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The Impact of Counterfeit Pharmaceuticals: Supply Chain Issues and Resolutions

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THE IMPACT OF COUNTERFEIT DRUGS: SUPPLY CHAIN ISSUES AND RESOLUTIONS

By

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Abstract

This paper addresses the issue of counterfeit pharmaceuticals, using the supply chain as a lens through which to view problems and resolutions. The issue of counterfeit pharmaceuticals is one that is only going to increase in magnitude, and the proliferation of internet access greatly impacted the counterfeiter's role. As more consumers have gained access, the internet has become a viable venue through which to purchase and sell counterfeit products. Through the research of this topic, the hope was to suggest possible resolutions for the supply chain and major stakeholders. Because of the illegal nature of the issue of counterfeit pharmaceuticals, accurate empirical data was largely unavailable. However, the Food and Drug Administration and the World Health Organizations were the two most informative sources. Concluding this research, I have found that the issue of counterfeit pharmaceuticals is one that needs much more attention than is currently being dedicated. Through government initiatives, such as the Prescription Drug Marketing Act, and IMPACT, the entire supply chain should be more integrated in their resolve to thwart the increase of counterfeit pharmaceuticals in the United States.

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Introduction

Counterfeit goods hold an established position in the history of this civilized world. As early as the fourth century, counterfeiters have attempted to profit by deceiving the public[1]. As a country matures economically, the amount of regulation and emphasis put on providing safe healthcare increases. The United States has developed into the established economy that it is today, and several administrations exist to regulate the pharmaceutical industry. However, within the last decade, the Food and Drug Administration's counterfeit drug investigations have risen significantly in the United States[2]. The World Health Organization reports that in 2010 the counterfeit pharmaceutical sales have risen 92% in the US since 1995. This 92% increase in sales means there is now a $75 billion dollar industry for counterfeit pharmaceuticals.[3] These numbers paint an alarming picture of the counterfeit pharmaceutical industry in North America. We, as Americans, have been comparably protected and sheltered by the rules and regulations set forth by the

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[1] Lybecker, Kristina. "Keeping it Real: Anticounterfeiting Strategies in the Pharmaceutical Industry." *Managerial and Decision Economics* 29 (2008): 389-495 Web. Nov. 2011

[2] United States. House. Committee on Government Reform. *Sick Crime: Counterfeit Drugs in the United States.* 109th Congress. First session. Washington: Government Printing Office, 2006. Print.

[3] http://www.who.int/mediacentre/news/releases/2006/pr09/en/

Food and Drug Administration (FDA). Unfortunately, following the development of the internet and less expensive technologies, the United States is struggling to thwart the increase of counterfeiters.

Throughout the rest of the world, many countries are unable to effectively regulate the production and distribution of counterfeit pharmaceutical goods, either by a lack of laws and regulations or a lack of effective implementation of these laws and regulations. Countries such as China and India have struggled with containing the problem of counterfeit medicines throughout recorded history, and this struggle is still evident today. The FDA claims that up to 15 percent of the drugs sold throughout the world are counterfeit. This number rises to as much as 50 percent in parts of Africa and Asia.[4] Although the prevalence of counterfeit drugs increase in developing countries, the issue of counterfeit pharmaceutical products plagues every country in the world, and the final consumer ultimately pays the price, both with their wallet and with their health.

The final consumer of a counterfeit drug may be very likely to suffer from alarming consequences. Also, the lack of treatment that the consumer would have received had they not consumed the counterfeit drug may also be a major detriment to a person's health. This paper will not only focus on the negative consequences of final consumption, but will also address the issues that the wholesaler, retailer,

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[4] Mathuna, Donal P., McAuley, Adam. "Counterfeit Drugs: Towards an Irish Response to a Global Crisis." (2005): Web Nov. 2011 (in the section "assessing the extent of the problem)

manufacturer, and consumer will encounter relative to obtaining pharmaceutical drugs. Another facet to the issue of counterfeit pharmaceutical goods includes that of detection. Unlike luxury goods, where you may be able to tell how a Louis Vuitton purse is stitched, pills themselves do not contain indicators that are easily recognizable. Therefore, without the use of rather advanced technology, the detection of counterfeit drugs becomes near to impossible in most instances. The standardized property of the pills themselves do not allow for consumers to deduce the quality of the medicine without relying wholly on the brand name or the pharmacists' recommendation. The packaging is the main indicator of a quality drug, and with developments in technology, counterfeiters are now able to reproduce labels with alarming accuracy.

In this paper, I will analyze the various ways that counterfeit drugs are introduced into the value chain from manufacturer to ultimate consumer, and the different ways that counterfeit drugs may affect the final consumer. There are varying degrees as to how much active ingredient a counterfeit drug may contain.[5] The severities of the consequences of consuming counterfeit pharmaceuticals also vary dramatically. If the drug is completely counterfeit, the consumer doesn't receive any of the medicinal value that is sought. If the drug contains only a portion of the active ingredient, then the virus or bacteria that the consumer is intending combat

[5] Forzley, Michele. "Combating Counterfeit Drugs: A Concept Paper For Effective International Cooperation." *World Health Organization, Health Technology and Pharmaceuticals: International Conference - Rome, Italy* (2006): Web Jan. 2012

develops antibodies, and becomes resistant to what the normal drug would contain. These two examples assume that the inactive ingredient of the counterfeit drug is not harmful to one's health. That being said, counterfeit pharmaceutical goods may not only contain little to no active ingredient, but may also contain substances that could possibly cause harm to the consumer's health and possibly prove to be fatal.[6]

Without investing in an effective system of detection that is translated across all four sections of the supply chain, counterfeit pharmaceutical increasingly becomes a threat to the overall health of society.

[6] Ibid

Research Methodology

In researching this topic, I have utilized EBSCO host and Google scholar, because these two sources have current articles pertaining to this topic as well as research that has been done over the last two decades. This will be my main source of information because the books that are available on this topic are somewhat out of date and do not contain the most current information. World Health Organization has a website that publishes a lot of information regarding what is currently being done to combat counterfeit pharmaceutical drugs. In addition to the WHO website, the FDA also has published information regarding this issue. Also, I have consulted news articles to gather as much up-to-date data as possible. "Empirical, reliable, and transparent statistics about drug counterfeiting are virtually non-existent."[7]

[7] Outterson, Kevin: Smith, Ryan. "Counterfeiting drugs: The Good, the Bad, and the Ugly." *Albany Law Journal of Science and Technology* 16 (2006) Pg. 527 Web. March 2012

Wellness and Recovery: The Impact of Counterfeit Drugs

The relevance and importance of intellectual property rights becomes a more critical issue as countries progress from emerging to developed economies. The differences between developments of countries around the world could have a negative impact on the effectiveness of laws pertaining to intellectual property rights. This not only causes some areas of trade and international relations to be complicated but also increases the opportunities to find loopholes and to twist the system into something that can be potentially harmful to many people.[8] When companies choose to manufacture their goods in a foreign country, they run the risk of exposing their product to counterfeiters. The differing intellectual property laws make it profitable and sometimes even legal for these counterfeiters to produce products without the consent or knowledge of the legitimate manufacturer.

The pharmaceutical industry of the United States is unique in that the rules and regulations of the FDA apply to both manufacturing firms located in the US and firms manufacturing outside of the US. Even though the intellectual property rights laws may differ from country to country, the FDA regulations remain the same across country borders for American businesses. Although this regulation should be effective in securing the supply chain of the United States, evidence has shown us

[8] Cabezas, Maria Dolores. "Counterfeit Medicines as Global Treat." *Pharmaceuticals Policy and Law* 12 (2010): 179-192. Web. Dec. 2011. Pg.181

that counterfeit drugs often slip through the cracks and unscrupulous behavior is still quite prevalent. The drug manufacturers themselves only need to comply with the FDA for safety, effectiveness and labeling of their drugs. After the drugs leave the manufacturer, the FDA has little control over where they go; which frequently includes the secondary market[9]. The limited jurisdiction of the FDA leaves the state to implement standards for distributors[10]. These standards often leave room for unscrupulous persons to take advantage of the opportunities that exist in buying and selling pharmaceuticals.

The regulation that the FDA provides to manufacturers does not translate to the commerce of internet pharmacies. Because the internet isn't regulated, internet pharmacies cannot guarantee as to where the drugs are coming from or what types of regulations are required of manufacturers.

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[9] United States. House. Committee on Government Reform. *Sick Crime: Counterfeit Drugs in the United States.* 109th Congress. First session. Washington: Government Printing Office, 2006. Print. Pg 2

[10] Ibid

Legal Perspective

The many facets of intellectual property rights include trademarks, counterfeit goods, and patents. Intellectual property rights provide a foundation for countries to be able to effectively and productively participate in global trade of the 21st century. The use of intellectual property rights also provides incentives for countries to be innovative. Although effective use of intellectual property rights is essential to a country's economic development, many countries classified as developing, often lack the resources necessary to enforce the laws and regulations surrounding intellectual property rights. [11]

According to the World Health Organization, "counterfeiting occurs both with branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients."[12] Pharmaceutical products and medicines are a unique category of intellectual property rights that has escaped the

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[11] Forzley, Michele. "Combating Counterfeit Drugs: A Concept Paper For Effective International Cooperation." *World Health Organization, Health Technology and Pharmaceuticals: International Conference - Rome, Italy* (2006): Web Jan. 2012 Pg. 3

[12] World Health Organization. (2006) "Counterfeit Medicines" http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/

attention of many because of the difficulty in monetizing their value and to be able to maintain their value to the organization. The act of producing a counterfeit medicine, like that of other counterfeit goods, disregards the rights that an original producer owns. Because the counterfeiter has little regard for the legality of the good, they could also very easily have little regard for making sure the medicines have the correct amount of active ingredients, which would increase the probability of causing harm to the final consumer. The unique nature of modern medicines includes the fact that ultimate consumers are typically unlikely to be able to analyze the drug itself and make judgments on its legitimacy. The properties of most medicines, and increasing accessibility of drug making technology allows for counterfeiters to produce a pill that is almost indistinguishable from an authentic drug.[13] {The most common property of a pill would be small enough to swallow, found, as to not hurt when being swallowed, and color may vary.} Consequently, most consumers rely completely on the pharmaceutical industry's labeling of a drug to provide a legitimate and safe product with the correct amount of active ingredient. This reliance on the pharmaceutical industry causes many consumers to unknowingly risk their health and even their lives when ingesting counterfeit drugs that were originally intended to save their lives and improve their health.

When the drugs leave the manufacturer, they often pass to and from several distributors. This provides opportunities for unscrupulous distributors to alter the packaging, the labels, and add inactive ingredients to the medicines. The FDA has attempted to curb these opportunities with the Prescription Drug Marketing Act (PDMA). Enacted in 1987, the PDMA included:

[13] Ibid: 21.

"a requirement for state licensure of wholesale distributors of prescription drugs; a requirement that wholesale distributors of prescription drugs who are not authorized distributors provide a statement of origin, also known as a drug "pedigree," to each wholesale customer. The pedigree traces each prior sale, trade, or purchase of the prescription drug; and requirements regarding the distribution and accountability of drug samples."[14]

The technology that is required to trace and track the drugs requires financial investments from the manufacturer, distributor, and retailer. Because of a lack of support from the pharmaceutical industry, the PDMA received many complaints and delayed requiring companies to implement the changes until 2006.[15]

In order to address the growing concern of counterfeit pharmaceutical products (CPP) many organizations including the US Food and Drug Administration (FDA), the World Health Organization (WHO), and the World Trade Organization (WTO) are and have been gathering information from many countries around the world and analyzing it in order to reduce the negative impact of counterfeit pharmaceutical products as much as possible.[16] In February of 2006, the WHO introduced a task force specific to fighting counterfeit pharmaceuticals, called the International Medical

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[14] United States. House. Committee on Government Reform. *Sick Crime: Counterfeit Drugs in the United States.* 109th Congress. First session. Washington: Government Printing Office, 2006. Print. Pg. 25

[15] Ibid: 26.

[16] Forzley, Michele. "Combating Counterfeit Drugs: A Concept Paper For Effective International Cooperation." *World Health Organization, Health Technology and Pharmaceuticals: International Conference – Rome, Italy* (2006): Web Jan. 2012

Products Anti-Counterfeiting Taskforce (IMPACT).[17] IMPACT is made up of five departments that focus on the following: "legislative and regulatory infrastructure, regulatory implementation, enforcement, technology, and communication."[18] Those five department are the, "communications, legislative and regulatory infrastructure, regulatory implementation, enforcement, and technology working groups."[19] IMPACT is focusing on providing a comprehensive framework of guidelines to the pharmaceutical industry. The five departments are committed to raising awareness of the issue of counterfeit drugs to all parties involved, improving upon the safety requirements, such as providing sufficient labeling for products, attempting to secure the distribution aspect of the supply chain, and investigating a region's capacity to prosecute and combat counterfeiting. [20]

Because of the scope of combating counterfeit drugs includes laws and regulations, it is clear that the supply chain alone cannot effectively prevent many counterfeit goods from entering a country or supply chain; consequently a country's

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[17] World Health Organization. (2009) "An Overview of the IMPACT Working Groups' documents and activities" http://www.who.int/impact/activities/overviewofIMPACTworkingdocs.pdf

[18] World Health Organization. (2012) "IMPACT" http://www.who.int/medicines/services/counterfeit/faqs/count_q-a/en/

[19] World Health Organization. (2009) "An Overview of the IMPACT Working Groups' documents and activities" http://www.who.int/impact/activities/overviewofIMPACTworkingdocs.pdf

[20] Ibid

government, the WHO, and other health oriented organizations have been and are going to be critical in the prevention of counterfeit pharmaceutical drugs distribution.

As drugs move from manufacturers to the final consumer, there are many opportunities for unscrupulous entities to infiltrate the system and exploit the practices of a legitimate supply chain. Focusing on the dangerous effects of counterfeit pharmaceuticals that are specific to each section of the supply chain, this paper will analyze the four sections of the supply chain and will suggest strategies that would reduce the likelihood of counterfeit pharmaceuticals entering the supply chain. This will include the manufacturing, wholesaling, retail and consumers. A transparent and thorough coordination between the four sections of the supply chain is essential to reduce the volume and increase the prevention of counterfeit pharmaceuticals entering a market; however, the ideal supply chain costs a business time and money.

A Brief History of Counterfeit Drugs in the Global Marketplace

When examining the issues associated with counterfeit drugs from a global perspective, the overall implications become much more serious. This is partly because the regulations of the pharmaceutical industry and laws of different countries allow for numerous opportunities to insert counterfeit pharmaceuticals into the supply chain.[21] The varying laws also come into play in internet pharmacies. In addition to the discrepancies between laws, the varying economic situations in relatively poor countries often force consumers to consider more economically viable prices.[22] Consequently, the final consumer has a much higher probability of obtaining a counterfeit drug in less developed countries.

The phenomenon of counterfeit pharmaceutical drugs is much more prevalent in underdeveloped and developing economies because of various economic and cultural reasons.[23] Counterfeit pharmaceuticals has affected both developed and

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[21] Forzley, Michele. "Combating Counterfeit Drugs: A Concept Paper For Effective International Cooperation." *World Health Organization, Health Technology and Pharmaceuticals: International Conference – Rome, Italy* (2006): Web Jan. 2012 Pg. 4.

[22] Cabezas, Maria Dolores. "Counterfeit Medicines as Global Treat." *Pharmaceuticals Policy and Law 12 (2010): 179-192. Web. Dec. 2011.* Pg. 180

[23] Ibid

developing countries; however, "weak drug regulatory control and enforcement, scarcity and/or erratic supply of basic medicines, unregulated markets and distribution chains, high drug prices, and significant drug differentials"[24] dramatically increase the prevalence of counterfeit pharmaceuticals in a particular country or region. Although developed countries such as America seemingly have a smaller percentage of counterfeit pharmaceuticals than do developing countries, due to the internet and increasingly sophisticated technology, any type of economy in the world is becoming more and more susceptible to counterfeit pharmaceutical drugs.[25] This is partly due to the fact that the punishment for such a crime is fairly light in some areas of the world.[26] In the past decade, the underdeveloped and developing economies have taken measures to increase the severity of the punishment that comes with being involved with counterfeit pharmaceutical goods. Adopting harsher punishments may reduce the incentives that counterfeiters may have to get involved

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[24] http://www.who.int/mediacentre/factsheets/2003/fs275/en/

[25] Lybecker, Kristina. "Rx Roulette: Combatting Counterfeit Pharmaceuticals in Developing Nations." *Managerial and Decision Economics* 28 (2007): 509-520 Web. Dec. 2011 Pg. 511

[26] Forzley, Michele. "Combating Counterfeit Drugs: A Concept Paper For Effective International Cooperation." *World Health Organization, Health Technology and Pharmaceuticals: International Conference - Rome, Italy* (2006): Web Jan. 2012 Pg. 15

in such a practice.[27] "Perhaps the best way to describe the motivation behind counterfeiting is offered by security chief Jackson of Novartis:

> "Pretend that you graduated from the 'University of Crime' and you are considering two career options. Which path you would follow? First, you can manufacture and sell cocaine, and if you get caught, you may spend 20 years or more in jail. Your second option is to manufacture and sell counterfeit pharmaceuticals. If you get caught, in many jurisdictions, you'll be sentenced to prison for two years and may be back on the street in six months."[28]

However, harsher punishment will not deter every counterfeiter as is seen in the illegal drug trade. This is due to the fact that the benefits of a higher profit margin outweigh the negative consequences of being punished in many economically unstable countries.

The severity of the counterfeit pharmaceutical industry increases as one considers the types of people and organizations who profit from this industry. Organized crime is a major player in the world of the production of counterfeit pharmaceutical goods.[29] In order for this system of counterfeit pharmaceuticals to take place, a country's level of corruption should come into consideration.

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[27] Cabezas, Maria Dolores. "Counterfeit Medicines as Global Treat." *Pharmaceuticals Policy and Law* 12 (2010): 179-192. Web. Dec. 2011. Pg. 183

[28] http://www.usatoday.com/money/industries/health/drugs/story/2011-10-09/cnbc-drugs/50690880/1

[29] Lybecker, Kristina. "Rx Roulette: Combatting Counterfeit Pharmaceuticals in Developing Nations." *Managerial and Decision Economics* 28 (2007): 509-520 Web. Dec. 2011 Pg. 512.

Internet and Technology

A major contributing factor to the dramatic increase of counterfeit drugs in the last decade or so has been the internet.[30] Through connecting the world, the internet has made it possible for almost anyone in any country to connect to another person or place. Unfortunately, connections made through the internet also include unscrupulous members of society, such as counterfeiters. The rapid development of the internet has made it easier for counterfeiters to establish an online presence, and has provided a vehicle for counterfeiters to connect with their clients and to more easily disperse a growing amount of counterfeit drugs.[31] Also, a lack of regulation on the internet makes it extremely hard to restrict the sale of any type of good, including counterfeit goods. Important technological advances of this decade not only include the proliferation of access to the internet, which has greatly increased the amount of counterfeit pharmaceutical goods available for sale, but also includes ways to more effectively track and monitor the distribution of pharmaceutical products.

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[30] Cabezas, Maria Dolores. "Counterfeit Medicines as Global Treat." *Pharmaceuticals Policy and Law* 12 (2010): 179-192. Web. Dec. 2011. Pg. 179.

[31] Letkiewicz, Slawomir; Andrzej, Gorski. "The Potential Dual Use of Online Pharmacies." *Science and Engineering Ethics* 16 (2010): 59-75 Web. Nov. 2011 Pg. 63.

Technology plays a major role in the production and distribution of pharmaceutical goods. Within the United States of America, the Food and Drug Administration is one of the major sources of innovation behind anti-counterfeiting efforts.[32] Whether through more effective research and development methods or through the methods used to track goods in the supply chain, the pharmaceutical industry is thriving with innovation. Unfortunately, as technological information has become more easily accessible, many counterfeiters around the world have gained access to these technological advances and have exploited them.

According to the Massachusetts Institute of Technology Auto-ID center, the two major ways to monitor the supply chain system is through tracking and tracing. Tracking is defined as, "knowing the physical location of a particular drug within the supply chain." Tracing is defined as, "the ability to know the historical locations, the time spent at each location, the record of ownership, the packaging configurations and environmental storage conditions for a particular drug."[33] Tracking and Tracing forms the basis for, "improved patient safety by giving manufacturers, distributors and pharmacies a systematic method to detect and control counterfeiting, drug

[32] Koh, Robin; Schuster, Edmund; Chackrabarti, Indy; Bellman, Attilio. "Securing the Pharmaceutical Supply Chain." *Auto-ID Labs at MIT.* White Paper. (2003) Web. Nov. 2011

[33] Koh, Robin; Schuster, Edmund; Chackrabarti, Indy; Bellman, Attilio. "Securing the Pharmaceutical Supply Chain." *Auto-ID Labs at MIT.* White Paper. (2003) Web. Nov. 2011. Pg. 4.

diversions, and mishandling".[34] A system of tracking and tracing requires equipment and a technological infrastructure. The cost of manually inspecting the drug batches becomes extremely expensive, thus the use of a comprehensive, automated system of checking for drugs becomes necessary. The one thing that makes tracking and tracing possible is the assumption that the entire supply would be working together.

Organizations independent of the pharmaceutical industry are recognizing the urgency behind counterfeit pharmaceutical goods. Another innovation was recently developed in the past two years. Sproxil, an independent company, has developed a system that is used in conjunction with a Mobile Product Authentication Service. The products that are registered with Sproxil all have a numeric code on the product itself. The consumer can text the code to Sproxil and receive confirmation of whether or not the drug is legitimate.[35] [36] This technology has been put into use in underdeveloped countries and has reduced the risks of unknowingly purchasing a counterfeit drug.[37] Through the development of technologies, the reduction of consumption of counterfeit pharmaceutical goods will be possible.

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[34] Ibid

[35] http://sproxil.comhttp://ijpsr.com/V2I7/6%20Vol.%202%20(7),%20IJPSR-289,%202011,%20Review%206.pdf

[36] http://ijpsr.com/V2I7/6%20Vol.%202%20(7),%20IJPSR-289,%202011,%20Review%206.pdf

[37] Ibid

Pharmaceutical Goods: A Case History of Abuse

The issue of counterfeit pharmaceuticals necessitates urgent attention from the public, government, and the pharmaceutical industries around the world. In order to convey the urgency of addressing counterfeit pharmaceutical goods, I would like to analyze a case in which the infiltration of counterfeit pharmaceutical goods into the legitimate supply chain causes physical harm to the final consumer, and in turn harms the companies that were involved in allowing the product to reach the consumer. One recent instance of counterfeit medicine that has been discovered to be counterfeited is the cancer medicine, Avastin. By looking at the case of Avastin, we can see the side of counterfeiting that makes its way into the supply chain. The case of Avastin illustrates key issues in the pharmaceutical industry and supply chain, such as dealing with pharmaceuticals manufactured abroad.

Although the FDA and WHO have attempted to implemented regulations, and have brought their attention to the counterfeit drugs market, this counterfeiting of Avastin brings to light the complexities behind the pharmaceutical industry and the ways reasons why it is extremely difficult to regulate and monitor this industry. Avastin is the best selling cancer treatment drug in the United States that was discovered to be counterfeit in February 2012.[38] It is produced by a Swiss company, Roche. They have a production branch located in San Francisco, California. This

[38] http://www.npr.org/templates/story/story.php?storyId=147582172

drug treats cancers of the colon, lungs kidneys, and brain. The counterfeit drugs that were found contain no active ingredient, which is key to the treatment of cancer, bevacizumab.[39] The counterfeit version of the drug, Avastin, was also found to have labels written in French.[40] Another deviation included differences in the lot number of the counterfeit drug and the lot number of the legitimate drug. Without knowledge of what to look for in terms of packaging, the doctors and medical professionals were not able to distinguish between a counterfeit version of Avastin and the real deal.

According to the WSJ, Avastin passed through wholesalers in Switzerland, Denmark, and the UK, before coming to the US. The Middle East may be a possible source of the counterfeit Avastin, however, it is unclear as to whether the Middle East is the producer of counterfeit drugs, or whether they are acting as a transmit corridor, or both.[41]

According to the Wall Street Journal, a 400-millligram vial of Avastin, costs $2,400. This cost provides great incentives for counterfeiters to start producing this drug. According to the FDA, the drugs were purchased by 19 medical practices in the

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[39] The New York Times. (2012) "Roche Says Counterfeit Avastin Distributed in the U.S. Market" http://0-www.lexisnexis.com.umiss.lib.olemiss.edu/hottopics/lnacademic/?shr=t&csi=6742&sr=HLEAD(Roche+says+counterfeit+Avastin+distributed+in+the+U.S.+market)+and+date+is+February,%202012

[40] Ibid

[41] The Wall Street Journal. (2012) "Tracing Fake Avastin to the Mideast" http://0-search.proquest.com.umiss.lib.olemiss.edu/docview/923176870/fulltext?accountid=14588

United States.[42] Before arriving at the practices, packages of Avastin were purchased from a foreign supplier, Quality Services Products.[43] Volunteer Distributors, a company in Tennessee, then distributed the drugs to the 19 medical practices.[44] The counterfeit version of Avastin did not contain any harmful substances, however it did lack the helpful substances.

Refer to figure 1 in the appendix to see illustrations of differences and similarities in the packaging.

Avastin is an example of how counterfeit drugs can leak into the legitimate supply chain in the US. The FDA and the United States government passed the Prescription Drug Marketing Act in 1988, which prohibits re-importation of drugs by any drug entity other than the manufacturer.[45] Although this act is intended to eliminate the influx of foreign counterfeit drugs, the FDA has no authority to inspect foreign drug distribution system; therefore, until the drug has made its way into the households of Americans, the FDA has no power to actively pursue the elimination and punishment of foreign counterfeiters.

Figure 2 in the index illustrates the intended results of the Prescription Drug Marketing Act.

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[42] Ibid
[43] Ibid
[44] The Wall Street Journal (2012) "US Finds Fake Cancer Drug" http://0-search.proquest.com.umiss.lib.olemiss.edu/docview/921412814/fulltext?accountid=14588

[45] US Food and Drug Administration (2003) "Background: Vulnerabilities in the US Drug Distribution System" http://www.fda.gov/Drugs/DrugSafety/ucm174479.htm

The case of Avastin illustrates the fact that the prevention of an influx of counterfeit drugs not only requires government intervention, but it also requires diligence and ethical behavior from the distributors.

Although the pharmaceutical industry has implemented regulations, the internet is not regulated, and the pharmaceuticals bought from internet pharmacies can very easily be a front for a counterfeiting organization. The internet is another vehicle through which counterfeit drugs enter the United States. Online pharmacies have attracted many consumers through low prices and privacy of at home delivery. Whether they are aware or unaware, consumers are taking great risks when purchasing drugs from online pharmacies. The anonymity of the internet has made it into the most popular venue through which to buy counterfeit pharmaceuticals. When purchasing drugs from an illicit online pharmacy, the entryway that is created is often targeted by counterfeiters. The combination of small purchases from foreign countries into large purchases makes it easier for counterfeiters to infiltrate America, because the larger the volume of drugs, the more difficult it is for the FDA to intercept. This is because there are many more resources focused on preventing small quantities of drugs from entering the U.S. distribution system.[46]

[46] Ibid

Why Prevalence of Counterfeit Drugs Is Growing so Rapidly in USA

The World Health Organization estimates that 10%-20% of drugs in the entire world are counterfeit.[47] This number is assumed to be much lower in the United States of America because of our highly regulated pharmaceutical industry. The extent to which counterfeit medicines are a problem in developed countries such as the US is minute compared to the some developing parts of the world. However, the United States is not completely excluded from harm caused by counterfeit pharmaceutical goods. In the US, The number of cases investigated has risen from around five per year in the 1990's to more than 200 per year in 2000 and to over 2000 per year in 2009.[48] The increase is due to many different factors. K. N. Lybecker points out that three of the factors that have increased counterfeiting include, "increasing globalization, advancing technology, and the controversies surrounding the WTO Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement and access

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[47] Liang, Brian A. "Fade to Black: Importation and Counterfeit Drugs." *American Journal of Law & Medicine* 32 (2006): 279-323. Web. Dec. 2011 Pg. 281

[48] Cockburn R., Newton PN., Agyarko EK., Akunyili D., White NJ. "The Global Threat of Counterfeit Drugs: Why industry and governments must communicate the dangers." PLoS MED 2(4): e100. (2005): 0302-0308. Web. Nov. 2011 Pg. 0302

to medicine."[49] He suggests that the supply chain links also have room for improvement. "Firms must ally themselves with their wholesalers, distributors, retailers, and prescribers, securing each link in the supply chain. This will only be accomplished through technology, cooperation across the supply chain, and by enforcing efforts that safeguard product quality and intercept counterfeits."[50]

The degree to which the public realizes the problem of counterfeit drugs is an issue in both developed and developing companies. PLoS Medicine reports, "Many pharmaceutical companies and governments are reluctant to publicize the problem to the public of counterfeit drugs, seemingly motivated by the belief that the publicity will harm the sales of brand-name products in a fiercely competitive business. In order to avoid any alarm that could prevent patients taking their genuine medicines, the pharmaceutical industries justify this secrecy."[51] Consumer awareness is an increasingly important aspect of the problem of counterfeit pharmaceutical drugs due to the increased control of consumers. Largely because of the internet, consumers have gained access to more vehicles through which to buy drugs; therefore, they are given more opportunities to search for the cheapest price.

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[49] Lybecker, Kristina. "Keeping it Real: Anticounterfeiting Strategies in the Pharmaceutical Industry." *Managerial and Decision Economics* 29 (2008): 389-495 Web. Nov. 2011 Pg. 390

[50] Ibid

[51] Cockburn R., Newton PN., Agyarko EK., Akunyili D., White NJ. "The Global Threat of Counterfeit Drugs: Why industry and governments must communicate the dangers." PLoS MED 2(4): e100. (2005): 0302-0308. Web. Nov. 2011 Pg. 0302

Because of the loose restrictions on the internet, it is difficult to verify the authenticity of pharmaceuticals sold through this vehicle. So, although there is great demand for discounted drugs on the internet, it is more dangerous to the consumer to purchase reduced priced drugs on the internet. When examining counterfeit goods in the pharmaceutical industry, the influence of the internet must not be excluded.

The high prices of many pharmaceuticals are a major motivating factor in the purchase of counterfeit pharmaceutical drugs, not only in developing countries, but also developed countries. Many factors determine the cost of a pharmaceutical drug. In order to get a return on the cost of research and development, pharmaceutical industries are able to patent their product for a length of 20 years. This system, which was implemented in 1992, allows for a time period of heightened prices, because the patents provide protection from competitors, the companies are without incentives to lower prices. The high prices provide a higher profit margin for counterfeiters and also a higher incentive for consumers to consider purchasing drugs from a questionable source because of lower prices.

The weak punishment of counterfeiters is another reason why the practices of producing and selling counterfeit drugs is so attractive. The FDA reports that the amount of punishment for counterfeiting the label far outweighs the punishment received for counterfeiting the drug itself.[52]

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[52] US Food and Drug Administration (2003) "Background: Vulnerabilities in the US Drug Distribution System" http://www.fda.gov/Drugs/DrugSafety/ucm174479.htm

Supply Chain Issues and Counterfeit Drugs

Another major problem in the pharmaceutical industry is its supply chain. The 3rd figure in the appendix illustrates three different distribution routes. The dotted lines of the third route indicate potential illegal sales.[53] The pharmaceutical supply chain is complex to the point of being convoluted. The opportunities for unscrupulous parties to enter this system are many because of its complicated nature. Although counterfeiters sometimes reach consumers through the internet or other sources, the supply chain still provides a viable and profitable market to be targeted. This section will separate the supply chain into four parts: consumers, retailers, wholesalers, and manufacturers. By separating these sections, I will attempt to suggest improvements for each pharmaceutical at each separate level of the supply chain.

Manufacturers

The manufacturers of pharmaceuticals are the producers of the drugs. This requires a manufacturing plant where chemicals are combined and made into medicines. In a legitimate plant, there are many safety regulations and many rules provided by the FDA that make the transition of the medicines from the production plant to the next section in the supply chain, usually the wholesaler, as smooth as possible. Because of the nature of the product, it is imperative that these rules and

[53] Ibid

regulations be followed thoroughly. In a place where counterfeit medicines are produced, there is little regulation, little regard for the well being of the final consumer.

In most instances, the responsibility for providing a legitimate drug to the final consumer is placed on the producer of the drug. If the drug is a generic, then the accountability of the manufacturer is lessened greatly; however, in the case that the drug carries the brand name of the manufacturing company, the public will place most of the responsibility in the hands of the manufacturer. In The United states, many pharmaceutical companies are reluctant to publicize the problem of counterfeit drugs, mostly because they are motivated by the fear that the publicity will harm the sales of their brand name product in a competitive business.[54] An instance of counterfeit drugs does have the potential to reduce the value of their brand name; however, there are many cases in which drug companies have been very open with the public about their struggles with counterfeit drugs. Johnson and Johnson set this standard in 1982, when Tylenol was laced with cyanide.[55] There is also an issue of manufacturing companies being reactive instead of proactive in the battle of counterfeit medicines. Because of the aggressiveness of the counterfeiters in recent years, pharmaceutical companies are going to have to be much more proactive in

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[54] Cockburn R., Newton PN., Agyarko EK., Akunyili D., White NJ. "The Global Threat of Counterfeit Drugs: Why industry and governments must communicate the dangers." PLoS MED 2(4): e100. (2005): 0302-0308. Web. Nov. 2011 Pg. 1

[55] O'Rourke, Morgan. "Tylenol's Headache" *Risk Management* 57.5 (2010): 8-9. Web. Feb. 2012

their regulations and rules. This will require the battle against counterfeit to become much more of a priority in the pharmaceutical industry.

Another aspect of the pharmaceutical industry is the sometimes outrageous pricing of certain drugs. There are many factors that contribute to the pricing of counterfeit medicines. The major components of pricing are research and development costs and promotional costs. Research and development is interesting in the fact that it is extremely time consuming and expensive to produce a drug; however, when competitors know the formula, it is costs much less to reproduce the drug. To counter this, the pharmacy industry uses patents and a patent is another factor that increases prices for consumers. In the US in particular, the only direct interaction that manufacturers have with consumers is through direct-to-consumer advertising. Therefore, the physicians and pharmacists are the only other representations of drug companies that consumers come into contact with. Pharmaceutical manufacturers are estimated to spend approximately $165 million in promotional activities directed towards physicians who prescribe the drugs.[56] The costs of research and development can't be easily eliminated; however, the cost of promotions can be reduced and reducing the cost of promotion could reduce the final cost to consumers.

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[56] Cravens, Karen S.: Glover, Hubert D. "Pricing complexities in the Pharmaceutical industry: Implications for external auditors" *Managerial Auditing Journal* 10,7 (1995): Pg. 11. Web. Feb. 2012

Manufacturing companies should be the catalyst for allowing the rest of the supply chain to be held accountable. When choosing a wholesaler to sell to, they should be fervently attempting to ensure prospective wholesalers are operating with high business practice standards. Reducing the cost of promotions can greatly reduce the cost to the final consumer, and can reduce the incentive to counterfeit, because the profit margin will be smaller.

Wholesalers

The wholesaling section of the supply chain has been credited as being the weakest link. The United States has 3 major wholesalers: AmerisourceBergen Corp, Cardinal Health Inc., and McKesson Corporation. These major wholesalers handle from 80 to 90 percent of pharmaceutical products in the USA.[57] The three major wholesalers "stock thousands of drugs from hundreds of manufacturers". "They procure almost all of their stock directly from producers and sell to most pharmacies around the country."[58] The remaining 10-20 percent of pharmaceutical products moves through a smaller secondary wholesaling system.[59] This secondary system is mainly used to compensate for shortages. Another interesting aspect to the

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[57] Lybecker, Kristina. "Keeping it Real: Anticounterfeiting Strategies in the Pharmaceutical Industry." *Managerial and Decision Economics* 29 (2008): 389-495 Web. Nov. 2011 Pg. 391

[58] deKieffer, Donald. "Trojan Drugs: Counterfeit and Mislabeled Pharmaceuticals in the Legitimate Market." *American Journal of Law and Medicine* 32 (2006): 325-349 Web. Nov. 2011 Pg. 328

[59] Ibid: 391-392

secondary wholesaling system is the fact that the three major wholesalers also purchase from the secondary wholesalers. They primarily do this in order to find a cheaper price. According to Donald deKieffer, the major distributors operate with a very thin profit margin. Traditionally, purchasing cheaper drugs from a secondary wholesaler has been too tempting for most of the major wholesalers to completely resist.

Through this trading between wholesalers, counterfeiters are more easily able to take advantage of the system. The transfer of drugs from wholesaler to wholesaler requires that inventory be taken more often, and will have more opportunities to overlook a possible counterfeit situation. According to Abbot Laboratories, 'It is often through a secondary market that counterfeit, adulterated or improperly stored and handled products make their way into the distribution system. The secondary market products are generally products purchased from any source other than from the original manufacturer and are commonly referred to as secondary, gray or diverted products. When the product comes from the secondary market it is difficult to assure patients and healthcare professionals of the product's quality or safety.'[60] By selling the drugs at irresistibly low prices, the counterfeiters are initially able to enter the supply chain.

The wholesaling section of the supply chain is seemingly the weakest link in the counterfeit pharmaceutical industry. This is partly because of the nature of the wholesaling industry in general. These companies obtain profits by moving the products from the manufacturer's hands to the pharmacies. This may include

[60] Ibid: 392

several changes of possession before it reaches the final pharmacy. The more a product changes hands, the more likely counterfeit drugs will be able to slip into the supply chain.

Effective and enforced laws and regulations of a third party entity should have the most impact on eliminating the opportunities for unscrupulous parties to sell their counterfeit drugs into a legitimate supply chain. Also a reduction in the number of times that pharmaceuticals change possession will reduce the opportunities to purchase illegitimate pharmaceuticals. Additionally, a more regulated secondary market will greatly reduce the opportunities for counterfeiters to enter the supply chain.

Retailers

In the pharmaceutical supply chain, the retailer is the window through which consumers are able to access drugs and to receive information about drugs. The majority of medicines that are carried by retailers are purchased from three wholesalers in USA. They are AmerisourceBergen Corp, Cardinal Health Inc., and McKesson Corporation. Although around 80 percent of pharmaceuticals that retailers carry are purchased from these three wholesalers, a secondary wholesale market accounts for nearly 20 percent of purchases from the pharmaceutical industry.[61] The retailers in the United States are gradually becoming aware of the scope of the problem of counterfeit medicines. Before 2005, CVS announced that it will 'no longer purchase drugs from wholesalers that trade in the secondary market,

[61] Ibid

which has been a point of entry for counterfeit drugs into the supply chain.'[62] As mentioned before in the manufacturing section, a reactive attitude towards counterfeit drugs will not be acceptable in the future. Pharmacies and hospitals will need to be proactive in reducing the amount of counterfeit drugs that come into contact with the final consumer.

In order to intercept the entry of counterfeit drugs into the supply chain, the pharmacies should be aware of the amount of responsibility they possess. Through recklessly purchasing drugs from secondary markets, pharmacists are increasing their risk of unknowingly purchasing a counterfeit drug. In addition to the strategies that are already in place, pharmacies and hospitals should be more accountable for the wholesalers that they are purchasing from. The pharmacists have extremely important roles, including educating patients, making prudent purchases, and detecting counterfeit drugs. These responsibilities are seemingly not a problem; however, when detection of counterfeit pharmaceuticals includes the alteration of business practices and added expense, the pharmacist may be inclined to turn a blind eye.[63]

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[62] Lybecker, Kristina. "Keeping it Real: Anticounterfeiting Strategies in the Pharmaceutical Industry." *Managerial and Decision Economics* 29 (2008): 389-495 Web. Nov. 2011 Pg. 399

[63] Ziance, Ronald J. "Roles for Pharmacy in Combatting Counterfeit Drugs." *Journal of the American Pharmacists Association* 48.4 (2008): e71-e91. Web. Nov. 2011 Pg. 72

In order to prevent counterfeit drugs from reaching the final consumers, pharmacists should limit or eliminate or reduce the amount of purchases from secondary wholesalers, and scrutinize their business practices. The pharmacies should also be able to communicate effectively with consumers in a way that will not cause any alarm. An inspection of the labeling and the pills themselves would also help to prevent any counterfeit drugs from reaching the final consumer. These actions that may be taken by pharmacies will make a substantial difference In the amount of drugs that come into contact with the final consumer.

Drug Consumers

The nature of the pharmaceutical industry requires large sums of money invested in the research and development of drugs. The investment that goes into the development of drugs is usually reflected in the final prices of drugs. After the research and development of the drug is complete, the actual manufacturing cost is not high, but in order to recover costs of research and development, the final price of the drug is usually set to be able to recover the high cost of the development until the patent expires. This high price, not only entices counterfeiters to become interested in the pharmaceutical industry, but it also causes many consumers to seek the cheapest price regardless of the risks they may encounter. Where there is a demand for something, there will usually always be a supply. One major eliminator of counterfeit drugs would be a reduced profit margin for counterfeiters.

The internet has provided our society with countless advantages and resources; however, when abused, it can be deadly. Many consumers are looking to the internet for online pharmacies, where the prices are much cheaper than in brick

and mortar pharmacies. The development of the internet and computers has provided an easily accessible venue for which consumers are able to search for and purchase the cheapest drugs.

The consumer has become an increasingly important link in the supply chain because of the role that they are now playing in purchasing pharmaceutical products. Through technological developments such as the internet, this increase in available venues has increased the amount of responsibility that should be placed on the final consumer. By purchasing a drug from an internet pharmacy, they are assuming that the pharmacy is handling the drug as a brick and mortar pharmacy would. However, according to an investigation conducted by the United States General Accounting Office, online pharmacies were found to be generally unreliable. They obtained 68 samples of 11 different drugs and encountered many problems with the drugs, the labeling on the bottles, and the online pharmacies themselves.[64] Regardless of the risk involved, many consumers are turning towards the internet to find cheap pharmaceuticals. Internet pharmacies are fairly successful in world trade, and this is reflected in their "high share in the general share of medications". This amounts to about a 10% share in the market of pharmaceuticals.[65] This indicates the general demand for online pharmacies. Although a large percentage of online pharmacies

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[64] Crosse, Marcia. "Internet Pharmacies: Some Pose Safety Risks for Consumers and Are unreliable in Their Business Practices." *Highlights of GAO-05-888T, a testimony before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate.* (2004) Web. Nov. 2011 Pg. 1

[65] Letkiewicz, Slawomir; Andrzej, Gorski. "The Potential Dual Use of Online Pharmacies." *Science and Engineering Ethics* 16 (2010): 59-75 Web. Nov. 2011 Pg. 63

are unscrupulous in their activities, many online pharmacies are legitimate alternatives to the brick and mortar pharmacies.[66] Because of the nature of the internet, and the risk involved when purchasing anything on the internet, the consumer should realize the amount of responsibility that is required when purchasing pharmaceuticals from the internet. According to an Ernst and Young study, "the internet and mail-order operations will be the biggest source of counterfeit drugs over the next five years."[67]

The consumers who buy counterfeit pharmaceutical goods should be held accountable as to what outlets they purchase medicines from. When buying medicines from the internet, they should be aware of the associated risks. Consumers should be more involved in the authenticity verification process. In many developing countries, the involvement of the final consumer is crucial to the consumers' health. A company has produced Sproxil, which is a system that includes a barcode that will allow the consumers to text the number on the medicines to a company who texts back an OK if the medicines are legitimate. If they are not guaranteed by the company, they will receive a NO. This involvement of the final consumer has greatly reduced the amount of deaths due to counterfeits in developing countries.[68]

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[66] Ibid

[67] Lybecker, Kristina. "Keeping it Real: Anticounterfeiting Strategies in the Pharmaceutical Industry." *Managerial and Decision Economics* 29 (2008): 389-495 Web. Nov. 2011 Pg. 399

[68] http://sproxil.com/

Consumers play an increasingly large role in the supply chain, and as the internet continues to pervade more aspects of society, they will increasingly be subject to risks – much of the time at their own doing.

The Role of Supply Chain Members and Control of Counterfeit Drugs

In order to effectively participate in the efforts to reduce the amount of counterfeit pharmaceutical goods, all the members of a pharmaceutical good supply chain must coordinate their efforts. A thorough coordination of efforts must entail:

1) More efforts focused on selection of quality drugs, not cheap drugs (a movement away from secondary supply chain purchases).
2) Cooperation with the government in the area of prosecuting counterfeiters.
3) A movement towards a comprehensive supply chain tracking and tracing system and the use of authentication technologies.

A pharmaceutical company, such as Roche, should have very specific ways in which it should deal with counterfeit pharmaceuticals. Because of their recent encounters with counterfeit Avastin, they should be looking to increase security of their supply chain and deliver quality pharmaceuticals to their consumers. Among other things, this would entail requiring pedigrees, requiring authentication technologies, and limiting or carefully monitoring the importation of pharmaceuticals. A pedigree states the source or origin of the medicine. It contains information about all of the transactions that the drug undergoes. By requiring a pedigree, the drug companies will be able to ensure the quality of the drugs. An authentication process is another way that pharmaceutical companies can combat counterfeit drugs from entering their supply chain. This would require equipment and tools to evaluate

whether the product's labeling and packaging is the manufacturer's original. The authentication process has three different levels of involvement.[69] The first one is overt authentication. These are things that are visible to the eye, such as hologram or distinct colors. Another, somewhat more expensive, mode of the authentication process includes covert authentication technologies. This requires special equipment and sometimes includes watermarks. These two methods will require some degree of investment in training and/or equipment. In order for these methods to be effective in combating counterfeit goods, all members of the supply chain should adopt these two authentication processes. Forensic technology is the final and most sophisticated authentication technology. This type of authenticity requires equipment usually found in a forensic chemistry lab. The more thorough a company is with its authenticating products, the more confidence it can have about providing quality drugs to its consumers. The third way in which US pharmaceutical companies can guard themselves against counterfeits is through carefully considering which wholesalers to use. The reputation of the wholesaler should be a major factor in deciding whether or not to forge a business relationship. Although all of these methods have the potential to greatly reduce the amount of counterfeit pharmaceuticals being distributed to the final consumer, until the manufacturer, wholesaler, and retailer are diligent in their efforts to deal with this problem, the problem of counterfeit goods will always plague our society.

[69] US Food and Drug Administration (2003) "Background: Vulnerabilities in the US Drug Distribution System" http://www.fda.gov/Drugs/DrugSafety/ucm174479.htm

These steps towards securing a supply chain are extremely costly. The authentication technologies require new equipment and maintenance of the equipment. This also requires doctors and medical professionals to be trained in the uses of these technologies. Although it is the hope that customer safety is first and foremost in the minds of healthcare professionals, the costs of implementing these technologies is often more than members of the pharmaceutical industry can bear. Although the increased costs is often a great deterrent to investing in these technologies, the long term benefits may compensate for the short term costs. According to the FDA, some of the long term benefits would include, "improved inventory management, reduced labor costs, reduction in theft, protection from intentional tampering, and reduction in diverted products."[70]

Ideally, through these steps, the supply chain will be able to sustain the quality of medicines. Internet pharmacies, however, will only be changed through raising customer awareness and cooperation from the government. These changes will make it easier to maintain a channel of distribution that can be held accountable by other members of the supply chain as well as by the general public.[71] Because the nature of the pharmaceutical industry is extremely complicated, secure business practices are essential in diligently providing quality drugs to final consumers. The two pronged entryway for counterfeit drugs entering the US include those that enter through the supply chain and those that are bought from the internet. In order to

[70] Ibid

[71] Cabezas, Maria Dolores. "Counterfeit Medicines as Global Treat." *Pharmaceuticals Policy and Law* 12 (2010): 179-192. Web. Dec. 2011. Pg. 188

lower the amount of drugs that are bought from the internet, consumers should be aware of the risks that they are taking by purchasing drugs from an internet pharmacy.

The priorities of a pharmaceutical good supply chain must be different from the supply chains of many other goods. This is because the health of the consumer relies completely on where they are positioned in the supply chain's list of priorities. Because the pharmaceutical industry has such a slim profit margin, the temptation to search out the lowest prices and attempt to overlook the source the medicine may be much greater in the pharmaceutical supply chain.

Creating, manufacturing, and selling a pharmaceutical product require many to consider the costs of production and that of prevention. Prevention costs are that which cover the cost of defective products. The more a company has to inspect its goods for defects, the more it costs to operate a business. This aspect is an incredible disincentive for businesses to actively participate in the reduction of counterfeit pharmaceuticals beyond the point where their costs would be any higher. "Raising the standards of intellectual property protection presents long-term benefits but short-term costs."[72] Persuading members of the supply chain that the quality and legitimacy of drugs are more important than the profit margins is going to be the biggest obstacle of decreasing the amount of counterfeit pharmaceuticals that enter the system.

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[72] Long, Clarisa. *Intellectual Property Rights in Emerging Markets.* Washington D.C.: The AEI Press. 2000.

In order to effectively combat the rise of counterfeit pharmaceutical products, a comprehensive and effective plan must be made that includes all members of the supply chain. The plan must include incentives and motivations for members of the supply chain to invest more time and resources towards combating counterfeit pharmaceutical. Impact is an international forum that exists to allow representatives to convene and discuss measures that can be taken to combat counterfeit pharmaceuticals. Although it has no actual power over the pharmaceuticla industry, the rules presented in this document could presenta an effective way to combat counterfeit drugs.

Another unique aspect of the pharmaceutical industry is the high cost of research and development. Being able to take advantage of a lack of research and development costs is a huge motivation for coutnerfeiters to begin the act of producing or distributing counterfeit pharmaceuticals. This is because "in the pharmaceutical industry, the discovery process is extraordinarily resource-intensive, but once an effective drug is on the market, the compound is comparatively easy to syntehsize."[73] Counterfeiters can relatively easily replicate the drug, and therefore completely leave out the actual drug's research and development costs. The research and development costs are usually covered by a the final price of a drug. Without having to cover costs for research and development, counterfeiters have a great probability to make a large profit, with little production costs.

[73] Ibid: 4

Conclusion

The resolution to the problem of counterfeit pharmaceuticals is one that encompasses the entire supply chain, the government, and education of the public; and the battle with counterfeit drugs will continue to be a major problem in the world for many more years. However, through the connection and cooperation of all of the members of the supply chain, more effective actions can be taken to prevent counterfeit drugs from entering the supply chain. This will start with the manufacturer. Through implementation of tracing and tracking technologies, the supply chain will be more easily able to be aware of what drugs are where. This is assuming that the entire supply chain has necessary resources and capabilities to implement this type of technology. The drug manufacturing companies should be the catalyst to a comprehensive technological infrastructure that supports tracking and tracing technologies. Additionally, the manufacturers need to be proactive in choosing the wholesalers with which they engage in business transactions. The manufacturer's role in the supply chain and the final consumer's experiences with the drug is usually associated with the manufacturer's brand name.

Counterfeit drugs enter the wholesaler section of the supply chain easier than any other section. This is because of the complicated nature of the pharmaceutical supply chain. The continuous purchase and selling of pharmaceuticals require extremely efficient organization, and thus require a way to thoroughly track what

medicines are bought and what medicines are sold. The secondary wholesalers add to the confusion of the supply chain. Through the elimination or thorough monitoring of secondary wholesalers, the pharmaceutical industry will be able to eliminate a major area of weakness that counterfeiters often have opportunities to exploit. The wholesaling business operates on the premise of buying drugs for discounts and selling them for a profit. The goal of obtaining a profit often surmounts ethical decision making by the wholesaling companies. In order to combat unethical behavior in the wholesaling section of the supply chain, the FDA should raise the standards that exist to obtain a license to operate as a wholesaler in the pharmaceutical industry.

By educating patients, making prudent purchases, and detecting counterfeit drugs, pharmacies can play a major role in preventing counterfeits from reaching the final consumers. Also, the interactions that pharmacists have with pharmaceutical consumers put the pharmacists in a position of being able to inform consumers of issues that may exist in the pharmaceutical industry. Additionally, pharmacists hold the power to discontinue purchasing from a wholesaler that has a debauched reputation. The pharmacists themselves also have an obligation to become educated on the drugs they purchase. This will include being alert and informed as to news in the pharmaceutical industry.

Last, but certainly not least, the final consumers also have a major role to be playing in this system. As the purchasing power of consumers grow, the need to make informed purchases increases. The internet has introduced a seemingly unlimited amount of venues through which to purchase pharmaceuticals. This has

attracted many unscrupulous parties, and a large portion of the consumers in the United States have yet to realize the serious implications that come from making uninformed purchases of pharmaceuticals. In order to make better purchase decisions, consumers should be able to access any information that involves counterfeit goods. Available information is imperative in the consumer portion of the supply chain.

Laws and regulations would have a major impact on the wholesaler section of the supply chain. Through laws and regulations that restricted the use of secondary wholesalers and required wholesalers to provide information about source of the drug, the supply chain would be able to more effectively intercept counterfeits. However, stricter laws and regulations would require more resources focused on the problem of counterfeiting. This requires that resources be pulled from another area of our society. The final consumer may also benefit from specific laws and regulations regarding the purchase of pharmaceuticals on the internet; however, this would require regulation of the internet. In addition to government regulations, pharmaceutical companies themselves also have an obligation to require wholesalers and distributors' business practices to operate at a certain standard. Turning a blind eye to the risk of purchasing a counterfeit because a business does not want to pay an extra buck will not suffice in the near future. Counterfeiters have already harmed many people in the pursuit of a profit, and in order to reduce the amount of harm caused, the public, government, and organizations affiliated with pharmaceutical companies will need to demand ethical business practices.

In order to counteract the increased flow of counterfeits into the US, the pharmaceutical industry should set high standards in the area of diligent business practices. This will include tracking and tracing equipment, educated pharmacists who will know how to look for a counterfeit, cooperation from the government in harsher punishment of counterfeiters, and diligence in purchasing quality, legitimate drugs.

This research highlights issues in the supply chain and what steps should be taken as the pharmaceutical industry as a whole and what steps should be taken as individual entities of the pharmaceutical industry. This research also brings to light the overwhelming complexity of the pharmaceutical industry and ways in which the government can assist in helping pharmaceutical companies deal with counterfeiters. Also, the naiveness of the general public illustrates how vulnerable we are to counterfeiters.

The problems of counterfeit pharmaceuticals plague developed and developing countries, alike. Through effective cooperation of the entire supply chain, participation of the government, and acknowledgment that the problem of counterfeit drugs exist in America, we can begin to work together towards a realistic resolution for the problem of counterfeit drugs.

Bibliography

Cabezas, Maria Dolores. "Counterfeit Medicines as Global Treat." *Pharmaceuticals Policy and Law 12 (2010): 179-192. Web. Dec. 2011.*

Cockburn R., Newton PN., Agyarko EK., Akunyili D., White NJ. "The Global Threat of Counterfeit Drugs: Why industry and governments must communicate the dangers." PLoS MED 2(4): e100. (2005): 0302-0308. Web. Nov. 2011

Cravens, Karen S.: Glover, Hubert D. "Pricing complexities in the Pharmaceutical industry: Implications for external auditors" *Managerial Auditing Journal* 10,7 (1995): Pg. 11. Web. Feb. 2012

Crosse, Marcia. "Internet Pharmacies: Some Pose Safety Risks for Consumers and Are unreliable in Their Business Practices." *Highlights of GAO-05-888T, a testimony before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate.* (2004) Web. Nov. 2011

deKieffer, Donald. "Trojan Drugs: Counterfeit and Mislabeled Pharmaceuticals in the Legitimate Market." *American Journal of Law and Medicine* 32 (2006): 325-349 Web. Nov. 2011

Forzley, Michele. "Combating Counterfeit Drugs: A Concept Paper For Effective International Cooperation." *World Health Organization, Health Technology and Pharmaceuticals: International Conference - Rome, Italy* (2006): Web Jan. 2012

Groombridge, Mark. *The Political Economy of Intellectual Property Rights Protection in the People's Republic of China.* Washington D.C. 2000. Print

Held, David. McGrew, Anthony. *Governing Globalization.* Malden, MA. Blackwell Publishers. 2002.

Chapter 8. Susan K. Sell
<http://books.google.com/books?hl=en&lr=&id=UshmkxDiAWsC&oi=fnd&pg

=PA171&dq=intellectual+property+rights&ots=j0Xo5-9rjU&sig=6SQAcwAkBVY6AeSCBaEubT0R3cY#v=onepage&q=intellectual%20property%20rights&f=false>

Koh, Robin; Schuster, Edmund; Chackrabarti, Indy; Bellman, Attilio. "Securing the Pharmaceutical Supply Chain." *Auto-ID Labs at MIT.* White Paper. (2003) Web. Nov. 2011

Letkiewicz, Slawomir; Andrzej, Gorski. "The Potential Dual Use of Online Pharmacies." *Science and Engineering Ethics* 16 (2010): 59-75 Web. Nov. 2011

Liang, Brian A. "Fade to Black: Importation and Counterfeit Drugs." *American Journal of Law & Medicine* 32 (2006): 279-323. Web. Dec. 2011

Long, Clarisa. *Intellectual Property Rights in Emerging Markets.* Washington D.C.: The AEI Press. 2000.

Lybecker, Kristina. "Keeping it Real: Anticounterfeiting Strategies in the Pharmaceutical Industry." *Managerial and Decision Economics* 29 (2008): 389-495 Web. Nov. 2011

Lybecker, Kristina. "Rx Roulette: Combatting Counterfeit Pharmaceuticals in Developing Nations." *Managerial and Decision Economics* 28 (2007): 509-520 Web. Dec. 2011

Mathuna, Donal P., McAuley, Adam. "Counterfeit Drugs: Towards an Irish Response to a Global Crisis." (2005): Web Nov. 2011

The New York Times. (2012) "Roche Says Counterfeit Avastin Distributed in the U.S. Market" http://0-www.lexisnexis.com.umiss.lib.olemiss.edu/hottopics/lnacademic/?shr=t&csi=6742&sr=HLEAD(Roche+says+counterfeit+Avastin+distributed+in+the+U.S.+market)+and+date+is+February,%202012

O'Rourke, Morgan. "Tylenol's Headache" *Risk Management* 57.5 (2010): 8-9. Web. Feb. 2012

Outterson, Kevin: Smith, Ryan. "Counterfeiting drugs: The Good, the Bad, and the Ugly." *Albany Law Journal of Science and Technology* 16 (2006) Pg. 527 Web. March 2012

United States Food and Drug Administration (2003) "Background: Vulnerabilities in the US Drug Distribution System" http://www.fda.gov/Drugs/DrugSafety/ucm174479.htm

United States. House. Committee on Government Reform. *Sick Crime: Counterfeit Drugs in the United States.* 109th Congress. First session. Washington: Government Printing Office, 2006. Print.

The Wall Street Journal. (2012) "Tracing Fake Avastin to the Mideast" http://0-search.proquest.com.umiss.lib.olemiss.edu/docview/923176870/fulltext?accountid=14588

World Health Organization. (2006) "Counterfeit Medicines" http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/

World Health Organization. (2009) "An Overview of the IMPACT Working Groups' documents and activities" http://www.who.int/impact/activities/overviewofIMPACTworkingdocs.pdf

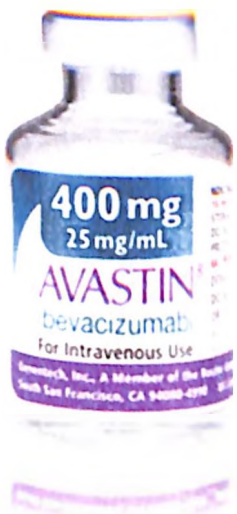
World Health Organization. (2012) "IMPACT" http://www.who.int/medicines/services/counterfeit/faqs/count_q-a/en/

The Wall Street Journal (2012) "US Finds Fake Cancer Drug" http://0-search.proquest.com.umiss.lib.olemiss.edu/docview/921412814/fulltext?accountid=14588

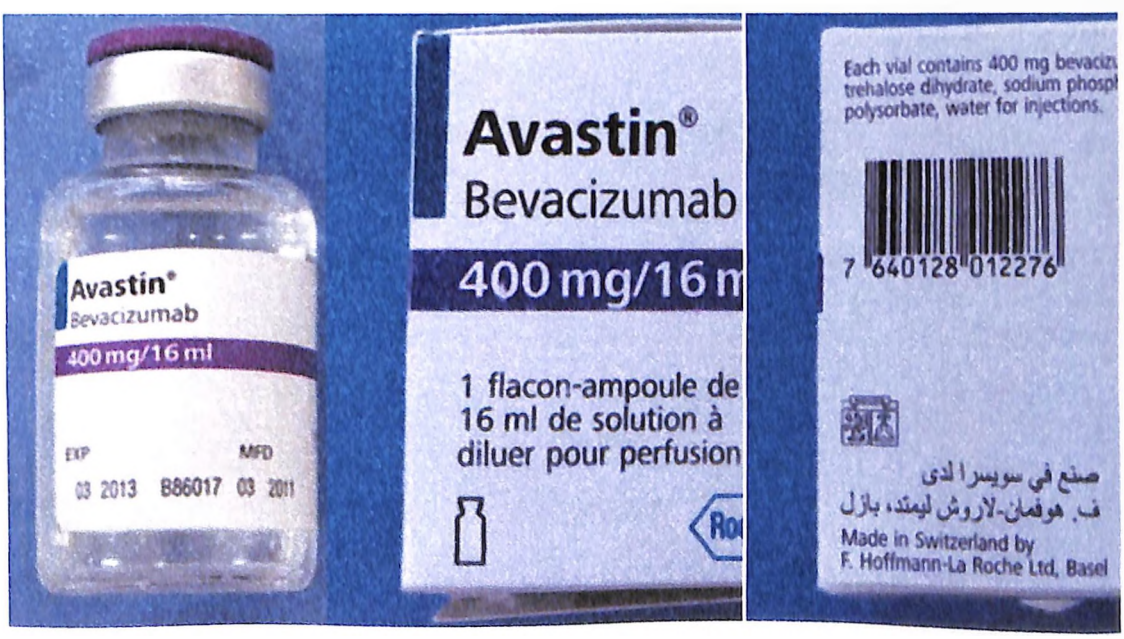
Ziance, Ronald J. "Roles for Pharmacy in Combatting Counterfeit Drugs." *Journal of the American Pharmacists Association* 48.4 (2008): e71-e91. Web. Nov. 2011

Figure 1:

Authentic Avastin FDA-Approved for Use in the United States



Counterfeit Product



http://www.gene.com/gene/news/press-releases/press_statements/ps_021412.html

Figure 2:

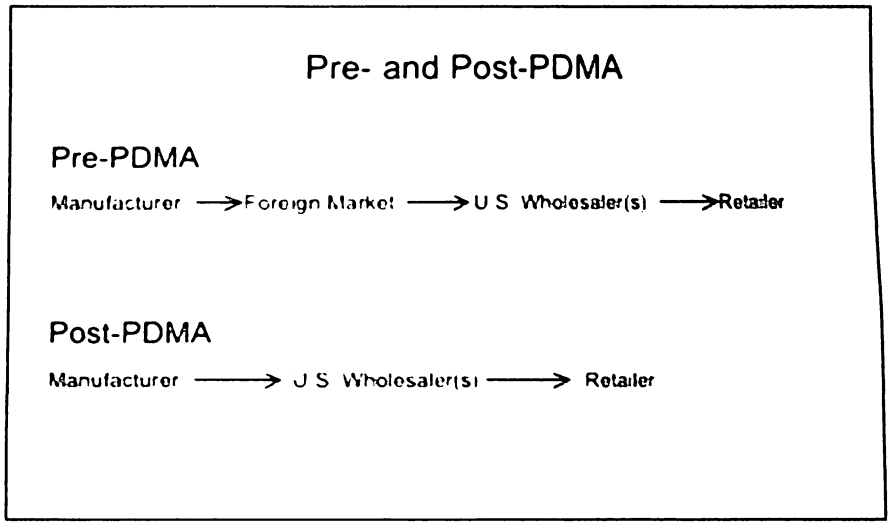


Figure 3: