

THE ECONOMIC IMPACTS OF COUNTERFEIT PHARMACEUTICALS ON THE UNITED STATES MEDICAL SUPPLY CHAIN AND RELATED INDUSTRIES

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ABSTRACT

The entrance of counterfeit pharmaceuticals into the legitimate medical supply chain is a growing health and economic concern, though there is little academic literature. Rising healthcare costs and consumer desire for cheaper prescription drug alternatives has only increased demand for counterfeit drugs. Consumers may travel abroad, access criminal networks, or utilize online pharmacies for alternative pharmaceutical purchases [8]. This paper uses a combination of detailed literature review and statistical analysis to estimate the size of the counterfeit markets, the application of computable general equilibrium (CGE) modeling to understand the impact of counterfeit goods on legitimate industries.

INTRODUCTION

Counterfeit pharmaceuticals have emerged as a major concern for policy makers worldwide in recent years [37][11][49]. The entrance of counterfeit pharmaceutical drugs in the United States medical supply chain poses a threat to public health and the economy. While the risks are relatively low, and U.S. regulatory standards are relatively high, counterfeit products do enter medical supply chains, potentially causing serious and even deadly health problems [11][49]. Such health problems can cause economic concerns, including impacts to the labor force due to illness, and the erosion of consumer trust in medicines and brands.

This paper provides insights by analyzing the impact of pharmaceutical imports seizures using computable general equilibrium (CGE) modeling. We look at neighboring industries, which are impacted by such shifts in import levels, and impacts to household consumption and prices. We also analyze the impact of changes in producer and consumer surpluses relating from seizures – following an approach outlined by Rose and colleagues (2016) [36] – and translate these to economywide impacts. With both of these questions, we examine the impacts of these different measures on lower-income households in particular. This paper aims to better inform policy making by agencies such as CBP and FDA by deepening our understanding of the counterfeit pharmaceutical industry, its economic impact on related US industries, as well as the related health and economic impacts to U.S. citizens.

LITERATURE REVIEW

Due to the paucity of academic literature in this area, this paper uses a combination of academic, government, and professional literature with respect to three important aspects of counterfeit pharmaceuticals: the health implications of counterfeit pharmaceutical drug use; the pharmaceutical medical supply chain; and the role of pricing in consumer decision making.

Health Implications of Counterfeit Pharmaceutical Drug Use

In 2012, the Food and Drug Administration (FDA) released a letter of notice to clinics and physician of the entrance of counterfeit Avastin and Altuzan (Bevacizumab), common cancer-treatment medications, into the legitimate medical supply chain [19]. Counterfeit versions of these drugs lack the active ingredient Bevacizumab and were distributed through foreign-based pharmaceutical suppliers into the US [19]. Currently, it is not known how many vials of counterfeit have entered the market. Those who may have taken counterfeit Avastin may have an increased risk of cancer recurrence due to ineffective drug treatment. Table 1 below shows additional counterfeit pharmaceutical drug cases in the US.

TABLE 1. COUNTERFEIT PHARMACEUTICAL DRUG CASES

Counterfeit Pharmaceutical Drug Incidents	Case Details	Health Impacts
Internet purchases of anti-anxiety medication Diazepam [17][20]	The FDA released a warning to US consumers for online purchases of the anti-anxiety medication Diazepam. The World Health Organization (WHO) has reported approximately 700 cases of counterfeit and mislabeled Diazepam containing the incorrect active ingredients being taken by patients in Central Africa. Foreign versions of Haldol (haloperidol), an anti-psychotic drug, were found in the counterfeit tablets.	Patients were hospitalized suffering from difficult breathing, muscle spasms, dystonia, and muscle stiffness.
Online sale of counterfeit weight loss pharmaceutical drugs [15][16][17]	Weight loss medication imported from China being sold under the brand names of "Superslim," "2 Day Diet," Meitzitang, and Alli. Alli is an FDA-approved drug for weightloss through online websites such as eBay. Counterfeit Alli purchased online were found to contain the unlisted and incorrect active ingredients such as, sibutramine, antidepressants, and diuretics. Sibutramine is a controlled substance and is the active ingredient of another FDA-approved weight loss drug, Meridia.	Though patients taking the counterfeit Alli experienced the desired effect of weight loss, sibutramine places patients at additional health risk. The purchased counterfeit Alli often contained dangerous levels of sibutramine, which can lead to high blood pressure, seizures, tachycardia, palpitations, heart attack or stroke.
Unlicensed pharmaceutical supplier/distributor shipping and distributing counterfeit Botox [18]	The FDA released a warning for physicians' offices and medical clinics of unintentional purchases of counterfeit Botox from unlicensed pharmaceutical suppliers/distributors in the US. The counterfeit Botox are deemed unsafe by the FDA due to the lack of assurance that the products follow US standards of manufacturing, quality, storage, and handling.	No reports of adverse side effects have been associated with the counterfeit Botox.

Pharmaceutical Supply Chain Management and Security

The legitimate pharmaceutical supply chain consists of a multi-tiered system that revolves around the flow of data, money, and products between the following key financial players: (1) pharmaceutical manufacturer, (2) drug wholesale distributor, (3) pharmacies (retail, mail order), (4) pharmacy benefits manager, (5) employee/plan sponsor or health insurer, and (6) consumers [23]. The primary role of each financial player is summarized in Table 2.

TABLE 2. PLAYERS IN THE PHARMACEUTICAL SUPPLY CHAIN

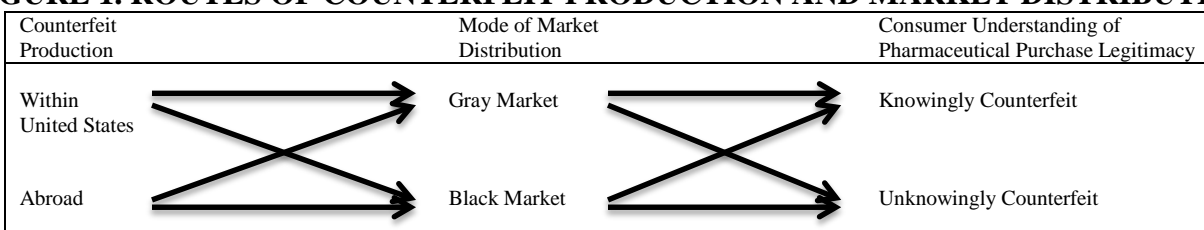
Key Players	Role in the Supply Chain	Impact of Counterfeit Products on Legitimate Industry
<i>Pharmaceutical Manufacturers</i>	<ul style="list-style-type: none"> - Pharmaceutical manufacturers are tasked with producing brand-name or generic pharmaceutical drugs on behalf of research and development pharmaceutical firms. - This group maintains the greatest influence on pharmaceutical pricing, controlling supply for the expected demand, controlling the competitiveness of the future marketplace, and establishing wholesale acquisition costs (WAC) [23]. 	<ul style="list-style-type: none"> - Decreases consumer trust in brand - Competition with counterfeit drug sales may alter pricing of pharmaceutical drugs
<i>Drug Wholesale Distributor</i>	<ul style="list-style-type: none"> - Wholesalers and distributors mediate the purchase, re-packaging, and transport of manufactured pharmaceutical products from manufacturers to pharmacies. 	<ul style="list-style-type: none"> - Increased spending on packaging and transportation security by distributors - Continued association of counterfeit entrance through the distributor may hinder organizational trust with manufacturer and pharmacies leading to a reduction of contracts
<i>Pharmacies (retail, mail order)</i>	<ul style="list-style-type: none"> - Primary distributors of pharmaceutical products to consumers. - Through strategic contract pricing, pharmacies purchase pharmaceutical units either through wholesale distributors or directly from manufacturers to sell to consumers. 	<ul style="list-style-type: none"> - Decreases consumer trust in pharmacies and retailers - Decreased sales of legitimate pharmaceutical drugs due to market competition with counterfeit

<i>Pharmacy Benefits Manager (PBM)</i>	- PBMs contracts between drug manufacturers, pharmacies, and employer/plan sponsor or health insurers further reduce the transportation costs and WAC through negotiated payments.	- Contracting may result in greater downstream expenses for consumers due to PBMs placing themselves in greater financial risk by contracting with manufacturers and pharmacies having a history with counterfeit
<i>Employer/Plan Sponsor or Health Insurer</i>	- Sponsors and Insurers contract with pharmacies and pharmacy benefits manager to reduce purchasing costs for consumers as part of insurance premiums.	- Contracting with certain pharmacies that have a history with counterfeit distribution/sales may be terminated - Higher health insurance premiums for consumers
<i>Consumers</i>	- Pharmaceutical product acquisition sources for consumers are typically limited to pharmacies. Discounted costs associated with the purchase of pharmaceutical products are directly impacted by a consumer's access to employee/plan sponsor or health insurer.	- Less spending on legitimate pharmaceutical drugs as they substitute towards cheaper alternatives due to the ease of access/convenience - Increased health risks

Typically, the pharmaceutical supply chain maintains a single wholesaler structure where manufacturers directly sell to wholesalers [22]. This practice is based in the belief that the fewer parties involved, the less counterfeiting risk to the supply chain security. Occasionally, pharmaceutical companies may use secondary wholesalers to reduce costs by through repackaging medical shipments [22][33]. This method leads to the “secondary wholesale” or “gray markets;” or the sale of counterfeit and substandard drugs. Also, outsourcing production activities to other countries is common practice in the industry, due in part to cheaper manufacturing practices that are a result of lower labor costs and differences in regulation practices in some countries [48].

Counterfeit pharmaceuticals become available to consumers by then entering either the “gray market” or the black market [10][22]. In addition to the gray market, consumers are able to obtain goods via the black market, which is a mixture of illegally distributed counterfeit and legitimate pharmaceutical drugs, oftentimes operating though deep-web online marketplaces [10]. Consumers can either knowingly or unknowingly take ineffective, counterfeit pharmaceutical drugs depending on consumer understanding of distributor reliability as displayed by Figure 1.

FIGURE 1. ROUTES OF COUNTERFEIT PRODUCTION AND MARKET DISTRIBUTION



Online marketplaces for counterfeit pharmaceutical drugs are difficult to monitor due to the speed of electronic funds transfer and the turnover rates of pop-up pharmaceutical websites. Here, online pharmacies, often based outside the US where US government oversight is limited, are difficult to trace [8]. According to the World Health Organization, upwards of 50% of cases involved in Internet sales of medicines are counterfeit [46]. Patients, who are limited by financial constraints, may look to the Internet as a source for discounted medicines to aid in their needed care, but buyer discretion is advised.

METHODS

We used CGE modeling to provide insight into the impacts of pharmaceutical import seizures on neighboring industries, producer/consumer surplus, impact to lower-income households, and health impacts. The Social Accounting Matrix data at the core of the model are obtained from IMPLAN (2012), and the version of the model used in this analysis is based on 2012 data for the US economy.

To provide a framework for the counterfeit pharmaceutical industry issue, an estimate of the impact of the counterfeit industry on the legitimate industry is taken with respect to other areas of the economy (such as downstream purchasers and households). Utilizing the lower and upper bound estimates of market shares, a price differential estimate is taken to determine a new average price. This estimated new average price is a result of collected data regarding the counterfeit market share of all pharmaceuticals, in addition to the price differential between counterfeit and legitimate pharmaceuticals.

From this, development of drug seizure scenarios is based on available CBP seizure data, which is used to estimate the of the impacts of counterfeit pharmaceutical industry size reductions on the legitimate pharmaceutical industry and other related areas of the economy. This begins with taking an initial look at the impact of price change in pharmaceutical industry drug products. The result gives a simplified look into the economy-wide economic impacts of counterfeit drugs and seizures of them.

Another challenge that arises with this CGE modeling is that as we shift all pharmaceutical prices simultaneously, the following assumptions arise: 1) equal distribution of counterfeit pharmaceuticals across different areas of the economy (i.e., same market share of imports); 2) any seizures have equal impact across the economy. To address these issues the following considerations are taken: (1) Price/quantity of pharmaceutical imports increases/decreases with respect to the number of seizures made; (2) Domestic production of pharmaceuticals changes in response to import changes; costs of imported inputs increase, yet there may be simultaneous increases in output to address shortage (i.e., substitution from imported to domestic production); (3) Household spending on medical services increases as pharmaceutical price increases.

In assessing the economic impacts of counterfeit pharmaceutical trade, it is crucial to delineate the quality differences between counterfeited goods. Counterfeit pharmaceutical drugs will be uniquely defined as products manufactured by illicit means (i.e., produced by individuals beyond the means of legitimate pharmaceutical industry production). Clearly defining counterfeit from genuine and substandard quality types is essential especially since each is seen in black market pharmaceutical trade. Additionally, quality of production exposes the relative health risks consumers place themselves under by consuming drugs with null or harmful ingredients that may be detrimental to their general health. Since the majority of consumers are unknowing of the exact origin of drug manufacturing during illicit market purchase, defining counterfeit allows for a better understanding of the issue. Consequently, herein lies the difficulty of understanding the impact of the illicit pharmaceutical drug trade.

Lower And Upper Bound Estimation

Given the paucity of information about the size and reach of the counterfeit pharmaceutical industry, in this paper we develop lower and upper bound scenarios to provide insight into the relative size of the counterfeit pharmaceutical industry in the United States.

The lower bound estimate of the counterfeit pharmaceutical industry relies on known data obtained from the U.S. CBP. Based on 2014 Fiscal Year Seizure Statistics, seizures of pharmaceuticals/personal care commodity equaled \$72.9 million [42]. If this seizure statistic is compared to the total value of US imports of pharmaceuticals (\$93.5 billion), seizures make up only 0.08% of imports [41].

For the upper bound (See Appendix A), we identify where counterfeit drugs are likely to be imported from using estimates of the relative propensity of goods to be counterfeited developed by the Organisation for Economic Co-operation and Development (OECD) [26]. From these calculations, we estimate that the US counterfeit pharmaceutical industry can be valued at \$9.2 billion in 2014 based on

data available for 83 economies. This estimation is based on countries, which the US imports from and that have partnered with the OECD to determine their individual General Trade-Related Index of Counterfeiting for economies (GTRIC-e) value.

TABLE 3: LOWER AND UPPER BOUND ESTIMATION

Estimation Technique	Estimations
Lower Bound [42]	\$72,939,399
Upper Bound	\$9,192,206,496

RESULTS

Upper and Lower Bound CGE Simulation Results

To explore the economywide impacts of pharmaceutical imports seizures, chemical manufacturing (MCHM) and neighboring industries were provided an upper and lower bound estimate (see Appendix B). In the following simulations, the output change refers to the relative change in imports; change in GDP refers to impacts to the overall economy; and employment change is an indicator of health impact.

The macroeconomic CGE simulation results reveal a positive stimulus to domestic production of pharmaceutical industries as well as other sectors when imports are reduced. It is observed in the upper bound estimate that output in the pharmaceutical sector decreases by 4.92% resulting in a negative effect of 7.71% on GDP and 5.38% on employment (see Appendix B and Appendix C, Table 1). For comparison, the initial upper bound estimate based on OECD General Trade-Related Index of Counterfeiting for economies estimated a \$9.2 billion impact to US trade. Additionally, the lower bound scenario simulation results show a decrease in output of 1.64% resulting in a 2.57% GDP and 1.79% employment change decrease. Whereas, US CBP 2014 seizure statistics show an initial lower bound estimate of \$72.9 million. As there is an increase in the cost on counterfeit pharmaceutical industry imports, this leads to increased costs to other sectors of the economy. The upper and lower bound CGE results provide a scope into the influence of the counterfeit pharmaceutical industry on pricing of legitimate pharmaceuticals and medical services. Though these results provide only a small glimpse into the size and impact of the counterfeit pharmaceutical industry, it aids in better understanding the influence of illegitimate marketplaces.

DOMESTIC PRODUCTION AND CONSUMPTION

A simulation observing the impact of counterfeit pharmaceutical seizures on the domestic production and consumption side of chemical manufacturing was done (see Appendix C, Table 2). Domestic production and consumption reveals the economywide impacts of producer/consumer surplus related to changes in pharmaceutical seizures. At minimum, the lower bound estimate places a 0.09% increase in domestic production whereas there is a 0.20% increase in domestic consumption. Taking an upper bound approximation of increases in domestic good production and consumption in the chemical manufacturing sector reveals a 0.03% and 0.07% increase, respectively.

HOUSEHOLD CONSUMPTION BY INCOME BRACKETS AND COMMODITY GROUP

Simulations on impact of counterfeit pharmaceutical drug seizures on household consumption are geared at approximating which household incomes are drivers of the counterfeit market (see Appendix C). As pharmaceutical seizures increase, there is an expected increase in household spending for lower income

households following a decrease in more affordable, counterfeit pharmaceutical drugs. Accordingly, low to median-income households (HH1 – HH5) experience a greater decrease in expenditures across all commodity groups than those of higher income households. Looking at the upper bound simulation of low income household (HH1) and high income household (HH9) percent change in household consumption, HH1 experiences a decrease in consumption across all commodities whereas HH9 experiences increased change amongst household goods and services (HOUS), public transport (LTRN), and water and services (WTER) commodities (see Appendix C, Table 3). As for a comparison with lower bound household consumption, HH9 experiences a decrease in consumption across all commodities except public transportation (LTRN) and HH1 experiences increases in consumption of household goods and services (HOUS), public transport (LTRN), water and services (WTER), and electricity (ELEC) commodities (see Appendix C, Table 4). As there is an increase in legitimate pharmaceutical spending, households that are affected by pharmaceutical seizures are expected to shift spending priorities away from other commodities and toward legitimate products. Increases in counterfeit pharmaceutical drug seizures show that lower income households experience an increase in demand for legitimate products than higher income households in both upper and lower bound approximations.

CONCLUSIONS

Pharmaceutical imports seizures provide insight into the presence of the pharmaceutical counterfeiting industry within the United States. Observing the neighboring industries that work with the legitimate pharmaceutical industry, it can be deduced that any imported counterfeit pharmaceuticals will act as a negative stimulus on the industries related to the legitimate pharmaceutical industry, household consumption, and pricing of legitimate goods.

Looking at producer and consumer surpluses, seizures of counterfeit brings about an increase in demand for legitimate pharmaceutical drugs. This demand can lead to legitimate pharmaceutical retailers to sell their products at increased profit margins since there is less competition from the counterfeit pharmaceutical industry and forces consumers to invest more in the legitimate pharmaceutical industry. Additionally, lower income household are expected to be the most impacted by an increase in pharmaceutical seizures as counterfeit pharmaceutical drugs are heavily marketed towards lower income households, especially those populations with limited health education [45]. Counterfeiters target lower-income households to monetize on the consumer demand for more affordable prescription drug alternatives to more expensively priced brand-name and generic drugs distributed by legitimate retailers.

The use of counterfeit drugs can be likened to either foregoing medical treatment or taking the incorrect medication for an illness. In healthcare, management of time in medical treatments is crucial to preventing or limiting the effects of a sickness. Though the true magnitude of the counterfeit industry is difficult to accurately capture, bettering the methods with which it can be monitored is the first step to combating the negative economic and health impacts of counterfeit pharmaceutical drugs.

Appendices and references available upon request from:

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