

## **WAYS TO BATTLE THE \$431 BILLION FAKE PHARMACEUTICAL INDUSTRY**

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### **ABSTRACT**

*Nowadays, counterfeit drugs are available in the marketplace more than ever. One has no idea whether they are acquiring the genuine drug or not. Many deaths have occurred because of mistakes made by consuming counterfeit medication. Not only does it alter one's health but it also crushes their hopes. The data concerning counterfeit drugs are increasingly being published in reports and reviews. It seems like government does not care about the issue since it is ongoing and growing. Governments seem to underestimate the importance of the issue, hence its growing prospect. Harsher sanctions are needed to prove that counterfeiting is not an unpunished crime. Whoever commits that felony has to face the consequences that come along with breaking the law and possibly participating in harming and endangering one's life.*

**JEL:** I10, I18, I19, K20, K42, F19, F23

**KEYWORDS:** Medicine, Counterfeit Drugs, Generic, Regulation

### **INTRODUCTION**

Over the years, the world as we now know it, has witnessed great progress. But with progress comes many issues. One issue of great consequences is pharmaceutical counterfeiting. Pharmaceutical counterfeiting stands for fraudulently producing or mislabeling medicines that are being purchased by consumers who believe them to be genuine. The illegitimate drugs can cause many serious health complications. Packaging is also identical to the legitimate ones, making it extremely difficult to distinguish them. But with close examination of their chemical formula, he/she notices that the ingredients were most likely misused.

Counterfeiting does not only target brand-names but generic ones as well. Medical devices and medical-related products do not escape this problem.

Counterfeiting has not only increased but has also targeted terminal and incurable diseases, giving people a prospect of an affordable and easy to get solution. On one hand, it raises people's hopes and gives them something to hold on and look forward too. On the other hand, the outcomes are unpredictable since no one knows what the impact of some components are to human health. Counterfeiting is an issue that is looking to dominate the pharmaceutical world. With its low cost and easy access, more individuals turn to the illegitimate drugs for salvation.

This paper proceeds as follows. Section 2 presents a brief overview of literature. Section 3 presents an analysis of the situation. Section 4 presents a path forward. Section 5 concludes.

## LITERATURE REVIEW

One way to fight counterfeiting is to send the supposedly fake drug to the original maker and have them analyze it. Many renowned companies employ undercover detectives to help them track down and find out who is counterfeiting their drugs. Those detectives then share the information they found with each other since they are all fighting the same crime and criminals. Pfizer, which is the world's largest drug company fights continually concerning the safety of their trademark since their products are the most counterfeited. During 2010, counterfeited drugs generated about \$75 billion (Gillette (2013)).

Counterfeiting does not only effect the economy but also people's lives. Each year, about 100,000 million people worldwide may succumb to these fraudulent medicines. Counterfeit pharmaceuticals sometimes contain chalk, brick dust, paint, and even pesticides. Some of them even contain the remains of human fetuses. Others contain no active ingredients at all. Miraculously enough, the fake medications sometimes do actually work (Gillette (2013)).

According to OseiTutu (2013), one form of the distribution of counterfeit pharmaceuticals into the hands of public is through the illicit drug trade. Individuals that traffic in the distribution of illegal drugs such as cocaine or heroin may also choose to enter the counterfeit medicine trade. Evidence shows that some counterfeits are as deadly as the illegal substances.

When one hears about how much profit is made out of fictitious drugs, he/she wonders how they get their hands on them. One way is the internet. Since its creation, the internet has only grown and been accessed all over the world. Finding fake drugs online is as easy as typing something on the computer. Specialized websites offer hundreds of drugs for whatever illness one may suffer from. Even websites like "Craigslist" offer fake drugs. Counterfeiters play on patients' feelings to get them to turn to them. People do feel some embarrassment and shame when seeking pharmaceuticals for their health and they would much rather order their medication online in the intimacy of their own home. Another way to get customers is their unbeatable prices. In fact, anyone would prefer to pay \$1 rather than \$15 per tablet.

In fact, the number one driver for the purchase of counterfeit drugs is price. One study of 144 American students showed that the perceived legal and social risk or societal consequences did not influence the intent to purchase counterfeit goods. In many cases, consumers of counterfeit drugs feel they are 'getting away with something.' They feel the discounted price they pay is somehow 'getting even with the large pharmaceutical companies,' for the prices they charge.

High drug costs drive Chinese consumers into the counterfeit marketplace, especially in rural areas. Chinese officials are more prone to ignore the activities of drug counterfeiters and in fact may aid the production of fake medicines supported by corruption in both the police and military (Bird (2008)).

In addition, the deception of websites offering pharmaceuticals runs wide and deep. A recent study funded by the Food and Drug Administration found that of 11,000 purportedly "Canadian" websites, only 214 were actually registered in Canada. Websites may display a pharmaceutical company's logo, company symbols, national flags, etc. in attempt to legitimize their presentation. It's also important to note that even drugs shipped through countries such as Canada are not subject to those countries' safety requirements if the products are not for domestic consumption. From a business perspective, the transportation of counterfeit pharmaceuticals is an act of trade (Liang (2008)).

Detectives investigate counterfeited pharmaceuticals by looking at the small leads that would eventually take them to the "big fish". For that purpose, criminals resort to the express mail service to get their drugs wherever they need to be. The bigger the package, smaller the odds of inspecting it. Once the package reaches its first recipient, usually a drop shipper, the drop shipper serves as an intermediary between the

original sender and the customer. The reason behind this is to not scare off the customer if the package is searched. Drop shippers are the ones that usually use “Craigslist” to make more money on the side, without thinking about the consequences. Asia is leading in counterfeiting, especially China. It is not surprising that counterfeiting is this prominent since the laws against it are very weak. Criminals do not fear the consequences hence there are more of them.

Counterfeiters pay attention to every detail to make sure that their drug looks identical to the original one. Because of how much thought they put in it, many licensed distributors are not able to distinguish between the real drug and the fake one. It is tough to evaluate the severity of the issue because of the lack of resources available to detect counterfeited medicines, the different definitions of counterfeiting around the world and the variation in the distribution system (World Health Organization (WHO) (2010)).

To try and assess the problem’s gravity, WHO (2010) sent on a questionnaire to a handful of countries. Only 13 countries out of the 22 in the WHO Regional Office for Eastern Mediterranean region (EMRO) responded. They found out that only 3 countries in EMRO have distinct legislation on counterfeit medicine. They also discovered that 23 countries would welcome a specific legislation on counterfeit medicine (13 from WHO Regional Office for Africa (AFRO); 10 from EMRO). Unfortunately, information on counterfeiting is rarely shared with other National Medicines Regulatory Authority (NMRA) or WHO.

Some recommendations were made, starting with Member States developing a specific legislation that empowers NMRAs and criminalizes counterfeit medical products. Second, proposing that information should be shared between NMRAs and police and customs. Joining efforts will increase the odds of lessening counterfeiting. Third, declaring that Single Points of Contact (SPOC) should be established to facilitate exchange of information on counterfeiting at regional, national and international levels. Fourth, saying that Member States are encouraged to declare cases of counterfeiting to WHO and INTERPOL. Fifth, proposing that pharmaceutical components or finished goods in free trade zones should be controlled by legislation. And finally, suggesting that information on counterfeiting should be shared with other NMRAs and law enforcers within the country (WHO (2010)).

Counterfeiting is underestimated crime even though it makes billions of dollars annually and is harmful to one’s health and the society as a whole. The illicit pharmaceutical trade usually occurs with post-Soviet organized criminals, Columbian drug cartels, Chinese triads, and Mexican drug gangs. Hezbollah and al-Qaeda are believed to be involved. It proves that counterfeiting is not assigned to one special country or part of the world. It originates from all over the world, especially from the “rough” areas. Counterfeiting provides jobs in the roughest areas of Asia such as China and India. Private entrepreneurs, state officials, and online criminals play an important role as facilitators of counterfeiting. The internet advertises counterfeiting through spams. Out of all the criminals that are involved in counterfeiting, only 1,300 people worldwide were arrested over the past five years. More than the half of the arrests occurred in China. With so few arrests potential traffickers are likely never to get caught (Shelley (2012)).

About 2 billion consumers worldwide purchase counterfeiting medicine and fall victim to its dangerous consequences. Between 1999 and 2008, counterfeiting revenues increased by \$8.2 billion per year (Shelley (2012)). Poverty plays a major role in counterfeiting. Fake drugs are very affordable, making it easier for needy people to get to them. One of the most important consequences to fake drugs is that most people tend to develop drug-resistant strains of the deadliest diseases. It was also discovered that licensed pharmacists use counterfeited drugs to make more money, selling them to customers as genuine. No one is willing to confront and address the issue, which is ongoing and still growing.

Online acquisition of counterfeit pharmaceuticals through the Internet has become much more pervasive. Some websites simply require an ‘online profile,’ followed by a brief review by a physician. The

physician never examines or communicates with the patient before the order is dispensed. One online pharmacy in particular was found to fill virtually every order that was placed. The physicians were compensated based upon the number of prescriptions they approved.

The main focus of law enforcement today are online outlets called ‘rouge pharmacies.’ These sites distribute drugs to consumers without a prescription. They are harder to track by regulatory bodies because they are not registered anywhere. If the drug or counterfeit is available, a credit card is all that is needed. These pharmacies are largely located outside the U.S., but may advertise their products as being “FDA Approved.”

Given the light penalties and the time lag for regulators or law enforcement to shut down these Internet websites, operators simply take down the website and relocate to another region of the country or perhaps to another country. From a business perspective, this is merely a relocation of a distribution center. Large and important pieces of the supply chain remain intact.

A recent study found nearly 10,000 websites out of compliance with U.S. federal and state regulations. 2,274 of the sites have physical addresses located outside the U.S. and 3,708 maintain servers in foreign countries. Because of variations in drug laws from country to country, some countries may not be aggressive with either investigation or prosecution. In fact, extradition may not be possible if the defendant’s actions are not considered criminal in the extraditing country (Lipman (2013)).

According to Faucon et. al (2013), a cargo ship originating in Guangzhou, China set sail for Luanda, Angola. Part of the cargo was a shipment of loudspeakers. Within the loudspeakers, 1.4 million packets of counterfeit Coartem, a malaria drug, was discovered by Angolan customs. The destination of the loudspeakers was a Luanda pharmaceutical distributor. He was arrested, questioned and released with no charges filed. It was enough to treat more than half the country’s annual malaria cases, if only they were genuine. Because of how many fake antimalarial drugs are being sent to Africa, health administrators fear a relapse. The counterfeit “Coartem” found in Angola did not have any active ingredients found in the real drug. Instead, they consisted of calcium phosphate, fatty acids and yellow pigments. Patients turn to markets where fake “Coartem” is known to be sold because it is much cheaper and easier to get. Some of the counterfeited “Coartem” found seemed to be destined for African countries specifically.

According to WHO (2010), counterfeit and substandard medicines constitute a \$431 billion market, which accounts for a 300% increase since 2000. Because of that increase, an estimated 25-60% of the medicine supply in developing countries is either substandard or counterfeit. The WHO also reported that more than 100 patients were killed in Panama by counterfeit glycerin contained in cough medicine. WHO also reported that around 100,000 deaths per year in Africa are linked to counterfeit drugs. Furthermore, Nayyar et al. (2012) collected surveys that examined 2,634 malaria drugs samples across 21 sub-Saharan African countries and found that one-third of them failed on the basis of chemical analysis. The London-based International Policy Network attributes 700,000 fatalities to fake malaria and tuberculosis medicines every year.

In 2008, an active ingredient in “Heparin” was replaced with with a cheaper counterfeit substitute that resulted in 81 deaths. 2012 statistics show there were 841 counterfeiting incidents involving customs seizures or police/health inspector raids, 1,238 people arrested for counterfeiting worldwide, and 123 countries were impacted by pharmaceutical crime (Asia and Europe were the most highly impacted).

## ANALYSIS OF THE SITUATION

The human will to survive is a basic instinct. In regions with widespread chronic afflictions such as malaria, HIV/AIDS, tuberculosis, diabetes, etc., counterfeits can easily find markets to serve. These and other medical conditions drive consumers into the counterfeit market because they usually cost less than

the authentic product and they are more easily obtained. The vast majority of these consumers are unaware that counterfeits do not undergo the rigorous testing of manufacturers and regulatory bodies. They also risk consuming material that was formulated in a setting that was void of the Good Manufacturing Practices (GMP) and may be void of the active ingredients necessary to address the medical condition.

Criminal organizations and individuals are discovering that there is less risk and penalties associated with counterfeit pharmaceuticals than human trafficking and illegal drugs. Courts and judges generally do not view counterfeit pharmaceuticals as they may a violent crime. It seems to fall somewhere between what may be referred to 'white-collar' crime and a violent offense.

For example, a pharmacist in Ontario, Canada was arrested in 2005 for substituting talcum powder in heart medicine. The coroner cited "unauthorized medication substitution" in four deaths. The pharmacist was acquitted by a court in 2007 because prosecutors failed to prove criminal intent. He sued to get his license back and is now the owner of a pharmacy in Toronto (LaGanga (2014)).

In another example, a Chinese national was accused as being the architect of a world-wide pharmaceutical counterfeiting operation when he was arrested in New Zealand in 2010. He was released on bail and failed to appear for an extradition hearing. Authorities suspect he fled to China (Gillette (2013)).

Finally, a U.S. citizen pled guilty to one count of conspiracy to traffic and one of trafficking. He received 10 months in prison and a \$5,100 fine. According to Donnelly, director of PfiZers global security team in the Americas, "...the laws against drug counterfeiting are too weak. If he were a crack dealer, for the same type of operation, he'd be looking at a five-year minimum" (Gillette (2013)).

The research in the area of counterfeit pharmaceuticals and law enforcement seems to reference "arrests," "questioning," "detainment." It's rare that any paper published in this area ends with the phrases "sentencing" or "incarceration." In the rare occasion the phrase 'sentencing' is mentioned it's usually in the context of 'ridiculously low'.

In fact, some counterfeit drug distribution has occurred from totally unsuspected sources, For example, in 1995 Niger suffered a widespread outbreak of meningitis. In an effort to provide aid to its neighbor, the government of Nigeria shipped 88,000 doses of meningitis vaccine to Niger. The vaccine was discovered to be counterfeit and resulted in the deaths of 2,500 people. Counterfeit drugs currently account for approximately 30% of the medicines distributed in developing African nations (Chavez (2009)).

Counterfeiting is more prevalent in countries where government and regulatory officials choose to turn a 'blind eye' to the situation. The depth and breadth of counterfeiting can also differ from rural to urban settings with a country.

According the WHO's (2010) survey of 24 African and Eastern Mediterranean countries, only three in the eastern Mediterranean have specific legislation on counterfeit medicines. Based upon subsequent discussions and meetings of survey responses, the number one recommendation was, "Member states should develop specific legislation that empowers National Medicines Regulatory Authority's (NMRA's) and criminalizes counterfeit products".

Organized criminal elements within Italy have played a lead role in the importation and dissemination of a variety of counterfeit goods. According to the U.S. Department of Treasury, the criminal group Camorra may earn as much as \$2.5 billion of their annual profit from counterfeit goods, including pharmaceuticals. According to Shelley (2012), "Corruption within the Italian government is a key component in their ability to operate on such a large scale". Central and South America are fast emerging as a production and

sales territory for a wide variety of counterfeit goods, including medicines. Many of these medicines travel north into the U.S. This trade survives because of "...corrupt officials of all ranks..." (Shelley (2012)).

The Australian government recently threatened to withhold a \$38 million medical aid project destined for Papua New Guinea (PNG) due to corruption allegations. A large contractor, Borneo Pacific Pharmaceuticals was accused by the PNG medical society of "giving presents to people in the government procurement system" and branded the process "corrupt". The PNG Health Departments' drug supply division was described by its minister in 2011 as "riddled with corruption" (Towell (2013)).

The continent of Africa is an example of a large group of countries with borders that ill defined and is easily breached. During a 9-month period in 2012, China exported \$1.5 billion worth of medical products to Africa which in some cases have few or no active ingredients at all (Good Governance Africa (2013)).

According to the United Nations Office on Drugs and Crime, in 2012, 500 million container movements were recorded. Of those containers, only 2% received any attention in regard to inspection.

## A PATH FORWARD

Some administrators are looking into finding some way to battle counterfeiting. They are using private investigators and many new technologies such as RFID to trace medicine. But to get right to the problem's core, one has to understand it.

One of the major reasons is poverty. People hold on to the tiniest bit of hope, which, in this case is what usually hurts them more. But it is the only alternative they can afford, without having a prescription. If medical care was cheaper, no one would look into buying a medicine that can possible hurt them in any way. Consequently, economical, educational and social policy implemented by local government can help avoid the proliferation of counterfeited medicine.

Another part of fighting counterfeit drugs is enforcing the laws. Laws regarding counterfeiting are way too weak and does not intimidate the criminal element. Illegal drug dealers face a harsher sentence compared to medicine counterfeiters. The government has to make it clear that they are not facing a few months of incarceration but more like a couple of years.<sup>[1]</sup> Finally, another way to fight counterfeiting is to check larger cargos rather than just letting them go. Not only will it take them by surprise but it will also make it possible to arrest the people that are higher in the supply chain rather that just the drop shippers.

## CONCLUSION

Counterfeiting is a terrible problem that has become worldwide. Not only is it crushing the economy but it also is crushing people's health and hopes. It would be easier if customers stopped buying medicines online. Sadly, there are many other factors that play along, such as poverty or emotions.

Economics combined with a severe medical condition tend to establish an end user market for counterfeit pharmaceuticals. This demand is more easily serviced when laws are nonexistent or not rigorously enforced. One reason laws may not be enforced is because of the lack of an effective regulatory system and a government in place that chooses to ignore certain criminal activities. The last major piece is access – the challenge to counterfeiters to move their materials into the country and establish the forward distribution networks.

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