
ISSUE BRIEF

Fraud in Your Pill Bottle The Unacceptable Cost of Counterfeit Medicines

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Executive Summary

Counterfeit drugs may look like real medicines, but they are not. These fakes do not contain enough, or any, of a prescribed medicine’s active ingredient. Often, they contain harmful contaminants, which have included cement, gypsum, talcum powder, baking soda, sawdust, industrial solvents, yellow highway paint, and spurious pharmaceuticals. In addition to threatening the health of patients, these illegal medicines also impose large costs on the economy. While difficult to quantify, studies that have attempted to measure this large illegal market estimate that total global sales are between \$200 billion and \$431 billion annually.

From a health perspective, counterfeit drugs deny patients safe and effective treatments, which is particularly dangerous for patients with life-threatening diseases. Counterfeit drugs expose patients to potentially lethal contaminants, unprescribed drugs to which they may be allergic, or unprescribed drugs that will have adverse interactions with other medicines they may be taking. They may also increase public health risks by failing to effectively treat contagious diseases like Covid-19 or tuberculosis, or exacerbating public health crises like the problem of anti-microbial resistance (AMR).

“ While difficult to quantify, studies that have attempted to measure this large illegal market estimate that total global sales are between \$200 billion and \$431 billion annually.

Table ES1 summarizes the negative economic impacts created by counterfeit drugs, including reduced pharmaceutical innovation, slower economic growth, and lost high-paying jobs. In order to account for the uncertainty regarding the precise size of the counterfeit market, four potential economic scenarios are evaluated that are associated with estimated global counterfeit markets of \$100 billion, \$200 billion, \$300 billion, and \$431 billion, respectively.

Table ES1
Summary of Annual Economic Costs Due to Counterfeit Drugs

	ESTIMATED SIZE OF GLOBAL COUNTERFEIT DRUG SALES			
	\$100 BILLION	\$200 BILLION	\$300 BILLION	\$431 BILLION
Lost R&D Revenue (billions)	\$17.0	\$34.0	\$51.0	\$73.3
Lost Number of New Drugs	6	13	19	28
Lost Revenue to U.S. Industry (billions)	\$37.6	\$75.2	\$112.8	\$162.1
Lost U.S. Output (billions)	\$82.0	\$163.9	\$245.9	\$353.3
Lost Federal and State Tax Revenue (billions)	\$4.5	\$9.0	\$13.6	\$19.5
Lost U.S. Jobs	57,495	114,990	172,485	247,803

Source: Authors’ calculations

Starting with the impact on innovation, counterfeit drugs reduce global pharmaceutical industry revenue, which, in turn, reduces the resources the global pharmaceutical industry can devote to R&D efforts. Since the industry invests approximately 17 percent of its gross revenues in new R&D, the revenues lost due to counterfeiting reduces annual R&D expenditures by between \$17 billion and \$73 billion. Based on the

average cost to develop a new drug of \$2.6 billion, every year these revenues are lost translates into the loss of between six and 28 new medicines, a detriment to both industry and public health.

From an economic impact perspective, and based on U.S. firms' share of global revenues, the U.S. biopharmaceutical industry is annually losing between \$37.6 billion and \$162.1 billion in revenues. Based on the industry's economic multiplier, these lost revenues reduce total U.S. economic output by between \$82.0 billion and \$353.3 billion, and have reduced the total number of jobs in the U.S. by between 57,500 and 247,800. This lost output also denies the federal and state governments tax revenues of between \$4.5 billion and \$19.5 billion.

Reducing the economic and public health damage from counterfeit drug sales should be a top policy priority. The first priority should be to stop proposing policies that would make the counterfeit drug problem worse. These include proposals to allow drug importation or impose price controls on drugs. Allowing drug importation opens the drug supply chain to a wide number of less secure sources, usually Internet based, from which it is easier for counterfeit drugs to infiltrate. Price controls, wherever they have been implemented, lead to drug shortages that will increase the incentive to purchase drugs from alternative, less secure, sources where counterfeit drugs are often sold.

“ Allowing drug importation opens the drug supply chain to a wide number of less secure sources, usually Internet based, from which it is easier for counterfeit drugs to infiltrate.

Simply stopping the introduction of policies that will worsen the counterfeit drug problem is insufficient. Government policies need to discourage the supply of, and demand for, counterfeit products by increasing the costs to counterfeiters, securing the drug supply chain, and educating the public. Specific policy changes should:

- Increase the punishment for selling counterfeit medicines;
- Boost enforcement efforts in order to increase the probability that counterfeiters will be caught;
- Improve the data- and information-sharing across government departments including the FDA, Customs and Border Patrol, Department of Homeland Security, and United States Postal Service;
- Adopt cutting-edge track-and-trace systems that would make it more difficult to introduce counterfeit drugs into the U.S. market;
- Implement consumer education programs that explain the risks from using counterfeit drugs, the signs that a drug could be a counterfeit, and provide information regarding where consumers can find reputable Internet pharmacies; and,
- Implement provider and pharmacist education programs on the consequences from counterfeit medications.

Introduction

Counterfeiting is a global problem that harms consumers and businesses in all industries. According to a 2020 report published by the Department of Homeland Security (DHS), counterfeit and pirated goods were worth around a half trillion dollars annually as of 2016, or about 3.1 percent of global imports.¹ These counterfeited products impose large costs on the economy, harm individual businesses, and endanger lives. Summarizing the scope of the counterfeiting problem, Interpol documents that “there is a clear link between illicit trade [in counterfeits] and other types of crime, such as human trafficking, drug trafficking, corruption, bribery, and money laundering. Illicit trade damages the global economy and harms public health worldwide. All regions of the world and all industry sectors are affected.”²

Among all of the goods subject to counterfeiting, the problem of illicit and counterfeit drugs is, arguably, among the most urgent to resolve. As the United Nations Office on Drugs and Crime put it, “fraudulent medicines are one of the most harmful forms of illicit activity with the manufacturing, trade and consumption of these products posing a particularly dangerous threat to people’s health.”³

Counterfeit drugs lead to all of the problems associated with other illicit goods. For instance, organized crime entities (e.g. the Russian mafia, Chinese triads, and Columbian drug cartels) and terrorist groups (e.g. Hezbollah and Spain’s separatist organization, ETA) are major producers of counterfeited drugs.⁴ This large revenue source for criminal organizations is gained at the expense of the businesses and employees that produce legitimate, safe, and effective medicines. These lost revenues impose large costs on the economy and hurt investors and workers.

In addition to all of these costs commonly created by fake products, counterfeit drugs undermine the ability of medical practitioners to treat diseases, infections, and other ailments. These illegal medicines deceive patients into believing they are using an effective treatment when they are, in fact, taking ineffective and sometimes dangerous drugs that are a direct threat to their health. Compared to patients using legitimate medicines, patients taking fake drugs have a higher risk that their underlying health conditions will worsen and have a higher mortality rate due to either the preventable progression of their disease or the toxicity of the fake medicines.

What are counterfeit medicines?

The FDA states that counterfeit drugs “may be contaminated or contain the wrong or no active ingredient. They could have the right active ingredient but at the wrong dose. Counterfeit drugs are illegal and may be harmful to your health.”⁵ The formal definition of a counterfeit medicine in U.S. law is a drug that

bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.⁶

To account for the variety of ways counterfeit drugs can be inauthentic and dangerous to patients, the WHO proposes that counterfeit drugs should be separated into three categories: falsified medical products that deliberately misrepresent their identity and are distributed with criminal intent, substandard medical products that fail to meet quality standards, and unregistered or unlicensed medical products that have not been evaluated or approved.⁷

Put simply, counterfeit drugs do not contain enough, or any, of the prescribed medication and may even contain contaminants that could harm patients. These have included cement, gypsum, talcum powder, sawdust, industrial solvents, baking soda, and even yellow highway paint. Other problems associated with counterfeit drugs include tampering, contamination, dilution, repackaging, or mislabeling in a way that misrepresents the contents, dosage, origin, or expiration date. Often, this means that dangerous substances have been substituted for the active ingredient. Clearly, counterfeit drugs that contain industrial solvents, are contaminated, or do not contain the medicine's active ingredients, create significant health risks for patients.

Unfortunately, the entities and groups engaging in this illegal activity are skilled at duplicating the appearance of pills and capsules and even the security measures on the packaging, including serial numbers on the blister packs and holograms. Without performing sophisticated chemical or spectral analyses, the counterfeits are practically impossible to identify, which makes it possible for these medicines to easily enter the legitimate drug supply chain.

Fraudulent medicines primarily enter the drug supply when counterfeiters take advantage of alternatives to the mainstream pharmaceutical manufacturing and distribution pathway. The legitimate pathway moves drugs securely from the manufacturer to the distributor, pharmacy (and/or physician), and finally to the patient. Counterfeiters bypass this safe supply chain and typically source the counterfeited drugs through many countries, often repackaging the fake medicines in order to disguise the actual country of origin.

Counterfeiters use the Internet as one of the primary entry points into the legitimate supply chain, which allows counterfeiters to bypass the secure drug supply chain and sell their fake medicines directly to patients. The Internet opened a Pandora's box of opportunities for counterfeiters to run drug scams on unsuspecting patients. Approximately 35,000 online pharmacies have set up Internet operations over the last decade, and many of them sell unapproved or counterfeit drugs.⁸ One FDA operation found that nearly half of the imported drugs intercepted by federal officials from four selected countries—India, Israel, Costa Rica, and Vanuatu—had been shipped to fill orders that consumers believed they were placing with Canadian pharmacies. Of the drugs being promoted as Canadian, 85 percent actually came from 27 other countries around the globe. A significant number of these products were found to be counterfeit. Fake erectile dysfunction drugs such as sildenafil (Viagra) and vardenafil (Cialis) are among the most popular products peddled to unsuspecting clients over the Internet.

Drugs purchased via mail order or courier are also susceptible to being illegitimate. In one anti-counterfeiting operation, spot-checks by the FDA and the U.S. Customs Service found that 88 percent of drugs imported into the country by mail or courier violated federal safety standards in some way. Counterfeit medicines can also find their way into various nodes of the legitimate U.S. supply chain. According to the Partnership for Safe Medicines, law enforcement caught smugglers selling 63 different types of medications to over 3,000 doctors, clinics, and hospitals in the U.S. since 2012.⁹

“ Fraudulent medicines primarily enter the drug supply when counterfeiters take advantage of alternatives to the mainstream pharmaceutical manufacturing and distribution pathway.

Counterfeit medicines are a large and growing problem

Counterfeit medicines have been a significant global problem for many years, typically targeting high-demand, expensive medications. These include:

- Chemotherapeutic drugs
- Antibiotics
- Vaccines
- Cholesterol-lowering agents
- Anti-arthritis medications
- Erectile dysfunction drugs
- Weight loss aids
- Hormone replacements
- Analgesics
- Steroids
- Antihistamines
- Antivirals
- Antianxiety drugs

Like any black-market activity, the people selling counterfeit drugs go to great lengths to hide and/or disguise their activities. Consequently, the evidence on the size of this illegal activity is murky, and often indirect.

One way to evaluate the scope of the problem is to estimate the number of Americans who purchase medicines outside of the traditional supply chain and are, consequently, at high-risk of using counterfeit medicines. According to the Partnership for Safe Medicines, "...as many as 19 million Americans buy medicines outside [the U.S.] supply chain, from foreign online pharmacies or other unlicensed sources."¹⁰ Another method for measuring the size of the problem is to document the amount of illegal drugs seized by government authorities. A 2010 study by the World Health Organization (WHO) estimated the scale:

in 2009, 20 million pills, bottles and sachets of counterfeit and illegal medicines were seized in a five-month operation coordinated by the International Criminal Police Organization (Interpol) across China and seven of its south-east Asian neighbors; 33 people were arrested and 100 retail outlets closed.

Also last year, a series of raids in Egypt found counterfeit medicines worth hundreds of millions of dollars and exposed a criminal network feeding consumers across the Middle East. And in Europe, customs officers seized 34 million counterfeit pills in just two months in 2009, a haul that the European Union's industry commissioner Guenter Verheugen said "exceeded our worst fears".

Results from this string of law enforcement operations around the world are slowly building a profile of the trade that shocks even regulators familiar with the issue. Health experts believe such operations have only scratched the surface of a flourishing industry in counterfeit medicines that poses a growing threat to public health around the world.¹¹

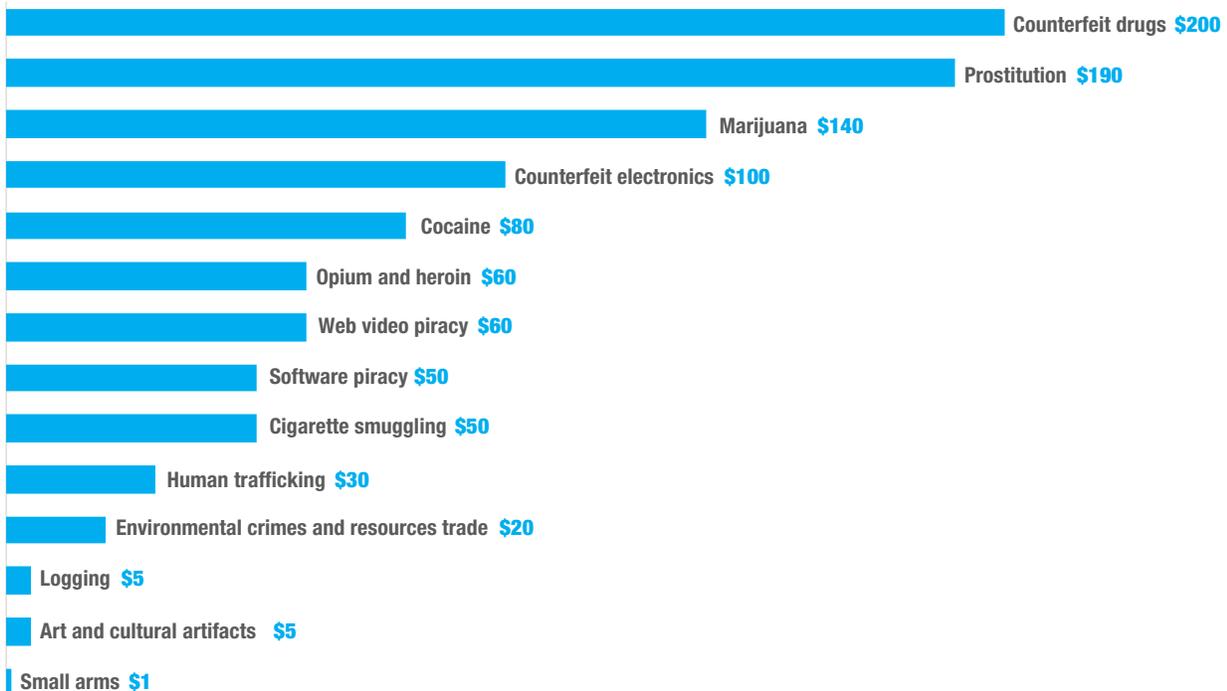
In an attempt to get a sense of how large the problem is, the WHO analyzed “100 studies from 2007 to 2016, covering more than 48,000 samples, [which] showed 10.5 percent of drugs in low and middle-income countries to be fake or substandard. With pharmaceutical sales in such countries running at nearly \$300 billion a year, this implies that trade in fake medicines is a \$30 billion business.”¹²

Wealthier countries are not exempt. As the Department of Homeland Security documented, “in March 2019, Europol, the European Union’s law enforcement agency, seized 13 million doses of counterfeit medicine ranging from opioids to heart medication. Europol noted that this type of counterfeiting is on the rise due to the relatively low risk of criminal detection.”¹³ In response to the crisis in the U.S., the FDA consistently monitors the problem and warns doctors when new threats emerge. As an example of these constant efforts,

on March 21, 2016, FDA issued more than 1,300 letters to medical practices in the United States that purchased unapproved prescription drugs and/or injectable devices from TC Medical, an unlicensed supplier that distributed counterfeit Botox found in the United States. On May 7, 2015, TC Medical pleaded guilty to orchestrating a multi-year conspiracy to smuggle misbranded prescription products into the United States.¹⁴

The number of counterfeit drugs sold annually is unacceptably large. One estimate by O’Hagan and Garlington (2018) noted that while “the overall scope of the market remains unknown, it has been approximated that 10% of drugs sold worldwide are counterfeit, with the prevalence of these drugs in certain areas of Africa and Asia believing [sic] to have reached 70%.”¹⁵ The authors’ estimates of the annual size of alternative illegal markets is presented in Figure 1. According to the authors, annual global counterfeit pharmaceutical sales are approximately \$200 billion, which is exceptionally large relative to the sales of other classes of illegal products.

Figure 1
Estimated Annual Global Sales of Alternative Illegal Products (in billions)

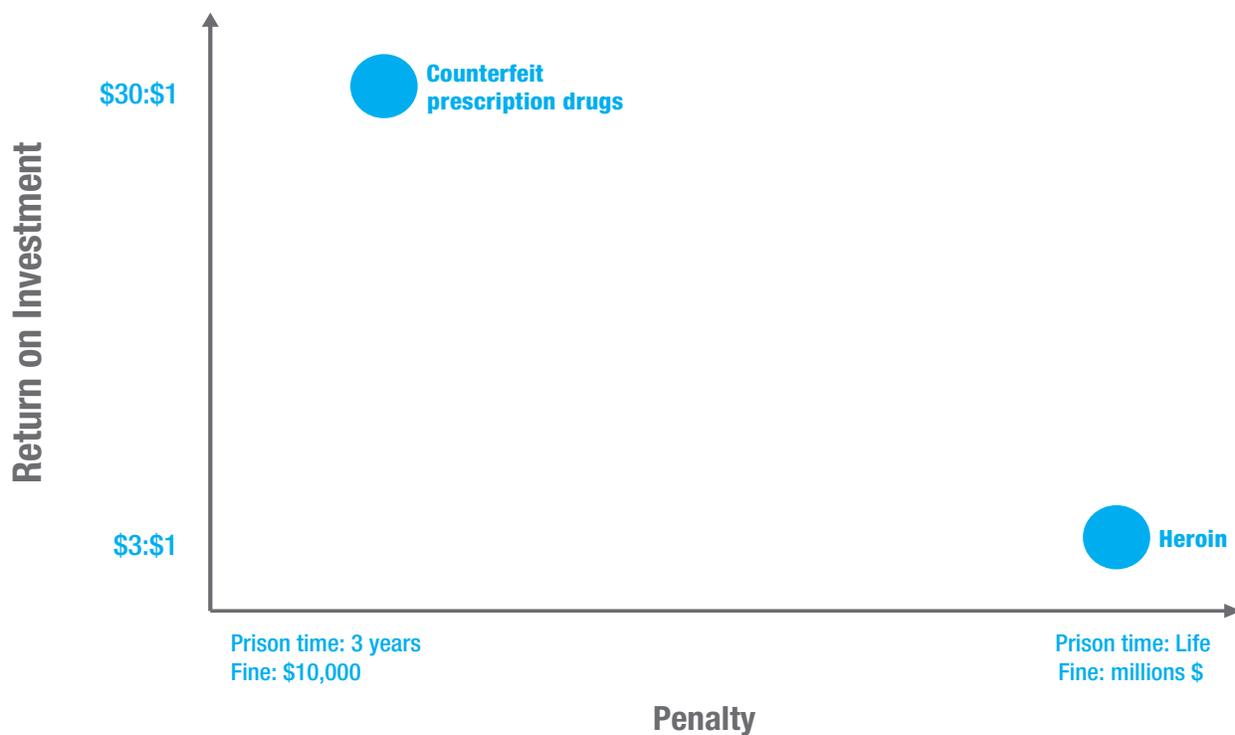


Source: O’Hagan and Garlington (2018)

The O'Hagan and Garlington (2018) estimate could even be low. Gurney et al. (2017), citing a WHO analysis, noted that “counterfeit and substandard medicines constitute a \$431 billion [global] 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.”¹⁶

The size of the illegal pharmaceutical market is so large, in part, because the risk-return trade-off is attractive compared to other illegal activities. This trade-off with respect to heroin, as estimated by Blackstone et al. (2014), is demonstrated in Figure 2. Figure 2 compares the profitability of selling counterfeit prescription drugs and heroin—both of which are illegal—to the potential penalty if caught engaging in selling either of these illegal products.

Figure 2
Risk-Return Trade-off Comparison – Counterfeit Drugs versus Heroin



Source: Blackstone et al. (2014)

According to Blackstone et al., counterfeit drugs offer the opportunity to earn \$30 for every dollar invested by the criminal, which is significantly higher than the potential return from selling heroin. Selling heroin offers the opportunity to earn about \$3 for every dollar invested. Just as important, if caught selling counterfeit prescription drugs, criminal penalties in the U.S. include up to three years in jail and fines up to \$10,000. Penalties for selling narcotics are much more draconian – up to a life-sentence in jail, and fines in the millions of dollars.

The combination of higher profits and lesser potential punishment risk offers criminals a much more compelling risk-return trade-off from selling counterfeit pharmaceutical drugs compared to other illegal products. Given these incentives, it is unsurprising that the problem of counterfeit drugs is both large and growing.

Counterfeit medicines are a clear and present danger to the health of patients

Fake medicines create unique problems and risks. Like all counterfeits, fake drugs impose large costs on the economy, but unlike fake handbags and clothing, counterfeit drugs directly harm people's health and create risks for the broader patient community in multiple ways. The degree and kind of harm depends on the specific defects of the counterfeit drug and the indication for the drug.

If counterfeit drugs are ineffective because they lack active ingredients, or contain substandard amounts, patients are being misled about receiving safe and effective treatments and will continue to suffer from the health risks of their sickness or disease. When these patients are relying on the drugs to treat life-threatening diseases such as cancer, the lack of efficacy of the drugs can directly lead to a patient's death or greater disability.

An example of this problem occurred in 2013 when the FDA issued a *Health Care Provider Alert* in February warning doctors that a counterfeit version of Avastin had been found in the United States.¹⁷ Avastin is a widely used intravenous drug that treats cancers of the colon, lung, kidney, and brain, and is also used off-label to treat age-related macular degeneration. The counterfeit drug contained none of Avastin's active ingredient (bevacizumab) and, while regulators did not say what was actually in the vials, in previous incidents they had contained salt, starch, and a variety of chemicals that are potentially carcinogenic or otherwise harmful.

Clearly, it is highly unlikely that cancer patients will go into remission if they are receiving fake drugs with no active ingredients. The possibility that these counterfeits contain potentially carcinogenic chemicals or other toxins introduces additional health risks. This substitution of something inactive, or even harmful, for a life-saving drug was most likely lethal. According to Professor Nimesh Nagarsheth of the Mt. Sinai School of Medicine in New York, the "people who receive[d] a fake medication instead of Avastin could have lost several months of their lives".¹⁸

Unfortunately, the increased mortality risk also extends to patients taking medicines that address more common health issues. During the H1N1 flu epidemic of 2010, the FDA warned consumers about a potentially harmful counterfeit of an anti-flu drug, Tamiflu, that could have been a killer in two respects: It lacked the flu-preventing and modulating medicine (oseltamivir), and it contained an antibiotic similar to penicillin that can be lethal to people who are allergic to it. Another example from 2010 was counterfeits of the weight-loss drug Alli. These counterfeits, sold over the Internet but containing none of the active ingredient in the real drug, contained sibutramine, the prescription-strength weight-loss drug Meridia, which has since been removed from the U.S. market because of concerns about the drug's cardiac side effects. From a global perspective, the Organization for Economic Cooperation and Development (OECD) documented that counterfeit pneumonia drugs cause the death of between 72,000 and 169,000 children annually, and fake anti-malarial drugs cause 116,000 deaths annually.¹⁹

In 2015, the FDA alerted health care practitioners and the public that a counterfeit version of Botox was found in the United States and had possibly been sold to doctors' offices and medical clinics nationwide.²⁰ Botox is approved for several medical conditions and for removing facial wrinkles. Because the FDA could not confirm that the manufacture, quality, storage, and handling of those products met U.S. standards, the counterfeit products were considered unsafe.

More recently, the importation of large amounts of counterfeit opioids caused an explosion of overdose deaths in the United States, according to a Drug Enforcement Administration (DEA) report.²¹ The DEA described how hundreds of thousands of counterfeit prescriptions, many containing deadly amounts of potent fentanyl-related compounds, made their way into the U.S. drug market, with deadly consequences:

In March 2016, law enforcement officers in Lorain County, Ohio, seized 500 pills that visually appeared to be oxycodone. The pills were blue and had ‘A 215’ markings, consistent with 30 milligram oxycodone pills. Laboratory analysis indicated that the pills did not contain oxycodone, but were instead the research chemical U-47700. U-47700 is an unscheduled synthetic opioid not studied for human use that has caused at least 17 overdoses and several deaths in the United States.

There are also broader public health risks created by the counterfeit medicine problem. Counterfeit medicines thwart the efforts of the public health community to control infectious diseases like Covid-19 and can worsen current public health crises like the problem of bacteria developing anti-microbial resistance (AMR), which is a large and growing public health threat.²² According to the Centers for Disease Control and Prevention (CDC), there are “more than 2.8 million antibiotic-resistant infections in the U.S. each year, and more than 35,000 people die as a result.”²³

The adverse economic consequences

Beyond the impact on health, counterfeit medicines impose large economic costs. The amount of these adverse economic consequences depends on the size of the counterfeit drug market. While its clandestine nature makes it difficult to precisely measure these activities, according to the studies by O’Hagan and Garlington (2018) and the WHO (cited above in the section *Counterfeit medicines are a large and growing problem*) the total global sales value of counterfeit drugs could be between \$200 billion and \$431 billion, respectively.

Such a large counterfeit market imposes exceptionally high economic costs on pharmaceutical innovation, economic activity, jobs, and government tax revenues. To provide a sense of these costs, and accounting for the uncertainty surrounding these estimates, this section estimates the economic costs from the counterfeit drug market based on four scenarios to account for the size of the global counterfeit drug market: \$100 billion, \$200 billion, \$300 billion, and \$431 billion. These scenarios demonstrate that even if the size of the counterfeit drug market is one-half the smaller estimate by O’Hagan and Garlington (2018), it still imposes huge costs on patients and the broader economy.

Adverse impact on innovation

Starting with the adverse impact on innovation, the pharmaceutical and biopharmaceutical industries are among the top investors in research and development. According to a 2015 report that analyzed the important economic contributions from industries that invest heavily in intellectual capital, “the three industries with the highest amount of R&D investment per employee were pharmaceutical and medicine manufacturing, semiconductor manufacturing, and aerospace manufacturing.”²⁴ Counterfeit drugs divert revenues away from the legitimate industry, which reduces the resources available for developing new and better treatments. Based on the potential size of the counterfeiting problem, this impact is sizable.

Pharmaceutical companies devote approximately 17 percent of their gross revenues toward research & development.²⁵ Based on this investment level, even if the counterfeit drug problem were *only* a \$100 billion annual problem, this would, on average, still deprive researchers of \$17 billion that could have been devoted to discovering new and more efficacious medicines (Table 1). If the WHO’s estimated size of the market is correct, then, as described in Table 1, the global amount of R&D is being denied over \$73 billion in research funds. Based on the estimated \$2.6 billion it costs to develop one new treatment according to DiMasi, Grabowski, and Hansen (2016), these funds are the equivalent of between six and 28 potential treatments over time.²⁶ And those losses are *annual*. Each year that the counterfeit drug problem festers costs the equivalent of another six to 28 potential treatments over time, imposing exceptionally large health and economic costs on current and future patients.

Table 1
Estimated Annual Impact on Drug Innovation from the Estimated Counterfeit Drug Problem
(\$s in billions)

	LOW-END ESTIMATE	O'HAGAN & GARLINGTON	MIDDLE ESTIMATE	WHO ESTIMATE
Estimated Size of Global Counterfeit Drugs	\$100.0	\$200.0	\$300.0	\$431.0
R&D Share of Revenue	17%	17%	17%	17%
Lost R&D Revenue	\$17.0	\$34.0	\$51.0	\$73.3
Cost to Develop 1 New Drug	\$2.6	\$2.6	\$2.6	\$2.6
Number of Lost New Drugs	6	13	19	28

Source: Authors' calculations

Adverse impact on the economy and tax revenues

The industry’s lost revenues also impose large global economic costs. Table 2 presents the estimated impact on the U.S. economy. According to the Organization for Economic Cooperation and Development (OECD), “the United States, Switzerland, Germany and France are the largest producers of pharmaceuticals worldwide. According to data provided by the United Nations Industrial Development Organization’s (UNIDO) Industrial Statistics Database, in 2016 the United States’ share of the global output of pharmaceuticals was 37.6 percent, making it the leading producer of pharmaceutical products and medicines worldwide. It was followed by Switzerland (14 percent), Germany (8.9 percent) and France (6.8 percent).”²⁷

Assuming that the counterfeit drug problem impacts the U.S. manufacturers proportionally to their share of global revenue, the problem of counterfeit drugs reduces total industry revenues in the U.S. between \$37.6 billion and \$162.1 billion, depending upon the estimated size of the counterfeit market (Table 2). Of course, the extent of the economic damage goes beyond the lost revenues. All of the follow-on economic activity that could have been generated from these revenues is also lost.

According to an analysis of the biopharmaceutical industry’s economic impact conducted by TEconomy Partners, the economic multiplier of the biopharmaceutical industry is 2.18.²⁸ Economic multipliers account for the additional economic activity that would have occurred had the biopharmaceutical industry been able to spend these revenues on purchasing supplies and resources. Therefore, based on an economic multiplier of 2.18, the revenues that have been lost due to counterfeit drugs resulted in a total economic loss that ranges from \$82 billion to \$353 billion (Table 2). And due to the economic losses to the private sector,

federal and state tax revenues are lower than they would otherwise be. Based on the average taxes raised in the TEconomy study, state and federal governments are losing between \$4.5 billion and \$19 billion in potential tax revenues. Again, these are annual losses, and will consequently recur each and every year.

Table 2
Estimated Annual Impact on U.S. Economy from the Estimated Counterfeit Drug Problem
(\$s in billions)

	LOW-END ESTIMATE	O'HAGAN & GARLINGTON	MIDDLE ESTIMATE	WHO ESTIMATE
Estimated Size of Counterfeit Drugs	\$100.0	\$200.0	\$300.0	\$431.0
U.S. Share of Global Output	37.6%	37.6%	37.6%	37.6%
U.S. Share of Lost Revenue	\$37.6	\$75.2	\$112.8	\$162.1
Output Multiplier	2.18	2.18	2.18	2.18
Lost U.S. Potential Output	\$81.97	\$163.94	\$245.90	\$353.28
State/Local Personal Tax Revenue	\$0.60	\$1.19	\$1.79	\$2.57
Federal Personal Tax Revenue	\$3.92	\$7.85	\$11.77	\$16.91

Source: Author calculations

The loss of these revenues also deprives the economy of tens of thousands of potential jobs. To get a sense of the potential job losses, according to the industry’s direct effects (according to the TEconomy study), the U.S. industry generated \$558 billion in economic output, while employing over 850,000 people. Based on this relationship, the lost revenues due to counterfeit drugs are sufficient to create between 57,500 jobs and 247,800 jobs. Considering the estimated multiplier, the total number of jobs that could exist today, but have been lost due to the proliferation of counterfeit drugs, could be as high as between 299,000 and 1.3 million.

Although there are always uncertainties regarding the precise dynamics that include which products are sold, at what prices, and the competitive environment, these estimates demonstrate that in addition to the large impacts on public and individuals’ health, the counterfeit drug problem imposes exceptionally large economic costs on the U.S. economy. These losses include billions of dollars in lost potential income, and hundreds of thousands of jobs. They also include the loss of innovation that could lead to the development of dozens of potential treatments that will either be delayed or, in the worst case, never created, because the resources to develop these treatments were diverted to the illegal market. The size of these losses argues that minimizing, or, ideally, eliminating the counterfeit drug problem should be a top policy priority.

Policies to address the counterfeit problem

The large costs of counterfeit medicines make it imperative for federal and state governments to implement policies to address this large and growing problem. Borrowing from the Hippocratic Oath, the first priority of federal and state government policy should be, “do no harm.”

That might seem an odd admonition in this context, but unfortunately, while not necessarily designed to address the issue of counterfeit medicines, there are several policies under consideration that would make this bad situation worse. Of particular concern are the proposals that would allow drug importation and/ or impose drug price controls. Drug importation directly worsens the counterfeit problem by creating a less

secure drug supply chain. In fact, every former Health and Human Services Secretary and FDA Commissioner, whether under a Republican Administration (e.g. Alex Azar) or a Democratic Administration (e.g. Donna Shalala), has expressed concern that drug importation will make it impossible for the government to ensure that the drugs entering the country are safe and cost effective.²⁹ The evidence supports their concerns. In 2018, for example,

An online pharmacy that bills itself as Canada’s largest was fined \$34 million . . . for importing counterfeit cancer drugs and other unapproved pharmaceuticals into the United States, a sentence that one advocacy group called too light for such a heinous crime.

Canada Drugs has filled millions of prescriptions by offering itself as a safe alternative for patients to save money on expensive drugs, and its founder, Kristian Thorkelson, has been hailed as an industry pioneer for starting the company in 2001.

But U.S. prosecutors say Canada Drugs’ business model is based entirely on illegally importing unapproved and misbranded drugs not just from Canada, but from all over the world. The company has made at least \$78 million through illegal imports, including two that were counterfeit versions of the cancer drugs Avastin and Altuzan that had no active ingredient, prosecutors said.³⁰

In addition to exposing patients across the country to dangerous counterfeit medicines, drug importation will fail to address the affordability problems patients face, in part because Canadians would never let that happen. As former Canadian Minister of Health, Ujjal Dosanjh, noted, “if we allow the United States to import drugs from Canada in numbers that could actually impact prices there, our own drug inventories will be depleted, and the pharmaceutical companies will have no financial incentives to restock those shelves.”³¹ Should Canadians act in their own self interest and prevent legitimate drugs from being exported to the U.S., it all but ensures that the drug importation proposals (such as Governor Ron DeSantis’ proposal to allow drug imports into Florida) will worsen the counterfeit problem in the U.S. and endanger patient health.

Price controls indirectly worsen the counterfeit problem by creating problems of access (i.e., shortages) that increase the incentive to pursue alternative sources for medicines – which, in turn, increases the number of illegitimate pathways for counterfeit drugs to enter the supply chain. Either way, these policies increase the incentives to use counterfeit medicines and/or decrease the security of the U.S. pharmaceutical supply chain. Consequently, these policies would lead to a significant increase in counterfeit medicines’ share of the U.S. drug supply. If implemented, the results from these policies would compromise patient health outcomes and have adverse economic impacts.

Pro-active changes that could improve safety and efficacy of the drug supply

However, given the size of the current problem, simply avoiding policies that make the problem worse is insufficient. The government should proactively implement policies that will reduce the use and availability of counterfeit drugs. The goals of these policies should be to discourage both the supply of, and demand for, counterfeit products.

The analysis above demonstrated that one of the incentives for criminal organizations to sell counterfeit drugs is the high profits coupled with the relatively light punishment if caught. Increasing the punishment for selling counterfeit medicines and increasing enforcement efforts, in order to increase the probability

that counterfeiters will be apprehended, would increase the costs of selling fake drugs. Toward this goal, an inter-agency working group from 2011 provided important suggestions that could help secure the nation's drug supply and increase the chances of intercepting the counterfeit drugs.³² These include improving data- and information-sharing among government departments, particularly the FDA, Customs and Border Patrol, and the United States Postal Service. The increased coordination should focus on intercepting the larger sources of illegal pharmaceuticals that enter at U.S. ports of entry as well as the smaller shipments that tend to enter via post, overnight mail, and air cargo services. Ideally, the coordination would extend to international agencies such as the World Customs Organization and Strategic Alliance Group, which consists of enforcement agencies from the USA, UK, Canada, Australia, and New Zealand.

Technology can also play a critical role controlling the problem. For instance, the enactment of a pharmaceutical track-and-trace system could make it more difficult to introduce counterfeit drugs into the U.S. market. This would require continual monitoring of a unique serial number on each package; security features such as holograms, color-shifting ink, and difficult-to-reproduce chemical or radioactive tags; and the use of technologies that reveal each product's source and distribution history.

Consumer and provider education are another important part of this effort. In 2011, one in six Americans purchased medicines of some kind on the Internet; many, perhaps most, of these were counterfeit or sub-standard in some way. Education campaigns should explain the risks from using counterfeit drugs, teach consumers the signs that a drug could be a counterfeit, and provide information regarding where consumers can find reputable Internet pharmacies (e.g. the pharmacies on the National Board of Pharmacy's recommended list).³³

Conclusion

Counterfeit medications are dangerous to individuals and society at large. Their use may result in adverse side effects, including treatment failure, antibiotic resistance of pathogens, toxicity, and even death. From an economic perspective, counterfeit drugs diminish drug innovation, cost the economy billions of dollars in potential output annually, and have eliminated hundreds of thousands of potential jobs. In light of these costs, securing the U.S. pharmaceutical supply should be a top policy priority.

Securing the drug supply chain requires a broad-based effort in which governments, pharmaceutical companies, drug distributors, pharmacists, and individuals assign a high priority to combating the drug counterfeiting problem. There is not a single policy that would instantaneously resolve the issue, but a concerted effort across these groups can significantly reduce this problem.

“ Securing the drug supply chain requires a broad-based effort in which governments, pharmaceutical companies, drug distributors, pharmacists, and individuals assign a high priority to combating the drug counterfeiting problem.

Endnotes

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An important caveat about economic impact models is warranted. There are significant concerns regarding the efficacy of how many economic impact studies are conducted when used to evaluate potential government projects. For an excellent discussion of these problems, particularly the failure of these models to account for an activity’s opportunity cost, see: “Economic Impact Studies: The Missing Ingredient Is Economics” John Locke Foundation March 30, 2017, <https://www.johnlocke.org/research/economic-impact-studies-the-missing-ingredient-is-economics/>. In the case of counterfeit drugs, the opportunity cost of the revenues evaluated is the use of these funds by criminal organizations. Due to the harm imposed by these entities, the opportunity costs of these funds are assumed to be zero in this analysis.

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About PRI

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