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Strategies for Preventing and Mitigating Counterfeit Medication From Entering the U.S. Supply Chain

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This is to certify that the doctoral study by

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Abstract

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by

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MS, Pace University, 2006

BS, University of Southern Maine, 1994

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Business Administration

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June 2022

Abstract

Some pharmaceutical brand protection managers lack strategies to mitigate financial losses from counterfeit prescription drugs. A multilayered approach involving guiding principles, supply chain security, investigations, enforcement, advocacy, and awareness can help mitigate potential financial losses and keep patients safe. Guided by the Six Sigma define, measure, analyze, improve, and control (DMAIC) model and the fraud triangle conceptual framework, the purpose of this multiple case study was to explore strategies brand protection managers use to mitigate financial losses from counterfeit prescription drugs. Data collection included three semi-structured interviews using Zoom. Analyzing data entailed transcribing and coding themes within data and relating findings to the composite conceptual framework and peer-reviewed literature. Four key themes emerged: (a) guiding principles, (b) securing the supply chain, (c) investigations and enforcement, and (d) advocacy and awareness. The primary recommendation for pharmaceutical brand managers is to build a risk profile for each product based on knowledge of how counterfeiters behave and implement a multilayered approach for improved supply chain security while educating consumers on risks associated with purchasing medications outside the legitimate supply chain. The implications for positive social change include the possibility to inform more consumers on potential risks, which could save lives.

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Dedication

I would like to dedicate this study to the pharmaceutical companies and healthcare professionals for all that they do to keep our US healthcare system safe. The Covid-19 pandemic brought so many challenges that few imagined. Yet their passion and commitment to care for others helped so many in ways they will never know. Experts in all areas answered the call to help patients despite putting themselves at risk, both physically and mentally. Thank you.

Acknowledgments

I would like to thank the experts that participated in this study. Without your involvement, this study would not be possible. I deeply appreciate all the support that I received from experts, managers, colleagues, fellow students, family, and friends. I hope this study brings enlightenment on the topic and helpful information to people that can positively impact the pharmaceutical distribution process. This journey was the most rewarding process I have every been through. As a result of completing the doctoral program I gained confidence in myself, my abilities, and faith that with hard work and persistence, anything is possible. Thank you all so very much.

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Section 1: Foundation of the Study

The purpose of the qualitative multiple case study was to explore successful strategies that brand protection managers use to mitigate financial losses resulting from counterfeit prescription drugs. The pharmaceutical industry involves manufacturers, wholesalers, distributors, dispensers, third-party repackaging companies, and third-party logistics providers as key stakeholders. The primary function of the pharmaceutical supply chain is to ensure a consistent flow of medications to consumers immediately, at an optimal price when required, and with 100% accuracy (Tripathi et al., 2019). The increasing global complexity of the supply chain leads to gaps that create opportunities for counterfeiting, which is the creation of substandard, fake, falsely labeled, and falsified counterfeit drugs, as well as grey markets that can cause severe harm to patients (Brechtelsbauer et al., 2016; Mackey & Cuomo, 2020). Guarantees of authenticity and integrity of medications do not exist in the current supply chain, which may lead to ineffective or deadly treatments for patient illnesses (Brechtelsbauer et al., 2016; Mackey & Cuomo, 2020). Manufacturers' reputations and financial positions are also at risk when counterfeits enter the supply chain.

To address the issue, the Federal Drug Administration (FDA) proposed legislation to ensure better transparency among supply chain trading partners. On November 27, 2013, President Barack Obama signed into law the Drug Supply Chain Security Act (DSCSA) to focus on adopting approaches for product tracking and tracing of package-level information, detection, suspect product removal, and wholesaler licensing and

reporting requirements for the FDA. The legislation lays out a 10-year plan with various milestones leading to a fully interoperable electronic system for tracking and tracing products throughout the complete supply chain by 2023 (FDA, 2015). Kumar and Tripathi (2019) said none of the existing preventative or reactive strategies automatically verifies product authenticity and manufacturer validity. Therefore, exploration of successful brand protection strategies may provide a comprehensive view of the issue as well as effective strategies to help brand protection managers mitigate financial losses due to counterfeit medications.

Background of the Problem

Innovative medications are vital to public health, especially during a pandemic and growing health crisis. Pharmaceutical counterfeiting is a silent but growing type of global fraud found in developing countries and increasing in developed countries such as the United States (US) and Canada due to the increasing complexity of the global supply chain (Peltier-Rivest & Pacini, 2019). The FDA (2018b) stated that counterfeit drugs may contain too little or too much of an active ingredient, contain harmful chemicals, contain incorrect active ingredients, and eventually ruin consumer confidence in the pharmaceutical supply chain. Manufacturers, especially those in the US supply chain, can incur significant losses and liabilities and cause severe reactions in patients (Organization for Economic Cooperation and Development & European Union Intellectual Property Office [OECD/EUIPO], 2020). The impact of counterfeit drugs is far-reaching.

While quantifying the size of the issue is impossible, recent statistics indicate a substantial problem, especially since the outbreak of the COVID-19 pandemic. Counterfeit drugs are infringements of US trademarks (Lund, 2019). In the fiscal year 2019, US Customs and Border Protection (USCBP), along with US Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HIS) officials conducted 858 seizures of counterfeit pharmaceuticals worth approximately $48,771,870, which is an increase of 47% from fiscal year 2018 that involved 403 seizures (USCBP, 2020b). Fake products are often difficult to detect because of the advanced ability of criminals to mimic authentic product labeling, pill formation, and packaging.

The pharmaceutical supply chain faces several regulatory milestones through 2023. Manufacturers and trading partners within the industry must collaborate to identify innovative protection strategies and opportunity gaps in the supply chain that enable counterfeiters to insert products into the market due to by diverse stakeholders with fragmented responsibilities (OECD/EUIPO, 2020; Peltier-Rivest & Pacini, 2019). Peltier-Rivest and Pacini (2019) stated that implementing quick response (QR) code tracking technology would aid in more efficient tracking of data among partners where interoperability requires technology. The pharmaceutical industry must support active monitoring of package-level product information by 2023 per DSCSA regulations (FDA, 2015). However, some brand protection managers may lack strategies to mitigate financial losses resulting from counterfeit prescription drugs.

Problem Statement

Counterfeit pharmaceuticals are a growing global problem, not only affecting developing countries, but also developed countries such as the United States (Peltier-Rivest & Pacini, 2019). As much as $700 billion in losses occurs per year because of healthcare fraud, waste, and abuse (Sullivan & Hull, 2019). The general business problem is costs to improve operational inefficiencies in the fragmented supply chain are significant, and unlike other industries, dependent on the number of production lines needed to produce the final product and selected strategies for each unique medication (Papalexi et al., 2020). The specific business problem is that some pharmaceutical brand protection managers lack strategies to mitigate financial losses resulting from counterfeit prescription drugs.

Purpose Statement

The purpose of this qualitative multiple case study was to explore strategies that pharmaceutical brand protection managers use to mitigate financial losses resulting from counterfeit prescription drugs. The targeted case population comprises of at least three pharmaceutical brand protection managers in the US who have successfully implemented anticounterfeiting strategies to mitigate financial losses and protect patients. Implications for positive social change include the potential to (a) improve the ability to confirm the source of a medication, (b) ensure efficient identification and recall of substandard counterfeit drugs, (c) ensure efficacy and potency of prescribed medications, and (d) improve patient health by reducing number of deaths caused by counterfeit medications.

Nature of the Study

The three research methods are qualitative, quantitative, and mixed methods (Saunders et al., 2019). I selected the qualitative methodology for this study to gain a rich understanding of strategies that pharmaceutical brand protection managers use for mitigating losses due to counterfeiting to protect patients. Using qualitative research enables studying and comparing participants' experiences and associated records to identify themes (Saunders et al., 2019). When elements of the study are difficult to measure precisely, the qualitative methodology is more suitable for conducting research (Yin, 2018). The qualitative method was appropriate for this study because the practice is associated with an inductive research approach, which allowed for exploration of strategies to help mitigate financial losses resulting from counterfeit prescription drugs and protect patients. By contrast, quantitative researchers use a deductive approach that is theory-driven to examine variable characteristics or relationships by testing hypotheses to examine and interpret data (Bloomfield & Fisher, 2019). After careful consideration, I concluded that the qualitative methodology was an appropriate method to use because my intent was not to develop new theories or test hypotheses about variable characteristics or relationships, but rather identify and explore strategies used by pharmaceutical brand protection managers to prevent and mitigate financial losses resulting from counterfeit prescription drugs and protect patients. Mixed methods research involves incorporating both qualitative and quantitative methods (Saunders et al., 2019). Therefore, neither

quantitative nor mixed methods were appropriate methodologies to use for addressing my proposed study.

Four principal research designs that one can use in a qualitative study are case study, phenomenology, ethnology, and narrative designs (Saunders et al., 2019). I chose to use a multiple case study research design. The goal of case study research is to understand what the case is, how it works, and how it interacts with real-world contextual environments (Yin, 2018). Using case studies allows researchers to study persons, groups, or organizations, as well as many other subjects (Saunders et al., 2019). A single case study would provide a limited view of strategies used by brand protection managers to prevent and mitigate financial losses resulting from counterfeit prescription drugs and protect patients. Yin (2018) indicated that using results from multiple cases is more compelling and robust. By using a multiple case study, a researcher can determine similarities or differences between cases (Saunders et al., 2019). I chose a multiple case study design to determine if pharmaceutical brand protection managers from different companies use similar strategies and face similar challenges when adopting strategies to mitigate financial losses resulting from counterfeit prescription drugs and protect patients. Phenomenology researchers seek to explore lived personal meanings of participants' experiences (Neubauer et al., 2019). However, findings concern only specific subjects under exploration and do not go beyond the group under investigation (Neubauer et al., 2019). Researchers use an ethnographic design when studying cultural or social aspects of a group (Saunders et al., 2019). For the proposed study, strategies

under investigation were business related, not culturally or socially related. The narrative approach involves gathering participants' personal stories and oral histories to depict a narrative of historical events (Saunders et al., 2019). However, this design involves individual assumptions regarding events, which can be challenging to prove credibility or plausibility (Ford, 2020). Phenomenology and narrative design were not appropriate for this study, because strategies under investigation involved neither personal strategies nor historical perspectives of a series of events. Therefore, I chose a multiple case study design.

Research Question

What strategies do pharmaceutical brand protection managers use to mitigate financial losses resulting from counterfeit prescription drugs?

Interview Questions

1. What strategies do you use to define the brand protection program at your company?
2. How do you measure success or failure of the program?
3. What were key barriers to implementing your organization's brand protection strategies?
4. How do you address key barriers to implementing your organization's brand protection strategy?
5. What strategies do you use to improve the brand protection program implemented at your company?

6. What anticounterfeiting strategies does your organization identify as being most efficient and cost effective?
7. What anticounterfeiting strategies does your organization identify as being least effective and cost prohibitive?
8. What other strategies beyond brand protection do you use to mitigate the opportunity for counterfeit drugs from entering the supply chain?
9. What additional information would you like to share about strategies you use to mitigate financial losses resulting from counterfeit prescription drugs?

Conceptual Framework

The study's conceptual framework was a composite of the Six Sigma define, measure, analyze, improve, and control (DMAIC) model and fraud triangle theory. Harry (1998) popularized the Six Sigma philosophy while working with Bill Smith at Motorola in 1986, which became a leading practice to boost profitability, increase market share, and increase customer satisfaction through defect-free work. The Six Sigma DMAIC methodology involves a series of five steps that include (a) defining the problem, (b) collecting data to measure against, (c) analyzing data to determine the cause of the problem, (d) implementing improvement strategies to resolve the issue, and (e) applying control mechanisms to maintain improved performance for the future (Mareček-Kolibiský & Kučerová, 2020). Pharmaceutical companies should continuously improve brand packaging and supply chain processes to stay ahead of criminals to prevent counterfeit medication. By relating the Six Sigma DMAIC process to the constant need to

improve brand protection processes, one may identify and understand successful strategies pharmaceutical manufacturers use to mitigate financial losses resulting from counterfeit drugs and protect patients.

The second theory used for the proposed study framework was the fraud triangle theory, which is a conceptual framework established in 1953 by criminologist Donald R. Cressey to explain why criminals commit crimes (Cressey, 1953). Cressey (1986) expanded on Edwin Sutherland's white–collar crime theory to describe that a criminal commits a crime based on (a) having perceived financial problems, (b) the perception of an opportunity to commit the crime, and (c) rationalizing the criminal act. When a person is in financial trouble and sees a chance to make money, the criminal justifies illegal activity as fair to survive. Babyar (2018) explained that the primary cause for counterfeit medicine is profit gained from low-quality manufacturing outsourced to developing countries, gaps in the supply chain that provide opportunities, and lack of punishment that allows criminals to justify their actions. Therefore, the Six Sigma DMAIC model and fraud triangle theory were suitable for facilitating my understanding of strategies to prevent and mitigate financial losses resulting from counterfeit prescription drugs and protect patients.

Operational Definitions

The purpose of the operational definitions section is to provide readers with definitions of terms used throughout the doctoral study to provide clarity.

Brand crisis: A negative event that lowers the reputation of the brand image and company equity (Srivastava, 2019). Pharmaceutical drug counterfeiting can place companies' brand reputation at risk and financially hurt them.

Brand equity: Breadth and depth of brand awareness that is critical to company strength (Formisano et al., 2020). The process of establishing the uniqueness of the brand and beneficial effects of medications to consumers to increase brand equity so the company is profitable and can invest in additional research.

Brand name drug: The pharmaceutical manufacturer's original version of a drug which contains a new active ingredient protected by a patent that a consumer can differentiate from products produced by competitors (Beall et al., 2019). The drug may be a prescription drug or available over the counter.

Brand protection program: The process that brand protection managers implement to address risks of counterfeiting by implementing proactive and reactive strategies to reduce negative financial implications to the company's brand value (Kennedy et al., 2017). Examples include incorporating special inks, seals, dyes, or holograms for proper product authentication, or serialization and two-dimensional bar codes for tracking products through the supply chain to ensure product pedigree.

Counterfeit drug: A contaminated medicine containing wrong, limited, or no active ingredients that is illegal and potentially harmful to patient health (FDA, 2019). Some organizations differentiate counterfeit drugs as being either substandard or

falsified. Drugs manufactured under poor conditions are substandard and drugs created with false components are falsified (Babyar, 2018).

Assumptions, Limitations, and Delimitations

Assumptions

A researcher should recognize that personal beliefs may play a role in the research process. Researcher assumptions are common and could relate to population sampling, study settings, and data analysis, which could negatively impact study findings (Theofanidis & Fountouki, 2018). Theofanidis and Fountouki (2018) explained that researchers should document their assumptions to prevent misunderstandings and clarify points of view taken for granted. I assumed participating pharmaceutical brand protection managers had existing proactive and reactive strategies to protect medications as well as methods for sharing serialized product information with authorized trading partners to mitigate financial losses resulting from counterfeit prescription drugs and protect patients. Hertig et al. (2020) expressed the need for healthcare leaders to take a lead on improving brand protection and interoperability of the industry to secure the global pharmaceutical supply chain through implementation of innovative technologies. A second assumption is that study participants voluntarily participated in the study without compensation in return. A third assumption is that participants had confidence that their corporate identity, name, products, and other confidential information provided during interviews remained entirely protected using pseudonyms. I assumed each participant provided accurate, honest, and complete information for all interview questions.

Limitations

Every study has limitations based on factors that are out of the researchers control. Limitations are potential weaknesses of the research that pose a threat to the study's internal validity (Busse et al., 2017). Theofanidis and Fountouki (2018) described that when using a qualitative research method, one cannot truly replicate and verify results of the study. Young and Casey (2019) determined that in-depth results could still result from a small qualitative sample size. Time and resources limited the scope of the research to a specific point in time and strategies currently used by brand protection managers prior to final realization of the Drug Supply Chain Security Act regulation mandates outlined for 2023. Furthermore, while a process to confirm knowledge and experiences of participants did take place, a certain level of trust in each member to reveal accurate information about the experience applied. A final limitation related to inability to conduct face-to-face interviews due to social distancing mandates implemented to prevent spreading of the COVID-19 pandemic. Instead, I used Zoom to record and capture data from a group of qualified participants.

Delimitations

Delimitations of the study involve the participant population. Delimitations are constraints intentionally determined by the researcher that help define boundaries of the research (Theofanidis & Fountouki, 2018). Participants selected for the study were pharmaceutical manufacturers located in the US. Including only organizations that had experience with product counterfeiting and implemented anticounterfeiting strategies

further delimited the participant pool. Participants came from one of two sources. One source was a consortium group developed to share anticounterfeiting strategies with other pharmaceutical companies. Two participants came from a list of members of the consortium who had years of experience implementing anticounterfeiting strategies. The third participant came from connections made networking with industry experts (snowball method) with anticounterfeiting experience, further eliminating organizations with no anticounterfeiting experience.

Significance of the Study

The healthcare industry faces increased pressure due to counterfeiting and governmental regulations to serialize medications in order to provide added protections and increase transparency among authorized trading partners. The DSCSA outlines requirements to develop national licensure standards and build an electronic and interoperable system to identify and trace certain prescription drugs distributed in the US by 2023 (FDA, 2015). Therefore, brand protection managers seek strategies to further automate the supply chain and protect medications to mitigate financial losses resulting from counterfeit prescription drugs and protect patients.

Identifying and exploring brand protection strategies may enable drug companies to remedy gaps in the supply chain to reduce existing opportunities for counterfeit drugs to enter the market. Implications for positive social change include patients' ability to confirm proactively the validity of medicine when distributed, leading to increased confidence in the efficacy and potency of prescriptions coming from secure supply

chains. Derived expected benefits to patients include reducing the number of deaths, injuries, and concomitant costs caused by counterfeit drugs.

A Review of the Professional and Academic Literature

The purpose of this multiple case study was to explore strategies that pharmaceutical brand protection managers use to mitigate financial losses resulting from counterfeit prescription drugs. Leite et al. (2019) stated that the purpose of the literature review is to identify existing research on the topic that the researcher critically analyzes and synthesizes, distinguishing similar and contrasting perspectives, pinpointing gaps, and using a conceptual framework through which to view the phenomenon. I focused on opportunities that allow counterfeit drugs to enter the market, the impact of counterfeit drugs, and preventative and mitigating strategies used to protect medications in the supply chain. I searched for peer-reviewed articles using the following databases: EBSCOHost, Science Direct, PubMed Central, IEEE Xplore, and Emerald Insight. Seminal books and governmental resources served as additional sources of information for the review. Keywords I used to locate peer-reviewed articles, books, governmental websites, and seminal articles were: *Six Sigma DMAIC*, *fraud triangle theory*, *fraud diamond theory*, *fraud pentagon theory*, *fraud scale model*, *counterfeit prescription drugs*, *anticounterfeiting*, *track and trace*, *Drug Supply Chain Security Act*, *pharmaceutical supply chain*, and *blockchain*. Sources selected for the literature review were 85% peer-reviewed and included governmental articles published between 2018 and 2022 (see Table 1).

Table 1

Literature Review Sources

Literature type	Older than 5 years	2017 or later	Total
Peer-reviewed/Government	13	119	132
Books	1	0	1
Total	14	119	133
Percentage of total	11%	89%	100%

The entire doctoral study includes 215 resources of which at least 85% were peer-reviewed articles published between 2018 and 2022. Table 2 includes the breakdown of resources used for the study.

Table 2

Total Doctoral Study Sources

Literature type	Older than 5 years	2017 or later	Total
Peer-reviewed/Government	15	196	211
Books	1	3	4
Total	16	199	215
Percentage of total	7%	93%	100%

In the literature review, I analyzed the Six Sigma DMAIC model and fraud triangle theory to relate contributing factors that lead to counterfeiting drugs as well as continuous improvement methods to enhance supply chain processes and increase efficiencies. I addressed opportunities in manufacturing, distribution, legal, and pricing structures that brand protection managers use when mitigating financial losses resulting from counterfeit prescription drugs. I explain concepts related to the conceptual framework used for the study and why it applies to the business problem while also

addressing rival and supporting theories considered for this research. I then disclose research related to factors that contribute to the counterfeiting problem that require consideration, as well as the impact on pharmaceutical manufacturers, consumers, the economy, and the US government. I present current strategies to combat the counterfeiting problem, how they play a role in mitigating opportunity gaps that allow criminals to conduct illegal activities, and the act of counterfeiting.

Six Sigma DMAIC Model

The Six Sigma DMAIC model is one of two frameworks used in the study to address the counterfeiting phenomenon. I chose the Six Sigma DMAIC framework because the model is a structured process involving continuous improvements steps to enable organizations to build better quality products and use techniques to reduce manufacturing errors. The Six Sigma philosophy became a leading practice to boost profitability, increase market share, and increase customer satisfaction through defect-free work (Harry, 1998). General Electric later extended the Six Sigma method to improve business profitability instead of just focusing on the manufacturing sector (Stankalla et al., 2018). Criminals adapt quickly, requiring pharmaceutical manufacturers to persistently improve processes to prevent and mitigate financial losses resulting from counterfeit medications entering the supply chain.

It is critical for pharmaceutical manufacturers to follow proven methodologies to protect patient lives. Moon (2020) suggested the Six Sigma DMAIC risk-based approach is an implied requirement in regulated industries where a company makes a product that

can harm customers. Additionally, Roberts et al. (2017) explained that the manufacturing industry widely adopts quality improvement practices of the Six Sigma methodology for reducing errors in manufacturing. Rehman et al. (2018) emphasized supply chain efficiencies. Tripathi et al. (2019) discovered that manufacturers should improve productivity and control supply chain costs by implementing innovative technology and automation in the manufacturing process. The pharmaceutical supply chain's effectiveness depends on implementation of innovative technology like blockchain among trading partners (Tripathi et al., 2019). Hence, the Six Sigma DMAIC model was an appropriate lens to view brand protection managers' responsibility to identify and reduce risks of counterfeit products from entering the supply chain.

The success of the pharmaceutical manufacturing sector is critical to bring innovative and safe new drugs to market. However, the healthcare industry is fraught with crime and corruption, which requires continuous international attention (Babyar, 2018). In particular, the pharmaceutical industry faces many challenges involving competing with criminals to provide innovative measures to secure prescription medicines in the complex supply chain (Wilson & Grammich, 2020). Therefore, using the Six Sigma DMAIC model was ideal to view the counterfeiting problem. Limited studies exist involving the Six Sigma DMAIC process to mitigate financial losses resulting from counterfeit issues, which is a gap in the literature.

The practice of Six Sigma enables business leaders to use data to drive strategies that address industry challenges. The DMAIC method involves five stages: define,

measure, analyze, improve, and control to guide successful process improvement projects (Mareček-Kolibiský & Kučerová, 2020). The five constructs of the DMAIC process are logical in terms of enabling an organization to understand a problem, measure data related to existing processes, analyze data, make improvements to enhance processes, and maintain improved performance levels. These constructs follow a specific order that when repeated leads to improved results.

Define

Defining the problem is the first step in the DMAIC process. During the defining stage, the organization decides which problem takes priority, agrees on the scope, identifies how to measure the problem, and selects the right team and tools (Ahmed, 2019). Stankalla et al. (2018) discovered that implementing improvements can be a significant investment for the organization that requires management commitment, proper training, and excellent project prioritization for small and large organizations to ensure a successful project. The organization should also link the Six Sigma process to the organization's overall business strategy (Stankalla et al., 2018). Without proper support and prioritization, the project may encounter budgetary constraints and not deliver effective strategies to combat the problem. The increasingly complex supply chain requires that all departments affected by the change should contribute expert knowledge to maintain a collaborative approach. In my research, I demonstrate that defining gaps in the supply chain and brand protection strategies is a task that brand protection managers should consider when designing anticounterfeiting strategies.

Measure

Measuring the current process allows the team to have data to compare pre and post improvement processes to ensure the enhanced process results in a better product, service, or cycle time. Ahmed (2019) explained during the measuring stage, development of a data collection plan, mapping current and future processes, and using several Pareto and control charts serve as baseline metrics for measuring existing and postimplementation processes. Furthermore, identifying the correct problem and precise data to capture is critical to ensuring a successful outcome because many misuse data to justify incorrect perspectives (Ahmed, 2019). In addition, measuring the current process allows the team to understand where adjustments can lead to significant improvements. DMAIC steps could apply to pharmaceutical manufacturing processes that are internal to the company as well as interactions with supply chain partners such as wholesale distributors, dispensers, and repackagers. During the research process, I show how measuring risks associated to each product is critical in terms of understanding what strategies to apply to different medicines.

Analyze

The third step in the DMAIC process is to analyze collected data for key areas of improvement. The analysis phase allows the team to compare value-added customer requirements against identified gaps that lead to low quality, delays, and waste in the process (Sharma et al., 2019). Likewise, use of cause-and-effect diagrams, Ishikawa diagrams, and statistical tools like Statistical Package for the Social Sciences (SPSS) aid

in analyzing data (Mareček-Kolibiský & Kučerová, 2020; Nedra et al., 2019). Data analysis can indicate patterns that require investigation. I establish that using data analytical tools to identify areas of risk is necessary to assess risks for each medication.

Improve

The improvement stage is where the team determines all root causes of the problem from collected data to develop effective strategies to mitigate errors or gaps in the process that cause inefficiency (Mareček-Kolibiský & Kučerová, 2020; Sharma et al., 2019). Thus, tools such as the customer matrix tool, brainstorming sessions, regression testing, and hypothesis testing help identify solutions and assess impacts of the solution (Ahmed, 2019). The improvement stage is where subject matter experts play a critical role in determining new strategies that might involve new technologies, better transparency, proper organization, and improved communication to achieve better-quality products, services, or processes. I explored successful improvement strategies that brand protection managers use to mitigate risk and financial losses related to counterfeit drugs.

Control

The final step of the DMAIC process is maintaining control of the new approach. Sustainment of improved performance levels allows the organization to realize financial gains from investments. Hence, the project team should record changes, monitor automated systems, and transfer all knowledge involving maintaining improvements through updated procedural documentation (Ahmed, 2019). Mareček-Kolibiský and Kučerová (2020) stated that if results deteriorate, the team can swiftly identify the source

of the problem. As a result, production staff will support the new process while the project team focuses on other improvement projects. Therefore, obtaining proper training regarding the new approach can ensure continued benefits for customers and protect the pharmaceutical brand. I show how brand protection managers must always be aware of new risks involving new and existing products. The process of brand protection is iterative throughout the life of the product.

Much of the pharmaceutical industry depends on new technology to improve processes to address the counterfeit problem. Botcha et al. (2019) emphasized each component of the pharmaceutical ecosystem consisting of raw materials, manufacturing, distribution channels, wholesalers, and dispensing retailers require secure tracking of products and information in order to become tamper resistant. Specifically, implementation of newer technology that involves the Internet such as radio frequency identification (RFID), barcode readers, and Global Position Systems (GPS) trackers aid in terms of tracking products from manufacturers through distribution channels (Aich et al., 2019; Botcha et al., 2019). Currently, the existing supply chain does not include sophisticated technology to address tracking of medications because of the sudden growth in globalization (Aich et al., 2019). Dossou et al. (2020) described how a pharmacy at a hospital in France used the Six Sigma DMAIC process to find an appropriate solution to distribute serialized medications to prevent patients from receiving counterfeit medications and comply with mandatory governmental regulations for traceability of products within hospitals. Brand protection managers can collaborate

with trading partners when using the Six Sigma DMAIC framework to identify areas where technology can play a role in terms of gaining efficiencies and added security to better track medications throughout the entire distribution process. I used the Six Sigma DMAIC conceptual framework to address pharmaceutical brand protection managers' lack of strategies to mitigate financial losses resulting from counterfeit prescription drugs.

Fraud Triangle Theory

The second conceptual framework used for the study was the fraud triangle theory. The fraud triangle theory is the most widely adopted conceptual theory to explain fraud (Vousinas, 2019). Donald R. Cressey, a criminologist professor, introduced the theory in his 1953 book *Other People's Money* (Cressey, 1953). Cressey was previously a mentee of Edwin H. Sutherland, who coined the term white-collar crime in 1937 when he expanded on the differential association theory (DAT) to describe causes of crime committed by professionals (Cressey, 1986; Lokanan, 2018). Cressey used DAT to form the three constructs of the fraud triangle theory (Lokanan, 2018). Although the fraud triangle theory does not explain why criminals commit every type of fraud or fraudulent behavior, it does help in explaining why and how people commit fraud (Huber, 2017). Similarly, Huber (2017) defined fraud as knowingly misrepresenting facts (including being silent) with the intention to cause another to act (or abstain from acting), causing damage to the other party. Cressey (1986) recognized that the world benefited significantly in terms of reduced malaria, tuberculosis, and other infectious diseases when scientists focused on understanding disease causation and germ theory to develop

programs for eliminating causes. Therefore, mitigating causes involving why people commit crimes would help eliminate the need for people to feel there is no other choice. Cressey (1986) interviewed hundreds of embezzlers in the Illinois State Penitentiary and the U.S. Penitentiary over a few years to develop the fraud triangle that contained three constructs that must exist simultaneously to explain why people commit crimes are:

- financial pressure: having a financial problem perceived as private.
- opportunity: secret knowledge to solve the problem by violating a relationship of trust.
- rationalization: justifying the act of violating trust so that one believes the action is acceptable.

Thus, no matter who commits the crime, the standard component is the opportunity to perpetrate the crime (Azam, 2018). It is up to each organization to put measures in place to prevent a brand crisis from occurring. The next section includes three critical constructs of the fraud triangle theory.

Financial Pressure

Financial pressures can cause significant amounts of stress for people trying to survive, particularly in developing countries where poverty is prevalent. Financial pressure occurs when people cannot obtain money from ordinary, legitimate sources (Cressey, 1986). Hence, Cressey (1986) explained that the person often feels ashamed or too proud to ask for help and must keep the issue private, increasing the need to commit fraud. Accordingly, the person assumes others will not help and avoid reaching out in a

time of need. However, through numerous interviews, Cressey discovered criminals will not keep an adverse financial circumstance private if one perceives the community may help. Hence, relieving financial pressures might mitigate people's propensity to commit fraud or prevent a person from resorting to illegal activity.

People of all income levels are capable of fraud. Azam (2018) explained that most criminals spend the money gained through deception rather than saving money. Similarly, managers at the highest levels of an organization are also capable of committing fraud. In fact, Sandhu (2016) conducted a qualitative study on participants who recently investigated or experienced fraud within the last 3 years and found criminals demonstrated seven behavioral red flags, which include

- strong ambition,
- social aloofness,
- working extended hours and refusing promotions/postings/vacation,
- dissatisfaction with the current job,
- justification of unethical/dishonest behavior,
- family/legal/financial problems, and
- a living standard inconsistent to current means.

The pharmaceutical industry is extremely profitable. Likewise, Le et al. (2018) claimed that producing fake medications generates a significant amount of money, and the penalties and odds of capture are minimal. Similarly, Babyar (2018) confirmed the primary attraction to counterfeiting is profits. Specifically, biological medications are

high-cost drugs made from natural sources criminals target because of the high-profit margin (Abma, 2016). In addition, Venhuis et al. (2018) posited oncology drugs used to treat many forms of cancer are also high on the list of profitable medications that appeal to counterfeiters. Although, a criminal may also target lower-cost generic drugs or lifestyle drugs by making profits through high volume sales. The primary concern is that the pharmaceutical industry provides a lucrative market for criminals to direct illegal activities for financial gain and numerous gaps in the supply chain enable criminals with opportunity.

Opportunity

The second condition that needs to be in place to commit fraud is opportunities allowing individuals to perpetrate the crime. Cressey (1953) described opportunity as the individual's awareness to solve the private financial problem by deceitfully violating others' trust, while Lokanan (2018) defined opportunity as the person who has knowledge and technical skills to commit fraud. An organization’s lack of supervision, weak internal controls, limited enforcement, and likelihood of capture provide opportunities for criminals to take advantage of situations for personal financial benefit (Lokanan, 2018; Peltier-Rivest & Pacini, 2019). In the same way, Peltier-Rivest and Pacini (2019) claimed pharmaceutical counterfeiting of generic drugs is more prevalent in low-income countries because of a lack of controls and enforcement efforts. Many counterfeiters hide behind fake corporations on the Internet to disguise one’s identity while pretending to be legitimately licensed pharmacies (Hertig et al., 2020). With this in mind, brand protection

managers can implement better supply chain controls and work collaboratively with other industry partners to increase enforcement efforts and reduce opportunities for criminals. Therefore, lobbying policymakers for higher penalties for counterfeiters would help lessen supply chain opportunity gaps and cause criminals to consider consequences before committing a criminal act.

Motivated criminals see significant potential to earn large sums of money by learning skills and obtaining necessary equipment to deceive the public by reproducing medications which resemble valid medications. Likewise, manufacturers and dispensers of medicines face significant financial risk if counterfeit drugs are ineffective or cause harm by entering the supply chain (Babyar, 2018). Consequently, a brand crisis can reduce a company's reputation, consumers' perception of the company, and brand equity (Srivastava, 2019). The stronger a company's brand equity, the more willing consumers will remain faithful to a brand because of the emotional connection and positive reputation (Srivastava, 2019). Therefore, organizations should invest in implementing strategies that eliminate opportunity gaps in manufacturing and distribution that allow counterfeiters to deceive the public into obtaining counterfeit medications. For this reason, consumers' health is imperative, and consumers should have confidence in knowing the pharmaceutical supply chain is safe.

Rationalization

The third element thought to be present when one commits fraud is rationalizing the criminal act. In fact, Cressey (1986) explained that several criminals interviewed as

part of a study claimed each had “fooled” or “kidded” themselves into justifying the criminal activity. Without the rationalizing step, the act of fraud would not occur, making rationalization the most critical component in the fraud triangle (Cressey, 1986). Similarly, Vousinas (2019) posited that individuals who commit fraud do not perceive themselves as criminals and lack accountability based on justifying the activity. In developing countries, overlooking crime as expected to survive.

Individuals living in developing countries where meager penalties exist for counterfeiting and people struggle to survive financially makes for a prime environment to enter the criminal world to survive. In fact, Peltier-Rivest and Pacini (2019) described how criminals dealing in illegal drugs like either heroin or cocaine switched to counterfeiting prescription drugs because of limited regulations, weak penalties, and significant profits gained with making fake prescription drugs. Indeed, inconsistent and inadequate legislation globally makes enforcement ineffective in deterring criminals (Lee et al., 2017). Criminals are very competent in producing counterfeit medication while remaining undetected. One can understand an individual's rationalization to commit the crime when limited measures exist to impede activity and quickly make a significant profit.

Counterfeiting prescription drugs is a real problem with sometimes dire consequences. Hence, the brand protection manager's job is to ensure that organizations assess risks for each unique product in the supply chain and develop strategies to mitigate financial losses resulting from counterfeit drugs. In addition, Kennedy et al. (2017)

suggested that generic brand protection strategies are less effective than a product-focused approach. By working with internal and external resources to focus on each product's vulnerabilities, gaps in the supply chain, and reactive measures to prosecute criminals, brand protection managers could implement effective strategies to remove opportunities and rationale that enable criminals (Kennedy et al., 2017). Therefore, constructs of financial pressure, opportunity, and rationalization in the fraud triangle theory align well with the problem statement and helped answer the research question that some pharmaceutical brand protection managers lack strategies to mitigate financial losses resulting from counterfeit prescription drugs.

Rival and Supporting Theories

Other rival and supporting theories I considered for the lens to view the problem were the fraud diamond theory; fraud pentagon theory; and the stimulus, capability, opportunity, rationalization, and ego (SCORE) model. Each of these theories expanded on the fraud triangle theory to explain the reasons why people commit fraud but focused more on internal organizational fraud. In this section, I uncover the consideration of other views and why each did not apply specifically to the study.

Fraud Diamond Theory

The fraud diamond theory contains four elements that must be present for a person to commit fraud. The fraud diamond theory, established by David Wolfe and Dana Hermanson in 2004, is an extension of the fraud triangle theory to explain that a person must also have added capabilities to commit fraud beyond Cressey’s financial

troubles, opportunity, and rationalization constructs to execute the criminal act (Wolfe & Hermanson, 2004). Wolfe and Hermanson (2004) believed opportunities provide the opening to commit fraud, but the individual requires capability to recognize weaknesses in the internal process to commit fraud and get away with doing so repeatedly. Indeed, an individual in a position of power within an organization could understand how to breach the internal control and possess the ego to execute the criminal activity without detection as the main characteristics of a fraudster (Wolfe & Hermanson, 2004). Therefore, the fraud diamond theory expands on the fraud triangle but focuses on the individual within the organization who can commit fraud internally. Similarly, Peltier-Rivest (2017) suggested using the fraud diamond theory to explain pharmaceutical companies' strategies to prevent internal corruption. Lokanan (2018) also posited that fraud diamond theory helps answer the question of who can turn the opportunity to commit fraud into a reality. Consequently, I did not select the fraud diamond theory because my focus is to explore strategies that brand protection managers use to mitigate financial losses resulting from counterfeit drugs, which occur primarily through illegal activities of criminals external to the organization.

Despite focusing on traits of internal individuals who can commit fraud, the fraud triangle theory and fraud diamond theory share a common theme of addressing the cause of crime. A critical strategy to consider is to reduce gaps in the pharmaceutical supply chain by reviewing where opportunities exist to apply corrective measures. Therefore, Wolfe and Hermanson (2004) suggested assessing executive personnel's capabilities and

implementing control measures to eliminate the organization's risk. Similarly, Mackey and Cuomo (2020) confirmed that opportunity gaps extend to the complex and global pharmaceutical supply chain, where consequences of illegal activity can negatively impact public health. Furthermore, Kamble et al. (2019) defended that an organizations' supply chain is one of the most critical elements for achieving efficiency and responsiveness. Subsequently, making use of innovative technology can help eliminate manual processes that allow opportunity gaps to occur. Secondly, Wolfe and Hermanson (2004) explained that improved legislation, increased enforcement efforts, regulatory control, improved standards, and enhanced technology are excellent strategies to prevent and detect fraud. Hence the reason for choosing the fraud triangle theory to view the counterfeiting problem within the pharmaceutical supply chain as a suitable choice to understand the cause of fraud to mitigate financial losses resulting from counterfeit prescription drugs.

Fraud Pentagon Theory

Researchers developed other fraud theories based on three core constructs of the fraud triangle theory. In 2011, Crowe Howarth extended the fraud diamond theory by adding arrogance as a fifth element to explain additional types of fraud (Haqq & Budiwitjaksono, 2020). Triyanto (2020) posited that a criminals' arrogance creates opportunity and rationalization to commit fraud in both internal and external crime events. Similarly, Sandhu (2016) confirmed that criminals often display an increased level of self-interest that may contribute to why criminals commit fraud when combined

with other elements of the fraud pentagon. Counterfeiting pharmaceutical medications to look exactly like real drugs takes a significant amount of confidence and intelligence. However, the pharmaceutical manufacturer knows the product best and compels brand protection managers to stay ahead of criminals to prevent and mitigate financial losses related to counterfeit prescription drugs. In addition, all known recent studies using the fraud pentagon theory relate to exploring financial accounting fraud (Haqq & Budiwitjaksono, 2020; Triyanto, 2020; Uciati & Mukhibad, 2020), which does not apply to the research's purpose. Thus, I did not select the fraud pentagon theory as a lens to view the counterfeiting problem because the focus of the study is to explore strategies to prevent and mitigate external counterfeiting fraud.

SCORE Model

The final alternative conceptual framework considered to view the counterfeiting problem is the SCORE model. Georgios Vousinas (2019) developed the SCORE model, which has five elements that stand for stimulus/incentive, capability, opportunity, rationalization, and ego (SCORE) to explain why individuals commit fraud. Similarly, incentive, capability, opportunity, and rationalization come from the core constructs found in the fraud triangle and fraud diamond theories. Vousinas suggested that ego is the most common driving element for committing fraud and has proven to be the common theme in the most shocking fraud schemes in recent history. Moreover, Vousinas explained that the SCORE model should expand to SCCORE by adding collusion as a sixth construct to represent recent crimes involving coercion of other individuals to

conceal fraud. In fact, crimes that involve large groups of individuals are a growing problem and more difficult to eliminate (Vousinas, 2019). Because the pharmaceutical market is so lucrative, the industry is attractive for individuals to target prescription medications.

The pharmaceutical supply chain is growing in complexity. In fact, Lund (2019) explained that many pharmaceutical companies moved manufacturing processes overseas where limited intellectual property laws exist, acceptance of corruption exists, and the Internet provides a new method to target products with high-profit margins while remaining inconspicuous. Hence, organized crime rings often coerce other individuals to purchase legitimate products, alter them through diluting or replacing them with other ingredients, and later resell product online (Lund, 2019). Nevertheless, the SCORE model is very new. Because of limited information on the SCORE model, I did not find the model suitable for the doctoral research project.

Six Sigma DMAIC and Quality Risk Management

The pharmaceutical supply chain's global complexity makes monitoring and addressing quality risk extremely challenging, endangers public health, and rarely discussed. In fact, Kumar and Park (2019) explained that current supply chains critical to a company’s infrastructure are often vulnerable to significant risk. In a review of 260 surveyed professionals, Kumar and Jha (2018) discovered that there is a need by brand managers in the industry to be more aware of the quality of the product in the distribution process. A challenge for the study was a lack of necessary databases that track losses

from defects during distribution and storage (Kumar & Jha, 2018). Quality risk management is the practice of defining, measuring, analyzing, mitigating, and controlling risk within the product lifecycle (Ismael & Ahmed, 2020; Kumar & Jha, 2018; Wu & Chaipiyaphan, 2020). Similarly, Kennedy et al. (2017) established that brand managers should calculate how often, desirable, difficult, likely, and easily counterfeiters can obtain equipment, knowledge, and materials to determine the threat of product counterfeiting. Furthermore, a limitation is that much of the quality control process happens internally within the manufacturing process and less in the distribution process (Kumar & Jha, 2018; Wu & Chaipiyaphan, 2020). Therefore, by focusing on risk management, the pharmaceutical manufacturer can allocate correct resources in the precise place and at the right time to make best use of finances and resources (Ismael & Ahmed, 2020). In the same way, Kennedy et al. (2017) suggested that estimating risk for each product is a proactive measure that some brand managers take toward mitigating counterfeiting efforts. Additionally, Papalexi et al. (2020) reaffirmed that pharmaceutical organizations cannot consider all products the same because each has different properties and distribution routes, which carry varying levels of risk. Thus, estimating quality risk and implementing mitigating steps in the supply chain is much like the DMAIC process of the Six Sigma methodology to improve processes continually to build better quality products.

Quality risk management starts in collaborating with professionals internal and external to the company to map out distribution processes and identify areas of risk where

a medication might be mishandled, altered, or replaced with counterfeit medications. The result is to gather necessary data to calculate the risk priority number (RPN), which involves multiplying the estimated detectability of the risk by the likelihood of occurrence and level of severity that risk might pose to the organization (Banach et al., 2019; Ismael & Ahmed, 2020; Kumar & Jha, 2018). The more detectable the risk, the less risk to the organization because simple processes can mitigate or eliminate threats. But even so, mitigating high-risk areas involve significant investment by organizations, which means addressing every risk is impossible (Fan & Stevenson, 2018). The define, measure, analyze, and improve process of the DMAIC model is much like identifying risks, calculating the potential impact to the organization, and determining what level of risk the organization is willing to accept. Consequently, the purpose of the improvement steps is to enhance either the product or processes that increase quality and reduce risk of adverse events that can negatively impact the organization (Kumar & Jha, 2018). Accepting too much risk might put patients' health in jeopardy and cost the company financially through lost sales, lawsuits, and damage to its reputation. However, eliminating all risk might place the company at a competitive disadvantage through unnecessary financial investments in practices that yield little value.

The most critical step in the DMAIC process is to control the quality of either the product or process to maintain an acceptable level of risk or Six Sigma level to remain competitive while protecting consumers' lives. Kumar and Jha (2018) suggested using cause-effect diagrams or fishbone diagrams to identify and prioritize emerging issues

similarly used in the Six Sigma DMAIC process. Data should be at the core of all decisions made in the risk management process, and documentation of implemented mitigating factors should indicate how to determine when the process faulters (Kumar & Jha, 2018). In the same way, managers should assess interrelated risks by considering how eliminating one risk might intensify another (Fan & Stevenson, 2018). Thus, risk mitigation is a continuous process required of brand protection managers in mitigating financial losses resulting from counterfeit prescription drugs and is a supporting model to the Six Sigma DMAIC process.

The identification, measuring, and remediation of risk in the supply chain allows organizations to be aware of potential disruptions, assess the organization's impact, and implement measures to either minimize or prevent negative impact to the company. Just as Fan and Stevenson (2018) posited that a firm that manages risk better than competitors stands a better chance of gaining brand loyalty with customers. Leaders' risk management efforts also reduce costs and exposure to safeguard profitability, stability, and long-term growth (Fan & Stevenson, 2018). Moreover, Gligor et al. (2019) emphasized that managers should be aware of the environment to predict potential risks and guarantee resiliency. Therefore, to gain a competitive advantage, managers should understand the importance of collaborating with suppliers, customers, and even competitors to improve processes and products to ensure patients' safety (Gligor et al., 2019). Patients' overall health should be the guiding force in the manufacturing and securing of the distribution supply chain. In doing so, pharmaceutical brand managers should involve multiple

internal departments, external suppliers, customers, law enforcement, and other pharmaceutical companies in developing ways to mitigate financial losses resulting from counterfeit medications and protect the health of patients.

Opportunities That Contribute to Counterfeiting

Weaknesses in the supply chain must exist for counterfeit drugs to enter the supply chain. Iacocca and Mahar (2019) described the global supply chain as an exceptionally complex relationship between manufacturers, wholesalers, pharmacies, and patients. Likewise, Pisani (2017) described a complex example where

> A medication taken in Germany may be made in Egypt from ingredients imported from India, Brazil and Spain, packaged in foil that came from China, inserted into a box designed for the United Kingdom of Great Britain and Northern Ireland, and shipped to Liverpool by way of Dubai. A trader in the United Kingdom, taking advantage of fluctuations in the foreign exchange rate, might legally repackage the medicines with information written in German and ship it to Munich. (p. 6)

Approximately 80% of active pharmaceutical ingredient manufacturers exist outside the United States (FDA, 2020b). Also, 53% of counterfeit drugs meant for the United States come from China and 31% from Hong Kong (Chaudhry, 2019). Over 20,000 prescription drug products approved for marketing are the FDA's responsibility to oversee, regardless of where production occurs (FDA, 2020b). Despite spending 33% of the FDA’s $5.9 billion total budget on protecting human drugs (FDA, 2020b), not even well-funded

regulatory agencies can continue to protect public health because of a lack of resources, authority, and growing complexity of the global supply chain (Denigan-Macauley, 2020; Pitts, 2020). While the U.S. pharmaceutical supply chain received many praises for being one of the safest in the world, the task of maintaining a high-level of security intensifies with increased global complexity and organized criminals anxious to claim part of the profits (FDA, 2021a; Pitts, 2020). The growth in complexity requires that brand protection managers coordinate closely with internal departments and external trading partners to close the opportunity gaps to better protect patients.

The literature reveals that multiple opportunities exist that enable counterfeiters to insert falsified products with limited punishment. Pisani (2017) explained that counterfeit products exist where there is inadequate access to quality drugs, low governance standards, and limited technical capacity to maintain quality control and distribution processes. The World Health Organization (WHO, 2020) added that changes in supply and demand, new channels of distribution, flexible regulatory conditions, and understaffed regulatory agencies increase drug access capabilities. The FDA's Customs and Border Protection agency face numerous challenges in ensuring that the pharmaceutical industry abides by regulations and protects medications that millions of Americans consume every day. Indeed, the U.S. Customs and Border Protection (2020b) reported processing $2.7 trillion in imports consisting of 35.5 million items, 28.7 million cargo containers, and 600 million express mail shipments in 2019, but Chaudhry (2019) elaborated that border patrol is only able to inspect a small percentage of all products

entering the United States. Therefore, each member of the pharmaceutical supply chain needs to play a role in protecting public health instead of relying on other agencies to catch all counterfeit drugs. The focus of the research was to explore strategies brand protection managers use to prevent and mitigate financial losses resulting from counterfeit prescription drugs from entering the supply chain. The first step in the research process was to identify where opportunities exist in the supply chain that enable counterfeiters to commit fraud to understand why brand protection managers lack strategies to prevent and mitigate financial losses.

Drug Pricing and Constrained Access

To protect public health, consumers require access to needed drugs to treat numerous medical conditions that are sometimes life-threatening. A medications price is a critical factor for low-income Americans and citizens without appropriate health insurance (Pisani, 2017). The resulting financial pressure causes consumers to seek cheaper medications from any source, including illegitimate suppliers (Abma, 2016). To contain costs, executives at all levels in the supply chain, including pharmaceutical manufacturers, seek ways to save money by obtaining raw materials and manufacturing products overseas (Pisani, 2017), increasing supply chain complexity. However, the pharmaceutical industry must invest significantly in developing strategies to protect the company brand and protect public health (Papalexi et al., 2020); otherwise, the company risks a brand health crisis that may cause death and significant financial losses for the organization. Importing medications into the United States from external manufacturing

sites creates risks and opportunities for criminals to insert counterfeit drugs into the supply chain.

Drug Pricing. U.S. consumers have the right to be concerned about the ever-increasing cost of medications. When compared to other countries, the United States has higher prescription costs. Sarnak et al. (2017) confirmed that United States spending per capita on prescription drugs is 30%–190% higher than Australia, Canada, France, Germany, Netherlands, Norway, Sweden, Switzerland, United Kingdom, and is consistently growing. Also, prescription prices for common drugs are 5%–117% higher in the United States than in Canada, United Kingdom, France, Germany, Switzerland, and Australia (Sarnak et al., 2017). Based on this information, U.S. consumers are at a significant disadvantage regarding access to reasonably priced prescription drugs compared to other high-income countries.

Riley and Lanford (2019) said Mylan increased the price of a two-pack EpiPen package, which patients use to treat severe allergic reactions, from $100 in 2007 to $600 by 2016. Similarly, Carrier et al. (2017) and First (2018) described how Turing Pharmaceuticals' CEO, Martin Shkreli, increased the price of Daraprim from $13.50 to $750 per pill, a 5500% increase on a dosage of a 10-year-old HIV related drug, immediately upon acquisition from Impax Laboratories in 2015. Both companies continued to charge exorbitant prices for the respective medications despite antitrust investigations into the matter. Drug patents also provide manufacturers with a 7–20-year period of legal price protection, limiting any competitor's ability to create a generic

equivalent to sell at a lower cost (Nguyen et al., 2020; O'Donnell, 2018). These cases demonstrate how a lack of transparency of drug pricing, monopoly pricing, and ineffective antitrust laws in the United States enable some pharmaceutical companies to charge unreasonable prices for medications (First, 2018). However, other factors have a place in determining the final cost beyond the initial price pharmaceutical manufacturers charge.

Pharmacy Benefit Managers and Insurance Companies. Consumers have limited ability to negotiate drug prices, so employers hire insurance companies to negotiate better pricing. Further, insurance companies hire pharmacy benefit managers (PBM) who pay dispensers to purchase drugs from wholesalers, who procure medications from manufacturers (Nguyen et al., 2020; Riley & Lanford, 2019). The three primary PBM organizations (Express Scripts, CVS Caremark, and OptumRx) that exist in the United States, handle over 70% of prescriptions (Iacocca & Mahar, 2019). Manufacturers pay PBM's in the form of after-sale rebates to place drugs on an approved formulary list for dispensing facilities to purchase from either at a lower price (Nguyen et al., 2020; Riley & Lanford, 2019) or risk limiting coverage for a drug by the insurance company (Lamm, 2018). Consumers primarily blame pharmaceutical manufacturers for the excessive costs for medications, but PBMs and insurance companies have more control than most people realize.

PBM's profit in many ways as intermediaries between manufacturers and dispensers. Riley and Lanford (2019) stated that PBM's similarly profit from pharmacy

spread pricing, which is the difference between what a PBM charges a health plan for a drug and the provided reimbursement back to pharmacies and state programs like Medicaid for the same medication. However, many of contract terms between PBM's and health plans lack pricing transparency, allowing PBM's to keep a more sizable portion of the difference for profit (Nguyen et al., 2020; Riley & Lanford, 2019). Consequently, Riley and Lanford described how West Virginia stopped using PBM's to negotiate prices for public health plans because an investigation revealed a PBM charged the state 1% more than the pharmacy for the same drugs, costing the state $10 million more per year. Likewise, the lack of drug pricing and drug rebate transparency drive PBM revenues (Nguyen et al., 2020). Riley and Lanford noted that pharmaceutical manufacturers view PBMs as intermediaries controlling rising prices and seem to support the enactment of laws to regulate PBMs. PBMs also manage reimbursements to insurance companies for drugs covered under numerous plans.

The insurance companies, with help from PBM’s, determine how much consumers pay out-of-pocket for each prescription. In 2003, passing of the Medicare Prescription Drug, Improvement, and Modernization Act mandated that only insurance companies managing the Medicare Prescription drug program can legally negotiate drug prices with pharmaceutical manufacturers (Dennis, 2003). As a result, Lamm (2018) described how consumers are stuck in the middle of the negotiation war between pharmaceutical manufacturers and insurance companies while PBM’s make a significant profit. Furthermore, manufacturers claim lower prices can impact future development,

which is important economically and for a patients' quality of life (Lamm, 2018). However, in a study designed to determine costs of developing a new molecular drug for cancer, Prasad and Mailankody (2017) discovered manufacturers gain ten times the profit above development costs within 4 years after launching the drug. Therefore, there is no concrete evidence that exists that prove increased pricing justifies better innovative outcomes. In addition, if a person has no insurance, consumers might stop taking the drug, have no choice to take less expensive generic drugs, or seek assistance programs because out-of-pocket costs for a prescription is the consumer's sole responsibility. Depending on the number of ailments that a patient has and insufficient alternatives, the prescriptions' cost can be high.

Personal Drug Importation. Consumers continue to push policymakers to allow importing of lower-cost prescription drugs to alleviate financial burden. However, the Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 mandated that in most cases it is illegal for an individual to import drugs or devices into the United States from another country because unapproved drugs could pose a threat to consumers (FDA, 2020a). Specifically, regulations prohibit the importation of biological medicines, controlled substances, infused drugs, intravenously injected drugs, drugs inhaled during surgery, and any other drug the FDA considers to be a threat to public health (FDA, 2020a). Exceptions are that (a) the prescription is for a severe condition that is not available locally, (b) there is no known commercialization of the drug in the United States, (c) the product does not pose a risk, (d) the product is for personal use, and (e) the prescription is

no greater than a 90-day supply (FDA, 2020a). Accordingly, the Secretary of Health and Human Services could grant waivers for prohibiting importation from Canada if the imported drug (a) comes from a licensed pharmacy, (b) does not exceed a 90-day personal use supply, (c) requires a prescription, (d) is manufactured and packaged in a registered facility, and (e) and meets any other condition the Secretary deems appropriate (United States Code, 2020). However, there has been little progress over the last 16 years in allowing importation (Bollyky & Kesselheim, 2020). Many restrictions prevent large-scale importation of medications from making a financial difference to consumers.

Importation of medications has benefits and challenges that require consideration. Proponents of importation legislation believe that importing drugs from foreign countries can lessen financial worry of many Americans but feel that hesitancy of many politicians lies in the Thalidomide tragedy (Bollyky & Kesselheim, 2020; Kelly, 2019). Yashiro et al. (2018) explained that Thalidomide, which launched in 1957 in Europe to improve sleep and morning sickness in pregnant women, caused severe congenital defects in over 10,000 babies across 47 countries, and known as the biggest man-made disaster in modern medical history. The advantage is that the FDA relied on its own research and never approved the drug for U.S. consumption for that purpose, saving pregnant mothers from a potentially devastating outcome (Kelly, 2019). The challenge lies with the lack of facility regulation in foreign countries and complex distribution processes provides opportunities for counterfeiters to insert fraudulent medications into the market. Denigan-Macauley (2020) expressed that the U.S. Government Accountability Office had

concerns over the last two decades about the FDA's inspection of foreign manufacturing sites, which the COVID-19 pandemic amplified based on dependencies on Chinese manufacturing of U.S. pharmaceuticals. The growing trend of foreign manufacturing and external sourcing of active ingredients causes significant challenges for the FDA in continuing to protect public health. Creation of grey markets and diversion can also occur when pricing differences occur between countries.

Grey Markets and Diversion

Grey markets and diversion are also opportunities where counterfeit drugs could enter the supply chain and impact pharmaceutical manufacturer's profits, pose risks to the brand name, and consumers. Hong et al. (2019) described grey markets as distributing products purchased through unauthorized channels in lower-priced countries and reselling product in countries where the price is higher. Likewise, Zhang and Yao (2019) agreed that increasing online sales and reduction of trade barriers contribute to the surge of grey markets. Likewise, Zhao et al. (2021) added that differences in geography and economic standing allows for price gaps to exist allowing opportunities for grey markets to flourish. In addition, Peltier-Rivest and Pacini (2019) agreed that conflicting federal and state laws enable criminals to insert counterfeit product into the supply chain without consumers knowing. Managing proper inventory levels and using strategic pricing strategies globally help eliminate large price differences that influence grey market existence (Zhao et al., 2021). Pricing of medications globally requires significant

consideration by pharmaceutical manufacturers to help discourage grey markets to develop.

Illegal practices within the supply chain with authentic medications also contribute to the counterfeit problem. Peltier-Rivest and Pacini (2019) described that diversion occurs when distribution of approved drugs planned for sale in either one country or region end up in another unintended jurisdiction. The FDA (2021f) described an example where a 35-year-old wholesale distributor purchased authentic cancer, HIV, and psychiatric drugs obtained illegally worth $78 million, and sold them to another criminal wholesaler using falsified paperwork, which pharmacies purchased and distributed to unsuspecting consumers in Miami. Yet tracking technologies, thorough border inspections, and consumer awareness are key in detecting drugs in the supply chain (Peltier-Rivest & Pacini, 2019). However, detection becomes increasingly more difficult as criminals develop enhanced skills in copying manufacturing and packaging processes.

Growth of Online Pharmacies

Consumers turn to a growing number of online pharmacies to obtain needed medications at a lower cost. In the United States, online pharmacies provide a legitimate and convenient means of distributing drugs to patients with valid prescriptions (Hertig et al., 2020; Kelly, 2019; Lee et al., 2017), where 88% of the population use the Internet (Kelly, 2019). Furthermore, authors noted that online importation would increase competition, lower the cost of medications, and provide better patient access to drugs

(Lee et al., 2017; Peltier-Rivest & Pacini, 2019). However, a rising number of rogue Internet pharmacies that distribute expired, banned, and counterfeit product without a prescription is a violation of FDA regulation and use of such pharmacies is punishable under Federal law for both the rogue pharmacy and consumer (Drug Enforcement Administration [DEA], n.d.; FDA, 2018b; Hertig et al., 2020; Lee et al., 2017). Illegal Internet pharmacies exist without state licenses where the patient resides, where dispensing occurs, where there is no valid prescription required, and where distribution of unapproved drugs enables criminals to skirt drug safety measures (Hertig et al., 2020). Consequently, Hertig et al. (2020) suggested that low-income households are more vulnerable to accepting risk in purchasing from online pharmacies. Also, consumers who buy from online pharmacies do not reveal to either the pharmacist or doctor that they obtained the medication, causing a real danger to the patient for possible adverse drug interactions (Peltier-Rivest & Pacini, 2019). Counterfeiters go to great lengths to pose as legitimate pharmacies to unsuspecting consumers and can with little effort in an online world.

Online pharmacies can originate from anywhere in the world making for a challenging investigation process. The National Association of Boards of Pharmacy (2020) tasked with helping member boards administer pharmacy licensing and competency assessment programs, stated that the agency cannot verify legitimacy of 90% of the COVID related websites registered anonymously asserting the sale of COVID-19 related treatment drugs. Furthermore, the ease of setting up websites and limited ability to

bring legal actions against anonymously created sites requires international cooperation to succeed (Chaudhry, 2019). Similarly, Mackey et al., (2020) conducted a study of 6,029,323 Twitter tweets and 204,597 Instagram posts filtered for terms related to COVID-19 products. The research revealed 1,042 tweets and 596 posts related to suspect COVID-19 immunity boosting kits, cures, testing kits, and anti-body detection kits. In addition, INTERPOL (2017) spearheaded Operation Pangea X including 197 police in 123 countries, which resulted in shutting down 3,584 illegitimate websites, 400 arrests, and seizure of more than $51 million worth of counterfeit dietary supplements, pain pills, epilepsy, erectile dysfunction, and antipsychotic medication. Despite significant success stories, counterfeiters have few barriers from setting up online pharmacies quickly as learned during the recent COVID-19 pandemic. Therefore, consumers should always be weary of lower cost medications found on the Internet from unverified sources.

Drug Shortages

Occasionally, drug shortages can also cause consumers and distributors to resort to desperate measures to obtain needed medication, sometimes from untrustworthy sources. Pisani (2017) stated that counterfeiters have an easy time inserting counterfeit drugs into the supply chain when consumers need medications that they either cannot obtain or afford. Also, changes in demand, supply shortages, panic buying and stocking, and lack of distribution coordination are all short-term implications of the recent COVID-19 pandemic (Ayati et al., 2020). The COVID-19 pandemic came on swiftly and with little time to prepare. Increased numbers of patient hospitalizations and the compounded

need for medications such as hydroxychloroquine, dopamine, propofol, fentanyl, heparin, and midazolam, among several others to treat the virus, contributed to drug shortages (Ayati et al., 2020). Drug shortages placed practitioners in a difficult position.

Increased manufacturing of drugs overseas worsens matters. China, India, and Hong Kong are primary sources for active ingredients to make many medications (OECD/EUIPO, 2020; Rasheed et al., 2018), which intensified problems when production of active ingredients halted as each country tried to address the virus internally, leading to shortages in materials (Ayati et al., 2020). However, during the COVID-19 pandemic, the federal government took control of ordering, payment, and procurement of the vaccine from manufactures, which helped ensure a safer supply (Freed, 2021), but distribution efforts of the vaccine at local levels faced many obstacles that required significant improvements (Laine et al., 2021). Pisani (2017) noted other causes for drug shortages relate to poor infrastructure, war, disasters, bad planning, theft, or geographical isolation. As a result, criminals seized opportunities by flooding the market with counterfeits because consumers were in dire need and more willing to purchase medications from untrustworthy sources, especially when the drugs look remarkably like real medication.

Saleable Returns

Handling of saleable returns provides another opportunity for counterfeit medications to enter the supply chain. Mattke et al. (2019) explained that saleable returns are drugs returned by dispensers to wholesale distributors because of overstocking and

other reasons who then resell product in the market after inspection. The number of returns is astronomical. In fact, Mattke et al. (2019) estimated that wholesalers in the United States process $7 billion worth of 60 million pharmaceuticals, which is an astounding quarter million returns per day. Similarly, Chamekh et al. (2017) estimated that of the 3%–4% of drugs returned, 1.5%–2% of returned medications get destroyed, leaving 1.5%–2% of medications placed back into the market. Before the wholesaler can place returned product back into the market, they must verify that the drug comes from a reliable source. However, the ability of wholesalers to quickly authenticate the many origins of returned medication depends on antiquated technology that is slow and prone to errors (Chamekh et al., 2017; Mattke et al., 2019). As a result, criminals who understand the saleable returns process may try and insert counterfeit medications by submitting fraudulent product for return that can end up in the market due to inability to properly trace product back to a valid manufacturer.

Ineffective and Timely Detection Methods

Importation of a large quantity of medications manufactured overseas requires regulatory agencies and healthcare personnel to have effective screening measures to identify counterfeit drugs. Lund (2019) claimed that some fraud detection methods are not consistently effective. Indeed, some methods require time, special equipment, technical expertise, and access to labs (OECD/EUIPO, 2020; Shinde et al., 2020). Similarly, Pisani (2017) confirmed obtaining, running, maintaining, and training on how to use detection equipment is difficult and expensive. The OECD and EUIPO (2020)

added that many counterfeiters place counterfeit medication in the original packaging, requiring testing to identify. Roth et al. (2019) described how customs personnel use visual, physical, and chemical screening techniques to detect counterfeits. Considering multiple modes of transportation and millions of packages coming into the United States, as mentioned earlier, patrol officers cannot inspect every package in depth. Technical tools such as vibrational, infrared, Raman, and x-ray fluorescence spectroscopy, among many other methods, provides quick identification of counterfeit medications (Roth et al., 2019). Likewise, Arora and Sharma (2019) suggested visual inspection along with disintegration assay, colorimetric assay, and thin-layer chromatography (TLC) for field detection. However, a lack of guidelines, continuous training, and standards on how to use the technology negatively impacts effective use of such tools (Naughton et al., 2017; Opuni et al., 2019; Roth et al., 2019). Even with improved documentation, Roth et al. (2019) stated that manufacturers should involve surveillance organizations to fix packaging interferences that obstruct proper detection, conduct comparative analysis of different techniques, and incorporate user-specific deployment methods to ensure accurate use of the devices. Since no specific technique can detect all counterfeit medications, employing multiple screening methods is necessary, timely, and can be costly (Opuni et al., 2019; Peltier-Rivest & Pacini, 2019). Choosing either the wrong combination of techniques or having limited time to evaluate drugs during the recent COVID-19 pandemic where copious quantities of certain drugs are in high demand could prove disastrous.

Corruption

As with any organization, opportunity for corruption to infiltrate regulatory agencies is a realistic occurrence. The U.S. Customs and Border Protection (CBP) (2020c) formed of 60,000 employees, one of the largest law enforcement agencies in the world, is responsible for keeping terrorists and weapons outside of the United States, while enabling legal travel and trade. Specifically, Jancsics (2019a) reported that agents who earn low wages, often influenced by crime organizations, have more opportunity to enable counterfeiters to distribute illegal product across borders by taking bribes. Some agents might purposely slow or block trade to force criminals into paying bribes (Jancsics, 2019b). Particularly male customs agents with less than 5 years of experience along the southern border are vulnerable to drug-related corruption compared to more senior agents involved in immigration corruption as noted in a study of 156 cases of border corruption (Jancsics, 2019b). Similarly, Mackey and Cuomo (2020) confirmed that specific types of corruption that happen in medical procurement are bribery, cartelism, kickbacks, over-payments and altered invoicing. U.S. Customs and Border Protection (2020a) reported that of the 7,739 employee disciplinary cases logged in 2018, 90% of cases were employees from the Office of Field Operations and Customs and Border Protection, which remained at 90% since 2011, and 52% were CBP personnel arrested for alleged criminal conduct. Although, advances in technology reduce the potential for corruption, physical inspection is still necessary (Jancsics, 2019a). Despite significant opportunity and related impact of border patrol corruption, limited empirical

and theoretical literature exists (Jancsics, 2019a, 2019b). However, the growing size of the CBP increases risk of corruption. The sheer volume of goods that cross the border by land, sea, and air poses a significant challenge for regulatory agencies to prevent criminal activity entirely.

Complex Enforcement and Limited Punishment

Equally challenging is investigating and prosecuting criminals. Pisani (2017) reported that probability of prosecution from counterfeiting is low. Manufacturing of medications oversees where intellectual property rights lack protections and cultural differences that encourage counterfeiting, makes enforcement difficult (Lund, 2019). Lund (2019) expanded by noting that intellectual property rights filed in each country might vary based on territorial limitations. In addition, Lee et al. (2017), Peltier-Rivest and Pacini (2019), and Papalexi et al. (2020) agreed that multiple stakeholders in the supply chain increases complexity, requiring considerable collaboration among prosecuting agencies. Likewise, the FDA (2018c) admitted that growing globalization of crime presents new challenges for enforcement. Also, Pisani (2017) explained that a significant amount of responsibility for ensuring the safety of drugs relies on the importing country rather than the regulatory agencies of foreign countries where manufacturing occurs. The FDA (2018d) and Vogel (2017) noted that Kristjan Thorkelson sold counterfeit drugs to American doctors with no active ingredient, unapproved in the United States, and labelled in foreign languages, through an online pharmacy. Vogel (2017) described how governmental agencies in Canada took months to

determine if sufficient evidence existed to extradite Thorkelson to the United States while the website remained active. Eight years after first learning of the fraudulent business, Thorkelson received a fine of $250,000 and 5 years of probation where he served the first 6 months in home confinement (FDA, 2018d; Vogel, 2017). Delays in lengthy international investigations and legal prosecutions places patients in significant danger because consumers assume drugs are safe but may cause either severe injury or death.

More sophisticated technology and lack of consistent international regulations allows criminals to go undetected. Pisani (2017) stated that only a minority of reported crimes lead to successful legal action because investigators invest considerable time either tracing medications back through the complicated supply chain or proving the string of locations where violations occur. OECD/EUIPO (2020) described that in many countries illicit drug smugglers face greater punishment than counterfeiters who infringe on trademark laws. In fact, in some countries, intellectual property owners can file lawsuits to recoup damages, but can vary significantly by country (OECD/EUIPO, 2020). Similarly, criminals use technology to hide from police who struggle with limited experience in cross border pharmaceutical investigations, where language barriers exist, and inadequate access to testing labs continues (OECD/EUIPO, 2020; Pisani, 2017). However, the International Criminal Police Organization (INTERPOL) formed in 1914, is one of several international agencies that works with 194 member countries to share data on crimes and criminals by providing training, technical, and operational support (International Criminal Police Organization [INTERPOL], n.d.-b). Consequently,

Operation Rainfall, conducted in 2018, involved 15 suspects across seven countries where 295,000 units seized worth $122,400 disrupted drug and medical device trafficking in Asia (INTERPOL, n.d.-a). In addition, the FDA cited numerous cases where multiple agencies such as local police agencies, Drug Enforcement Agency (DEA), Office of Criminal Investigations (OCI), Homeland Security Investigations (HIS), Federal Bureau of Investigation, and the U.S. Postal Inspection Service played a pivotal role in shutting down sophisticated counterfeiting cases (FDA, 2021c, 2021d, 2021e). Nevertheless, every country should participate in improving intellectual property right protections, technology, and police skills to facilitate quick apprehension of criminals to protect the lives of every citizen.

However, crimes of counterfeiting can happen within the United States. The FDA (2021e) stated that between 2014 and 2018, a husband-and-wife team imported and distributed between $550,000 and $1.5 million worth of male enhancement drugs from China, by encouraging the supplier to mislabel boxes as legal items to pass customs inspections. Finally, after receiving numerous notices to stop the illegal activity, the couple received only 18 months in prison followed by 3 years of supervised release, a $200 fine, and revocation of U.S. citizenship (FDA, 2021e). Another example involved the arrest of a Seattle man pretending to be a biotech expert who injected unsuspecting people across the United States with a substance claimed to be a COVID-19 vaccine that he charged $400 to $600 per shot (FDA, 2021b). After continuing the investigation, the FDA (2021b) discovered Stine had another fraudulent business related to providing

consumers with untested treatments for malignant cancer tumors and may serve only one year in prison. Countries cannot solve the problem individually. Mitigating counterfeiting crime involves expanding collaboration, sharing real-time data across organizations, and developing stronger laws worldwide to deter criminals from highly dangerous activities.

Impact of Counterfeiting

Counterfeit drugs entering the U.S supply chain have many business and health implications that are difficult to quantify because much of the injury goes either unreported or attributed to other causes. Pisani (2017) established that only sparse, reliable information on the actual impact of counterfeit drugs exists. In a literature review of articles in PubMed up to 2017 using relevant key terms, Rahman et al. (2018) discovered 48 incidents worldwide related to counterfeit drugs, involving 7,200 casualties and 3,604 deaths. The country with the greatest number of incidents was the United States at 16 cases (Rahman et al., 2018). Some involving adverse events and in other cases, death. Despite dire consequences of ingesting counterfeit drugs, manufacturers, governments, and economy suffers as well.

Consumer Health

The most tragic result of counterfeit drugs is the potential to cause harm to unsuspecting consumers who might already be in a compromised health situation. Pisani (2017) and the OECD/EUIPO (2020) described ingesting counterfeits might result in

- adverse reaction from either toxic chemicals or incorrect doses of active ingredients

- inability to resolve the illness from lack of any active ingredient
- added growth in antimicrobial resistance
- death
- loss in trust of the pharmaceutical industry
- additional healthcare costs to treat symptoms
- loss in income because of lengthened illness
- loss in income to the household because of the extended illness.

A study conducted by Rahman et al. (2018) involved similar U.S. instances of death, adverse events, rashes, seizures, painful spasms, and respiratory paralysis as result of counterfeit medications entering the supply chain. Of particular interest, Sylim et al. (2018) emphasized that risks in counterfeit antimalaria medications that contain little active ingredient cause consumers to become immune to medication causing either additional unnecessary deaths or increased spread of extremely resistant infectious viruses worldwide. The best way to avoid counterfeit drugs is to buy from local licensed pharmacies, with a valid prescription, for FDA approved medications (Hertig et al., 2020). When using online pharmacies, Hertig et al. (2020) recommended consumers use domains certified by the National Association of Boards of Pharmacy that end in .pharmacy to identify safe pharmacies. By using authorized retailers, consumers have a better chance of accessing authentic medications.

Manufacturers

Pharmaceutical manufacturers, like any other company, must remain profitable to stay in business to bring innovative drugs to the market. However, counterfeit drugs are a threat to the reputation, financial standing, and competitiveness of the company (Babyar, 2018; Kennedy et al., 2017; OECD/EUIPO, 2020). Not only do manufacturers either incur lost or unrealized sales because of counterfeiting but the company must invest significant resources in fighting counterfeiting efforts such as (a) implementing preventative strategies, (b) disposing of the counterfeit materials, (c) incurring legal costs to prosecute criminals, and (d) paying reparations to victims (Kennedy et al., 2017; OECD/EUIPO, 2020). Manufacturers must also invest in good manufacturing practices (GMP) and years of research while criminals do not incur such expenses. Building company reputation takes time, effort, and sizable investments to build consumer trust, awareness, and brand loyalty that counterfeiters wish to capitalize (Salamacha, 2021). In fact, Lukinović and Jovanović (2020) stated that branding is one of the most crucial intangible elements for achieving a competitive advantage. Therefore, manufacturers should always try to earn and preserve consumer trust, even after a brand crisis (OECD/EUIPO, 2020; Srivastava, 2019). Manufacturers should consider potential risks to the organization and continuously put preventive measures in place to protect brand equity.

Impact of an adverse event of a consumer ingesting a counterfeit drug assumed to be authentic and safe would create a brand crisis. In a study of 28 pharmaceutical

companies that sold competing products to Johnson and Johnson (J&J), conducted by Dowdell et al., (1992), revealed that after Tylenol pills tainted with cyanide killed five Chicago residents in 1982, J&J suffered -28.92% in returns worth $2.3 billion in the following nine days, and competing pharmaceutical companies also suffered -11.83% collectively in returns from days ten through 28 after because of new packaging regulations instituted by the FDA. Adverse incidences damage consumer's trust in the pharmaceutical company impacted, related competitors in the pharmaceutical industry, and regulatory agencies responsible for protecting public health (Babyar, 2018). Despite significant impact on pharmaceutical manufacturers, inadequate information exists on the monetary impact.

Economy

Pharmaceutical manufacturers invest significantly in research and development to produce innovate medications, which boosts the economy. Pirimova (2019) posited that investing in modern technology and innovative products enables corporate efficiency, competitiveness, and exports which is a primary component in increasing economic growth. Similarly, Lund (2019) noted that the U.S. economy depends on intellectual property focused businesses, which the U.S. Department of State (n.d.) estimated to generate 27.9% in jobs and 52% in exports. Yet, when counterfeit drugs enter the supply chain unrecognized revenues impact employment rates, humanitarian programs, corporate taxes, enforcement costs, litigation costs, and higher health care costs (OECD/EUIPO, 2020). Technology and resources needed to protect the borders and

investigate counterfeit criminals is growing as individuals and organized crime groups become more sophisticated in copying pharmaceutical packaging. Protecting intellectual property rights is imperative for a country's economy to thrive.

Prevention and Mitigation Strategies

Regulatory Strategies

The U.S. government has a long history of implementing regulatory guidelines to help protect public health. In Table 3, the (FDA, 2018a) noted the passing of several important regulatory milestones in drug safety.

Table 3

Notable Advancements in U.S. Regulatory History

Year	Regulation	Description
1820	U.S. Pharmacopeia	Establishment of the book of U.S. Pharmacopeia, which defined quality drug standards in the United States.
1848	Drug Importation Act	To stop counterfeit drugs from entering the U.S. from oversees.
1906	Food and Drugs Act	Outlawing interstate trade of adulterated drugs.
1938	Federal Food, Drug, and Cosmetic (FDC) Act	Expanded the scope of the 1906 Food and Drugs Act with additional guidance.
1982	Tamper-resistant packaging	Enacted tamper-resistant packaging regulations to prevent deaths from tainted drugs such as the Tylenol case involving cyanide capsules.
1988	Prescription Drug Marketing Act (PDMA)	To ban drug diversion, requires state licensing of wholesalers, and prevent reimportation from external countries.
2013	Drug Quality and Security Act including the Drug Supply Chain Security Act (DSCSA)	Includes the Drug Supply Chain Security Act (DSCSA), which requires the pharmaceutical industry to develop an electronic interoperable system to track and trace prescription drugs throughout the U.S. supply chain.

Each piece of legislation builds upon prior advancements to address increasing complexities of counterfeit medications entering the supply chain and a reactionary approach to address the problem. However, the beginning of the most recent Drug Supply Chain Security Act regulation began in California when the state enacted an electronic pedigree law that mandated all drug packages contain a serialized number for tracking medications through the supply chain by January 2009 to prevent entry of counterfeit drugs (Barlas, 2008). At the time, each state implemented separate laws to address the

same issue, making compliance by supply chain members impossible and costly. Barlas (2008) noted for Pfizer to place radio frequency identification tags on Viagra coming from France and to share data with one trading partner took over six months of work and considerable collaboration among technology experts and trading partners. An estimation by one pharmacy chain to authenticate drug packages at the item-level from manufacturers in different states, using different technology would cost the company $54 million to upgrade one distribution center to comply (Barlas, 2008). Consequently, the regulation never moved forward until the Obama administration passed the Drug Quality and Security Act, which negated all past and future state regulations to develop one unified approach toward a national track and trace system (Le et al., 2018). Enactment of the regulation was the first step in proactive measures to encourage the pharmaceutical industry to work together in defining a set of standards that would lead to a fully electronic interoperable track and trace system by 2023.

Title II of the Drug Quality and Security Act is the Drug Supply Chain Security Act (DSCSA), which provides a national plan to eliminate some current opportunities that criminals have with inserting counterfeit drugs into the supply chain by requiring serialization of products via a 2-dimensional bar code at the package level. Yet inclusion of all products is not in scope for the DSCSA. The FDA (2015) noted that some transactions such as the distribution of

- products within a company
- products within a hospital or healthcare facility under the same control

- medications for emergency medical treatment
- radioactive drugs or biologics
- samples from manufacturers or wholesalers
- blood or blood components used for transfusions, and
- medications between a licensed pharmacy and doctors office

are some exceptions that do not apply under the DSCSA. The FDA (2015) defined four areas of focus to attain a fully electronic interoperable track and trace system by 2023 to include

- Licensing requirement of all manufacturers, wholesalers, third party logistic providers, repackagers, and dispensers to participate in the legitimate supply chain and transmission of transaction history information by January 1, 2015.
- Printing of a unique serial number consisting of the National Drug Code (NDC), serial number, expiration date, and lot/batch number via a two-dimensional bar code on each product package by November 27, 2018, for manufacturers and November 27, 2019, for repackagers, later extended to 2023.
- The ability for manufacturers to verify within 24 hours authenticity requests from a repackager, wholesaler, or dispenser on a returned product before redistributing product back into the supply chain by November 2019, later extended twice to 2023.
- To achieve a full end-to-end track and trace system by 2023.

However, the regulation does not provide either guidance or specification of technology for the industry to use to achieve a fully interoperable track and trace system, leaving pharmaceutical trading partners questioning how to make such a system work. Yet the FDA did specify using transaction information (TI), transaction history (TH), and transaction statement (TS) product tracing information for each product exchanged in the supply chain to track product from manufacturer to dispenser (FDA, 2015). As a result, a more equipped industry would detect and prevent harmful drugs from entering the supply chain and respond quickly when discovering harmful drugs to prevent further impact (FDA, 2015). Subsequently, enactment of the regulation made protection of the pharmaceutical supply chain a priority for all trading partners to commit to finding a solution to a complex problem.

Interoperability

The primary goal of the Drug Supply Chain Security Act is to implement interoperable strategies to protect patients by sharing data with trading partners to track and trace medications through the entire supply chain. The pharmaceutical industry is not unique in benefiting from collaborative supply chain networks to improve performance and gain knowledge in sharing data. In fact, Cabral and Grilo (2018) discovered in a case study of a Portuguese reverse logistics cooperative supply chain network that implementing a proper level of business interoperability positively impacted performance of collection points, recyclers, and energy recovery partners within the supply chain.

Consequently, Cabral and Grilo (2018) learned how building interoperable supply chain networks allows managers to understand

- the complex supply chain and implement strategies to improve operational performance
- how relationships among trading partners need to evolve because of changing market conditions
- how changes impact partners downstream from the organization
- how to invest in interoperability strategies that help prevent either unnecessary or unsuccessful investments
- how changes in legislation, crises, innovative technology, and new competitors could impact the overall supply chain network, and
- problems within the supply chain to apply proactive strategies to mitigate financial losses.

However, researchers focused primarily on one case study limiting the generalizability of the results to other industries. Nevertheless, research conducted by Cisneros-Cabrera et al. (2018) and Jepsen et al. (2020) proposed using fourth industrial revolution (Industry 4.0) technologies such as smart sensors, Internet of Things (IoT), and machine-to-machine communication to improve information transparency, decentralization, and automated assistance to digitize manufacturing processes. In addition, modern technology could provide advancements in vertical and horizontal integration to encourage collaboration between members within the organization and across the supply chain

(Marques et al., 2017). However, a significant barrier in implementing interoperable technology relate to trust and confidence in exchanging data amongst partners with different consideration of data and use of dissimilar applications (Marques et al., 2017). Businesses prefer incorporation of the electronic product code information system (EPCIS), a global service for sharing supply chain data using global standards (GS-1) for tracking and tracing of products (Tolcha et al., 2021). However, the EPCIS system is vulnerable to data tampering, does not provide privacy protection, and offers a minimal degree of decentralization needed for a future interoperable system (Lin et al., 2019). Limited guidance from the FDA on using a particular technology and different systems used by each trading partner, poses significant challenges for the pharmaceutical industry, resulting in a gap in literature that requires attention. Distributed systems like blockchain might enable interoperability within the pharmaceutical industry.

Blockchain as a Solution

Many peer-reviewed articles focused on how blockchain technology could be a suitable technology to provide a trusted, decentralized, interoperable platform to share serialized information between trading partners as drugs pass each step in the supply chain. The blockchain platform is a secure, decentralized network of computers that allows people to exchange blocks of data without requiring a third-party entity to confirm validity because the network uses cryptography to maintain data integrity (Kamble et al., 2019). Indeed, Bai and Sarkis (2020), Saberi et al. (2018), and Teodorescu and Korchagina (2021) predicted that blockchain would revolutionize business models

specifically in the area of supply chain management since introduction of the Internet. Moreover, Botcha et al. (2019) and Jangir et al. (2019) emphasized that members of the pharmaceutical supply chain lack trust because of limited transparency of data sharing between trading partners to improve demand forecasting in preventing drug shortages, capabilities to conduct real time track and trace, and to prevent drug counterfeiting. Hence, the need for innovative technologies to enable trading partners to share important package-level drug information so the industry can safeguard the supply chain and identify counterfeit drugs quickly to prevent injury to patients.

Distribution of life-saving drugs is a critical process that requires smooth interoperability of the entire supply chain to maintain product integrity. In a literature review of 15 articles to identify success factors of implementing blockchain technology in the pharmaceutical supply chain, Fernando et al. (2019) uncovered that blockchain technology offers

- track and trace capabilities
- immutability and accuracy of data to enable trust among supply chain members
- transparency of data stored and accessed by members only
- quick, real-time access to data to enable efficient distribution
- accurate data from reliable sources, and
- security through transfer of encrypted data.

Similarly, several researchers proposed using blockchain technology by incorporating smart contracts, integration of radio-frequency identification (RFID) tags, two-dimensional barcodes, Internet-of-Things (IoT) sensors, smart phones, algorithms, and different blockchain platforms. Table 4 lists some peer-reviewed articles identified during the research process on using blockchain as a technology platform to solve the problem of interoperability within the pharmaceutical supply chain.

Table 4

Recent Articles Suggesting Blockchain for DSCSA

Year	Author(s)	Includes	Pros and Cons
2019	Jangir et al.	Smart contract agreements, Ethereum blockchain	Pros: User privacy, transparency, immutability, availability, real-time track and trace, no single point of failure. Cons: Slow transaction speed with increased members (Jangir et al., 2019).
2020	Premkumar and Srimathi	Sensors, communication networks, IoT devices, smart contracts	Pros: Unified platform, end-to-end tracking. Cons: Interoperability, large data storage needed, scalability, acceptance, and lack of current standards (Premkumar & Srimathi, 2020).
2020	Singh et al.	Quick response (QR) codes, temperature sensors, smart phones, smart contracts, Raft consensus algorithm, bloXroute server	Pros: Temperature control, counterfeit prevention, track and trace. Cons: Scalability, integration of IoT devices, requires significant processing power, and sensor tampering (Singh et al., 2020).
2020	Garcia et al.	IBM Hyperledger fabric blockchain as a service, web interface, smart contracts, and cloud system	Pros: Transparency, immutability, and traceability. Cons: Increased errors and response time with increased transactions and users (Garcia et al., 2020).
2020	Saindane et al.	Smart contracts, QR codes, 2D barcodes, and blockchain	Pros: Track and trace, ability to reduce counterfeiting, supply chain corruption, and lower overhead costs (Saindane et al., 2020).
2021	Teodorescu and Korchagina	MYTIGATE risk management platform, CSecure system, ToolChain software service, BigchainDB blockchain	Pros: Cross-country track and trace, immutability, real-time information, reduced errors and costs, transparency, temperature tracking, and security. Cons: Limited knowledge of the platform, cultural barriers, and costly to implement (Teodorescu & Korchagina, 2021).

All articles reveal promising potential for blockchain technology to provide needed interoperability within the industry. However, a significant limitation of the studies is that few end-to-end real-world implementations of the suggested strategies exist to confirm generalizability that blockchain technology could be a solution to building interoperability between pharmaceutical supply chain partners (Botcha et al., 2019; Garcia et al., 2020; Jangir et al., 2019; Premkumar & Srimathi, 2020; Saindane et al., 2020; Singh et al., 2020; Teodorescu & Korchagina, 2021). Nevertheless, the FDA (2020c) noted results of several pilot programs that took place between 2019 and 2020 among leading pharmaceutical manufacturers, wholesale organizations, and blockchain experts that show promising results. Considerable collaboration among technology experts, manufacturers, wholesalers, repackagers, and dispensers provides the best opportunity for examining capabilities of the blockchain platform.

Manufacturer Brand Protection Strategies

Manufacturers also implement overt and covert layered solutions to brand packaging to deter counterfeiting and protect the company's reputation. In fact, some manufacturers spend a significant amount of time and money in developing strategies to deter counterfeiters by making counterfeits identifiable to inspection authorities and consumers (Lund, 2019), whereas other manufacturing companies have limited protections in place (Wilson & Grammich, 2020). Based on researcher experience, Wilson and Grammich (2020) determined that some brand protection strategies are weak, fragmented, enforcement focused, and reactive in nature because some brand protection

managers fail to incorporate strategies that are cross-functional. Ideally, proactive measures should be the primary focus to prevent counterfeiting rather than reacting to a brand crisis.

The most obvious strategies are overt approaches where manufacturers place an identifiable feature on the packaging to prove authenticity. Arora and Sharma (2019) and Leem et al. (2020) documented using 2-dimentional barcodes, holograms, color shifting ink, serialization, and watermarks as overt physical strategies that manufacturers use to help protect medications. In addition, S. Huffman (personal communication, March 9, 2021) referred to observing packaging seals, coloration, and package construction as methods of confirming validity of the product. However, today's criminals have access to similar equipment as manufacturers and can easily copy overt measures meant to protect medications (Arora & Sharma, 2019; Leem et al., 2020). Brand protection managers consistently seek new methods to stay ahead of counterfeiters.

Some counterfeit packages do not mimic authentic packaging exactly. Pisani (2017) noted how in 2015, a health care worker at a facility in Niger, noticed that a smudged expiration date on a bottle of meningitis C vaccine looked suspicious and reported the incident to authorities, which turned out to include minimal expected antigens. In addition, some vaccines were in a vial size discontinued several years prior (Pisani, 2017). Therefore, educating medical personnel and consumers to know what medications should look like helps people in the distribution chain readily identify

counterfeit product. Using overt strategies is a quick method to determine an initial level of authenticity.

Covert strategies are less obvious and serve as a more concealed form of protection for medications. Few peer-reviewed articles exist on the latest measures used by pharmaceutical manufacturers. One approach offered by G. Pond (personal communication, March 10, 2021) presented at the Pharmaceutical Supply Chain & Security World 2021 conference, demonstrated printing of either logos on the coating of a tablet using silica dioxide or using a clear varnish over existing quick response (QR) codes containing a taggant that when read by a smartphone could provide product authenticity. Similarly, A. Ruegg (personal communication, March 9, 2021), F. Jordan (personal communication, March 9, 2021), and Camille Diss (personal communication, March 10, 2021) referred to taking microscopic images of packaging characteristics such as micro-holes in the varnish layer of the plastic cap or package label to create an electronic fingerprint capable of a person using a smartphone to scan to authenticate medications. In addition, A. Ruegg described a digital security label designed with multiple layers of security that included a code involving text with an invisible secure marking, a picture offering a strong anticounterfeiting capability, a logo with invisible secure markings, and a barcode with anti-copy technology. Strategies that involve minimal changes to packaging lines are ideal, so manufacturers do not invest a significant amount of money in redesigning packaging lines every time criminals are able to mimic current anticounterfeiting measures.

Not surprising, much of the newest strategies are digital, which enables trading partners to quickly scan labels with commonly used smart devices, providing a significant amount of data to analyze, and enabling consumers to play a role in identifying counterfeit medications. Manager's analysis of scanned serial number data could either help identify risk through patterns or gain critical insight into issues in the supply chain.

Data Analytics

Enormous amounts of data can be difficult for managers to sort through to make better business decisions. However, data from digital solutions in the supply chain increases transparency and decision making, enabling managers to build better anticounterfeiting strategies (Mackey & Cuomo, 2020). In fact, in a survey of 200 pharmaceutical distribution organization employees in China, Shafique et al. (2019) discovered that previous studies on using big data predictive analytics and RFID does significantly improve supply chain performance by tracking real-time data on medications. Kumar et al. (2020) suggested that drivers behind the necessity to digitize the pharmaceutical industry are market competition, complicated regulations, and complex global production and distribution challenges. Subsequently, data analytics allows managers to provide statistical control on processes to ensure stability and efficiencies by moving from reactive reporting to predictive capabilities within the supply chain (Kumar et al., 2020). Furthermore, in a literature review of 79 wide-ranging publications related to using big data analytics for decision making, Koot et al. (2021)

uncovered that using big data analytic strategies should allow businesses to move from predictive analytics to prescriptive analytics, which uses computational and mathematical science to suggest options for decision-making. By automating business processes and interpreting real-time data, brand protection managers could better identify new and existing risks, react quickly, and control business processes, while empowering patient involvement toward a safer supply chain.

Layered and Multi-Dimensional Approach

A common theme throughout the research process was that no single technology or strategy could protect a medication from counterfeiting. Wilson and Grammich (2020) stressed the importance of layering strategies, specifically strategies that involve the entire organization. Functional areas such as security, legal, supply chain, procurement, packaging, logistics, risk management, among many others should provide input on designing the organization's proactive and reactive plan (Wilson & Grammich, 2020). Another Pharmaceutical Supply Chain & Security World 2021 conference speaker, K. Mor (personal communication, March 10, 2021) concurred that a multi-dimensional approach to product safety involving logistics security, trademark protections, investigations, and consumer awareness help provide a comprehensive protection plan. Similarly, additional speakers at the conference, P. Merckell (personal communication, March 9, 2021) and Gary Pond (personal communication, March 10, 2021) emphasized that no one should consider serialization or any other individual technology as the single solution to prevent counterfeiting. In addition, regulatory agencies recommend

combining multiple authentication methods like holograms and invisible printing (Pascu et al., 2020). In fact, P. Merckell suggested that a user-oriented strategy could be as important as a manufacturer's brand strategy. The types of strategies used depends on expected risk exposure and type of threat presented for each medication (G. Pond, personal communication, March 10, 2021). Each component of a layered approach serves a particular purpose in securing drugs so consumers can trust the safety of life-saving medications.

The review of literature highlighted several opportunities in the distribution process that allow counterfeit medications to enter the U.S. supply chain. Primary reasons being the inability to track and trace medications in the supply chain, increasing costs of medications, and drug shortages in times of emergency. With the occurrence of the recent COVID-19 pandemic, the topic of protecting medications in the supply chain is timely. A significant percentage of medications manufactured outside of the country creates a complex supply chain that provides many opportunities for criminals to insert medications into the supply chain. Introduction of the Internet makes processes easier for criminals to remain anonymous and create an online presence quickly. Also, money invested in the pharmaceutical industry is extremely appealing to people who feel financial pressures, have opportunities, and can rationalize the act of counterfeiting. Finally, when punishment for counterfeiting is minimal, one can understand why some people take the chance, despite considering either negative repercussions or rationalizing ones' actions.

Brand protection managers responsibility is to assess risk for each product, identify the proper anticounterfeiting strategy, and monitor the supply chain to ensure measures taken provide a suitable level of protection until dispensing medications to consumers. Because of changing capabilities of criminals, advancements in technology, and competition from counterfeiters, brand protection managers should consider continuous process improvements in many different areas to stay ahead of criminals in protecting each product in the supply chain. Such a task requires considerable collaboration with different internal functional areas, upstream suppliers, downstream wholesalers, security, and consumers. Also collaborating with other pharmaceutical companies, software and hardware vendors, academia, and governmental agencies is extremely important. Educating one another on how to detect counterfeits as well as using data analytics to develop more preventative measures to avoid a brand crisis, maintain brand equity, and protect patients is of utmost importance.

Transition and Summary

The rationale of Section 1 involved explaining foundations of the research to explore strategies to prevent and mitigate financial losses resulting from counterfeit prescription drugs. Topics included the background of the problem, purpose of the study, significance to business and social impacts, the core research question, related interview questions, and a review of extensive literature on the topic. Also included in Section 1 was a detailed description of the conceptual frameworks both used and considered for the study.

Section 2 includes the role of the researcher, population, sampling of participants, data collection methods, data organization, and techniques to ensure reliability and validity of the study. Section 3 includes data collection information, themes, and results. This is followed by a conclusion including strategies and potential recommendations.

Section 2: The Project

The goal of this multiple case design study was to explore strategies that US brand protection managers use to mitigate financial losses resulting from counterfeit drugs. The growing problem requires brand protection strategies that can protect organizations from economic damage and save lives. Section 2 includes the participant selection process and my responsibility to protect participants' privacy and confidentiality throughout the research process. Additional sections include the qualitative multiple case study design, data collection tools, analysis techniques, and processes to ensure reliability and validity of the study.

Purpose Statement

The purpose of this qualitative multiple case study is to explore strategies that pharmaceutical brand protection managers use to mitigate financial losses resulting from counterfeit prescription drugs. The targeted population comprised of at least three pharmaceutical brand protection managers in the US who have successfully implemented anticounterfeiting strategies to mitigate financial losses and protect patients. Implications for positive social change include the potential to (a) improve the ability of patients to confirm validity of medication sources, (b) ensure efficient identification and recall of substandard counterfeit drugs, (c) ensure efficacy and potency of prescribed medications, and (d) improve patient health by reducing the number of deaths caused by counterfeit medicines.

Role of the Researcher

The researcher's role is to understand the research process, collect pertinent data by following ethical practices, follow Walden University guidelines, and present findings. Researchers are an essential research instrument in a qualitative study (Shufutinsky, 2020; Yin, 2018). For the case study, I was the primary researcher and data collection instrument. Azzari and Baker (2020) identified that researchers should understand the context of the problem related to people and issues to offer greater insight on the topic by asking probing questions that provide valuable information. I have 20 years of experience in the pharmaceutical industry as a Senior Principal Business Analyst from 2002 to 2022, and I have attended several brand-security conferences and webinars.

I treated participants of the study with respect and ensured confidentiality. Gumede et al. (2019) posited that to avoid risk of coercion to participate in the study, the researcher should not have existing relationships with potential study participants. While I work in the pharmaceutical industry, I had no prior or existing personal or professional relationships with participants who volunteered for the study or partner organizations used to help identify qualified participants. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (NCPHSBBR, 1979) mandated in *the Belmont Report* three basic ethical principles regarding treatment of human subjects in behavioral research that researchers must consider: (a) protect participants' privacy, (b) avoid harm, and (c) exhibit fairness (see Appendix A). The American Psychological Association provided additional guidance on protecting

participants' rights and wellbeing by obtaining informed consent using language that one can understand, avoiding emotional or physical harm, and protecting confidential information. I treated participants with respect and vowed to keep names, organizations, and products anonymous. Interviews occurred in a private meeting environment to ensure participants' safety and provide comfortable settings that were void of intimidation. Using the same interview protocol and restraining discussions to the same amount of time led to equal and just opportunities for each participant to provide information regarding relevant strategies.

The researcher performs many jobs during the research process, including collecting and reviewing data, improving data collection strategies, understanding the material, verifying data interpretation with participants, and pursuing alternative participant responses (Karagiozis, 2018). Yin (2018) emphasized that a researcher should strive to maintain the highest ethical standards while performing research by not falsifying information, being honest, ensuring accuracy, and communicating assumptions and limitations of the research. Researchers should understand unique perspectives on the topic, biases that might influence interpretation of data, and relationships with participants to remain subjective and unbiased (Karagiozis, 2018). Although I work in the pharmaceutical industry, I had limited knowledge of the counterfeiting problem within the United States. Primary sources of knowledge during the research process were literature, conferences, and interviews with experts in the industry. While I take prescription medications, I know of no personal incidents involving counterfeiting.

Several methods exist to help prevent personal bias from entering the study. Being aware of any personal biases that might affect results is important. Plews-Ogan et al. (2020) suggested that eliminating personal bias completely is unrealistic, but one can avoid personal bias by either not incorporating leading questions or making statements that might influence participants' viewpoints. Member checking, which is the process of allowing participants to review written summaries of interviews to ensure information is accurate, provides an opportunity to correct and add details to clarify viewpoints and avoid personal bias (Brear, 2019). Yin (2018) described that in a multiple case study the researcher should demonstrate fair treatment of participants, and no bias toward any participant. I followed *the Belmont Report* for ethical treatment of participants in the study. The primary reason for selecting a multiple case study design was to prevent a single perspective on the topic and triangulate different forms of data to confirm participants' perspectives. Following a standard process for each case study helped ensure similar treatment for each case.

Development of a structured interview protocol guaranteed use of consistent research procedures for each participant. Braaten et al. (2020) emphasized that interview protocols used in research help to ensure capture of pertinent data to answer the research question. During the prospectus review process, several interview questions changed. Yin (2018) stated that the study protocol should include (a) an overview of case study objectives, (b) data collection procedures, (c) a list of interview questions, and (d) a tentative format overview of findings. Appendix B contains the developed interview

protocol with data collection procedures. Appendix C and D includes an invitation letter to participants with research procedures and a follow-up reminder letter. Appendix E includes a list of interview questions developed to answer the research question.

Participants

The population sample comprised of experienced brand protection managers from within the US who understood challenges of implementing successful strategies to prevent counterfeit drugs from entering the US supply chain. Kennedy et al. (2017) stated that brand owners affected by counterfeiting apply considerable resources toward fighting counterfeiters and prosecuting criminals. Brand protection managers are responsible for having a comprehensive plan to prevent and respond to internal and external product issues that arise (Wilson & Grammich, 2020). Therefore, selecting brand protection managers most knowledgeable in protecting products are responsible for strategies used to combat counterfeiting. A critical task of brand protection managers is to identify products most at risk to ensure the most effective anticounterfeiting strategy (Kennedy et al., 2017). Brand protection managers interact with all levels of the organization to ensure end-to-end collaboration of trading partners, enforcement agencies, marketing and sales, and legal department are working together to limit the opportunity of counterfeit drugs from entering the market.

Challenges arose that made gaining access to experienced participants difficult as an outside researcher. Saunders et al. (2019) confirmed that researchers with no previous relationship with participants could pose significant problems. However, Pallisera (2020)

noted that if organizations perceive the research to be relevant and beneficial, the gatekeeper might grant permission to participate. For example, Saunders et al. suggested demonstrating continuous sensitivity to the criticality of the topic, dependence on the goodwill of participants, and the ability to clearly explain the purpose of the study to all levels of the organization, which is critical for external researchers to gain trust of organization members. Based on the literature review and attendance at industry-related conferences, I demonstrated competence on the topic while showing genuine interest and confidentiality in exploring practical strategies, which may help less experienced pharmaceutical companies learn from knowledgeable industry experts. While the FDA deferred some milestones of the DSCSA to 2023, trading partners within the pharmaceutical supply chain understand the complexity and effort needed to comply, demonstrating the importance of acting now on developing strategies to combat the problem.

Gaining access to participant groups required developing personal relationships with participants to ensure a level of comfort and trust to encourage willingness to volunteer for interviews. Anderson and Henry (2020) referenced many benefits for the researcher who listens, fosters relationships with participants gradually and openly, and refuses to allow differences to affect the researcher–participant relationship. Communicating anonymity of participants in the study provided an incentive that strategies relevant to a specific company or product would not reveal confidential proactive or preventative measures that affect competitive approaches. Anderson and

Henry (2020) emphasized the importance of proper body language, posture, facial expression, and eye contact to demonstrate enthusiasm and openness to talk about the issue. Building trusted relationships with participants boosts quality research findings by fostering authentic answers (Nyirenda et al., 2020). Passion for the topic and the potential impact of learning practical strategies to prevent and mitigate financial losses related to counterfeit drugs positively affected the researcher–participant relationship. I learned and became the conduit of capturing critical data that might help industry members overcome challenges in developing anti-counterfeiting strategies.

Research Method and Design

Research Method

I selected the qualitative methodology for the study to gain a rich understanding of strategies that pharmaceutical brand protection manager's use for preventing and mitigating financial losses resulting from counterfeiting. Qualitative research allows the researcher to gather prolific information, which one cannot obtain through quantitative research (Kian & Beach, 2019). Similarly, Świeczkowski et al. (2019) stated that research studies on the awareness of counterfeiting focus on a quantitative approach, which represents a critical gap in the knowledge base of qualitative studies on the topic. Therefore, the approach for the study might help fill a notable gap in literature on the topic. Brand protection managers had the knowledge and expertise to provide critical information on challenges faced in developing an anticounterfeiting strategy for the organization.

An alternative approach is to conduct a quantitative research strategy. House (2018) described the quantitative research method as an objective technique to explain human behavior using statistical data related to theoretical constructs to test hypotheses. Quantitative research involves random sampling and data analysis software to measure data to determine generalizability of the findings (House, 2018). Furthermore, Saunders et al. (2019) maintained that researchers who use quantitative analysis derive meaning from numbers. The objective of the study was to explore strategies that brand protection managers use to mitigate financial losses resulting from counterfeit drugs from entering the supply chain. To answer the research question, the qualitative methodology applied to gaining an in-depth understanding of many strategies brand protection managers use that a quantitative research methodology might not provide. Therefore, I determined that the quantitative research method was not appropriate for the study.

The last research method considered for the doctoral study was a mixed method research approach. Mixed method research is using a combination of quantitative and qualitative research approaches to answer the research question, which requires more than one single method to solve (Sahin & Öztürk, 2019). Sahin and Öztürk (2019) suggested that while the mixed method approach might appear to be an ideal methodology, the expectation is that a researcher become an expert in both research procedures. A researcher may use the quantitative method to analyze data, followed by qualitative research practices to explore expert participant perspectives to gain an exhaustive understanding of the problem (Saunders et al., 2019). Because of limited time,

financial budget, and restricted access to statistical data, I determined the mixed method research methodology was not a suitable approach for the report.

The qualitative research method is an effective method for gaining a thorough understanding of the problem. In qualitative research, interviewing participants allows a researcher to extract, organize, and make sense of data to find common themes (Azzari & Baker, 2020). A valuable skill during qualitative research is for a researcher to establish a relationship with the participant to gain an honest and insightful perspective on the phenomenon (Azzari & Baker, 2020). In addition, Bush and Amechi (2019) posited that qualitative research allows researchers to focus on the voice of the participant, explore complex meaning, experiences, viewpoints, and reasoning behind human actions. A quantitative research method would not allow a researcher to compare personal perspectives among participants. Employing a qualitative research method would allow for opportunities to ask probing questions in addition to semi-structured interview questions to gain a deep understanding of successful strategies pharmaceutical brand protection managers use to mitigate financial losses resulting from counterfeit drugs.

Research Design

I selected a multiple case study design to explore how different organizations face the challenge of designing brand protection strategies to mitigate financial losses resulting from counterfeit drugs. The rationale behind selecting a multiple case study design was to substantiate information from numerous sources to come together through triangulating information across organizations. Azzari and Baker (2020) emphasized that

interviewing a single organization would provide one organization's perspective and provide limited insight into challenging schools of thought on the subject based on unique organizational characteristics. Likewise, Yin (2018) added that having at least two cases would allow researchers to avoid critique and uncertainty of study findings. Multiple case studies offer an advantage of being more vigorous and convincing (Yin, 2018). Therefore, a multiple case study design was a sound research design for the study to gain an in-depth perspective from real-world experts across different organizations in the same industry that produce different and competing products.

The multiple cases for exploration consisted of individual brand protection managers from a few of the top 15 pharmaceutical companies located in the United States who demonstrates success and experience in implementing anticounterfeiting measures to mitigate financial losses resulting from counterfeit drugs. Yin (2018) stated that a tangible example of a case study is either an individual, organization, small group, or project. Involving multiple pharmaceutical manufacturing organizations to participate in the study allowed for capturing a broad range of successful strategies from various contexts and identifying actions taken to overcome challenges. The number of cases identified for the multiple case study would need to provide a thick and rich amount of data to demonstrate replication and saturation (Yin, 2018). Indeed, Lowe et al., (2018) agreed that qualitative research involves achieving data saturation, which is when interviewing more people would not produce added information. Moreover, Leppink (2017) stated that researchers can demonstrate replication by documenting all decisions

made throughout the study. I was transparent about processes followed during the research endeavor to enable others to feel confident in the research results. I also continued to interview experts until no added information surfaced.

Another research design method a researcher could use is phenomenology. Ranse et al. (2020) stated that phenomenology is the technique of understanding a distinct group of people's lived experiences. For example, phenomenology relates to gaining an understanding what a person feels when faced with a tragic disaster. While use of phenomenology over the years is prevalent, it is difficult for researchers to continually apply the design strategy because of the design's intense philosophic quality (Ranse et al., 2020). Likewise, Fernandez (2020) explained that phenomenological design does allow a researcher to explore personal experiences not usually reflected upon, permitting one to empathize with participants. However, phenomenology did not apply to the study because the research question focused on business strategies that brand protection managers use to mitigate financial losses resulting from counterfeit drugs, not brand protection managers' personal lived experiences.

The narrative design is yet another qualitative research design method that a researcher may select. Ford (2020) explained the practice of narrative research design centers on examining human stories through interviews, oral histories, photo and voice projects, biography, and autoethnography. Capturing personal stories from participants is a time-consuming undertaking (Ford, 2020). Furthermore, Eichsteller (2019) emphasized a challenge exists with narrative research design in establishing validity within the study.

Since the study's purpose was to answer the research question centered on a business problem and limited time to conduct the study, narrative design was not an appropriate choice of research design for the project.

The final research design method considered for the research project was ethnography. Ethnography is a social research method to ascertain details of a group's culture concerning ethnicity, nationality, gender, country of origin, occupation, and generation (Kian & Beach, 2019). Ethnography involves observing human action compared to the rest of society (Kian & Beach, 2019). Again, ethnography requires a researcher to observe participants in the field over a significant period (Bird, 2020). Because of time constraints and the purpose of the study was to focus on exploring strategies to mitigate financial losses resulting from counterfeit medications, which are not cultural differences; ethnology was not a suitable research design method to answer the research question.

Data Saturation

Establishing data saturation in a qualitative study can be challenging. In fact, Alam (2020) emphasized that limited instructions exist on how to achieve data saturation for new researchers and debated significantly in academia to confirm validity in qualitative research. No specific metrics exist to help researchers determine if findings meet data saturation standards (Guest et al., 2020). For that reason, a researcher uses interviews as a primary method of gathering data and triangulating data from articles related to the topic to find themes (Yin, 2018). In addition, Low (2019) described how the

scholarly community must relinquish false hope that data analysis can ever be conclusive because data changes continually and perspectives change. Similarly, Fusch et al. (2018) suggested triangulating multiple data sources to improve chances of reaching data saturation. Finally, Alam (2020) referred to three steps in the research process to obtain saturation as obtaining redundancy of interview data, matching respondent comments to other participants, and using NVivo data analysis software to code collected data. I asked each participant to provide information relevant to mitigating strategies to find themes and asked probing questions until no new data surfaced. I compared information from each participant to see where information intersected or deviated. I also used the NVivo application to help code data for the study. Yin (2018) suggested to refrain from using sampling logic in case study research and instead refer to case replications. Based on the study's conceptual framework, I demonstrated at least three theoretical replications to ensure a high degree of certainty of strategies used by brand protection managers.

The primary data source was from in-depth interviews with experienced brand protection managers who implemented effective anticounterfeiting strategies. Other resources consisted of triangulation of peer-reviewed articles. Guest et al. (2020) acknowledged that a researcher’s knowledge and judgement on the topic help determine the point of data saturation. Alam (2020) suggested that if a researcher reached no new data, the data does not contain any new themes, resulting in data saturation. I did not seek additional participants to interview because no new themes or codes appeared when analyzing data. By conducting thorough semi-structured interviews with probing

questions and an interview protocol, I obtained critical strategies that brand protection managers might find helpful in mitigating financial losses resulting from counterfeit drugs. Using a consistent line of questions helped ensure data saturation; otherwise, different questions might provide a never-ending new data source.

Member checking is another strategy I employed to ensure data saturation for the study. Saunders et al. (2019) stated that member checking is the process of sending summarized transcribed interview data back to give a participant the ability to enrich, change, and confirm accuracy of data collected. Rather than transcribe interviews and make conclusions based on personal assumptions, I certified with each participant that captured themes were accurate and complete. Brear (2019) posited that member checking allows a researcher to build a better relationship with participants by remaining transparent with how the researcher interprets data and empowering the participant to be a vital part of a study in providing an objective perspective. The goal was to avoid personal bias by gaining knowledge through informative interviews, triangulating data against peer-reviewed articles to ensure accuracy and data saturation.

Population and Sampling

Selecting an appropriate group of participants was critical to the research study. Berndt (2020) explained that a population, in research terms, is the complete set of individuals and a sample is a subset of the population that participates in the research. Probability and non-probability sampling are two distinct methods for sampling, but qualitative research only involves non-probability sampling (Gill, 2020). More

specifically, Gill (2020) described convenience, snowball, purposive, and theoretical sampling as the most common forms of qualitative sampling methods. The purpose for defining the population and sample was to ensure the researcher interviewed people best equipped to answer the research question.

The population for this study consisted of three pharmaceutical brand protection managers from the top 15 pharmaceutical companies located in the United States that currently experience or had previous experience with negative impacts of counterfeit brand name products. One source of participants came from a non-probability purposive sampling method from a pharmaceutical security industry group composed of manufacturing companies committed to sharing information on counterfeiting tactics and collectively initiating enforcement action with authorities to protect the brand's reputation and public health. Saunders et al. (2019) stated that purposive sampling allows a researcher to use personal judgment to select the most relevant cases to enable a researcher to answer the research question. Similarly, Campbell et al. (2020) indicated that using a purposive sampling technique is effective when selecting participants with specific in-depth knowledge on the topic to increase rigor. Saunders et al. recommended the strategy of continually collecting data until reaching data saturation. In addition, Gill (2020) recognized the initial sample size may change as research progresses. The objective was to interview three industry experts to assess themes and pursue additional participants if new themes continued to surface.

A secondary source to find participants involved volunteers from a snowball sampling method obtained from business network contacts to find experienced volunteers to participate in the study. Snowball sampling involves a researcher asking volunteers to recommend other contacts to join in the study (Saunders et al., 2019). Saunders et al. (2019) noted using snowball sampling might result in a homogeneous population, which incorporates bias but works in cases where a researcher has difficulty finding members of the preferred population. Khan and Bashir (2020) noted snowball sampling helps when sharing of security measures prevents members from participating. In contrast, Gill (2020) stated that using the snowball method might produce participants when limited volunteers exist. The recommended sample size for a homogeneous population is between four and twelve participants (Saunders et al., 2019). Yin (2018) suggested that the number of cases sufficient for a multiple case study should relate to the number of replications one would like to research. Involvement of two to three replications might apply when clear-cut theory exists, and the solution does not require an elevated level of certainty (Yin, 2018). I did not consider theoretical sampling for the study. Gill (2020) described that theoretical sampling is important in generating theory in grounded theory studies, which is not the theory used for the study. Strategies explored during the research process were not the only strategies one could use to prevent and mitigate counterfeiting but represent commonly used strategies recognized as effective measures in fighting the counterfeiting problem. In addition, anticounterfeiting strategies are specific to the type of medication and risk associated to that drug. Therefore, research would unlikely reveal

exact strategies mimicked at each company because of the variety of products each manufacturer produces.

Both sampling methods required developing personal relationships with participants to ensure comfort and trust to encourage candor and a willingness to volunteer for interviews. Anderson and Henry (2020) referenced many benefits of the researcher who listens, fosters relationships with participants gradually and openly, and refuses to allow differences to affect the researcher–participant relationship. Explaining the anonymity of participants in the study provided an incentive that strategies relevant to a particular company or product would not reveal either confidential preventative or reactive measures that affect competitive approaches. Passion for the topic and the potential impact of learning practical strategies to prevent and mitigate financial losses related to counterfeit drugs positively affected the researcher–participant relationship.

To certify a quality study, data saturation is essential, but often vague when determining if achieved. Gill (2020) noted that data saturation relates to the sample strategy and sample size. In addition, Gill (2020) noted that some participants articulate information better than others, requiring few participants for the study. I triangulated peer-reviewed articles, interview transcripts, and governmental documents to find consistent and divergent themes that required further investigation. I reached data saturation when further questions did not reveal added information on the topic.

To ensure I involved the correct participants, I sought participation from members of organizations known to collaborate on successful anticounterfeiting strategies. I also

sought to contact pharmaceutical manufacturing firms mentioned in the literature and through conferences as having successful anticounterfeiting strategies in place. After receiving consent but before conducting interviews I requested details from the participant on experience and involvement in brand protection strategies within the organization to eliminate anyone with insufficient experience.

Ethical Research

A doctoral study requires a researcher to protect participants, data, and follow proper protocols. In fact, Gomes and Duarte (2020) confirmed that conducting research requires following ethical principles that (a) produce a safe environment, (b) address potential conflicts, and (c) protect the privacy and security of all participants. An ethical framework developed by Corbie-Smith et al. (2018) specified that researchers should determine with the participants what *just* treatment means, involve participants in all phases, assess risks and benefits together, and ensure all individuals follow ethical practices. More specifically, Sipes et al. (2020) explained that researchers should follow ethical research practices by obtaining (a) internal review board approval, (b) assessing the participant group's impact, (c) protecting participant's privacy, (d) obtaining consent, (e) being sensitive to delicate topics, and (f) avoiding direct quotations. In demonstrating desire to follow ethical research practices, I completed seven modules of the Collaborative Institutional Training Initiative (CITI) program related to confidentiality, addressing unanticipated problems, and reviewing ethical principles highlighted in *the Belmont Report*. Appendix A is proof of successful completion of the training. Before

conducting any research, I obtained Walden University Internal Review Board approval number 08-10-21-1000542 to certify the study design met ethical protocols. In recruiting participants, I had thorough discussions answering questions about what and how the information could help less experienced practitioners address counterfeiting challenges without sacrificing privacy.

Pharmaceutical brand protection managers received invitation letters (Appendix C) to participate in the study along with a consent form for the participants to review and respond. A reminder letter followed seven days later (Appendix D). The consent letter included instructions on the study's voluntary nature and ability to withdraw at any time. The consent form contained details on the study's intent, procedures followed during the research process, sample interview questions, risks, and benefits of participation, privacy measures, and storage practices of all research data. The consent form incorporated the intent to record interviews to properly document all findings. Saunders et al. (2019) recommended including the process of recording of the interview in the consent form to gain formal consent. With the spread of COVID-19 and doing online interviews, the recording of the interview was important. Hence, I included a statement in the consent form to be transparent about expectations. To ease the anxiety of potential participants, I explained the research purpose to explore brand protection managers' perspectives on anticounterfeiting strategies from an industry-level outlook rather than focus on specific product strategies that might compromise the organization's integrity's brand security program or financial position.

I did not incentivize any volunteers with money or gifts to participate in the study. However, as required by Walden University, all participants would receive a 1–2-page summary of the findings. Sipes et al. (2020) warned of the readers' ability to use reverse identification when directly quoting participants' views. Protecting individual names and organizations was paramount to the study's success. Therefore, I used participant x, company x, and product x to refer to specific perspectives. I stored all electronic data on an external thumb drive protected with VeraCrypt virtual encryption to protect access to study data. Following proper data handling procedures includes securing data by storing all paper and electronic research for 5 years in a locked safe, after which time shredding of paper data and deleting electronic data using the Eraser application will occur to meet Walden University doctoral study requirements.

Data Collection Instruments

In qualitative research, the researcher conducts much of the work for the study. Indeed, Yin (2018) and Azzari and Baker (2020) suggested that researchers are the primary data collection instrument in qualitative studies who prepares for research by (a) considering the design and methods to follow, (b) collecting data from diverse sources, (c) analyzing data, (d) reporting on results, and (e) anticipating challenges that might arise. The six sources where qualitative evidence may originate are (a) documents, (b) archived records, (c) interviews, (d) direct personal observations, (e) participant-observation, and (f) physical objects (Saunders et al., 2019; Yin, 2018). Yin (2018) stated the power of interviews is in targeted discussions that focus on expert participants' views

and opinions but allows for researcher and participant bias to enter the study. I used semi-structured interviews, peer-reviewed articles, governmental documents, and publicly available annual reports to explore and triangulate strategies used by brand protection managers to prevent and mitigate financial losses from counterfeit drugs.

The purpose of a multiple case study was to explore strategies that brand protection managers use to prevent and mitigate counterfeiting. I used a semi-structured interview approach employing open-ended questions. Saunders et al. (2019) described that using a semi-structured interview method is best suited for exploratory research, which is the study's purpose. In addition, Saunders et al. stated that using a semi-structured method allows researchers to develop a list of critical questions to ask based on relevant themes, which require more than a yes or no answer and enables the researcher to ask additional probing questions to clarify participant responses. I did not select using a questionnaire because the topic warrants a more in-depth discussion. Likewise, using a structured interview method, typically a questionnaire, would constrict the researcher to use an identical standardized list of questions for each participant without allowing for clarifying questions to gain an in-depth understanding of the participant's response (Saunders et al., 2019). Unstructured interviews are less formal and do not require a list of predetermined questions to ask participants (Saunders et al., 2019; Yin, 2018). Due to the importance of the topic and limited time allotted with each participant, I did not conduct unstructured interviews. I used a semi-structured interview approach based on the research themes, developed a relationship with a participants, and gained an in-depth

understanding of strategies used to answer the research question by asking probing questions.

Using a semi-structured interview protocol allowed flexibility during the interview process to ask additional questions based on participant's responses. Semi-structured interviews, also referred to as qualitative research interviews, would allow a researcher to uncover why participants have certain attitudes on the topic (Saunders et al., 2019). Following the interview protocol (Appendix B) and conducting interviews based on a list of prepared questions noted in Appendix E, interviews lasted approximately 60 minutes. Yin (2018) emphasized that developing an interview protocol is critical to case study research in attaining reliability and validity within the study. Interviews shorter in length would not allow for an in-depth discussion on the topic. More extended interviews could impede too much on a participants' schedule and willingness to participate.

In addition, the semi-structured interview process provided enough structure to seek knowledge on related topics. Thorsteinson (2018) discovered that adding some structure to the interview process significantly influences reliability and has a negligible effect on the data's validity. Therefore, a semi-structured interview method would improve chances of gaining reliable strategies over using an unstructured interview method. Other methodologies used for establishing reliability and validity within a multiple case study are member checking, using replication reasoning, using an interview protocol, and developing a database to store case study information (Yin, 2018). Once the interviews took place, I transcribed the conversations to provide a written account for

each participant to review and confirm the data's accuracy. Distributing and allowing each participant to review the transcript required extra time but ensured reliability and validity of participant's perspectives. Caretta and Pérez (2019) claimed that by using member checking, a researcher could obtain a more effective form of validity than achieved by triangulating multiple data sources to corroborate evidence. A researcher must be receptive to receiving constructive feedback on data capturing and transcription efforts to improve data and rectify participant perspectives' divergent opinions (Caretta & Pérez, 2019). I stored all data collected for the study in NVivo to query on data to find common themes and relate themes to reviewed literature.

Data Collection Technique

In qualitative research, a researcher aims to gather an in-depth understanding of experienced participants' perspectives concerning the phenomenon. I conducted semi-structured interviews involving open-ended questions with brand protection managers to solicit successful strategies used by pharmaceutical manufacturers to prevent and mitigate financial losses resulting from counterfeit prescription drugs from entering the U.S. supply chain. Bearman (2019) and Yin (2018) underscored that semi-structured interviews are the most common and crucial method to obtain a rich interpretation of personal perspectives in qualitative research and the most straightforward technique to collect data. Similarly, Saunders et al. (2019) explained that using semi-structured interviews in qualitative studies could help to explore what is happening and how an organization implements specific strategies. Open-ended probing questions would be the

best method to draw rich participant responses (Bearman, 2019). To complete the study judiciously, I executed online interviews as the best data collection technique.

The COVID-19 pandemic that started in 2020 limited the ability for the researcher to conduct face-to-face interviews. Therefore, the free Zoom online video application provided a flexible alternative method to allow the research to proceed conveniently for both the researcher and participant. I safeguarded privacy by having all participants access the Zoom application using a unique link to provide a safe and secure environment to share information. Upadhyay and Lipkovich (2020) confirmed that using online video programs is financially feasible for obtaining interviews, would provide flexibility in scheduling interviews, offers a safe and secure environment for interviews, allows participants to withdraw without further pressure, and the ability to record meetings. Since the pandemic forced many manufacturing executives to work remotely, their familiarity with online video conferencing technology was advantageous. In addition, the ability to record each meeting allowed me to summarize the results, transcribe the interview for each participant to review the accuracy, and the option to add additional comments. However, a disadvantage of using online conferencing applications is the potential interruption from members in aparticipant's location and unexpected cell phone distractions. However, addressing potential issues when scheduling the interview provided a solution. In addition, Iivari (2018) explained that member checking could increase validity and credibility within the study and allow participants to construct data for the study alongside the researcher. Consequently, as the primary data collection

instrument, I involved participants by performing member checking in the research process to build a solid relationship and obtain an in-depth understanding of challenges faced by brand protection managers.

Interviews do pose challenges for inexperienced researchers. In fact, Wadams and Park (2018) described how the questions a researcher asks, the sampling method used, having tunnel vision, and anticipating the study outcome, may allow a researcher to insert personal bias into the study. Regardless, if performed intentionally or unintentionally, introducing bias could influence the authentic representation of the participant's experience. Accordingly, a researcher could reduce researcher bias and promote rigor by incorporating bracketing, open-ended probing questions, peer reviews, inductive work, and researcher reflexivity throughout the research process (Wadams & Park, 2018). I asked probing questions to clarify information provided and refrained from incorporating any personal opinions during the research process. Before starting the research, I had limited experience with brand protection strategies used by pharmaceutical manufacturers. Consequently, I conducted interviews using objective listening skills and taking notes to mitigate researcher bias.

I was the primary data collection instrument for the study. I developed the following list of nine interview questions to ask each participant:

1. What strategies do you use to define the brand protection program at your company?
2. How do you measure success or failure of the program?

3. What were key barriers to implementing your organization's brand protection strategies?
4. How do you address key barriers to implementing your organization's brand protection strategy?
5. What strategies do you use to improve the brand protection program implemented at your company?
6. What anticounterfeiting strategies does your organization identify as being most efficient and cost effective?
7. What anticounterfeiting strategies does your organization identify as being least effective and cost prohibitive?
8. What other strategies beyond brand protection do you use to mitigate opportunities for counterfeit drugs from entering the supply chain?
9. What additional information would you like to share about strategies you use to mitigate financial losses resulting from counterfeit prescription drugs?

Each question relates to successes and challenges faced in implementing anticounterfeiting strategies to answer the research question: What strategies do pharmaceutical brand protection managers use to mitigate financial losses resulting from counterfeit prescription drugs? Bearman (2019) stated that interviews should flow like a natural conversation that starts with an introduction, explores the topic by using interview questions and closes out by allowing each participant to reflect on information provided while allowing each person the opportunity to add additional information. Use of an

interview protocol (see Appendix B) ensured that each interview followed a similar structure and help keep meetings on topic to answer the research question.

To gain access to participants, I explained the background, purpose, and potential benefits of the research to form a relationship with each participant to gain informed consent to participate in the research process. Interview transcripts, articles, personal journal notes, and other documents available for public use provided multiple data sources to perform methodological triangulation to increase the findings' credibility and validity. Fusch et al. (2018) posited that triangulation is critical to safeguard the results' reliability and validity. Similarly, Farquhar et al. (2020) recommended methodological triangulation as a good practice in case study research to increase validity by associating similar findings from multiple sources. Therefore, I used methodological triangulation as an effective data collection technique.

Data Organization Technique

As with any study, a qualitative research process requires a researcher to gather substantial amounts of data through interview transcripts, literature, governmental website information, and researcher notes. Yin (2018) suggested using multiple sources of data, creating a case study database, maintaining a chain of evidence, and exercising care when using social media data as four principles one should follow to establish validity and reliability within the study. Specifically, Yin (2018) recommended using computer-assisted qualitative data analysis software (CAQDAS) or other word-processing tools such as Microsoft Word or Excel. In addition, Wilk et al. (2019)

explained that CAQDAS software enables a researcher to store text-based electronic data to analyze study findings more easily than previous methods. Allowing time in the research process to learn an application and understand the functionality before using it is critical to the study's analysis phase.

I installed Zotero to manage all research literature collected during the research process to keep track of articles used in the doctoral study to ensure citations remained within the last 5 years. Zotero is a free reference management program to help organize literature based on topic and document reference information for use in the doctoral study. Organization of the articles was by topic and themes encountered during the research process, which contained articles spanning the entire research cycle up to the current date. I used the NVivo application to store research data. Using the NVivo application to store all interview data, journal notes, and corporate documents provided a means to code data quickly and identify common themes across cases and information, increasing the case study's reliability (Yin, 2018). I uploaded all journal notes in the NVivo tool for quick reference. Incorporating an application like NVivo helped organize all forms of data used in the research process.

I stored all electronic data on an external thumb drive protected with VeraCrypt virtual encryption. Saunders et al. (2019) underscored that all data stored on external drives should follow a similar process as storing paper documents in a restricted, secure, and safe place. To ensure all data remains safe and secure, I will hold the thumb drive

and any paper documents in a locked safe for 5 years, after which I will use a paper shredder and Erasure software to destroy all research evidence.

Data Analysis

I used methodological triangulation as the data analysis method. Throughout the research process, a researcher must ensure validity of data used to base study findings. Yin (2018) suggested using multiple sources of evidence to triangulate similarities and differences among data, which allows a researcher to provide a more convincing and accurate account of the phenomenon. In addition, Farquhar et al. (2020) explained that a researcher may use one of four triangulation methods: data triangulation, investigator triangulation, theoretical triangulation, and methodological triangulation to analyze data. Methodological triangulation involves collecting data from various sources to increase the study's validity by eliminating researcher or participant bias that might occur using one source of data (Saunders et al., 2019; Yin, 2018). I triangulated data from participant interview transcripts, peer-reviewed articles, governmental websites, and publicly available company annual reports to enhance validity and accuracy of the findings.

In today's digital world, use of computer applications to analyze data is gaining importance. Andrade et al. (2019) highlighted scientific researchers have several applications to choose from to organize and analyze research data. Similarly, Dalkin et al. (2020) discovered that using NVivo would not necessarily reduce time needed for analysis but could make writing findings easier based on apparent justification of the conclusions presented. Using NVivo would allow a researcher to quickly find new

themes presented in collected data to determine data saturation within the study (Dalkin et al., 2020). I used functionality available within the NVivo application to provide an audit log of theory development throughout the research process by entering notes and linking documents.

As an initial step to the data analysis process, I imported all articles related to the topic into a central NVivo database to find keywords and relevant themes in the literature. O'Kane et al. (2019) stated that computer-aided qualitative analysis database software (CAQDAS) applications facilitate searching of key terms in the literature, allowing a researcher to explore hunches early, and apply codes to literary data to relate other forms of data collected throughout the study. An application like NVivo, can help a researcher quickly determine word frequencies across many articles on the topic (O'Kane et al., 2019). After transcriptions of the interviews and member-checking took place, I used NVivo to code each interview to find similar or rival themes across participants' interpretation of the problem. Likewise, Saunders et al. (2019) stated that coding involves placing a label on associated data with similar meaning. Codes can originate from either participant interview data, terms used in the literature, constructs in conceptual theories, or organizational documentation (Saunders et al., 2019). In addition, comparison of the literature against interview data could reveal new or rival themes not addressed previously that would require further investigation. Moreover, O'Kane et al. (2019) suggested that CAQDAS helps with identification of themes that a researcher might miss. I identified themes across all forms of data to relate findings to the composite conceptual

framework used to view the phenomenon and provide additional credibility to the research process. As research progressed, I searched for new articles pertaining to the topic to add to the research database to further triangulate themes across all sources of data.

Reliability and Validity

A key objective in any research project is to certify the reliability and validity of data and research process so the reader can rely on the quality of the study findings. Yin (2018) emphasized that a researcher must consider how to certify reliability and validity in each phase of the research process to eliminate either personal or participant bias from entering the process to deliver a quality study. Researchers refer to reliability and validity in a qualitative study as rigor (Rose & Johnson, 2020). Specifically, terms commonly used for establishing quality in a qualitative study are reliability through dependability, and validity through credibility, transferability, and confirmability (FitzPatrick, 2019). Johnson et al. (2020) suggested following a five-step approach of:

- identifying an appropriate research question and related conceptual framework,
- incorporating best practice methods,
- using computer software to triangulate collected data,
- drawing valid conclusions through interpretation of results, and
- reporting results of the research in a clear, organized, and concise manner to the reader.

I followed similar principles to demonstrate rigor by identifying multiple sources of evidence to triangulate perspectives, established a research process that was transparent, and incorporated a range of best practice techniques.

Reliability

A key objective of any formal study is to ensure reliability of the data findings. Dependability in qualitative research is equivalent to reliability (replication) of a study (Saunders et al., 2019). Johnson et al. (2020) described dependability as the researcher communicating the study process in significant detail for a reader to understand the process followed to determine trustworthiness. I used a semi-structured interview protocol with professionals from multiple cases, read a considerable number of peer-reviewed articles, performed member-checking, conducted transcript reviews, and sought expert advice on literature thoroughness to ensure dependability of a quality study to eliminate any potential research bias from entering the research process. Likewise, Yin (2018) posited that aresearcher could demonstrate dependability through using a case study protocol, developing a research database, and developing processes that would allow another researcher to reach similar conclusions. Appendix B identifies the protocol developed for the interview process with all participants. In addition, I used the NVivo research database to store and analyze all data. I also embraced recommended research processes such as member-checking and transcript review to safeguard a quality study.

Validity

Procedures a researcher follows are critical to delivering a quality study. FitzPatrick (2019) explained that some term validity as trustworthiness, credibility, confirmability, or transferability of a qualitative research. Trust in the conclusions derived through transparency of a study's design, credibility from detailed descriptions of the problem triangulated against the literature, and transferability by using consistent research procedures for each participant (FitzPatrick, 2019). Validity within a study relates to the process of verifying data and interpreting results to establish quality outcomes (Saunders et al., 2019). FitzPatrick (2019) posited that without following recommended practices a reader might not trust the conclusions. A researcher must consider how each step of the research process affects various aspects of the studies trustworthiness.

Data Saturation

Estimating the number of interviews to reach data saturation in a qualitative study before the study begins was challenging. Guest et al. (2020) stated that data saturation is the point during data analysis when new data obtained from interviews produces little or no added information related to the topic and the ability to replicate the study occurs. One way to achieve data saturation is to conduct more structured interviews that involve asking additional participants the same questions to ensure coverage of related topics for the problem to triangulate data among diverse sources of evidence (Fusch et al., 2018). By conducting a multiple case study, I gained a more thorough understanding of

challenges facing brand protection managers than if I focused on only one organization. To guarantee the correct understanding of each participant's perspectives, I conducted member checking, which is a review of a summarized version of the interview with each participant (Brear, 2019). I then ensured each participant reviewed my interpretation of their interview responses and asked if they agreed with my synopsis of their ideas. Since the third participant I interviewed did not reveal new data, I did not pursue additional participants to interview because I reached data saturation.

Credibility

Research findings should be believable. Saunders et al. (2019) stated that credibility within a study relies on a researcher representing socially constructed realities of the participants as intended through the interview process. Shufutinsky (2020) suggested incorporating the "use of self" through self-transparency and reflexivity as methods of tackling personal bias in qualitative research to increase validity, credibility, and trustworthiness. Memos and journaling are tools used by researchers to analyze and triangulate with other data sources later in the research process (Shufutinsky, 2020). I took notes throughout the research process to refer to when reporting outcomes of the study. Saunders et al. (2019) recommended performing member checking to confirm participant perspectives are accurate and include documentation of conflicting perspectives to produce a thorough explanation of the situation. After transcribing the interviews, I provided a summarization of the interview and asked that each participant

review the accuracy of interview content and allow each participant to either add additional information or correct any misunderstandings.

Triangulation is another method aresearcher may use to improve the quality of the study. Saunders et al. (2019) suggested that methodological triangulation entails using more than one source of data and collection method to confirm that data depicts a true story of the phenomenon. If a participant provides a perspective that contradicts the literature, one might need to consider if participant bias played a part in the data collected from each resource and research the alternative view further to determine cause for the alternative point of view. Fusch et al. (2018) explained that interviews, focus groups, direct observation, document analysis, participant observation, and study notes are forms of methodological triangulation. I conducted semi-structured interviews using a standard interview protocol, incorporate probing questions to gain a deep understanding, and made notes on participant observations regarding the research topic to triangulate data to reach saturation.

Transferability

Research quality also depends on transferability. Transferability in qualitative research places responsibility of applying conclusions of the study to a different setting, group, or population on the reader of the study for use in further research (Korstjens & Moser, 2018). To enable a reader to transfer results to another group, the researcher must explain in detail the research questions, design, circumstances, outcomes, and interpretations of participant perspectives (Saunders et al., 2019). Varying cultures across

multiple organizations, inconsistent research processes, and new experiences encountered by participants are potential threats to transferability of the research. I followed standard ethical, interview, and research processes to certify the research findings.

Confirmability

Another method to establish trustworthiness of study data is through confirmability. Korstjens and Moser (2018) described confirmability as the ability of a researcher to corroborate findings of the study through describing steps taken from the beginning of the study to reporting of the findings to demonstrate transparency that the findings are a direct result of analyzing data and not the opinion of the researcher. The process for reinforcing confirmability is to maintain an audit trail of decisions made, reflective thoughts, sampling methods, and methods for data management (Korstjens & Moser, 2018). Yin (2018) underscored that researcher notes are the most common component of case study research. To validate results of the study I documented the methods followed to prepare for the study, the methods, and design of conducting the research, use of a standard interview protocol, member checking information with participants, and use of multiple databases to maintain references to articles and strategy used for thematically coding data.

Transition and Summary

In Section 2, I addressed how I conducted the study to determine successful strategies that pharmaceutical brand protection managers use to mitigate financial losses resulting from counterfeit prescription drugs. Section 2 includes information about how I

was the primary research instrument in conducting this qualitative research, methodology and design of the research process, methods for gaining access to participant experts, types of data collected, organization of data, analysis techniques, and reliability and validity of research outcomes. In Section 3, I present research findings of the study, how findings relate to professional business practice, implications for social change, and recommended actions to mitigate financial losses. In addition, I suggest topics for future research, personal reflections regarding the research process, and conclude the study.

Section 3: Application to Professional Practice and Implications for Change

Introduction

The purpose of this qualitative multiple case study was to explore strategies that pharmaceutical brand protection managers use to prevent and mitigate financial losses resulting from counterfeit prescription drugs. My goal was to include detailed information from expert participants based on lived experiences working in the pharmaceutical industry involving measures to prevent counterfeit medications from entering the US supply chain. Grodal et al. (2021) confirmed that qualitative data is an excellent source of rich data for researchers to categorize into common or disparate themes. Based on knowledge gained through the research process and prior experience, a researcher can then arrange themes that answer the research question and relate answers to the conceptual framework (Grodal et al., 2021). Interviewing participants from multiple pharmaceutical companies allowed knowledge of varying perspectives on the same topic in order to obtain a thorough understanding of challenges faced by brand protection managers.

Section 3 includes a summary of findings, applications to professional practice, and implications for social change. In addition, I provide recommendations for action and further research. I close Section 3 by sharing my reflections and a conclusion.

Presentation of the Findings

The primary purpose of this qualitative multiple case study was to explore strategies that pharmaceutical brand protection managers use to mitigate financial losses

resulting from counterfeit prescription drugs. Each participant provided consent to participate in the study. Information resulted from three recorded semi-structured interviews over a period of 5 months. Appendix B includes the interview protocol for each interview and Appendix E includes a list of interview questions used during the interview process. Additional probing questions allowed for clarifying ideas and specific topics. After transcribing interviews and summarizing data, each participant took part in a member checking exercise to review and verify that I interpreted their points correctly to ensure accuracy.

In place of participant names, I used pseudonyms such as Participant 1, Company A, and Product 1 to protect identities of each participant. After member checking, I uploaded all transcriptions into NVivo to code key facts and identify common themes within and across all participant perspectives. By using methodological triangulation, I compared themes to peer-reviewed literature to support the validity and reliability of study results.

Four key themes emerged from data analysis (see Table 5).

Table 5

Summary of Themes, Strategies, and Coding

Themes	Strategy	References Coded for Theme
Guiding Principles	Patient Safety & Brand Protection	31
Securing the Supply Chain	Securing warehouses and logistics Effective/Ineffective covert/overt packaging methods	70
Investigations & Enforcement	Assessing risk Understanding capabilities and motives of criminals Understanding patient engagement with healthcare professionals Proactive surveillance on perceived risks Reactive data collection Focused Investigations based on complaints Forensic laboratory to build cases against criminals Building cases for civil action Administrative enforcement Collaboration with internal and external partners	66
Advocacy & Awareness	Encourage stronger legislative measures and penalties Educate employee's, patients, law enforcement agencies	34

Theme 1: Guiding Principles

The first theme involves what each company deems important in terms of strategic goals involving mitigating financial losses resulting from counterfeit prescription drugs. Two points highly emphasized by all three participants during the interview process involved guiding principles that drive each company's brand protection program. Ensuring patient safety was the primary focus, followed by protecting the company's reputation by implementing successful strategies to mitigate counterfeits from entering the supply chain that could harm patients and cause financial losses. Babyar

(2018) established that enabling elements and significant financial rewards are key causes of counterfeiting. Because of the enormous financial opportunities that making counterfeits provides, each participant recognized counterfeiting would never go away. Each acknowledged if patients do not feel comfortable taking medications that have considerable value in terms of improving lives, then the company would suffer financial impacts and leave diseases untreated. Participant 3 stated,

> The primary mission is to protect patients. It has nothing to do with either revenue protection, revenue creation, revenue recovery, or any business aspect of that, which is not even tracked, nor do we try. It would not guide our work. What we found is that people who did, made so many assumptions in generating that number that it was relatively invalid. Revenue loss would never trump a patient safety issue. If our reputation is damaged in some way, then patients are reluctant to take our medications.

Participant 2 stated,

> The number one thing that is most important, is protecting patients. That is what we are in this for. The second thing is to protect our brand. We want to make sure that if you take one of our products, that you have a good assurance that it is an efficacious product that is going to treat your condition. So, those are our guiding principles.

Participant 1 stated:

> Our big concern is patient safety. We know we cannot stop counterfeiters from counterfeiting product. So, my primary role is to do what I can to prevent those counterfeit products from getting into or breaching the legitimate supply chain. A business might not see a need to protect medications if they do not know the type of risks that are out there.

Figure 1 is a word cloud that represents some of the most used terms by participants.

Figure 1

Most Frequent Words from Interviews Related to Theme 1

The size of each word characterizes the frequency of the word in combined interviews. Key words included patients, protect, reputation, safety, and company.

Findings Related to the Composite Conceptual Framework

The findings from the participant interviews align with the constructs related to the Six Sigma DMAIC model by the organization initially defining an approach the company wishes to prioritize and improve. Byrne et al. (2021) highlighted that the COVID-19 pandemic brought visibility to pharmaceutical manufacturers as an essential service that required continuous production to meet increased prescription demand to try

and avoid drug shortages, especially companies producing drugs that aid in the care of COVID-19 patients. Six Sigma practices allow organizations to improve the movement of information and materials between various steps in the manufacturing process (Byrne et al., 2021). Similarly, Sony et al. (2020) stated that prioritization of Six Sigma type projects primarily focuses on improvements with greatest impact to customers. In highlighting patient safety and brand protection as top priorities, each organization could work to implement successful strategies that would protect patients and mitigate financial losses resulting from counterfeit medications from entering the supply chain.

The study findings also relate to the second conceptual framework by identifying the need to remedy gaps in the supply chain by implementing measures that prevent criminals from inserting counterfeit medications into the supply chain. Each participant recognized that counterfeiting would always exist because of significant financial benefit to the criminal as a motivator. Tickner and Button (2021) explained that within the fraud triangle theory a perceived financial pressure, perceived opportunity, and ability to rationalize criminal activity must exist to commit a fraud. The profitable pharmaceutical industry provides financial motivation for criminals and the various gaps in the supply chain with limited punishment allow opportunity for criminals to justify illegal action of making counterfeit medications.

Findings Related to the Literature Review

The study findings correspondingly align with peer-reviewed literature on the topic. Significant research emphasizes risks that drug counterfeiting poses on public

health and the importance of safety (Abma, 2016; Ančevska-Netkovska et al., 2020; Benchekroun et al., 2020; Bollyky & Kesselheim, 2020; Leem et al., 2020; Świeczkowski et al., 2021). In addition, Srivastava (2019) noted that a brand crisis could contribute to lowering a company's reputation, consumer perception, and brand equity. However, when a company properly responds to a crisis, brand equity does not depreciate (Srivastava, 2019). Therefore, prioritizing patient safety and implementing proactive and reactive strategies to prevent counterfeit drugs from entering the supply chain would help protect patients and maintain a company's reputation from negative monetary impact.

Theme 2: Securing the Supply Chain

The second theme that answers the research question is one of three specific strategies that pharmaceutical brand protection managers use to mitigate financial losses resulting from counterfeit prescription drugs. Separately each participant explained a need to secure the supply chain as one component in a multilayered approach to the overall protection program. Strategies to protect the supply chain involve safeguarding warehouses, logistics, attaching security measures to product packaging, and instituting policies and procedures to mitigate opportunities for improper distribution practices.

Securing Warehouses and Logistics

An essential method of proactively protecting medications relies on security measures implemented to safeguard newly created product through the supply chain until patients take possession. Because of the complex nature of the pharmaceutical supply chain, handing off medications to packagers, distributors, and wholesalers is widespread

practice. Le et al. (2018) supported that every step a medication takes in the supply chain is an opportunity and risk for something to go wrong. Participant 1 described how,

> Once you start selling product to third parties and they are selling it and reselling it, you have distributors and wholesalers, then the opportunity for counterfeits entering the supply chain goes up. So, we implement GPS systems on trucks, add locks, and seals. We also have a whole conveyance security program related to logistics people. We have someone in global security that works primarily on logistics and conveyance security. We have a whole guidance around freight forwarders and truckers that they have to provide seals that have locks that can prevent counterfeits from getting into the supply chain. However, some percentage of loss is factored into the business projections. If we feel a breach occurred in the legitimate supply chain, we make a referral to the FDA by completing a form. Lastly, if a patient is going to go to Craigslist to find the cheapest version of Product B without a prescription, I cannot help that person. They are going to get a counterfeit product. They are taking that risk when they do it.

Participant 3 described how,

> We implement security systems at our warehouses and provide access control systems. When a trucking company is taking our product from our warehouse to a distributor, we can contractually control the security requirements of that truck by trying to prevent theft, mitigate the risk of theft, and product diversion. The advantage is that we can control that very explicitly, although only to the first level of distribution.

Participant 2 explained how,

> We work with our partners across the world who ship our products, so they are not stolen or taken out of proper temperature. We see what is out on the Internet and we can see when counterfeits come up and what they look like. We take that information to learn from it, which helps guide us on what we do as it relates to how we package our products and what features we put on them. We monitor the illegitimate supply chain, doing what we can to disrupt that so some of these folks will move away from our products.

Securing the supply chain could also involve implementing covert and overt measures onto medication packaging to help track and trace product through the supply chain.

Effective/Ineffective Covert and Overt Measures

A sub-theme of securing the supply chain relates to product packaging for each pharmaceutical company and more cost-effective or ineffective measures used by the three manufacturers. Each participant revealed strategies associated to effective or ineffective covert and overt anticounterfeiting measures placed on product packaging.

Such methods not only help protect the product from counterfeiting, but also help manufacturers and law enforcement in identifying valid product from counterfeit product. Participant 1 indicated that:

> We use microtext in certain places on the label of the packaging. We might purposefully include a misspelling that our lab people know about, but the counterfeiters do not know about. We also place a varnish on the higher-risk products that contain a hologram. The risk of counterfeiting the product determines the measures implemented for the product. A lot of the things we try and put in place, is a one-time cost when you set up the packaging line and not a cost per unit. Anything that you can embed within the template, that is probably the best method from a cost perspective. If you include microtext in the printing of a carton, you put it in the computer, and it is no additional cost to do it per package because it has a template. We save the varnish with the hologram, which we apply separately, for our highest risk products because they are a per unit cost. We do millions and billions of units. If we have to pay two cents for a sticker, that is too much money and are the less cost-effective measures to implement. By law, we also include a serialization number that includes a global identification number, a tracking number, and 2D barcode, which includes the lot number, expiration date etc.

Participant 2 disclosed:

> Our secure strategy is implementing overt features that you can see with the naked eye, and some covert features that cannot be seen that we put on our products so that we can readily identify them as being legitimate products or not. And that, more importantly, patients can use to identify if those products are legitimate or not. Some of the fancier measures are not necessary. Also, having a team of individuals that understands how the illegitimate supply chain works and how criminals act for the business to make informed decisions as things develop is efficient. If you have that in place that makes the program cost-efficient because you are not spending a lot of time looking for resources to learn how to deal with a situation as it develops.

Participant 3 provided:

> We do adversarial analysis by looking at all the counterfeit events to understand how it was counterfeited. We recommend which features should be implemented and which ones to stop if we feel that they are no longer effective. If we implement a security feature, we already know what the potential failure modes are and what we are doing to monitor them because we cannot prevent those failure modes, but we can surveil for them. Temper evident closure seals are the most effective ways of enabling tamper evidence in a way that is efficiently done on a high-speed packaging line. We stopped using holograms because criminals placed them on products we did not, which gave patients a false sense of security. Every measure we use, we know why we use it. We know what it is intended to

> protect, we know what the failure modes are, and we can make rational decisions to the business about stopping or incorporating certain features. We also found that putting the highest level of protection on the low and high-risk products was more cost-efficient because the packager could run the same packaging process for all products. It reduced the complexity of the effort for the packager and reduced the cost for us.

A requirement of the Drug Supply Chain Security Act of 2013 mandated that all pharmaceutical companies apply a serial number to every package for the future goal of tracking and tracing products through the entire supply chain by 2023. The milestone date for pharmaceutical manufacturers to comply with attaching serial numbers was November 2017 (Le et al., 2018). Furthermore, Le et al. (2018) stated that the milestone date for wholesalers to comply is 2023. However, Participant 1 explained:

> While trying to investigate where product went, the three big wholesalers, McKesson, AmerisourceBergen, and Cardinal Health, which move 90% of product in the US, claim they are not obligated to tell us and don't track where they sold the product. If we have a problem that occurred in the legitimate supply chain somewhere and we are trying to track where it went, it is like a black hole. I would say that is one of the biggest hurdles to prevent us from actually tracking product through the entire supply chain in the US. I do know that some of those big three have filed suit against the FDA claiming it is a competitive advantage to not reveal where they sold the product. Company A's expertise is not in logistics,

> it is in manufacturing. We are still going to sell to McKesson or AmerisourceBergen. As a pharmaceutical manufacturer we are required to make an entry for the serial number that it is stolen, so it does not make it back into the legitimate supply chain. AmerisouceBergen sends us a copy of the report they send to the FDA. If the same issue occurs with McKesson, they put the information on a website saying manufacturers have to go check it, which is not in the spirit of DSCSA. Cardinal Health is not doing any of it.

Participants 2 and 3 felt serializing product was good for the industry to have better visibility into the supply chain.

In summary, numerous anticounterfeiting methods exist for pharmaceutical manufacturers to use. Many not mentioned in the study. However, all participants use a variety of strategies based on potential risk to counterfeit, type of packaging, and risk to patients, which are unique to each pharmaceutical company's brand protection program for the types of products each manufactures.

Measuring Success

As criminals evolve, so must the practices that pharmaceutical manufacturers use to protect medications. Criminals are always looking for new ways to make counterfeit drugs look like legitimate medication and insert counterfeits into the supply chain. Some strategies manufacturers implement involve proactive as well as reactive measures to ensure success of the program. All participants mentioned collecting data on global

complaints, adverse events, and incidences to measure increases or decreases. Participant 3 said:

> A reactive method would consist of either a notable geographical increase or a cluster of adverse events, even trip wire measurements that might indicate a counterfeit issue that requires investigation. A proactive method is when we know this drug was coming out for 18 months and conducting surveillance from the second we learned that the product existed. We were already building a protective strategy around that. By the time it got to market, we were already able to stop things before they occurred because we knew that they were going to occur. So, success is sometimes measured by detecting more and sometimes by not detecting what you expected.

Potential Barriers

The FDA highly regulates the pharmaceutical industry. Bollyky and Kesselheim(2020) claimed that the FDA is more comprehensive and demanding about regulation than similar agencies in other countries. Therefore, some barriers exist when implementing anticounterfeiting strategies. Although Participant 1 did not specifically state financial constraints were an issue, Participants 2 and 3 have to justify risks involved to upper management to gain financial resources and senior stakeholder support in implementing the suggested protection programs. For new medications the perceived risk comes from knowing criminals and capabilities of such organizations. Another challenge of a highly regulated industry is the time needed to implement some new

anticounterfeiting strategies because certain changes to packaging require FDA approval. Reacting quickly to a crisis might not always be possible. The final barrier is resistance of wholesalers to cooperate in providing more transparency in the supply chain by playing a role in the tracking and tracing of medications as expected with the DSCSA deliverable of a fully interoperable system by 2023.

Findings Related to the Conceptual Framework

The findings from participant interviews align with the constructs related to the first Six Sigma DMAIC model by demonstrating that securing the supply chain is a constant and iterative process similar to the continuous process improvement methodology. Byrne et al. (2021) emphasized the goal of using Six Sigma practices is to bring added improvement that transforms steps within the process. Similarly, Moon (2020) emphasized the essential need to use the DMAIC approach in a highly regulated industry that makes products that could harm customers. Each participant company defined goals of protecting patients and data used to measure complaints, analyze events, make improvements to product security features, and control the process after implementing new measures. As criminals adapt and risks change, the process of following the DMAIC cycle enables a brand protection team to enhance or remove security measures based on necessity to protect patients and mitigate financial losses from counterfeit prescription drugs.

The study findings also relate to the fraud triangle conceptual framework by brand protection managers having to think like criminals to mitigate gaps in the supply chain.

When new medications are in development, the brand protection team has to understand the motivational behavior of criminals to estimate the level of security measures needed to protect medications. Tickner and Button (2021) claimed that the fraud triangle is simple to understand and used significantly in research related to fraud motivation. By understanding past criminal behavior brand protection managers could implement effective security measures specific to individual products based on either administration method or type of packaging.

Findings Related to the Literature

The study findings also align with the peer-reviewed literature on the topic. Hertig et al. (2020) proclaimed that the US supply chain is extraordinarily complex and subjected to many external threats like counterfeit medications, importation, gray markets, diversion, and the Internet, which challenge protection programs. Similarly, Pisani (2017) explained that complexity of the pharmaceutical supply chain involves a significant amount of exchange of medications through different stakeholders, which increases the chance for mistakes, bad practices, and criminal activity. Pitts (2020) stressed the ability to maintain product quality and supply chain security relies on a multilayer approach consisting of proactive, reactive, and detection strategies. Pharmaceutical manufacturers have the most control over only the first level of distribution. However, once product leaves the warehouse, the company relies on other logistic providers, wholesalers, and distributors to continue to protect medications until distributing the medication to patients because limited visibility exists further down the

distribution process. Therefore, providing either contractual or technical strategies that can protect medications are crucial to ensuring counterfeit drugs stay out of the legitimate supply chain.

Figure 2 includes a word cloud that represents some of the most commonly used terms by participants.

Figure 2

Most Frequent Words from Interviews Related to Theme 2

The size of each word characterizes frequency of words in the combined interviews. Key words were security, product, chain, supply, features, and company.

Theme 3: Investigations and Enforcement

The next theme contributing to answering the research question is the second of three specific strategies brand protection managers use to mitigate financial losses resulting from counterfeit prescription drugs. All participants in the study reflected on how critical investigations and enforcement are to identifying how counterfeits enter the

supply chain and tracking down criminal entities to prosecute them to the fullest extent of the law. Several sub-themes related to investigations were (a) assessing product risk, (b) forensic laboratories, (c) collaboration, and (d) potential barriers to investigations. Enforcement included (a) civil action, (b) administrative enforcement, and (d) potential barriers to enforcement.

Investigations

All participants underscored a need for investigating complaints coming from a variety of sources related to potential issues with products. Participant 3 specifically mentioned that complaints could come from customers, adverse event reporting, law enforcement, healthcare workers, health authorities, and news reports. Similarly, Participants 2 and 3 highlighted that data collected during the investigation process contributes to evidence handed over to either legal or regulatory agencies for enforcement. The process of verifying whether or not a product is counterfeit is a majority of the proof required to properly prosecute criminals. Dégardin et al. (2018) confirmed that either the medication, packaging, or both the medication and packaging could be counterfeit. Criminals now use very sophisticated technologies that make identifying a counterfeit more difficult and complex (Dégardin et al., 2018). As a result of investigations, brand protection managers use data and experience gained to assess risk of each product to know what strategies to build or apply.

Assessing Product Risk. Participants 1, 2, and 3 specified different but similar procedures for calculating product risk. Participant 1 said:

> Company A has the business complete a questionnaire for every product. A team of experts from global security with experience in security, another global security expert with a background in the laboratory, an artwork specialist from the packaging team, and an expert from the trade group reviews the form. The form contains questions such as what is the estimated demand? What is the estimated price? What is the estimated cost? etc. Based on the risk level, we assign different levels of anticounterfeiting features on the product. Some of it has to do with what is available to be done based on how it is either packaged if it is a vaccine in a syringe or if it is a pill in a carton.

Likewise, Participant 2 stated:

> We do an assessment for every product on an X and Y axis. Risk of counterfeit verses the risk to the patient. We make decisions on what we do based on that X and Y axis. We do the risk assessment at the time the product is launched, and then we will change that based on if we see a compromise or we see an issue, then we will make a change as needed, based upon the additional risk to a patient.

Also, Participant 3 specified:

> Company C uses adversarial analysis of criminal behavior, which gives us a pretty good idea of what the bad guy is capable of doing, what motivates them, and what their capabilities are. Using the COVID-19 vaccine as a hypothetical example, everybody in the world knows it exists. Everybody in the world wants one, at least for the most part, and they are produced in limited quantity and very

> difficult to distribute. So, there is this access motivated illicit trade that is occurring. Others are economically motivated because people would be willing to pay multiple times the list price for the COVID vaccine. We also know how people engage with their healthcare providers. People are not going to inject themselves most likely. So, we probably will not see people trying to buy counterfeits on Facebook to give themselves their own injections. So, you will probably see people targeting healthcare providers and other medical practices with product to distribute. We conduct proactive surveillance and collect reactive data on complaints to assess the risk profile.

Collaboration. Collaboration with other pharmaceutical companies and numerous external agencies prior to needing help is important. Pisani (2017) expressed that investigation into counterfeit medications require an exceptional amount of collaboration. Participant 1 said:

> Collaboration with internal departments such as the legal and quality departments when a breach in the supply chain occurs. Involvement of the logistics department if a product theft occurs. Also involved is the global security group for monitoring the illegitimate supply chain as well as the US trade group to determine where product was supposed to go. We also have a good collaboration with other pharmaceutical companies, FDA, and enforcement agencies.

Participant 2 mentioned a different collaboration that the other two participants did not. Because the selling of medications moved from the Internet to social media, Participant 2

stated:

> The selling of counterfeits went from the Internet to eBay and then sites like Alibaba. We have to constantly be aware of where drugs are being sold and work with those organizations to learn about what their terms of service are and what it takes to get something like that taken down by developing a relationship with them. Involving the legal depart to file patents for each product in the respective country and sharing strategies with other pharmaceutical companies is a big piece.

Similarly, Participant 3 said:

> Building relationships with enforcement agencies such as the Federal Bureau of Investigation (FBI) and Homeland Security. Also important are connections with distributors, suppliers, legal department, industry trade organizations, and other pharmaceutical companies to share information on different strategies.

Having relationships in place with each of the internal and external groups enables the sharing of experiences, learning of new strategies, and consolidating resources in fighting counterfeiters.

Forensic Laboratories. Participants 2 and 3 confirmed the creation of an internal laboratory dedicated to testing potential counterfeit product as part of the investigation process. Testing of potential counterfeit product in the field is not always possible because of a lack of expertise. Field resources also do not have the necessary equipment to conduct the proper analysis (Shinde et al., 2020). Likewise, Pisani (2017) stated that investigations rely on laboratory testing and tracking drugs back to the manufacturing

location. Therefore, having a lab to perform in-depth testing by experts that know the formulation of the medication is crucial. In addition, results of the analysis contribute to authority's identifying similarities among counterfeiters and building cases to prosecute criminals (Salim et al., 2021). The pharmaceutical company that manufactured the medication is the best resource to determine if product is counterfeit or legitimate.

Potential Barriers. Within theme 3, participants identified barriers to investigations. Participant 3 disclosed that far more risks exist than the capacity to investigate. Similar to most companies, each company operates on a budget. Participant 3 stated that a challenge with investigating potential incidences is the unpredictability of the number of cases to investigate each year while working within a yearly budget. Pisani (2017) confirmed that investigating the origins of online sources of criminal activity could cross international boundaries with jurisdictional challenges that make investigations complex because of the multiple countries involved. Nevertheless, Participant 3 stated, we will respond to every reactive event, but we would prefer to proactively deploy our resources. Participant 2 reflected that evidence obtained from an investigation might not be a priority for the agency receiving the information. Therefore, knowing what to collect and how to build good evidence is important in getting the attention of agencies for enforcement purposes. The final barrier mentioned by Participant 3, was introduction of Covid-19 that significantly motivated criminals and increased the number of potential incidences requiring investigation.

Enforcement

Pharmaceutical companies have limitations in regard to pursuing confirmed counterfeiters. Arrests and prosecution must occur by the appropriate legal or regulatory agency. Therefore, pharmaceutical companies have two types of action that could help mitigate financial losses resulting from counterfeit prescription drugs. The two types are civil and administrative enforcement.

Civil and Administrative Enforcement. Participant 3 said:

> A pharmaceutical company can take civil action against a bad actor, which could be very powerful. A great example is a recently unsealed federal case where Gilead was able to shut down a criminal network that produced approximately $250 million in counterfeit HIV product through civil enforcement.

Participant 2 said:

> We use our legal division to potentially go after people that are engaged in the sale, manufacture, and distribution of counterfeit drugs from a civil legal manner. That may be cease and desist order, litigation, whatever we can do in a jurisdiction area that has rule of law as it relates to that.

The second form of enforcement mentioned by participant 3 was administrative enforcement. Participant 3 said:

> Administrative enforcement includes using detailed contracts and standard operating procedures for an external partner to abide by or face sole liability if a theft occurs. Termination of the contract with the supplier

could also occur if the supplier fails to comply with the contractual requirements to ensure security of the medication.

Measuring Success. A measure of success for investigations and enforcement noted by Participant 3 was the success rate of prosecuting criminals. Similarly, all participants agreed that having experience in building an effective case against criminals was important in gaining the attention of prosecuting agencies and obtaining convictions.

Potential Barriers. Pharmaceutical companies face limited legal enforcement capabilities toward criminals. Moreover, complexity of the supply chain and international spread of criminal networks makes identifying the origin and scope of counterfeits difficult. Similar to most businesses, some participants noted budgetary limitations to perform more proactive investigations. Investigating and building cases against criminals always pursuing new methods to introduce counterfeits into the supply chain is also a constant challenge.

Findings Related to the Conceptual Framework

The findings from participant interviews align with the constructs of the Six Sigma DMAIC model by demonstrating that measuring and analyzing data is critical to continuous process improvement initiatives of the pharmaceutical supply chain. The measurement step of the DMAIC cycle is where an organization collects data on the process, establishes a baseline to compare, and determines how the process is currently running (Mendes & Soares, 2021). Similarly, Moon (2020) explained that during the measurement step organizations choose tools to quantify the occurrence and severity of

trends in data. To compare to the study findings, investigations start with collection of customer complaints and adverse event reporting that lead to further analysis of the root cause of an incident. Following the data collection step is the analysis phase.

The analyze phase involves examining data to determine if actions can improve the process. Moon (2020) stated that the analysis stage involves detection of trigger conditions in the data. Participant 3 mentioned that Company C sets trip wire type indicators to alert security and safety personnel of potential product issues that require further investigation. Likewise, if the data trigger proves to be a valid deviation, then an investigation should take place to implement improvements that bring the process back under control (Moon, 2020). Knowing what to measure and how to measure data is important in the two phases of the DMAIC framework. Otherwise, measuring performance against faulty data could be problematic.

Another important connection is the link between the study findings and the supporting quality risk management framework. In a case study conducted in 2020 over 13 weeks in a pharmaceutical plant, Ismael and Ahmed (2020) revealed that using the four stages of risk assessment, control, communication, and review process steps enable pharmaceutical companies to find issues in the manufacturing process and associate a risk level to each based on severity and occurrence to prioritize improvements. Table 6 demonstrates the level of severity, occurrence, and likelihood of detection used in the study.

Table 6

Scale of Severity, Occurrence, and Detection

No.	Severity of Failure	No.	Occurrence of Cause	No.	Detectability of Cause	
10	Injure to the customer or employee	10	At least once a day	10	No detection of cause or failure	Bad
9	Illegal	9	More than once a week	9	Occasional test or inspection	
8	Complete loss of performance and	8	Once per week	8	Systematic sampling and inspection of units	
7	Extreme customer dissatisfaction	7	Once per month	7	Manual inspection of all units	
6	Partial loss of performance and	6	Once every 3 months	6	Manual inspection with mistake proofing	
5	Customer complaint	5	Once every 6 months	5	Statistical monitoring of process	
4	Minor loss of performance and	4	Once per year	4	Statistical monitoring for out-of-control conditions	
3	Minor nuisance	3	Once every 1-3 years	3	Above and 100% inspection surrounding out of control	
2	Noticeable with no effect on performance	2	Once every 3-6 years	2	All units are automatically inspected	
1	Unnoticeable: no effect on performance	1	Once every 6-100 years	1	The defect is obvious and can be kept from customer	Good

Note. Adapted from "Using Quality Risk Management in Pharmaceutical Industries: A Case Study" by Omar A. Ismael and Moyassar I. Ahmed, 2020, Quality - Access to Success, 21(178), 106–113. p. 108. (https://www.calitatea.ro/arhiva_revista.html#2020). Adapted with permission.

Figure 3 shows the risk matrix resulting from the data in the study.

Figure 3

Risk Matrix

	Occurrences									
Severity	10	20	30	40	50	6	7	80	90	100
	9	18	27	36	45	54	63	72	81	90
	8	16	24	32	40	48	56	64	72	80
	7	14	21	28	35	42	49	56	63	70
	6	12	18	24	30	36	42	48	54	60
	5	10	15	20	25	30	35	40	45	50
	4	8	12	16	20	24	28	32	36	40
	3	6	9	12	15	18	21	24	27	30
	2	4	6	8	10	12	14	16	18	20
	1	2	3	4	5	6	7	8	9	10

Note. Adapted from "Using Quality Risk Management in Pharmaceutical Industries: A Case Study" by Omar A. Ismael and Moyassar I. Ahmed, 2020, Quality - Access to Success, 21(178), 106–113. p. 108. (https://www.calitatea.ro/arhiva_revista.html#2020). Adapted with permission.

All participants mentioned a similar process of assessing risk for each product to decide what level of protection to apply to each product package based on similar factors such as likelihood of occurrence and risk to patient safety.

The findings also align with the fraud triangle conceptual framework by looking at data that pharmaceutical investigations uncover to understand what motivates criminals. Pitts (2020) described how criminals not only focus on lifestyle drugs but also lifesaving drugs because of significant financial benefit. Unfortunately, opportunities to commit the crime also exist. The Internet and social media channels provide new opportunity for criminals, especially since the start of the Covid pandemic (Moureaud et al., 2021). However, as a result, information learned from investigations allows brand protection managers to implement new sophisticated technology to mitigate financial

losses resulting from counterfeit drugs and to protect patients. Pisani (2017) highlighted that penalties for counterfeiting prescription medications are much less than penalties for selling illicit drugs and patients are unaware of the risks. Measuring and analyzing complaint data used in investigations could lead to more effective laws and regulation for the future.

Findings Related to the Literature Review

Additionally, the findings from participant interviews align with the literature on the topic. Investigating all complaints logged by consumers, as mentioned by each participant, helps pharmaceutical companies act more quickly to remove potentially harmful medications from the supply chain. Wu and Lin (2019) stated that pharmaceutical manufacturers could proactively remove product with safety issues as a result of information analysis and investigations. Specifically, the process of calculating risk to patients relates closely with quality risk management processes. Furthermore, Peltier-Rivest and Pacini (2019) confirmed that low penalties in place today do not deter counterfeits. However, notable cases against counterfeiters such as ongoing efforts of Operation Pangea demonstrate that collaborative efforts led by Interpol are effective in removing millions of harmful medications from the market (Peltier-Rivest & Pacini, 2019). Therefore, pharmaceutical companies play a vital role in investigating and building cases against criminals contributes significantly to larger enforcement efforts.

Figure 4 includes a word cloud that represents some of the most commonly used terms by participants related to theme 3.

Figure 4

Most Frequent Words from Interviews Related to Theme 3

The size of each word characterizes the frequency of words in the combined interviews. The key words were enforcement, people, information, and product.

Theme 4: Advocacy and Awareness

The fourth and final theme coded from interview data that contributes to answering the research question are efforts toward advocacy and awareness. All participants acknowledged the need to campaign for stronger penalties to deter criminals from counterfeiting and bring awareness of risks involved with obtaining medications outside the legitimate supply chain. Purchasing medications from illegitimate sources on the Internet, social media sites, and from other countries is a growing problem that consumers need to understand the risks. Moureaud et al. (2021) conducted a cross-sectional study of Amazon Mechanical Turk (MTurk) workers, which included 269 participants located in the U.S. between August and September 2020 and found that the

higher the participant's education the less likely that person would be to order medications online. To demonstrate further, Zhao et al. (2020) estimated that worldwide online pharmacies would grow from $29.35 billion in 2014 to approximately $128 billion in 2023. Moureaud et al. also observed that participants believed Amazon and Google+ were legitimate sources to purchase medications. Therefore, educating people without alarming consumers of safe sources to purchase medications and what to look for in legitimate product was an important theme mentioned by all participants in the study.

Advocacy

Despite all the time and money that the pharmaceutical industry invests in securing the supply chain and in investigations, legislators need to implement stiffer penalties to deter counterfeiting. All participants of the study agreed on the importance of being actively involved in trade organizations like the Pharmaceutical Security Institute, Partnership for Safe Medicines, Alliance for Safe Online Pharmacies, and the Healthcare Distribution Alliance, among others, to drive increased penalties for criminals. Unfortunately, limited and weak legislative policies exist (Pitts, 2020). The length of investigations puts the public at risk. Pitts (2020) proclaimed that the FDA is the most suitable federal agency to spearhead the fight against counterfeiting and incorporate other federal and state agencies to create and enforce new policies. Regulations initiated by the FDA that support transparency of the supply chain and tracking and tracing of medications are key initiatives already in progress.

Trade industry groups can also help influence legislation. Zhao et al. (2020) stated that continued effort to combat online pharmacies that distribute counterfeits is essential to protecting patients and the reputation of the legitimate supply chain. The best way is to work with trade organizations to advocate for better legislation in all areas. All participants stated that trade organizations provide an excellent resource group of experienced professionals that share information about criminal activities to help inspire legislation that is effective and meaningful to deter criminals. Similarly, trade organizations enable coordination of investigation efforts into large crime organizations that impact multiple pharmaceutical companies.

Awareness

All participants emphasized the importance of education. The specific groups include training internal employees, consumers, law enforcement, legislators, suppliers, distributors, wholesalers, executives, and customs personnel. Each could play a vital role in mitigating opportunities of counterfeit drugs from entering the supply chain by following standard operating procedures, reporting incidences, knowing what to look for in a counterfeit drug, and staying within the legitimate supply chain to obtain medications. Knowing when, where, and how to report potential issues is critical to protecting lives and mitigating any financial risk. Participant 1 gave examples of guidance for freight forwarders and truckers, education campaigns for internal employees and consumers, and training sessions with law enforcement and customs agents. Participant 2 referred to collaborating with various government affairs people in the US

and around the world to bring attention to the issue. Advocating for either more law enforcement resources to be available or different strategies to help secure the supply chain. Participant 3 added working with global public policy colleagues and communications group to draft public statements so that government agencies, legislative bodies, patients, and physicians could take steps within their sphere of influence to protect patients and themselves.

Findings Related to the Conceptual Framework

The findings from participant interviews align with the constructs related to the first Six Sigma DMAIC conceptual framework by demonstrating the importance of training and education once improvement steps are in place, which are part of the DMAIC improve step. Similarly, by working with industry partners and trade organizations, pharmaceutical companies could help improve stronger penalties for criminals to deter criminals from counterfeiting. Olliaro et al. (2020) underscored the need for effective legal frameworks to combat counterfeit drugs to protect public health. Likewise, Nedra et al. (2019) indicated that education and training are crucial components of the DMAIC improve step to ensure that people impacted by the change are aware of any new processes. In addition, the findings relate to the control step of the DMAIC framework in that information shared on improvement strategies support new improvements from reverting back to prior poor practices (Nedra et al., 2019). The goal is to learn from past mistakes by implementing either new strategies or technologies that

improve procedures going forward to mitigate counterfeits and financial losses from happening in the future.

The findings from participant interviews also align with the constructs related to the fraud triangle framework by explaining how advocating for better penalties and training help eliminate gaps in the supply chain that criminal's access. Azam (2018) explained that criminals always develop creative ways to commit fraud even when existing opportunities are intentional or unintentional. Therefore, as brand protection managers learn how criminals circumvent the supply chain to insert counterfeit drugs, implementing either new security measures or practices is a standard response. In addition, pharmaceutical companies have limitations with prosecuting criminals for counterfeiting. For example, limited regulations exist for growing illegitimate online pharmacy markets (Miller et al., 2021). In advocating for increased penalties and passage of new regulations that address new criminal methods would help mitigate some existing gaps in the supply chain that provide opportunities to criminals.

Findings Related to the Literature Review

The findings from participant interviews align with peer-reviewed articles by reporting on the importance of following standard operating procedures and education. Derrong Lin and Hertig (2021) stated that successful pharmaceutical leadership strategies during the Covid-19 crisis were to advocate for patient safety, correct medication usage, effective communication, and implementing drug shortage and protection procedures. Counterfeiters took advantage of drug shortages and helped spread misinformation on the

efficacy of certain drugs to treat Covid-19, which led to increased concerns of patient safety. As a result, Internet searches for purchasing hydroxychloroquine and chloroquine between February 1, 2020, and March 29, 2020, topped 216,000 despite news reports of deaths from taking the medication (Derrong Lin & Hertig, 2021). Similarly, Moureaud et al. (2021) discovered that top motivators for purchasing medications online were to obtain drugs at a cheaper cost, recommendation from friends, and the ability to purchase medications without a prescription. Therefore, educating people on safe practices to follow and informing consumers on real risks that exist is crucial in protecting patients and mitigating and financial losses resulting from misuse or counterfeit medications.

Figure 5 includes a word cloud that represents some of the most commonly used terms by participants related to theme 4.

Figure 5

Most Frequent Words from Interviews Related to Theme 4

The size and color of each word characterizes the frequency of the word in the combined interviews. The key words were awareness, company, patients, public, people, counterfeit, and pharmaceutical.

Applications to Professional Practice

In this study, I explored strategies that experienced pharmaceutical brand protection managers use to mitigate financial losses resulting from counterfeit prescription drugs. The eligibility criteria for selecting participants for the multiple case study included three executive brand protection managers in the US who had successfully implemented anticounterfeiting strategies to protect medications. The four themes that emerged from data collection were (a) guiding principles (b) securing the supply chain, (c) investigations and enforcement, and (d) advocacy and awareness. During all interviews, participants discussed many effective strategies to protect medications, patients, and the company brand, which mitigate financial losses from counterfeit drugs.

The results of the investigation could help less experienced brand protection managers who are unaware of different strategies and technologies available for protecting medications that could mitigate financial losses. Strategies mentioned in the study could benefit either small or new pharmaceutical companies with limited resources dedicated to protecting medications. The findings could also help bring awareness to other leaders in the company of risks associated to medications in the supply chain and extensive collaboration required to form an effective brand protection program. The information provided in the study gives guidance to less experienced professionals of

industry groups that exist to help share information on successful protection program strategies. Industry leaders might also use findings of the study to educate others on components of a well-defined brand protection program. Investing in a sound brand protection program helps protect the company reputation and maintains consumer trust that could be a competitive advantage.

A significant success factor related to strategies mentioned relate to collaboration. The results of the study could help bring attention to brand protection managers to build relationships within the organization that might otherwise work in silos. The findings show that managers who develop relationships with external organizations to share information could gain significant guidance in learning successful strategies that other pharmaceutical companies use to mitigate financial losses and protect patients. Law enforcement, distributors, and regulatory agencies stand to gain significant knowledge on successful measures to help mitigate gaps in the supply chain that enable criminals.

Implications for Social Change

The results of the study could positively impact social change by enabling a more secure pharmaceutical supply chain, which builds consumer trust, and boosts the economy. Federal and state governments could benefit financially from having a healthier society with reduced medical costs. A more secure supply chain might help reduce the number of adverse events that could cause severe harm to consumers, resulting in lower costs for patients. Medications that patients receive might be more effective by further mitigating gaps in the supply chain. As a result of the study, patients might also be more

aware of the importance of purchasing medications within the legitimate supply chain no matter how inexpensive and discrete online methods might appear. Consumers might also be more willing to report any anomalies in either the packaging or medication based on information uncovered in the investigation.

Recommendations for Action

The findings of the study revealed effective strategies used by pharmaceutical brand protection managers to mitigate financial losses resulting from counterfeit prescription drugs from entering the supply chain. Current and future pharmaceutical brand protection managers may consider recommendations in the study to improve mitigation strategies within their own organizations. I recommend four strategies to mitigate financial losses resulting from counterfeit prescription drugs.

The first recommendation is to join industry groups that specialize in helping to secure the pharmaceutical supply chain. Becoming an active member will enable sharing of successful mitigation strategies among all pharmaceutical companies. The industry groups can assist with influencing better legislation to penalize criminals and bring awareness of risks involved with online procurement of medications. Protecting patients is immensely important as is protecting significant investments in building a good company reputation and developing lifesaving medications. A second recommendation is to gain visibility to all adverse event and customer complaint information to obtain early indication of any issues with the product. Complaint data could reveal additional improvement strategies needed to further protect medications in the supply chain.

Configuring key performance indicators and metrics could enable early investigations that could mitigate a large incident from occurring. A third recommendation would be to form a team of experienced individuals that know how criminals behave, the medication, distribution, and legal capabilities available to pharmaceutical manufacturers. Having experienced professionals within the organization allows the company to be proactive in implementing the best security measures and policies specific to the types of medications each produces. Legal experience also aids in understanding how to build effective cases against counterfeiters to guarantee convictions. The final recommendation is to bring awareness to the community of dangers with purchasing medications outside the legitimate supply chain without scaring consumers. Explaining challenges of safeguarding drugs imported from other countries and how to find legitimate online pharmacies might make consumers think before making a purchase from an unsavory source.

Recommendations for Further Research

The goal of the investigation was to learn successful strategies that pharmaceutical brand protection managers in the US use to mitigate financial losses resulting from counterfeit drugs. I was able to interview three experienced professionals from the top 15 pharmaceutical companies. Because of limited time allotted for the study, a recommendation for future research would be to interview brand protection managers in different countries to compare and contrast the successful strategies used in a different part of the world. The Drug Supply Chain Security Act milestone is to deliver a fully

interoperable track and trace program in 2023. Perhaps conducting a similar study after the track and trace system is in place to identify any further strategies that emerge as a result of additional transparency into gaps in the supply chain might provide further guidance. Researchers highly recommended using blockchain technology as a solution for interoperability in the pharmaceutical supply chain. Further investigations into what technologies the pharmaceutical industry uses for interoperability and protecting products could prove insightful.

Reflections

My decision to investigate strategies to mitigate financial losses resulting from counterfeit prescription drugs emerged from my personal interest in technology and my professional experience working in information technology within the pharmaceutical industry. I have a passion for observing how technology could benefit business processes, especially processes that have a transformative impact. A desire to learn more about blockchain technology led to the selection of the topic that had significant impact to protecting patients. The study evolved into investigating successful anticounterfeiting strategies to help mitigate financial losses resulting from counterfeit drugs.

The journey to learn more about blockchain seemed to tie well into investigating a topic as part of a doctoral degree in business administration. Throughout the courses, residencies, intensives, and research process, I learned so much and met so many wonderful people willing to share their knowledge. The participants were so enthusiastic about the work they do and take immense pride in keeping the pharmaceutical supply

chain safe while protecting the company reputation. Understanding and moderating my personal bias was critical for the study as I work in the pharmaceutical industry. However, I followed Walden University's guidelines to prevent inclusion of any personal, researcher, and participant biases from entering the study by selecting a topic that was unfamiliar and included participants that I had no prior association. As a result of this journey, I plan pursue a position related to protecting medications by using innovative technology.

Conclusion

The purpose of the qualitative multiple case study was to explore strategies that experienced pharmaceutical brand protection managers use to mitigate financial losses resulting from counterfeit prescription drugs. A sizable portion of a company's financial performance relies on the supply chain (Tripathi et al., 2019). Particularly, the distribution of life saving medication to patients. Any introduction of counterfeits could negatively impact lives, company reputation, and fail to help patients as intended. Therefore, implementing mitigating strategies to protect medications in the supply chain would increase safety of the supply chain and protect the company from any financial losses.

The chosen composite conceptual framework for the study was the Six Sigma DMAIC model and the fraud triangle. I used the Six Sigma DMAIC practice to relate the continuous process improvement steps of define, measure, analyze, improve, and control to the processes that brand protection managers use to persistently review data to improve

security measures for medications. The reason for selecting the fraud triangle as the second conceptual framework was to demonstrate that gaps in the supply chain give criminals the opportunity to insert counterfeit medications. The significant financial benefit of selling counterfeit drugs with limited penalties entices criminals with perceived financial problems, making the rationalization of committing the crime easier for criminals. I explored strategies that experienced brand protection managers use to mitigate opportunities that criminals use to insert counterfeit drugs into the supply chain. Because criminals are always looking for new methods and becoming more sophisticated, brand protection managers must continuously analyze data to improve upon safety measures that protect medications.

Four themes emerged from participant interviews. The themes were (a) guiding principles, (b) securing the supply chain, (c) investigations and enforcement, and (d) advocacy and awareness. The identified themes align with the composite conceptual frameworks and the academic literature on the topic. The strategies highlighted in the study could demonstrate successful components necessary for pharmaceutical brand protection managers when building an effective brand protection program. The study results could positively influence social change by helping to improve the supply chain, which improves public health, benefits the economy, and reduces healthcare costs. Through innovative technology, increased transparency, penalties, and awareness could bring additional mitigating strategies that prevent opportunities for criminals.

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Appendix A: CITIProgam Certificate

CITI PROGRAM

Completion Date 03-Oct-2020
Expiration Date N/A
Record ID 38801192

This is to certify that:

Denise Blais

Has completed the following CITI Program course:

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

Student's (Curriculum Group)
Doctoral Student Researchers (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Walden University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w6fc94653-6eb9-4508-8258-832c9cb12d6c-38801192

Appendix B: Interview Protocol

1. The goal of the interview is to obtain information that answers the research question pertaining to strategies brand protection managers use to prevent and mitigate financial losses resulting from counterfeit prescription drugs.
2. I will complete the following steps for each interview:
3. Ensure that the participant meets the requirements for the study by having personal experience with developing successful anticounterfeiting strategies.
4. Confirm that a signed consent form exists and that using Zoom as an online video conferencing application is acceptable for recording the meeting. I will provide instructions on how to install the application, if necessary.
5. Set up a convenient time, date, and location for each participant interview that is safe and free of interruption or any external influence.
6. Create a folder for each participant with a list of the interview questions and potential probing questions.
7. At the start of the interview, thank each participant for agreeing to participant in the research study.
8. Remind the participant that involvement in the study is voluntary, and that they can withdraw from the study at any time without prior notice.
9. Remind the participant that I will use a sequentially coded number such as A1, B1, and C1 to identify the participant to prevent the use of actual names. I will explain that I will be the only person aware of each participant's name and

pseudonym. The storage of data collected will reflect the participant's pseudonym name to maintain confidentiality.

10. Begin the interview with a brief overview of the purpose of the research and kindly reconfirm that the participant is agreeable to recording the interview.
11. Explain that the participant has the right to end the interview at any time or refuse to answer a question if the participant has any concerns.
12. Inform the participant that the interviewer might ask probing questions to gain a deeper understanding of the response or clarify points made in the interview.
13. Ask the participant if there are any questions before proceeding.
14. Conduct the interview.
15. Thank each participant for taking the time to participate in the study.
16. Explain to the participants that once the transcribed interview data is complete, the researcher will send the transcription and summary to each participant for review.
17. Explain that I will follow-up with a meeting invitation to discuss any issues with the transcription and summarization.

Appendix C: Invitation Letter

Researcher seeks experienced participants implementing strategies to prevent and mitigate counterfeit medications

There is a new study called *"Strategies for Preventing and Mitigating Counterfeit Medication From Entering the U.S. Supply Chain"* that could help other pharmaceutical brand protection managers to mitigate financial losses resulting from counterfeit drugs. For this study, you are invited to describe your experiences implementing effective strategies to prevent counterfeit medications from entering the U.S. supply chain.

This invitation is part of the research process by Denise Blais, a doctoral student at Walden University.

About the study:

- One 60 minute confidential, audio recorded interview using the Zoom platform.
- Participate in a 30-60-minute follow-up meeting to verify interview information.

Volunteers must meet these requirements:

- Managers responsible for developing and maintaining brand protection strategies in a pharmaceutical manufacturing organization
- Organization located in the United States.
- Current or previous experience with negative impacts of counterfeit brand name products.

To volunteer for the study please contact the researcher at

Denise.Blais@waldenu.edu

Appendix D: Reminder Letter

Researcher seeks experienced participants implementing strategies to prevent and mitigate counterfeit medications

This is a friendly reminder that I am seeking experienced participants with knowledge in implementing strategies to prevent and mitigate counterfeit medications from entering the U.S. supply chain. The knowledge you share could help other pharmaceutical brand protection managers to mitigate financial losses resulting from counterfeit drugs.

This invitation is part of the research process by Denise Blais, a doctoral student at Walden University.

About the study:

- One 60 minute confidential, audio recorded interview using the Zoom platform.
- Participate in a 30-60-minute follow-up meeting to verify interview information.

Volunteers must meet these requirements:

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- Organization located in the United States.
- Current or previous experience with the negative impacts of counterfeit brand name products.

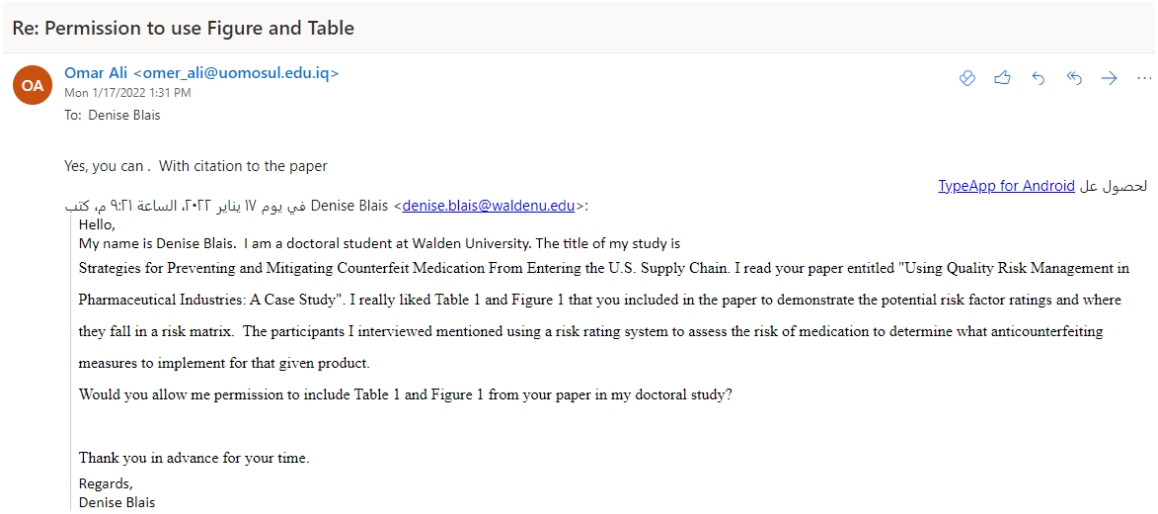
To volunteer for the study please contact the researcher at

Denise.Blais@waldenu.edu

Appendix E: Interview Questions

1. What strategies do you use to define the brand protection program at your company?
2. How do you measure success or failure of the program?
3. What were the key barriers to implementing your organization's brand protection strategies?
4. How do you address the key barriers to implementing your organization's brand protection strategy?
5. What strategies do you use to improve the brand protection program implemented at your company?
6. What anticounterfeiting strategies do brand protection managers perceive to be most efficient and cost effective?
7. What anticounterfeiting strategies do brand protection managers perceive to be least effective and cost prohibitive?
8. What other strategies beyond brand protection do you use to mitigate the opportunity for counterfeit drugs from entering the supply chain?
9. What additional information would you like to share about strategies you use to mitigate financial losses resulting from counterfeit prescription drugs?

Appendix F: Permission from Author for Table and Figure



Re: Permission to use Figure and Table

OA

Omar Ali <omer_ali@uomosul.edu.iq>
Mon 1/17/2022 1:31 PM
To: Denise Blais

Yes, you can . With citation to the paper

لحصول على TypeApp for Android

في يوم ١٧ يناير ٢٠٢٢، الساعة ٩:٢١ م، كتب Denise Blais <denise.blais@waldenu.edu>:

Hello,
My name is Denise Blais. I am a doctoral student at Walden University. The title of my study is
Strategies for Preventing and Mitigating Counterfeit Medication From Entering the U.S. Supply Chain. I read your paper entitled "Using Quality Risk Management in Pharmaceutical Industries: A Case Study". I really liked Table 1 and Figure 1 that you included in the paper to demonstrate the potential risk factor ratings and where they fall in a risk matrix. The participants I interviewed mentioned using a risk rating system to assess the risk of medication to determine what anticounterfeiting measures to implement for that given product.
Would you allow me permission to include Table 1 and Figure 1 from your paper in my doctoral study?

Thank you in advance for your time.
Regards,
Denise Blais