

Confronting the Virtual Sea of Fake Medicines on the Web: The Battle Continues

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ABSTRACT

Purpose: The World Health Organization identified the problem of counterfeit medicines over three decades ago. Yet, the rise in the deaths of people taking opioids from illicit online sales is just one example of the growth of digital drug dealers peddling an array of fake medicines through illegal online pharmacies. Estimating the size of counterfeit trade in pharmaceuticals is a monumental task since the web is literally littered with illegal pharmacies that lure naive consumers through various social media sites. Several agencies, such as the Center for Safe Internet Pharmacies (CSIP) strive to educate consumers about the need to verify these websites before purchasing their pharmaceuticals. The debate continues about whether consumers will authenticate the pharmaceutical product that arrives from the online pharmacy—a holographic image can be affixed to pharmaceutical packaging that just requires the sun to reveal the dual color images. The discussion in this article centers on illustrating the size and growth of illegitimate pharmaceuticals; debating the ability to measure harm to unsuspecting consumers; describing supply chain vulnerability and the criminal groups involved in pharmaceutical crime; highlighting the enormous profitability of the illicit trade; and concluding with a few anti-counterfeiting tactics designed to thwart the problem.

Design/Methodology/Approach: Descriptive study

Findings: There are a variety of trends related to battling the growth of counterfeit pharmaceuticals that have been highlighted in this paper. Overall, the illicit trade in this sector must be monitored and studied in more depth by academics, managers, health-care officials, and other stakeholders that govern this sector.

KEYWORDS Counterfeit Medicine | Fake Drugs | Illegal Online Pharmacy | Illicit Trade | Pharmaceutical Crime

Introduction

A “perfect storm” analogy questions whether anyone can predict the size of the storm in terms of the mounting supply of fake pharmaceuticals in virtual markets—there is literally a virtual sea of fake online pharmacies (Chaudhry and Stumpf, 2013; Chaudhry 2017). The traffickers of fake pharmaceuticals range from cottage-type industries to full-

scale manufacturing facilities the fuel that storm. An array of agencies have evolved in the past decade to stifle the bluster of this storm, such as the Center for Safe Internet Pharmacies (CSIP) and the World Health Organization's (WHO) Global Surveillance and Monitoring System (GSMS). Yet counterfeit medicines are still flourishing in the online marketplace.

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The World Health Organization identified the global problem of counterfeit medicines in 1985, but, over three decades later fake drugs continue to thrive in an environment where illicit pharmaceutical traders have “no shame, no boundaries and no limits” (Frazer Institute, 2018, p. 2). Sumathi Reddy of *The Wall Street Journal* asserts the “uphill battle” of decreasing the consumption of fake prescription drugs, especially via illegal online pharmacies. Both drug companies and enforcement agencies are attempting to educate consumers who are willing to obtain their medicines online, especially millennials enticed by advertisements in social media that lure them to illegal pharmacies (Reddy, 2018).

Several agencies continue to work on creating an awareness of the illicit trade in pharmaceuticals by highlighting the loss of human life caused by fake medicine, the reaction of leading public health authorities, and the low risk and high reward that attracts criminals to sell fake drugs. But, the criminal penalties associated with selling fake pharmaceuticals continue to be minimal (Chaudhry, 2014). Paul Newton, a professor of tropical medicine at the University of Oxford, states “the penalties are relatively weak for trading in falsified pharmaceuticals compared to those for trade in narcotics and human trafficking” (Ossola, 2015, ¶9).

The discussion in this article centers on 1) estimating the size and growth of illegitimate pharmaceuticals; 2) describing a porous pharmaceutical supply chain; 3) clarifying the types of illicit traders involved in pharmaceutical crime; and 5) illustrating various anticounterfeiting tactics designed to thwart the problem.

Defining Counterfeit Pharmaceuticals

There is still debate amongst various stakeholders (e.g., brand holders, enforcement agencies, multilateral organizations) about the generic use of the term ‘counterfeit pharmaceutical’. Many defer to the WHO definition that separates the product into three categories (2018):

1. **Falsified medical products** deliberately misrepresent their identity and are distributed with criminal intent;
2. **Substandard medical products** fail to meet quality standards; and
3. **Unregistered or unlicensed medical products** have not been assessed or approved.

Analysts at the Institute of Medicine (IOM) clarify the problem of a unified definition of counterfeit pharmaceutical since a legal definition would have to involve an infringement of the registered trademark for the pharmaceutical. But, the fake pharmaceutical term can also be given to substandard medical products (Buckley and Gostin, 2013). The Pharmaceutical Security Institute (PSI) defers to the WHO definition for both branded and generic products. Overall, the diversity of viewpoints on the definition of

counterfeit pharmaceuticals has been debated for several years. But, in this paper, we use the terms “counterfeit” and “fake” pharmaceuticals in a general sense throughout the discussion.

Legitimate Pharmaceutical Market Thrives

MarketLine’s report on the global pharmaceutical industry estimated the 2018 market value in this sector at \$1,111.8 billion and expects the market to grow 32.2 percent in the next five years (2023) to an estimated value of \$1,469.8 billion (MarketLine, 2019a, p. 2).

In 2018 the global market share for legitimate pharmaceuticals was primarily made up of sales in the United States (35.3 percent), Asia-Pacific (29.2 percent), Europe (25.8 percent), and the Middle East (1.7 percent) (MarketLine, 2019a, p. 10). In terms of market dominance, four firms controlled 23.2 percent of the global marketplace in 2018: Johnson & Johnson (7.4 percent), Bayer (5.4 percent); Novartis (5.2 percent) and Pfizer (5.2 percent) (MarketLine, 2019a, p. 11).

MarketLine forecasts the market value of the U.S. pharmaceutical industry in 2023 will be \$484.7 billion, an estimated increase of 23.4 percent from the 2018 market value of \$303.9 billion (MarketLine, 2019b, p. 2). The U.S. pharmaceutical market share parallels the global market—a few principal players, such as Johnson & Johnson (10.0 percent), Pfizer (6.5 percent), Merck (4.3 percent) and AstraZeneca (2.5 percent) control 23.3 percent of the market in the United States (MarketLine, 2019b, p. 11). Overall, there is intense market rivalry in both the global and U.S. pharmaceutical marketplaces since both multinational pharmaceutical firms and smaller generics are striving for a greater share of this business.

Seizures of Counterfeit Pharmaceuticals

The U.S. Customs and Border Protection reported the domestic value of fake pharmaceutical/personal care products confiscated at 7% of total seizures in 2018 (2,209 seizures out of a total of 34,143) with a manufacturer’s suggested retail price (MSRP) of \$131.45 million. In 2018, the top two source countries based on the domestic value and volume of *all* counterfeit goods seized in the United States was China (54 percent) and Hong Kong (31 percent). The next source country, India, accounts for 1 percent of the total value of goods seized (U.S. Customs and Border Protection, 2018, p. 24).

To understand the formidable task facing U.S. Customs and Border Protection, this agency’s staff must oversee the annual flow of 11 million maritime containers at seaports; 10 million containers by truck and 3 million containers by

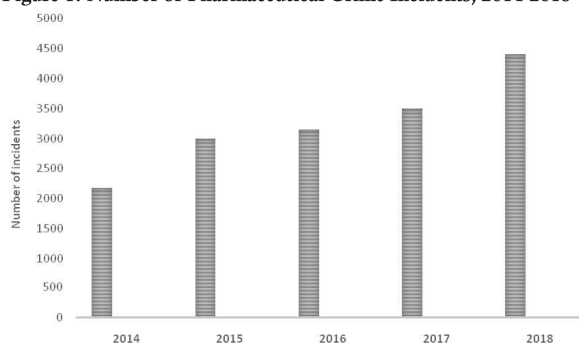


rail. To this add the explosion of cargo, postal and express packages via air travel. Over 90% of all seizures in 2018 stemmed from international express and mail shipments (U.S. Customs and Border Protection, 2018, p. 6 and 15). Bear in mind, that the U.S. Customs and Border Protection searches a very small percentage of *all* products entering the United States, and we have asserted for over a decade that seizure data significantly *undervalues* the enormity of illicit trade in numerous sectors, not just pharmaceuticals (Chaudhry and Zimmerman, 2013; Chaudhry 2017).

The media is literally flooded with estimates of the size of the illicit pharmaceutical market that encroaches on both physical and virtual markets. INTERPOL, the international police organization, has been at the forefront of tackling online counterfeit pharmaceutical sales through various sting operations, such as Operation Pangea, for the past ten years. In 2018, INTERPOL seized 10 million units of fake pharmaceuticals worth an estimated \$14 million, arrested 859 persons and shut down 3,671 websites (2018, ¶1). As illustrated in Figure 1, the Pharmaceutical Security Institute (PSI) reveals the uptick in pharmaceutical crime incidents (includes counterfeits, illegal diversion and theft) from 2014 to 2018—a 102% growth in this time frame. However, the PSI warns that the incident data can be highly *underreported* and that many counterfeit medications remain undetected for a variety of reasons.

In 2018 the PSI reported 4,405 incidents of pharmaceutical crime and outlined the type of crime represented in terms of commercial (49%) vs. non-commercial (37%) volume of fake drugs seized. The PSI categorizes a seizure of over 1,000 dosage units as *commercial size*—this represented 49 percent of the goods confiscated by law enforcement agencies, with non-commercial incidents, 37 percent, being in the *non-commercial* category (2019c, ¶4).

Figure 1. Number of Pharmaceutical Crime Incidents, 2014-2018



Source: Adapted from Pharmaceutical Security Institute, Incident Trends (2019c), accessed on 19 November, 2019 at <https://www.psi-inc.org/incident-trends>

In 2013, the World Health Organization launched its Global Surveillance and Monitoring System (GSMS) to monitor substandard and falsified (SF) medical products. The key objectives of this real-time detection system are as follows (WHO, “WHO Surveillance and Monitoring System”, 2017, ¶3):

- Improve reporting of SF medical products
- Assess more accurately the scope, scale and harm caused by SF medical products
- Provide immediate co-ordination and technical support in emergencies
- Issue medical products rapid alerts
- Gather and analyze a detailed body of validated evidence for Member States to enable evidence-based policy making and investment
- Strengthen regional and national regulator capacities to prevent, detect and respond to SF medical products

Table 1 illustrates that substandard and falsified medicines can be found across all therapeutic categories ranging from antibiotics to vaccines. In addition, the agency asserts that the problem exists for both branded and generic pharmaceutical products.

Table 1. Examples of Substandard and Falsified Products Reported to the GSMS (2013-2017)

Type of product	Number of Member States reporting	Total number of product reports	Percentage of all products reported to the database*
Anesthetics and painkillers	29	126	8.5
Antibiotics	46	244	16.9
Cancer medicines	19	100	6.8
Contraception and fertility treatments	19	29	2.0
Diabetes medicines	7	11	0.8
Heart medicines	22	75	5.1
HIV/hepatitis medicines	9	43	2.9
Lifestyle products	37	124	8.5
Malaria medicines	26	286	19.6
Mental health medicines	19	45	3.1
Vaccines	11	29	2.0

*Note: Only selected products are used in this table, so this column does not add up to 100%

Source: Adapted from WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products, 2017, p. 12.

The Pharmaceutical Security Institute continues to underscore that pharmaceuticals in *every* therapeutic category are copied by criminal entities and compiles seizure data based on this classification: cytostatic, hormones, musculo-skeletal, respiratory, central nervous system (CNS), anti-infective, alimentary, cardiovascular, genitro-urinary and, metabolism. No pharmaceutical category is immune to fakes – the illicit traders will counterfeit more than lifestyle drugs (PSI, 2019d).

Estimating Harm to Consumers

In 2018, the *Wall Street Journal* alerted consumers about the death of a young adult after consuming a fake Xanax that was laced with fentanyl—a synthetic opioid usually sold on the black market (Reddy, 2018). The purchase of drugs through social media sites is a trend that criminal organizations are leveraging to sell illicit drugs – most of these sites provide the drugs without a medical examination or prescription. Pfizer's global security team reported over 10,000 Facebook accounts were selling counterfeit pharmaceuticals last year (Reddy, 2018). The National Association of Board of Pharmacy (NABP) investigated 12,000 internet outlets that sold prescription medicines to U.S. consumers and discovered that an alarming 95% of these web sites were noncompliant with state and federal laws (Reddy, 2018).

Fake pharmaceuticals result in premature deaths. Attempting to find an accurate estimate of the toll that this illicit trade takes on humans is an elusive task. Often the death is not attributable to the counterfeit medication and goes undetected (Eban, 2005; Bate, 2012). If we look at just one metric, a joint sting operation conducted by Pfizer and law enforcement purchased 138 Xanax products on the dark web – only 7 of the products were legitimate (Reddy, 2018). Most importantly, the use of counterfeit pharmaceuticals can kill. *The Guardian* recently reported that more than 250,000 children each year die from counterfeit drugs used to treat malaria and pneumonia (Sample, 2018). The U.S. Drug Enforcement Agency (DEA) claims that counterfeit pills resulted in over 700 fentanyl-related deaths between 2013 to 2014 (DEA, 2016).

Counterfeit drugs sometimes kill patients outright, such as the fake Xanax laced with fentanyl consumed by a U.S. resident. Most of the time, however, counterfeit medicines kill patients by denying them the proper treatment that would be provided by using the correct medicine; this denial often remains concealed until it is too late, resulting in the deaths. In some cases, the active ingredient in the legitimate drug is included in the fake drug, but the latter contains a much smaller dosage level. The active ingredient level itself is not enough to properly treat or cure the patient, but rather promotes resistance to the actual drug. Partially due to counterfeit drugs, some strains of malaria have mutated, posing an urgent threat to marginalized populations and

jeopardizing progress made in combating malaria (Aminake and Pradel, 2013). Illegitimate medicines that lead to diseases mutating and developing resistances to the drugs, and the pharmaceuticals most effective at countering them, are among the deadliest threats to the health of the world's population (Bate, 2012).

Supply Chain Vulnerability

Howard Sklamberg, the former U.S. Deputy Commissioner for Global Regulatory Operations and Policy, the Food and Drug Administration (FDA), provided testimony to the Committee on Energy and Commerce, Subcommittee on Oversight and Investigation, U.S. House of Representatives, to caution government policymakers about the continued threat of fake drugs and its encroachment on public health and safety (2014, ¶6):

“Nearly 40 percent of the drugs Americans take are made elsewhere, and about 80 percent of manufacturing sites of active pharmaceutical ingredients (APIs) used in drugs manufactured in the United States are located outside our borders—in more than 150 countries, many with less-sophisticated manufacturing and regulatory systems than our own. In addition to the sheer volume of imports and foreign facilities, there has been an increase in the variety of sources, shippers, methods of transportation, and supply chain complexity of products. Combined, these factors create great challenges to FDA and industry in ensuring that all drugs and drug components are high quality and travel safely throughout their complex supply chains. These factors also provide opportunities for criminals to adulterate drugs for economic or other malevolent reasons.”

This alarming narrative about the source of origin for pharmaceuticals involve a developed country—the United States. The supply chain can be more porous in developing country markets and is even more vulnerable to fake drugs (Buckley and Gostin, 2013). To better understand the actors in the pharmaceutical marketplace, a succinct description of the market served by both manufacturers and wholesalers is provided with a discussion of illicit traders and how they supply fake pharmaceuticals, especially by way of the rogue online pharmacies.

The Legitimate Distribution Network

In general, manufacturers typically sell directly to pharmaceutical drug wholesalers. The analysts at Modern Distribution Management (MDM), a firm that provides competitive intelligence on the wholesale distribution of pharmaceuticals, reports on the oligopolistic market dominance of firms that control 92 percent of the U.S. market. In 2017, three companies shared \$425.1 billion in annual revenues: AmerisourceBergen Corporation (\$149.6 billion), Cardinal Health, Inc. (\$114.1 billion), and



McKesson Corporation (\$161.4 billion) (MDM, 2019, ¶4). The remaining 8 percent of the wholesale pharmaceutical market is fragmented by a variety of smaller players, such as CuraScript (\$4.4 billion) and Anda Distribution (\$1.1 billion) (MDM, 2019, ¶6). Overall, there are hundreds of secondary wholesalers and repackagers that can handle prescription drugs before the product reaches the pharmacy or mailbox of the consumer. As mentioned previously, these extra layers in the distribution network create a permeable system which limits visibility leaving opportunities for counterfeit drugs to enter the supply chain (Chaudhry and Stumpf, 2013).

Eban's asserts in her book, *Dangerous Doses*, that illicit traders infiltrate the "Big Three" U.S. wholesalers and other distribution channels with their lower prices. After months of investigation, the journalist described the U.S. supply chain as (2005, p. 130):

"Everybody bought from everybody. The biggest, most established wholesalers, including Cardinal and Amerisource, vetted their vendors in advance. After that, price was the guiding criterion: the lower, the better. Once suspect medicine entered the Big Three's warehouses, it became intermingled with, and inseparable from, medicine purchased directly from manufacturers."

In developed countries, patients typically require medication from licensed pharmacies or doctors' offices. In the United States, about 75 percent of pharmaceuticals are bought in retail pharmacies, roughly half of which are national food chains or food stores with an internal pharmacy (Buckley and Gostin, 2013, p. 199). In fact, these vendors buy inventory from wholesalers and manufacturers. Middle- and low-income countries have similar systems of distribution, but with many more manufacturers and distributors. In general, developed countries tend to have an established, coordinated distribution chain dominated by a few large market players, and pharmaceutical markets in developing countries have few large players and many smaller providers and distributors. Therefore, the supply chain in developing countries can be much more fragmented and complicated. The multitude of smaller companies and distributors means that it is easier for counterfeit pharmaceuticals to enter the supply chain, and thus more difficult to detect and counter (Buckley and Gostin, 2013).

Rogue Pharmacies on the Web

Illegal online pharmacies are flourishing as a result of high profits, relatively low barriers to entry, and limited legal recourse for engaging in this dark side of Internet commerce (Chaudhry and Stumpf, 2013). Attempting to estimate the market value of this illicit online trade is a formidable task. Various stakeholders, such as the Center for Safe Internet Pharmacies (CSIP) and the National Association of Boards of Pharmacy (NABP), have been describing the purchase of

prescription drugs online as one of the major issues fueling the growth of fake pharmaceuticals. The distribution of fake drugs online is a labyrinth of illicit traders who continuously deceive consumers regarding the legitimacy of both their website(s) and products. Unfortunately, illicit traders have flourished in a virtual market that can easily fool the consumer regarding the legitimacy of the pharmaceuticals, using professionally developed websites and possibly linking their site to a country well known for cheaper prescription drugs, such as Canada. Overall, these websites lure unsuspecting consumers into believing that the pharmaceuticals are legitimately sold at a discounted price, when, the complete opposite is true.

The NABP recently surveyed social media platforms and discovered that over 11,000 web sites were selling pharmaceuticals—95% these sites were non-compliant sellers of drugs. The agency provides a comprehensive list of these 'not recommended' web sites for consumers to consult. Table 2 summarizes the key characteristics of these illegal online pharmacies. The data metrics listed in Table 2 clearly show the magnitude of unscrupulous sellers and the vulnerability of consumers visiting these sites.

Marcia Crosse, Director of Health Care at the U.S. Government Accountability Office (GAO), in her testimony before the U.S. Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, described the problem on the Internet as follows (U.S. GAO, 2014, p. 5):

"Rogue Internet pharmacies are often complex, global operations, and federal agencies face substantial challenges investigating and prosecuting those involved. According to federal agency officials, piecing together rogue Internet pharmacy operations can be difficult because they may be composed of thousands of related websites, and operators take steps to disguise their identities. The ease with which operators can set up and take down websites and their activities, as websites can be created, modified, and/or deleted in a matter of minutes, supports the reality that we are faced with complex challenges in combating these operations conducted through cyberspace. Officials also face challenges investigating and prosecuting operators because they are often located abroad, with components of the operations scattered throughout several countries."

The NABP secured a top-level domain name, .pharmacy, to be used for identifying which online pharmacies are genuine (<https://www.safe.pharmacy>). On April 1, 2015, the NABP first began accepting all applications for dispensing pharmacies to apply to have their pharmacy name registered with the .pharmacy domain name. Of the over 10,900 online pharmacies that the NABP has reviewed, over 97 percent have been found to not follow pharmaceutical standards and laws established to protect the health of the public. The use of the

.pharmacy domain name helps to establish which operators are legitimate and which are cooperating with laws and standards designed to protect the public. Whether consumers will take advantage of the new .pharmacy domain name to identify and make their purchases from safe, authentic, and genuine online pharmacies is a critical concern (American Pharmacists Association, 2015).

Criminal Groups involved in Pharmaceutical Crime

INTERPOL defines pharmaceutical crime (regardless of the national legislation and the source of the crime) as, “the manufacturing and distribution of counterfeit or falsified (spurious/fake/falsely labelled) pharmaceutical or medical devices, through licit and illicit supply chains, involving theft,

Lipitor®, and received a nine-year sentence in 2010. The value of his trafficking of just one fake version of Lipitor® was estimated at \$43 million (LaMendola, 2010).

The United Nations Office on Drugs and Crime (UNODC), *The Globalization of Crime: A Transnational Organized Crime Threat Assessment*, described illicit traders in China as (2010, p. 8):

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

Table 2. Characteristics of the ‘Not Recommended’ pharmaceutical web sites

Physical location	<ul style="list-style-type: none"> • 2,609 (23%) outside the US • 1,580 (14%) inside the US • 7,085 (63%) no location posted on website
Prescription requirements	<ul style="list-style-type: none"> • 10,086 (89%) do not require valid prescription • 6,270 (55%) issue prescriptions per online consultations or questionnaires only
Medications	<ul style="list-style-type: none"> • 5,890 (52%) offer foreign or non-FDA-approved medications
Encryption	<ul style="list-style-type: none"> • 1,964 (17%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location	<ul style="list-style-type: none"> • 4,835 (43%) outside the US • 6,008 (53%) inside the US • 464 (4%) have unknown server locations
Affiliations	<ul style="list-style-type: none"> • 9,689 (86%) appear to have affiliations with rogue networks of internet drug outlets

Source: Adapted from *Internet Drug Outlet Identification Program: Progress Report for State and Federal Regulators: September 2018*, The National Association of Boards of Pharmacy, accessed 5 November 2019 at <https://nabp.pharmacy/wp-content/uploads/2018/09/Internet-Drug-Outlet-Report-September-2018.pdf>

fraud, diversion, smuggling, illegal trade, money laundering, and/or corruption” (2014, p. 6). But, attempting to describe these ruthless players is an elusive task since narratives of these criminals must be cultivated from a multitude of sources which lack an in-depth portrayal of these criminals (Chaudhry and Zimmerman, 2013). For example, some have argued that there are such low barriers to entry for pharmaceutical crime that smaller, entrepreneurial sellers have evolved to reap substantial profits of counterfeit medicines. For example, the array of reports on illicit traders range from profiling a person, such as Michael Carlow, the leader of a group that had “sold tens of millions in phony medicine” in Florida (Eban, 2005), to full-scale manufacturing facilities in China (UNODC, 2013). Michael Carlow specialized in the sale of counterfeit cancer, HIV, and cholesterol drugs, such as

The UNODC further clarifies that the counterfeit fentanyl crisis in the USA is fueled by the fact that illicit traders can easily obtain the materials and machines needed to make the fake drug from online vendors and that the process does not require state-of-the-art laboratories. This allows a smaller-scaled operation to make the illicit pharmaceutical in their homes (UNDOC, 2017).

In 2014, prior to INTERPOL’s comprehensive study on pharmaceutical crime, enforcement experts openly admitted that “pharmaceutical crime ... is generally not understood to be as organized as more criminal activities, such as drug trafficking or people smuggling”. A key reason for INTERPOL to conduct an analysis of counterfeit drugs was to discern whether organized criminal groups (OCGs) are heavily involved in this crime. The agency’s report, *Pharmaceutical*



Crime and Organized Criminal Groups (INTERPOL, 2014), delves into the types of criminals involved in this illicit activity. INTERPOL differentiates between “informal” and “organized criminal groups” (OCG) to categorize these distinct illicit actors in pharmaceutical crime. INTERPOL’s definition of an OCG consists of the following elements (2014, p. 6):

Collective element: significant group of criminals working together;

Structure: hierarchical collective or network of criminals with specific roles;

Constant activity: continual criminal activity over a significant period of time; and

Large profit: substantial profits gained from criminal activity.

INTERPOL reported the results of its survey (n = 84 respondents) were targeted at police (via INTERPOL National Central Bureaus), customs (via the World Customs Organization), and drug regulatory authorities (via the Working Group of Enforcement Officers and the Permanent Forum on International Pharmaceutical Crime) to confirm that most of the criminal elements involved in this type of crime are *not* primarily OCGs, but either well-organized *informal* international affiliated networks selling pharmaceuticals by way of illegal online pharmacies or smaller groups (e.g., 3–10 members) that are not as organized and/or involved in different aspects of organized crime (2014, p. 7). The respondents of this survey alluded to only two OCGs: one in Asia and another in North America. This is an extremely important assertion, since the explosion of articles in the media, and prior research, portrays the lure of this high profit/low criminal penalty activity involves mainly organized criminal organizations (Chaudhry and Stumpf, 2013). Thus, other agencies, such as the World Health Organization (WHO) and Pharmaceutical Security Institute (PSI) continue to caution that much smaller cottage industries produce the fraudulent medicines also.

Windfall Profits Lure Pharmaceutical Crime

INTERPOL reported that just one rogue Internet pharmacy in the United States, which allegedly had been active for five years, earned \$55 million during just two years of its criminal operations. Subsequently, these profits are then simply laundered through the purchase of legitimate companies (even operating within the legitimate pharmaceutical sector), or through the use of offshore banks in places like St. Kitts and Nevis, to channel the illicit profits. Even more disturbing, the analysts at INTERPOL point

out that the ease of access to establishing operations on the Internet is one of the reasons that informal networks thrive in this virtual marketplace over more traditional organized crime groups (2014, p. 10).

The joint research study of the Organization for Economic Development (OECD) and the European Union Intellectual Property Office (EUIPO) estimates that 2% of the global pharmaceutical market is counterfeit – valued at \$200 billion annually that is comparable to the \$246 billion in narcotics trade (OECD/EUIPO, 2019). Analysts continue to, assert that dealing in fake pharmaceuticals is more lucrative than narcotics since limited criminal penalties exist for pharmaceutical crime (Chaudhry and Stumpf, 2013).

Low Barriers to Entry

The overarching problem on the supply side is that the barriers to entry for making counterfeit drugs have been lowered by the ease of buying pharmaceutical machinery on Internet auction sites and by the proliferation of printing technology that makes any unskilled trader able to duplicate pharmaceutical packaging that is simply indistinguishable to anyone but experts (Chaudhry, 2017). The necessary equipment and materials to set up production for illicit drugs is just one click away on the web. For example, a recent search (November 25, 2019) for a “pill making machine” at Alibaba.com yielded 1,415 results starting at \$500 per machine. Another query, “packaging pharmaceutical”, yielded 82,367 hits for various packaging materials, such as blister aluminum foil packaging from suppliers around the globe, primarily China.

In 2013, the Executive Summary of the UNODC report, *Transnational Organized Crime in East Asia and the Pacific: A Threat Assessment*, the source of illicit pharmaceutical trade was described as mainly coming from India and China. Due partially to their proximity to China and India, and in part to weak government capacity to act, Southeast Asian markets have high percentages of counterfeit drugs being sold as legitimate medicines. The Philippines, Thailand, Indonesia, and Vietnam all have large percentages of fakes in their market. Estimates for the Philippines range from 8 to 30 percent of medicines sold as fakes, whereas for Indonesia an estimated 10 percent of its total market (around \$200 million) is made up of counterfeit drugs according to the International Pharmaceutical Manufacturers Group (IPMG), a non-profit association of global R&D-based pharmaceutical companies operating in Indonesia (IPMG, 2016). Vietnam serves as a transit route for fake drugs from China, and smuggling is rife across borders. The Indonesian Drug and Food Control Agency (BPOM) cites weak law enforcement, lenient sentences for counterfeiters and smugglers, and judicial corruption as contributors to the flourishing markets for fake medicines (Redfearn, 2013).

Tactics Designed to Defray Illegal Online Pharmaceutical Trade

There is a plethora of recommendations available from a variety of stakeholders that give an array of solutions to diffusing the prevalence of pharmaceutical crime. Several experts advocate the use novel authentication technology; others propose changing the consumer demand for pharmaceuticals online through consumer awareness campaigns; whilst enforcement agencies continue to accelerate the closure of web sites selling illegal pharmaceuticals (Chaudhry, 2017).

Empowering Stakeholders with Authentication Technology

Enabling the consumer at the point of purchase to verify the authenticity of the pharmaceutical has been debated for several years. A decade ago, holographic images that were affixed to pharmaceutical packaging allowed consumers to authenticate using the sun – since the image would change color in sunlight. Bowater, an authentication firm in the U.K., continues to develop technological solutions to verify the authenticity of products with its “everyone/everywhere” mission to empower both consumers and customs officials who do not have access to the internet or smartphone technology. Both the BowaterHologram™ and Bowater Hologram™ Numeric provide two entirely separate real color images that can be easily identified using any direct bright light, such as the sun. The technology is very simple to use and does not require any type of machine to authenticate the holographic image that can be affixed to the pharmaceutical packaging – the consumer will see the change in the color of the holographic image (Bowater, 2019). Alucare® is an example of a holographic foil used in blister packs to provide both airtight packaging and authentication. With blister packs the typical tablet packaging in Europe and Asia, pharmaceutical companies are continuing to employ holographic foils as an authentication tool for consumers.

The use of an app on a smartphone is another novel way to authenticate. For example, consumers can download the “Check my Meds” app from iTunes or Google Play as a free tool to authenticate the serial numbers found on most of EMD Serono pharmaceutical products that sells HIV-associated wasting, infertility and relapsing MS therapeutics (CSIP, 2019).

Advocating Consumer Awareness of the Problem

The National Association of Boards of Pharmacy attempts to educate the consumer on how to validate the real vs. fake pharmaceutical, by providing the following (Chaudhry, 2017, p. 182):

- **Packaging** – Does the packaging look as though it has been compromised?
- **Labeling** – Is the label on crooked? Is it different than the label the prescription drug had before?
- **Pill Appearance** – Are the pills cracked or chipped? Has the pill color changed? Does it appear a shade different from earlier prescriptions?
- **Pill Taste** – Did the drug taste different?
- **Side Effects** – Did you experience any adverse effects?

There are a variety of public awareness messages that have been developed to address fake pharmaceuticals, such as the multi-stakeholders “Fight the Fakes” (fightthefakes.org) and the “Verify Before You Buy” campaigns. The Fight the Fakes agency prompted the WHO to establish on 17 September 2019 the first “World Patient Safety Day” to create a forum for patients, communities and governments to raise awareness of the problem of falsified medicines (Fight the Fakes, 2019). The “Verify Before You Buy” website empowers consumers to authentic the purchase of a pharmaceutical product by simply typing in the online pharmacy’s address to see whether the website is legitimate (verifybeforeyoubuy.org). The National Association of Boards of Pharmacy also provides a means to search for legitimate websites online at its “Buy Safely” site (<https://safe.pharmacy/buy-safely/>) and allows the consumer a mechanism to report suspicious pharmaceutical internet sellers.

The use of the .pharmacy domain name, by the NABP, may serve as a means to persuade consumers to purchase from legitimate pharmacies. However, many consumers still purchase from illegitimate online pharmacies due to cost differences. The problem will be to see if this type of education works to change buyer behavior. Thus, the key question here is whether consumers heed the warnings and take a closer look at their pharmaceuticals distributed both in physical and virtual marketplaces? One study addressed the viability of health promotion campaigns and social media designed to educate consumers on the dangers of obtaining medicine from online pharmacies. The researchers’ summarized the key findings of this study (Anderson et al., 2016, p. 397):

“Overall, our results indicate that though some organizations are actively engaged on the issue, communication and education initiatives have had questionable effectiveness in reaching the public. We note that only a few organizations offered comprehensive and dedicated content to raise awareness on the issue and were effective in social media communications. In response, more robust collaborative efforts between stakeholders are needed to educate and protect the consumer about this public health and patient safety danger.”



Accelerating Closures of Illegal Online Pharmacies

Since 2008, law enforcement has tackled the problem of illegal pharmacies online through a succession of take down operations known as “Operation Pangea.” The key objectives of these operations led by INTERPOL are to safeguard public health; seize counterfeit and illegal products and remove them from the market; identify the producers and distributors of counterfeit and illegal medical products and the criminal networks supporting them; shut down fraudulent websites; raise public awareness of the risks of buying medicines online; and enhance cooperation amongst agencies combating illicit trade of counterfeit and illegal medical products (INTERPOL, 2018, p. 2).

INTERPOL, the U.S. Department of Justice, the FDA, are just a few of the agencies involved in the continual task of shutting down a virtual sea of fake online pharmacies. The most recent effort, Operation Pangea XI, resulted in 3,671 websites taken down, such as <http://www.bestgenericstor.com>, <http://www.nextday-pills.com> and <http://top-meds-discounts.com> (INTERPOL, 2019). Other agencies, such as the World Customs Organization (WCO), the Permanent Forum of International Pharmaceutical Crime (PFIPC), the Heads of Medicines Agencies Working Group of Enforcement Officers (WGEO), EUROPOL, and the Pharmaceutical Security Institute (PSI) have played a supporting role in the overarching goal to reduce counterfeit medicines. In addition, the Center for Safe Internet Pharmacies (CSIP) and private sector companies including LegitScript, Google, MasterCard, Visa, and PayPal have worked together to battle illegal online pharmacies (Chaudhry, 2017).

In the past, regulators and law enforcement entities worked in tandem to shut down Internet sites that spoofed consumers into thinking that these online pharmacies were related to pharmacy chains, such as Walgreen Company and CVS Caremark Corporation, by using websites like “walgreens-store.com” and “c-v-s-pharmacy.com” (Dooren, 2013). However, if one website is shut down, the illicit traders can have another site working within a day, if not hours, to supply the fake pharmaceuticals. Like the mythical Hydra, if enforcement agencies take down an illicit website, it is very likely that the fake online pharmacies can rejuvenate and cultivate another site, or more, to continually stay ahead of the efforts to curb the sale of fake pharmaceuticals on the web.

Conclusion

There are a variety of trends related to battling the growth of counterfeit pharmaceuticals that have been highlighted in this paper. Overall, the illicit trade in this sector must be monitored and studied in more depth by academics, managers, health-care officials, and other stakeholders

that govern this sector. Several of the key factors that were addressed to curtail the growth of illegitimate pharmaceuticals through the various anticounterfeiting initiatives employed are each separate areas for future research, such as the relevance of educating the consumers about authentication of the pharmaceutical product and/or their awareness of anti-counterfeit pharmaceutical campaigns. A study on consumer authentication of pharmaceuticals purchased online would merge the disciplines of consumer behavior and information systems to ascertain the level of confidence-building the consumer recognizes in order to safeguard his or her consumption of pharmaceuticals. Overall, what type of education is required to get consumers to authenticate the pharmaceutical product? The technology already exists, but, the consumer awareness of the problem of counterfeit medicines is low—what can be done to change this situation? For example, further research could investigate the efficacy of agency-led initiatives, such as whether the .pharmacy top-level domain actually deterred the growth of “look-alike” illegal pharmacies that hide behind confusingly similar websites like c-v-s-pharmacy.com. In addition, did the “Fight for Fakes” campaign work to alert consumers about the need to verify the pharmaceutical website? Overall, there are many unanswered questions about changing the minds of consumers that are easily lured to the virtual sea of illegal pharmacies on the internet.

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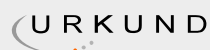


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Annexure 1

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Reviewers Comment

Reviewer's comment 1:

Counterfeit medicine is fake medicine. It may be contaminated or contain the wrong or no active ingredient. This article gives all the intellect about fake medicines market.

Reviewer's comment 2:

The manufacture and distribution of medicines is a global industry, tainted by fake and substandard products. Not only might these drugs not work as expected, but some are even contributing to antimicrobial resistance. So, what's in your medicine cabinet

Reviewer's comment 3:

This is a story of how the manufacture and distribution of medicines today is such a complex, globalized affair that it is often hard to track where fake or substandard medicines come from and where they go. This is a story of how these medicines could make you ill or even kill you, even if you don't take them.

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EDITORIAL BOARD EXCERPT

At the initial Time of Submission (ToS) the paper had 7% of plagiarism level, which is an accepted percentage as per the norms of publication. Timely communication has been made by the editorial board to the author (Peggy E. Chaudhry) and the paper had been rectified and amended accordingly based on remarks as and when required to do so. The comments related to this manuscript are noteworthy related to "Fake Medicines on the Web" both subject-wise and research-wise. The paper presents a negative side of the technological disruption in the prevalent pharmaceuticals market. There has been a rapid increase worldwide in purchasing medicines online via web but this trend has given rise to illicit activities of criminal organizations for selling hazardous drugs without any medical examination or prescription. This issue is of great concern for everyone and the same has been addressed by the author in the study as usage of fake medicines can result in premature deaths or can kill patients outrightly. The authors have organised the paper in a well-structured manner. The introduction of paper represents a clear perspective on the need for the research. Overall the paper promises to provide a strong base for the further study in the area. All the comments had been shared at different dates by the authors' in due course of time and same had been integrated by the author in calculation. By and large all the editorial and reviewer's comments had been incorporated in paper and the manuscript had been earmarked and decided under the "Research Thought" category, as the consumer awareness of the problem of counterfeit medicines is very low and must be given a greater concern.