COUNTERFEIT PHARMACEUTICALS: ARE THE U.S. CONSUMERS AWARE OF THE POTENTIAL RISKS?

A doctoral dissertation presented by

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ABSTRACT

The presence of counterfeits in the pharmaceutical product market is an increasing risk that places consumers in potential harm, or in some cases, even results in death. While the United States Food and Drug Administration has taken steps to mitigate the risk of counterfeit pharmaceuticals from entering the supply chain, consumers are in the dark regarding the growing dangers that they face. The intent of this study was to determine the overall level of understanding of the U.S. consumer regarding the risk of counterfeit pharmaceuticals to their long-term health and well-being. The hypothesis was that consumers would be unaware of the risk of counterfeit pharmaceuticals due to the lack of federal and state policies communicating or educating consumers.

A questionnaire was utilized for this descriptive quantitative study to determine how respondents from the North East region of the United States identified counterfeit pharmaceuticals as a risk to their overall health, their definition of counterfeit pharmaceuticals, and their perceptions of the government actions to mitigate the risk. The sample population from the North East was achieved utilizing volunteerism through the social media application LinkedIn and used Qualtrics as the tool to administer the questionnaire and collect the data.

Demographics of the respondents identified that the majority of the sample population in the study were highly educated and in the prime of their careers. Though the respondents are identified as potentially successful individuals, the conclusion was that they were not overly aware of the risk of counterfeit pharmaceuticals. The findings determined that these respondents did not fully understand what defined a counterfeit pharmaceutical nor did they have a high level of understanding of the risk that exists within the United States. The risk of counterfeit pharmaceuticals in the United States may be relatively low compared to the rest of the world, but
the risk does exist. Counterfeit pharmaceuticals will continue to flourish within the United States without a formalized communication policy which will educate consumers regarding the potential risk to their health and long term well-being.

*Keywords: counterfeit pharmaceuticals, counterfeit drugs, supply chain, DSCSA, communication plan, informed user, education plan, pharmaceuticals, falsified medicines, e-Pedigree, risk*
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<tr>
<td>3PL</td>
<td>Third-Party Logistics Provider</td>
</tr>
<tr>
<td>ANVISA</td>
<td>Agência Nacional de Vigilância Sanitária</td>
</tr>
<tr>
<td>BMS</td>
<td>Bristol-Myers Squibb</td>
</tr>
<tr>
<td>BoP</td>
<td>Board of Pharmacy</td>
</tr>
<tr>
<td>CDSCO</td>
<td>Central Drug Standard Control Organization</td>
</tr>
<tr>
<td>CFDA</td>
<td>Chinese Food and Drug Administration</td>
</tr>
<tr>
<td>DSCSA</td>
<td>Drug Supply Chain Security Act</td>
</tr>
<tr>
<td>DQSA</td>
<td>Drug Quality and Security Act</td>
</tr>
<tr>
<td>e-Pedigree</td>
<td>Electronic Pedigree</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FMD</td>
<td>Falsified Medicines Directive</td>
</tr>
<tr>
<td>GAO</td>
<td>Government Accountability Office</td>
</tr>
<tr>
<td>GS1</td>
<td>Global Standard One</td>
</tr>
<tr>
<td>GSK</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization of Standards</td>
</tr>
<tr>
<td>MHLW</td>
<td>Japanese Ministry of Health, Labour, and Welfare</td>
</tr>
<tr>
<td>MHRA</td>
<td>British Medicines and Healthcare products Regulatory Agency</td>
</tr>
<tr>
<td>NECC</td>
<td>New England Compounding Center</td>
</tr>
<tr>
<td>PDMA</td>
<td>Prescription Drug Marketing Act</td>
</tr>
<tr>
<td>PSI</td>
<td>Pharmaceutical Security Institute</td>
</tr>
<tr>
<td>RAPS</td>
<td>Regulatory Affairs Professional Society</td>
</tr>
<tr>
<td>Acronym</td>
<td>Acronym Definition</td>
</tr>
<tr>
<td>---------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>TGA</td>
<td>Australian Therapeutic Goods Administration</td>
</tr>
<tr>
<td>U.S. FDA</td>
<td>The United States Food and Drug Administration</td>
</tr>
<tr>
<td>U.S. HELP</td>
<td>U.S. Senate Committee on Health, Education, Labor, and Pension</td>
</tr>
<tr>
<td>U.S. HHS</td>
<td>United States Department of Health and Human Services</td>
</tr>
<tr>
<td>USTR</td>
<td>Office of the U.S. Trade Representative</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
Chapter 1: Introduction

The threat and proliferation of counterfeit pharmaceuticals has escalated over the last 15 years (Blackstone, Fuhr, & Pociask, 2014). The World Health Organization (WHO) estimated that 10 to 30 percent of all pharmaceuticals globally are counterfeit, though this number can increase up to 50 to 70 percent in some underdeveloped and in-transit nations (World Health Organization, 2016). While WHO estimated that only 10 percent of the pharmaceuticals in the United States (U.S.) market are counterfeit, this was still a considerable amount (World Health Organization, 2016). According to the IQVIA Institute for Human Data Sciences, in 2016 the United States dispensed a total of 4.453 billion prescription drugs. This quantity is estimated to grow to over five billion by 2021 (IQVIA Institute for Human Data Sciences, 2017). If 10 percent of those prescriptions dispensed were counterfeit according to WHO’s estimates, then nearly 500 million counterfeit prescriptions were consumed throughout the United States in 2016.

Consumers within the United States are unaware of the risk of counterfeit pharmaceuticals (Steel, 2015). While the U.S. Food and Drug Administration (U.S. FDA) has focused on implementing laws and policies to mitigate the risk of counterfeit pharmaceuticals seeping onto the market, consumers are left unaware of the danger (Drug Quality and Security Act, 2013). Due to the lack of U.S. policies focused on informing consumers regarding counterfeit pharmaceuticals, this research study sought to determine the level of awareness of the pharmaceutical consumer has regarding the risk of consuming a counterfeit. The goal of this study is to support the development of a targeted, risk-based consumer educational policy based on the findings from this research.
Background

Even though counterfeit pharmaceuticals have been around since the days of traveling “miracle” medicine men, the proliferation of them has exploded with the usage of internet pharmacies and the increase in the price of medicines (Blackstone et al., 2014; Eckly, 1984; Giago, 2017). As Table 1 demonstrates, trends of the global black market researched by the independent research organization, Havocscope Group, determined counterfeit pharmaceuticals are the most counterfeited products in the world with profits estimated at nearly $200 billion dollars annually (Havocscope Group, 2017b).

Table 1

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Counterfeit Goods</th>
<th>Value in U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Counterfeit Drugs</td>
<td>$200 billion</td>
</tr>
<tr>
<td>2</td>
<td>Counterfeit Electronics</td>
<td>$169 billion</td>
</tr>
<tr>
<td>3</td>
<td>Software Piracy</td>
<td>$63 billion</td>
</tr>
<tr>
<td>4</td>
<td>Counterfeit Foods</td>
<td>$49 billion</td>
</tr>
<tr>
<td>5</td>
<td>Counterfeit Auto Parts</td>
<td>$45 billion</td>
</tr>
<tr>
<td>6</td>
<td>Counterfeit Toys</td>
<td>$34 billion</td>
</tr>
<tr>
<td>7</td>
<td>Music Piracy</td>
<td>$12.5 billion</td>
</tr>
<tr>
<td>8</td>
<td>Fake Shoes</td>
<td>$12 billion</td>
</tr>
<tr>
<td>9</td>
<td>Counterfeit Clothing</td>
<td>$12 billion</td>
</tr>
<tr>
<td>10</td>
<td>Cable Piracy</td>
<td>$8.5 billion</td>
</tr>
</tbody>
</table>

Note: Adapted from Ranking of Counterfeit Goods, by Havocscope Group, retrieved from http://www.havocscope.com/counterfeit-goods-ranking/ Copyright 2018 by Havocscope, LLC. Adopted with permission

Between 2002 and 2016, the non-profit organization, Pharmaceutical Security Institute (PSI), which has been dedicated to sharing information regarding counterfeiting of pharmaceuticals, identified that the number of incidents reported globally increased from 196 in 2002 to 3,375 in 2016 resulting in a 1,700 percent increase over 15 years (Pharmaceutical Security Information,
2017). This increase in reported incidents is displayed in Figure 1 (Pharmaceutical Security Information, 2017).

As stated by Alexandra Ossola in a 2015 Newsweek article, entitled *The fake drug industry was exploding, and we can’t do anything about it*, counterfeit pharmaceuticals conceptually have little to no active ingredients. Though, at their worst, counterfeit pharmaceuticals are providing hospitals and patients with products that are life-threatening poisons (Ossola, 2015).

In 2010, the Commissioner of the U.S. FDA, Margaret A. Hamburg, M.D., made it a priority for the agency to ensure the safety and efficacy of pharmaceutical and medical products. The U.S. FDA focused on the pharmaceutical products as they arrived at the pharmacies and hospitals (Hamburg, 2010). The U.S. FDA’s efforts to counteract this growing epidemic within the U.S. is exclusively on controlling the pharmaceutical supply chain (U.S. Senate Committee on Health, Education, Labor, & Pension, 2011a; U.S. Senate Committee on Health, Education, Labor, & Pension, 2011b). Resulting from the efforts of the U.S. FDA and the United States

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*Figure 1. Counterfeit Drug Incidents per Year (2002 through 2016). Reprinted from Pharmaceutical Security Information.*

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Senate Committee on Health, Education, Labor, and Pension (U.S. HELP), on November 27, 2013, former President Obama enacted the Drug Quality & Security Act (DQSA) (Drug Quality & Security Act, 2013). Under DQSA Title II the U.S. FDA is granted the ability to monitor and control pharmaceuticals throughout the supply chain from the point of manufacturing to dispensation (Drug Quality & Security Act, 2013; PEW Research Center, 2014).

In 2013, the U.S. FDA started implementing measures to control or mitigate instances of counterfeit pharmaceuticals from entering the U.S. pharmaceutical market under the DQSA. Even with the DQSA in place, the U.S. has observed an increase in reported counterfeit instances reported as seen in Figure 1 (Pharmaceutical Security Information, 2017). With the U.S. FDA focused on drug pathways, the patients representing the most significant segment of the U.S. pharmaceutical supply chain are ignored regarding their risk of being impacted by counterfeits (Blackstone et al., 2014). The U.S. pharmaceutical consumers are at an increased risk of purchasing a falsified or counterfeit pharmaceutical without being aware of the risk or the consequences (Pharmaceutical Security Information, 2017; Steel, 2015). Between January and May of 2017, most U.S. states had already reported over 55 incidents each of counterfeit pharmaceuticals as illustrated in Figure 2 (Partnership for Safe Medicines, 2017).
The laws and policies enacted within the U.S. mostly neglect consumers (Pharmaceutical Security Information, 2016; S.959, 2013). A study performed on behalf of the drug manufacturer Sanofi in 2015 identified that most consumers within the U.S. are unaware of the existence of counterfeit pharmaceuticals and believed they are safe solely because they are in a highly-developed nation (Steel, 2015). If consumers were educated regarding the risk of counterfeit pharmaceuticals, they could be the driving force behind the reduction in purchasing counterfeits and possibly a grass-roots campaign within their government to enforce more stringent regulations.
Counterfeit pharmaceuticals are becoming a greater global risk. With the number of incidents increasing over the last 15 years and the profits soaring for the counterfeit pharmaceutical manufacturers, the weight of mitigating the risk falls on the shoulders of the various government health authority agencies. The United States government has been working on resolving this issue since the early 1900s. While the U.S. Food and Drug Administration was created in 1906, they were not authorized to oversee the safety of food, drugs, and cosmetics until the enactment of the Federal Food, Drug, and Cosmetic Act (FD&C Act) in 1938 (U.S. Food and Drug Administration, 2018b). Since the FD&C was enacted, the U.S. FDA has continued to focus on counterfeit pharmaceuticals. Most recently, the FDA has enacted the Drug Quality and Security Act (DQSA), and more importantly Title II the Drug Supply Chain Security Act, in 2013. This recent legislation stems from need to implement tighter controls over the pharmaceutical supply chain within the United States as well as control the local State Boards of Pharmacies that were creating their own unique laws for the same purpose. In this Law and Policy Review, the DSCSA, the state legal origins, the federal history that lead to the creation of the DSCSA, as well as a comparison to the European Unions (EU) Falsified Medicines Directive (FMD) were examined.

**Drug Supply Chain Security Act**

Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA), was enacted in 2013. The DSCSA controlled prescription pharmaceutical products throughout the supply chain to mitigate the risk of counterfeit products from entering the market (U.S. Senate Committee on Health, Education, Labor, & Pension, 2011a; U.S. Senate Committee on Health, Education, Labor, & Pension, 2011b). This control includes monitoring each level of the supply chain from the manufacturer to the point of dispensation (pharmacies, clinics, hospitals, etc.) as illustrated in
Figure 2. Pharmaceuticals manufactured either domestically or internationally with the intent to distribute within the U.S. would fall under the scope of the DSCSA (S.959, 2013).

The U.S. FDA separated the implementation of the requirements into three phases to stagger the cost of compliance over a 10 year period. The DSCSA phases are: Phase I – Lot Level Management, Phase II – Item Serialization, and Phase III – Serialized Item-level Traceability. As Figure 3 details, each phase has a set of expectations that various levels of the supply chain must meet at specific times (Willis, 2017).

<table>
<thead>
<tr>
<th>Phase I: Lot-Level Management</th>
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<tr>
<td>• January 1, 2015</td>
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<tr>
<td>• Manufacturers, Wholesalers, Repackers, and Pharmacies to provide Transaction Information (TI), History (TH), and Statements (TS) at the Lot (or Batch) level</td>
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<th>Phase II: Item Serialization</th>
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<tr>
<td>• 2017 – 2020</td>
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<tr>
<td>• Serialization of drug products using a Product identifier</td>
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<td>• Receipt and return of serialized drug products only</td>
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<tr>
<th>Phase III: Serialized Item-Level Traceability</th>
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<tr>
<td>• 2021 - November 2023</td>
</tr>
<tr>
<td>• Centralized database to track product back to the Manufacturer or Repacker.</td>
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*Figure 3. Drug Supply Chain Security Act Phases*

Phase I of the DSCSA was to set a baseline throughout the U.S. pharmaceutical supply chain. During development of the DSCSA, states had varying levels of maturity regarding Pedigree legislation (Gallenagh, Ducca, Freisleben, & DiLoreto, 2014). Pedigrees are a legal requirement to document the chain of custody throughout the distribution system. Pedigree laws have been around since Congress enacted the Prescription Drug Marketing Act (PDMA) (Applebaum & Kusiatin, 2007). At the time of enactment, only California was discussing the requirement of serialization. Most other states had requirements tracing packages to the shipping
location. So, with Phase I, the U.S. FDA was attempting to level-set the industry by making sure that all states were at the same starting point (Woodcock, 2016). For this initial phase of the implementation, it required all manufacturers to develop the transactional information (U.S. Food and Drug Administration, 2017b). Each level of the supply chain described in Figure 2 needed to determine how to manage the newly created data.

Currently, the DSCSA is in Phase II of the implementation lifecycle. Phase II has been divided further into sub-sections due to its perceived complexity. During this phase of the project, manufacturers need to apply unique serial numbers to each saleable unit; repackagers need to consume and commission new serial numbers; and wholesale pharmaceutical distributors and dispensers need to halt the reception of unserialized pharmaceuticals. By the end of this phase of the implementation, the U.S. FDA’s goal is to ensure all pharmaceuticals are serialized (S.959, 2013).

The final phase of the implementation is the most ambiguous section of the policy (Cao, 2016). Products are required to be serialized and traced from birth to consumption (Ducca, 2017). The regulations and guidance documents published by the U.S. FDA have not identified how this occurs. A software system does not currently exist to manage this process the United States. The magnitude of data produced and the security requirements equate to the need for a highly complex system (Pilot Project Program under the DSCSA, 2017).

The DSCSA is a start to controlling the U.S. market and mitigating the risk of counterfeit pharmaceuticals. The U.S. FDA recommended additional aspects to controlling the risk of counterfeit pharmaceuticals. In 2004, a U.S. FDA report entitled Combating Counterfeit Drugs: A Report of the Food and Drug Administration identified six areas to better protect Americans from counterfeit pharmaceuticals (U.S. Food and Drug Administration, 2004). The report stated:
Securing the actual drug product and its packaging; securing the movement of the product as it travels through the U.S. drug distribution chain; enhancing regulatory oversight and enforcement; increasing penalties for counterfeitors; heightening vigilance and awareness of counterfeit drugs; and, finally, increasing international collaborations. (p. 11)

The DSCSA attempted to achieve four of the six identified required measures that would protect Americans from the threat of counterfeit pharmaceuticals.

An understanding of the context as to the development of the law is required to examine the effectiveness of the DSCSA. In addition, an analysis of comparable policies determines the extent of the effectiveness of the application of the U.S. regulations.

State Level Legal History

Before the enactment of the DSCSA, the quality assurance of the pharmaceuticals on the U.S. market was a function of each state’s Board of Pharmacy (BoP). The various Boards of Pharmacy regulated the sale and quality standards of the pharmaceuticals. In a 2005 U.S. House of Representatives hearing on Sick Crime: Counterfeit Drugs in the United States, Rep. Elijah E. Cummings stated,

State regulators and industry also have taken notice of the counterfeit drug threat. For its part, the National Association of Boards of Pharmacy has taken the important step of proposing new model rules for the licensing of wholesale distributors, and to date 11 States have adopted the tougher standards. In addition, some major wholesalers and retailers have announced their attention to avoid obtaining drugs from secondary markets. (p. 110)

The Boards of Pharmacy recognized the threat of counterfeit pharmaceuticals while the Federal government was still in its infancy stages. This early identification and adoption at the state level resulted in varying application in policies due to a lack of centralized guidance from the Federal government.
While some states collaborated to define a standard, certain states like Florida and California stood out from the rest as having particularly difficult requirements (California Business and Professions Code section 4034(d), 2008; Chap. 2003-155, Laws of Florida, 2003). In 2003, the state of Florida became the first state to pass legislation to revise the Florida Drug and Cosmetic Act to require an electronic Pedigree (e-Pedigree) for pharmaceuticals sold into the state (Chap. 2003-155, Laws of Florida, 2003). The term Pedigree, as defined by the U.S. FDA in the 2006 Compliance Guide for the Prescription Drug Marketing Act (PDMA), is a statement of origin that documents each transactional movement of a pharmaceutical product (U.S. Food and Drug Administration, 2006). Florida became the first state to require the electronic exchange of the data for the ePedigree.

By 2007 the bulk of e-Pedigree activity had been at the state level (Harrison, 2007). Nevada, Arizona, Colorado, Indiana, Oregon, and Florida had e-pedigree requirements as of 2006. In 2007, the state Board of Pharmacy’s from Idaho, Wyoming, Maryland, and North and South Dakota enacted similar laws. California, Iowa, Kansas, Mississippi, Nebraska, New Mexico, Texas, and Vermont had all proposed legislation or planned a timeline for enacting e-pedigree (Harrison, 2007). With each state developing unique versions of the pharmaceutical track and trace legislation, it was quickly becoming more and more difficult for pharmaceutical manufacturers to do business within the United States. For a pharmaceutical manufacturer to sell a product within the United States, they needed to understand the laws of the state of origin, the laws of the state where dispensed, and any potential laws for the states where the product might travel through. By 2008, most states either had legislation in place, in-draft or proposed as shown in Figure 4 (Smith, 2009).
The policy developed by California was the driving force behind the laws in place today. While most states were focusing on traceability, California was the first state to initiate the concept of pharmaceutical serialization (California Board of Pharmacy, 2008). The California BoP had drafted requirements for serializing pharmaceutical products with a 2013 effective date. The federal law superseded California’s law before it was enacted. The California requirement to include a serial number was the catalyst for the federal level policy to apply its focus in the same direction. Before the Federal government could enact the DSCSA, most organizations were trying to determine how to serialize products without a single legal direction. The problem that most organizations were facing was not in trying to serialize the products but preventing the delivery of products to California that were not specifically labeled for the state.
Federal Level Legal History

In September 2011, Senator Thomas Harkin (D-IA) presented to the U.S. Senate Committee on Health, Education, Labor, and Pension (U.S. HELP) regarding the need to secure the pharmaceutical supply chain within the United States (U.S. Senate Committee on Health, Education, Labor, and Pension, 2011a). Sen. Harkin originally addressed the need to control the pharmaceutical supply chain back in 2004. The original recommendation focused on foreign pharmaceuticals entering the U.S. market as a measure to protect Americans from counterfeit drugs. In Sen. Harkin’s 2011 address to the Senate, he stated that,

FDA and Customs have tried to increase their vigilance to keep pace with the increasingly global nature of our supply chain, but FDA does not have the authority and flexibility it needs to make sure that foreign facilities adhere to the same quality standards as U.S. facilities. Some domestic companies have tried to fill that gap by adopting robust Quality Control practices that include inspecting their overseas suppliers, but others have not. The result was a supply chain rife with gaps. (p. 1)

Senator Mike Enzi (R-WY) added to Harkin’s comments by stating that the Government Accountability Office (GAO) found that the U.S. FDA does not police the supply chain efficiently (U.S. Senate Committee on Health, Education, Labor, and Pension, 2011b). In a similar statement from Eleanor Holmes-Norton, Washington D.C. representative on the Subcommittee on Criminal Justice, Drug Policy, and Human Resource found it surprising the lack of federal regulation regarding counterfeit pharmaceuticals (Sick Crime, 2005). Ms. Holmes-Norton stated,

No one can doubt we're in interstate commerce this time, I think, and when we have the industry saying that the hodgepodge of State regulations and difficulty of enforcing at the State level means we ought to have Federal regulation. It looks like this problem was growing way out of proportion and anybody can understand why. (p 110)

Pharmaceuticals are interstate commerce without a strong federal regulation governing them.

This lack of governance led to the disjointed implementation of state legislation. Corporations
do not manufacture pharmaceuticals specifically for each state. Due to the lack of federal level guidance, this individualization was exactly where the industry was ending up.

In September 2012, an incident occurred that resulted in the death of 64 individuals and caused serious illness to over 800 individuals. The New England Compounding Center (NECC) in Framingham, Massachusetts knowingly sent out pharmaceuticals that were mislabeled and unsanitary through the process of compounding (Lupkin, 2013). Compound pharmaceuticals were not being regulated at the federal level and left to each state Board of Pharmacy to govern (U.S. Food and Drug Administration, 2013). Compounding is the process where a pharmacy or licensed facility, is allowed to mix medical substances to create a pharmaceutical tailored to a specific individual (U.S. Food and Drug Administration, 2015c). This incident received global press requiring immediate action to be taken by the U.S. Department of Justice (Outterson, 2012). In April 2013, U.S. HELP sought to mitigate the compounding risks by initiating the Pharmaceutical Compounding Quality and Accountability Act (U.S. HELP, 2013a). The subcommittee that worked on the draft of this document was U.S. HELP Chairman, Sen. Harkin, ranking member Lamar Alexander (R-TN), Sen. Pat Roberts (R-KS), and Sen. Al Franken (D-MN) (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013c). As stated by Sen. Alexander, “[the] primary goal with this legislation was to erase the confusion over who regulates pharmacies and manufacturing facilities, and make it clear exactly who oversees each business” (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013b, p. 1).

While Sen. Harkin’s subcommittee was working on the Pharmaceutical Compounding Quality and Accountability Act, U.S. Senators Michael Bennet (D-CO) and Richard Burr (R-NC) started to work on a national pharmaceutical traceability system (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013h). The intent of the system was to understand the U.S. market and trace a pharmaceutical product from the point of manufacturing to the point of
dispensation (U.S. Senate Committee on Health, Education, Labor, and Pension, 2011b). This traceability would support the U.S. FDA’s efforts to control the pharmaceuticals in the supply chain (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013a). On May 15, 2013, the national pharmaceutical traceability system transferred under the Drug Supply Chain Security Act (DSCSA) presented by Sen. Bennet in the Senate bill S.957 (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013b, S.957, 2013).

Following the release of the Drug Supply Chain Security Act, Senator Harkin presented the Senate Bill S.959 for the Pharmaceutical Quality, Security, and Accountability Act (S.959, 2013). This bill replaced his previous Pharmaceutical Compounding Quality and Accountability Act. The reason for this change was that Sen. Harkin had worked with Sen. Bennet to include the DSCSA proposal under a single unified law. Senate bill S.959 split into two separate titles. Title I was the Human Drug Compounding and Title II was the Drug Supply Chain Security (S.959, 2013). Sen. Harkin spearheaded the effort to push the Pharmaceutical Quality, Security, and Accountability Act through the House and the Senate (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013d). Throughout these efforts, Sen. Harkin continuously utilized the story of the NECC deaths and illnesses as the beacon to rush this bill through the process. As each additional person passed away from the NECC incident, Sen. Harkin would hold another press conference stating the need and the urgency for the House and the Senate to pass this law without hesitation (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013e).

Bill S.959 was introduced to the House on September 27, 2013, by its sponsor, Representative Fred Upton, from Michigan's 6th congressional district, and passed 24 hours later. The only amendment at the House was the name of the Bill which changed from Pharmaceutical Quality, Security, and Accountability Act to the Drug Quality and Security Act.
The vote was verbal, and no record exists of individual votes (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013i). The Senate passed S.959 on November 18, 2013, with no amendments to the bill (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013o). The Drug Quality and Security Act was enacted on November 27, 2013, after being signed into law by President Obama (S.959, 2013).

From the point of conception in April 2013 to the enactment in November 2013, this bill was pushed through the process without much review or amendment. Both titles under the law only received two readings by the Senate Committee U.S. HELP, and the bill received only minor amendments from the House and none from the Senate (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013l; U.S. Senate Committee on Health, Education, Labor, and Pension, 2013o). With the focus on a response from the government regarding compounding, little time was spent determining the efficacy of the DQSA.

If one examines the history of the Drug Supply Chain Security Act (DSCSA) in the U.S. from its conception to its enactment, the intent of its origins do not resemble what is in place today. Going back to Harkin’s original purpose statement in 2011, the U.S. needed to control the products that were coming from outside the country. The U.S. imports 80 percent of all the pharmaceuticals consumed domestically (Altstedter, 2017; U.S. Senate Committee on Health, Education, Labor, and Pension, 2011a). The law evolved in the early part of 2013 when the U.S. needed a system to track the movements of compounded pharmaceuticals. Based on the problems with NECC, the U.S. FDA and the Massachusetts BoP were unprepared to deal with the incident and did not have the data to determine the destination of those compounded pharmaceuticals. NECC initiated a voluntary recall of all products compounded and distributed from its facility in Framingham, Massachusetts (Center for Disease Control and Prevention, 2015a).
The law changed again with the requirement of serialization. As the documents progressed through the House and Senate, all comments focused on the first Title of the Drug Quality and Security Act (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013i). Of the 29 organizations and companies that reviewed the law for comment, Title II was never mentioned in the letters of endorsement (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013i). All focus was on Title I and the compounding aspect that was so prevalent in the news. Out of the 29 reviewing and endorsing bodies, only one entity was a pharmaceutical manufacturer, Pfizer (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013i). Pfizer was a large pharmaceutical manufacturer which could not represent small to mid-sized pharmaceutical companies. Pfizer was also the only participant from the pharmaceutical supply chain represented. There was not a single distributor, third-party logistics provider (3PL), or dispenser on the initial review. The initial review performed under the guise of the Pharmaceutical Compounding Quality and Accountability Act only required manufacturers to participate. It was not until months later that the bill evolved into what exists today after it was reviewed and submitted to the House. Those that are affected by the law never had a chance to provide input.

Another area of concern was the methods used to migrate the bill through the stages of the government. This campaign utilized scare tactics to get this bill approved. Senator Harkin testified in front of the Senate and stated, “If we fail to act now, it will only be a matter of time until we’re all back in this room asking why more people have died and what could have been done to prevent it” (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013e). These tactics and pushing the approval of these laws through the court of public opinion resulted in a rushed construction of the bill. With the bill starting as a concept to support the tracking of
compound products in April to a system to track every serialized pharmaceutical in the U.S. by June did not provide any time to think through all of the aspects of the law before acting.

The participants within the pharmaceutical industry, both in the U.S. and abroad, have been spending millions of dollars attempting to develop systems to comply with this regulation. Many organizations have determined varying opinions on the definition of compliance through the three phases of the law. Currently, Phase III of the law remains vague without details regarding the reporting system. With the lack of direction regarding the U.S. FDA’s centralized database scheduled for release in 2023, anything implemented previously might be in vain. The industry is currently trying to aim at a target that is undefined.

**European False Medicines Directive**

As the United States has started implementing a federal solution for the tracking and tracing of pharmaceuticals, the European Union (EU) had been drafting a solution to implement throughout its member states. The EU Falsified Medicines Directive (FMD), the publication of the Delegated Act on Safety Features identified that any corporation that manufactures sells, or dispenses medications in the European Union has until February 2019 to comply with their new track and trace regulations (Directive 2011/62/EU, 2011). Directive 2011/62/EU was adopted into law in 2013 and further developed to identify the traceability requirements in 2017 (Directive 2011/62/EU, 2011). FMD identified a single system that all levels of the pharmaceutical market would utilize. Within this single source of data traceability, the EU can monitor any transaction to determine when duplicates or fraudulent are introduced for investigation (Directive 2011/62/EU, 2011).

While the EU FMD has already factored in a single system into the regulation while the DSCSA has not, the EU law does have its own unique challenges. FMD separates traceability into three main subsections; serialization, compliance reporting, and verification. FMD has
additional complexities where medications in Europe are generally packaged and sold at the “unit of use” level and not in the larger, bulk quantities as in the United States. Where the U.S. sees a package of 30 tablets or capsules in a blister package as a single unit, the EU FMD regulation would require 30 unique products packaged together. So, where the U.S. would require a single serial number for the package, the EU would require each tablet or capsule on the blister pack of 30 to have a unique serial number (Directive 2011/62/EU, 2011). Overall, the magnitude of data to be produced, managed, and reported is expected to be extensive.

While the FMD is an overarching regulation for manufacturing and distributing products in the European Union, it was not the only requirement for the EU (Directive 2011/62/EU, 2011). Like the policies within the United States, the EU provides standards which all of its Member States must follow. The EU FMD also allowed for the flexibility for Member State to apply unique requirements. Each Member State determines the form and format of the serial number utilized on the product. An approved product by the European Union must also be submitted for approval for each country.

Conclusion

The history of the counterfeit pharmaceutical laws within the United States has experienced a long and complicated road. The first attempts to regulate pharmaceuticals at a federal level was in 1892 when the U.S. Senate tried to apply a professed standard to the medicines that were being sold within the country (Anderson, 2000). This initial attempt to regulate and control the pharmaceuticals proved to be unsuccessful. The first pharmaceutical law enacted came in the form of the Food, Drug and Cosmetic Act in 1938. This law required all proprietors to list all ingredients associated with the pharmaceuticals. It was not until 1992 with the Prescription Drug User Fee Act (PDUFA) that the law took shape into what is in place today (U.S. Food and Drug Administration, 2018a). While the U.S. FDA started to conceive the
need to regulate counterfeit pharmaceuticals in 2004 with the report titled *Combating Counterfeit Drugs: A Report of the Food and Drug Administration*, it was not until the NECC incident that drove action to be taken in 2013 (Lupkin, 2013; U.S. Food and Drug Administration, 2004). Unfortunately, it takes the death and injury of individuals to act as the driver for change at the federal level.

While the U.S. Federal government might not have taken action on counterfeit pharmaceuticals until 2013, the state BoP had been working on this potential risk since the early 2000s. As the risk of counterfeit pharmaceuticals increased, individual states started to implement their own strategies. These individual laws were not consistent and created a complicated environment in which corporations participated. These variations stressed the need for federal intervention.

The disjointed state laws and the NECC event resulted rushed regulations at a federal level. Between April and November 2013, the Drug Quality and Security Act was developed and enacted. Gaps and lack of clarity in the law was the result of regulators spending minimal time drafting the law. The European Union implemented similar legislation with a greater level of detail that the U.S. FDA did not provide. While the EU FMD is closer to a solution with a centralized data hub in comparison to the U.S. FDA, the DSCSA is still in its infancy stage and not fully realized. As described in the historical development of the DSCSA, the concept of pharmaceutical traceability required further exploration before submission to Congress (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013i). The NECC incident used to get this bill passed was impulsive (U.S. Senate Committee on Health, Education, Labor, and Pension, 2013e; U.S. Senate Committee on Health, Education, Labor, and Pension, 2013f; U.S. Senate Committee on Health, Education, Labor, and Pension, 2013g).
The DSCSA was a good first step in controlling counterfeit pharmaceuticals, but it was not a complete solution. Without a firm understanding of the utilization of the data or the reporting of suspect products due to serial number sales, the only thing the DSCSA has accomplished was adding another layer to the current process (Snyder, 2017).

**Problem Statement**

Health authority agencies around the world have identified that counterfeit pharmaceuticals are placing the lives and well-being of consumers at an elevated risk, a problem that has escalated dramatically over the last fifteen years (Blackstone et al., 2014; Hamburg, 2010; Pharmaceutical Security Information, 2016; World Health Organization, 2016). Most consumers within the United States are not aware that 10 percent of all pharmaceuticals they are consuming are counterfeits (Steel, 2015). Due to this lack of awareness, an exploration into the level of understanding regarding counterfeit pharmaceuticals by U.S. consumers was needed.

**Purpose Statement**

The purpose of this descriptive quantitative study was to explore the level of awareness of the U.S. consumer regarding the risk of consuming counterfeit pharmaceuticals. The study is limited to prescription and over-the-counter pharmaceuticals for any adult consumer 18 years or older within the North East region of the United States. Findings generated from this study are expected to add to the body of knowledge that supports the proposal of targeted consumer-based communication policy regarding counterfeit pharmaceuticals.

**Research Questions and Hypotheses**

The primary research question is, are U.S. consumers aware of the risk of the counterfeit pharmaceuticals? To ascertain the level of understanding of a population regarding the risk of counterfeit pharmaceuticals, the overarching research question was separated into subparts.
These subparts analyze the demographics of the respondents, determine their knowledge of counterfeit pharmaceuticals, and analyze perceptions of the government and policy efficacy.

The understanding of what consumers perceive to be a risk to their health directly aligns to decision-making processes. If consumers do not perceive counterfeit pharmaceuticals as an immediate threat, the assumption is that consumers would be ill-informed on the risk. Therefore, the first sub-question examined was, “How do U.S. consumers prioritize counterfeit pharmaceuticals in their decision-making process as a potential risk to their health and long-term safety?”

Following the determination if consumers prioritizes counterfeit pharmaceuticals into their decision-making process, a determination of what the respondents perceive as a counterfeit pharmaceutical must be established. Identification of what the respondents’ perception of what defines a counterfeit pharmaceutical and where they perceive a counterfeit pharmaceutical is most likely to be purchased establishes a baseline of consumers understanding. These findings support the sub-question, “Are the U.S. consumers understand what defines a counterfeit pharmaceutical as it exists within the United States pharmaceutical market?”

The last research question determines consumers perceptions of the efforts by the government to mitigate the risk of counterfeit pharmaceuticals. While the previous sub-questions determined if consumers were aware of the risk, it is important to understand perceptions of government impact on the control of counterfeit pharmaceuticals. Therefore, the last sub-question is, “What are U.S. consumers perceptions of the government’s effort to control counterfeit pharmaceuticals?”

These three sub-questions provide adequate information to assess the level of awareness of the U.S. consumer regarding the risk of consuming counterfeit pharmaceuticals. The hypothesis for this study is that common U.S. consumer is not aware of the risk of consuming
counterfeit pharmaceuticals within the United States. The review of the law and policy background revealed that consumers were largely ignored during the construct of policies regarding counterfeit pharmaceuticals. The absence of informational or educational programs for the average pharmaceutical consumer, supports the assumption that consumers may not be informed of the risk of consuming a potentially harmful and deadly product. Based on the hypothesis, the counterfeit pharmaceutical risk would rank low in the priority of potential harms and subsequently result in a large gap in the knowledge of possible risk.

**Theoretical Foundation**

The study focuses on the level of awareness of the U.S. consumer regarding the risk of consuming counterfeit pharmaceuticals. There is an economic theory which may deduce why a consumer may willingly participate in potentially hazardous buying habits. The social choice theory considers the problem of aggregating the preferences of each member of a given society or population to determine a common social preference that represents the target community. Factors considered within this framework include the individual opinion, preferences, interests, and welfares to reach a collective decision or social welfare for the society the individual has been assigned (Gaertner, 2006). A social preference is developed as the basis to define the society and then is expressed as a common good. The market economic mechanism cannot be viewed as the social welfare function since any moral or ethical principles do not govern it. Often paired with the rational choice theory, the social choice theory is methodologically individualistic in that it requires that causal accounts of the social phenomena explaining the motivations and actions of individual agents (Nitzan, 2010).

When given an option between the possible consumption of a counterfeit pharmaceutical and a potentially dangerous disease, the society or community defined individual social choice in
which they are participating. The individual draws upon the collective social choice to either educate themselves on the risk or withdraw from the economic market. Since the decision of whether to consume a pharmaceutical has a larger impact than just the immediate health benefits on the individual, both positive and negative economic externalities need examination.

Originally developed by Nicolas de Condorcet in 1785 in his essay on the *Application of Analysis to the Probability of Majority Decisions*, the social choice theory is the observation that majority preferences can be irrational even when the individual preferences are rational (Condorcet, 1785). In 1951, Condorcet’s theory was expanded by Kenneth Arrow with the Arrow’s Impossibility Theorem. Arrow’s Impossibility Theorem sought to determine if specific variables, such as methods and values, structured the aggregated taste of a societies vote or an economic market to satisfaction. Arrow proposed removing the distinctions between terms like voting and markets to create a more general category of *collective social choice*. This analysis of the collective social choice used ordinal rankings of individual choices to represent behavioral patterns. Avoidance of individual utility and interpersonal comparisons of utility because such measures are unnecessary to represent behavior and depend on mutually incompatible value judgments (Arrow, 1951).

The consistency of the relationships among different preferences over various outcomes would be stated through mathematical axioms. In this scenario, a rational agent is one whose choices reflect internal consistency demanded by the axioms of rational choice (Amadae, 2016). The rational choice theory states that factors such as sympathy, sense of fairness, attitude toward risk will be incorporated into an individual’s ranking of risk. Due to limited information regarding an individual’s desires and decision making techniques, researchers make inferences based on observed behavior to determine the preference hierarchy that regulates rational decisions making (Amadae, 2016).
Social Choice Theory Critics

Even though the core of the social choice theory has been around for hundreds of years and has evolved further in the last 100 years, counter-arguments have been made to its overall validity. A study performed in 1998 at the California Institute of Technology examined how the social choice theory performed in relationships between the collective preference and non-cooperative game theory approaches to positive political theory (Austin-Smith & Banks, 1998). Dr. Austen-Smith and Dr. Banks believed that while social choice theory has provided great insight over the decades, there is an apparent decisive difference between the two approaches that in sufficiently complex environments, direct preference aggregation models are incapable of generating any prediction at all (Austin-Smith & Banks, 1998). If two separate variables are indeed individual as defined by the social choice theory, then a complex environment created from society would result in the inability to generate a solid prediction on how the community would react. In comparison, non-cooperative game-theoretic models almost always generate a prediction. In game theory, two participants presented two different options will always select the option that leads to the dominant strategy that benefits them the most (Mankiw, 2008). The focus on the dominant strategy is also considered the Nash equilibrium. Austen-Smith and Banks determined that a complex society will always skew the results of a social choice due to a community having multi-faceted variables. When modeling collective decisions on a specific situation, like the prioritization of the risk of counterfeit pharmaceuticals, there is a fundamental tension between ensuring the existence of well-defined predictions and general applicability to complex environments (Austen-Smith & Banks, 1998).

In 2011, Dr. Aki Lehtinen from the University of Helsinki argued that observability and risk-attitudes presented within the social choice theory fails due to strategic voting. The concept that established social norms under the social choice theory does not satisfy the conditions that
guarantee individual behaviors. In his research paper entitled, *A Welfarist Critique of Social Choice Theory*, Dr. Lehtinen (2011) stated,

Social choice theory is criticised not just by showing that some of its most important conditions are not normatively acceptable, but also by showing that the very idea of imposing condition on social choice function under the assumption of sincere behaviour does not make much sense because satisfying a condition does not guarantee that a voting rule actually has the properties that the condition confers to it under sincere behaviour. (Lehtinen, 2011, p. 1)

The argument that social choice assumes behavior has been the primary dispute to the theory for years. In 1953, Dr. John C. Harsanyi of the University of Budapest made similar claims. Dr. Harsanyi argued that “if somebody prefers an income distribution more favorable to the poor for the sole reason that he is poor himself, this can hardly be considered as a genuine value judgment on social welfare” (Harsanyi, 1953, p. 434).

Dr. John Quiggin of the Australian National University argues a similar point concerning the social choice and public choice theories. Dr. Quiggin believed that economists historically focused on the egoistic rationality of human behavior rather than a more imperialistic approach (Quiggin 1987). The egoistic rationality states that the human participant will focus on their more dominant strategy of the Nash equilibrium rather than the strategy aligned with the social norm. Individuals seek to maximize the utility of the consumption of goods (Quiggin 1987).

The use of cardinal utility models of social choice has been encouraged by the popularity of contractarian models such as that of Rawls (Quiggin 1987). John Rawls introduced in 1971 the thought that the device or thought of the *veil of ignorance* behind which individuals choose social arrangements without knowing what place they occupy in those arrangements (Rawls, 1971). The social choice theory determines how a community focus its efforts and make a decision aligned to that of its neighbors is an ignorant and blind view of the world. Rawls argued that the larger the community or sample size of the population examined, the more likely
that rational individuals adopt a worst possible outcome scenario. The worst possible outcome scenario is an extreme form of the decision-weighting process represented in rank-dependent expected utility derived from the social choice theory (Rawls, 1971). Rawls developed modifications to the social choice theory because of the identified flaws and created the Theory of Justice. This theory requires decisions, or identification of implied justice, based on the concern for the worst-off members of the community. The social choice bases the decisions on the average individual and largely forgets to worst off member.

Regarding utilizing social choice theory in the modern age, Dr. David M. Pennock of Pennsylvania State University argues that social choice theory is no longer of value. The growth of Internet commerce has stimulated the use of collaborative filtering algorithms as recommender systems. Such systems leverage knowledge about the behavior of multiple users to recommend items of interest to individual users (Pennock, 2000). With the advent of targeted marketing, there is no longer an individual choice. Everything in the individuals’ immediate community is based on a pre-established algorithm and not off of the collective social choice. Social choice is now being established for the community and not being defined by the community. If a social norm cannot be developed and constructed without the participation of the individual, there is a collapse of the theoretical construct (Pennock, 2000).

Rationale

At its core, social choice theory is the process of systematically studying how to utilize an individual preference or concern and determine a ranking system for the collective community. As discussed, scholars have debated the use of the social choice for decades. While the original 1785 Condorcet Theory might struggle in today’s economy, the addition of Arrow’s Impossibility Theorem has developed the highly adopted notion of the social welfare. This notion of social welfare has served as the foundation for many disciplines within economics such
as optimal tax theory or the economics of climate change and even the economics of counterfeit pharmaceuticals (Adler, 2018).

In the sense that the social choice theory is thought of as a reflection of individual preferences in a group setting, it deals with the principles of aggregating individual preferences to define or predetermine the actions of the entire community. At this general level, the social choice theory applies to decision making by committees, the political voting process, and most aspects of welfare economics (Roberts, 2006). The social choice was originally developed to determine voting habits. The most well-known aspect of the theory that Condorcet developed in 1785 is the paradox of majority voting. This theoretical paradox considers three different individuals: individual A prefers social state or outcome x to y to z, individual B prefers y to z to x, and individual C prefers z to x to y: a majority (A and C) prefer x to y, a majority (A and B) prefer y to z and a majority (B and C) prefer z and x. Note that based on the ranking, y is never preferred to x, though one can infer that y is preferable to x because y is preferred to z which is preferred to x two out of the three scenarios (Condorcet, 1785).

Arrow’s main concern is to consider if individual decisions are satisfied by a social choice (Shaile, 2017). The main problem with social choice is the introduction of democracy. The introduction of a dictator solves the social aspect or community determination of a decision that affects a sample population. Under dictatorship, social decisions are made by a single individual from the small group. In a democratic society, individuals have unique beliefs of what social welfare entails. It is therefore difficult to construct a social welfare function which reflects the individual orderings or rankings (Shaile, 2017). Arrow’s impossibility theory resolves these open gaps introduced in the social choice theory with reasonable conditions which social choices must meet to reflect individual’s preferences.
Theory Application

The primary research question for this study is to determine the level of awareness of the U.S. consumer regarding the risk of consuming counterfeit pharmaceuticals. Prioritization of the risk of counterfeit pharmaceuticals to consumer health and long-term well-being is a key aspect as to whether individuals will spend time educating themselves. With social choice theory, an attempt is made to understand why the community or sample population has ranked the prioritization of the risk.

Definitions

Active Pharmaceutical Ingredient - Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product (Registrar Corp, 2017).

Awareness - the accurate appraisal and understanding of your abilities and preferences and their implications for your behavior and their impact on others (Furnham, 2015).

Compounding – practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient (U.S. Food and Drug Administration, 2015c).

Corruption – an improbity or decay in the decision-making process in which a decision-maker consents to deviate or demands deviation from the criterion which rules his or her decision-making, in exchange for a reward or the promise or expectation of a reward, while these motives influencing his or her decision-making cannot be part of the justification of the decision (United States Department of State, 2003).
**Counterfeit Medicine** - Counterfeit medicine was fake medicine. It may be contaminated or contain the wrong or no active ingredient. They could have the right active ingredient but at the wrong dose. Counterfeit pharmaceuticals are illegal and may be harmful to your health (U.S. Food and Drug Administration, 2017a).

**Developed Nation** – a sovereign state that has a highly developed economy and advanced technological infrastructure relative to other less industrialized nations. Most commonly, the criteria for evaluating the degree of economic development are the gross domestic product (GDP), gross national product (GNP), the per capita income, level of industrialization, amount of widespread infrastructure and general standard of living (Developed Nation, 2005).

**Educated Consumer** - a demonstrated ability to listen carefully, to think critically, to evaluate facts rigorously, to reason analytically, to imagine creatively, to articulate interesting questions, to explore alternative viewpoints, to maintain intellectual curiosity and to speak and write persuasively (Denning, 2011).

**Grassroots Campaign** – A movement (often referenced in the context of a political movement) in which the people in a given district as the basis for a political or economic movement. Grassroots movements and organizations use the collective action from the local level to effect change at the local, regional, national, or international level. Grassroots movements are associated with bottom-up, rather than top-down decision making, and are sometimes considered more natural or spontaneous than more traditional power structures. Grassroots movements, using self-organization, encourages community members to contribute by taking responsibility and action for their community (Gove, 1961; Poggi, n.d.).
In-Transit Nation – a country that was more stable and more developed than an under-developed country but was less-stable and less-developed than a developed or “first-world” country (In-Transit Nation, 2017).

Informed Consumer – having or showing that the purchaser of a product was knowledgeable regarding a particular subject (U.S. Food and Drug Administration, 2016b).

Marketing Authorization Holder – The person or company in whose name the marketing authorization has been granted. This party was responsible for all aspects of the product, including quality and compliance with the conditions of marketing authorization. The authorization holder must be subject to legislation in the country that issued the marketing authorization, which normally means being physically located in the country (World Health Organization, 1998).

Pedigree – a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them (U.S. Food and Drug Administration, 2015b).

Pharmaceutical – a finished dosage form of a prescription or over-the-counter remedy, for example, a tablet, capsule or solution that contains an active pharmaceutical ingredient, generally, but not necessarily, in association with inactive ingredients (Registrar Corp, 2017).

Public Awareness – the public’s level of understanding about the importance and implications of concepts (United Nations, 2012).

Public Education - Utilizing messaging to help proactively engage key audiences and asking them to respond to a specific call to action to help achieve your goal (Bouder, 2013).

Risk - Exposure to the chance of injury or loss; a hazard or dangerous chance (Risk, 2017).
Supply Chain – a network between a company and its suppliers to produce and distribute a specific product, and the supply chain represent the steps it takes to get the product or service to the customer (Supply Chain, 2017).

Underdeveloped Nation – a country that was considered lacking regarding its economy, infrastructure, and industrial base. The population of a lesser-developed country often has a relatively low standard of living, due to low incomes and abundant poverty (Underdeveloped Nations, 2014).

Assumptions

The assumptions underlying this study include the researcher worldview, the honesty of the responses, the rationale supporting the generalization of the responses, and the application of the study to other regions of the United States.

Every study is driven by the philosophical worldviews or basic sets of beliefs that guide research (Creswell, 2014). The pragmatic worldview, while often applicable to mixed methods research, applies to a quantitative study based in a descriptive analysis. Pragmatic worldviews emphasize the solution over the method due to its focus on the social aspects of a problem. The pragmatic paradigm relies on a combination of a social, historical, and political context (Creswell, 2014). In this study, it is assumed that the North East region of the U.S., the geographic boundary set for this study, is more likely to have similar historical and social perspectives in alignment with the pragmatic worldview.

The use of a questionnaire as the tool for the quantitative study relies on the assumption that the respondents will answer the questions honestly and to the best of their ability. With any questionnaire, the findings are based upon the assumption that the respondents have taken the questionnaire seriously.
The study is also based on the assumption that the sample population allows for generalizations to the total regional population. The sample population is a subset of the larger population of the North East region of the United States. The scope of the study is narrowed to include just the North East region of the U.S. to allow for more accurate generalization from the sample to the total regional population because this is a region where the potential respondents had similar historical and social perspectives (Mills, Durepos & Wiebe, 2010).

While the study is focused on the North East region of the United States, generalizations cannot be applied from the findings to the other regions of the United States. Larger scale populations from a broad geographic area are the more likely to contain varying results. The North East region of the United States has the highest concentration of participants in the healthcare professional field. With 21 percent of the North East region employed in some faction of the healthcare industry, the assumption is that this region is the most educated region regarding pharmaceuticals out of the entire country (U.S. Department of Labor, 2017). Therefore, the outcomes of this study cannot be generalized to the entire population of the U.S. due to the high concentration of employment of the sample in the healthcare profession within the North East region. They may be more knowledgeable about the risk of counterfeit pharmaceuticals.

Scope and Delimitations

The goal of this study was to determine the pharmaceutical consumer level of awareness of the risk of consuming a counterfeit pharmaceutical. This study utilized a limited sample population from the North East region of the United States. A crucial feature of the sampling method was the inclusion criteria used in this study to select the population. For the study sample, the following features were included in the study frame:
• Adult population 18 years or older
• Resides within the North East region of the United States
• Native U.S. citizen
• Has consumed a pharmaceutical (prescription, Over-the-Counter, or dietary)
• Has access to the internet
• Has created a LinkedIn account

Utilizing these features for the frame, generalizations can be made on the study sample against the total population. While the frame will be used to draw generalizations, it is not a complete representation of the whole region of the North East.

According to the U.S. Census Bureau, only 82.5 percent of the population of the North East have access to the internet (U.S. Census Bureau, 2012). Of the total adult population of the North East, only 65 percent have created a LinkedIn account (no statistics available on how active the users are within the site). While a large section of the North East was able to voluntarily participate in the questionnaire, the study frame did exclude some of the total population resulting in a biased sample.

The population for this study was exclusive to those that are native to the U.S. This limited study population excluded both naturalized citizens and legal immigrants from being factored into the resulting data analysis. The reason for these exclusions is that the intended purpose of this study was to examine the understanding of a sample population within the U.S. This exclusion has applied to respondents originating from other countries.

Since the research topic focused on consumer awareness of the counterfeit pharmaceutical risk, it was important that the respondent had previously consumed a pharmaceutical. If the respondent believed that they had never consumed a pharmaceutical, then
they would not likely have any concern regarding counterfeit drugs. According to the Center for Disease Control and Prevention, 48.9 percent of the total population of the North East consume at least **one** prescription pharmaceutical on a monthly basis, 72.5 percent of the total population were administered a drug treatment at a hospital or clinic each year, and 79.1 percent of the population consumed an over-the-counter pharmaceutical in 2014 (Center for Disease Control and Prevention, 2017). Based on a year-over-year average of 72.5 percent of the population being administered a drug treatment, the likelihood that a potential respondent had never consumed a pharmaceutical during their lifetime is statistically low.

**Limitations**

The limitations restricting this study included generalization of the conclusions to the broader population of the United States, the understanding of the industry that the respondents work in, and the alignment of the sample geographic demographics to the total population.

As stated in Assumptions, the North East region has a high concentration of residents working within the healthcare industry. The assumption was made that participating in the healthcare industry would result in an individual being more likely to be aware of the risk of counterfeit pharmaceuticals. Therefore, the North East region of the U.S. would be considered above average compared to the other regions. The purpose of the study was to determine consumer awareness of the risk of counterfeit pharmaceuticals. Due to the fact that this study sample is assumed to be above average, this study limitation cannot apply a generalization from the findings to the broader population of the United States.

This descriptive quantitative study utilized a questionnaire as the tool to collect data from the respondents. While this questionnaire did include 10 demographic questions, it did not ask which industry the respondents worked in. The U.S. Department of Labor has identified that 21
percent of the population of the North East work in the healthcare industry. Since employment industry demographics were not captured, this study is limited to utilizing the U.S. Department of Labor statistics for analytics.

Following the collection of the research data, it was determined that the demographics of study sample does not match that of the demographics of the total North East region population. For generalizations to be formed from a sample population, the sample must be representational of the total population. Due to the limitations that the sample population not aligning to the total population for the geographic area a respondent bias may exist.

**Significance**

Counterfeit pharmaceuticals are harmful products that are affecting the health and well-being of consumers on a global scale. As the U.S. FDA stated,

An individual who receives a counterfeit drug may be at risk for a number of dangerous health consequences. Patients may experience unexpected side effects, allergic reactions, or a worsening of their medical condition. A number of counterfeit products do not contain any active ingredients, and instead contain inert substances, which do not provide the patient any treatment benefit. Counterfeit drugs may also contain incorrect ingredients, improper dosages of the correct ingredients, or they may contain hazardous ingredients. (U.S. Food and Drug Administration, 2017a, Q2)

Counterfeit pharmaceuticals are harming people every day throughout the world. The World Health Organization (WHO) has estimated that between 10 to 30 percent of all pharmaceuticals are counterfeit (World Health Organization, 2016). Countries vary in the severity of counterfeit pharmaceuticals showing up in their local market due to the governing laws. The U.S. is at the lower end of the severity of the risk spectrum, though 10 percent of the prescription pharmaceutical market has been assumed to be counterfeit (World Health Organization, 2016). The most alarming aspect is that the U.S. consumer population currently does not perceive themselves to be at risk according to a study performed in 2015 (Steel, 2015).
While the U.S. FDA has implemented the DSCSA to attempt to control the pharmaceutical market, consumers are still largely unaware of the potential risk (Steel, 2015). When consumers ingest the counterfeit pharmaceuticals, not only are they putting their health at risk, but they are affecting the larger community and economy. When digesting counterfeit pharmaceuticals, the person affected runs the risk of potentially getting additional, more severe symptoms due to the hazardous ingredients consumed. Ineffective counterfeit antibiotics have proven to be one of the leading causes of resistant organisms and may have harmful effects on a wide segment of society (Williams & McKnight, 2014). The malaria vaccine situation in Nigeria is an example. Between 60,000 to 80,000 Nigerian children receive counterfeit malaria vaccines every year. These counterfeit vaccines may only contain chloramphenicol, which was just one component of the required makeup of the life-saving medicine (Malaria Foundation, 2016; Williams, 2014). Counterfeit malaria vaccines have long-term effects on the national health care system and the local Board of Pharmacies to control and regulate (Williams, 2014). If consumer health continues to erode while having been prescribed medication for their ailments, overall confidence in the healthcare system, the healthcare providers, the product manufacturers, and the pharmacists are irreparably damaged (Williams, 2014). Consumer education and communication play a vital role in combating counterfeit pharmaceuticals from a usage and policy driver point-of-view.

By gathering demographics of the quantitative study respondents, the analysis determined how to best focus the communication campaign for consumers to increase the likelihood of success for the grassroots campaign (Turner, 2015).
Summary

Counterfeit pharmaceuticals are a risk to the health and well-being to those within the U.S. and around the globe. While the U.S. market was estimated to be made up of only 10 percent of the counterfeit product, this was still a significant amount based on such a highly developed nation. The U.S. FDA has attempted to mitigate the risk of counterfeit pharmaceuticals from entering the U.S. supply chain with the Drug Supply Chain Security Act (DSCSA). The laws and policies enacted within the United States have largely neglected to inform consumers of the potential risk of receiving a counterfeit pharmaceutical (Pharmaceutical Security Information, 2016). Most consumers within the United States are ignorant of the risk of counterfeit pharmaceuticals and believe that they are safe solely because they are in a highly-developed nation (Steel, 2015). It is this largely ignored portion of the supply chain that requires greater focus. The incidents that have occurred within the borders of the U.S. that have caused its citizens to get sick or, in worst case scenarios, even cause some to die.

This quantitative research study is intended to support the development of both a consumer education policy as well as a localized grassroots campaign. As stated in the purpose statement, to explore U.S. consumer understanding as it relates counterfeit pharmaceuticals to the risk of consumption, it was important to determine why to focus on consumers.
Chapter 2: Literature Review

Governments throughout the world have identified counterfeit pharmaceuticals as a risk to the health and well-being of their citizens (Hamburg, 2010). Understanding the background and purpose of the laws of the United States (U.S.) and comparable laws in the world is not enough to understand the risk that consumers are facing; the focus needs to be on consumers. While the U.S. has been identified to be at the lower end of risk scale for counterfeit pharmaceuticals the risk still exists (World Health Organization, 2016). The potential risk to the well-being of consumers within the U.S. required examination of the current threat of counterfeit pharmaceuticals to the U.S. population and the establishment of how such a product is defined. This literature review analyzed both consumer communication programs within the U.S. in comparable industries and reviewed counterfeit pharmaceutical education programs as they exist in other countries. These literature streams establish a baseline for both the research and the methodology of this study approach.

Literature Search Strategy

To perform a thorough literature review, a well-constructed search strategy was the core of a systematic review (Monash University Library, 2017). The search strategy that was utilized to construct this literature review used a five-phase approach to searching for data. The phases included: 1) identify key concepts and terms; 2) selecting relevant databases and resources; 3) combine search terms with Boolean operators; 4) run searches in selected resources; and 5) review and refine search results (Monash University Library, 2017). The search strategy retrieves the majority of the studies that assessed the eligibility and inclusion within the literature review. The importance of developing a thorough and quality search strategy mitigates the risk of missing important information or the exclusion of data that may contradict the original
hypothesis. A well-defined methodology also reduces the likelihood of introducing a bias into the literature review (Rooney, 2015).

For this literature review, to identify key concepts and terms that support the research question, the conceptual and theoretical frameworks of the study were referenced to determine the structure of the literature review. To answer the primary research question for this study, “Are U.S. consumers aware of the risk of the counterfeit pharmaceuticals?” The literature review was broken up into four key search concepts as shown in Table 2. For each concept list, keywords derived from the research question were developed to define the preliminary searches.

Table 2

<table>
<thead>
<tr>
<th>Search Concept 1</th>
<th>Search Concept 2</th>
<th>Search Concept 3</th>
<th>Search Concept 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitions</td>
<td>Pharmaceutical products</td>
<td>U.S. pharmaceutical law</td>
<td>Communication plan</td>
</tr>
<tr>
<td>Statistics</td>
<td>Counterfeit drugs</td>
<td>U.S. counterfeit pharmaceutical law</td>
<td>Education Program</td>
</tr>
<tr>
<td>Studies</td>
<td>Counterfeit pharmaceuticals</td>
<td>Court cases</td>
<td>Marketing</td>
</tr>
<tr>
<td>Strategies</td>
<td>Counterfeit medicine</td>
<td>International pharmaceutical law</td>
<td>Marketing plan</td>
</tr>
<tr>
<td>Methods</td>
<td>Illegal pharmaceuticals</td>
<td>International counterfeit pharmaceutical law</td>
<td>Marketing program</td>
</tr>
<tr>
<td>Laws / Policies</td>
<td>Illegal medicines</td>
<td>World Health Organization</td>
<td>Information program</td>
</tr>
<tr>
<td>Regulations</td>
<td>Food and Drug Administration</td>
<td>Consumer awareness</td>
<td></td>
</tr>
<tr>
<td>Efficacy</td>
<td>European Medicines Agency</td>
<td>Consumer prioritization</td>
<td></td>
</tr>
<tr>
<td></td>
<td>U.S. Regulated Industries</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>State Board of Pharmacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Center for Disease Control</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
For these key search concepts and terms, variations of the spelling and synonyms for the terms were utilized to ensure completeness of the topic search. Another consideration during this process was the usage of singular and plural forms of the concepts.

As part of this literature review, data elements were derived from two different types of sources. The main citation databases were: Scopus, Web of Science, Northeastern Library Scholar OneSearch, Sage Journals, and Google Scholar. Any legal or court research was sourced from LexisNexis Legal Reviews database. These sources provide the content for the empirical literature and the prior studies performed on these concepts. The second source of data for this literature review was the less scholarly type of information. The stories and situational information contained within the document utilized the same key concepts and terms of the scholarly but utilized regular Google search parameters. These sources provided supporting information and background where the scholarly sources were exclusively limited to scientific data.

The methodology, key concepts, and terms, as well as the data sources, were utilized specifically to respond to the primary research question as well as the sub-questions defined in the Research Questions and Hypotheses section. While all data feeds into the understanding of the overarching research question, the different search concepts support the research sub-questions. Search concept four explored the concepts of how the U.S. consumer ranks the potential risk of counterfeit pharmaceuticals to their health and long-term safety. A combination of the different search concepts utilizing Boolean search functions expands upon the U.S. consumers understanding of counterfeit pharmaceuticals. The final research sub-question on the U.S. consumer perception of the efforts by the government to control the counterfeit pharmaceuticals in the market utilized a combination of search concepts one, two, and three.
This siloing effect of the search terms into various categories and concepts allows for the exploration of variations of the terms without being limited to select words or phrases. In combination with the Law and Policy Review as well as the Theoretical Foundation, this literature search strategy provides a comprehensive view of the background to support the primary research topic.

**Key Themes in the Literature**

It is important to examine the context for the risk of counterfeit pharmaceuticals provided by the empirical literature beyond that of the law and policy background presented in Chapter 1. Through exploration of the context of counterfeit pharmaceuticals, two key themes arose. The first theme to be examined is the concept of counterfeit pharmaceuticals in the United States market. Counterfeits within the U.S. have been flourishing and costing the industry hundreds of billions of dollars in profit every year. Though, as this theme identifies, it must be understood exactly what defines a counterfeit pharmaceutical.

The second theme that arose is an examination of the communication to consumers. The findings generated from this study are expected to add to the body of knowledge that supports the proposal of a targeted consumer based communication policy. Through this theme of the literature review, the effectiveness of communication programs in the U.S. in comparable industries, as well as the efficacy of counterfeit pharmaceutical communication programs from other countries, is explored.

**Understanding the Current Risk**

Within this literature stream, the concept of counterfeit pharmaceuticals within the United States is explored. While the U.S. supply chain is considered comparatively safe from the risk of counterfeit pharmaceuticals, it still has its flaws (World Health Organization, 2016). The New
York-based information research group, Havocscope, determined that not only are pharmaceuticals the most highly counterfeited products globally, but the U.S. receives the largest losses in pharmaceuticals over any other nation in the world. Table 3 shows the annual losses per country due to counterfeit pharmaceuticals in 2016. This literature stream not only justifies why this study is focused on the U.S. population, but also establish the baseline for defining a counterfeit pharmaceutical product.
Table 3

*Global Losses to Counterfeit Pharmaceuticals by Country – Top 25 (2016).*

<table>
<thead>
<tr>
<th>Country</th>
<th>Losses in U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>$225 billion</td>
</tr>
<tr>
<td>Mexico</td>
<td>$75 billion</td>
</tr>
<tr>
<td>Japan</td>
<td>$75 billion</td>
</tr>
<tr>
<td>China</td>
<td>$60 billion</td>
</tr>
<tr>
<td>Germany</td>
<td>$32.3 billion</td>
</tr>
<tr>
<td>Canada</td>
<td>$30 billion</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>$21.6 billion</td>
</tr>
<tr>
<td>Brazil</td>
<td>$15 billion</td>
</tr>
<tr>
<td>South Korea</td>
<td>$14.2 billion</td>
</tr>
<tr>
<td>Paraguay</td>
<td>$12 billion</td>
</tr>
<tr>
<td>India</td>
<td>$11.9 billion</td>
</tr>
<tr>
<td>Italy</td>
<td>$9.3 billion</td>
</tr>
<tr>
<td>France</td>
<td>$7.9 billion</td>
</tr>
<tr>
<td>Turkey</td>
<td>$6 billion</td>
</tr>
<tr>
<td>Indonesia</td>
<td>$4.8 billion</td>
</tr>
<tr>
<td>Hungary</td>
<td>$4.6 billion</td>
</tr>
<tr>
<td>Colombia</td>
<td>$4.5 billion</td>
</tr>
<tr>
<td>Saudi Arabia</td>
<td>$4 billion</td>
</tr>
<tr>
<td>Australia</td>
<td>$2.9 billion</td>
</tr>
<tr>
<td>Spain</td>
<td>$2.56 billion</td>
</tr>
<tr>
<td>Peru</td>
<td>$2 billion</td>
</tr>
<tr>
<td>Switzerland</td>
<td>$1.6 billion</td>
</tr>
<tr>
<td>Thailand</td>
<td>$1.31 billion</td>
</tr>
<tr>
<td>Argentina</td>
<td>$1 billion</td>
</tr>
<tr>
<td>Poland</td>
<td>$919 million</td>
</tr>
</tbody>
</table>

*Note: Adapted from Losses to Counterfeit Pharmaceuticals by Country, by Havocscape Group, retrieved from http://www.havocscape.com/losses-to-counterfeit-goods-by-country/. Copyright 2018 by Havocscape, LLC. Adopted with permission.*
Counterfeit Pharmaceuticals within the United States. The U.S. prescription pharmaceutical market is not without risk to potential counterfeit products. While there is a risk of counterfeit products in every industry, falsified pharmaceuticals are especially concerning because of the potential impact on the health and safety of consumers (Havocscope Group, 2017b). In quantifying the risk in the North America, the Pharmaceutical Security Institute (PSI) has identified that North America has become the largest area for reported incidents of counterfeit products, second only to Asia as shown by Figure 5 (Pharmaceutical Security Information, 2016).

While a majority of the U.S. consumer population perceives the prescription pharmaceutical industry to be without risk, the United States market was one of the most targeted countries for high-end counterfeit pharmaceuticals globally and has a history of some of the most
egregious cases of counterfeit pharmaceuticals (Willis, 2017). In 2005, the FDA released a statement of the indictment of three businesses and eleven individuals for conspiracy to counterfeit Lipitor (U.S. Food and Drug Administration, 2005). In 2007 and 2008, over 100 U.S. citizens were killed due to counterfeit versions of the blood thinner; Heparin (Blease, 2012). Throughout 2011 and 2012, counterfeit versions of the cancer drug, Avastin, was discovered in the U.S. market that included no any trace of an active ingredient (Weaver, 2012). In 2012, tainted steroids entered the U.S. market resulting in the death of 64 and injuring over 800 (Blease, 2012). In 2015, the U.S. FDA sent a notice to all pharmacies that counterfeit versions of Eli Lilly’s Cialis had been discovered in the U.S. market (U.S. Food and Drug Administration, 2015a).

The worst cases of counterfeit pharmaceuticals within the U.S. are associated with Viagra. Since the release of Viagra to the market in 1998, counterfeit versions of the pharmaceutical have shown up on the market. These counterfeit products have ranged from no active ingredients to reduced active ingredients to industrial chemicals and rat poison (Roizen & Wiegman, 2016). In 2016, in a single pharmaceutical arrest, over 14 million dollars of counterfeit Viagra was seized (Mackenzie, 2016). These instances clearly show the risk of counterfeit products reaching the U.S. pharmaceutical consumer and affecting their health and safety.

Many researchers have attempted to identify the source of counterfeit pharmaceuticals to establish responsibility and potentially propose policy changes that can alleviate the risk. With a large percentage of pharmaceuticals sold in the U.S. being sourced from foreign countries, the U.S. FDA has stated that it cannot make safety or quality determinations of medicines imported from foreign countries (Carr, 2014; Taylor, 2004). In 2015, the Office of the U.S. Trade Representative (USTR) reported that of all the incidents of counterfeit pharmaceuticals that it
investigated at U.S. borders, 97 percent of those products came from either China, Hong Kong, India, or Singapore (Brennan, 2016). While these four countries are easy to single out, the U.S. cannot simply halt importing pharmaceuticals from these countries without disrupting the market. China alone was the world’s third-largest producer of generic pharmaceuticals and was also the manufacturing location for many U.S.-based pharmaceutical companies like GlaxoSmithKline (GSK), Bristol-Myers Squibb (BMS), and Eli Lilly (Dennis, 2012; Mauer, 2011; Morrison, 2012). Simply cutting all ties to any specific country in an attempt to reduce the risk of counterfeit pharmaceuticals from entering the U.S. market would result in a strain on the U.S. drug supply and end up increasing the costs of the products.

A study performed by the pharmaceutical manufacturer, Sanofi, identified why counterfeiting might be on the rise in the U.S. In research performed on their behalf by an unidentified third-party, Sanofi determined that only 15 percent of U.S. consumers associated the term *counterfeit* to medical products, and that 53 percent of consumers were not even aware that counterfeit pharmaceuticals existed (Steel, 2015). The Sanofi study also identified that 74 percent of consumers that purchase medicines online did not understand that there was a risk in purchasing pharmaceuticals online (Steel, 2015). The lack of awareness of online pharmacies is an increasing concern when organizations like WHO published statistics that 50 percent of all pharmaceuticals purchased online are counterfeit (World Health Organization, 2016). The U.S. FDA also stated that 97 percent of all online pharmacies are illegal and they are in the process of prosecuting many of them (U.S. Food and Drug Administration, 2015a). The one area in which the Sanofi study was lacking was the study population was limited exclusively to Sanofi customers. The study was therefore limited in scope to those affected by the diseases treated by Sanofi drugs, and that the study population was of the economic status that was able to afford name brand products. The fact that the Sanofi study respondents were purchasing the Sanofi
branded products may skew the results on how knowledgeable the population may have been on the topic. The respondents taking a Sanofi product and taking a Sanofi survey may feel more secure about the products they are taking and therefore would be less likely to feel at risk of consuming counterfeit pharmaceuticals.

**Definition of Counterfeit Pharmaceuticals.** While it was important to understand the problem of the presence of counterfeit pharmaceuticals in the United States, it is also equally important to understand exactly how a counterfeit pharmaceutical is defined. In comparison to other industries, global counterfeit pharmaceuticals are unique in that there is not a single, universally adopted definition of a counterfeit pharmaceutical. The general theme that can be discerned from definitions of a counterfeit pharmaceutical product was that it was not the original or intended product developed by the source manufacturer of record. Standards organizations like WHO, the International Organization of Standards (ISO), and Global Standard One (GS1), and regional, country, and local level government agencies tend to have a slightly different definition of counterfeit. While this has made compliance to a global directive increasingly complicated for the pharmaceutical industry, the reason for such variations was that the laws and definitions must be appropriate to the population in which they are applied. Since not all nations adhere to the same set of sociological norms, the thought that one definition could govern any one process is problematic. Simply put, variations exist in definitions to appropriately fit the needs of the diverse cultures.

For this literature review, the definition used by the U.S. FDA is the foundation of the analysis going forward. The decision to utilize the understanding of the term counterfeit pharmaceuticals as determined by the U.S. FDA was not made due to its superiority over any other definition. The focus of this literature review being isolated to the risk of counterfeit pharmaceuticals within the U.S. requires usage of U.S. definitions. According to the U.S. FDA,
Counterfeit medicine was fake medicine. It may be contaminated or contain the wrong or no active ingredient. Counterfeit medicine was illegal and may be dangerous. The quality, safety, and efficacy of counterfeit medicines are not known. Counterfeit medicine was often sold illegally over the Internet or by illegal operators posing as licensed pharmacies. (U.S. Food and Drug Administration, 2017a, p. 1)

The U.S. FDA goes on to further classify the counterfeit medicines into five categories; Heavy Metals, Known Poisons and Toxins, Common Household Cleaners and Products, Incorrect Medicine, and No Active Ingredients (U.S. Food and Drug Administration, 2017a).

The potential risk that may arise from utilizing the U.S. FDA definition of counterfeit pharmaceuticals as a global standard is vague. While the U.S. FDA specifies that counterfeit products are products with incorrect or no active ingredients, it does not classify substandard products or chemicals as does the WHO (World Health Organization, 2017). In comparison to the rest of the world, the U.S. FDA leaves a gap in the categorization of home remedies. This was unlike the definitions included in the regulations of most African nations (Sambira, 2013; World Health Organization, 2010). The vagueness within the U.S. FDA statute was the basis for the various state BoP’s to enhance or provide additional details to define and regulate counterfeit pharmaceuticals in their state as shown in Figure 4.

Utilizing the U.S. FDA standard for the definition of counterfeit pharmaceuticals, researchers performed an analysis of the effectiveness of the application of the U.S. definition in Sudan, Africa. Sudan pharmaceutical markets have been reputed to contain the lowest quality products and the highest risk for counterfeits in the world. The Sudan researchers, Alfadl, Ibrahim, and Hassali, visited different pharmacies in different sectors of the capital. Using the U.S. standard, the conclusion was that none of the pharmaceuticals were deemed counterfeit. As part of this conclusion, the products were noted to be of poor quality or expired, but neither of those categories falls under the U.S. definition of counterfeit. Both of those categories would result in the classification of counterfeit under both Sudanian and WHO definitions (Alfadl,
Ibrahim, & Hassali, 2013). These results call into question the depth of the U.S. FDA definition. The one failure of this study was that they used a very limited sample population of one type of pharmaceutical in a single city. The researchers limited the scope of their research to only two specific pharmaceuticals and collected one of each product from each of the various sectors of the city (Alfadl et al., 2013). If they may have broadened their sample size, they may have received completely different results.

Conclusion. As the U.S. FDA continues to make counterfeit pharmaceuticals a priority for the agency, more instances have occurred. The DQSA, and more specifically the Title II: Drug Supply Chain Security Act of the law, was a good first step in attempting to control and mitigate the risk. With the DQSA in place, the United States has continued to see an increase in the number of incidents reported within the U.S. (Pharmaceutical Security Information, 2017; S.957, 2013; S.959, 2013). With an increase of 1,700 percent in incidents reported in the U.S. over the last 15 years, the U.S. consumer was at great risk of harm due to these counterfeit pharmaceutical products (Pharmaceutical Security Information, 2017). With such grave statistics like the 1,700 percent increase of incidents over the last 15 year, it would be curious to determine what that number would be with a more limiting definition of counterfeit pharmaceuticals. While the U.S. FDA definition of the term counterfeit pharmaceutical may have its flaws and weaknesses, it is the baseline for this Literature Review going forward. Baselining the concept of counterfeit pharmaceuticals supports the perspective of the review, analysis, and proposal.

Communication Programs

The focus of this literature stream was the effects of the government-lead or privately funded education and communication programs. While it was said that the average U.S. citizen has little or no influence on government policy-making, this literature stream examines successes
of going against this trend (Biron, 2014). The current philosophy was that those with financial interests and big businesses almost exclusively dominate U.S. policy-making (Biron, 2014). In Maximino’s 2014 study published in *Perspective on Politics*, he determined that not only do ordinary citizens not have any substantial power when it comes to policy decisions, but they have little to no influence on the policy at all (Maximino, 2014). This literature stream reviewed consumer education and information programs implemented within the United States in other industries that have shown some success which challenged this historical perspective. This stream also reviewed other industries because the U.S. counterfeit pharmaceutical program currently does not have an educational or information program implemented. Since the U.S. does not have an educational program to review, it was important to review those implemented in other countries. This final literature stream supported the justification of the research in part two of this dissertation.

**Consumer Education and Communication Programs.** In a WHO study on regulating medicines entitled, *Effective Medicines Regulation: Ensuring Safety, Efficacy, and Quality*, the agency identified the key elements that are required to implement an effective regulation to govern medicine (World Health Organization, 2013). Of these key elements, strong public support was second only to strong political commitment (World Health Organization, 2013). This mirrors what the U.S. FDA’s Counterfeit Drug Task Force stated in their 2004 report entitled, *Combating Counterfeit Drugs: A Report of the Food and Drug Administration* (U.S. Food and Drug Administration, 2004). Nine years prior to the WHO study, the FDA task force identified heightening vigilance and awareness of counterfeit drugs as one of the six elements required to combat counterfeits from entering the U.S. market (U.S. Food and Drug Administration, 2004). Understanding that strong public support and education was one of the key elements to effective government regulations was in direct contrast to a Sanofi study which
states that 53 percent of the study population was not even aware there are counterfeit pharmaceuticals (Steel, 2015; World Health Organization, 2013). If WHO stated that public support was important, but over half of a study population was not aware of the risk, the U.S. FDA lacks one of the key elements to successfully supporting a regulation to mitigate counterfeit pharmaceuticals. It becomes apparent that education of consumers is required for there to be a chance for the government policies to reduce the number of counterfeits from coming into the U.S. market.

To combat the lack of consumer awareness, the U.S. FDA implemented a portal for reporting suspect products to allow any consumer with a concern to self-report an incident (U.S. Food and Drug Administration, 2016a). The reporting portal was not accompanied by a marketing campaign to publicize it. While there was not a direct marketing campaign from the U.S. FDA to inform consumers about counterfeit pharmaceuticals, the tobacco industry saw an overabundance of marketing campaigns by the U.S. FDA. Tobacco was the closest comparable industry in the United States to the pharmaceutical industry that had an already established education or communication program in place. Both end products contain active ingredients, they are both considered a drug, and they both have positive and negative side effects (Baz-Lomba, Salvatore, Garcia-Lor, Bade, Castiglioni, Castrignano, Causanilles, Hernandez, Kasprzyk-Hordern, Kinyuna, McCall, Van Nuijs, Ort, Plosz, Ramin, Reid, Rousis, Ryu, de Voogt, Bramness & Thomas, 2016). The U.S. FDA launched the campaign, thetruth.com, in 1999 to inform consumers about the risks of smoking. In 2008, the University of Michigan performed a research study on the efficacy of the anti-smoking campaign. The results of this study determined that the campaign supported a decline of teenage smokers by 17 percent between 1999 and 2008 as shown in Figure 6 (Meyer, 2008).
A report published by journalist Paul Toscano from CNBC, identified how pharmaceutical manufacturers perspective. According to drug manufacturer, Novartis, larger manufacturers believe they were required to inform patients (Toscano, 2015). Pfizer has been at the forefront of this initiative to inform patients. Pfizer has been investigating hundreds of counterfeit cases and was the first major pharmaceutical company to open its secure online pharmacy (Gillette, 2013; Isidore, 2013). The one area that manufacturers struggle with in their attempt to inform consumers without creating alarm and causing panic. A study on consumer buying habits performed at the University of Hong Kong by Dr. Biying Shou, showed that disruptive events in any one industry may never directly affect the supply chain, but there was a direct correlation with consumer spending. As a result of informing consumers of a potential shortage of a product or a potential crisis concerning a specific product, consumers are more likely to either consume unusually large quantities of the product or completely avoid the

product altogether, depending on the type of news they are receiving (Shou, Xiong & Shen, 2012).

While manufacturers and facets of the pharmaceutical industry may be leading the charge in place of the U.S. government for informing consumers, there was still a major role for the government to take. A study by research fellow David Muhlhausen (2014), of the Heritage Foundation Center for Data Analysis, concluded that federal social programs are the driver behind consumer information and has been found to be the catalyst for forming societies. Even when the programs were incorrect, they greatly modified perceptions and consumer buying habits. Muhlhausen noted the perfect example of the consumption of eggs. Federal programs have changed consumer thoughts on whether the consumption of eggs is bad or good for their health multiple times and demand for the products changed with the message from the government (Muhlhausen, 2014). This type of market influence by the Federal government needs to be utilized to mitigate the counterfeit pharmaceutical problem.

Informed consumers are the goal of making a change, while panicked users are detrimental to this program. There was a fear that informing consumers may have an extreme effect and may cause them to stop buying pharmaceuticals altogether (Toscano, 2015). Globally, public awareness of the detrimental impact and severity of the counterfeit pharmaceutical problem has increased markedly, as the media, policy institutes, and nongovernmental organizations worldwide have raised concerns to unprecedented levels (World Bank, 2007).
Global Counterfeit Pharmaceutical Communication Programs. While the U.S. is currently at the lower end of the risk spectrum for counterfeit pharmaceuticals entering the U.S. market, the rest of the world has been dealing with higher volumes of the counterfeit pharmaceuticals for a longer period of time. WHO recommends the need for public awareness on the growing trade in counterfeit pharmaceuticals and the public health risks associated with it (Burns, 2006; Nsimba, 2009; World Health Organization, 2013). However, information on public awareness on counterfeit pharmaceuticals and the ability to identify counterfeit pharmaceuticals was scarce. Without an accurate picture of the security of the medical supply chain, it was difficult for governments to crack down on pharmaceutical counterfeiting.

A study performed by Sarah Kollmorgen of the Global Health Policy Institute was the first global-scale assessment of pharmaceutical counterfeiting. The study found that counterfeit pharmaceuticals turned up in a range of settings: from small community pharmacies providing anti-malarial pharmaceuticals to U.S. clinics providing anticancer treatment (Kollmorgen, 2015). From 2009 to 2011, the study counted 1,799 different types of counterfeited pharmaceuticals reported in 1,510 incidents. These reported incidents encompassed a range of violations and quantities reported worldwide. For example, customs officials unearthing multiple counterfeited pharmaceuticals would be counted as a single incident (Kollmorgen, 2015). The study emphasizes the need for a standardized procedure and system for reporting counterfeit medicine worldwide. The majority of counterfeit pharmaceuticals identified in the study, roughly 53 percent of those identified, fall under the category of lifesaving-related pharmaceuticals according to the study (Kollmorgen, 2015).

A study performed by the Malaria Foundation (2016) determined that over one-third of all malaria vaccines sold in Africa are fake. This fake terminology was equivalent to the U.S. FDA definition of counterfeit medicines. While malaria runs rampant throughout Africa,
patients have to assess the risk of possibly receiving a counterfeit vaccine and potentially dying from the vaccine against not receiving aid and dying from the disease (Malaria Foundation, 2016). Throughout Africa, fake malaria pharmaceuticals are a great threat to the health of the citizens of each nation, but this threat has doubled in countries with great amounts of political corruption like Tanzania (GAN Business Anti-Corruption, 2016). Corruption was pervasive throughout Tanzanian society and was a serious problem across all sectors of the economy (GAN Business Anti-Corruption, 2016). The most affected sectors are government procurement, land administration, taxation, and customs. Foreign companies have identified petty corruption among Tanzanian customs officers as an obstacle to investment. In effect, bribes and irregular payments are exchanged when importing and exporting pharmaceuticals in the country (GAN Business Anti-Corruption, 2016). In a similar study, Linus Mhando, and a team of researchers from Tanzania, attempted to understand how aware the citizens of Tanzania were of counterfeit pharmaceuticals and if they could distinguish a counterfeit (Mhando, Jande, Liwa, Mwita, & Marwa, 2016). As Mhando established, information on public awareness and ability to identify counterfeit pharmaceuticals was scanty. The study aimed at assessing public awareness and the ability to identify counterfeit antimalarial pharmaceuticals based on simple observations such as the appearance of the pharmaceuticals, packaging, labeling, and the actual label itself. Their sample respondents (190 citizens) received government provided information packets before the test. While their results did not give the exact percentage, Mhando concluded that a substantial proportion of respondents were able to distinguish between genuine and counterfeit antimalarial pharmaceuticals (Mhando et al., 2016). This study performed in an “in-transit” nation like Tanzania proves that public empowerment and education in identifying counterfeit pharmaceuticals by simple observations was a major step towards discouraging the market of counterfeit pharmaceuticals. While this product sample was exclusive to malaria
pharmaceuticals and does not speak to the overall presence of counterfeit pharmaceuticals within the country, antimalarial vaccines are the most used pharmaceuticals in tropical African countries like Tanzania which have a high burden of malaria and other infections/infestations (Mullaicharam, 2011; Onwujekwe, Kaur, & Dike 2009).

Tanzania was not the only African country attempting to initiate a program or study like this. The Director-General of the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC), Dr. Paul Orhii, has initiated a massive public awareness campaign within his country (Ojeme, 2010). Dr. Orhii advocated for the collaboration of all respondents in the Nigerian supply chain and promised to work with all to improve the quality of products in Nigeria (Ojeme, 2010). Nigeria was one country whose pharmaceutical system has been impacted by corruption and has struggled to curtail the production and trafficking of substandard pharmaceuticals (GAN Business Anti-Corruption, 2017). In 2001, the NAFDAC underwent an organizational restructuring resulting in reforms to reduce counterfeit pharmaceuticals and better regulate pharmaceuticals (Cohen, Mrazek, & Hawkins, 2007). Despite these changes, there was still room for improvement. In a study by Habibat Garuba on the perceptions of policymakers in Nigeria in regards to the transparency in the pharmaceutical sector, Mr. Garuba assessed the perceived level of transparency and potential vulnerability to the corruption that exists in four essential areas of Nigeria’s pharmaceutical sector: registration, procurement, inspection, and distribution. (Garuba, Kohler, & Huisman, 2009). The most glaring deficiency identified as a result of this study was the absence of conflict of interest guidelines which, if present and consistently administered, would limit corrupt practices (Garuba et al., 2009). What was most critical from this study was the identification of areas that remain permeable to corruption and, perhaps, more appropriate checks and balances from the Nigerian government and the international community (Garuba et al., 2009). In an attempt to reduce the risk of counterfeit
pharmaceuticals within Nigeria, pharmaceutical experts from Kuala Lumpur, Malaysia, and Jakarta, Indonesia, held a seminar on the basics of this illegal practice was conducted in Nigeria. Awareness programs discussed during this seminar are moot and strictly academic with inadequate or nonexistent international and national policies (Anderson, 2016b). Both Tanzania and Nigeria known for having corrupt governments that abuse power for private gain, only Tanzania has improved while Nigeria continues to decline (Transparency International, 2017). Corruption was identified as one of the major reasons for the growth of counterfeit pharmaceuticals in Nigeria. Other reasons included inadequate legislation, ineffective enforcement of existing laws, non-health professionals in the pharmaceutical business, loose control systems, the high cost of pharmaceuticals, greed, and ignorance (Erhun, Babalola, & Erhun, 2001). In a study performed by NAFDAC (2007), public awareness campaigns showed the circulation of counterfeit pharmaceuticals reported to have been reduced by over 80 percent from what it was in 2001 (National Agency for Food and Drug Administration and Control, 2001; National Agency for Food and Drug Administration and Control, 2007). Unregistered pharmaceuticals in circulation were reduced from 68 percent to 19 percent, and the production capacity of local pharmaceutical industries increased tremendously (National Agency for Food and Drug Administration and Control, 2001; National Agency for Food and Drug Administration and Control, 2007). While these statistics are extremely positive, note that NAFDAC was a Nigerian government agency known for its lack of transparency and abuse of power (GAN Business Anti-Corruption, 2017). While these results are positive, studies performed in 2004, just three years after the NAFDAC studies, identified that 40-50 percent of the pharmaceuticals available in Nigeria were still counterfeits (Morris & Stevens, 2006; Nnani, 2001).

In another area of the world, China has developed a reputation for exporting fake and dangerous goods from pesticides, to fatal diet pills, cold medicine and Heparin which was
reported to have killed 81 in the U.S. in 2008 (Kuo, 2013). In April 2009, the China State Council approved the establishment of an inter-ministerial cooperative taskforce for combating counterfeit pharmaceuticals (Sun, 2012). The task force initiated public education programs to raise the awareness of basic medical and medication knowledge and guided the public to acquire medical treatment through legitimate channels. Through education campaigns, the committee was said to have raised consumer awareness of drug-related legal knowledge, and consumer ability in the identification of counterfeit pharmaceuticals (Sun, 2012). The State Food and Drug Administration (SFDA) at all levels of the agency participated in the opening of the mailbox, answering the hotline, emails, and website for counterfeit pharmaceutical complaints. Awards compensate counterfeit pharmaceutical information providers. In fact, raised awareness of patients, lower price of pharmaceuticals, policy support from pharmaceutical regulatory units and using effective legal tools are all effective solutions for the rampant counterfeit pharmaceuticals in the market (Sun, 2012). As part of the China State Council initiative, pharmaceuticals stores throughout China and its regions are required to advertise assurance that they do not sell fake pharmaceuticals on their store signs (Ossola, 2015).

Overall, studies have reported China as having the largest number of counterfeit incidents, followed by Peru, Uzbekistan, Russia, and Ukraine (Kollmorgen, 2015). However, countries such as China already have a reputation for counterfeit pharmaceuticals. Because of this perception, agencies might be looking for counterfeit pharmaceuticals which result in a higher than average incident rate. The countries and the counterfeit statistics would look different with more accurate reporting (Kollmorgen, 2015).

Pharmaceutical quality was currently receiving growing international attention. Over the past decade, public awareness has sharpened with the existence of counterfeit and substandard medicines especially in developing countries where pharmaceutical regulations remain
ineffective. Mass media received thousands of reviews revolving around the topics of fraud medicines, the methods used and strategies being done to take down the people behind it. (Anderson, 2016a).

**Conclusion.** As the literature has shown, consumers might not directly affect the government policies, but they have affected the economic landscape (Shou, Xiong & Shen, 2012). When the government has created consumer information programs, consumers have responded (Meyer, 2008; Toscano, 2015). While the U.S. has not attempted a campaign for counterfeit pharmaceuticals yet, we have seen the effects of the efforts of other countries (Kollmorgen, 2015; Malaria Foundation, 2016). Educational and information programs do have an impact on the industry which in turn affects state and Federal government.

**Summary and Conclusions**

As these literature streams have identified, the background and purpose of the laws within the U.S., as well as comparable laws in the world, were not enough to mitigate counterfeit pharmaceuticals from entering the U.S. economy. The U.S. imports 80 percent of all the pharmaceuticals consumed domestically (Altstedter, 2017; U.S. HELP, 2011a). In 2015, four of the top five sources of pharmaceutical imports came from Europe which puts stress on the European FMD. Ireland, Germany, the UK, and Switzerland all top the highest value of exporters of pharmaceuticals into the U.S. (Altstedter, 2017). The current state of counterfeit pharmaceuticals within the United States sources its products from other highly developed economic countries. When conceptualizing counterfeit pharmaceuticals, it must come with the understanding that these products originate from developed nations and not in-transit or under-developed nations. In a case study on counterfeit cancer pharmaceuticals entering the U.S.
market, the counterfeit pharmaceuticals were trafficked through Europe before they enter the U.S. (Pharmaceutical Research and Manufacturers of America, 2017).

Part of the problem is that a single definition of counterfeit product does not exist. Both the U.S. and the EU have defined this term, but it varies from country-to-country or standards organization-to-organization. For this study, the definition of the term “counterfeit” as defined by the U.S. FDA was most appropriate because it was the location the study was performed. But part of what must be understood was that while this study used the U.S. FDA definition, it does not apply 100 percent to the countries that are exporting pharmaceuticals to the United States.

With it stated that it is important to focus on the risk of U.S. counterfeit pharmaceuticals, this literature review needed to explain the focus on consumers. The average U.S. citizen has little or no influence on government policymaking; the empirical literature review identified that consumers could affect the economics of the industry (Biron, 2014). Consumers can modify the industry purely based on whether or not the government policies are put in place to restrict or restrain the industry and its negative effects (Biron, 2014).

As this literature review has shown, the policy enacted within the United States has not provided adequate coverage to ensure that the health and safety of consumers from counterfeit pharmaceutical products. Based on the analysis of the DSCSA, the policy was not focused on counterfeit medications or consumers (S.959, 2013). Consumer awareness plays a key role in the mitigating risk of the counterfeit pharmaceuticals as shown through various studies (Maximino, 2014). Understanding the pharmaceutical consumers within the U.S. was instrumental in determining the approach to education. Unfortunately, most consumers within the United States are not aware that 10 percent of all pharmaceuticals they are consuming are counterfeits (Steel, 2015; World Health Organization, 2016). A descriptive quantitative study to explore U.S. consumer’s understanding as it relates counterfeit pharmaceuticals to the risk of
consumption, controlling for over-the-counter medicines for any pharmaceutical consumer within the United States, is important to develop a targeted plan to educate consumers. As explained as part of the communication programs literature review stream, these educational policies have proven to be successful with consumers based in the United States for other relatable products.

Throughout the literature review, it was apparent that additional research was required to understand the risk of counterfeit pharmaceuticals. While research exists on counterfeit pharmaceuticals, it is limited in scope. A broader customer and product population was required to understand the perceived risk of counterfeit pharmaceuticals in order to address consumer needs.
Chapter 3: Methodology

The purpose of this descriptive quantitative study was to explore United States (U.S.) consumer level of awareness of the risk of consuming counterfeit pharmaceuticals. The study is limited to prescription and over-the-counter pharmaceuticals for any adult consumer 18 years or older within the North East region of the United States. Findings generated from this study are expected to add to the body of knowledge that supports the proposal of a targeted consumer-based communication policy regarding counterfeit pharmaceuticals.

As described throughout the literature review, most consumers within the United States are not aware that 10 percent of all pharmaceuticals they are consuming are counterfeits (Pharmaceutical Security Information, 2016; World Health Organization, 2010). While the United States Food and Drug Administration (U.S. FDA) has taken steps to mitigate the risk of counterfeit pharmaceuticals from entering the U.S. market, consumers are left unaware of the growing risks (Steel, 2015). It must be examined whether the law that was enacted within the United States to control the pharmaceutical supply chain from counterfeits has appropriately informed consumers regarding the risk to their health and well-being. This aspect of informing consumers and heightening their awareness of the risks of counterfeit pharmaceuticals was previously identified as a key element in the mitigation strategy by the U.S. FDA (U.S. Food and Drug Administration, 2004).

The methodology for this study describes the targeted respondents analyzed, the targeted sample population, as well as the study approach. Since counterfeit pharmaceuticals have the potential to affect a large portion of the U.S. consumers, a quantitative study was the most efficient way to collect data and make observations with measures that can be scored objectively (Pyrczak, 2014). This targeted sample selection, and the procedures used to recruit them, are
detailed in this methodology section. Following the recruitment of the respondents, the procedures for data was collection and analysis are presented.

**Research Design and Rationale**

Quantitative and qualitative research are commonly considered to differ fundamentally (McLeod, 2017). The objectives and the application of the different methods overlap in numerous ways. Quantitative research was considered to have as its main purpose the quantification of data (Yilmaz, 2013), allowing for generalizations of the results from a sample from the entire population and the measurement of the incidence of various views and opinions in a given sample. This method aligns with that of the social choice theory, identified in the theoretical foundation section of Chapter One, which utilizes a single individual response to build assumptions for the larger community. Quantitative research is infrequently followed by qualitative research that would aim to explore select findings further. Qualitative research is considered to be particularly suitable for gaining an in-depth understanding of underlying reasons and motivations (Yilmaz, 2013). Qualitative provides insights into the setting of a problem. At the same time, qualitative research also frequently generates ideas and hypotheses for later quantitative research. The main differences between quantitative and qualitative research are related to data sample, data collection, data analysis, and last, but not least the desired research (Yilmaz, 2013).

Qualitative research would allow for narratives and gathering of underlying reasoning; it strays from the ability to determine statistics and correlations between variables (Suter, 2012). With quantitative research, determinations are derived from a sample of the populations based on the fact that they are all responding similarly to the same questions (Simon & Goes, 2012). But the questions remains, what was a proper population sample when it comes to health and
understanding of risk. According to Simon and Goes (2012), there is no such thing as a sample population. Populations, no matter how large or small the participation rate, are still a population of individuals or items that share one or more characteristics from which data can be gathered and analyzed (Simon & Goes, 2012). With sampling size, prioritization of certainty or precision needed to be established as well as the tolerance for risk. The tolerance for risk is especially important given limitations to time and the availability to the sample population. As this research study consisted of descriptive methods, the research required more precision over certainty.

The study utilized a questionnaire as the tool to collect the data. The usage of a questionnaire over a survey as the collection method was based on the intent of the study. To perform an analysis of the responses from the sample population, a questionnaire with a set list of answer choices allows for consistent responses in which statistical analysis and correlations can be drawn (PEW Research Center, 2018). In comparison, a survey allows for the measurement of experiences and opinions from the population with no consistency among the responses. The usage of the survey as a tool would have required an interpretation of the answers which may have resulted in the inclusion of a bias.

**Methodology**

For this descriptive quantitative study a questionnaire was implemented to capture the data from the respondents. The questionnaire included a total of 25 questions that supported each aspect of the research question to determine the U.S. consumer level of awareness regarding the risk of counterfeit pharmaceuticals (see Appendix D).

An approved LinkedIn article discussing the research as well as the link to the descriptive quantitative questionnaire was published to the target audience. To develop generalizations from the findings for the total population, the study required a sample population in which the
respondent demographic such as sex, economic stature, age, and ethnicity were representative of the total. With a total adult population over the age of 18 at 44,619,710 in the North East, a confidence level of 95 percent based on the standard for quantitative studies, and a confidence interval of 5, the desired sample size of 384 was required for the study to be statistically significant (Creative Research Systems, 2017; Simon, 2012; United State Census Bureau, 2013).

Using volunteerism to select the sample population, the questionnaire was administered to the pharmaceutical consumer via Qualtrics. This method of sampling resulted in a wide range of consumers that were both pharmaceutical industry experts and average consumers. This variety of consumers allows for causal inference to the characteristics of the population to the awareness of counterfeit pharmaceuticals (Xie, 2013). The usage of the LinkedIn application provided the population of pharmaceutical industry experts as well as those from other industries that were potentially unaware of the risk of counterfeit pharmaceutical within the United States.

Qualtrics was utilized as the tool that collected and performed basic data analysis. Qualtrics was a secured cloud system with access to the system controlled by a single ID and password. This system ensures that no one outside of the primary researcher has access to the data. The professional version of Qualtrics also included basic data analysis but allowed for data exporting into Excel for correlation analysis via the Analysis Toolpak.

**Positionality Statement**

As a doctoral researcher, I relate to the issue of the presence of counterfeit pharmaceuticals in the U.S. market from several perspectives. Each point of connection has enhanced and broadened my approach to the research topic in different ways. In relation to counterfeit pharmaceuticals, I approach this topic from the aspect of the consumer, from the aspect of a member of the pharmaceutical industry, and from the aspect of a member of our
global society. I had to define the positionality of each of these to describe appropriately the inner turmoil brought about by my thesis topic.

**The Pharmaceutical Industry**

One of the greatest constraints going into this study was the potential conflict of interest that may or may not exist because I work for a large pharmaceutical manufacturer. I approach counterfeit pharmaceuticals from a profit and loss point-of-view as any business person would. Counterfeit products are a burden on the pharmaceutical industry, and they are taking money away from the corporation that spent many years and many billions of dollars developing them. When it comes to the corporate point of view, I view counterfeit pharmaceuticals not as an "evil" that is harming society, but as another competitor that was stealing market share. Yes, the corporation always has the patient at the forefront of consideration, but second to that has been the strategy to increase market share. When it comes to counterfeit pharmaceuticals, the corporation struggles to determine the best approach. In a traditional market, Company A attempts to get more customers than Company B. With counterfeit products; corporations are competing against themselves because the customers all believe they are purchasing from company A when they are really purchasing from company A2, or the counterfeiter. Because of counterfeit pharmaceuticals, corporations now have to spend millions of dollars above and beyond the cost of developing the pharmaceutical to comply with laws that may not mitigate or reduce the risk of counterfeit products getting into the supply chain. Corporations have to start being more proactive if they want to take their market share back from the counterfeiters like Pfizer has been doing (Gillette, 2013; Isidore, 2013). Pfizer has performed more counterfeit pharmaceutical busts in the last year than the U.S. government had. Why did this happen? Some might infer that it is because Pfizer cares about making a profit and the U.S. government does not care if Pfizer makes a profit (Gillette, 2013; Isidore, 2013).
Member of the Global Society

My involvement with both ISO and the UN have broadened my understanding of the unfortunate situations going on in regions like Africa and the Middle East. Working with different standards, societies, and industry experts for pharmaceuticals around the globe, I’ve been impacted emotionally by the struggles that people experience due to counterfeit pharmaceuticals. In some areas of Africa, it is estimated that as much as 70 percent of the pharmaceuticals on the market are counterfeit (World Health Organization, 2016). Consumers throughout Africa are deciding to deal with diseases rather than die from the pharmaceuticals that are supposed to help them. Women and children are dying every day from counterfeit pharmaceuticals (Malaria Foundation, 2016). Consider the example of malaria vaccines. The estimate was that a child dies from malaria every 45 seconds and that only one in three malaria vaccines administered are the actual product (Malaria Foundation, 2016). These diseases can be cured, but poisons are being administered instead of cures.

The Consumer

At the end of the day I am also a consumer of pharmaceuticals. Because I am aware of the situation, I have to be concerned with the risk of purchasing pharmaceuticals and giving them to my children. I was one of these uninformed consumers at one point in my life. I did not become educated until the "worst-case scenario" occurred and I consumed a counterfeit product. I had a severe reaction to the medicine administered to me by the hospital from what was supposed to be my regular medicine. An investigation of the situation determined the injections were counterfeit and contained harmful elements. I was fortunate to recover. From that point forward, I have spent my time trying to work within the supply chain to remove counterfeit products as well as informing the ill-informed U.S. consumer.
From these three, different point-of-views, my positionality to this research has taken on many different faces in articulating my bias which comes from a personal position, from an *insider* from the industry position, and a position of someone who was aware of the global crisis related to counterfeit pharmaceuticals. While any one of these point-of-views may result in a researcher bias, the validation of the questionnaire using third-party auditors eliminate most of the bias that may have been inherited from the researcher.

**Population Selection**

A biased sample, in which not all members of the North East were likely to be included in the research if they were not on LinkedIn, was obtained utilizing volunteerism as the approach to gathering the data (Cortes, Mohri, Riley & Rostamizadeh, 2008; Patten, 2014b). For the volunteerism sampling, the questionnaire was made available to any pharmaceutical consumer via LinkedIn using Qualtrics as the tool to create the questionnaire instrument. Volunteerism resulted in a wide range of knowledgeable and common knowledge consumers with causal inference to the characteristics of the population to the risk awareness (Xie, 2013). This causal inference supports the conclusion that demographics may possibly cause a lack of understanding of the risk or cause someone to be more at risk. LinkedIn, used as the interface to obtain the sample, provided a dynamic population of pharmaceutical industry experts as well as those from industries unrelated to the health profession.

To understand the overarching research question, “Are U.S. consumers aware of the risk of the counterfeit pharmaceuticals in the U.S.? the sample population could potentially have to be representative of the entirety of the United States. A comprehensive analysis of the entire population of the U.S. was not feasible for this, or any other, research study (Kalton, 1983). To perform a study on a heterogeneous population such as pharmaceutical consumers the population
within the North East region of the United States was utilized to scale the sample (Xie, 2013). With an adult population of over 44 million, the North East region of the U.S. not only had a sufficient population basis for this study but was also the home of four of the world’s largest pharmaceutical manufacturers (Christel, 2017; U.S. Census Bureau, 2017).

The sample size for this research study was 442. The major concern in the sample size was that it would be large enough that it can represent the population to establish the inference (Simon, 2012). For this study, the adult population is over 44 million in the North Eastern area. Utilizing the adult population of the North East, a confidence level of 95 percent based on the golden standard for quantitative studies, and a confidence interval of 5, a sample size of 384 was required for the study to be statistically significant (Creative Research Systems, 2017; Simon, 2012). This statistically significant sample size is calculated using the equation Necessary Sample Size = (Z-score)^2 * StdDev*(1-StdDev) / (margin of error)^2 (Qualtrics, 2018). In this case, the confidence score of 95 percent corresponds to a Z-score of 1.96 (Qualtrics, 2018).

Increasing the sample population to a minimum of 400 allowed for a slightly greater degree of precision to reduce the risk of the study. When the population size was of a certain, unobtainable size (at approximately n>5,000), the population itself becomes almost irrelevant. In most cases of N>5,000, a minimum sample size of 400 was considered adequate (Simon, 2012).

**Procedures for Recruitment and Participation**

For this descriptive quantitative research study, respondents were recruited utilizing the social media platform LinkedIn. An article was published on the social media platform that explained the intent of the study, the estimated duration to complete the study, and how the data would be used (see Appendix B), and included a link to the Qualtrics questionnaire. The article was published on the open LinkedIn forum for any member of the site to read and volunteer to
participate. Following the original publishing of the study article, the article was republished every five days until the required sample population was achieved. A link to the article was also directly sent to any member of the primary researchers LinkedIn network as approved by the Institutional Review Board. During the seven week period that the study was conducted, the LinkedIn network continued to expand. As the network expanded, new members received a note of gratitude for joining the network as well as the link to the LinkedIn article for the study (see Appendix B).

**Data Collection**

Upon Institutional Review Board (IRB) approval to commence data collection, the approved article directed respondents to the Qualtrics questionnaire was published to LinkedIn (see Appendix B and D). Between the dates of February 13, 2018, and April 2, 2018, 677 respondents completed the study questionnaire. A sample of 442 questionnaires were selected from the data collected. Responses were filtered out of the sample population to adhere to the scope and delimitations of the study. Collection of the 400 required responses was completed on Saturday, March 3, 2018. The questionnaire was closed on Monday, April 2, 2018, after collecting 442 responses that fell within the study inclusion criteria. Beyond the 442 responses that would be analyzed for this quantitative study, a total of 677 responses were submitted during the period of seven weeks. The 235 responses that were excluded were either international, from states that were outside of the North East, or from respondents that said they have never consumed a pharmaceutical product.

During data collection, responses were reviewed on a daily basis over the seven week period to determine if the respondent could be included for analysis for the findings. Utilizing the LinkedIn social network as the interface to the study resulted in respondents outside of the
targeted demographics. Inclusion questions were integrated into the questionnaire to eliminate these out-of-scope respondents and support the data validity process. Three questions were included that provided a filter to determine data validity. Since this research was exclusive to the North East region of the United States, two questions were included to filter the responses. The first question was, “Are you from the United States?” This initial question filtered the population from those that live abroad. This question was closely scrutinized during initial reviews due to the structure of the wording. It was questioned whether the phrasing of this question would exclude Americans living abroad or include foreigners that have become U.S. citizens. Either one of those potential populations could skew the results of the questionnaire. After analyzing the structure of the question, it was determined that the collection of results beyond the required 384 would mitigate any potential discrepancy that this might cause. Once understanding if the respondent lived in the United States, the second filter question was, “If you are from the United States, in which state do you live?” Again, the wording here was very specific and intentional. Most consumers develop their buying habit as adults. Therefore, it was important to understand where the respondent currently lived as an adult and not which state they were from.

The last filtration question was, “Have you ever consumed a pharmaceutical (prescription and over-the-counter)?” The purpose of this question was to identify if they are an actual consumer of pharmaceuticals or not. If the respondent answered in the negative, the response would then be excluded since they do not have any interactions with the products. The respondent also had the option of selecting “Not Sure.” These responses were included because it was assumed that if the respondent selected this answer, it means they do not really know what a pharmaceutical was but they have consumed something. If the respondent responded with an answer outside of the intended scope of the research, the questionnaire would automatically end,
and the respondent would not have to complete the remainder of the questionnaire. Since these responses were outside of the scope, the IRB did not approve this data to be collected, and therefore it would be unethical to have the respondent continue with the questionnaire. The only data that was maintained were the answers up to the point of questionnaire closure.

**Data Analysis Plan**

For this quantitative analysis, a five-step approach was utilized to demonstrate the chain of evidence for the discussion of the data. These five steps as based on the processes outlined by John Creswell (Creswell, 2014).

**Step 1: The Sample.** The first step in analyzing the data is to identify the respondents. While the exact identities of the respondents remain anonymous, the characteristics of the participants need to be analyzed to determine how to recommend future policy changes. As part of the report on the sample population, a tabular representation of the data was developed to describe the elements that were collected. As part of this analysis, the demographic data described the respondent's gender, age range, ethnicity, geographic origins, education level, marital status, employment status, and salary level. These independent variables were utilized later in the analysis to develop an inference to the dependent variable of consumer understanding. Both respondent and non-respondent data were analyzed to establish the respondent bias.

**Step 2: Bias Determination.** Following the establishment of the respondent demographics, the determination of the existence of the respondent bias was analyzed. Included in this bias analysis was the identification of the non-respondents potential to substantially change the overall results of the study (Creswell, 2014). A wave analysis for the study determined that over the period of seven weeks the average response rate remained consistent for
all demographics excluding the geographic locator in comparison to the statistics published by the U.S. Census Bureau.

Step 3: Descriptive Analysis. Establish the mean, standard deviation, and range of scores for each of the independent and dependent variables for the study. To establish the mean (M) and the standard deviation (S) a cross-tabular presentation of the independent and dependent variables was utilized.

Step 4: Major Inferences. To establish major inferences between the research questions and hypothesis against the variables statistical testing was performed. These statistical tests included the t-tests and ANOVA test to compare a group of two or more outcomes, chi-square testing to determine associations between two different variables, and the Pearson product moment correlation to establish the magnitude and direction of the association between two variables measured at specific intervals (Creswell, 2014). The variables measured within these statistical tests included both the continuous scores and the categorical scores.

Step 5: Presentation of Data. Provide the results of the statistical tests and descriptive analysis in table and figure form. Utilizing the suggestions of the American Psychological Association (APA), reporting of the data included extensive descriptive analysis, statistical significance testing, establishing confidence intervals, and determining effect sizes (Nicol & Pexman, 2011).

The results of the data analysis were utilized to determine the three outcomes of the study. The data developed a risk profile of what the U.S. consumers classifies and identifies as the most potential impact on their health and long-term safety.
Threats to Validity

With quantitative research, there are risks to the validity of the study to be considered (Simon, 2012). Validity, in this case of a quantitative study, is defined as the measurability of the accuracy to a concept (Heale & Twycross, 2015). But with a questionnaire, because of the human factor from various regions of the United States, there was a lack of reliability to the extent to which a research instrument consistently has the same results (Heale & Twycross, 2015). The questionnaire was intended to provide results aligned to the respondents’ understanding of the risk of counterfeit pharmaceuticals. Because of this, the focus of this descriptive quantitative study was on content validity to ensure that the questionnaire fully measured the intended population and content (Heale & Twycross, 2015). This content validity focused on the sub-questions of the research topic defined in the Research Questions and Hypothesis section of Chapter 1. Specifically, the demographics section of the questionnaire was the initial gating mechanism to determine inclusion and exclusion of the responses from the respondent. Utilizing volunteerism and sample of convenience resulted in respondents outside of the U.S.; the demographic information determined if the data needed to be excluded.

Theory evidence was utilized to demonstrate the research instrument had construct validity (Heale & Twycross, 2015). Under theory evidence, the demographics determined if the behavioral results of the research sub-questions align with the theoretical propositions. The hypothesis was that lower ranking of the risk by respondent would correlate to a lack of understand regarding the risk of counterfeit pharmaceuticals. As part of the analysis of this research, the correlation between these two variables determined how to implement a targeted education campaign effectively.

In terms of the quantitative method questionnaire itself, challenges can arise during the collection of this data. The first challenge, which may also present to be the greatest hurdle, was
that the collection technique would be a questionnaire. Society tends to avoid questionnaires, and in an industry like prescription pharmaceuticals, this was no different (Bowling, 2005). While there was a method of volunteerism, the task of ensuring a proper sampling of the U.S. population was a monumental task (Simon, 2012). The goal was to get a statistical representation of respondents from each state within the North East region of the U.S. The sampling based on the volunteerism was open to any and all respondents and was utilized to the sampling results.

For the questionnaire itself, based upon positionality, there was a risk of introducing a bias into the questions. Because the positionality comes from various sources, it can result in leading questions that may or may not direct the respondent to answer in such a way that they are influenced to provide the researchers desired results. The questionnaire was reviewed and analyzed by a third party to ensure the removal of leading and biased questions.

**Ethical Procedures**

Prior to performing any specific data review or analysis, any data that was outside the scope of the intended study was filtered out. In this study, three inclusion/exclusion criterion were included within the questionnaire that was published. The criterion included if the respondent was from the United State, which states that respondent was from if they were from the United States, and finally asking consumers if they had ever purchased or consumed a pharmaceutical in their life. The first two inclusion questions served to filter out the responses to just the North Eastern region of the United States. The third response focused on the respondent's personal history with pharmaceuticals. If the respondent had never interacted with pharmaceuticals, the responses to the questions would be skewed due to the respondent’s lack of involvement with the products.
Fabrication and falsification of research results is a serious form of research misconduct (Jenkins, 2011). Anticipated results that had not been observed at the time of submission of the report were not included. To preserve accurate documentation of observed facts with which later reports or conclusions can be compared, researchers have an obligation to maintain a clear and complete record of data acquired (Jenkins, 2011). For this study, the review of each response to determine if there were any inconsistencies between the answers of a specific respondent. Corrections or modifications were not made to the data once it was submitted. If the respondent had inconsistencies in the data, the specific response would be noted and removed from the data analysis. An example would be if the respondent had noted that they were unsure if they had ever consumed or purchased a pharmaceutical, but they also responded that they knew exactly where their pharmaceutical originated from prior to consumption. These types of discrepancies of conflicting answer resulted in an exclusion of the data from the analysis.

If an error was discovered within the data, either intentional or inadvertent, the investigator has an obligation to submit a correction or retraction, in the case of research misconduct, in a form specified by Northeastern University (Jenkins, 2011).

Research integrity requires not only that reported conclusions are based on accurately recorded data or observations but that all relevant observations are reported (Jenkins, 2011). It was considered a breach of research integrity to fail to report data that contradict or merely fail to support the reported conclusions. When recruiting the sample population for this study, it was done so with the specific intent to get as wide of a range of the population to assure representation of the population as a whole. Through the utilization of LinkedIn, it can be assumed that responses would be received from leading industry subject matter experts. Since these respondents would know more than their counterparts or the general public, their results could skew the analysis of the data. During a pilot quantitative study on subject matter experts
from the pharmaceutical industry performed in 2016, incorrect responses were received from “industry experts” as well as the U.S. FDA. What this shows was that even if a respondent was considered a subject matter expert does not mean that he or she would be right. Therefore, it was encouraged all respondents to respond to the questionnaire no matter what their educational or professional background may be.

**Summary**

The goal of this descriptive quantitative study was to assess the awareness of a sample population regarding the risk of counterfeit pharmaceuticals to their health and well-being. While a qualitative study would have provided unique in-depth understanding of a respondents interactions with counterfeit pharmaceuticals, this methodology is not optimum for reaching a large population. To conduct a study on a large population, a descriptive quantitative study was implemented that would allow for generalization of the findings from the sample population. The total adult population in the North East region over 44 million, a confidence level of 95 percent, and a confidence interval of 5, the desired sample size of 384 was required for the study to be statistically significant. In order to increase data validity, a total sample population of 442 was collected over a period of seven weeks.

This biased sample was obtained utilizing volunteerism to gather the data. For the volunteerism sampling, the questionnaire was made available to any pharmaceutical consumer via LinkedIn using Qualtrics as the tool to create the questionnaire instrument. Volunteerism resulted in a wide range of knowledgeable and common knowledge consumers with causal inference based on the demographics of the respondents.

To establish major inferences between the research questions and hypothesis against the variables statistical testing was performed. These statistical tests included the t-tests and
ANOVA test to compare a group of two or more outcomes, chi-square testing to determine associations between two different variables, and the Pearson product moment correlation to establish the magnitude and direction of the association between two variables measured at specific intervals (Creswell, 2014). Findings from this study were used to develop a risk profile of U.S. consumer’s classification of the potential impact of counterfeit pharmaceuticals on their health and well-being.
Chapter 4: Results

The purpose of this quantitative study was to explore the U.S. consumer level of understanding as it relates to the risk of consuming counterfeit pharmaceuticals. This study is controlled for prescription and over-the-counter pharmaceuticals. The geographic scope of the respondents is limited to the North East region of the United States. Knowledge generated from this quantitative data supports the proposal of modifications to the current policy for a targeted consumer based communication and education program.

The primary research question for this study was, “Are U.S. consumers aware of the risk of the counterfeit pharmaceuticals in the U.S.?” Since the U.S. consumers perceive themselves as being safe from harm as inferred from the independent research performed by the drug manufacturer, this overarching research question had to be broken down into subparts to properly analyze consumer awareness (Steel, 2015). Each of the subsections of this research, the demographics of the respondent, assessed consumer level of knowledge of counterfeit pharmaceutical within the U.S.

The hypothesis presented for the overall research question is that the U.S. consumer is not aware of the risk of consuming counterfeit pharmaceuticals. This hypothesis is supported by the 2015 study performed by Steel (2015). Based on the information discovered as part of the policy background as well as the empirical literature review, the pharmaceutical consumers were not included and largely ignored in the construction of the laws enacted by the United States Food and Drug Administration (U.S. Food and Drug Administration). Due to the lack of a well-structured communication or education program regarding counterfeit pharmaceuticals, the assumption is made that the common consumer would not be aware that the risk of counterfeit drugs exists.
The United States Food and Drug Administration (U.S. Food and Drug Administration) has already taken steps to attempt to control the pharmaceutical market to combat entry of counterfeit pharmaceuticals; consumers are left in the dark regarding the growing risks that they face (Steel, 2015). This research examined whether the law that was enacted within the United States, the Drug Quality and Security Act (DQSA), informed consumers and provided education on how to protect themselves.

To properly assess the level of understanding of a large population of pharmaceutical consumers within the United States, a pragmatic quantitative research strategy was adopted (Creswell, 2014). For this study, a questionnaire was utilized to reach respondents from the North East region of the United States comprised of the New England states, New York, New Jersey, and Pennsylvania (U.S. Census Bureau, 2013). A quantitative approach, utilizing descriptive and correlational methods, was deployed to analyze the relationship between the dependent and independent variables (Balnaves & Caputi, 2013; Given, 2008). A bi-variant and multi-variant analysis of the correlation between respondent demographics and the perceptions of the risk of consumption and government actions supports the determination of a potential policy approach to the counterfeit pharmaceuticals.

The social choice theory constructs determined how the relationships between the dependent and independent variables were drawn upon to establish a correlation between the individual and their effects on the community. A reflection of this quantitative data established an understanding if the respondents were focused on the collective community or their own individual dominant strategy.

Since counterfeit pharmaceuticals could potentially affect the entire population of the U.S., a quantitative study was the most efficient way to collect data and make objective observations and inferences (Pyrczak, 2014). Utilizing a questionnaire for such a large, diverse
population yielded responses easily tabulated and scored (Patten, 2014a). This information was important to understand the variables in the descriptive aspect of the quantitative research strategy (Creswell, 2014). Exploratory and descriptive quantitative data determined statistically significant correlations between the independent and control variables, the dependent, and any possible confounding variables like consumer awareness and their demographics (Creswell, 2014; Patten, 2014b).

The resulting data from this quantitative research presented in this chapter provided the basis for a risk-based, target education and communication policy regarding counterfeit pharmaceuticals.

**Response Rate**

The desired sample size for this research study was equal to or greater than 400. With an adult population of over 44 million in the North Eastern area, a confidence level of 95 percent based on the golden standard for quantitative studies, and a confidence interval of 5, a sample size of 384 was required for the study to be statistically significant (Creative Research Systems, 2017; Simon, 2012). This statistically significant sample size is calculated using the equation

\[
\text{Necessary Sample Size} = \frac{(Z\text{-score})^2 \times \text{StdDev}^2 (1-\text{StdDev})}{\text{margin of error}^2}
\]

In this case, the confidence score of 95 percent corresponds to a Z-score of 1.96 (Qualtrics, 2018). Increasing the sample population to at least 400 provided a slightly greater degree of precision to reduce the risk of the study. In the case of this study, the questionnaire remained open for an additional four weeks following the collection of the solicited 400 responses. These additional four weeks or data collection resulted in an additional 42 responses for a total of 442 in-scope responses. Figure 7 displays the total weekly response rate for both the in scope and out of scope responses.
Upon initiating data collection, the majority of the responses occurred within the first week that the article and the questionnaire were published. This initial influx of responses was provided by close or common connections within the network. The first week of data collection resulted in the largest return of out of scope responses. This was due to the fact that over half of the LinkedIn network located outside of the intended geographic area. When the research was initiated, the LinkedIn Network was just over 4,000. The original expectation was that of the potential original sample population within the network was going to yield the desired number of responses. This assumption proved to be incorrect. Of the original LinkedIn network, only nine percent of the possible population responded within the first week and the questionnaire response rate slowed considerably after eight days.

Figure 7. Questionnaire Response Rate of Total Responses.
While there was an uptick in responses in days six and seven, responses from the target respondents were nearly non-existent by day nine. The increase in participation was attributed to the republishing of the LinkedIn article that occurred every five days following the initial post as defined in the IRB application. Between weeks nine and ten, participation increased 540 percent. This new influx of responses was the result of targeted connection approach to increase the LinkedIn network from the geographic area in the scope of this study. As a result of the targeted connection process, an additional increase in the participation rate of out of scope respondents increased by 250 percent occurred during this same time period. While the additional connections targeted the North East region of the U.S., this did not equate to a dramatic increase in the response rate. Figure 8 details the response rate over the seven weeks of data collection.

![In Scope Response Rate](image)

*Figure 8. In Scope Responses – Seven Week Response Trend.*
The desired participation count of 400 was achieved 19 days following IRB approval. While the desired response count was achieved, the questionnaire remained open for an additional 30 days. The primary reason for leaving the questionnaire open beyond the intended response rate was due to the request of the potential respondents. Some respondents requested additional time to fill out the questionnaire. Since the potential respondent was kind enough to respond, the questionnaire remained open. In addition, the questionnaire remained open to increase the data validity.

**Demographic Data**

The sample population for this study was made up of pharmaceutical consumers over the age of 18 originating from the North East region of the United States. This region of the United States includes Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont according to the U.S. Census Bureau (United States Census Bureau, 2013).

With a total adult population over the age of 18 at 44,619,710 in the North East, to perform a statistically significant sample population with a confidence level of 95 percent, 384 questionnaires would have to be received. While this sample population does not appear to be of a significant percentage to the total, once population exceeds 5,000 the population itself became almost irrelevant. In most cases of n>5,000, a sample size of 384 was considered adequate (Simon, 2012). For this particular study, to increase the validity of the data, a collection of more than the mandatory 384 responses was performed. It was estimated that 400 responses would increase the validity of the data, but a total of 442 responses were collected. Of these 442 responses, if aligned to the U.S. Department of Labor statistics, 93 of the responses would have come from knowledgeable respondents within the U.S. pharmaceutical industry. Since the
respondents are sourced from a professional network, LinkedIn, the sample population had an increased likelihood of working within the U.S. healthcare industry.

An earlier study performed by a pharmaceutical manufacturer within the confines of Los Angeles, California determined that the wealthy, older, white, male population were at greater risk due to the type of pharmaceuticals that they were consuming (Steel, 2015). Due to the limited sample size of both the population and the pharmaceuticals that were being reviewed, the results may not have aligned to those of a broader community. When the primary research, in that case, it was a pharmaceutical manufacturer, is limiting the scope to align to bias, the results returned are usually more favorable to the primary hypothesis. If a sample size that is too small or limited, there is a reduction in the overall power of the study (Deziel, 2018). This limitation of scope may have increased the margin of error of the original study performed in 2015 rendering the study meaningless. With this study, the expanded population sample size broadened the geographic coverage and removed the limitations on the type of pharmaceuticals included in the study. The broadening of the study scope provided for a greater range of respondents.

The other demographic data that was excluded from this initial study was the job level. Since employment status, education level, and income levels were going to be requested; it was determined that job level could be inferred from this information and would be repetitive.

The demographic data that was collected was strategic in its collection and how it could be utilized to target the policy at a specific sub-population. Table 4 describes the demographic information collected and how it may be utilized during the policy creation.
Table 4

Demographic Data Characteristics

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Demographic Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Gender plays a significant role in how consumers may be targeted by counterfeiters.</td>
</tr>
<tr>
<td>Age Range</td>
<td>Identification of age range determined which portion of our society may be at risk due to things like consuming habits or attention span.</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Ethnicity may be a relation independent variable data point that would narrow the population that was being targeted for counterfeit pharmaceuticals</td>
</tr>
<tr>
<td>Marital Status</td>
<td>Examination of additional means of information influencing the respondent's opinion or understanding of potential risk. This demographic determined if a respondent is more likely to become aware of a risk to their health or if respondent that are part of a couple is more informed.</td>
</tr>
<tr>
<td>Education Level</td>
<td>With education level, employment status, and income level, there was an expectation that the more educated or more successful person would be more likely to be aware of the risk of counterfeit pharmaceuticals. This study examined this assumption that was derived from the 2015 study performed by the independent pharmaceutical manufacturer (Steel, 2015).</td>
</tr>
<tr>
<td>Employment Status</td>
<td></td>
</tr>
<tr>
<td>Income Level</td>
<td></td>
</tr>
</tbody>
</table>

For quantitative research, to build inferences on the data to relate a sample population to the total population, an examination of the responses against the non-responses must be performed. With this research, the responses represent the 442 questionnaires that were returned to the total population provided by the United States Census Bureau. Table 5 demonstrates the comparison between the total adult population in the North East region of the United States to that of the responses received from the questionnaire.
Table 5

Adult Population by State

<table>
<thead>
<tr>
<th>State</th>
<th>Research # (n = 442)</th>
<th>Research %</th>
<th>U.S. Census # (in millions) (n = 44.62)</th>
<th>U.S. Census %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connecticut</td>
<td>26</td>
<td>6</td>
<td>2.8</td>
<td>6</td>
</tr>
<tr>
<td>Maine</td>
<td>17</td>
<td>4</td>
<td>1.1</td>
<td>2</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>282</td>
<td>64</td>
<td>5.5</td>
<td>12</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>22</td>
<td>5</td>
<td>1.1</td>
<td>2</td>
</tr>
<tr>
<td>New Jersey</td>
<td>17</td>
<td>4</td>
<td>7</td>
<td>16</td>
</tr>
<tr>
<td>New York</td>
<td>23</td>
<td>5</td>
<td>15.7</td>
<td>35</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>14</td>
<td>3</td>
<td>10.1</td>
<td>23</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>24</td>
<td>5</td>
<td>0.9</td>
<td>2</td>
</tr>
<tr>
<td>Vermont</td>
<td>17</td>
<td>4</td>
<td>0.5</td>
<td>1</td>
</tr>
</tbody>
</table>

As Table 5 demonstrates, the sample population of the questionnaire does not completely represent the total population. In a state-to-state comparison, the responses from the state of Massachusetts represent a majority of the data while the total adult population represents a higher percentage of the population from the states of New Jersey, New York, and Pennsylvania. Due to the sample population not aligning to the total population for the geographic area a respondent bias may exist. To determine if a respondent bias exists, a wave analysis was performed on the major demographic points as shown in Figures 11 through 13.

Figure 9. Seven Week Wave Analysis - Geography.
While there are a few discrepancies in each of the wave analyses above, the statistics show that the seven-week collection of data did not include respondent bias. In all figures, week five of the data did not align with the overall average for the category. This was due to the circumstance that only two responses were received during week five. Two total results could not provide possible alignment to the overall breakdown of the respondent population. With the removal of week five from the wave analysis due to the lack of responses, the seven-week demographic data aligns with the average demographic percentages.

Table 6 contains the demographic data for the entire sample population.
Table 6

Respondent Demographic Data ($n = 442$)

<table>
<thead>
<tr>
<th>Gender</th>
<th>Connecticut (n = 26)</th>
<th>Maine (n = 17)</th>
<th>Massachusetts (n = 282)</th>
<th>New Hampshire (n = 22)</th>
<th>New Jersey (n = 17)</th>
<th>New York (n = 23)</th>
<th>Pennsylvania (n = 14)</th>
<th>Rhode Island (n = 24)</th>
<th>Vermont (n = 17)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Female</td>
<td>12</td>
<td>46</td>
<td>10</td>
<td>59</td>
<td>194</td>
<td>69</td>
<td>10</td>
<td>45</td>
<td>11</td>
</tr>
<tr>
<td>Male</td>
<td>14</td>
<td>54</td>
<td>7</td>
<td>41</td>
<td>88</td>
<td>31</td>
<td>11</td>
<td>50</td>
<td>6</td>
</tr>
<tr>
<td>Non-Binary</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>31</td>
<td>11</td>
<td>1</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Black or African American</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>8</td>
<td>3</td>
<td>2</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>9</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Native Hawaiian or Pacific Islander</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>White</td>
<td>17</td>
<td>65</td>
<td>16</td>
<td>94</td>
<td>220</td>
<td>78</td>
<td>18</td>
<td>82</td>
<td>7</td>
</tr>
<tr>
<td>Not Identified</td>
<td>4</td>
<td>15</td>
<td>0</td>
<td>0</td>
<td>8</td>
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Table 6

**Respondent Demographic Data (n = 442)**

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<th>Pennsylvania (n = 14)</th>
<th>Rhode Island (n = 24)</th>
<th>Vermont (n = 17)</th>
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Table 6

Respondent Demographic Data (n = 442)

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<td>0 0</td>
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<td>2 12</td>
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<td>3 21</td>
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<td>3 18</td>
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<tr>
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<td>37 13</td>
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<td>3 18</td>
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<td>1 7</td>
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<td>71 25</td>
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<td>0 0</td>
<td>2 8</td>
<td>5 29</td>
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The primary research question for this doctoral study was, “Are U.S. consumers aware of the risk of the counterfeit pharmaceuticals in the U.S.?” To properly assess the null hypothesis of this question to determine that no statistical significance exists between the demographics and consumer understanding of the risk within the United States of counterfeit pharmaceutical consumption, the analysis of the research needed to be divided into three separate parts to assess how the determination was made. Reviewing the data as a single, distinct unit could skew the results.

In alignment with the Conceptual Framework shown in Figure 12, the primary research question has been broken down into multiple supporting concepts to attempt to answer the question. As part of this data analysis, this findings section attempts to identify how the respondents prioritize the risk of consuming counterfeit pharmaceuticals as it relates to their long-term health and well-being, establish a baseline of how knowledgeable consumers are regarding counterfeit pharmaceuticals, and determine the perceptions of respondents of the government actions to mitigate the risks. As each of these sub-questions is investigated and analyzed, a determination as to whether there was a correlation between the demographics of the respondent and each sub-section was made. These individual sub-sections result in an inference as to whether the U.S. consumer was aware of the risk of counterfeit pharmaceuticals and support the structure of targeted communication and educational policy to mitigate this risk.
For each of the concepts shown in Table 14, questions were developed to support the overall research goal. For the first sub-question investigating how the U.S. consumer prioritizes the risk of counterfeits to their health and long-term safety, scenarios were presented to the respondent to determine the ranking of risk for various scenarios. The respondent has presented a list of scenarios and asked to determine a ranking order for the causation of most deaths during 2016. Both of these questions were asked directly following the demographic questions so that the user was not preconditioned to focus on counterfeit pharmaceuticals. Even though the LinkedIn article outlined the purpose of the study and what the research data would be used for,
the expectation was that the respondent might have omitted this following the completion of the demographic questions.

After understanding the prioritization of the risk of counterfeit pharmaceuticals, an exploration of the respondents understanding of counterfeit pharmaceuticals on the global and local market and subsequent government actions was examined. The assumption being that prioritization of the risk of consuming counterfeit pharmaceutical directly aligns with an individual’s desire to be knowledgeable. The combination of the sub-sections of the conceptual framework, an inference can be made on the understanding of consumers regarding the risk of counterfeit pharmaceuticals

Findings

The findings for this study were separated to align to the three specific sub-questions for this study. The prioritization of the counterfeit pharmaceuticals, the understanding of the counterfeit risks, and the perceptions of the respondents of the government’s actions and communications build the chain of evidence to answer the study problem statement.

Prioritization of Counterfeit Pharmaceuticals

The prioritization of perceived risk of counterfeit pharmaceuticals to the individual's health and long-term safety established an overall baseline for the average respondent. For this analysis, the respondents were posed with two separate questions regarding potential risks. Understanding what the respondents identified has the greatest risk to their health and well-being supported the understanding of how well consumers understands the risk of counterfeit pharmaceuticals.

The first scenario presented to respondents was a ranking of 15 different risks to establish the prioritization to their health and well-being. Respondent were asked to rank from 1 (highest)
to 15 (lowest) how they prioritized the following scenarios as they are a risk to their health.

Those scenarios were 1) Tobacco / Alcohol Intake; 2) Car Accident / DUI; 3) Victim of Terrorism / Hate Crime; 4) Communicable Diseases; 5) Terminal Illnesses; 6) Home Invasion / Crime; 7) Counterfeit / Fake Pharmaceuticals; 8) Vaccine; 9) Natural Disaster; 10) Allergic Reaction / Anaphylaxis; 11) Obesity; 12) High Blood Pressure; 13) Pesticides / GMO Consumption; 14) General Accident; or 15) Other. For the list of scenarios, listing Counterfeit / Fake Pharmaceuticals as the seventh option out of fifteen was strategic. Most respondents focus on the first few options within a given list and rank them as the greatest threat. If Counterfeit / Fake Pharmaceuticals was elevated to a higher ranking by the respondent, then this indicated that consumers truly felt that it was a priority. If counterfeit or fake pharmaceuticals decreased its positioning from its original ranking of seventh, then that would be viewed as other scenarios taking priority and Counterfeits just not making an impact on consumers. The results of this scenarios are displayed in Figure 13.
The results displayed in Figure 13 demonstrate that only 20 percent of the respondents prioritize counterfeit pharmaceuticals as a major risk to their health and well-being. While the original rank of seventh place ended up with 41 responses and 9 percent of the total, that number was skewed because 15 percent of those responses were due to the fact that the respondent chose to make no changes to the original list. It cannot be determined if those 6 responses left the ranking alone because the agreed with the original positioning or because they decided not to make any changes. If those responses that did not make any changes to the order are removed from the equation, then only 29 percent of the entire sample population believe that counterfeit pharmaceuticals rank in the top 50 percent of risks to their health.

This statistic was not significantly tied to any one gender. Both females and males rank counterfeit pharmaceuticals evenly with 30 percent of the female population and 29 percent of
the male population identifying counterfeit pharmaceuticals amongst the top risks. These results can be observed in Table 7.

Table 7

<table>
<thead>
<tr>
<th>Rank</th>
<th>Female (n = 269)</th>
<th>Male (n = 164)</th>
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<td></td>
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<td>%</td>
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<tr>
<td>15</td>
<td>10</td>
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</table>

Based on the results listed in Table 13, it can be determined that there is not a correlation between gender and how priority is ranked. The null hypothesis being that gender does not play a significant role in the prioritization of counterfeit pharmaceuticals to consumers long-term health and well-being. With a Chi-Square of $\chi^2(14)$ equal to 16.55 with an $\alpha$ of 0.05, the $\chi^2$ is less than the Critical Value (CRIT) of 23.68. The null hypothesis that gender does not influence how the respondents prioritized the risk of counterfeit pharmaceuticals is confirmed.
Overall, when compared to the other 14 scenarios in this list, Counterfeit / Fake Pharmaceuticals was only chosen as the largest risk to the health and well-being of consumers two percent of the time. Amongst the 15 different options, counterfeit pharmaceuticals ranked tenth as the top risk to consumer health. As shown in Figure 14, counterfeit pharmaceuticals only ranked higher than Pesticide Consumption, Other, Natural Disaster, Home Invasion / Crime, and Vaccines.

![Figure 14. Highest Prioritized Risks According to Responses.](image)

While the population sample might be extremely minimal, the Asian population had the highest ranking of all ethnicities at 50 percent ranking counterfeit pharmaceuticals as high risk (n = 39). Of the total population that believes that counterfeit pharmaceuticals are in the upper 50 percent of risk to their health, 84 percent of those respondents had either a Bachelor’s or
Master’s Degree. While this may indicate that higher education results in more educated consumer, when viewed independently as a population, both Bachelor’s and Master’s degree respondents scored rather low when viewed as a singular population. Only 27 percent of all Bachelor’s Degree respondents (n = 145) viewed counterfeit pharmaceuticals as a high risk to their health, and all Master’s Degree respondents (n = 143) came in just a slightly higher at 31 percent. Respondents between the ages 55-64 had the largest ranking of counterfeit pharmaceuticals as a risk to their health with a total 35 percent of total 65 respondents.

In terms of rank among the leading cause of deaths for 2016, counterfeit pharmaceuticals ranked either the third, fourth, or fifth cause of the most deaths in 2016 by the respondents.

![2016 Perception of Counterfeit Pharmaceutical as Cause of Death (n = 428)](image)

*Figure 15. Ranking Counterfeit Pharmaceuticals for Cause of Death in 2016.*

While 25 percent (n = 107) of the sample population selected Counterfeit Pharmaceuticals as either the top or second cause of most death for 2016, less than half of those respondents selected counterfeit pharmaceuticals to be in the top risks for their immediate health
and well-being. Only 44 out of a total 107 respondents that determined that counterfeit pharmaceuticals were one of the leading cause of death in a given year thought that it would directly affect their health. This statistic was in contradiction to rational perception. The majority of respondents that thought counterfeit pharmaceuticals was either the first or second leading cause of death in 2016 came from respondents that listed counterfeit pharmaceuticals as either eighth, twelfth, or thirteenth in terms of risk to their own health. These respondents represent 31 percent of the total 107 that listed counterfeit pharmaceuticals as the leading cause of deaths in 2016.

In comparison to all six scenarios for the leading cause of death in 2016, counterfeit pharmaceuticals ranked fourth. Counterfeit pharmaceuticals only ranked higher than acts of terrorism and natural disasters in terms of which scenario caused the most deaths during the calendar year 2016.

![2016 Perceived Top Cause of Deaths](image)

*Figure 16. Respondent Perception of Top Cause of Death.*
Counterfeits were the leading cause of death within the scenarios presented (though it was not the leading cause for that year). The goal of the research question was to understand how the respondents perceived counterfeit pharmaceuticals as a threat. Since the prior question specifically asked how the respondent perceived counterfeit pharmaceuticals as a risk to their health, it was important to understand if the respondents translated this same risk to the community around them. Table 8 shows the deaths during 2016 for each of the given scenarios.

Table 8

2016 Deaths by Category

<table>
<thead>
<tr>
<th>Category</th>
<th>2016 Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counterfeit Pharmaceuticals</td>
<td>91,364*</td>
</tr>
<tr>
<td>Suicide</td>
<td>44,965</td>
</tr>
<tr>
<td>Pancreatic Cancer</td>
<td>41,780</td>
</tr>
<tr>
<td>Car Accidents</td>
<td>40,200</td>
</tr>
<tr>
<td>Terrorism</td>
<td>433</td>
</tr>
<tr>
<td>Natural Disaster</td>
<td>262</td>
</tr>
</tbody>
</table>

*Represents reported deaths in the U.S. only, may not be total

While Figure 16 identifies that respondents perceived car accidents as the leading cause of deaths within the United States in 2016, the data presented in Table 8 shows that it was actually fourth on the list of causes of deaths in 2016 amongst the list of scenarios.

While counterfeit pharmaceuticals did not truly align with these two prioritization questions, other statistics did. Car accidents were far and away viewed as the leading cause of deaths in 2016 at 57 percent. Those that identified car accidents as the main risk to their health and well-being also identified that same category as the leading cause of death. While pancreatic cancer was viewed as a lesser cause of death at 12 percent, terminal illness was view as the top
concern for the respondent's health and well-being. If the questionnaire had been less exact in the type of cancer, this might have lead this scenario in total perceived deaths. Both terrorism and natural disasters had relatively minor effects on the respondent's health and well-being; this might have changed given a broader demographic. Both scenarios are aligned to their 2016 cause of death percentages, though terrorism ranked higher than counterfeit pharmaceuticals in terms of immediate risk to the respondent's health. Suicide was not identified as a personal risk to the respondent due to the sensitive nature of the event. While ethical considerations prevented suicide from being included in the personal risk, it was not a factor in asking about the overall 2016 cause of death scenario.

**Understanding Counterfeit Risks**

The primary research goal of this study was to determine if consumers within the United States are aware of the risk of the counterfeit pharmaceuticals. To determine this, direct questions were posed to the respondents regarding counterfeit pharmaceuticals. As part of this exploration, an investigation was needed to determine the drug buying habits of the respondent. After examining the buying habits of consumers to determine if they believe they have ever purchased a drug before, it can then be assessed how knowledgeable consumers were of counterfeit pharmaceuticals.

Based on the research regarding the prioritization of counterfeit pharmaceuticals, it can be inferred that consumers are not too worried about counterfeit drugs and their buying habits are reflective of this. To examine the buying habits, three questions were asked of the respondents. Each respondent that fell within the approved geographic profile for this study were asked if they have either consumed a pharmaceutical within their lifespan, what type of drug product they have consumed, and finally, where they have purchased their drug products. While these
questions would provide little in terms of assessing the respondent's knowledge of counterfeit pharmaceuticals, they would provide a baseline of consumer type.

As it was discussed in the Response Rate section of this report, an inclusion criteria question was whether or not the respondent had ever consumed a pharmaceutical in their lifetime. Since the intent of this study was to determine the understanding of counterfeit pharmaceuticals if a respondent believed they have never consumed a product before they would be excluded. There would be no need to research and spend time learning about an irrelevant situation. Therefore, any response in the negative was excluded from this analysis. Even though it was not the focus of this study, three respondents were excluded based on their response to whether they had ever consumed a pharmaceutical before. No data was collected beyond the point of answering this question, but the demographics were collected. All three respondents were fairly young, between 18 and 34, and all three were Asian and had a Master’s Degree.

While these results are excluded, it was believed that the respondents might not have fully understood what a pharmaceutical was since they would need to have submitted vaccine records to get into a college within the United States. Vaccines are pharmaceuticals as well, so terminology or translation may have affected these responses.

In addition to the three negative responses, 11 respondents stated they did not know if they had consumed a pharmaceutical. While a response of Unknown would still allow the data to be included, it was not as easy to determine a reason for such an answer. The respondents were of both genders, wide age ranges, and a diverse ethnicity and educational background.
Table 9

Respondents Unaware of Consuming Pharmaceuticals – Demographic Data (n = 11)

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Native Indian / Alaskan</th>
<th>Female (N = 7)</th>
<th>Male (N = 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-24 years old</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>25-34 years old</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>45-54 years old</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>55-64 years old</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Following the understanding of whether the respondent either have or have not consumed a pharmaceutical, an examination of consumer buying habits was required. In terms of buying habits, the type of pharmaceuticals that were consumed and the location the pharmaceuticals were purchased defined the respondents consumer type. For the type of pharmaceutical, three different categories were utilized. Those categories were 1) Prescription Drugs, 2) Over-the-Counter Drugs (OTCs), and 3) Dietary / Vitamins. While it was explored as to whether to include recreational drugs, it was determined that the respondent might not be able to understand the difference between a recreational pharmaceutical and an illegal recreational substance. For this purpose, the assumption was made that anything that could be classified as a recreational drug could be purchased over-the-counter or as a dietary substance.

As part of this analysis, the type of pharmaceutical was examined by gender and by age range. These types of analysis were able to identify that females were more likely to consume a dietary or vitamin product than their male or non-binary counterparts. According to the sample population, 88 percent of the females consume a dietary product in comparison to 79 percent of the males and 0 percent of the non-binary. Since dietary and vitamin products are not controlled by the United States Food & Drug Administration, it was important to note that these products run a greater risk of being counterfeit. In looking at the breakdown of the female consumption,
91 percent women between the ages of 45 to 54 and 97 percent between the ages of 55 to 64 consume dietary products.

In terms of the location that consumers purchased pharmaceuticals, the data identified that both Retail Outlets and Drug Store are the most widely used source for getting the products. Of the total sample population of 442 viable subjects, 94 percent purchase the products from a drug store and 37 percent purchase the products from a retail outlet. While there was a large gap between these two variables, they were the top two sources for acquiring the products. The startling piece of information derived from this dataset was the number of consumers that utilize online retailers to get their pharmaceuticals from. A total of 19 percent of the sample population purchases their products online, with a breakdown of 15 percent of the female consumers, 24 percent of the male consumers, and 100 percent of the non-binary consumers. As identified in the Literature Review, this was an alarming concern when organizations like WHO publishes statistics that 50 percent of all pharmaceuticals purchased online are counterfeit, and the FDA states that 97 percent of all online pharmacies are illegal and they are in the process of prosecuting many of them (U.S. Food and Drug Administration, 2015a; World Health Organization, 2016). While it may have been assumed that the younger generation that does most of their shopping online would be the greatest offenders, it was actually the older generations that are purchasing online. Of the female population that was purchasing their products online, 57 percent of those were between the ages of 35 and 54. Of the male population that was purchasing their products online, 53 percent of those were between the ages of 45 and 64. These results align to the user population of LinkedIn. As can be seen from the Tables 10 and 11, the majority of the population that was purchasing pharmaceutical products online are white males and females with a Bachelor’s and Master’s degree.
Table 10

*Female Respondent Pharmaceuticals Purchased and Location – By Generation (n = 275)*

<table>
<thead>
<tr>
<th>Female</th>
<th>18-24 years</th>
<th>25-34 years</th>
<th>35-44 years</th>
<th>45-54 years</th>
<th>55-64 years</th>
<th>65-74 years</th>
<th>75 years +</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 27)</td>
<td>(n = 69)</td>
<td>(n = 69)</td>
<td>(n = 69)</td>
<td>(n = 30)</td>
<td>(n = 8)</td>
<td>(n = 3)</td>
</tr>
<tr>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Prescription Drugs</td>
<td>23</td>
<td>85</td>
<td>60</td>
<td>87</td>
<td>67</td>
<td>97</td>
<td>66</td>
</tr>
<tr>
<td>Over-the-Counter Drugs</td>
<td>26</td>
<td>96</td>
<td>64</td>
<td>93</td>
<td>67</td>
<td>97</td>
<td>66</td>
</tr>
<tr>
<td>Dietary / Vitamins</td>
<td>24</td>
<td>89</td>
<td>58</td>
<td>84</td>
<td>61</td>
<td>88</td>
<td>63</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Where Pharmaceutical Purchased</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
</tr>
<tr>
<td>Drug Store</td>
</tr>
<tr>
<td>Retail Outlet</td>
</tr>
<tr>
<td>Doctors Office / Clinic</td>
</tr>
<tr>
<td>Online</td>
</tr>
</tbody>
</table>
Table 11

*Male and Non-Binary Respondent Pharmaceuticals Purchased and Location – By Generation (n = 167)*

<table>
<thead>
<tr>
<th>Type of Pharmaceutical Purchase</th>
<th>Male</th>
<th>Non-Binary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>18-24 years</td>
<td>25-34 years</td>
</tr>
<tr>
<td></td>
<td>(n = 11)</td>
<td>(n = 36)</td>
</tr>
<tr>
<td>Prescription Drugs</td>
<td>6 (55%)</td>
<td>32 (95%)</td>
</tr>
<tr>
<td>Over-the-Counter Drugs</td>
<td>9 (82%)</td>
<td>32 (90%)</td>
</tr>
<tr>
<td>Dietary / Vitamins</td>
<td>6 (55%)</td>
<td>25 (69%)</td>
</tr>
</tbody>
</table>

| Where Pharmaceutical Purchased  | Male | Non-Binary |
|                                 |      |            |
|                                 | 18-24 years | 25-34 years | 35-44 years | 45-54 years | 55-64 years | 65-74 years | 75 years + | 35-44 years |
|                                 | (n = 11) | (n = 36) | (n = 21) | (n = 43) | (n = 35) | (n = 19) | (n = 1) | (n = 1) |
| Hospital                        | 1 (9%)  | 6 (17%)  | 5 (24%)  | 3 (7%)   | 4 (11%)  | 2 (11%)  | 0 (0%)  | 0 (0%)  |
| Drug Store                      | 9 (82%) | 33 (92%) | 20 (95%) | 39 (91%) | 32 (91%) | 16 (84%) | 1 (100%) | 1 (100%) |
| Retail Outlet                   | 4 (36%) | 10 (28%) | 11 (52%) | 22 (51%) | 13 (37%) | 9 (47%)  | 0 (0%)  | 1 (100%) |
| Doctors Office / Clinic         | 1 (9%)  | 8 (22%)  | 6 (29%)  | 4 (9%)   | 5 (14%)  | 3 (16%)  | 0 (0%)  | 0 (0%)  |
| Online                          | 1 (9%)  | 7 (19%)  | 6 (29%)  | 10 (23%) | 11 (31%) | 4 (21%)  | 0 (0%)  | 1 (100%) |
Table 12

*Type of Pharmaceuticals Purchased Demographics (n = 443)*

<table>
<thead>
<tr>
<th></th>
<th>Females Prescription Drugs</th>
<th>Ethnicity</th>
<th>Males Prescription Drugs</th>
<th>Dietary / Vitamins</th>
<th>Non-Binary Prescription Drugs</th>
<th>Dietary / Vitamins</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prescription Drugs</td>
<td>Over-the-Counter Drugs</td>
<td>Over-the-Counter Drugs</td>
<td>Prescription Drugs</td>
<td>Over-the-Counter Drugs</td>
<td>Prescription Drugs</td>
</tr>
<tr>
<td>American Indian</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Hispanic of Latino Hawaiian or Pacific Islander</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>White</td>
<td>31</td>
<td>32</td>
<td>30</td>
<td>30</td>
<td>29</td>
<td>26</td>
</tr>
<tr>
<td>Other</td>
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<td>0</td>
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<td>0</td>
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<td>Not Identified</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Prescription Drugs</th>
<th>Education Level</th>
<th>Prescription Drugs</th>
<th>Dietary / Vitamins</th>
<th>Prescription Drugs</th>
<th>Dietary / Vitamins</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prescription Drugs</td>
<td>Over-the-Counter Drugs</td>
<td>Over-the-Counter Drugs</td>
<td>Prescription Drugs</td>
<td>Over-the-Counter Drugs</td>
<td>Prescription Drugs</td>
</tr>
<tr>
<td>Some high school, no diploma</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>High school graduate</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Some college credit, no degree</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Trade/technical/vocational training</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Associate degree</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>11</td>
<td>11</td>
<td>12</td>
<td>13</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>Master’s degree</td>
<td>14</td>
<td>15</td>
<td>13</td>
<td>10</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Professional degree</td>
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<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Professional certification</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Doctorate degree</td>
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<td>1</td>
<td>1</td>
<td>6</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Employment Status</td>
<td>Prescription Drugs</td>
<td>Females Over-the-Counter Drugs</td>
<td>Dietary / Vitamins</td>
<td>Prescription Drugs</td>
<td>Males Over-the-Counter Drugs</td>
<td>Dietary / Vitamins</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>--------------------</td>
<td>--------------------------------</td>
<td>-------------------</td>
<td>--------------------</td>
<td>--------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Employed for wages</td>
<td>26</td>
<td>26</td>
<td>22</td>
<td>26</td>
<td>25</td>
<td>20</td>
</tr>
<tr>
<td>Self-employed</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>7</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Out of work and looking for work</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Out of work but not currently looking for work</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Household caretaker</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Student</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Retired</td>
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<td>5</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>
Although the research results show that respondents have demonstrated unsafe buying habits, it also examined how consumers defined a counterfeit pharmaceutical. As the literature review revealed, a counterfeit pharmaceutical product was defined as not meeting the original or intended product specifications developed by the source manufacturer of record and approved by the U.S. FDA. Most people focus this definition on the chemical makeup of the physical product, but this definition includes the packaging and labeling as well. With this definition in mind, the sample population was asked to select criteria that they would consider to be a counterfeit pharmaceutical. The questionnaire provided the respondents seven different criteria and requested that they select all the answers that they felt applied. The options included 1) mislabeled products, 2) products that included a higher dose, 3) products that included a weaker dose, 4) products that did not include all of the ingredients, 5) products that did not include any of the ingredients, 6) products that contain contaminated material, and 7) products that included poisonous ingredients. It is important to understand that a consumer would not be able to determine a majority of these responses when examining a pharmaceutical to determine if it is counterfeit or not. The purpose of this question was exclusively for the purposes of determining if the respondent understood what defines a counterfeit pharmaceutical.

Though there was a valid sample population of 442, 10 respondents did not participate in this question and needed to be excluded from the analysis. Even though all six possible options are considered counterfeit, only 202 or 47 percent out of the total potential 432 possible respondents answered this question with the correct responses.
Almost all of the respondents understood that if the product did not include the intended ingredients that it would be considered a counterfeit product. It was surprising that a complete lack of ingredients or the inclusion of poisonous ingredients did not rank higher in the percentage of the respondents believe that this would define a product as counterfeit.

Even though nearly the entire sample population thought that a product missing some of the active ingredients defined a counterfeit pharmaceutical, an analysis must be performed to determine if there a specific portion of the population that was at a greater risk due to a lack of understanding or misunderstanding of what a counterfeit product was. In viewing the population that did not select each of the scenarios, the breakdown of the sample by gender provided no significant answers. The demographics that did present some kind of significant findings were ethnicity, age range, marital status, and income range. According to the data shown in Table 13, the demographics that largely misunderstood how counterfeit pharmaceutical products are defined are white (non-Latino) individuals between the ages of 25 to 54 that have either a Bachelor’s or Master’s degree, making over $150,000 a year that are currently married. These
are highly educated individuals that are lacking the basic definition of a counterfeit pharmaceutical.
Table 13

Demographics of Non-Selected Definition Criteria (n = 432)

<table>
<thead>
<tr>
<th></th>
<th>Mislabeled (n = 108)</th>
<th>Less Ingredients (n = 124)</th>
<th>More Ingredients (n = 136)</th>
<th>Missing Ingredients (n = 38)</th>
<th>No Active Ingredients (n = 100)</th>
<th>Contaminated Ingredients (n = 90)</th>
<th>Includes Poison (n = 72)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>54 (50)</td>
<td>65 (52)</td>
<td>66 (49)</td>
<td>19 (50)</td>
<td>65 (65)</td>
<td>47 (52)</td>
<td>41 (57)</td>
</tr>
<tr>
<td>Male</td>
<td>53 (49)</td>
<td>58 (47)</td>
<td>69 (51)</td>
<td>19 (50)</td>
<td>35 (35)</td>
<td>43 (48)</td>
<td>31 (43)</td>
</tr>
<tr>
<td>Non-Binary</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amer. Indian or Alaskan</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>2 (1)</td>
<td>2 (3)</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Asian</td>
<td>6 (6)</td>
<td>15 (12)</td>
<td>13 (10)</td>
<td>4 (11)</td>
<td>7 (7)</td>
<td>8 (9)</td>
<td>8 (11)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>6 (6)</td>
<td>8 (6)</td>
<td>8 (6)</td>
<td>2 (5)</td>
<td>4 (4)</td>
<td>4 (4)</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>5 (5)</td>
<td>6 (5)</td>
<td>6 (4)</td>
<td>3 (8)</td>
<td>5 (5)</td>
<td>4 (4)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Hawaiian or Pacific Islander</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>1 (3)</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (3)</td>
<td>4 (3)</td>
<td>3 (2)</td>
<td>2 (5)</td>
<td>2 (2)</td>
<td>3 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>White</td>
<td>77 (71)</td>
<td>84 (68)</td>
<td>72 (58)</td>
<td>76 (76)</td>
<td>64 (71)</td>
<td>52 (72)</td>
<td></td>
</tr>
<tr>
<td>Not Identified</td>
<td>8 (7)</td>
<td>4 (3)</td>
<td>5 (4)</td>
<td>3 (8)</td>
<td>5 (5)</td>
<td>5 (6)</td>
<td>8 (11)</td>
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<tr>
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<td></td>
<td></td>
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<tr>
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<td>17 (17)</td>
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<td>2 (3)</td>
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<tr>
<td>25-34 years old</td>
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<td>37 (30)</td>
<td>34 (25)</td>
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<td>30 (30)</td>
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<tr>
<td>35-44 years old</td>
<td>25 (23)</td>
<td>26 (21)</td>
<td>27 (20)</td>
<td>4 (11)</td>
<td>16 (16)</td>
<td>16 (18)</td>
<td>10 (14)</td>
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<tr>
<td>45-54 years old</td>
<td>25 (23)</td>
<td>28 (23)</td>
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<td>24 (24)</td>
<td>24 (27)</td>
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<tr>
<td>55-64 years old</td>
<td>18 (17)</td>
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<td>8 (8)</td>
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<td>10 (14)</td>
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<td>65-74 years old</td>
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<td>3 (3)</td>
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<td>8 (11)</td>
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<tr>
<td>&gt;75 years old</td>
<td>1 (1)</td>
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<td>0 (0)</td>
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</tbody>
</table>
Table 13

**Demographics of Non-Selected Definition Criteria (n = 432)**

<table>
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<tr>
<th></th>
<th>Mislabeled (n = 108)</th>
<th>Less Ingredients (n = 124)</th>
<th>More Ingredients (n = 136)</th>
<th>Missing Ingredients (n = 38)</th>
<th>No Active Ingredients (n = 100)</th>
<th>Contaminated Ingredients (n = 90)</th>
<th>Includes Poison (n = 72)</th>
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<tbody>
<tr>
<td>Some College credit, no degree</td>
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<td>Bachelor’s degree</td>
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<td>23 (26)</td>
<td>19 (26)</td>
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<td>26 (36)</td>
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<tr>
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**Marital Status**

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<th>n</th>
<th>%</th>
<th>n</th>
<th>%</th>
<th>n</th>
<th>%</th>
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<tr>
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<td>41</td>
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<td>24</td>
<td>35</td>
<td>35</td>
<td>27</td>
<td>30</td>
</tr>
<tr>
<td>Married or Domestic Partnership</td>
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<td>50</td>
<td>51</td>
<td>41</td>
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<td>4</td>
<td>2</td>
<td>5</td>
<td>9</td>
<td>9</td>
<td>6</td>
<td>7</td>
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**Professional / Employment Status**

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<th>%</th>
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<th>%</th>
<th>n</th>
<th>%</th>
<th>n</th>
<th>%</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
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<td>64</td>
<td>80</td>
<td>65</td>
<td>89</td>
<td>65</td>
<td>21</td>
<td>55</td>
<td>70</td>
<td>70</td>
<td>61</td>
<td>68</td>
</tr>
<tr>
<td>Household caretaker</td>
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<td>3</td>
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<td>1</td>
<td>1</td>
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<td>0</td>
<td>0</td>
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<td>3</td>
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<tr>
<td>Military</td>
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<td>2</td>
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<td>1</td>
<td>1</td>
<td>1</td>
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<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Out of work and looking</td>
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<td>5</td>
<td>4</td>
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<td>8</td>
<td>2</td>
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<td>5</td>
<td>6</td>
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<tr>
<td>Out of work and not looking</td>
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<td>0</td>
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<td>0</td>
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<td>0</td>
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<td>18</td>
<td>13</td>
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<td>7</td>
<td>18</td>
<td>13</td>
<td>13</td>
<td>9</td>
<td>10</td>
</tr>
</tbody>
</table>
Table 13

Demographics of Non-Selected Definition Criteria (n = 432)

<table>
<thead>
<tr>
<th>Unable to work</th>
<th>Mislabeled (n = 108)</th>
<th>Less Ingredients (n = 124)</th>
<th>More Ingredients (n = 136)</th>
<th>Missing Ingredients (n = 38)</th>
<th>No Active Ingredients (n = 100)</th>
<th>Contaminated Ingredients (n = 90)</th>
<th>Includes Poison (n = 72)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n %</td>
<td>N %</td>
<td>n %</td>
<td>n %</td>
<td>n %</td>
<td>n %</td>
<td>n %</td>
<td>n %</td>
</tr>
<tr>
<td>Unable to work</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Household Income Range

- < $25,000
  - 9 | 8 | 14 | 11 | 13 | 10 | 5 | 13 | 8 | 8 | 7 | 8 | 1 | 1 |
- $25,000 to $49,999
  - 6 | 6 | 11 | 9 | 13 | 10 | 4 | 11 | 10 | 10 | 10 | 11 | 8 | 11 |
- $50,000 to $74,999
  - 8 | 7 | 13 | 10 | 13 | 10 | 2 | 5 | 11 | 11 | 4 | 4 | 4 | 6 |
- $75,000 to $99,999
  - 14 | 13 | 10 | 8 | 14 | 10 | 1 | 3 | 13 | 13 | 12 | 13 | 10 | 14 |
- $100,000 to $124,999
  - 14 | 13 | 15 | 0 | 16 | 12 | 3 | 8 | 17 | 17 | 10 | 11 | 11 | 15 |
- $125,000 to $149,999
  - 16 | 15 | 16 | 13 | 16 | 12 | 7 | 18 | 11 | 11 | 12 | 13 | 6 | 8 |
- > $150,000
  - 29 | 27 | 32 | 26 | 35 | 26 | 11 | 29 | 18 | 18 | 24 | 27 | 19 | 26 |
- Not Identified
  - 12 | 11 | 13 | 10 | 16 | 12 | 5 | 13 | 12 | 12 | 11 | 12 | 13 | 18 |
To further explore this sample population and understand their knowledge of counterfeit pharmaceuticals, the population’s beliefs about the risk of counterfeit pharmaceuticals needed to be examined. Even though the researched showed was a gap in the understanding of the counterfeit pharmaceutical definition, it was important to understand if that same sample believed counterfeits are likely to be purchased in the U.S. market. The questionnaire attempted to identify the type of retail outlet the respondents thought was more likely to find a counterfeit pharmaceutical.

The data describing how the respondents defined a counterfeit pharmaceutical established a baseline for the understanding of the population, but it was equally important to determine if consumers believe that there was a risk for counterfeit pharmaceuticals within the United States. Like the prioritization analysis that was done, the respondents may not prioritize the risk of a counterfeit pharmaceutical because they do not believe those products can be found in the United States. The respondents were posed with two separate questions to determine how they prioritize the risk of counterfeit pharmaceuticals. The first question explored how the respondent viewed the counterfeit pharmaceuticals on a global scale and the second question targeted the percentage of the U.S. market they perceived as counterfeit. Respondents were presented with eight different countries to provide a global view understanding of consumers perceives a higher likelihood to discover a counterfeit pharmaceutical. The question allowed the respondents to select as many or as few answers as they so choose from a mixture of highly industrialized countries, in-transit countries, and underdeveloped countries. Those countries that the respondents had to choose from were the United States, Nigeria, Germany, China, India, Australia, Brazil, and Ukraine.
Figure 18. Perception of Likelihood to Have Counterfeit Pharmaceuticals.

As the literature review identified in Chapter 2, counterfeit pharmaceuticals are located in almost every country. Of the total sample population of 442, only 232 or 52 percent selected each of these countries as a viable source of counterfeit pharmaceuticals. These results demonstrate a lack of understanding of counterfeit pharmaceuticals on the global scale. In comparison, only two-thirds of the respondents thought that counterfeit pharmaceuticals could be found in the United States. This was the third lowest percentage of the eight possible responses behind Germany and Australia. This shows that the majority of the respondents believe that highly industrialized nations are rather secure from counterfeit pharmaceuticals.

Even though 64 percent of the population believes that counterfeit pharmaceuticals are likely to be found on the U.S. market, there are conflicting results when viewing the responses against the assumption of what percentage of the pharmaceuticals in the United States are counterfeit. As a follow-up question to whether the respondent feels that the United States was likely to have counterfeit pharmaceuticals, the questionnaire asked the question as to what
percentage of the pharmaceuticals sold within the United States are counterfeit. The questionnaire provided the respondent groupings of percentages using options such as 0 percent, 1 to 3 percent, 4 to 6 percent, 7 to 9 percent, 10 to 15 percent, 16 to 25 percent, and greater than 25 percent of the products being counterfeit. The assumption would be that the 36 percent of the respondents that did not think the U.S. was likely to have a counterfeit pharmaceutical would have also have answered that zero percent of the pharmaceuticals sold in the U.S. are counterfeit since those questions aligned in logic and followed each other on the questionnaire. The results that were returned were quite the opposite. Only three percent of the total sample population believed that zero percent of the products within the U.S. were counterfeit. This results in 37 percent of the respondents that did not think that it was likely to find counterfeit pharmaceuticals in the U.S. market believe that there was some percentage higher than zero as the amount of counterfeit pharmaceutical on the U.S. market. This leaves a large discrepancy of 146 respondents whose responses contradict each other. In fact, 49 (or 31 percent) of those 146 respondents that did not think it was likely to find a counterfeit in the U.S. market identified that over 10 percent of the pharmaceuticals sold in the United States were counterfeit.
Table 14

Perceived Percent of Counterfeit Pharmaceuticals Sold in the United States (n = 442)

<table>
<thead>
<tr>
<th>Percent of Counterfeit Pharmaceuticals</th>
<th>The U.S. Not Likely (N = 159)</th>
<th>The U.S. Likely (N = 283)</th>
<th>Total U.S. Allocation (N = 442)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#</td>
<td>%</td>
<td>#</td>
</tr>
<tr>
<td>0 percent</td>
<td>13</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>1-3 percent</td>
<td>37</td>
<td>23</td>
<td>20</td>
</tr>
<tr>
<td>4-6 percent</td>
<td>31</td>
<td>19</td>
<td>41</td>
</tr>
<tr>
<td>7-9 percent</td>
<td>19</td>
<td>12</td>
<td>33</td>
</tr>
<tr>
<td>10-15 percent</td>
<td>31</td>
<td>19</td>
<td>88</td>
</tr>
<tr>
<td>16-25 percent</td>
<td>13</td>
<td>8</td>
<td>52</td>
</tr>
<tr>
<td>&gt;25 percent</td>
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<td>3</td>
<td>49</td>
</tr>
<tr>
<td>No Response</td>
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</table>

As identified earlier, WHO has estimated that 10 percent of the pharmaceuticals on the market in the U.S. are counterfeit (World Health Organization, 2016). While 10 to 15 percent was the correct answer and had the highest return rate according to the table above, the percentage of the population that answered correctly was relatively low at 27 percent. Of the 54 percent of the total sample population that believes that 10 percent or more of the products sold in the U.S. were counterfeit, 20 percent of that population did not believe it was likely that counterfeit pharmaceuticals were sold within the U.S.
Table 15

Demographics of Perceived Counterfeit Percentage in the United States (n = 442)

<table>
<thead>
<tr>
<th>Gender</th>
<th>0 % (n = 13)</th>
<th>1-3 % (n = 57)</th>
<th>4-6 % (n = 72)</th>
<th>7-9 % (n = 52)</th>
<th>10-15 % (n = 119)</th>
<th>15-25 % (n = 65)</th>
<th>&gt;25 % (n = 54)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>7</td>
<td>33</td>
<td>38</td>
<td>24</td>
<td>73</td>
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<td>42</td>
</tr>
<tr>
<td>Male</td>
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<td>23</td>
<td>34</td>
<td>28</td>
<td>46</td>
<td>14</td>
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<tr>
<td>Non-Binary</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Age Range</th>
<th>0 % (n = 13)</th>
<th>1-3 % (n = 57)</th>
<th>4-6 % (n = 72)</th>
<th>7-9 % (n = 52)</th>
<th>10-15 % (n = 119)</th>
<th>15-25 % (n = 65)</th>
<th>&gt;25 % (n = 54)</th>
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<tbody>
<tr>
<td>18-24 years old</td>
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<td>9</td>
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<td>7</td>
</tr>
<tr>
<td>25-34 years old</td>
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<td>20</td>
<td>6</td>
<td>29</td>
<td>15</td>
<td>14</td>
</tr>
<tr>
<td>35-44 years old</td>
<td>1</td>
<td>15</td>
<td>23</td>
<td>14</td>
<td>17</td>
<td>14</td>
<td>6</td>
</tr>
<tr>
<td>45-54 years old</td>
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<td>15</td>
<td>12</td>
<td>32</td>
<td>15</td>
<td>17</td>
</tr>
<tr>
<td>55-64 years old</td>
<td>0</td>
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<td>5</td>
<td>9</td>
<td>23</td>
<td>12</td>
<td>9</td>
</tr>
<tr>
<td>65-74 years old</td>
<td>0</td>
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<td>4</td>
<td>8</td>
<td>2</td>
<td>1</td>
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</table>

<table>
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<th>Ethnicity</th>
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<th>4-6 % (n = 72)</th>
<th>7-9 % (n = 52)</th>
<th>10-15 % (n = 119)</th>
<th>15-25 % (n = 65)</th>
<th>&gt;25 % (n = 54)</th>
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<tr>
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<td>1</td>
</tr>
<tr>
<td>Hispanic or Latino Native Hawaiian or Pacific Islander</td>
<td>0</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>6</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
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<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>White</td>
<td>7</td>
<td>36</td>
<td>54</td>
<td>41</td>
<td>97</td>
<td>49</td>
<td>46</td>
</tr>
<tr>
<td>(blank)</td>
<td>0</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>7</td>
<td>6</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Education Level</th>
<th>0 % (n = 13)</th>
<th>1-3 % (n = 57)</th>
<th>4-6 % (n = 72)</th>
<th>7-9 % (n = 52)</th>
<th>10-15 % (n = 119)</th>
<th>15-25 % (n = 65)</th>
<th>&gt;25 % (n = 54)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some High School</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>High School graduate</td>
<td>2</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Some College credit</td>
<td>0</td>
<td>4</td>
<td>7</td>
<td>4</td>
<td>15</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Vocational training</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Associates degree</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>3</td>
<td>13</td>
<td>25</td>
<td>19</td>
<td>49</td>
<td>18</td>
<td>12</td>
</tr>
<tr>
<td>Master’s degree</td>
<td>6</td>
<td>22</td>
<td>26</td>
<td>19</td>
<td>32</td>
<td>22</td>
<td>15</td>
</tr>
<tr>
<td>Professional certification</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Professional degree</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Doctorate degree</td>
<td>1</td>
<td>7</td>
<td>7</td>
<td>5</td>
<td>8</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Marital Status</th>
<th>0 % (n = 13)</th>
<th>1-3 % (n = 57)</th>
<th>4-6 % (n = 72)</th>
<th>7-9 % (n = 52)</th>
<th>10-15 % (n = 119)</th>
<th>15-25 % (n = 65)</th>
<th>&gt;25 % (n = 54)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Divorced</td>
<td>3</td>
<td>9</td>
<td>7</td>
<td>7</td>
<td>10</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Married or Domestic Partnership</td>
<td>5</td>
<td>32</td>
<td>43</td>
<td>29</td>
<td>69</td>
<td>29</td>
<td>27</td>
</tr>
</tbody>
</table>
When reviewing the demographics of the perceived percent of the counterfeit drugs in the U.S. market, 73 percent of the sample population was not able to correctly identify what portion of the U.S. pharmaceutical supply chain was counterfeit. According to the demographic data shown in Table 15, white (non-Latino) individuals between the ages of 25 to 54 that have either a Bachelor’s or Master’s degree, making over $150,000 a year that are currently married were most likely to incorrectly identify what percentage of the U.S. pharmaceuticals are counterfeit.

To conclude the understanding of counterfeit pharmaceuticals by the U.S. consumers, an analysis of where the respondents believe the counterfeits are most likely to be sold must be
explored. While the majority of the sample populations believes that there are counterfeits on the U.S. pharmaceutical market according to the perceived percentage statistics, it must be understood where the respondents believe the products are being sold. The respondents were asked what type of outlet they believe the counterfeit pharmaceuticals are more likely to be sold. Similarly to the early question asking the respondents where they sourced their pharmaceuticals from, they were provided with the same options and asked which one they believed was most likely to sell a pharmaceutical.

![Figure 19. Outlet Most Likely to Sell a Counterfeit Pharmaceutical.](image)

Even though a total of 19 percent of the sample population purchased their products online, nearly three-quarters of the total population believed that the online market was the most at risk outlet when it comes to selling counterfeit drugs. This perception of the source of counterfeit pharmaceuticals falls in line with the WHO published statistics that 50 percent of all
pharmaceuticals purchased online are counterfeit and the FDA statistics that 97 percent of all online pharmacies are illegal (U.S. Food and Drug Administration, 2015a; World Health Organization, 2016). Another key point from this data was the continued inconsistency of responses. Previously the data had identified that 164 of the total sample population believed that it was not likely to find counterfeit products in the U.S. market, but that translated to only 13 total respondents believing that 0 percent of the pharmaceuticals sold in the U.S. were counterfeit. With this new data on where the counterfeit products were being sold in the U.S., 17 respondents responded stating that there were no counterfeits on the market. This was an increase of four over the prior question. While this was an increase of four responses, the data continues to vary. Of the 13 that originally stated that 0 percent of the drugs sold in the U.S. were counterfeit, only eight provided a response that no counterfeits were on the U.S. market. The other five respondents believe that the counterfeits sold in the U.S. were coming from online. The remaining nine responses came from respondents that previously believed that some percentage of the U.S. market were counterfeit products.

Table 16

**Counterfeit Outlet versus Counterfeit Perception (n = 442)**

<table>
<thead>
<tr>
<th>Outlet</th>
<th>0 percent</th>
<th>1-3 percent</th>
<th>4-6 percent</th>
<th>7-9 percent</th>
<th>10-15 percent</th>
<th>15-25 percent</th>
<th>&gt;25 percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors Office / Clinic</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Drug Store</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>5</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Hospital</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Online</td>
<td>5</td>
<td>34</td>
<td>64</td>
<td>41</td>
<td>94</td>
<td>46</td>
<td>40</td>
</tr>
<tr>
<td>Retail Outlet</td>
<td>0</td>
<td>18</td>
<td>6</td>
<td>4</td>
<td>13</td>
<td>13</td>
<td>7</td>
</tr>
<tr>
<td>No Counterfeits in U.S.</td>
<td>8</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
In addition, of the 82 respondents that identified that they purchase their pharmaceuticals from online pharmacies, 65 percent of that population identified the online outlet to be the source most likely to sell a counterfeit. In alignment to the social choice theory, consumers do not always make choices like purchasing pharmaceuticals online on an individual basis but solely on the collective acceptance of the practice by the community. Of the 82 respondents that participate in the risky business of purchasing and consuming products from an online retailer, only four respondents identified counterfeit pharmaceuticals as a top risk to their health and well-being.

**Communications and Government Efforts**

In Understanding Counterfeit Risks section of this chapter, consumer understanding of counterfeit pharmaceutical was thoroughly examined. The findings developed the perception of the sample population regarding counterfeit pharmaceuticals. To progress this thought process beyond the perceptions of the individual to the understanding of the government involvement, required a more in-depth review.

As discussed, the primary research goal of this study was to determine if consumers within the United States are aware of the risk of the counterfeit pharmaceuticals. One of the primary elements of this research goal is to determine consumer perceptions of government actions regarding counterfeit pharmaceuticals. To determine how informed consumers perceived themselves to be regarding the governments’ efforts to mitigate the risk, the questionnaire asked both leading and direct questions. The questionnaire inquired where the sample population believed their pharmaceutical products came from before they purchased them, if anyone had actually informed consumers at any point regarding counterfeit pharmaceuticals, who respondents assigned responsibility of mitigating the risk of counterfeit pharmaceuticals, if the
respondent was aware of the efforts of the government, and how effective has the government been at communicating and mitigating the risks of counterfeit pharmaceuticals. These variables build upon each other to discover the true understanding of consumers regarding the government efforts and communication of counterfeit pharmaceuticals.

As previously identified, the sample population purchase their products from a wide variety of outlets from their doctor’s office to an online retailer. While the respondents perceive online retailers as having a higher risk of having counterfeit pharmaceuticals, it must be examined how they view the origin of the products. Figure 20 describes how the sample population believes their pharmaceuticals came from.

![Figure 20. Respondents Knowledge of Pharmaceutical Origin.](image)

As it can be determined from Figure 20, over half of the respondents were not knowledgeable regarding the source of the pharmaceuticals that they have purchased. A quarter of the respondents believed that the pharmaceuticals that they have purchased had come directly from the manufacturer. This statistic details a lack of understanding of how the pharmaceutical
supply chain works by the respondent. It is rare that a pharmaceutical that is purchased at a retail outlet, pharmacy, clinic, hospital, or online pharmacy come directly from the manufacturer. As described earlier in Figure 2, a pharmaceutical travels from a manufacturer to at least one distributor, and through a third-party logistics provider (3PL) before it reaches the point of dispensation. The assumption that a pharmacy is able to place orders for each product they carry from the original manufacturer demonstrates a lack of understanding of how the process works. Of the 109 respondents that believe the products are sourced directly from the manufacturer, the participants either purchase their products from a retail outlet or an online pharmacy.

This lack of understanding of the pharmaceutical supply chain process relates to the hypothesis that the respondents are not aware of the risk of counterfeit pharmaceuticals based on the fact that they do not understand the processes surrounding pharmaceuticals. If a respondent is unaware of where their pharmaceuticals originate, they would be unaware if there is a risk that the product is being substituted at some point in the delivery. To explore whether respondents were aware of the risk of consuming counterfeit pharmaceuticals, the respondents were asked the direct question of whether they have received any communications regarding counterfeit pharmaceuticals. Figure 21 displays the responses to this inquiry.

![Figure 21](image-url)

*Figure 21. Were the Respondents Informed of Counterfeit Pharmaceuticals?*
Nearly 80 percent of the respondents identified that they had not received any form of communication regarding the risk of counterfeit pharmaceuticals within the United States. Of the population that identified that they had received some form of communication, 33 percent prioritized counterfeit pharmaceuticals as a top risk to their long-term health and well-being compared to just 15 percent of those that did not receive any form of communication. While the content of the communication was not in scope of the research, the fact that some form of information had been sent to the population resulted in an increase of the prioritization of the risk from the vantage point of the respondent.

The content of the communication was out of scope of the study, but the form in which the communication occurred was. If the respondents identified that they had received some form of communication regarding counterfeit pharmaceuticals in the past, they were presented with a question asking them how they received this information. These respondents were given the options of information brochures, commercials, news articles, warning from doctors or pharmacists, government programs, or word of mouth. Table 17 displays the responses from the sample population that had received some form of communication regarding counterfeit pharmaceuticals. It is important to note that this question was not enforced and only 88 of the total 90 possible respondents answered the question.
Table 17

**Source of Counterfeit Pharmaceutical Communications by State (n = 88)**

<table>
<thead>
<tr>
<th></th>
<th>Connecticut (n = 12)</th>
<th>Maine (n = 1)</th>
<th>Massachusetts (n = 55)</th>
<th>New Hampshire (n = 5)</th>
<th>New Jersey (n = 2)</th>
<th>New York (n = 4)</th>
<th>Pennsylvania (n = 3)</th>
<th>Rhode Island (n = 5)</th>
<th>Vermont (n = 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female (n = 48)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government program</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Information brochure</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>News article / report</td>
<td>5</td>
<td>1</td>
<td>21</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Verbal Warning</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Word of mouth</td>
<td>1</td>
<td>0</td>
<td>5</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Male (n = 40)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Government program</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>News article / report</td>
<td>5</td>
<td>0</td>
<td>17</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Word of mouth</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
The communication of counterfeit pharmaceuticals was fairly equal between both male (n = 40) and females (n = 48). The one non-binary respondent did not participate in this question because they had not received any communication regarding the risk of counterfeits and were subsequently not included in this question. Since communication of the risk of counterfeit pharmaceuticals is the primary objective of this study, it was imperative that geographical information was included in this analysis to determine if any one particular state was performing better than any other within the North East region.

As shown in Table 17, 63 percent of all informed consumers were from Massachusetts. The other eight states from the region dividing up the remaining 37 percent, and of that, only Connecticut and Rhode Island provided results with the ability to analyze. The results show that most, 68 percent, of the respondents have become aware of counterfeit pharmaceuticals from the news. This portion of the population is the group which has prioritized counterfeit pharmaceuticals as a top risk to their long-term health and well-being. This demonstrates that the messages being communicated in the news are having an impact on their intended population. The important statistic here is that only five participants that have identified that they have received communications identified that government programs were the source of their information. An analysis could be performed to determine the difference between the message being communicated from the government and that of the message contained in the news.

Understanding that nearly 80 percent of the population has not received any form of communication regarding the risk of counterfeit pharmaceuticals, the study attempted to understand whom the respondent perceived as being the responsible party to ensure that they did not consume a counterfeit product. As identified in Figure 24, nearly 50 percent of the population believe that the government is responsible for controlling or mitigating the risk of
counterfeit pharmaceuticals. The data also demonstrated that only four percent of the population take personal ownership of their own health.

Further detailed in Table 18, interesting correlations between the responsibility of consumer health regarding the risk of counterfeit pharmaceuticals and the demographics of the respondents. Large portions of both the female and male perceived that the Government and the Pharmacies were the responsible parties for counterfeit pharmaceuticals, 22 percent of the female population put the ownership of the risk of counterfeits on the manufacturer compared to only six percent of their male counterparts. In terms of ethnicity, the Asian respondents put more ownership on the government, at 64 percent, than any other group. They may be reflective of their culture and worldview. In regards to the education level of the respondents, the respondents scored the ownership of the counterfeit risk evenly across all educational backgrounds.
Since of the majority of the respondents identified that the government was responsible for ensuring that counterfeit pharmaceuticals were not on the market, the study attempted to
ascertain the respondents’ perceptions of government to mitigate the risk. To establish the respondents’ perceptions, the questionnaire asked whether the respondents they were aware of the governments’ actions and the communications regarding the risk.

As detailed in Table 19, there is almost an even split in the population’s perception of whether the government is taking action to mitigate the risk of pharmaceuticals or not. While only five percent of the population believe that they are fully aware of the actions of the government to mitigate the risk of counterfeit pharmaceuticals, eight percent felt confident that the government is not doing anything. As identified in the demographics portion of this document, 20 percent of the population of the North East region of the United States is employed in the medical industry. If 20 percent of the population works in some type of health care or medical field, a result of only five percent of the respondent population being knowledgeable regarding the government’s actions is surprisingly low. If this population is to be regarded as above average in terms of knowledge and understanding of pharmaceuticals in comparison to the rest of the U.S. population, the inference would be that the remainder of the U.S. would score their knowledge of the government’s actions more towards the uninformed.

Table 19

<table>
<thead>
<tr>
<th>Respondent Perception of Government Actions to Counterfeit Pharmaceuticals (n = 424)</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government is taking action and respondent fully aware</td>
<td>22</td>
<td>5</td>
</tr>
<tr>
<td>Government is taking action, but respondent is not aware what is being done</td>
<td>184</td>
<td>43</td>
</tr>
<tr>
<td>Respondent is not aware of any government actions</td>
<td>184</td>
<td>43</td>
</tr>
<tr>
<td>Respondent believes the government is not doing anything</td>
<td>32</td>
<td>8</td>
</tr>
<tr>
<td>Not the Governments Responsibility</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
While it was previously asked if the respondents had personally been informed regarding the risk of counterfeit pharmaceuticals, the questionnaire also inquired whether the participants believed that the government had communicated anything regarding the risk. The findings demonstrate that 28 percent of the respondents believe the government has sent communications regarding the risk of counterfeit pharmaceuticals, as shown in Table 20.

Table 20

<table>
<thead>
<tr>
<th>Respondent Perception of Government Communications (n = 425)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government has communicated the risk</td>
</tr>
<tr>
<td>Government communicated the risk with no details</td>
</tr>
<tr>
<td>Government has not communicated</td>
</tr>
<tr>
<td>Not the Governments responsibility</td>
</tr>
</tbody>
</table>

Based off of the information in Table 20, a large portion of the population, 70 percent, believed that the government has not communicated the risk of counterfeit pharmaceuticals to the public. This is a condemingly large percentage of the population given the severity of the potential risk to health and well-being. It is unknown as to the driver of this perception which may need to be explored at a later time.

Table 21 details the demographics of the respondents that perceived that no communication had been distributed by the government regarding the risk of counterfeit pharmaceuticals. Based off of the information contained in this data, the population that believes the government is not communicating the risk of counterfeit pharmaceuticals is between 25 and 54 years old, highly educated (Bachelor’s or Master’s degrees), married white individuals, and employed with salaries exceeding $125,000. While the age range provides a larger age range
than initially expected, the remainder of the demographics mirror the findings of the misinterpretation of what defines a counterfeit pharmaceutical.
Table 21

*No Communication of Counterfeit Pharmaceuticals Demographics (n = 400)*

<table>
<thead>
<tr>
<th></th>
<th>Female (n = 247)</th>
<th></th>
<th>Male (n = 153)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#</td>
<td>%</td>
<td>#</td>
<td>%</td>
</tr>
<tr>
<td><strong>Age Range</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-24 years old</td>
<td>26</td>
<td>11</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>25-34 years old</td>
<td>58</td>
<td>23</td>
<td>32</td>
<td>21</td>
</tr>
<tr>
<td>35-44 years old</td>
<td>64</td>
<td>26</td>
<td>20</td>
<td>13</td>
</tr>
<tr>
<td>45-54 years old</td>
<td>60</td>
<td>24</td>
<td>43</td>
<td>28</td>
</tr>
<tr>
<td>55-64 years old</td>
<td>28</td>
<td>11</td>
<td>32</td>
<td>21</td>
</tr>
<tr>
<td>65-74 years old</td>
<td>8</td>
<td>3</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>75 years or older</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>15</td>
<td>6</td>
<td>17</td>
<td>11</td>
</tr>
<tr>
<td>Black or African American</td>
<td>5</td>
<td>2</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>10</td>
<td>4</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Hawaiian or Pacific Islander</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>White</td>
<td>198</td>
<td>80</td>
<td>112</td>
<td>73</td>
</tr>
<tr>
<td>No Response</td>
<td>10</td>
<td>4</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td><strong>Education Level</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some High School</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>High School graduate</td>
<td>13</td>
<td>5</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Some College credit</td>
<td>34</td>
<td>14</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Technical training</td>
<td>6</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Associates degree</td>
<td>18</td>
<td>7</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>79</td>
<td>32</td>
<td>50</td>
<td>33</td>
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<tr>
<td>Master’s degree</td>
<td>68</td>
<td>28</td>
<td>60</td>
<td>39</td>
</tr>
<tr>
<td>Professional certification</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Professional degree</td>
<td>5</td>
<td>2</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Doctorate degree</td>
<td>19</td>
<td>8</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single, never married</td>
<td>54</td>
<td>22</td>
<td>36</td>
<td>24</td>
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<tr>
<td>Married or Domestic Partnership</td>
<td>137</td>
<td>55</td>
<td>80</td>
<td>52</td>
</tr>
<tr>
<td>Separated</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Divorced</td>
<td>29</td>
<td>12</td>
<td>21</td>
<td>14</td>
</tr>
<tr>
<td>Widowed</td>
<td>7</td>
<td>3</td>
<td>5</td>
<td>3</td>
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<td>No Response</td>
<td>16</td>
<td>6</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Employment Status</td>
<td>Female (n = 247)</td>
<td>Male (n = 153)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>------------------</td>
<td>----------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed for wages</td>
<td>169</td>
<td>101</td>
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<td></td>
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<tr>
<td>Household caretaker</td>
<td>16</td>
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<tr>
<td>Military</td>
<td>0</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Out of work and looking for work</td>
<td>7</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Out of work but not currently looking for work</td>
<td>2</td>
<td>0</td>
<td></td>
<td></td>
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<tr>
<td>Retired</td>
<td>8</td>
<td>8</td>
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<tr>
<td>Self-employed</td>
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<tr>
<td>Student</td>
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<tr>
<td>Unable to work</td>
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<tr>
<td>Salary Level</td>
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<tr>
<td>&lt; $25,000</td>
<td>15</td>
<td>10</td>
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<td>$25,000 to $49,999</td>
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<td>$50,000 to $74,999</td>
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<td>9</td>
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<td>$75,000 to $99,999</td>
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<td>&gt; $150,000</td>
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<td>Geographic Location</td>
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<tr>
<td>Maine</td>
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<tr>
<td>Massachusetts</td>
<td>173</td>
<td>82</td>
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<td>New Hampshire</td>
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<tr>
<td>New Jersey</td>
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<td>4</td>
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<tr>
<td>New York</td>
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<td>15</td>
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<tr>
<td>Pennsylvania</td>
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<td>4</td>
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<tr>
<td>Rhode Island</td>
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<tr>
<td>Vermont</td>
<td>7</td>
<td>9</td>
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</tbody>
</table>
Summary and Conclusion

The goal of this descriptive quantitative study was to determine the overall level of understanding of the U.S. consumer regarding the risk of counterfeit pharmaceuticals to their long-term health and well-being. The hypothesis is that consumers would be unaware of the risk of counterfeit pharmaceuticals due to the lack of federal and state policies communicating or educating consumers. The demographics of the sample population demonstrated that consumers were not specifically targeted. With the North East region of the United States heavily concentrated with pharmaceutical companies which employ 21 percent of the population, the respondents would not be considered average consumers (U.S. Department of Labor, 2017). These statistics may lead to the assumption that the North East population is more aware or more knowledgeable about pharmaceuticals and the potential for counterfeits than any other region of the United States. The demographics of the respondents yielded the following findings:

1. 46 percent were between the ages of 35 and 54
2. 73 percent had either a Bachelor’s, Master’s, or Doctoral degree
3. 80 percent were employed
4. 41 percent had a professional career that earned more than $125,000 a year

From these demographic findings, it is concluded that the majority of the responses received were from a highly educated population in the prime of their careers. The assumption based on the salary is that the respondents hold a higher position within their company since the median salary within the U.S. is $59,039 in 2016 (Internal Revenue Service, 2017). Salaries above $125,000 put the individual in the top five percent in terms of salaries in the U.S. (Van Dam, 2016). If 41 percent of respondents are in the top five percent of earnings for the U.S., then the conclusion is that the respondents had achieved success in their given industries. Couple the employment success with a high percentage of respondents with a college degree
results in an assumed educated respondent. These findings align to the profile of the average LinkedIn user (LinkedIn, 2018).

The findings of the demographics from this descriptive quantitative study are highly educated compared to average demographics in the United States. The North East region has the highest concentration of pharmaceutical companies per capita employing 21 percent of the population from the area, the assumption was that these respondents would be more aware of the risk of counterfeit pharmaceuticals than the average consumer. The findings demonstrate that the assumption may be incorrect that the population of the North East would be more aware of the risk of counterfeit pharmaceuticals. The findings from the questionnaire yielded the following on the respondents’ perceptions of counterfeit pharmaceuticals:

1. 80 percent of the respondents did not prioritize counterfeit pharmaceuticals as a risk to their health
2. Only 47 percent of the respondents were able to identify what defined a counterfeit pharmaceutical
3. 17 percent of the respondents did not believe the inclusion of poisonous ingredients qualified as a counterfeit pharmaceutical
4. Only two-thirds of the respondents believed that the U.S. was likely to have counterfeit pharmaceuticals
5. Only 27 percent of the respondents believed that 10 percent of the U.S. pharmaceutical market was counterfeit
6. Only 73 percent of the respondents believed that online pharmacies were most likely to contain counterfeits
7. Almost 20 percent of the respondents purchase from online pharmacies
While the respondents are identified as highly educated and successful individuals, the conclusion is that they are not overly aware of counterfeit pharmaceuticals. The conclusion based upon these statistics is that respondents did not know what a counterfeit pharmaceutical was nor did they have a high level of understanding of the risk that exists within the United States. While the sample population was not completely ignorant of counterfeit pharmaceuticals, over half of the respondents were not able to define a counterfeit pharmaceutical. It was assumed that if an individual does not perceive counterfeit pharmaceuticals as a risk to their health and well-being, they would not focus their attention to understand and mitigate the risk. Since 80 percent of the sample population did not perceive it as a risk, this may influence why 53 percent of the respondents incorrectly identified what a pharmaceutical was.

The one disturbing finding was that when presented with multiple options as to the make-up of a counterfeit pharmaceutical, 17 percent of the study sample did not believe the inclusion of poisonous materials in a product constituted a counterfeit. The majority of the respondents that did not believe including poisonous materials in a pharmaceutical defines it as counterfeit, 85 percent had either a Bachelor’s or Master’s degree. The perception from the respondents with higher education degrees that the inclusion of poisonous materials in a pharmaceutical leads to the conclusion that consumers do not understand what a counterfeit pharmaceutical is or the risk of consuming these products.

From the findings on consumer perceptions of counterfeit pharmaceuticals, it can also be concluded that consumers are still willing to participate in commerce that is believed to be risky. Almost three-quarters of the respondents identified online pharmacies as the most likely source of counterfeit pharmaceuticals. Even though consumers understand the risk involved with purchasing pharmaceuticals online, almost 20 percent continue to purchase their products online.
Of the 20 percent that purchases their pharmaceuticals online, 85 percent believe that this is the source of counterfeits.

To determine why consumers do not fully understand what defines a counterfeit pharmaceutical of the severity of the risk of consumption in the United States, an analysis of the communication of the problem was performed. The findings from the questionnaire yielded the following results regarding communications and possible government actions:

1. Only 20 percent of the respondents had been informed about counterfeit pharmaceuticals
2. Of the 20 percent that has been informed about counterfeit pharmaceuticals, only 25 percent of those respondents perceive it as a risk to their health
3. Almost 50 percent of all respondents believe it is the U.S. FDA's responsibility to ensure that counterfeit pharmaceuticals are not on the market
4. Only 4 percent of the respondents believe it is their responsibility to ensure their own safety from the risk of counterfeit pharmaceuticals
5. 77 percent of the respondents do not believe the government (federal or state) is doing anything to control or mitigate counterfeit pharmaceuticals

These findings conclude that the majority of the respondents have not been informed regarding the risk of counterfeit pharmaceuticals or the actions of the government to mitigate the risk. Nearly half of the respondents placed the ownership of the mitigating the risk of counterfeit pharmaceuticals and ensuring consumer health and well-being on the U.S. FDA, but most respondents do not believe the government has taken any actions. Even though a pedigree process has been around since the early 2000’s at the state level and the Federal government enacted the DQSA in 2013, 77 percent of the population does not believe their government has
not taken any actions. This belief that the government has not taken any action correlates
directly with the lack of communication regarding counterfeits. Only 20 percent of the
respondents have previously been communicated to regarding counterfeit pharmaceuticals. It is
assumed that nearly 80 percent of the respondents perceive that the government is not taking
actions to mitigate the risk counterfeit pharmaceuticals if they have not received any
communications regarding the actions.

The overall conclusion based on the findings is that the original hypothesis was
confirmed that the U.S. consumers would not be aware of the risk of counterfeit pharmaceuticals.
Table 22 contains the findings that support this statement.

Table 22

Summary of Findings

<table>
<thead>
<tr>
<th>Finding #1: Prioritizing Risks</th>
<th>The majority of the respondents (80 percent) chose not to prioritize the consuming a counterfeit pharmaceuticals as a high risk to their health and well-being.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finding #2: Identification of the Risk</td>
<td>When asked to identify what defined a counterfeit pharmaceutical, only 47 percent of the respondents were able to correctly define the aspects of counterfeit pharmaceuticals.</td>
</tr>
<tr>
<td>Finding #3: Perceptions of the Risk in the U.S.</td>
<td>Only 27 percent of the respondent population correctly perceived the amount of counterfeit pharmaceuticals on the U.S. market.</td>
</tr>
<tr>
<td>Finding #4: Communication</td>
<td>The majority of the respondents did not believe that they have ever been informed about counterfeit pharmaceuticals. Those that had been informed about counterfeit pharmaceuticals were twice as likely to identify it as a risk to their health and well-being.</td>
</tr>
<tr>
<td>Finding #5: Government Actions</td>
<td>Over three quarters of the sample population do not believe the government has taken any actions to mitigate the risk of counterfeit pharmaceuticals.</td>
</tr>
</tbody>
</table>
The portion of the respondents that were aware of the risk of counterfeit pharmaceuticals identified it is a risk to their long-term health and well-being. While the overall risk of counterfeit pharmaceuticals in the United States is relatively low compared to the rest of the world, the risk still exists and would continue to flourish if consumers do not make themselves aware of the potential risk to their health.
Chapter 5: Recommendations and Conclusions

In the time that it takes to read this short sentence, two people have died somewhere in the world due to the consumption of counterfeit pharmaceuticals (Interpol, 2013). Conceptually, counterfeit pharmaceuticals have little to no active ingredients, but at their worst, they are providing hospitals and patients with products that are life-threatening poisons (Ossola, 2015). Counterfeit pharmaceuticals are a worldwide dilemma that has continued to grow at a rapid rate. The World Health Organization (WHO) has estimated that globally 10 to 30 percent of all pharmaceuticals globally are counterfeit, though this number can increase up to 50 to 70 percent in some underdeveloped and in-transit nations (World Health Organization, 2016). While only 10 percent of the pharmaceuticals sold within the United States (U.S.) are estimated to be counterfeit, this is still a disturbingly large number given that nearly five billion prescription drugs are dispensed every year (IQVIA Institute for Human Data Science, 2017; World Health Organization, 2016). Despite these overwhelming statistics, the U.S. population remains largely unaware of the risk of consuming a counterfeit pharmaceutical which may be attributed to the lack of federal and state policy focused on consumers.

While the concept of counterfeit pharmaceuticals has been around since the days of traveling miracle medicine men, the counterfeit pharmaceutical industry has exploded as of late with the usage of internet pharmacies and the increase in the price of medicines (Giago, 2017). Research on the trending of the global black market has determined that counterfeit pharmaceuticals are the most counterfeited products in the world with profits estimated at nearly $200 billion annually (Havocscope Group, 2017b). Between 2002 and 2016, the number of incidents of counterfeit pharmaceuticals reported globally increased from 196 in 2002 to 3,375 reported in 2016 resulting in a 1,700 percent increase over a 15 period (Pharmaceutical Security
Information, 2017). This is an alarming increase, but this only focuses on the reported cases of counterfeit pharmaceuticals.

The Commissioner of the United States Food and Drug Administration (U.S. FDA) has made it a priority for the agency to ensure the safety and efficacy of medical products. The U.S. FDA’s efforts to counteract this growing epidemic within the U.S. has been focused on controlling the pharmaceutical supply chain (U.S. Senate Committee on Health, Education, Labor, & Pension, 2011a; U.S. Senate Committee on Health, Education, Labor, & Pension, 2011b). As a result of the efforts of the U.S. FDA and the United States Senate Committee on Health, Education, Labor, and Pension (U.S. HELP), on November 27, 2013, former President Obama signed into law the Drug Quality & Security Act (DQSA, 2013). Under this law, Title II grants the U.S. FDA the ability to monitor and control pharmaceuticals throughout the supply chain from the point of manufacturing to the point of dispensation (DQSA, 2013).

The U.S. FDA has started to implement measures to control or mitigate instances of counterfeit pharmaceuticals from entering the U.S. pharmaceutical market under the Drug Quality & Security Act (DQSA). Even though this law has been in place, there has been an increase in the number of counterfeit instances reported over the last ten (10) years (Pharmaceutical Security Information, 2017). With the U.S. FDA focused exclusively on the pathway for pharmaceutical entry into the market, the largest segment of the United States (U.S.) pharmaceutical supply chain has been largely ignored and left in the dark regarding the risk of consuming counterfeit pharmaceuticals (Blackstone et al., 2014). The U.S. pharmaceutical consumers are at an increased risk of purchasing a falsified or counterfeit pharmaceutical, as demonstrated in Figure 1, without being aware of the risk or the consequences (Pharmaceutical Security Information, 2017; Steel, 2015). Between January and May 2017, most states within
the U.S. had reported over 55 incidents of counterfeit pharmaceuticals discovered in the supply chain. The laws and policies enacted within the United States largely neglect to inform consumers of the potential risk of receiving a counterfeit pharmaceutical (Pharmaceutical Security Information, 2016; S.959, 2013). Most consumers within the United States are unaware of the risk of counterfeit drug, and believe that they are safe solely because they are in a highly-developed nation (Steel, 2015). It was this largely ignored portion of the supply chain that requires greater focus. Educated consumers are the driving force behind the reduction in purchasing counterfeits, and grass-roots campaigns within their government to enforce more stringent regulations.

If consumers constitute the greatest source for influencing change within the government, then the question to pose is: Have the U.S. laws and policies effectively communicated the risk of counterfeit pharmaceutical products?

**Summary of the Study Purpose**

The purpose of this descriptive quantitative study was to explore U.S. consumer level of awareness of the risk of consuming counterfeit pharmaceuticals. The study is limited to prescription and over-the-counter pharmaceuticals for any adult consumer 18 years or older within the North East region of the United States. Findings generated from this study are expected to add to the body of knowledge that supports the proposal of targeted consumer-based communication policy regarding counterfeit pharmaceuticals.
Summary of the Literature Review

The background and purpose of the laws and policies that govern the entry and movement of pharmaceutical products in the U.S. market, as well as comparable laws in the world, have not been enough to mitigate counterfeit pharmaceuticals from entering the U.S. economy. The U.S. imports 80 percent of all the pharmaceuticals consumed domestically (Altstedter, 2017; U.S. HELP, 2011a). In 2015, four of the top five sources of pharmaceutical imports came from Europe which puts stress on the European FMD. Ireland, Germany, the UK, and Switzerland all top the highest value of exporters of pharmaceuticals into the U.S. (Altstedter, 2017). The current state of counterfeit pharmaceuticals within the United States sources its products from other highly developed economic countries. When conceptualizing counterfeit pharmaceuticals, it must come with the understanding that these products originate from developed nations and not in-transit or under-developed nations. In a case study on counterfeit cancer pharmaceuticals entering the U.S. market, the counterfeit pharmaceuticals were being trafficked through highly-developed countries in Europe disproving the perception of where counterfeit pharmaceuticals are originating (Pharmaceutical Research and Manufacturers of America, 2017).

The literature review also showed that part of the problem is that there is not a universal definition for counterfeit pharmaceuticals. Both the U.S. and the EU have defined this term, but it varies from country-to-country or standards organization-to-organization. For this study, the definition of the term “counterfeit” as defined by the U.S. FDA was most appropriate because it was the location the study was performed. But part of what must be understood was that while this study used the U.S. FDA definition, it does not apply to the countries that are exporting pharmaceuticals to the United States.
The literature review addressed why the focus should be on consumers. The average U.S. citizen may have little or no influence on government policymaking, but empirical literature identifies that consumers could affect the economics of the industry (Biron, 2014). Consumers can impact the industry purely based on whether or not the government policies are put in place to restrict or restrain the industry and its negative effects.

As the literature review has shown, the policy enacted within the United States has not provided adequate coverage to ensure that the health and safety of consumers from counterfeit pharmaceutical products. Based on the analysis of the DSCSA, the policy was not focused on counterfeit medications or consumers (S.959, 2013). Consumer awareness plays a key role in the mitigating risk of counterfeit pharmaceuticals as shown through various studies (Maximino, 2014). Understanding the demographics of pharmaceutical consumers is instrumental to determine an approach to developing an education policy. Unfortunately, most consumers within the United States are not aware that 10 percent of all pharmaceuticals they are consuming are counterfeits (Steel, 2015; World Health Organization, 2016). This lack of understanding was the reason why the examination of whether consumers are aware of the counterfeit pharmaceutical risk within the United States, and the government actions to mitigate the risk. The literature review demonstrated that educational policies have proven to be successful with U.S. consumers for relatable products.

Throughout the literature review it was apparent that additional research was required for the risk of counterfeit pharmaceuticals. While research exists on counterfeit pharmaceuticals it is limited in the scope. A broader customer and product population was required to understand the perceived risk of the counterfeit pharmaceuticals.
Summary of the Methodology

The goal of this descriptive quantitative study was to assess the awareness of a sample population regarding the risk of counterfeit pharmaceuticals to their health and well-being. While a qualitative study would have provided unique in-depth understanding of a respondents interactions with counterfeit pharmaceuticals, this methodology is not optimum for reaching a large population. To conduct a study on a large population, a descriptive quantitative study was implemented that would allow for generalization of the findings from the sample population. The total adult population in the North East region over 44 million, a confidence level of 95 percent, and a confidence interval of 5, the desired sample size of 384 was required for the study to be statistically significant. To increase data validity, a total sample population of 442 was collected over a period of seven weeks.

This biased sample was obtained utilizing volunteerism to gather the data. For the volunteerism sampling, the questionnaire was made available to any pharmaceutical consumer via LinkedIn using Qualtrics as the tool to create the questionnaire instrument. Volunteerism resulted in a wide range of knowledgeable and common knowledge consumers with causal inference based on the demographics of the respondents.

To establish major inferences between the research questions and hypothesis against the variables statistical testing was performed. These statistical tests included the t-tests and ANOVA test to compare a group of two or more outcomes, chi-square testing to determine associations between two different variables, and the Pearson product moment correlation to establish the magnitude and direction of the association between two variables measured at specific intervals (Creswell, 2014). Findings from this study was used to develop a risk profile of U.S. consumer’s classification of the potential impact of counterfeit pharmaceuticals on their
health and well-being. This data supports a targeted education program that determines where to achieve the greatest benefit.

**Summary of the Findings**

The intent of the primary research question was to determine the level of understanding of the United States consumer regarding the risk of counterfeit pharmaceuticals. This understanding included not just the analysis of whether the respondent understood what defines a counterfeit pharmaceutical, but also their perceptions of the actions of the government to mitigate the problem posed by this risk. Due to the limitations introduced into the study by utilizing LinkedIn as the tool to obtain respondents, generalizations cannot be made of the entire U.S. population and their understanding of the risk of counterfeit pharmaceuticals. What can be determined from these findings is that the sample population from this study aligns to the hypothesis that the consumers are unaware of the risk of consuming counterfeit pharmaceuticals.

A population of 442 respondents from the North East region of the United States provided input to support the findings of this study. While it was originally determined that a sample population of 400 was going to be utilized to be statistically significant for the size of the total population, additional responses were collected to increase data validity. Even though the sample population did not match up statistically to that of the total population, based on wave analysis, it was determined utilizing a wave analysis on the demographics that response bias was not included in the data.

The bias that may exist in the data is the expertise of the respondents from the medical industry. The North East region of the United States has the highest concentration of medical industry per square mile. Of the total population, 20 percent is employed by the medical industry. Where this research is intended to determine the level of understanding of consumers
regarding counterfeit pharmaceuticals, the population of the North East would be considered above average in that respect. This would be taken into account as the data was analyzed knowing that any statistics may be skewed slightly due to the abundance of potential knowledge of this subject matter from the geographic area.

From this sample population, it was determined that for the majority of the respondent's counterfeit pharmaceuticals was not perceived as a priority as a risk to their long-term health and well-being. Only 29 percent of the population ranked counterfeit pharmaceuticals as a top priority for their health. While gender does not play a strong statistically significant role in the prioritization of counterfeit pharmaceuticals to consumers long-term health and well-being (p value equal to 0.05), for each gender the distribution of prioritization is not equal. With a Chi-Square of $\chi^2(14)$ equal to 63.9554 with an $\alpha$ less than 0.0001, the null hypothesis that being that the prioritization of the risk of counterfeit pharmaceuticals was distributed equally for each gender was rejected. The null hypothesis that gender does not influence how the respondents prioritized the risk of counterfeit pharmaceuticals is confirmed.

This lack of prioritization was reflected throughout the study. The assumption was that if a population does not prioritize a risk, they would not educate themselves about the risk. This assumption was supported by the findings that only 47 percent of the respondents were able to accurately define a counterfeit pharmaceutical. Beyond being able to define a counterfeit pharmaceutical, 17 percent of the respondents did not believe that the inclusion of a poisonous ingredient into a product constituted a counterfeit.

Though there was a lack of understanding the definition of a counterfeit pharmaceutical, the population knowingly participated in risky purchasing habits. Nearly three-quarters of the sample population believe that purchasing pharmaceuticals online provides the greatest chance
for consuming a counterfeit product, but 19 percent of the population still participates in this purchasing practice. This may be due to the fact that almost 40 percent of the population does not believe it is likely that counterfeit pharmaceuticals are included in the U.S. market. Of those that do believe it is likely that the U.S. market may contain a counterfeit pharmaceutical incorrectly perceived the percentage of the counterfeits assumed to be in the market. Only 27 percent of the sample population were able to guess that 10 to 15 percent of the products in the U.S. pharmaceutical market are counterfeit (note: 10 percent is the correct answer, but respondents were provided with ranges in percentages).

In addition, only 53 percent of the population is unaware of where their products originated. The assumption is made that the pharmaceuticals that they are purchasing at a pharmacy or clinic or retail outlet are genuine due to the fact that they have transferred the ownership of the risk of counterfeit to a third-party. Only one percent of the total population took ownership for the responsibility to ensure they are not consuming a harmful or unhealthy product. All other consumers delegated the responsibility to the government or their pharmacy.

Even though 49 percent of the study sample believe that the government is responsible for ensuring they do not consume counterfeit pharmaceuticals, only five percent of the study sample know what actions the government is actually taking. Fifty-one percent of the study sample either are not aware of the actions the government is taking or believe the government is not doing anything at all. Of those that believe the government is not taking any action, gender played a statistically significant role. With a Chi-Square of $\chi^2 (1)$ equal to 24 with an $\alpha$ less than 0.0001, the null hypothesis that gender does not factor into the perception of government mitigation of the risk of counterfeit pharmaceuticals was rejected.
The goal of this study was to contribute to the pool of knowledge that supports the creation of a new education and communication policy regarding counterfeit pharmaceuticals. What these findings have done is identify that a communication policy is needed. Consumers in the region of the country that is assumed to be above average in terms of knowledge of healthcare and pharmaceuticals has been found to be unaware of the risk of counterfeit pharmaceuticals.

**Discussion**

Who should be concerned about counterfeit pharmaceuticals? Based upon the findings, the respondents did not believe that they should be. The respondents assign the responsibility of their health and well-being to some other third-party. Of the 442 respondents to the questionnaire, only 18 total individuals believed that it was their responsibility to ensure they are safe from counterfeit pharmaceuticals. A majority of the respondents placed the responsibility of their health directly on the shoulders of the U.S. FDA, or the manufacturers, or the distributors, or the pharmacies. This lack of accountability for their own health and well-being shows a direct correlation to how the respondents prioritize the risk of consuming a counterfeit pharmaceutical. The lack of prioritization of counterfeit pharmaceuticals by 80 percent of the population is a possible result of the fact that the population has potentially transferred the risk to a third party without any confirmation that this other party is taking action. But why is this?
Discussion of Findings in Relation to Literature Review

The findings identified that the respondents were not aware of the risk of counterfeit pharmaceuticals. This finding is not surprising as the Literature Review has documented an increasing number of reports of counterfeit pharmaceuticals over the last 15 years. This lack of awareness of the risk of counterfeit pharmaceuticals may stem from a lack of understanding in regards to what defines a counterfeit pharmaceutical.

Only 47 percent of the respondents in this sample population were able to correctly define a counterfeit pharmaceutical. While the percentage that correctly identified what a counterfeit pharmaceutical was less than half, the respondents were able to identify some aspect of it. This confusion or gap in consumer knowledge may not be the fault of the consumer. As the Literature Review showed, there is not one universal definition of the term. Each Health Authority agency and each standards organization has their own definition. If the governing bodies for counterfeit pharmaceuticals cannot agree on a single definition, how can we expect consumers to understand this concept? These findings support Sanofi’s 2015 study that only 15 percent of U.S. consumers associated the term counterfeit to medical products, and that 53 percent of consumers were not even aware that counterfeit pharmaceuticals existed (Steel, 2015).

Based off of the finding that the U.S. consumers from the North East region are not aware of the risk of counterfeit pharmaceuticals, communication and education of the risk is needed. The U.S. FDA identified back in 2004 that one of the six actions needed to be taken to eliminate counterfeit pharmaceuticals is an awareness of the risk (U.S. Food and Drug Administration, 2004). The laws and policies that have been implemented by the U.S. FDA does not factor in consumers which is the largest portion of the pharmaceutical supply chain (S.959, 2013). The fact that the laws have ignored consumers correlates to the finding that 79 percent of the respondents do not believe that they were ever informed about counterfeit pharmaceuticals.
Communication and education programs have proven to work historically as well as in the findings from this study. The U.S. FDA educational program for tobacco has shown to reduce teenage smokers by 17 percent between 1999 and 2008 (Meyer, 2008). When the respondents from this study received information regarding counterfeit pharmaceuticals, the likelihood that they would identify counterfeit pharmaceuticals as a risk to their health and well-being more than doubled. While it is improbable to educate the entire pharmaceutical user community within the United States, the findings show that there is a statistically significant correlation between demographics and respondents awareness of the risk of counterfeit pharmaceuticals.

**Discussion of Findings in Relation to Theoretical Framework**

The social choice theory demonstrates that an individual would make a decision based on the patterns of their community. If the majority of the community views pharmaceuticals as a necessity for life and the risk of counterfeits is negligible, then the entire community would view it as such. As it relates to Arrow’s impossibility theorem, the qualification to follow the social choice theory are nearly impossible to achieve. At least one of the rules of the theory’s construct would have to be broken. In this case, it would have to be the dynamic of the *no dictator* rule. As it relates to pharmaceuticals, there is an overarching dictatorship that rules the perceptions. What happens if someone attempts to inform consumers regarding the risk of counterfeit pharmaceuticals? That person is usually disregarded or thought of like a conspiracy theorist. The problem does exist and the results can be extremely negative. So, in following the social choice theory, the community accepts the risk of pharmaceuticals and transfers the ownership of the counterfeit problem to a third party out of necessity. As the findings demonstrated, the study sample overwhelmingly transferred ownership of their health and well-being to either the U.S.
FDA or their local pharmacy. Only two percent of the respondents identified that protecting themselves from risk counterfeit pharmaceuticals was their responsibility.

The primary research question for this study is to determine the level of awareness of the U.S. consumer regarding the risk of consuming counterfeit pharmaceuticals. Prioritization of the risk of counterfeit pharmaceuticals to consumer health and long-term well-being is a key aspect as to whether individuals will spend time educating themselves. With social choice theory, an attempt is made to understand why the community or sample population has ranked the prioritization of the risk.

**Implications for Future Research, Practice and Recommendations**

Based on the findings from this study, there are numerous implications for future research, for practice (including law and policy and for the pharmaceutical industry), and two main recommendations that can be made.

The goal of this study was to generate data to support the creation of a policy that would focus on a targeted communication and education program regarding counterfeit pharmaceuticals. While this study did generate data to use for such a policy, a single study does not justify the means for creating federal policies and oversight. To that end, to generate enough supporting material to substantiate the need for the federal policy, additional research would need to be performed.

*Broadening the Geographic Scope.* The first recommendation stems from the final question in the discussion section. If the North East region of the U.S. was assumed to be above average in knowledge of the pharmaceutical industry, how would the rest of the country identify themselves in their level of understanding? This study needs to be broadened to determine if the
correlation between the demographics of the respondents, and the understanding of counterfeit pharmaceuticals is unique per region or if it can be generalizable across the country.

**Refining the Scope of the Study**. The second recommendation calls for additional details of the participant demographics and their understanding of the risk of counterfeit pharmaceuticals. This study was able to establish a baseline for consumer knowledge but needs to go further and in greater details of the personal data of the respondent. Additional research can be performed to develop a more refined focus on the potential population at risk of counterfeits. Additional data that may need to be collected would include medical history, pharmaceutical format, and method of consumption.

**Implications for Laws and Policies**

Through the utilization of the findings produced through this study and the recommendations for additional research, the potential to create policies related to the education of the U.S. consumer population regarding counterfeit pharmaceuticals exists.

**Heighten awareness**. The U.S. FDA identified in 2004 that one of the six areas required to protect Americans against counterfeit pharmaceuticals was to heighten vigilance and awareness of counterfeit drugs (U.S. Food and Drug Administration, 2004). Even though this recommendation was made to the U.S. Senate, when drafting laws to mitigate the risk of counterfeit pharmaceuticals from entering the U.S. market, the education and communication of consumers were completely ignored. The U.S. FDA has focused all of its attention on the monitoring and controlling of the U.S. pharmaceutical supply chain that it has ignored consumers. Consumers represent the largest portion of the market and the greatest area of potential for change if a grassroots campaign is utilized. Since a nationwide information campaign is not feasible due to the $636 billion cut in 2018 for the United States Department of
Health and Human Services (U.S. HHS), this marketing campaign would have to be targeted to the population that would have the great potential for consuming a counterfeit pharmaceutical (Lee & Dickson, 2017). Starting up an educational program targeted directly at this subset of the U.S. society remains to be an expensive endeavor. Due to this cost, the recommendation is for further exploration of the counterfeit pharmaceutical risk within the U.S. could support the development of a well-defined consumer education program. If this policy is coupled with the phased rollout of the U.S. FDA’s Drug Supply Chain Security Act (DSCSA) that is expected to complete its implementation by November 2023, an end-to-end understanding of the risk of counterfeit pharmaceuticals from the point of manufacturing to the point of consumption would be potentially achieved.

Grassroots campaigns. Grassroots campaigns are the most successful way to deter or reduce a potentially harmful situation or adverse reaction. The main reason that grassroots campaigns are successful is due to the strategic focus on the voter/consumer (Turner, 2015). Regarding grassroots movements, the geographical locations matter about where transition initiatives take root and the extent of their success, and place attachment may have a role in the diffusion of successful initiatives (Feola, & Nunes, 2014). As the U.S. Health and Human Services (U.S. HHS), as the parent organization to the U.S. FDA, receives a significant budget cut of $636 billion in 2018 (Lee & Dickson, 2017), a national communication campaign is not feasible to attempt to target the entire population (Kalton, 1983). With such drastic budget cuts as the one proposed for the U.S. HHS in 2018, education and information campaigns require focus on areas that receive the greatest benefit or segments of the population that would be impacted the most by the program. Grassroots campaigns introduce modifications to the current state and federal policies to include a targeted consumer based communication program that have
the greatest value to the population.

Rejection of sampling studies. With that in mind, statistical sampling studies have been rejected by the courts as a means to define or update the laws. The Supreme Court rejected the use of statistical sampling by the U.S. Census Bureau when counting population for purposes of reallocating congressional seats. In the Cobell et al. v. Gale Norton et al. case decision, the judge ruled that an “accounting” of funds due Native Americans from the individual Indian trust was required, and sampling would not provide such an accounting (Cobell v Norton, 2003). In the Falise v. American Tobacco Co. case, a class of smokers of light cigarettes was decertified on the grounds that the Racketeer Influenced and Corrupt Organizations Act requires each plaintiff to prove injury, and as a result, extrapolation based on a sample was not adequate proof (Falise v American Tobacco, 2000). Depending on the context, there may be a similar case decisions suggesting that sampling is not permitted.

Implications for Pharmaceutical Industry

While the findings from this study identified that there are gaps within the current laws and policies in terms of educating consumers regarding counterfeit pharmaceuticals, there is a greater impact to the pharmaceutical industry as a whole.

The research group, Havocscope, determined that in 2016, the U.S. economy lost $225 billion dollars due to counterfeit pharmaceuticals (Havocscope Group, 2017a). Even though the U.S. FDA has implemented the Drug Supply Chain Security Act (DSCSA) in 2013 to control the pharmaceutical supply chain and potentially mitigate the risk of counterfeit pharmaceuticals ending up on the market, North America continues to be the largest region for reported incidents of counterfeit products (Pharmaceutical Security Information, 2016). Since the laws to not focus on educating consumers, the U.S. population remains at risk of consuming a potentially harmful
product because they are unaware the risk exists. This has been supported through these findings based on the understanding of respondents from the North East.

The findings identified that 49 percent of the sample population believe that the ownership of controlling the risk of counterfeit pharmaceuticals belongs to the government while 47 percent believe that it belongs to the pharmaceutical industry. Since the government has not implemented a policy to communicate the risk to consumers, many are going to look to the pharmaceutical industry to take the lead. According to drug manufacturer, Novartis, larger manufacturers believe they were required to inform patients (Toscano, 2015). Pfizer has been at the forefront of this initiative to inform patients. Pfizer has been investigating hundreds of counterfeit cases, and was the first major pharmaceutical company to open its secure online pharmacy (Gillette, 2013; Isidore, 2013). The pharmaceutical industry will need to expend resources (monetary and human) to combat this risk if the government cannot because it is their brand that is ultimately being effected.

The one area that manufacturers struggle with in their attempt to inform consumers is how to do so without creating alarm and causing panic. The concept of alarming consumers or causing a panic in the industry was included in a study on consumer buying habits performed at the University of Hong Kong by Dr. Biying Shou. Dr. Shou’s research demonstrated that disruptive events such as consumer alarm or panic in any industry may never have a direct effect on the supply chain, but there was a direct correlation with consumer spending. As a result of informing consumers of a potential shortage of a product or a potential crisis concerning a specific product, consumers are more likely to either consume unusually large quantities of the product or completely avoid the product altogether, depending on the type of news they are receiving (Shou, Xiong & Shen, 2012).
Final Recommendations

This study has identified a clear gap in the awareness of the U.S. consumer of a potentially harmful product. The sample population utilized in this study were not fully aware of the definition of a counterfeit pharmaceutical, how these types of products can affect them, and just how prevalent these harmful products are within the U.S. market. Due to this lack of understanding, actions need to be taken to mitigate the risk for consumers.

It is the recommendation of this study that further research be performed to further understand the awareness of consumers regarding the counterfeit pharmaceuticals. While this study aimed to determine a correlation between demographics and the awareness of the consumer regarding the risk of counterfeit pharmaceuticals, due to the limitations derived from utilizing LinkedIn, generalizations of the population were not able to be achieved. To develop a targeted communication campaign to the population most at risk of consuming a counterfeit pharmaceutical, additional understanding of the consumer population must be performed. Since the budget of the U.S. Department of Health and Human Services has been cut by $636 billion dollars in 2018 a communication and education policy cannot be effectively implemented to the entire population (Lee & Dickinson, 2017). Once a comprehensive profile of the U.S. pharmaceutical consumer has been developed, only then can policies be enacted to attempt to mitigate the risk of consuming a counterfeit pharmaceutical.

Conclusions

In 2015, a similar study to this was performed by the pharmaceutical manufacturer Sanofi to attempt to establish which section of the population was most at risk for counterfeit pharmaceuticals (Steel, 2015). The 2015 study was more limited in scope and focused on the area in and around Los Angeles, California, and was only distributed to their customers from that
region. Based on the results of that survey, it was determined that older, wealthy, Caucasian males were the most at risk population for consuming counterfeit pharmaceuticals (Steel, 2015). The respondent demographics were identified based on the type of pharmaceutical products that were being purchased and the source of the product they were consuming. While similar findings were derived from this study, there are some variances. To establish a true baseline of the level of understanding that consumers have for the risk of consuming a counterfeit pharmaceutical, the scope limitations would have to be modified. The geographic range was increased to include potential respondents from nine states, and the limitation on who could participate in the study was increased to include any adult on the social application LinkedIn. This increase in the scope allowed for a broader generalization of the population at risk of consuming a counterfeit pharmaceutical. These findings were not able to narrow down the results to a single gender like the previous study. Both males and females alike proved to be equally at risk based off of buying habits and lack of understanding. What these findings were able to demonstrate was that despite being identified as individuals with a high level of education and a higher level of annual income, the respondents were still uninformed regarding the risk of counterfeit pharmaceuticals. Do the wealthier and more educated portions of the population believe they have a reprieve from being affected by counterfeit pharmaceuticals that the average population does not?

Focusing on the sample population for this study it was determined that the sample population could not be utilized to draw a generalization as to the average pharmaceutical consumer throughout the United States. The North East region of the United States contains the highest concentration of pharmaceutical manufacturers and offices, employing over 20 percent of the population of the region. Based on the high percentage of the population being involved in
the healthcare industry, the assumption is that this sample population could potentially have a
greater understanding for the risk of counterfeit pharmaceuticals than any other region in the
country. Also, given the fact that respondents were reached utilizing a professional networking
social media outlet such as LinkedIn resulted in a greater likelihood that the respondents work in
the pharmaceutical industry in some form. When comparing these assumptions to the findings
that were provided, it is startling how unaware and ill-informed the respondents are about
counterfeit pharmaceuticals. If the sample population is assumed to have been potentially higher
degree of knowledgeable of pharmaceuticals than consumers from other regions of the United
States regarding pharmaceuticals, the question needs to now focus on the level of understanding
of counterfeit pharmaceuticals from the rest of the United States?

The overall purpose of this study was to ascertain the understanding of the awareness of a
sample population in regards to the risk of consuming a counterfeit pharmaceutical. The data
obtained for this study to will be utilized to add to the body of knowledge that supports the
creation of legislation to control counterfeit pharmaceuticals. The findings have made it
apparent that policies focused on the education of consumers is required due to the lack of
understanding of the risk of counterfeit pharmaceuticals. Consumers within the United States
remain unaware of counterfeit pharmaceuticals even though the government has already
implemented policies and taken actions to mitigate the risk. If U.S. consumers continue to
remain uneducated the risk will continue to escalate.

To quote Senator Harkin in his address to the U.S. Senate in 2013, “If we fail to act now,
it will only be a matter of time until we’re asking why more people have died and what could
have been done to prevent it.” (U.S. Senate Committee on Health, Education, Labor, & Pension,
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U.S. Senate Committee on Health, Education, Labor, & Pension (2013m, November 12).


Appendix A – Institutional Review Board (IRB) Form

For NU IRB use:

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**A P P L I C A T I O N  F O R  A P P R O V A L  F O R  U S E  O F  H U M A N  P A R T I C I P A N T S  I N  R E S E A R C H**

Before completing this application, please read the Application Instructions and Policies and Procedures for Human Research Protections to understand the responsibilities for which you are accountable as an investigator in conducting research with human participants. The document, Application Instructions, provides additional assistance in preparing this submission. Incomplete applications will be returned to the investigator. You may complete this application online and save it as a Word document.

If this research is related to a grant, contract proposal or dissertation, a copy of the full grant/contract proposal/dissertation must accompany this application.

Please carefully edit and proof read before submitting the application. Applications that are not filled out completely and/or have any missing or incorrect information will be returned to the Principal Investigator.

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**REQUIRED TRAINING FOR RESEARCH INVOLVING HUMAN SUBJECTS**

Under the direction of the Office of the Vice Provost for Research, Northeastern University is now requiring completion of the NIH Office of Extramural Research training for all human subject research, regardless of whether or not investigators have received funding to support their project.

The online course titled "Protecting Human Research Participants" can be accessed at the following url: [http://phrp.nihtraining.com/users/login.php](http://phrp.nihtraining.com/users/login.php). This requirement will be effective as of November 15, 2008 for all new protocols.

Principal Investigators, student researchers and key personnel (participants who contribute substantively to the scientific development or execution of a project) must include a copy of their certificate of completion for this web-based tutorial with the protocol submission.

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**A. Investigator Information**

Principal Investigator (PI cannot be a student) J.D. LaRock

Investigator is: NU Faculty X NU Staff ________ Other ________

College: _______ Northeastern University

Department/Program CPS – Doctorate of Law and Policy
Address 360 Huntington Avenue, Boston, MA 02115-5000

Office Phone 617-373-8302 Email jd.larock@northeastern.edu

Is this student research? YES X NO _______ If yes, please provide the following information:

Student Name Mark Willis Anticipated graduation date 6/2018
Undergrad ___ MA/MS ___ PhD ___ AuD ___ EdD ___ DLP X ___ Other Degree Type ___
College: ___ Northeastern University CPS ___
Department/Program Doctorate of Law and Policy ___
Full Mailing Address 360 Huntington Avenue, Boston, MA 02115-5000
Telephone 508-272-9647 Primary Email willis.m@husky.neu.edu
Cell phone 508-272-9647 Secondary Email WillisQSConsulting@gmail.com

B. Protocol Information

Title Counterfeit Pharmaceuticals: Are the U.S. Consumers Aware of the Potential Risks?

Projected # subjects 400
Approx. begin date of project November 20, 2017 Approx. end date October 31, 2018

It is the policy of Northeastern University that no activity involving human subjects be undertaken until those activities have been reviewed and approved by the University's Institutional Review Board (IRB).

- Anticipated funding agency/source for project (or none) None __________
- Has/will this proposal been/be submitted through:
  • NU’s Office of Research Administration and Finance (RAF) No ______
  • Provost No ______
  • Corp & Foundations No ______
  • Other No ______
- Grant Title: Not Applicable
- Grant ID: Not Applicable

C.

Will Participants Be: Yes No X
Children (<18) ________ X ________

Does the Project Involve: Yes No X
Blood Removal? ________ X ________

Blood Collection? Yes X No
D. What are the goals of this research? Please state your research question(s) and related hypotheses.

For this doctoral research study, the main question that is being explored is, “Is the U.S. consumer aware of the risk of the counterfeit pharmaceutical in the United States?” In order to understand if consumers are aware of the risk, the research is broken down into two separate sub-questions. The first sub-question will deal directly with the consumer knowledge of the risk of counterfeit pharmaceutical in the U.S. and establish the demographics of the consumer. This data will be gathered under the sub-question, “How does the U.S. consumer prioritize counterfeit pharmaceuticals as a potential risk to their health and long-term safety?” Understanding how a consumer prioritizes the risk of a given scenario is the basis for how knowledgeable the consumer will be regarding it. The second sub-question will establish the consumer understanding of the efforts that the government has put in place to mitigate the risk of counterfeit pharmaceuticals from entering the supply chain. This information will establish the answer to, “Is the U.S. consumer aware of the efforts by the government to control counterfeit?” While this last question will define if the consumer is aware of the efforts, it is important to ask of those that believe themselves to be informed “do they feel like government efforts to controls counterfeit drugs are effective?”

The hypothesis of the overall research question that the US consumers are not aware of the current risk of consuming counterfeit pharmaceuticals nor are they even aware that a counterfeit exists within the United States. Based off of the information discovered as part of the policy background as well as the empirical literature review, the consumer of the pharmaceutical products has been largely ignored. If there have not been any informational or educational programs, the assumption would be that the consumers could not possibly know that there is a risk that they would have to be concerned with. So, based off of that hypothesis, the counterfeit drug risk should score relatively low in the priority of potential harms and should then subsequently result in a large gap in the knowledge of the possible risk. The one sub-question that has the ability to pose a wide variety of responses would be the last sub-question. If consumers are uninformed of a risky scenario, they can either feel that they government has provided them with sufficient protections because they do not feel they are at risk or they can feel that they government needs to do a better
job at communicating because of the exact same reason. As part of this research, while the first two sub-questions should fall in line with the hypothesis, the expectation is that the third and final sub-question can provide mixed results. The intention here is to determine if there is a possible correlation between the feelings about the government and the demographics of the respondent.

E. Provide a brief summary of the purpose of the research in non-technical language.

Health authority agencies around that world have identified that counterfeit pharmaceutical products are placing the lives and well-being of the consumer at an elevated risk. The United States Food and Drug Administration (U.S. FDA) has implemented a law to mitigate this risk, but the problem has continued to escalate over the last fifteen years. Most consumers within the United States are not aware that 10% of all pharmaceuticals they are consuming are counterfeits. It must be examined whether the consumers are aware of the counterfeit pharmaceutical risk within the United States and if they feel the government has done enough to protect them from harm.

The purpose of this quantitative study is to explore US consumer understanding as it relates to counterfeit pharmaceuticals risk of consumption, controlling for over-the-counter medicines for any Rx pharmaceutical consumer within the United States. Knowledge generated is expected to support the proposal of modifications to the current policy to include a targeted consumer based communication program.

F. Identify study personnel on this project. Include name, credentials, role, and organization affiliation.

The only personnel on this project that is required is the primary researcher, Mark Willis. Mark is a part-time lecturer at Northeastern as well as a Global Director of the Program Management Office at Fresenius Medical Care. Mark is affiliated to the Project Management Institute, Healthcare Distribution Alliance, and the American Society of Quality.

G. Identify other organizations or institutions that are involved. Attach current Institutional Review Board (IRB) approvals or letters of permission as necessary.

Other organizations or institutions are not involved in this research.

H. Recruitment Procedures

To understand the overarching research question, “Are the US consumers aware of the risk of the counterfeit pharmaceuticals in the US?” the sample population could potentially have to be representative of the US as a whole. A conducive analysis of the entire population of the US is not feasible for this, or any other, doctoral research proposal. To perform a study on a heterogeneous population such as pharmaceutical consumers, for the purposed of this doctoral study, the population within the Northeastern region of the United States will be utilized to scale the sample. The Northeast region of the US, as defined by the United States Census Bureau, consists of the states of New England, New York, New Jersey, and Pennsylvania (US Census Bureau, 2013).
Since the research topic is regarding the understanding of consumer knowledge of the risk of counterfeit pharmaceuticals, it is also important that the respondent has previously purchased and ingested an Rx pharmaceutical. If the respondent believes they have never taken a pharmaceutical before, the risk is not a high priority for them nor would they pay attention to the scenario. Therefore, the questionnaire would need to contain an inclusion/exclusion inquiry to ensure that the respondent believes they have consumed a pharmaceutical product. If the respondent responds negatively, their results will be automatically excluded from the analysis.

A biased sample will be obtained utilizing volunteerism as the approach to gathering the data. For the volunteerism sampling, the questionnaire will be made available to any pharmaceutical consumer via LinkedIn using Qualtrics. This method of sampling will result in a wide range of both knowledgeable and common knowledge consumers that will allow for a causal inference to the characteristics of the population to the awareness of the risk. The usage of the LinkedIn application will provide the dynamic population of pharmaceutical industry experts as well as those from other industries that are unaware of the risk.

**What remuneration, if any, is offered?**

No compensation will be offered.

**I. Consent Process**

The Informed Consent Form (ICF) will be included on the questionnaire. Using Qualtrics as the sole tool to distribute the questionnaire and obtain the data, the ICF will be used as the first page of the questionnaire. The participants will not be allowed to enter the questionnaire without first clicking the option to volunteer to participate in the questionnaire. Since the results will be anonymous, the names and signatures of the participants will not be recorded.

The questionnaire will only be presented in English. Since the questionnaire is distributed via LinkedIn, the questionnaire will be available to any participant whether they are English speakers or not. As the volunteering sampling does not restrict participation, it will be assumed that the participant can read English if they complete the questionnaire. As part of the demographic data that is collected, if the participant originates from a country outside of the Northeastern region of the U.S., their results will be excluded from the analysis.

**J. Study Procedures**

The study participants will only be required to complete a single questionnaire that is provided via LinkedIn. They will be able to perform this questionnaire from any location that has internet access. The questionnaire should not take more than 10 minutes to complete for the average native English speaking participant. The questionnaire will only be conducted via Qualtrics and will not be presented or conducted in person to ensure the security of the respondents’ identity.

**K. Risks**
With quantitative research, there is an inherent risk to the validity of the study. Validity, in this case, is defined as the extent to which a concept is accurately measured in a quantitative study. But with a questionnaire, because of the human factor is from a single region of the United States, there is a lack of reliability to the extent to which a research instrument consistently has the same results if it is used in the same scenario on repeated occasions. The questionnaire is intended to provide different results based off of the participants knowledge and/or understanding of the counterfeit pharmaceutical risk. Because of this, the focus of this quantitative study will be on content validity in order to ensure that the questionnaire fully measures what it is intended to. This content validity will focus on the sub-questions of the research topic. Specifically, the demographics section of the questionnaire will be the initial gating mechanism to determine inclusion and exclusion of the responses from the participant. Since the intended research topic is focused on the understanding of the U.S. consumer but utilizing volunteerism may result in participants outside of the Northeastern region of the U.S., the demographic information will determine if the results should be included in the analysis or excluded and disregarded.

In order to demonstrate the research instrument has construct validity, theory evidence will be utilized. Under theory evidence the demographics will determine if the behavioral results of the research sub-questions align to the theoretical propositions. The hypothesis is that the lower the risk ranking is by the respondent, the less they will know or understand about the counterfeit risk within the U.S. As part of the analysis of this research, the correlation between these two variables will be important to understand how to effectively implement a targeted education campaign.

In terms of the quantitative method questionnaire itself, there are a number of challenges that can arise during the collection of this data. The first challenge, which may also present to be the greatest hurdle, is that the collection technique will be a questionnaire. Most people in our society avoid questionnaires and in an industry like prescription pharmaceuticals, this is no different. While there will be a dual method of both volunteerism and sampling of convenience, the task of ensuring I receive a proper sampling of the U.S. population will be a monumental task. The goal is to get an equal representation of respondents with the different demographics within the chosen region of the U.S. By utilizing LinkedIn, the researcher will have access to over 2,100 member of his professional network that are from the Northeastern region of the U.S.

For the questionnaire itself, based off of my positionality, there is a risk of introducing a bias into the questions. Because my positionality comes from various sources, it can result in leading questions that may or may not direct the respondent to answer in such a way that they are influenced to provide the result that I desired. In order to prevent this from occurring, the questionnaire will be reviewed and analyzed by an independent third party. Dr. Brooke Rogers, professor at King’s College in London is an expert on risk and terror in human behavior. Dr. Rogers has performed research on reactions and interpretation of the risk of terrorism among the citizens of England. Dr. Rogers has agreed to review the questionnaire to determine if it has any built in bias as well as determining if it will provide valuable data for analysis.

L. Confidentiality
All questionnaire data will be recorded anonymously. The identification of the participants will never be recorded, nor will the IP address of the participants be identified. The participants will maintain 100% anonymity throughout the participation process. Once the data is entered, the only person that will have access to the results will be the primary researcher, Mark Willis.

The results of the data analysis will be utilized to determine three desired outcomes. The data will develop a risk profile of what the U.S. consumers classifies and identifies as the most potential impact to their health and long-term safety. This risk profile will assist in the assignment of the severity of the risk. The second outcome of the data analysis will be to determine the demographic information on the US pharmaceutical consumer to identify which socioeconomic class, geographic region, and ethnicity is at a greater risk of consuming a counterfeit drug based off of lack of understanding. The final outcome would be to propose modifications to the current policy to include a targeted consumer based communication program.

Once the initial data analysis is performed, the data will be archived and stored. The data may be utilized in the future as a reference point or a baseline to expand the research or build off of for future investigations. If any other researchers request the data in order to verify the results, a formal written request will need to be submitted and tracked to show the name and organization of the requester.

During data collection, Qualtrics will be utilize to collect and perform basic data analysis. Qualtrics is a secured cloud system that can only be accessed by a single ID and password. This will ensure that no one outside of the primary researcher, Mark Willis, will have access to the data. The professional version of Qualtrics also includes basic data analysis, but will allow for data exporting into Excel for correlation analysis via the Analysis Toolpak. Qualtrics will retain all information securely under the researchers account. This will include the informed consents. In the future, the data may be exported and stored in a personal storage device.

M. If your research is HIPAA-protected, please complete the following; Individual Access to PHI

This research is not HIPAA-protected.

N. Benefits

There are no direct benefits for the participants in this questionnaire.

O. Attachments

Identify attachments that have been included and those that are not applicable (n/a).

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
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<tbody>
<tr>
<td>N/A</td>
<td>Copy of fliers, ads, posters, emails, web pages, letters for recruitment *</td>
</tr>
<tr>
<td>N/A</td>
<td>Scripts of intended telephone conversations*</td>
</tr>
<tr>
<td>N/A</td>
<td>Copies of IRB approvals or letters of permission from other sites</td>
</tr>
<tr>
<td>X</td>
<td>Informed Consent Form(s)* (<a href="#">see our templates for examples</a>)</td>
</tr>
<tr>
<td>N/A</td>
<td>Debriefing Statement*</td>
</tr>
<tr>
<td>X</td>
<td>Copies of all instruments, surveys, focus group or interview questions, tests, etc.</td>
</tr>
</tbody>
</table>
Signed Assurance of Principal Investigator Form *(required)*

NIH Human Subject Training Certificate(s) *(required if not already on file at HSRP)*

*(Approved forms must be stamped by the IRB before use)*

**P. Health Care Provision During Study**

Please check the applicable line:

**X** I have read the description of HIPAA “health care” within Section 4 of the Policies & Procedures for Human Research Protection. I am not a HIPAA-covered health care provider and no health care will be provided in connection with this study.

**X** I am a HIPAA-covered health care provider or I will provide health care in connection with this study as described in Section 4 of the Policies & Procedures for Human Research Protection. This health care is described above under “Study Procedures,” and the Informed Consent and Health Information Use and Disclosure Authorization form will be used with all prospective study participants.

If you have any questions about whether you are a HIPAA-covered health care provider, please contact Nan C. Regina, Director, Human Subject Research Protection at n.regina@neu.edu or (617) 373-4588.

Completed applications should be submitted to Nan C. Regina, Director, Human Subject Research Protection with the exception of applications from faculty and students of the College of Professional Studies, which should be submitted to Kate Skophammer, IRB Coordinator for CPS.

<table>
<thead>
<tr>
<th>Nan C. Regina, Director</th>
<th>CPS applications only</th>
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<tbody>
<tr>
<td>Northeastern Univ., Human Subject Research Protection</td>
<td>Kate Skophammer, IRB Coordinator</td>
</tr>
<tr>
<td>360 Huntington Ave., Mailstop: 560-177</td>
<td>Northeastern Univ., College of Professional Studies</td>
</tr>
<tr>
<td>Boston, MA 02115-5000</td>
<td>Phone: 617.390.3450; <a href="mailto:k.skophammer@northeastern.edu">k.skophammer@northeastern.edu</a></td>
</tr>
<tr>
<td>Phone: 617.373.4588; Fax: 617.373.4595</td>
<td><a href="mailto:n.regina@northeastern.edu">n.regina@northeastern.edu</a></td>
</tr>
</tbody>
</table>

The application and accompanying materials may be sent as email attachments or in hard copy. A signed Assurance of Principal Investigator Form may be sent as a scan, via fax or in hard copy.
Appendix B – Letter to Respondents

LinkedIn Article Title: Northeastern University Doctoral Research Support

Distribution: Open Distribution to Mark Willis’s entire LinkedIn Network

Hello LinkedIn Network Members,

I, Mark Willis, am conducting a quantitative research study for my Doctorate of Law and Policy at Northeastern University and would greatly appreciate your support. The purpose of this quantitative study is to explore US consumer understanding as it relates prescription drugs to the risk of the consumer long-term health and safety. This study controls for over-the-counter medicines for any Rx pharmaceutical consumer within the United States. Knowledge generated is expected to support the proposal of modifications to the current policy to include a targeted consumer based communication program.

As the primary researcher, I will be pleased to answer any questions that you have concerning the study. If you have any questions during, between, or after your participation, please send an email to: willis.m@husky.neu.edu. Please do not discuss the content of questionnaire with other participants until the study has been completed. The results of this study will contribute to scientific knowledge, but will probably have no direct benefits or risks to you as a participant.

Any information that you provide will be kept strictly private, confidential, and anonymous. Your name will not be attached to your questionnaire responses in any way. Results from this study will be presented as statistical summaries, but no information will be presented about individual participants/respondents. You may discontinue participation at any time during assessment. The Informed Consent Form (ICF) will be attached to your questionnaire responses, but neither the ICF nor the questionnaire will ask for identifying information to
maintain anonymity. When you have completed the Informed Consent, you will be allowed to start the questionnaire. Once the ICF window closes, you will not be able to retrieve your agreement but a copy will be available to you if you submit a request to the primary researcher listed above. All participants will need to complete this ICF in order get access to the online questionnaire generated through a Qualtrics website. Once the online questionnaire is completed, the researcher will be utilized the data for statistical summaries only for the purposes of this study. Data will be stored securely without any names associated. THEREFORE, NO NAMES WILL BE WRITTEN ON THE QUESTIONNAIRE. This is to ensure anonymity (privacy/confidentiality).

Please note that you must be an adult 18 years or older to participate in this voluntary study. If you wish to decline or withdraw at any time, you may do so.

The entire study should take about 10 minutes to complete.

I would like to thank you in advance for your time and honesty in completing this questionnaire. I hope that this research will greatly benefit our regulators and support the education of pharmaceutical consumers going forward.

Thank You,

Prof. Mark Willis

Northeastern University

360 Huntington Avenue

Boston, MA 02115-5000

Email: willis.m@husky.neu.edu

Phone: 508-272-9647
Appendix C – Informed Consent Form

Northeastern University, Department of: College of Professional Studies – Doctorate of Law and Policy

Name of Investigator(s): Jean-Daniel LaRock, Mark Willis

Title of Project: Counterfeit Pharmaceuticals: Are the U.S. Consumers Aware of the Potential Risks?

Request to Participate in Research

I would like to invite you to participate in a web-based online questionnaire. The questionnaire is part of a research study whose purpose is to assess pharmaceutical consumer awareness of potential risk of counterfeit products. This questionnaire should take about 10 minutes to complete.

I am asking that you to participate in this study based on your experience as a pharmaceutical consumer. You must be at least 18 years old to take this questionnaire.

The decision to participate in this research project is voluntary. You do not have to participate and you can refuse to answer any question. Even if you begin the web-based online questionnaire, you can stop at any time.

There are no foreseeable risks or discomforts to you for taking part in this study.

There are no direct benefits to you from participating in this study. However, your responses may help me learn more about pharmaceutical consumer knowledge and buying habits based upon awareness.

You will not be paid for your participation in this study.

Your part in this study is anonymous to the researcher(s). However, because of the nature of web based study, it is possible that respondents could be identified by the IP address or other electronic record associated with the response. Neither the researcher nor anyone involved with
this questionnaire will be capturing that data. Any reports or publications based on this research will use only group data and will not identify you or any individual as being affiliated with this project.

If you have any questions regarding electronic privacy, please feel free to contact Mark Nardone, NU’s Director of Information Security via phone at 617-373-7901, or via email at privacy@neu.edu.

If you have any questions about this study, please feel free to contact Mark Willis via phone at +1 508-272-9647 or email at willis.m@huskey.neu.edu. Mark is the person mainly responsible for the research. You can also contact J.D. LaRock at jd.larock@northeastern.edu, the Principal Investigator.

If you have any questions regarding your rights as a research participant, please contact Nan C. Regina, Director, Human Subject Research Protection, 960 Renaissance Park, Northeastern University, Boston, MA 02115. Tel: 617.373.4588, Email: n.regina@neu.edu. You may call anonymously if you wish.

By clicking on the accept button below you are indicating that you consent to participate in this study. Please print out a copy of this consent form for your records.

Thank you for your time,

Prof. Mark R. Willis
Appendix D - Questionnaire

Note: Each of the sections below was maintained on a unique page. A backwards or “previous” button was not enabled to preserve the respondents answers.

Section 1: Demographics

1. Gender:
   a) Male
   b) Female
   c) Non-Binary

2. Age:
   a) 18-24 years old
   b) 25-34 years old
   c) 35-44 years old
   d) 45-54 years old
   e) 55-64 years old
   f) 65-74 years old
   g) 75 years or older

3. Ethnicity:
   a) White
   b) Hispanic or Latino
   c) Black or African American
   d) Native American or American Indian
   e) Asian / Pacific Islander
   f) Middle Eastern / Indian
4. What is your highest level of education?
   a) No schooling completed
   b) preschool to 8th grade
   c) Some high school, no diploma
   d) High school graduate, diploma or the equivalent (for example: GED)
   e) Some college credit, no degree
   f) Trade/technical/vocational training
   g) Associate degree
   h) Bachelor’s degree
   i) Master’s degree
   j) Professional degree
   k) Professional certification
   l) Doctorate degree

5. Marital Status:
   a) Single, never married
   b) Married or domestic partnership
   c) Widowed
   d) Divorced
   e) Separated

6. Professional or Employment Status:
   a) Employed for wages
b) Self-employed

c) Out of work and looking for work

d) Out of work but not currently looking for work

e) Household caretaker

f) Student

g) Military

h) Retired

i) Unable to work

7. Household Income:

a) < $25,000

b) $25,000 to $49,999

c) $50,000 to $74,999

d) $75,000 to $99,999

e) $100,000 to $124,999

f) $125,000 to $149,999

g) >$150,000

8. Are you from the United States?

a) Yes, I am in the United States

b) No, I am outside of the United States

9. If you are in the US, which state are you from?

a) (List of states)

10. If you are outside of the US, which country are you in?

a) (List of countries)
Section 2: Potential Risks

1. Please rank the following in order of greatest risk to your health and well-being
where 1 is the greatest risk and 15 is the lowest risk

   - Tobacco / Alcohol intake
   - Car Accident / DUI
   - Victim of Terrorism / Hate Crime
   - Communicable Diseases
   - Terminal Illnesses
   - Home Invasion / Crime
   - Counterfeit / Fake Pharmaceuticals
   - Vaccine
   - Natural Disaster
   - Allergic Reaction / Anaphylaxis
   - Obesity
   - High Blood Pressure
   - Pesticides / GMO Consumption
   - General Accident (Trip/Fall/Injury)
   - Other (describe)

2. Please rank the following in order of the cause of the most deaths in the US during
2016 where 1 resulted in the most amount of deaths and 6 resulted in the least amount

   - Car Accident / DUI
• Victim of Terrorism / Hate Crime
• Pancreatic Cancer
• Counterfeit / Fake Pharmaceuticals
• Natural Disaster
• Suicide

Section 3: Pharmaceutical Drugs

Part 1: Buying Habits

1. Have you ever consumed a pharmaceutical (prescription and over-the-counter)?
   a) Yes
   b) No
   c) Not Sure

2. What types of pharmaceuticals have you purchased? (select all that apply)
   a) Prescription pharmaceuticals
   b) Over-the-counter pharmaceuticals
   c) Dietary / Vitamins

3. What type of pharmacy do you purchase your pharmaceuticals from? (select all that apply)
   a) Hospital
   b) Drug Store (Ex. CVS, Right Aid, local corner store, etc)
   c) Retail Outlet (Ex. Walmart, Target, etc.)
   d) Doctors Office / Clinic
   e) Online
Part 2: Counterfeit Pharmaceuticals

1. Which of the following would be considered a counterfeit pharmaceuticals? (select all that apply)
   a) Mislabeled product
   b) Right ingredients but contains a higher dose than intended
   c) Right ingredients but contains a weaker dose than intended
   d) Does not contain all of the right ingredients
   e) Does not contain any ingredients at all (sugar pill)
   f) Contains contaminated ingredients
   g) Contains intentionally poisonous ingredients

2. Which of the countries listed below do you believe are likely to have counterfeit pharmaceuticals? (select all that apply)
   a) Nigeria
   b) Germany
   c) China
   d) India
   e) Australia
   f) Brazil
   g) United States
   h) Ukraine

3. What percentage of the pharmaceuticals in the US market are counterfeit?
a) 0%
b) 1-3%
c) 4-6%
d) 7-9%
e) 10-15%
f) 15-25%
g) >25%

4. Which pharmacy type do you believe is most likely to sell you a counterfeit pharmaceuticals in the US?
   a) Hospital
   b) Drug Store
   c) Retail Outlet
   d) Doctors Office / Clinic
   e) Online
   f) Not applicable, there are not any on the US market.

5. Do you know where the pharmaceuticals you purchased/consumed came from?
   a) Yes, I believe the product came from the manufacturer on the label
   b) Maybe, I believe it is the responsibility of my pharmacy to know that information and not mine
   c) No, I am not sure where the product was before I consumed it
   d) Not Applicable, I have never taken a pharmaceutical product before

Section 4: Government Effectiveness
1. Have you ever been informed about counterfeit pharmaceuticals?
   a) Yes
   b) No

2. If you have been informed about the risk of counterfeit pharmaceuticals, where did you hear about them?
   a) Information brochure from doctor
   b) Commercial
   c) Warning from pharmacist
   d) Government program
   e) Word of mouth

3. Whose responsibility is it to ensure that your pharmaceuticals are not counterfeit?
   a) Food and Drug Administration (FDA)
   b) Pharmaceutical Manufacturers
   c) Pharmaceutical Distributors
   d) Pharmacies
   e) Consumer (your responsibility)

4. How familiar are you with the efforts of the government to control or stop counterfeit pharmaceutical products?
   a) I am aware of everything that the government is doing
   b) I believe the government is doing something, but I am not too aware
   c) I am not aware of the Federal government doing anything
   d) I do not believe the government has taken any actions
   e) It is not the government’s responsibility to control the risk
5. Do you believe that the government is effective in communicating the counterfeit pharmaceutical risk in the US?

a) The government has kept me informed of the risk and what I should do if I find a counterfeit

b) The government has kept me informed of the risk of counterfeit pharmaceuticals

c) I have been told of the risk from the government, but they have not communicated too many details

d) The government has not communicated anything regarding the risk

e) It is not the government’s responsibility to communicate the risk, it is the consumers responsibility to make themselves informed
Appendix E – Image and Data Usage Approvals

Figure 4 and Figure 6

Permission to Reference Data
2 messages

Mark Willis <willis.m@husky.neu.edu>  Mon, Jul 2, 2018 at 2:47 PM
To: mtfinfo@isr.umich.edu

Hello Ms. Meyer,

I am a doctoral candidate at Northeastern University in Boston, MA in the Doctor of Law and Policy program. I’m doing my research on counterfeit pharmaceuticals and would like your permission to reprint an image from your website. While your study does not pertain to counterfeit pharmaceuticals, there is a connection between our studies. I’m attempting to show that communication and education of consumers raises awareness of health issues and would decrease the likelihood of usage. I’m utilizing the communication efforts of the TheTruth.com to show the success of the smoking campaign.

I would like to use Figure 2 from your study in my dissertation.

Please let me know if I would have permission to reference your website and utilize your data in my doctoral dissertation.

Thank You,
Mark Willis
Northeastern University,
506-272-9647

Referencing:
http://www.monitoringthefuture.org/pressreleases/08cigpr_complete.pdf

MTF Information <mtfinformation@umich.edu>  Tue, Jul 3, 2018 at 10:18 AM
To: Mark Willis <willis.m@husky.neu.edu>

Hi Mark,

All materials appearing in volumes, monographs, or press releases are in the public domain and may be reproduced or copied, whether in print or in non-print media including derivatives, in any reasonable manner, without permission from the authors.

Thanks,
Amanda Donovan
Youth and Social Issues Program
The University of Michigan
Permission to reference data
2 messages

Mark Willis <willis.m@husky.neu.edu> Mon, Jul 2, 2018 at 2:26 PM
To: psi@psi-inc.org

Hello PSI,

I am a doctoral candidate at Northeastern University in Boston, MA in the Doctor of Law and Policy program. I'm doing my research on counterfeit pharmaceuticals and would like your permission to reprint some of the information you've presented on your website in my Introduction and Literature Review. I would like to use the following charts in my dissertation:

- Incidents - Regions of the World
- Counterfeit Drug Instances Per Year (2002 - 2016)

Please let me know if I would have permission to reference your website and utilize your data in my doctoral dissertation.

Thank You,
Mark Willis
Northeastern University,
505-272-9647

Referencing
http://www.psi-inc.org/incidentTrends.cfm
http://www.psi-inc.org/counterfeitSituation.cfm

psi@psi-inc.org Mon, Jul 2, 2018 at 3:52 PM
To: Mark Willis <willis.m@husky.neu.edu>

Mr Willis

Thank you for checking. Feel free to reference our site and use the charts.

Good luck with your dissertation.

PSI
Table 1 and Table 3

Permission to adapt data
3 messages

Mark Willis <willis.m@husky.neu.edu>  Mon, Jul 2, 2018 at 2:20 PM
To: contact@havoscope.com

Hello Havoscope Group,

I am a doctoral candidate at Northeastern University in Boston, MA in the Doctor of Law and Policy program. I’m doing my research on counterfeit pharmaceuticals and would like your permission to adapt some of the information you’ve presented on your website in my Introduction and Literature Review. I would like to present an adaptation of your counterfeit goods ranking (to only display top 10) and the losses to counterfeit goods by country (to only display to 25).

Please let me know if I would have permission to reference your website and utilize your data in my doctoral dissertation.

Thank You,
Mark Willis
Northeastern University,
508-272-9647

Referencing
http://www.havoscope.com/losses-to-counterfeit-goods-by-country/
http://www.havoscope.com/counterfeit-goods-ranking/

Mark Willis <willis.m@husky.neu.edu>  Wed, Jul 25, 2018 at 9:36 AM
To: contact@havoscope.com

Hello Havoscope Group,

I am just following up on my earlier email. Please let me know if I have permission to include an adaptation of your data in my research.

Thank You,
Mark Willis
[Quoted text hidden]

Havoscope Contact <contact@havoscope.com>  Thu, Jul 26, 2018 at 3:18 PM
To: Mark Willis <willis.m@husky.neu.edu>

Hi Mark,

Sorry for the delay in getting back to you.

Feel free to reference our site or use any information from the site as you seem fit.

Thank you for asking. Good luck in your dissertation.
Havoscope
Permission to Reference Data
2 messages

Mark Willis <willis.m@husky.neu.edu>  Mon, Jul 2, 2018 at 2:36 PM
To: editors@safemedicines.org

Hello Safe Medicines,

I am a doctoral candidate at Northeastern University in Boston, MA in the Doctor of Law and Policy program. I’m doing my research on counterfeit pharmaceuticals and would like your permission to reprint an image from your website. I would like to use the image associated to the following article in my dissertation:

- Bipartisan Safety Issues: How Many Different Kinds Of Black Market Medicines Have Been Sold In Your State?

Please let me know if I would have permission to reference your website and utilize your image in my doctoral dissertation.

Thank You,
Mark Willis
Northeastern University,
508-272-9647

Referencing

Sarah Imber <sarah@safemedicines.org>  Tue, Jul 3, 2018 at 3:55 PM
To: Mark Willis <willis.m@husky.neu.edu>

Yes, you can use our image with credit please.
[Quoted text hidden]

--
Sarah Imber
The Partnership for Safe Medicines
sarah@safemedicines.org
415-692-1392