Pharmacy Canada said it was actually a company in Belize, in Central America, with only contract order-takers in Canada" (Gallagher, 2016). This case exemplifies the online pharmacy's ability to skirt the law by merely claiming that they do not sell products to anyone in Canada (Kubic, 2017). It is a significant loophole that undeniably endangers consumers.

6. Remedies and recommendations

Product counterfeiting constitutes a form of consumer fraud: the product in question is sold while purporting to be something that it is not. The problem is transnational in nature and the production and sale of counterfeit goods is a multi-billion-dollar problem with serious economic and health ramifications for consumers, governments, and businesses. Product counterfeiting is a lucrative business, with criminals relying on consumers' attraction to cheap goods combined with low production and distribution costs.

Without legal regulation and minimal recourse, consumers are at risk from unsafe and ineffective products. Goods subject to counterfeiting range from automotive parts to children's toys, alcohol to agricultural tools, clothes to cosmetics, electrical consumer goods to fraudulent medicines (UNODC, 2015). Faulty counterfeited products can lead directly to injury and death, and an expansive range of items which are illegally copied can have serious health and safety consequences. **Table 1** illustrates just how diverse this list of products can be.

Table 1: The diverse nature of illicitly produced goods (select categories)

Automotive	Scooters, engines, engine parts, body panels, air bags, windscreens, tires, bearings, shock absorbers, suspension and steering components, automatic belt tensioners, spark plugs, disc brake pads, clutch plates, oil, filters, oil pumps, water pumps, chassis parts, engine components, lighting products, belts, hoses, wiper blades, grilles, gasket materials, rings, interior trim, brake fluid, sealing products, wheels, hubs, anti-freeze, windshield wiper fluid.
Chemicals/ Pesticides	Insecticides, herbicides, fungicides, non-stick coatings.
Consumer electronics	Computer components (monitors, casing, hard drives), computer equipment, webcams, remote control devices, mobile phones, TVs, CD and DVD players, loudspeakers, cameras, headsets, USB adaptors, shavers, hair dryers, irons, mixers, blenders, pressure cookers, kettles, deep fryers, lighting appliances, smoke detectors, clocks.

Table 1, continued

Electrical components	Components used in power distribution and transformers, switchgears, motors and generators, gas, and hydraulic turbines and turbine generator sets, relays, contacts, timers, circuit breakers, fuses, distribution boards and wiring accessories, batteries.
Food, drink & agricultural products	Fruit (kiwis), conserved vegetables, milk powder, butter, ghee, baby food, instant coffee, alcohol, drinks, candy/sweets, hi-breed [sic] corn seeds.
Pharmaceuticals	Medicines used for treating cancer, HIV, malaria, osteoporosis, diabetes, hypertension, cholesterol, cardiovascular disease, obesity, infectious diseases, Alzheimer's disease, prostate disease, erectile dysfunction, asthma and fungal infections, antibiotics, anti-psychotic products, steroids, anti-inflammatory tablets, pain killers, cough medicines, hormones, and vitamins, treatments for hair and weight loss.
Tobacco	Cigarettes, cigars, and snuff.
Toiletry and other household products	Home and personal care products, including shampoos, detergents, fragrances, perfumes, feminine protection products, skin care products, deodorants, toothpaste, dental care products, shaving systems, razor blades, shoe polish, non-prescription medicine.

Source: UNODC, 2015.

The United Nations Office on Drugs and Crime (UNODC) describes a number of ways in which product counterfeiting may be tackled, both on the part of consumers and authorities. Their recommendations are echoed in many of the recommendations described here for Canada in the context of counterfeit pharmaceuticals. The UNODC (2015) recommendations include: legislative action, such as adopting and fully implementing the United Nations Convention against Transnational Organized Crime; consumer awareness campaigns; and cross-border/multi-sector partnerships.

In light of the tremendous threat posed by counterfeit pharmaceuticals, and the specifics of the Canadian situation, this study proposes several recommendations to limit the growth of pharmaceutical counterfeiting and protect patients, providers, and manufacturers.

Raise public awareness

“Addressing the counterfeit criminal market is complicated by the varying levels of societal tolerance toward counterfeit goods in Canada.” Criminal Intelligence Service Canada (2006)

As Kubic (2017) notes, the public does not fully understand pharmaceutical counterfeiting as health and safety issue. The growing problem results in more patient harm, but as is the case in Canada, it tends to be opioid abusers, who do not garner much sympathy.²⁴ Awareness is essential, and training is needed to develop the recognition that this is a particular criminal problem. Enforcement lacks any prioritization, such that addressing the problem becomes a question of resources. Resources are required that are commensurate with the size of the problem (Kubic, 2017).

We also believe identification of specific public health-sensitive counterfeit drug categories for policymaking attention and priority setting should be used. For example, the public health consequences associated with counterfeit vaccines should be a priority in counterfeit drug surveillance. Other drugs at potential high risk for counterfeiting, including drugs subject to critical manufacturing shortages and narrow therapeutic index drugs that require precise manufacturing to be effective, emphasize the need for this concept. Collecting robust data on key, agreed-on priority specific categories may be beneficial for these risk-based approaches and result in a shift in policy focus on the basis of specific, actionable information from the field. (Mackey, Liang, York, and Kubic, 2015: 65)

The importance of a public awareness campaign also features prominently in the recommendations of the Senate of Canada (2014). “The committee further recommends that Health Canada implement a public awareness campaign warning of the risks of purchasing prescription drugs from online pharmacies [Recommendation 19]” (Senate, 2014: 30). The Government of Canada provided specific advice for consumers, noting that patients should not purchase products from a website that sells products that do not have a Drug Identification Number (DIN) issued by Health Canada (Canada, 2012).

Efforts to inform consumers are increasingly important as information about pharmaceutical manufacture and distribution becomes increasingly global and information becomes difficult to obtain. This is compounded by the fact that all “generic” products are considered (by consumers) to be identical and interchangeable. As described by Bate (2017), western regulators face tremendous difficulties in overseeing production in countries such

²⁴ While such individuals may not garner much sympathy, it is important to recognize that this is a prominent public policy issue, and cities and municipalities, that is, taxpayers, are spending tremendous amounts of money on emergency response and other initiatives to deal with the opioid crisis.

as India and China, making the task all but impossible for individual consumers. In this context, public awareness campaigns would fill an important informational void.

Improve regulatory oversight

The passage of the Combating Counterfeit Products Act (Bill C-8) into law seemed like a promising start for Canada to meeting the challenges of pharmaceutical counterfeiting. “The law also amends the Criminal Code to make selling, distributing, possessing, importing or exporting counterfeit goods for the purpose of trade subject to fines and possible jail time” (Industry Canada, 2014). As expressed by then-Industry Minister James Moore, “[c]ounterfeit, pirated or knock-off goods threaten the integrity of Canadian brands and undermine the hard work of successful Canadian businesses. With the passage of this bill, Canada now has an effective way to stop the flow of these illegal and dangerous goods through our borders and into the marketplace. These goods are not only damaging for businesses but also dangerous for the health and well-being of all Canadians who rely on using safe, good-quality products” (Industry Canada, 2014).

Unfortunately, Bill C-8 was more of a missed opportunity than a leap forward. Most notably, it should have regulated transshipped goods, which it did not. Accordingly, as an additional step toward strengthening the enforcement of biopharmaceutical intellectual property rights, it is recommended that Canada strengthen their anti-counterfeiting legislation. To fully protect the health and safety of Canadian patients and protect the biopharmaceutical industry from the threat of fraudulent medicines, it is necessary that Canada adopt criminal sanctions in consort with regulatory provisions, including sanctions for counterfeit drugs that are transshipped via Canada. Similar endeavors such as the Council of Europe’s “Medicrime” Convention and the recommendations of the World Health Organization’s IMPACT Programme aim to strengthen product protection measures, ensure reliability in the wholesale distribution of pharmaceuticals, and define clear obligations for starting materials (EFPIA, 2010: 3).²⁵ The suggestions included in the IMPACT Handbook (2011) include: combatting internet distribution of counterfeit pharmaceuticals, establishing guidelines for a rapid response plan, developing good security practices for packaging materials, development of pharmacovigilance systems, and identifying regulatory and legislative gaps (WHO, 2011: 34–37).

25. The EFPIA White Paper cited here provides a great list of the elements that effective legislation should incorporate.

Echoing the concerns of the Senate of Canada, it is also recommended that a component of the improved oversight address the regulation of imports from non-MRA countries and the inspection of foreign manufacturing sites. Given that India and China manufacture and export to Canada a significant quantity of drugs, it is essential that Health Canada place additional focus on regulating these imports. This concern arises specifically because drug regulatory authorities of other countries have identified sites in non-MRA countries, particularly India, as non-compliant with good manufacturing practices (Senate, 2014). Moreover, it is recommended that Health Canada maintain country-of-origin information for all drugs currently authorized for sale in this country, addressing the lack of information that currently exists regarding source countries.

Incentivize domestic production

Moreover, increased domestic production may serve to reduce the import penetration of the Canadian market, lessening Canada's dependence on foreign imports to supply domestic biopharmaceutical needs. This independence is surprisingly important, especially in the context of increasingly prevalent pharmaceutical shortages in Canada and elsewhere. The Canadian Pharmacists Association (2010) recognized that the "globalization of the drug market may be a contributing factor" (p. 10). Given this, increased domestic production, and independence, may lessen the risk of a shortage. As discussed above, this is a significant contributing factor. Although imports represented just 18% of the domestic market in 1983, by 2000, the percentage was 75.5% (Lexchin, 2001: 8). Greater domestic production may also lessen supply chain risk, including appropriate regulatory oversight of manufacturing facilities, and shorter transport links reducing risks of adulteration, counterfeit entry, and cargo theft. A stronger domestic industry would also generate increased self-sufficiency and increased investment in local production.

While domestic production could deliver these benefits, it is essential to recognize the obstacles that exist in Canada that prevent such production. Fundamentally, the brand name manufacturers operating in Canada are affiliates of multinational corporations. A primary consideration of global firms is the cost of production, such that production is shifted to the locations with the lowest costs. To attract additional production, the Canadian governments would need to offer incentives for companies to build more manufacturing plants in Canada. In reality, the opposite has been true. According to the Patented Medicines Prices Review Board (PMPRB), total business expenditures on R&D by Canadian pharmaceutical companies have fallen below \$1 billion since 2011. Moreover, between the years 2001 and 2015, R&D spending in the biopharmaceutical industry fell by 20% (PMPRB, 2015).

In essence, companies have been discouraged from manufacturing in Canada by inadequate intellectual property protections,²⁶ high taxes, high salaries, and a general negativity towards the industry. The result is that more drugs are imported and the security that domestic production could offer never materializes.

Regulate transshipments

Under current legislation, Canada does not scrutinize or regulate drugs bound for export. If pharmaceuticals are not destined for Canadian citizens, they are not subject to the Canadian government's safety regulations. This provides the opportunity for unscrupulous drug exporters to mark pharmaceuticals as "for export only," thereby bypassing Canada's safety regulations, and enabling them to mail counterfeit or substandard drugs "made in China, India, and other countries notorious for ineffective and sometimes deadly products to patients abroad using a Canadian mailing address" (Partnership for Safe Medicines, 2017f). It is irresponsible and short-sighted of Canadian legislators not to try to regulate online pharmacies and drug transshipments. In addition, it is an abdication of Canada's international responsibility to safe medicines and a secure pharmaceutical supply chain. Again, given Canada's abysmal prosecution record, such regulations would be useful in making progress against counterfeiters.

Increase criminal sanctions

At a fundamental level, Canada requires an increase in the criminal sanctions in place to punish pharmaceutical counterfeiting. Given Canada's abysmal prosecution record of illegal online pharmacies, increased criminal sanctions are a necessary tool to give the authorities the "enforcement teeth" that the Food and Drugs Act currently lacks. In a statement before the Standing Senate Committee on Social Affairs, Science and Technology, Health Canada explains that "the penalties provided for under the Food and Drugs Act are not substantial ... [providing] for a maximum penalty of no more than three years imprisonment or a fine not exceeding \$5,000, or both" (Senate, 2014). Again, the punishment should be commensurate with the crime. A criminal endeavor that generates tens of millions of dollars and puts countless lives at risk should face more than a \$5,000 fine.

²⁶ Recommendations for how to strengthen Canada's intellectual property protections for the biopharmaceutical industry are presented in an earlier Fraser Institute study (Lybecker, 2017b).

One component of such a change should be the passage of federal legislation to restrict the sale of pill presses. This was done in Alberta in May 2016. The bill—once proclaimed into law—will limit the purchase of pill presses, tablet machines, capsule filling machines, and pharmaceutical mixers to pharmacists or individuals holding licenses. “A person found guilty of illegally possessing a press will face a fine of \$50,000 for a first offence. An amendment to the bill toughens the penalties for repeat offenders. A second conviction could mean a \$125,000 fine, up to six months in jail or both. Anyone convicted a third time can be fined \$375,000 and receive one year in jail” (Bellefontaine, 2016). A change in penalties of this scale reflects the reality of the criminal operations in place and a true effort to stop them.

Implement global harmonization

It is recommended that Canada work toward Global Regulatory Harmonization; to “reduce the burden of regulation harmonize regulatory requirements and achieve appropriate reciprocal arrangements.” Regulatory authorities should work toward harmonization through a variety of forums, including: International conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals in Human Use, Asia-Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee, International Pharmaceutical Regulators Forum, Pan American Network for Drug Regulatory Harmonization, Pharmaceutical Inspection Cooperation Scheme, and the World Health Organization (International Trade Association 2016). Future efforts should focus on:

... cooperative harmonization to expand the diversity, sources, number and quality of reports to improve data collection across all areas. ... Crucial to bringing the benefits of this approach to sustained global efforts will be harmonizing definitions and reporting fields, establishing cooperative public–private approaches to shared reporting responsibilities, and stakeholders committing to an appropriate level of transparency and public reporting of data to inform all impacted partners. Transparency that does not compromise law enforcement efforts is important to improve public awareness of the issue, disseminate important information on the inherent risk characteristics of the counterfeit medicines trade to promote prevention, and shared capacity building for prompt detection and remedial action. (Mackey, Liang, York, and Kubic, 2015: 65)

Pursue an international treaty

Given that the sale of counterfeit prescription drugs is conducted largely via illegal online pharmacies, an international effort to identify and prosecute said pharmacies will be required to combat them.²⁷ Accordingly, Canada should seek to enter into an international treaty to facilitate prosecutions of pharmaceutical counterfeiting at the global level. The Senate of Canada (2014) included this as a recommendation in their report as well, and for good reason. Consider the following argument:

Amir Attaran recommends “an international treaty whereby countries would all agree on a set of laws.” Attaran compares it to the aviation industry: “There are dozens of treaties on civil aviation, and every single country is following those. If not, they don’t fly.” To raise the standards for pharmaceuticals worldwide, Attaran says, we need a similar system that penalizes countries that don’t enforce medicinal quality controls. The closest protocol now is the Medicrime Convention: Since 2011, countries can sign the informal treaty to criminalize pharmaceutical fraud within their borders. But countries aren’t under much pressure to pass more formal legislation or to enforce the statutes of the convention. And in fact, they often have incentives not to. Some countries, like India and Brazil, are dragging their feet on international enforcement regulations because poor-quality pharmaceuticals make up such a large part of their economy, Attaran says. Others are trapped by policies that conflate fake and counterfeit drugs. (Ossola, 2015: 7)²⁸

²⁷. An excellent description of “Goals, Doctrines and Proposals for a Counterfeit Medicines Treaty” may be found in Attaran, Bate, and Kendall (2011). A discussion of all components and legal requirements is beyond the scope of this document.

²⁸. As explored in the Appendices, in the context of national legislation, the distinction between “fake” and “counterfeit” drugs largely hinges upon whether unauthorized production of a quality drug, without permission and in violation of the product’s patents, is included in the terminology.

7. Conclusion

Consumers have been cautioned about the dangers of adulterated medicines for centuries. Although the presence of counterfeit medicines in international commerce was initially identified as a problem in 1985, the problem has since grown in size and scope, impacting nations of every size and income level, and drugs of every class and description. Pharmaceutical counterfeiting now spans every continent and no medicine is immune (Clark, 2015). As the extent of pharmaceutical counterfeiting has grown, so have the dangers, even for nations with sophisticated supply chains, such as Canada. Masquerading as curative medicines, counterfeit pharmaceuticals are increasingly prevalent and profitable. Moreover, there is anecdotal evidence that the trade is being used to fund criminal organizations and terrorism.

While Canada maintains a safe drug supply chain, recent incidents point to the presence of counterfeit pharmaceuticals in Canada in both the legitimate supply chain as well as in the illicit drug trade and in illegal internet pharmacies. The battle against counterfeit pharmaceuticals has moved front and center, as policymakers address it in a manner that is both more public and more aggressive. In this light, it is essential to examine the extent of the problem, what is known about counterfeit production and distribution, links to organized crime, and appropriate policy responses. This report has presented a definition of the term “counterfeit” in the context of medicine, defined the contributing factors, described the magnitude of the problem at a global level, provided specifics on the Canadian situation, and set forth a number of recommendations to better equip Canada in the fight against spurious drugs. As the trade in counterfeit medicines grows, the stakes grow exponentially: in terms of the lives at risk, as well as the costs to legitimate manufacturers and national economies. This study points to the opportunity that Canada has to take concrete steps to secure the pharmaceutical supply chain, and protect patients, in Canada and across the globe.

Appendix A: Substandard, spurious, falsely labelled, falsified, and counterfeit (SSFFC) medical products

This information is taken directly from the World Health Organization's Fact Sheet (2016). This statement represents the World Health Organization's conception of SSFFC medical products, prior to May 2017. The World Health Organization's current definition (Appendix B) was changed to address concerns surrounding intellectual property rights.

Key facts

- SSFFC medical products may cause harm to patients and fail to treat the diseases for which they were intended.
- They lead to loss of confidence in medicines, healthcare providers, and health systems.
- They affect every region of the world.
- SSFFC medical products from all main therapeutic categories have been reported to [World Health Organization] including medicines, vaccines, and in vitro diagnostics.
- Anti-malarials and antibiotics are amongst the most commonly reported SSFFC medical products.
- Both Generic and Innovator medicines are falsified including very expensive products for cancer to very inexpensive products for treatment of pain.
- They can be found in illegal street markets, via unregulated websites through to pharmacies, clinics, and hospitals.

Scope of the problem

Substandard, spurious, falsely labelled, falsified, and counterfeit (SSFFC) medical products are by their very nature difficult to detect. They are often designed to appear identical to the genuine product and may not cause an obvious adverse reaction, however they often will fail to properly treat the disease or condition for which they were intended.

There are many estimates of the scope and scale of the market in SSFFC medical products but little validated evidence to underpin those estimates.

In 2013, the World Health Organization launched a global surveillance and monitoring system to encourage Member States to report SSFFC incidents in a structured and systematic format, to help develop a more accurate and validated assessment of the scope, scale and harm caused by this issue. Over 920 medical products have so far been reported representing all main therapeutic categories and representing both innovator and generic medicines.

Contents of SSFFC medical products

Falsified medical products may contain no active ingredient, the wrong active ingredient or the wrong amount of the correct active ingredient. They are also found to commonly contain corn starch, potato starch or chalk. Some SSFFC medical products have been toxic in nature with either fatal levels of the wrong active ingredient or other toxic chemicals. SSFFC medical products are often produced in very poor and unhygienic conditions by unqualified personnel, contain unknown impurities, and are sometimes contaminated with bacteria.

Identifying an SSFFC medical product

Some falsified medical products are almost visually identical to the genuine product and very difficult to detect. However, many can be identified by:

- examining the packaging for condition, spelling mistakes, or grammatical errors;
- checking the manufacturing and expiry dates and ensuring any details on the outer packaging match the dates shown on the inner packaging;
- ensuring the medicine looks correct, is not discoloured or degraded, and does not have an unusual smell; and
- discussing with your pharmacist or doctor as soon as possible if you suspect it is not working properly or you have suffered an adverse reaction.

SSFFC medical products and the Internet

Unregulated websites supplying medicines, particularly those concealing their physical address or landline telephone number are frequently the source of unlicensed, substandard, and falsified medical products. Consumers should be cautious of the following:

- spam email advertising medicines
- lack of authenticity; no verification logo or certificate
- spelling mistakes and poor grammar on the packaging
- websites that do not display a physical address or landline
- websites offering prescription only medicines without a prescription
- suspiciously low-priced products

Checklist for medicines purchased online

- Is it exactly the medicine ordered?
- Is it the correct dosage?
- Is the packaging in good condition, clean, with a patient information leaflet and in the language in which it was advertised?
- Does the medicine look, feel, and smell as it should?
- Are security seals intact with no signs of tampering?
- Does any customs declaration or postal label declare the contents as medicines?
- Does the batch number and expiry date on the primary internal packaging match the batch number and expiry date on the secondary (external) packaging?
- Have you noticed any unusual activity on your credit card since the purchase?

Global impact

Falsified medical products are manufactured in many different countries and in all regions. Many countries and the media frequently report successful operations against manufacturers of SSFFC medical products. Some reports refer to large scale manufacturing and others to small back street operations. With the availability of tableting machines, ovens, specialist equipment, ingredients and packaging materials, clandestine manufacturing facilities are quick and easy to assemble.

No countries remain untouched by this issue—from North America and Europe through to Sub Saharan Africa, South East Asia, and Latin America. What was once considered a problem suffered by developing and low-income countries has now become an issue for all. With the exponential increase in internet connectivity those engaged in the manufacture, distribution and supply of SSFFC medical products have gained access to a global market place. This extends both to consumers and business forums. A culture of self-diagnosis and self-prescribing has led to the emergence of thousands of unregulated websites providing unsupervised access to SSFFC medical products. However, it is low- and middle-income countries and those in areas of conflict, or civil unrest, with very weak or non-existent health systems that bear the greatest burden of SSFFC medical products.

Appendix B: Substandard and falsified medical products

This information is taken directly from the World Health Organization (2017b). This statement represents the World Health Organization's updated conception of SSFFC medical products, which does not cover the protection of intellectual property rights.

Substandard and falsified medical products

“Substandard” medical products (also called “out of specification”) are authorized by national regulatory authorities, but fail to meet either national or international quality standards or specifications—or in some cases, both. “Falsified” medical products deliberately or fraudulently misrepresent their identity, composition or source.

The Assembly also agreed a definition of “unregistered or unlicensed medical products”. These have not been assessed or approved by the relevant national or regional regulatory authority for the market in which they are marketed, distributed or used.

The new terminology aims to establish a common understanding of what is meant by substandard and falsified medical products and to facilitate a more thorough and accurate comparison and analysis of data. It focuses solely on the public health implications of substandard and falsified products, and does not cover the protection of intellectual property rights.

Substandard and falsified medical products can harm patients and fail to treat the diseases for which they were intended. They lead to loss of confidence in medicines, healthcare providers and health systems, and affect every region of the world. Anti-malarials and antibiotics are amongst the most commonly reported substandard and falsified medical products, but all types of medicines can be substandard and falsified. They can be found in illegal street markets, via unregulated websites, and in pharmacies, clinics and hospitals.

Delegates agreed to adopt the new name of “substandard and falsified” (SF) medical products for what have until now been known as “substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC)” medical products.

Appendix C: Health Canada's policy on counterfeit health products

This information is taken directly from Health Canada (2010).

Health Canada has defined a counterfeit health product as:

A counterfeit health product is one that is represented as, and likely to be mistaken for, an authentic product.

Counterfeiting can apply to both branded and generic products, and could relate to a product's identity or source, could include products with the correct ingredients/components, with the wrong ingredient/components, without active ingredients, with insufficient active ingredients, or with misleading packaging or labelling.

For functional purposes, the Inspectorate will consider counterfeit health products to be those which are unapproved and:

- fraudulent;
- fraudulently labelled with respect to identity, composition, origins, and/or source;
- falsifications which may look genuine; or
- forgeries (i.e., printed).

The range of "counterfeit health products" includes:

1. Products attempting to replicate genuine brands (i.e., products sold under authorized product name without proper authorization)
2. Products falsifying information such as the DIN, medical device license number, or other information implying the products are authorized for sale in Canada.

Although counterfeit products may include one of the following characteristics, products based exclusively on one of the following criteria will not necessarily be confirmed as counterfeit. As such, in most cases products

will not be deemed counterfeit solely based on any one of the following characteristics:

- Diverted products (see explanation below).
- Products using patented ingredients/design but which do not mislead or claim to be the rights holder, hold a Drug Identification Number (DIN), etc.
- Products not disclosing all ingredients, or with labelling issues.

In addition, as circumstances vary between incidents, counterfeit products will be confirmed on a case-by-case basis.

Typically, counterfeit products are illegal products which are packaged or marked to indicate that they have been legally manufactured by, or on behalf of, the market authorization holder. In contrast, diverted products are genuine products manufactured by an authorized manufacturer that end up on a different market than intended, one for which they are not specifically authorized (e.g., theft of expired or recalled product, illegal redirection of prescription drugs from legitimate sources). Although these products may or may not be obtained under suspicious circumstances, the integrity of the products is compromised due to the unknown manner of storage and distribution. While diverted products are to be included in the policy, they are not to be considered “counterfeit” unless proven otherwise. Within the policy, diverted products need to be considered as a potential indicator of counterfeit distribution.

Appendix D: Canada's current IP protection for pharmaceuticals

This information is taken directly from Lybecker (2017b). Citations in this text can be found there.

In Canada, there are three components mapping out the legal framework surrounding intellectual property rights protection in the biopharmaceutical industry. The primary intellectual property law enacted by the legislature is the Patent Act (R.S.C., 1985, c.P-4). Beyond this, there are two additional pieces of legislation expanding on the implementation of the regulations: the Patented Medicines (Notice of Compliance) Regulations (SOR/93-133) and “Data Protection” found in Canada’s Food and Drug Regulations (C.R.C., c.870). In addition, Canada is a signatory to several multilateral treaties, one of which is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which governs intellectual property protection for the biopharmaceutical industry. Canada is also a signatory to the North American Free Trade Agreement (NAFTA), a regional economic integration treaty which also addresses intellectual property protection for the biopharmaceutical industry.¹

After almost twenty years of compulsory licensing,^{2 3} of prescription drugs, Canada restored full patent protection to biopharmaceutical drugs

1. Smith (2000) gives an excellent description of relevant pieces of legislation and the chronology of significant events.

2. “Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO’s agreement on intellectual property—the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement” (World Trade Organization, 2006).

3. In 1923, Canada’s “Patent Act was amended to provide for compulsory licensing for manufacturing purposes for food and drug patents. In relation to patented medicines, the amendment allowed a compulsory license to be granted if a medicine’s active ingredients were manufactured in Canada. (A compulsory license is a statutory license that gives the licensee the right to manufacture, use, or sell a patented invention before the patent

when it repealed the 1969 amendments to the Patent Act, with the legislative changes, made in 1987 and 1992. On the road to NAFTA, the negotiations over the Free Trade Agreement (FTA) between Canada and the United States resulted in the amendments to the Patent Act contained in Bill C-22, which entered into effect on 7 December 1987. Bill C-22 provided a patent term of 20 years from the date of application, as of 1989. It also guaranteed patent owners a period of protection from compulsory licensing for 10 years in the case of license to import and seven years (if the chemical was sourced in Canada) in the case of license to manufacture, from the date of the first Notice of Compliance after 27 June 1986.

Beyond this, the Patent Act was again modified in 1992, under Bill C-91. In this case, the changes were made to implement the provisions on intellectual property contained in the World Trade Organization's (WTO) TRIPS provisions. With exceptions for compulsory licenses in existence before the Act came into force, Bill C-91 eliminated compulsory licenses for biopharmaceutical products. Notably, Bill C-91 provides for product patents for biopharmaceutical innovations beyond the process patents that were already available. The bill does include a "stockpiling" exemption, and an "early working" exception, under which a "generic drug manufacturer could develop a generic version of a medicine and take whatever steps were necessary to meet the regulatory requirements pertaining to its sale before the expiry of the relevant patents" (section 55.2(1)) (Smith, 2000).

expires. Licenses could be granted without the consent of the patent holder and the licensee was required to pay a royalty.) ... [Then in 1969,] the Patent Act was amended to permit compulsory licenses to import medicines into Canada" (Canada, 2008).

Appendix E: Counterfeit drugs vs. patent-infringing generics

As described in Appendices A and B, agreeing on a definition of counterfeit drugs is controversial and the debate over terminology has been very divisive. The discussion in this study of the social costs of counterfeiting and the payoff to using real resources to discourage counterfeiting focuses on counterfeit drugs that do not contain the correct ingredients or are otherwise degraded, so that they do not help the patient or do actual harm to the patient. This definition is utilized for several reasons, described below:

- ◆ The debate over definitions largely hinges on intellectual property protections and the efficacious generic versions produced in violation of existing patents. The fight has been led by manufacturers of these patent-infringing though efficacious drugs who object to their products being labeled as “counterfeit”. These drugs are not the focus of this paper because (1) they are not legally available in Canada, and (2) if consumers are moving outside the legitimate supply chain they are more likely to encounter bogus counterfeit drugs than these patent-infringing efficacious generic versions.
- ◆ Pharmaceutical counterfeiters are motivated by profits and they cut every corner possible to maximize those profits. They infiltrate legitimate supply chains with bogus medicines that have an appearance that is just sufficient to pass for the real thing. In addition, they may or may not contain the active ingredients, and the dosage may be too much or too little. They undoubtedly avoid the expense of precision measurement and formulation. Given this, the counterfeit drugs encountered by Canadian patients are not likely to be efficacious patent-infringing generics.

It is worth noting that to the extent that counterfeit drugs are efficacious patent-infringing generics, the narrative about social harms and the appropriate legal and regulatory remedies would presumably be modified. Indeed, cheaper versions of efficacious drugs would certainly benefit patients who could not otherwise afford legitimate, legal versions. Unfortunately, it is impossible to determine what share, if any, of the drugs purchased outside the legitimate supply chain might be beneficial to patients.

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