ALBIZU UNIVERSITY

MIAMI, FLORIDA

UNDERSTANDING TRENDS IN PHARMACEUTICAL COUNTERFEITING IN THE STATE OF FLORIDA: A QUANTITATIVE DESCRIPTIVE STUDY USING SECONDARY DATA

A DISSERTATION SUBMITTED IN PARTIAL SATISFACTION OF THE REQUIREMENTS FOR THE DEGREE OF

DOCTOR OF PHILOSOPHY IN HUMAN SERVICES

GORKA I. MENESES

MARIA PEREZ–ABALO

DISSERTATION CHAIR

2024

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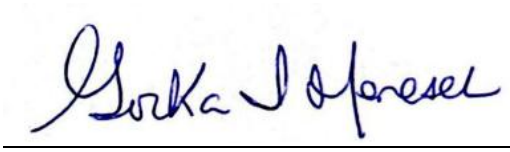

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DOCTOR OF PHILOSOPHY IN HUMAN SERVICES

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DATE

Dissertation Committee:

Maria Perez-Abalo MD, Ph.D., Dissertation Chair

Sharrie R. Dean, Ph.D., Project Member

Rafael Martinez, Ed.D., Project Member

DEDICATION

This dissertation is dedicated to my wonderful wife Aurely “Lely” Meneses, whose unwavering support and boundless love have been my anchor throughout this journey. Your patience, encouragement, and endless sacrifices have been invaluable. You have been my rock, my confidant, and my greatest cheerleader. This achievement is as much yours as it is mine, and I am profoundly grateful for every moment of support and understanding you have given me. Pura Vida!

This dissertation is also dedicated to our beloved son Inaki Imanol Meneses, whose innocent eyes inspire me every day. You are the light of my life and the beating heart of every step I’ve taken along this journey. Your unwavering love, boundless courage, and extraordinary spirit have shown me what true strength means. Every challenge I’ve faced in this work pales in comparison to the daily miracles I witness in you. You are not only my inspiration, but also my greatest teacher. Know that you are never alone. I will always be by your side, through every high and every low, now and forever. This dissertation is for you, my precious Iñaki—my heart, my teacher, and my inspiration. With all my love, forever and always.

To my dear mother, whose endless love, wisdom, and strength have been my guiding light. Your unwavering support and encouragement have been my foundation. From my earliest memories to this moment, you have always believed in me and pushed me to be my best. Your sacrifices and tireless dedication to our family have shaped who I am, and I am deeply grateful for everything you have done. This work is a testament to your love and the values you have instilled in me.

A special mention to my late father, who passed away four years ago. Your memory continues to inspire me, and I know you are watching over me with pride.

I give thanks to God, for His blessings and guidance that have led me to this achievement.

Lastly, to my pugs Leo, Gigi, Marley, Posty, and Baby Laz, for their companionship and unconditional love. Your presence has been a constant source of comfort and joy.

ACKNOWLEDGEMENTS

I would like to express my heartfelt gratitude to my dissertation chair, Dr. Maria Perez-Abalo, for your unwavering support and guidance throughout my research journey. Your encouragement during the most challenging moments, especially when I had to change my dissertation topic, was truly a beacon of hope. You believed in my potential even when I doubted myself, and your expertise provided me with the clarity I needed to move forward. Your insights were instrumental in helping me navigate the complexities of restrictive data analysis, transforming what felt like insurmountable obstacles into manageable challenges. I am deeply thankful for your patience, understanding, and genuine investment in my success. Your mentorship has not only shaped my work but has also profoundly impacted my growth as a researcher and as a person. Thank you for being such an inspiring leader and for making this journey a memorable one.

Additionally, I want to acknowledge my project member and PhD Program Director Dr. Rafael Martinez, for your leadership and guidance. Your support has been instrumental in helping me reach this milestone.

I would like to extend a special thank you to my favorite doctoral professor and Albizu University Interim Chancellor Dr. Sharrie R. Dean. Your passion for teaching and dedication to your students have profoundly impacted my academic journey. You have not only challenged me to think critically and creatively but have also inspired me to pursue my passions with confidence.

Your unwavering support and encouragement during my research have been a source of motivation, especially during the toughest moments. I am truly grateful for the knowledge and wisdom you have shared, which have shaped my growth as a scholar.

Thank you for believing in me and for being such a remarkable mentor. I will carry out the lessons I've learned from you throughout my life.

Finally, I would like to thank Mr. Ryan Kotowski for your exceptional assistance with the statistical analysis. Your ability to explain the data in a way that I could comprehend was crucial in helping me advance and complete this study.

Thank you all for your dedication and commitment to my success. I truly appreciate your contributions.

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1996 - 2018	--M.A., Criminal Justice Interamerican University San Juan, Puerto Rico
2019 - Present	--Pursuing Ph.D., Human Services Albizu University Miami, Florida
2003 - Present	--U.S. Department of Homeland Security U.S. Customs & Border Protection Consumer Products & Mass Merchandising Center of Excellence & Expertise Supervisory Import Specialist/Forced Labor Coordinator Miami, Florida
1999 - 2006	--Universidad Ana G. Mendez Recinto de Carolina Programa AHORA Facilitador/Profesor Adjunto Carolina, Puerto Rico
2012 - 2020	--Ana G. Mendez University South Florida Facilitator/Adjunct Instructor Miami Gardens, Florida
2013 - 2016	--Keiser University Pembroke Pines Campus Adjunct Instructor/Criminal Justice Pembroke Pines, Florida

ABSTRACT OF THE DISSERTATION

Understanding Trends in Pharmaceutical Counterfeiting in the State of Florida:

A Quantitative Descriptive Study Using Secondary Data

by

Gorka I. Meneses

Albizu University

2024

Maria Perez-Abalo, MD, Ph.D., Dissertation Chair

Pharmaceutical counterfeiting is an urgent and global issue that causes not only a loss of revenue of approximately $75 billion annually but is also associated with harmful outcomes for consumers of such products (Peltier-Rivest & Pacini, 2019). In response to this issue, researchers have explored detection models (Peltier-Rivest & Pacini, 2019) and have proposed solutions to prevent pharmaceutical counterfeiting (Haq & Esuka, 2018). However, there remains a lack of understanding of trends in pharmaceutical counterfeiting in terms of schemes and offenders. Such understanding is needed to develop crime prevention strategies and interventions based on the distinct offender and scheme characteristics. The purpose of this proposed quantitative descriptive study is to examine the trends in counterfeiting schemes and offender conviction and incarceration in pharmaceutical counterfeiting schemes in the State of Florida. The findings yielded in this study can be used to inform interventions and policies in countering pharmaceutical counterfeiting and have practical significance for human services in identifying potential inequities in conviction and incarceration trends. To address this research problem, the following study will demonstrate a strong need to promote policies, strategies, and

awareness in the human service, criminal justice, and for law enforcement (state and federal level) and U.S. Government partners to continue creating a resilient anti-counterfeiting strategy combating and deterring the illicit trade in their jurisdictions. In like manner, the pharmaceutical industry and private sector stakeholders to collaborate and prevent pharmaceutical counterfeiting in the U.S. To test the following hypotheses, access to the ICPSR 37177 dataset is requested after Institutional Review Board IRB approval is documented. Taking these data together, it is strongly suggested to take greater efforts in combatting substandard and counterfeited medical products to help secure supply chains to stem the tide of counterfeit and pirated goods.

CHAPTER I

Introduction

Pharmaceutical counterfeiting is a serious and rapidly growing problem causing a global healthcare crisis in both developed and developing countries (Yiu, 2021). Recent statistics suggest that the impact of illicit pharmaceutical products will cost the United States 30 billion dollars, and that this industry is expected to grow 5% through 2028 (Syed & Milburn, 2024). The toxicity of counterfeit medicines has increased over the years, as materials such as cement, industrial solvents, gypsum among others had been discovered in many of these illicit products producing negative effects on the patients receiving them (Lade et al., 2020). The reason for the rapid growth of counterfeit pharmaceuticals is that they can be manufactured or altered relatively low-cost thus generating a profitable product (Yiu, 2021). Another important problem is that counterfeit pharmaceuticals have become increasingly hard to identify, as the counterfeiters use techniques such as label copying, instruction and usage information substitution, and product packaging use (Lade et al., 2020). Accordingly, counterfeiting is a growing global enterprise that is generating high profits and becoming increasingly more difficult to detect.

The U.S. International Trade Commission (1984, p.vii) defines counterfeiting as "the unauthorized use of a registered trademark on a product that is identical or similar to the product for which the trademark is registered and used." The anti-counterfeiting code drafted by the General Agreement on Tariff and Trade (GATT) goes further in ascribing to the forger the intent to "wrongfully benefit through deceit from the efforts of a firm to establish and maintain a product or corporate image with the consumer or the public at

large". Counterfeiting, like patent and copyright infringement, represents a violation of a firm's property rights, in this case the rights to its trademark and associated goodwill. It is distinguished from these related practices, however, in that it alone involves an attempt to defraud consumers via misrepresentation and, in the case of medical drugs, can cause serious consequences for health and could be even life threatening.

The World Health Organization (WHO) defined a counterfeit medicine as: “a medicine which is deliberately and fraudulently mislabeled with respect to identity and/or source." (WHO, 2017) Under this definition, it is the deliberate mislabeling of a drug or medicine which makes it a counterfeit. A counterfeit medication or a counterfeit drug is a medication or pharmaceutical item which is produced and sold with the intent to deceptively represent its origin, authenticity, or effectiveness. A counterfeit medical drug may contain inappropriate quantities of active ingredients, contain no active ingredient at all, may be improperly processed within the body, may contain ingredients that are not on the label, or may be supplied with inaccurate or fake packaging and labeling.

Over the years, the number of counterfeit medications that have made their way into trusted pharmacies and subsequently to patients’ medicine cabinets has been on the rise. As estimated by Garankina et al., (2018), thousands of people worldwide have been affected and the problem continues to grow. This issue of counterfeit medications is a concern not only for the patient but also for pharmacists and pharmaceutical companies. Prekupec et al., (2017) indicated that the magnitude of the drug-counterfeiting problem is difficult to gauge since the crimes of producing and selling counterfeit drugs generally become known only when the perpetrators are caught thus making any accurate determination of prevalence difficult. Affirming the existence of this problem, the World

Health Organization (WHO) has estimated that 10% of global pharmaceutical commerce, or $21 billion worth, involves counterfeit drugs (Uddin, 2021).

Drug counterfeiting, although not a new problem, has become more widespread in recent years worldwide. A study by Uddin (2021) revealed that nearly one-half (48.7%) of the documented cases of drug counterfeiting was reported in developing countries of the Western Pacific inclusive of China, the Philippines, and Vietnam. This was followed by developing countries grouped within WHO's Regional Office for Africa, with a reported 18.7% of drug counterfeiting cases. The industrialized areas of WHO's Regional Office for Europe came in third, with 13.6% of reported cases (Uddin, 2021).

The Problem of Counterfeiting Drugs and Medications in the United States

In the United States, medical counterfeiting is on the rise and more difficult to control. Estimates from 2017 show that approximately 1% of counterfeit medications were sold to consumers. These figures have been increasing over the years (Sullivan, 2019). Although most counterfeit medications are purchased online in the United States, others have infiltrated legitimate supply chains (Kennedy et al., 2018).

Moreover, law enforcement efforts in combating counterfeit pharmaceuticals are still insufficient. Recent reports show that in 2020 at least 249,700 counterfeit Xanax pills were sold in Florida, with the majority (i.e., 187,321) sold in Miami. Despite the numerous enforcement actions adopted from 2016 to 2020 against counterfeit medication rings (Fernandes et al., 2021), high-demand, expensive medications such as various chemotherapeutic drugs, antibiotics, vaccines, erectile dysfunction drugs, weight loss aids, hormones, analgesics, steroids, antihistamines, antivirals, and antianxiety drugs are common counterfeiting targets (Sullivan, 2019).

Among those deceived into buying counterfeit drugs are consumers who use medicines inappropriately or who seek to purchase medications at discounted prices. The problem is further aggravated by the fact that, apart from being very cheap to make, counterfeit medicines often closely resemble actual medications with nearly identical labels and tablets thus duping unsuspecting pharmacists and patients. Fernandes et al., (2021) reported that drug counterfeiters use cheap and sometimes harmful materials such as brick dust, sheetrock, and flour to create their bogus tablets. Bolla et al., (2020) identified fourteen counterfeited pharmaceutical that were present in 36 different countries, including the U.S. Eleven million counterfeit tablets, capsules, and vials were seized through law enforcement efforts during the first nine months of 2009. During that same year, a US government crackdown uncovered some 800 packages of counterfeit medications that constituted Viagra (sildenafil citrate), Vicodin (hydrocodone bitartrate and acetaminophen), and Claritin (loratadine) (Prekupec et al., 2017).

Several factors have been associated with the pharmaceutical counterfeiting problem. As discussed in Szymonik et al., (2017), increasing access to the Internet coupled with new methods of manufacturing and distributing illegal pharmaceuticals have created new challenges to safeguarding the legitimate pharmaceutical supply chain. In support thousands of websites have been found that openly sell unapproved and/or counterfeit drugs, as well as prescription drugs without requiring a valid prescription, all of which were functioning in violation of federal and state laws (Fernadez et al., 2021). Furthermore, most of these sites are hosted by US registrars, accept payment by U.S. payment processors, and ship their products via U.S.-based express courier companies or the U.S. Postal Service (Grankina et al., 2018). These factors above may explain why

counterfeit drugs have become a public health concern. To date, this remains a persistent widespread problem that needs yet to be effectively resolved. To curb the problem, pharmaceutical companies have turned to anti-counterfeiting technologies.

Despite public and private efforts to-date, the online availability of counterfeit pharmaceuticals and pirated goods continues to increase. Strong government action is necessary to fundamentally realign incentive structures and thereby encourage the private sector to increase self-policing efforts and focus more innovation and expertise on this vital problem.

Anticounterfeiting Technologies

A variety of anti-counterfeiting technologies are being utilized by pharmaceutical companies to ensure the distribution of authentic products from the manufacturing site to the pharmacy (Fernandes et al., 2021). Among these technologies are holograms, color-shifting inks, embedded codes, images, and dyes allowing pharmacists to identify suspicious medications as possible counterfeits (Garankina et al., 2018, Bolla et al., 2020). However, the effectiveness of anti-counterfeiting technologies is limited by insufficient knowledge of the specific schemes and offender trends in pharmaceutical counterfeits that are occurring in the US and the particularities of different states, regions, and locations.

Previous research efforts have been directed toward understanding pharma counterfeiting criminal implications. For instance, Kubic (2008) undertook a study in which they investigated pharmaceutical counterfeiting. Through an analysis conducted by the Pharmaceutical Security Institute (PSI), the researchers examined the prevalence and extent of the new transnational crime, pharmaceutical counterfeiting. Highlights of key

findings included the discovery that counterfeiting of pharmaceuticals continued as the most common type of crime identified by PSI with 1,184 incidents or 86 percent of the total and that 755 persons involved in counterfeiting, diversion, or theft of pharmaceutical drugs worldwide were arrested annually in the United States (Kubic, 2008). Although these findings were critical in fostering insights into the challenge of pharmaceutical counterfeiting as evident from the Pharmaceutical Security Institute (PSI) data, the research no attempts were made to reveal specific offender schemes and trends by region or state.

Another approach to investigating pharmaceutical counterfeiting relies on the use of secondary data sources such as the Product Counterfeiting Database (PCD) to evaluate different aspects of this problem (Kennedy et al., 2018, Sullivan 2019). For instance, Kennedy (2018) carried out a study in which they explored occupational pharmaceutical counterfeiting schemes. The study stemmed from the realization that there have been no empirical investigations of pharmaceutical counterfeiting schemes, nor any attempts to disentangle the numerous elements and components underlying existing trends. Using content analysis, Kennedy et al., (2018) examined data from the A-CAPP Product Counterfeiting database related to pharmaceutical counterfeiting schemes and developed a crime script for pharmaceutical counterfeiting that describes key acts, and scenes, actors, activities, and enforcement conditions. Findings indicated that occupational counterfeiters leverage their position as health care providers to abuse patient trust and conceal their deviant acts (Kennedy et al., 2018).

On the other hand, Sullivan's (2019) study sought to understand the nature of the pharmaceutical counterfeiting issue in relation to problem-oriented policing, routine

activities theory, and situational crime prevention using the same PCD secondary data source. The author considered three related stages: identifying cases, searching cases, and typifying cases. This study provided a general understanding of pharmaceutical product counterfeiting schemes in the US, which was evidenced as a "dark figure" of criminal activity (Sullivan, 2019). However, to date, a solid empirical foundation and evidence-driven baseline describing product counterfeiting schemes, offenders, and victims in the United States remains challenging. This complicates further the implementation of effective controls to reduce such criminal activities. A more in-depth characterization of the schemes and types of counterfeit products by state and region is a necessary first step to address the problem more effectively. For this purpose, specific data-collection and analytics methods that can reveal existing particularities and differences in pharma counterfeiting within a state or region would be needed.

Statement of the Problem

This quantitative empirical research will use the ICPSR 37177 database (compiled by Sullivan, 2018) as a secondary data source to characterize the offender schemes and trends in pharmaceutical counterfeiting that is affecting the state of Florida. The study aims to examine particularities and possible differences in pharmaceutical counterfeiting that may exist between Florida in comparison to the national situation. These trends may contribute to understanding how Human Services professionals can mitigate the problem more effectively. According to Hall et al., (2017), the problem of counterfeiting has persisted because schemes can apply to both branded pharmaceuticals and their less expensive generic counterparts. The confusion between, generic drugs and counterfeit

medications poses an obstacle to their widespread use and acceptance of generic medications which are as effective (if the true product) and less costly.

The problem of distinguishing between counterfeit drugs and generic products creates a particular challenge for pharmaceutical industries in places such as India, Europe, and Japan, which are countries in which generic drugs are manufactured (Bamakan et al., 2021. Although the problem of counterfeit drugs is affecting the US in general, knowing the schemes and types of counterfeit products in a state such as Florida, and in which ways they could differ and show particularities from the national trends identified, could contribute to improving existing policies and control mechanisms to tailor the needs of a state. For this purpose, this investigation will use the national ICPSR 37177 database as a source of secondary data. By focusing on the State of Florida, the researcher will be able to conduct an in-depth characterization to identify cases, search cases, code typify the cases and evaluate possible differences with these national trends. The findings of the study may contribute to establishing and or further improving policies and existing anti-counterfeiting technologies in this region. Therefore, the researcher will make recommendations through this study for other departments and agencies to combat pharmaceutical counterfeiting in the US.

Study Aims

To characterize the problem of pharmaceutical counterfeiting in Florida, the ICPSR 37177 database will be used as a source of secondary data addressing the following specific aims:

- To characterize possible differences in pharmaceuticals counterfeited in Florida in comparison to the national trends.

- To examine offender schemes in Florida and the possible differences that may exist compared to the national trends.
- To develop a data analytic strategy that can identify, search, and typify the generic drugs and counterfeit products that are occurring more frequently in Florida.

This dissertation will explore the intersection of criminal justice theory and conflict theory in relation to pharmaceutical counterfeiting schemes in the United States. By applying the principles of criminal justice theory, the study will analyze how enforcement practices respond to these offenses. It will assess how these responses shape trends in offender conviction and incarceration rates, particularly examining whether current legal frameworks effectively deter such crimes or inadvertently contribute to their persistence. The results obtained will contribute to expanding existing knowledge regarding pharmaceutical counterfeiting in the targeted region. Moreover, the study would provide quantifiable data and statistical information that could be replicated in other studies to be generalized. Characterizing the pharmaceutical supply chain, from the initial raw materials to manufacturing and distribution could be useful for more effective control of the pharma counterfeiting problem in the region and allow to take adequate preventive measures.

The consequences of drug and medications counterfeiting are well-known, as the Department of Homeland Security (DHS) states, “counterfeit and pirated goods pose a serious threat to America's economic vitality, the health and safety of American consumers, and our critical infrastructure and national security.” Piracy and counterfeiting are not victimless crimes; they cost US businesses more than $200 billion

annually and account for the loss of more than 750,000 jobs. Trafficking in counterfeits can be extremely profitable; detection of counterfeits is difficult, and the penalties are modest. Counterfeit drugs pose a public health hazard, waste consumer income, and reduce the incentive to engage in research and development and innovation. To be developed shortly in connection with the above.

Philosophical Assumptions

This study philosophical assumptions are related to post positivism and the use of quantitative methodology. According to Van Manen (2016), post-positivistic research assumes that social reality is out there and has enough stability and patterning to be known and as well assumes that social reality can be conceived as coherent, whole, and singular. The fact that the current study will rely on a post-positivism perspective, it will be assumed that patterns regarding pharmaceutical counterfeiting as a social reality can be coherently described and understood. The study will also embody assumptions that stem from the utilization of the quantitative methodology.

The first assumption in this study is ontological in nature. As stated by Van Manen (2016), ontological assumptions come into play in cases where researchers investigate a world that is populated by human beings implying that their opinions, meanings, and interpretations of the phenomenon under study will influence what can be known. In the current study the researcher relies on secondary data. Thus, the researcher will have to assume that the evidence from previous research will provide valid information that will help achieve the study's objective. Further, the current study will consider that what has been studied already about the issue of interest remains to be

further analyzed in depth and can provide new insights regarding the investigation objectives.

On the other hand, the epistemological assumption is based on the notion of constructionism. According to Cruz and Tantia (2017), constructionism is the view that the knowledge generated through research investigations is constructed rather than discovered. This assumption applies to the study given that the researcher will have to draw information from analyses of data previously gathered by a separate researcher. Notably, the researcher will focus on obtaining secondary data for the purposes of the current study. The rationale for choosing secondary data is to allow the researcher to examine the relationship between the variables in a dataset that was previously collected on product counterfeiting schemes, offender, and victims in the United States. For this reason, data from ICPSR 37177 data set will be used which contains information on counterfeiting crimes that occurred from 2000-2015 in the US, and specifically on the schemes, the offenders (individuals and businesses) and the victims (consumers and trademark owners). Further, the constructionism assumption as stated by Morse (2015) means that there is no true or valid interpretation. This assumption holds in the current study because the interpretations of data acquired from secondary sources will not be deemed as absolute truth. Rather, previous studies will serve as a solicitation to re-interpretation.

Axiological assumptions as stated by Korstjens and Moser (2018) have to do with the values brought by the researcher into a study and the accompanying researcher interpretations relative to those of participants when using descriptive study designs. The current study reflects the researcher's position that relies on evidence, a scientific

approach and the appropriate quantitative methods to make inferences. The researcher also acknowledges that the research is value-ladened and that researcher and participant biases are significant possibilities (Marshall & Rossman, 2016).

The current study is pragmatic in nature. Researchers who adopt this philosophy focus on the outcomes, as opposed to conditions associated with the outcomes (Shusterman, 2016). The rationale behind pragmatism is about finding a solution to an existing social problem, focusing on the problem itself as opposed to the methods of resolving the particular issue (Sleeper, 2001). Researchers with a pragmatic approach aim to collect and analyze data about the research problem through many different approaches, thus choosing from a variety of methods, procedures, and techniques. Pragmatic philosophy is not centered on a specific reality or an absolute unity, and the truth can be the outcome of what is currently happening at the time (Sleeper, 2001).

Interpretive Frameworks

The proposed study is guided by the criminal justice theory (Bernard & Engel, 2001) and components of the conflict theory (Bartos & Wehr, 2002). Criminal justice theory is divided into police, court, and corrections segments, which together form a criminal system (Bernard & Engel, 2001). The theory stems from a multidisciplinary approach, applying theoretical propositions from criminology, political science, psychology, sociology, economics, and anthropology. Criminal justice theory is a framework that focuses on criminal justice and punishment. The core concepts of the criminal justice theory are rooted in political philosophy and ethics, which are applied to justice in practice (Kraska, 2006). The ethical component enters around the moral, psychological, and social underpinnings, which guide human behavior in criminal justice.

More specifically, the current study will focus on ethics in criminal justice. Pollock (2016) argued that the minds of human beings guide them toward making ethical and moral judgments, which guide their behavior.

Ethics in criminal justice can be defined as the cultivation of certain habits, which allows individuals to achieve a balance between the two extremes: the moral and the immoral. According to Aristotle (cited in Albenese, 2008), moral virtues could be cultivated through temperance, courage, prudence price, justice, ambition, temper, friendship, wittiness, and truthfulness. Pollock (2016) built on these concepts, arguing that Aristotle's concepts focused on the cultivation of moral and ethical habits over time, but failed to address the dilemmas of moral and ethical judgments made by individuals. According to Pollock (2016), two systems can address these dilemmas: the deontological system (non-consequentialism), and the teleological system (consequentialism). Deontological systems were defined as the rational basis of moral decisions possessed by everyone, who then chooses to act based on these decisions (Pollock, 2016). On the other hand, deontological systems can also refer to acting on the principle of duty, an act that one is supposed to fulfill. Concerning the teleological systems, which refer to the pain principle, otherwise known as the hedonistic calculus (Pollock, 2016). This principle refers to the justification of bad actions if the outcome is positive, called utilitarianism. Similarly, an action that is carried out to achieve the greatest good of the person doing the action is another part of teleological systems, otherwise called ethical egoism (Pollock, 2016). These systems help to focus on the consequences of the ethical actions carried out by others, and the needs these serve.

Conflict theory refers to the impact of power structures on the daily lives of people. Every day, people are faced with a conflict, which can affect their decision-making and daily life (Bartos & Wehr, 2002). The conflict can be characterized as structural inequality, power struggle, oppression, or discrimination. Focusing on these conflicts is often applied in social work, where asymmetries and tensions between different societal groups are reduced and managed (Bartos & Wehr, 2002). However, this theory is primarily applied in research focusing on white-collar crimes and drug-related offenses, while simultaneously highlighting the issue of racial profiling in criminal justice (Bystrova & Gottschalk, 2015; Moore & Morris, 2011).

The current research study will apply the tenets of the criminal justice theory and conflict theory to trends in counterfeiting schemes and offender conviction and incarceration in pharmaceutical counterfeiting schemes in the United States, followed by the potential inequities in conviction and incarceration trends. The rationale for choosing the criminal justice theory as the main theoretical framework was to allow the researcher to analyze the conviction and incarceration trends from the perspective of moral decisions and hedonism. Through observing the trends and patterns in product counterfeiting crimes, the researcher will be able to apply his interpretation of the theory to guide the findings. Simultaneously, the application of conflict theory will provide insight into the socioeconomic dynamics at play in pharmaceutical counterfeiting. This perspective will highlight how power imbalances and economic disparities influence the prevalence of counterfeiting schemes, as well as the societal reactions to offenders. By investigating these trends, the dissertation aims to reveal underlying systemic issues and propose recommendations for a more equitable and effective approach to addressing

pharmaceutical counterfeiting, ultimately contributing to the broader discourse on crime prevention and social justice.

Definition of Terms

The following key definitions will guide the current study:

Counterfeit. A product made as an exact imitation of another product, with a sole intention of fraud (Campbell & Lodder, 2021).

Detention. When US Customs & Border Protection (CBP) requires more information to make an appropriate determination regarding importation or exportation to release merchandise. 19 C.F.R. § 162.21 (2008)

Discrimination. Unfair and unjust treatment of different groups of people, based on their sex, age, race, or disability (Moore & Morris, 2011).

Ethics. Moral principles that help to guide individuals' behaviors and decision-making (Pollock, 2016).

Morality. The principles that help others to distinguish between what is right and wrong (Pollock et al., 2016).

Offender. Someone who had committed an illegal act (Anderson et al., 2017).

Oppression. Unjust treatment toward certain groups of people, or an excessive use of authority to create inequalities (Moore & Morris, 2011).

Power struggle. Competition for power, access, and authority with other groups within society (Moore & Morris, 2011).

Racial profiling. Act of relying on one's race or ethnicity alone as a way of suspecting or committing someone of a crime (Anderson et al., 2017).

Schemes. Generally, a systematic plan that allows for a particular idea to be put into the effect. In the current case, this refers to criminal acts (Campbell & Lodder, 2021).

Seizing officer. The US Customs & Border Protection (CBP) officer first collects or receives seized property and introduces it into the chain of custody. 19 C.F.R. § 162.21 (Albanese, 2008).

Seizure. When an officer takes custody of an item to enforce a violation of law, for evidence, for forfeiture, or both. 19 C.F.R. § 162.21 (Albanese, 2008).

Structural inequality. Organizations, governments, social networks, and institutions hold a bias toward a specific group, which contributes to their marginalization in society (Anderson et al., 2017).

Counterfeiting: A Worldwide Problem

Counterfeiting has always been viewed as a crime in the current dispensation. According to Abdel Salam et al., (2019), counterfeiting involves the illegal use or theft of another person's trademark in both large and small businesses. Thus, counterfeiting crimes involve cases where individuals and business entities use trademarks that belong to other parties to lure consumers into liking them and to identify their products in the marketplace. As indicated by Elsantil and Hamza (2021), a counterfeit is an item that uses someone else's trademark without their permission and through counterfeiting, criminals seek to profit unfairly from the trademark owner's reputation. From the same perspective, counterfeiting has been viewed as a forgery or fraudulent imitation of a trusted product or brand. Taking the description further, Khurelbat et al., (2020) described counterfeiting as the illegal act that involves creating documents, currency, or

product facsimiles and selling them at a high value to make a profit. Thus, counterfeiting takes place at both national and international levels.

The scale of the problem of counterfeiting can be understood by considering available statistics on the issue. As indicated by Harun et al., (2020), international trade in counterfeit products as of 2019 stood at 3.3% and threatened to rise. Before then, trends in counterfeit traded products had increased the value of imported fake products to 461 billion US dollars, which accounted for 2.5% of international trade in 2016. For the European Union, counterfeit trade represented 6.8% of imports from non-EU countries, up from 5% in 2013 (International Chamber of Commerce, 2016). However, it is important to note that these figures did not include domestically produced and consumed fake goods, or pirated products being distributed via the Internet. Other studies have affirmed the validity of these statements. For instance, Moshoeshoe et al., (2022) carried out a study in which they explored illicit trade trends in counterfeit and pirated goods in an attempt to determine the extent of the problem. Findings obtained from the study indicated that the international trade in counterfeit and pirated products amounted to as much as $509 billion in 2016, estimated to be 3.3% of world trade, which reflected an increase from $461 billion in 2013, representing 2.5% of world trade. As indicated by Moshoeshoe et al., (2022), the significance of the growth in these numbers occurred during a relative slowdown in overall world trade although the numbers are based only on global customs seizures and did not cover counterfeit goods that were not seized. In addition, these amounts do not include domestically produced and consumed counterfeit goods, or pirated digital products distributed online.

Research in this area is important given the diverse risks counterfeit products pose to modern-day society. As noted by Magdun (2021), counterfeit components and parts continue to create health and safety risks that affect a wide range of industries. For instance, in the pharmaceutical industry, using counterfeit medicine has the potential to be devastating. Further, Ozawa (2018) noted that within the pharmaceutical supply chain, from the initial raw materials to manufacturing and distribution, plenty of opportunities exist for providing fake or mislabeled materials and ingredients resulting in possibilities for creating counterfeit products. In the automobile industry, the amount of counterfeit vehicle parts available has been on the rise leading to notable increases in economic costs associated with infringement in the tires and batteries sectors.

The Organization for Economic Cooperation and Development (2019) undertook a study seeking to explore the economic and industry-sector costs of counterfeit products in diverse industries. Findings indicated that approximately two billion pounds worth of cash were lost annually due to counterfeit tires and batteries alone with the most common counterfeited vehicle parts worldwide including filters, brake pads, lights, wheel rims, and airbags (Organization for Economic Cooperation and Development, 2019). In support of these findings, Magdun (2021) found that additional safety risks associated with counterfeit products in this area include counterfeit circuit breakers, extension cords, and surge protectors often made with inferior materials without regard for meeting even minimal performance specifications.

This quantitative empirical research will use the ICPSR 37177 database as a secondary data source to address the problem of pharmaceutical counterfeiting that is affecting Florida by identifying particularities and possible differences that may exist

within the state in comparison to the national situation and trends. A major problem with counterfeiting crimes to be addressed in this study is pharmaceutical counterfeiting. The use of secondary sources of data is essential given the ability of such sources to help acquire quantitative information regarding the rise of criminal organizations that have mastered the art of seizing the high rewards and profits availed by counterfeiting. Soundarya et al., (2018) undertook a study aiming to investigate transnational criminal organizations and the rise of counterfeiting crimes. Findings obtained from the study indicated that transnational criminal organizations have been using their counterfeiting profits to expand their business into other related crimes, such as the smuggling of other contraband, money laundering, tax evasion, and corruption of government officials. Soundarya et al., (2018) concluded that the increases in transnational organizations that rely on counterfeit crimes and products have also taken advantage of the fact that e-commerce and social media sites have allowed several small retail counterfeiters without links to larger organizations to proliferate.

In agreement with these findings, O'Hagan and Garlington (2018) explored the rise in counterfeit products. Findings indicated that counterfeiting is a fragmented business that does not require a great degree of sophistication and management of finance and resources. For this reason, it is very difficult to control effectively and continues to grow. The COVID-19 pandemic has changed the business landscape making it even easier for transnational organizations to profit from counterfeit products. Geldenhuys (2021) undertook a study in which they investigated the impacts of the COVID-19 pandemic on global business and the supply chain. Borrowing from a statement made by the International Chamber of Commerce (ICC) that the pandemic has overwhelmed

global business and has created the most substantial negative supply chain security effect in history, Geldenhuys (2021) hypothesized that understanding the nature of transnational criminal organizations and their reliance on counterfeit products was essential to understand the opportunities availed to such criminal organizations by the pandemic. They concluded that the pandemic had provided more opportunities for criminal organizations that seek to take advantage of the rise in demand and subsequent shortages of parts and products.

Additionally, it has been reported that such problems were aggravated by the presence of certain counterfeiters who exploit weaknesses in legitimate supply chains by offering lower than normal prices for source and raw materials (Layachi 2020). The authors discussed that the threats associated with transnational criminal organizations if not identified and acted upon could taint legitimate supply chains and could be continuous within sectors.

Pharmaceutical Counterfeiting

Pharmaceutical counterfeiting is the fraudulent and deliberate mislabeling of medical products regarding a legal source or identity. Additionally, Venhuis et al., (2018) defined pharmaceutical counterfeiting as the engagement in the production of a drug or medicine and the inclusion of labeling without authorization. This definition implies that pharmaceutical counterfeiting not only involves the manufacturer but also involves individuals and organizations that are aware of the absence of authorization go-ahead to process, pack, and distribute a particular drug falsely presenting it as a product that bears the trademark, identifying mark, or trade name of a legalized manufacturer that has secured legal authorization (Peltier-Rivest & Pacini, 2019). Over the years, concerns have

risen regarding these definitions with some scholars suggesting that any expansion of the definition of pharma counterfeiting would include low-quality medications and substandard ingredients (Mackey et al., 2015).

Statistics/Scale of the Problem

Pharmaceuticals are particularly vulnerable to counterfeiting. According to Lade et al., (2020), the high IP intensity of the pharmaceutical industry and strong demand make pharmaceuticals vulnerable to counterfeiting. Such sentiments can be affirmed by available data. As indicated by Lade et al., (2020), between 2014 and 2016, based on customs seizures of 97 recorded product categories pharmaceuticals were the 10th most counterfeited type of product making the value of global trade in counterfeit pharmaceuticals approximately USD 4.4 billion, which translated to 0.84% of total world-wide imports in pharmaceutical products. These statements match the findings that were obtained by Haq and Esuka (2018) after they engaged in a study investigating the scale of pharma counterfeiting. The researchers utilized data from the PSI dataset on 16,240 counterfeiting, illegal diversion, and major theft incidents from 2014 to 2018. Findings obtained by Haq and Esuka (2018) revealed that from 2014 to 2017, total incidents of pharma counterfeiting increased by 102%. Further observations that corroborate these findings were reported by Falasca et al., (2021) indicating that the Pfizer Company reported discovering 14 of its counterfeited pharmaceutical products in at least 36 countries and reportedly seized more than 11 million counterfeit tablets, capsules, and vials.

These observations have also been affirmed by other researchers. For instance, Geldenhuys (2021) undertook a study exploring the prevalence of counterfeiting and

counterfeiting trends in the pharmaceutical industry across the globe. The researcher deployed a meta-analysis of 96 studies that tested 50 samples comprising over 67 000 samples. Findings obtained by Geldenhuys (2021) indicated that the prevalence of substandard and falsified medicines in low- and middle-income countries was 13.6%. Additionally, among the studies included in the meta-analysis the highest prevalence of falsified and substandard medicines was registered in Africa (18.7%) and Asia (13.7%). A similar study was carried out by Campbell and Lodder (2021) in which they examined transnational crime in East Asia and the Pacific. The researchers included a close investigation into the situation in pharmaceuticals. After undertaking forensic testing, the researchers found that one-third to two-thirds of the samples tested in the region were fraudulent. Further, the study findings revealed that the total number of fraudulent antibiotic reports accounted for 17% of total reports on substandard or falsified products. Thus, Campbell and Lodder (2021) concluded that while counterfeiters could likely attain a far higher rate of return in developed countries, the low risk of detection greatly enhanced the appeal of the lower-price markets.

The scale of the problem can further be understood considering the permeation of counterfeiting across diverse pharmaceutical products. Bottoni and Caroli (2019) undertook a study in which they explored the types of counterfeit pharmaceuticals. The researchers were driven by the literature-based realization that between 2014 and 2016, seized counterfeits included medicaments for various kinds of diseases, including malaria, HIV/AIDS, and cancer. Thus, Bottoni and Caroli (2019) sought permission, accessed, and reviewed customs data regarding counterfeit antibiotics, lifestyle drugs, and painkillers hypothesizing that these were the most targeted by counterfeiters.

Findings obtained from the study indicated that the initial study scope was limited given that other types of counterfeit pharmaceuticals such as those targeting treatment for malaria, therapeutic purposes, diabetes, epilepsy, heart diseases, allergies, blood pressure, cancer, and stomach ulcer were often seized by customs authorities.

These findings were affirmed by Kajidi et al., (2020) after they engaged in a study in which they investigated the prevalence of counterfeit pharmaceutical products with a particular focus on their diverse typologies. Specifically, the researcher explored pharmaceutical products that fall under the category of therapeutics. Kajidi et al., (2020) hypothesized that medicines within the genitourinary therapeutic category continued to be the most frequently targeted by counterfeiters. Findings obtained from the study indicated that due to increased activity and new sources of information, the counterfeiting of drugs in the genitourinary category were detected at a much higher rate in 2018. However, these are not the only counterfeited pharma products, which further describes the scale of the problem.

Another category that is frequently targeted by counterfeiters is the central nervous system (CNS) because it surpasses anti-infective treatments. Affirming this statement, Kennedy et al., (2018) noted that since 2016, CNS drugs have experienced a 57% increase in counterfeiting incidents, which is consistent with the increased reporting of counterfeit benzodiazepines and opioid pain medications in North America and Europe. On the other hand, it is critical to note that most drugs that are counterfeited in this industry do not contain the correct active ingredients in the correct proportions whereas others contain undeclared active ingredients that might have serious unwanted health consequences (Le et al., 2018).

High-demand, expensive medications have also been the target of pharma counterfeiters. According to the Organization for Economic Co-operation and Development (2019), these constitute chemotherapeutic drugs, antibiotics, vaccines, erectile dysfunction drugs, weight loss aids, hormones, analgesics, steroids, antihistamines, antivirals, and antianxiety drugs are common counterfeiting targets. Affirming the success of counterfeiters in selling these drug typologies, Parfilo (2018) stated that among those deceived into buying counterfeit drugs are consumers who use medicines inappropriately or who seek to purchase medications at discounted prices. Notably, there are reasons behind the interest of pharma counterfeiters in these types of drugs. Besides being very cheap to make, counterfeit medicines often closely resemble actual medications having nearly identical labels and tablets, which easily deceive unsuspecting pharmacists and patients (Organization for Economic Co-operation and Development, 2019).

Importance of Research in Pharmaceutical Counterfeiting

Several reasons make pharmaceutical counterfeiting an important research area. One of the chief reasons has to do with the impact that pharma counterfeiting has on the global economy. According to Shetty et al., (2022), the pervasive threat has been draining the global economy by approximately 200 billion dollars of profits annually. Such observations strongly suggest that pharmaceutical counterfeiting has become such a global menace because no country seems to be immune to the problem. From such a perspective, it is critical to engage in thorough research in this area to improve the strategies deployed by anti-counterfeit packaging agencies while seeking to combat the problem. As indicated by Ozawa (2018), although such agencies have attempted to

combat the problem over the years, organized counterfeit organizations have been consistently breaching the legitimate drug supply chain in many countries. Further, the fact that the Organization for Economic Co-operation and Development (2019) estimated that more than 10% of the global medicines are counterfeits, and more than 50% of the drug supply is made up of counterfeit drugs suggests that unless the research is focused in this area the world's economy will continue to lose billions to pharma counterfeiting.

Additionally, it is important to focus research in this area given that the persistence of pharmaceutical counterfeiting has continued to pose health risks making it an issue of public health concern. Saxena et al., (2020) undertook a study in which they explored the health concerns associated with the counterfeiting of pharmaceutical drugs. The researchers stated that counterfeiting drugs is not only illegal but is also a major public health concern since such drugs often contain the correct ingredients in incorrect quantities, wrong API, or no active substance at all. Thus, Saxena et al., (2020) investigated public health concerns that are related to treatment using ineffective counterfeit drugs such as antibiotics. Findings obtained by Saxena et al., (2020) indicated that most of the public health concerns were associated with the contribution of ineffective counterfeit drugs towards the emergence of resistant organisms as well as death. Several research-based statements have affirmed the existence of public concern when it comes to counterfeit drugs. For instance, Kennedy et al., (2018) undertook a study to link increasing death rates among children to the prevalence of counterfeit drugs. Particularly, the researchers focused on the treatment of malaria among children. Findings obtained by Kennedy et al., (2018) indicated that an estimate that between 60,000 and 80,000 children in Africa with fatal falciparum malaria were treated with a

counterfeit vaccine containing only chloramphenicol, which is an antibiotic that is generally combined with another medication resulting in more than 100 fatal infections and eventually death.

The case for study in the area of pharmaceutical counterfeiting is also justified by studies that point toward the toll that counterfeit pharmaceuticals have on public health. For instance, Schneider and Ho Tu Nam (2020) undertook a study in which they investigated the public health impacts of pharma counterfeits with a particular focus on the African continent. The study was driven by the literature-based realization that pharma counterfeiting exacerbated the impacts of diseases like malaria, HIV, and tuberculosis both for individual patients and at the economic level. For instance, Schneider and Ho Tu Nam (2020) discovered that malaria was estimated to cost African nations at least $12 billion annually whereas the economic cost of tuberculosis-related deaths, including those resulting from HIV co-infection in sub-Saharan Africa was estimated at approximately $50 billion annually. Findings obtained from the study indicated that these losses were compounded by counterfeit pharmaceuticals. Additional findings by Schneider and Ho Tu Nam (2020) revealed that of the one million annual global malaria deaths, 200,000 were associated with counterfeit anti-malarial drugs. Affirming these findings, Uddin (2021) also indicated that 700,000 Africans die annually from consuming fake anti-malarial or tuberculosis drugs, especially those from China and India.

It is also critical to study this area due to the association between declines in foreign investments and the prevalence of fake pharmaceuticals. Corroborating this statement, economic analyses by the Organization for Economic Cooperation and

Development (OECD, 2019) indicated that foreign direct investment from Germany, Japan, and the US was relatively higher in economies with lower rates of counterfeiting and that multinationals are less likely to invest in countries where they are likely to have their products copied. Additionally, Bottoni and Caroli (2019) observed that rights holders investing in Kenya reportedly lose an estimated $390 million annually to counterfeiting and piracy limiting the extent to which willing pharma investors would carry out their investment plans. Further, Zhang et al., (2020) noted that foreign investors are mostly interested in economic improvement through job creation besides their profit-making ambitions. From such a perspective, pharma counterfeiting negatively influences foreign direct investments given that the counterfeiting and product piracy problem that leads to economic and job losses that in turn can cause greater demand for cheaper but ineffective counterfeit goods (Fantasia & Vooys, 2018).

The need for research in pharmaceutical counterfeiting is also essential to help come up with more precise dimensions of the problem. According to Zoughalian et al., (2022), although previous researchers have attempted to explore this problem area the reliability of the estimates of the effects of counterfeit pharmaceuticals remains unclear and estimates for many dimensions of the problem do not exist. Moreover, studies that have attempted to provide succinct estimates are often imprecise in their sources or methods. For example, acquiring reliable estimates of the economic effects of pharmaceutical counterfeiting in developed and developing countries is difficult for several reasons. The first reason as cited by Schneider and Ho Tu Nam (2020) is that the trade of counterfeit goods is illicit, clandestine, and complex, which makes it difficult to identify and link to outcomes. The second reason as noted by Uddin (2021) is that the

pharmaceutical industry has competing interests in the sharing of data given that it wants to encourage enforcement but not frighten consumers. Moreover, there is little support for data collection and research in this area although policies and responses not supported by rigorous data and analysis have continuously resulted in ineffective and costly tactics (Zoughalian et al., 2022).

History of Pharmaceutical Counterfeiting Practices

The trend of drug counterfeiting has its origins in China during the 1990s. This explains why researchers have consistently cited China as the leading exporter of fake pharmaceutical products (Abdel Salam et al., 2019). Additionally, the origin of pharmaceutical counterfeiting practices has been linked to China's economic growth between the early 1990s and early 2000s. Further, Venhuis et al., (2018) noted that China's insurance schemes only covered 20% of the Chinese population by 1993 whereas out-of-pocket payments ballooned to a 60% share of China's total health expenditure by 2000. Moreover, domestic drug quality monitoring programs and government oversight were both weak, and proper drug manufacturing practices that were stipulated by the Chinese drug administration required over three million dollars and were very expensive for drug manufacturing companies to implement (Venhuis et al., 2018).

By the early 2000s, Chinese counterfeiters can manufacture nearly perfect pills with the same active ingredients as the originals. Nonetheless, the sophistication improvements were not able to prevent the pharma counterfeiting tragedy that took place in China in 2005. In the last 20 years, China has worked on turning its healthcare into a national priority by passing new insurance schemes in 2003 and 2007 and making associated efforts to improve the global position of the Chinese biotechnology market.

Affirming that China is the origin of pharma counterfeiting, Antonopoulos et al., (2020) noted that Chinese scientists reportedly publish disproportionately small amounts of negative clinical trial results whereas investigations carried out between 2016 and 2017 revealed that 80% of clinical data is fabricated. Moreover, Estacio (2012) noted that the reluctance of the Chinese drugs organization has been responsible for the heightened production and export of counterfeit drugs.

Pharmaceutical Counterfeiting as a Crime

Pharmaceutical counterfeiting involves diverse products. Alangot and Achuthan (2017) carried out a study in which they explored the nature of pharmaceutical counterfeit crimes with a particular focus on fake and counterfeit medicine. The researchers focused on establishing counterfeit drug-related crimes that involve lifestyle drugs. Additionally, the researchers hypothesized that among commonly falsified and counterfeited medicines three types of products are most significant. According to Alangot and Achuthan (2017), these include erectile dysfunction pills and gels, weight loss pills, and anabolic steroids, which are branded lifestyle drugs because they are meant to improve the image, performance, and physical appearance of the consumer. Findings obtained from the study indicated that whereas most counterfeit and fake medicines are produced outside of Israel, some are produced locally in hidden and unsupervised sites thus helping sustain pharma counterfeit crimes. After a similar study, Geldenhuys (2018) found that pharma counterfeit as a crime has been progressive fake and counterfeit lifestyle drugs are often of low quality and contain too much or too little active ingredient with some containing active ingredients not listed on the label.

These findings are consistent with the results obtained by Machado et al., (2018) after they undertook a study to investigate pharma counterfeit crimes based on the component of fake dietary supplements. The researchers hypothesized that just like regular dietary supplements, fake and counterfeit dietary supplements come in a variety of forms, including tablets, capsules, gummies, powders, drinks, gels, and snack bars. Findings obtained by Machado et al., (2018) indicated that pharmaceutical counterfeit crimes are marked by the fact that fake and counterfeit dietary supplements are commonly manufactured in places not supervised by the Ministry of Health. Similarly, Lade et al., (2020) reported that some fake and counterfeit dietary supplements masquerade as popular products, to mislead consumers whereas others contain active ingredients that are only permitted to be used in medicines. Thus, Lade et al., (2020) concluded that pharma counterfeit is considered a criminal engagement because fake and counterfeit dietary products mislead consumers into believing they are safe. This explains why Machado et al., (2018) noted that most counterfeited pharmaceutical products are often not harmless products and taking them may result in unwanted adverse effects. Furthering the study on pharmaceutical counterfeiting as a crime, Mikhailovich (2021) explored the issue of counterfeit medical devices. Particularly, the researcher focused on devices such as bandages, pregnancy test kits, inhalators, monitors, aesthetic laser devices, and CT scanners. Mikhailovich (2021) found that producing fake medical devices was considered a crime because fake and counterfeit devices are often of low quality and produced by unapproved manufacturers, which almost guarantees a real risk that they will malfunction during their use, hurting the treatment of patients and consumers

Impacts of Pharmaceutical Counterfeiting

The parallel trade of medicines has raised several issues due to its significant impact. Counterfeiting of pharmaceuticals can pose a serious and diverse threat to patients in terms of direct harm, treatment failure, or drug resistance cases. Drug manufacturers and the pharmaceuticals industry also suffer from counterfeiting of pharmaceuticals and experience loss of market share and revenue. As indicated by Obi-Eyisi and Wertheimer (2012), brand integrity is seriously affected and often companies must bear the cost of products recalled preventing any further harm from counterfeit versions of their products. Moreover, the national government too cannot escape from the serious adverse effects of counterfeit medicines, such as increased law enforcement costs, loss of foreign investments, and increased burden of public healthcare crisis (Mackey et al., 2015). Additionally, Mikhailovich (2021) noted that societal impacts are associated with pharmaceutical counterfeiting given that the practice of repackaging in parallel trade may pose serious threats to patient safety due to human error during packaging and may affect the product prices and stability. Further, the pharmaceuticals industry claims that they lose a considerable amount of revenue due to parallel trade, and this deprives the incentive to invest in research and development. Parallel trade may hinder product recalls and may act as a vehicle for the entry of counterfeit medicines into the legitimate drug supply chain (Pitts, 2020).

The issue of counterfeit drugs has been growing in importance in most countries with the supply of these counterfeit drugs coming from all over the world. Innovation is important to economic growth and pharma companies' competitiveness in the global marketplace, and intellectual property protections provide the ability for society to

prosper from innovation. As indicated by Fantasia and Vooys (2018), the most important in terms of innovation in healthcare are the pharmaceutical and biopharmaceutical industries, which are negatively impacted by pharma counterfeits. In addition to taking income from consumers and drug companies, counterfeit drugs also pose health hazards to patients, including death (Zoughalian et al., 2022). For instance, the case of bevacizumab has been presented as one recent example (Schneider and Ho Tu Nam, 2020). Moreover, internet pharmacies, which are often the source of counterfeit drugs often falsely portray themselves considering authorized companies' trademarks to enhance their consumer acceptance harming individual consumers, the industry, and the society (Zoughalian et al., 2022). As indicated by Uddin (2021), problems like drug shortages facilitate access to counterfeits whereas elongated and convoluted supply chains also facilitate counterfeits. In addition, the impacts of counterfeit pharmaceuticals are numerous because trafficking in counterfeits can be extremely profitable whereas detection is difficult the modest penalties notwithstanding (Schneider and Ho Tu Nam, 2020).

Conviction and Incarceration

Efforts against counterfeit pharmaceutical drugs has been going on for the last two decades. These efforts were heightened in 2006 when 755 persons involved in counterfeiting, diversion, or theft of pharmaceutical drugs worldwide were arrested and the United States ranked eighth in pharmaceutical crime arrests during this period (Masini et al., 2022). According to Bartos and Wehr (2002), 2006 showed a shift in law enforcement actions from arrests of distributors to arrests of manufacturers. Nonetheless, the recorded convictions and incarcerations in 2006 were only a mere 79 offenders

(Masini et al., 2022). Attempting to explain the issue, Bernard and Engel (2001) noted that in most cases the lawyers of the arrested offenders leaned on the clause that requires the establishment of proof of intention and direct evidence making it impossible for the prosecutors to secure offender conviction and incarceration. Recently, Europol carried out Operation Shield II a worldwide effort that targeted pharmaceutical counterfeits and the associated individuals and organizations (Antonopoulos et al., 2020). The operation generated tremendous results marked by the seizure of 63 billion Pounds worth of illegal pharmaceutical products and 544 arrests (Antonopoulos et al., 2020; Masini et al., 2022). Surprisingly, no convictions or incarcerations were reported.

Intersection of Pharmaceutical Counterfeiting and Human Services

Human service professionals are individuals trained to assist clients in navigating complex social, health, and economic systems to enhance their overall well-being. This diverse group includes social workers, counselors, and case managers who are dedicated to addressing various individual and community needs through advocacy, support services, and resource coordination. In the context of pharmaceutical counterfeiting, these professionals play a critical role in addressing multifaceted issues, particularly within Florida's public health landscape. Their advocacy is essential in raising awareness about the dangers posed by counterfeit medications, equipping communities with the knowledge necessary to identify legitimate pharmaceuticals and understand the associated health risks. Furthermore, these professionals provide vital support services to individuals impacted by counterfeit drugs, facilitating access to appropriate healthcare resources and emotional support for those who may suffer from adverse health effects. By participating in data collection and analysis, human service professionals contribute

valuable insights that inform public health strategies and policy development aimed at mitigating the risks of counterfeiting. Collaborative efforts with law enforcement and regulatory agencies enhance these professionals' ability to combat the prevalence of counterfeit pharmaceuticals, while their engagement in crisis intervention offers immediate assistance to affected individuals. Ultimately, through advocacy and policy influence, human service professionals not only address the immediate challenges posed by pharmaceutical counterfeiting but also work towards creating a safer, more informed community.

Summary

This chapter explored extant literature to understand schemes and offender trends in pharmaceutical counterfeiting. The theoretical framework selected for the study is the criminal justice theory put forward by Bernard and Engel (2001). Previous research efforts have been directed towards understanding pharma counterfeiting as a crime (Kubic, 2008) or the overall problem of counterfeiting in the US (Sullivan, 2019). However, the specific schemes, the trends in medical counterfeited products and the particularities or differences that may exist in a State or region remain to be further investigated. As reviewed in this chapter, pharmaceutical counterfeiting is a growing problem worldwide and in the US with negative impact on individuals, society, and the industry. Statistics show high demand, illegal diversion, and major theft incidents (Haq & Esuka, 2018). Also, this problem impacts negatively on the global economy, the individual patients, and the pharmaceuticals industry (Saxena et al., 2020; Shetty et al., 2022). Moreover, illegal medical products have been linked to treatment failure, drug resistance, and death (Falasca et al., 2021). Evidence shows that counterfeiting causes

considerable loss of revenue, higher costs for brand protection, and increased costs for managing litigations (Mamtashanti et al., 2020). Particularly, the need to incorporate added security measures has proven costly to companies in this industry (Yi et al., 2022) and had affected innovation and brands productivity (Plotnikov & Kuznetsova, 2018; Sylim et al., 2018). Although pharma counterfeiting is a crime (Machado et al., 2018), arrests have been made but convictions and incarcerations have been wanting. This is mostly because the lawyers representing arrested offenders take advantage of the clause that necessitates prosecutors to provide direct evidence and proof of intention which are difficult to obtain (Bernard & Engel, 2001). This explains why even the latest operation by the Europol despite having led to 544 arrests and seizure of 63 billion Pounds worth of illegal pharma products has had no convictions and incarcerations attached (Antonopoulos et al., 2020; Masini et al., 2022).

This investigation uses an exploratory descriptive approach and quantitative methodology to analyze a secondary data source on counterfeiting in the US (Sullivan 2019). And evidence particularities that may exist in the schemes, type of products and convictions rates in Florida. Explorative research is used to investigate patterns and trends in data, seeking a cause-and-effect relationship (Upadhyaya et al., 2018). On the other hand, descriptive research is used to describe the characteristics of the data. Descriptive research design will be relevant in describing trends or patterns in counterfeiting of pharmaceutical products (Upadhyaya et al., 2018). The descriptive design will be used to answer the 'how, what, when, and where questions (Sidel et al., 2018), as related to the seizure, scheme, convictions, and incarcerations related to pharmaceutical counterfeiting. The rationale for using both research designs is to allow

the researcher to investigate the causal relationship and trends between the variables (seizure characteristics, countries involved, length of scheme, number of convictions, and number of incarcerations) in pharmaceutical schemes in the United States during 2000-2015. Similarly, using both research designs will allow the researcher to discover the statistical differences between variables concerning individual offender demographics, incarceration and incarceration length, convictions, and alternative sentences.

The following research questions are formulated to be answered based on the ICPSR 37177 database as secondary data source:

RQ1: *What are the differences between pharmaceutical counterfeiting schemes in the State of Florida when compared to schemes from a national estimate?*

RQ2: *What are the differences between the individual offenders associated with pharmaceutical counterfeiting schemes in the State of Florida when compared to individual offenders in a national estimate?*

RQ3: *What are the differences between the conviction rates associated with pharmaceutical counterfeiting schemes in the State of Florida when compared to conviction rates in a national estimate?*

CHAPTER II

Method

The present study utilized the ICPSR 37177 database (compiled by Sullivan, 2018). This data source was chosen to contain variables of interest relating to pharmaceutical counterfeiting that could be examined from a Human Services perspective. In choosing a secondary data source, the researcher was able to leverage existing research and to use the data collected to compare pharmaceutical counterfeiting trends between the State of Florida and the wider national estimate. From a pragmatic perspective, the use of secondary data avoided the lengthy process of engaging in primary data collection.

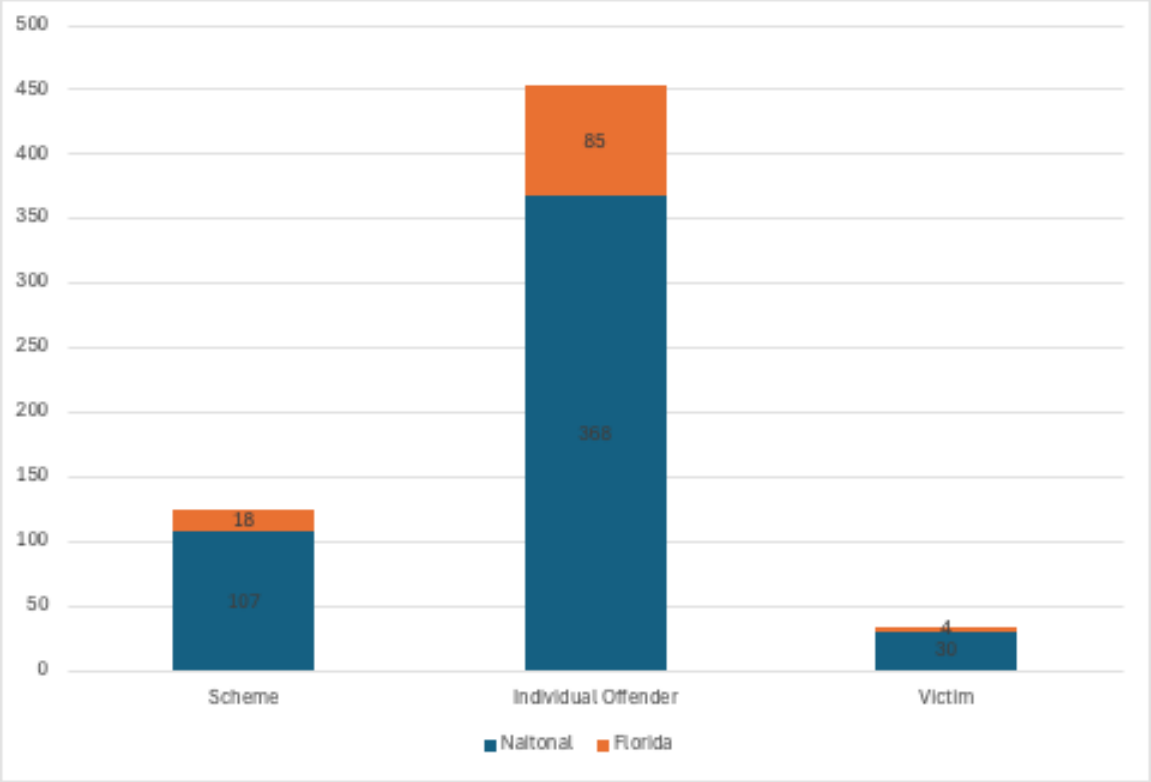
The ICPSR 37177 database compiled various sources of data on counterfeiting crimes that occurred from 2000 to 2015. Although the database possesses data on a variety of counterfeiting industries (i.e., pharmaceutical, food, and electronics), the present study focused on data from the pharmaceutical industry only. Furthermore, the database is divided into four subsets containing unique variables, namely: counterfeiting schemes, individual offenders, business offenders, and victims. For the purposes of the present study, only the scheme, individual offender, and victim subsets were used as they were deemed to be most appropriate for a Human Services study.

Sample

Since three sub-datasets were used in this study, there were three national and Florida samples that were compared. Figure 1 below illustrates the sample sizes of these estimates.

Figure 1

Number of Records for National and Florida Data



Variables

To answer Research Question 1, the following scheme-level variables (given in Table 1) were chosen to reveal differences between the Florida and national estimates. Descriptions of each variable are taken from the codebook provided by Sullivan (2018) as part of the ICPSR 17717 dataset.

Table 1

Variables for RQ1 (scheme descriptive variables)

Variable Name	**Description**	**Variable Type**
Length	Length of scheme in years	Continuous
Number of Products	Number of [unique] products counterfeited	Continuous
Number of Products Seized	Number of [unique] products seized	Continuous
Number of Items Seized	Number of [individual] items seized	Continuous
Seizure Value	Market value of products seize [in US dollars]	Continuous
Illicit Revenue	Estimated amount of illicit revenue generated from scheme [in US dollars]	Continuous

The variables given in Table 2 below were also used to answer Research Question 1. Although they involve scheme victims, these variables were included in the scheme-level sub-dataset.

Table 2

Variables for RQ1 cont. (victim variables in scheme-level data)

Variable Name	Description	Variable Type
Number of Consumer Victims	Estimated number of consumer victims	Continuous
Number of Trademark Owner Victims	Estimated number of trademark owner victims	Continuous
Physical Harm	Were there physical injuries associated with scheme	Continuous
Domestic Reach	Number of [US] states involved with scheme	Continuous
International Reach	Number of non-US countries involved in scheme	Continuous

To answer Research Question 2, the following variables were chosen from the individual offender sub-dataset as given in Table 3.

Table 3

Variables for RQ2 (individual offender)

Variable Name	Description	Variable Type
Sex	Individual [offender]'s sex	Binary (male/female)
Race	Individual [offender]'s race	Nominal (White, Black, Hispanic, Asian, Middle Eastern, Other)
US Citizen	Is the individual a non-US citizen	Binary (yes/no evidence)
Employment facilitated scheme	Did the individual's employment facilitate participant in the scheme	Binary (yes/no evidence)
Non-Intellectual Property Offenders	Was the individual charged with non-intellectual property offenses	Binary (yes/no evidence)
Intellectual Property Offenders	Was the individual charged with intellectual property offenses	Binary (yes/no evidence)
Convicted	Was the individual convicted?	Binary (yes/no evidence)
Probation	Was the individual sentenced to a period of probation?	Binary (yes/no evidence)
Deported from US	Was the individual deported from the US?	Binary (yes/no evidence)
Fugitive	Was the individual a fugitive?	Binary (yes/no evidence)

To answer Research Question 3, only one variable from the scheme-level data was needed. This variable indicated the number of individuals who were convicted as part of the scheme. This variable differs from the individual offender conviction variable since the latter is a frequency (i.e., a percentage can be calculated) whereas the former allows for a mean to be compared between the Florida and national estimates.

Procedures

This study was conducted in logical, sequential steps. After the proposal was discussed and approved by the dissertation committee, the researcher sought approval from administrators of ICPSR 37177 databases to again access the restricted-use data. In addition, the researcher obtained IRB approval from BRANY ethical review services utilized by Albizu University. The role of IRB review is to provide approval and conduct periodic assessments of the study's progress to ensure that ethical procedures are complied with to safeguard the rights of participants whose data will be used in the research (Tsan et al., 2020).

After receiving IRB approval and access to the ICPSR 37177 database, the research then screened the scheme, individual offender, and victim records. The inclusion criteria were that the records involved pharmaceutical counterfeiting incidences that (1) occurred between 2000 and 2015 and those that occurred outside this period were excluded (2) involve pharmaceutical products, and incidences not involving pharmaceutical products were excluded, and (3) the incidence must have occurred or penetrated the US market. The ICPSR 37177 data did not contain any personally identifying information, so no anonymization needed to be conducted. Using a supplementary Excel file provided with the ICPSR 37177 data, the researcher then

separated out Florida records from the wider national estimate and created a binary variable (Florida/National) in SPSS to facilitate the conducting of a comparative analysis.

Data Analysis Plan

For each of the variables outlined above, the research will first use SPSS to run descriptive statistics to characterize Florida and national estimates. For continuous variables, the following descriptive statistics were calculated: mean, standard deviation, and min/max values. For nominal variables, frequency counts and percentages were calculated. A descriptive narrative that summarizes key differences between the descriptive statistics of the Florida and national estimates was created before moving forward with the conducting of inferential statistical analysis to determine if these descriptive differences were statistically significant.

To determine if a statistically significant difference between continuous variables exists, an independent samples t-test was conducted. The independent samples t-test is used to compare the means of two independent groups (i.e., the data points in each group are mutually exclusive). A Wilcoxon Signed Ranks test was considered as a non-parametric alternative. To determine if a statistically significant difference between nominal or binary variables exists, a chi-square test was conducted. A chi-square test determines if there is a statistically significant difference between the frequencies of variables. In all cases, statistical significance was defined as a test having a p-value of less than 0.05 per scientific standard.

CHAPTER III

Results

This chapter presents the results of a quantitative study on pharmaceutical counterfeiting using, as secondary data source, the ICPSR 37177 dataset compiled by Sullivan (2018). The ICPSR 37177 data provides a multi-faceted characterization of pharmaceutical counterfeiting operations in the United States (including all 50 states, the District of Columbia, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the US Virgin Islands). The data describes the counterfeiting schemes or operations in place, the offenders who participated in the schemes, and the victims of these schemes. The data included schemes involved in the counterfeiting of food, electronic, and pharmaceutical products. To address the study research questions, we will focus on pharmaceutical counterfeiting as it is the most relevant for human services professionals. Out of the total 196 records in the database, 64% (125/196) were pertained to pharmaceuticals products with the remaining 31% (61/196) and 5% (10/196) pertaining to foods and electronics, respectively.

The data described throughout this chapter contains selected variables characterizing the counterfeiting schemes overall, individual offenders (business entity offenders were not included in the analysis since the focus was on human services which are concerned with individuals), and the victims impacted by these counterfeiting schemes. Since the purpose of this study was to evaluate possible differences between pharmaceutical schemes in the State of Florida and those across the United States, pharmaceutical counterfeiting data associated with the State of Florida was extracted

from the dataset and compared with an estimate of the rest of the United States. The national data was calculated with all remaining states and territories except Florida.

To address the research questions in this investigation, a comparative analysis of the trends and particularities of the pharmaceutical counterfeiting operations, the individual offenders and the victims in Florida versus the operations occurring elsewhere in the United States was conducted. Descriptive and inferential statistics were calculated for pharmaceutical counterfeiting variables sets which are grouped into three theoretical constructs:

1) A counterfeiting scheme was the basic unit of analysis of the ICPSR 37177 data Its defined as the overall operation of the counterfeiting crime and the components necessary to carry it out (Sullivan, 2018, p.3).
2) An individual offender included a person indicted in a US court for participation in activities relating to a counterfeiting scheme (Sullivan, 2018, p.4).
3) A victim was either a trademark owner (of a counterfeited product) or an individual consumer who suffered direct harm as a result of the operations of the counterfeiting scheme (Sullivan, 2018, p.4).

Although each of these theoretical constructs represent several individual variables (cite here the coding PDF), for the purpose of this study some variables (e.g, those of jurisprudential nature) were excluded focusing on those characteristics that were considered most relevant from a human services point of view or perspective.

Section 1a pharmaceutical counterfeiting schemes. Table 4 A, B summarizes the descriptive statistics for the pharmaceutical counterfeiting operations or schemes in Florida (A) vs National data (B)

Table 4 A, B

Descriptive Statistics of Pharmaceutical Counterfeiting Schemes Florida (A) vs. National (B)

	Florida	National
Length of Scheme in Years	*M* = 3.36, *SD* = 1.90 Range [1-7]	*M* = 3.03, *SD* = 2.27 Range [1-13]
Number of Unique Counterfeited Products	*M* = 3.0, *SD* = 2.7 Range [1-10]	*M* = 3.01, *SD* = 4.38 Range [1-40]
Number of Unique Counterfeited Products Seized	*M* = 1.82, *SD* = 1.66 Range [0-6]	*M* = 2.26, *SD* = 1.67 Range [0-7]
Number of Individual Counterfeited Items Seized	*M* = 173,124, *SD* =502,410 Range [90-1,600.000]	*M* = 81,092, *SD* = 236,653 Range [0-1,600.000]
Market Value of Counterfeited Products Seized (in millions of US dollars)	*M* = $2.3, *SD* = $3.4 Range [$2.31-$9.8]	*M* = $2.7, *SD* = $6.6 Range [$3.5-$2.9}
Estimated Illicit Revenue Generated by Scheme (in millions of US dollars)	*M* = $9.9, *SD* = $12.2 Range [$78-$129]	*M* = $4.9, *SD* = $11.8 Range [$0-$78}

In terms of the descriptive variables for counterfeiting schemes summarized in Table 4, the average length of the operations in years, the number of counterfeited products, and the seized products do not seem to differ much when comparing Florida with the national estimate. Interestingly, on average twice as many counterfeited items (2.1, 173,174/81,092) were seized in Florida than those seized in the national estimate. In addition, the average illicit revenue generated by Florida schemes, in US million dollars, was almost three times more ($9.9/$3.5, 2.8) than the illicit revenue generated by national counterfeiting schemes

To determine if there was a statistically significant difference in the above scheme descriptive variables between the Florida and the national estimate, a series of independent samples *t*-tests were calculated comparing the means of both samples for each variable or scheme descriptor. The results of the inferential t-tests are summarized in Table 5.

Table 5

Results of t-Tests on Descriptive Statistics of Pharmaceutical Counterfeiting Schemes

Variable	***df***	***t*-statistic**	***p*-value**	**Significance**
Length of Scheme in Years	99	-0.58	0.563	Not significant
Number of Unique Counterfeited Products	122	0.008	0.993	Not significant
Number of Unique Counterfeited Products Seized	72	0.942	0.349	Not significant
Number of Individual Items Seized	9.926	-0.677	0.515*	Not significant
Market Value of Counterfeited Products Seized (in millions of US dollars)	30	21.578	0.773	Not significant
Estimated Illicit Revenue	12.786	-1.082	0.299*	Not significant

Generated by Scheme (in millions of US dollars)						

Note. * Indicates *t*-test for equal variance not assumed

Based on the results given in Table 5, despite the observed differences in the means of the number of individual items seized and estimated illicit revenue generated by the scheme, none of the comparisons between any of these variables reached statistical significance.

Section 1b pharmaceutical counterfeiting schemes impact on victims. Another aspect that was evaluated when comparing pharmaceutical counterfeiting schemes in Florida versus the national estimate was variables relating to the victims of each scheme. Table 6 A, B shows the victims characteristics in Florida (A) and in the national estimate (B)

Table 6 A, B

Victims of Schemes Characteristics: Florida (A), National (B)

	Florida	National
Number of Consumer Victims	*M* = 208, *SD* = 443 Range [1-4000]	*M* = 503, *SD* = 1,119 Range [1-1,000]
Trademark Owner Victims	*M* = 2.5, *SD* = 1.9 Range [1-7]	*M* = 2.5, *SD* = 1.8 Range [1-10]
Percent of Victims with Physical Injury	4/14, 22.2%	9/98. 8.4%
Domestic Reach (N of US States Associated with Scheme)	*M* = 3.3, *SD* = 3.5 Range [1-13]	*M* = 1.5, *SD* = 1.1 Range [0-7]
International Reach (N of Non-US Countries Associated with Scheme)	*M* = 1.2, *SD* = 2.1 Range [0-7]	*M* = 1.4, *SD* = 1.5 Range [0-7]

Note that the average number of consumer victims in the national estimate is 2.4 times (503/208) than that of the Florida estimate. However, likely due to the large variability this difference did not reach statistical significance when comparing consumer victims means with an inferential *t*-test (t (15) = 0.530, p = 0.604). Similarly, Florida operations showed a higher percentage of victims who experienced physical injury or harm than national operations (22.20% versus 8.40%), however this difference was not statistically significant with a chi-square test (χ^2 = 3.154, p = 0.076). There was however a marked difference in the domestic reach of pharmaceutical operations. Florida schemes, on average, involved more US states than the National estimate (3.28 states for Florida versus 1.51 states for national). This suggests that Florida pharmaceutical counterfeiting operations are more ingrained in the domestic network than in the international counterfeiting network. The results of an independent samples *t*-test (equal variances not assumed) revealed that this difference in means is statistically significant: (t (17.566) = -2.145, p = 0.046).

Section 2a individual offender demographic results. Understanding the demographic profile of those individual offenders who engaged in pharmaceutical counterfeiting is particularly important from a human services perspective. Out of the 13 variables associated with the individual offender data (see methods for the variables codes and specifications), 10 individual offenders variables pertaining to demographics characteristics were selected as being most relevant from human services perspective. Those variables related to criminological aspects were not included. Overall, there were 273 records of offender data compiled in the database, 52 records were from Florida and the remaining 221 from other states and territories in the US. The individual offender

variables included in the analysis as well as the offender's demographics information are summarized comparatively in Table 7 A, B.

Table 7 A, B

Individual Offenders Characteristics: Florida (A) vs National (B)

	Florida	National
Sex	MALE = 72/85, 84.7% FEMALE = 13/85, 15.3%	MALE = 303/368, 82.6% FEMALE = 64/368, 17.4%
Race	WHITE = 45/67, 67.2% BLACK = 0/67, 0% HISPANIC = 21/67, 31.3% ASIAN = 0/67, 0% MIDDLE EASTERN = 1/67, 1.5%	WHITE = 174/368, 61.7% BLACK = 12/368, 3.3% HISPANIC = 36/368, 12.8% ASIAN = 30/368, 10.6% MIDDLE EASTERN = 30/368, 10.6%
US Citizen	YES = 3/85, 3.5% NE = 82/85, 96.5%	YES = 52/368, 14% NE = 316/368, 86%
Employment Facilitated	YES = 30/85, 35% NE = 55/85, 65%	YES = 150/368, 41% NE = 218/368, 59%
Non-Intellectual Property Offenders	YES = 76/85, 89% NE = 9/85, 11%	YES = 289/368, 79% NE = 77/366, 21%
Intellectual Property Offenders	YES = 15/85,18% NE = 70/85, 82%	YES = 154/366, 42% NE = 212/366, 58%
Convicted	YES = 56/62, 90%	YES = 290/321, 90%

	NE = 6/62, 10%	NE = 31/321, 10%
Probation	YES = 15/55,27 % NE = 40/55, 73%	YES = 71/300, 24% NE = 229/300, 76%
Deported from US	YES = 0/67, 0% NE = 67/67,100 %	YES = 7/325, 2% NE = 318/325, 98%
Fugitive	YES = 1/67, 1.4% NE = 66/67, 98.6%	YES = 14/325, 4% NE = 311/325, 96%

There are some aspects to the individual offenders' demographics data that should be noted. First, the racial distribution of individual offenders differs between the Florida and national estimates. The national estimate is more diverse with offenders representing all five races. In the Florida estimate, there were no Black or Asian offenders, but there was a higher percentage of Hispanic offenders. Second, a relatively small proportion of the offenders reported US citizenship in the Florida estimate (3.5%) whereas 14% of offenders reported US citizenship in the national estimate. In terms of the type of offense, it seems that intellectual property offenders are more frequent in the National estimate than in Florida (42% vs 18%) whereas non-intellectual property offenders are similarly distributed (89% in Florida vs 79% in National). To determine if these observations were statistically significant, a chi-square test was performed and is reported in Table 8 below.

Table 8

Results of Chi-Square Analysis on Individual Offender Data

Variable	**$\chi 2$**	***df***	***N***	***p***	**Significance**
Sex	0.225	1	349	0.636	Not significant
Race	26.774	4	452	<0.001	Significant
US Citizen	7.275	1	453	0.007	Significant
Employment facilitated	0.862	1	453	0.353	Not significant
Non-Intellectual Property Offenders	4.881	1	451	0.027	Significant
Intellectual Property Offenders	17.570	1	451	<0.001	Significant
Convicted	0.000	1	383	0.996	Not significant
Probation	0.329	1	355	0.566	Not significant
Deported	1.469	1	392	0.225	Not significant
Fugitive	1.196	1	392	0.274	Not significant

The results of the chi-square test revealed that there are indeed statistically significant differences between the frequencies of offenders' race and citizenship reporting. In addition, there was a statistically significant difference between the frequencies of non-intellectual and intellectual property offenders between the Florida and national estimates.

Section 2b *individual offender conviction results.* Although the above chi-square analysis in Table 8 did not reveal a statistically significant difference between the frequencies of offender convictions between the Florida and national estimates within the individual offender data, the scheme-level provided information about the number of individuals convicted in each scheme thus allowing us to determine if there is a statistically significant difference between the mean of individuals convicted. The 18 Florida schemes demonstrated a greater number of individuals convicted (M = 6.00, SD = 9.780) when compared to the 107 national schemes (M = 1.73, SD = 1.574). An independent samples t-test (equal variance not assumed) revealed that this difference in means is, however, not significant (t (17.156) = -1.850, p = 0.082) thus corroborating the above frequency comparison.

Section 3 additional victim data. The analysis presented in Section 1b above utilized victim-related data from the scheme-level dataset. The ICPSR 37177 database also contains data relating directly to the victims of the various pharmaceutical counterfeiting schemes. Although this data is impoverished (the Florida estimate has only four data points) and thus no inferential statistics could be reliably conducted on the differences between the Florida and national estimates, the data still provides us with valuable insights from a human services perspective. The average age of a victim was

34.36 years, 61.9% were male, and 0% could be determined to have US citizenship. The race data for national victims is particularly impoverished with only two individuals known to be White. Approximately one-quarter (23.3%) of victims had a relationship with an offender in a pharmaceutical counterfeiting operation and there were 12 known instances of death (representing 40% of the sample) and seven instances of physical injury (represent 23.3% of the sample) associated with these 30 victims. The lack of data for victims is meaningful and is indicative that victims of pharmaceutical counterfeiting schemes are not well understood, and better data collection metrics are needed to understand the impact of pharmaceutical counterfeiting on the individual.

CHAPTER IV

Discussion

This study offered a comparative analysis of pharmaceutical counterfeiting schemes, individual offenders of those schemes, and victims impacted by the schemes in the State of Florida versus a wider national sample. Three research questions guided this study, and the results presented in Chapter III will be discussed below vis-à-vis these three research questions.

Research Question 1

The first research question of this study was: *What are the differences between pharmaceutical counterfeiting schemes in the State of Florida when compared to schemes from a national estimate?* Three key differences in pharmaceutical counterfeiting schemes emerged from the data analysis of the ICPSR 37177. The first involves the scope of products being counterfeited and the revenue associated with those products. Although Florida schemes counterfeited a lesser number of unique pharmaceutical products and had a larger number of individual units of the products (e.g., pills) confiscated upon discovery of the scheme, Florida schemes still generated nearly three times as much illicit revenue than schemes in the national estimate. The second trend that emerged is that Florida schemes are more ingrained in the domestic counterfeit market than the international market. This means that despite its geographical location to the location of counterfeiting production in Latin America and the Caribbean, Florida schemes have a greater number of connections to schemes in other US States rather than schemes in other countries. The third trend that emerged is that the pharmaceutical products produced by Florida schemes caused greater harm to victims who purchased

those products from the scheme, indicating that counterfeiting pharmaceutical projects produced or procured by Florida schemes are of lower quality such that they result in death or injury.

Overall, the differences found in Florida schemes and their impact on victims compared to the national situation suggest that this state may be a key conduit for introducing counterfeited pharmaceutical products into the US domestic market. Some underlying factors could be considered. Florida is geographically the closest US state to the wider Latin American and Caribbean region. According to Hussaini et al., (2023), the incidence of pharmaceutical counterfeiting in this region is upwards of 30% of the market share (as compared to 10% worldwide as noted by Uddin, 2021 in Chapter I). Given that Florida is a key trade and tourist gateway with numerous seaports and airports (Florida Seaport Transportation and Economic Development Council, 2024). This fact may facilitate money laundering activities from organized crime and make Florida well-situated to act as an initial entry into the US domestic market for such a large body of counterfeit pharmaceuticals. Thus, it is important for human services professionals in Florida to be aware of these particularities and the risks involved for the potential victims and recipients of such products. Moreover, the current study shows that the counterfeited products in Florida seem to be causing more harm to victims compared to the national trend with Florida victims having more than a double chance of suffering injury than victims from national schemes (22.2% versus 8.4%, respectively). This finding suggests that the operational schemes in Florida are introducing poorer quality products. From a human services perspective, this would be important knowledge and would provide the basis to educate consumers on the dangers of purchasing illicit pharmaceutical products

or recognizing the fact that they are purchasing such illicit items, especially given the demand for pharmaceuticals overall in Florida according to the Drug Enforcement Administration (DEA) (2021) who states that "the state [Florida] remains a focal point for counterfeit pharmaceuticals due to its high demand for prescription medications."

US Reports from the National Institute on Drug Abuse suggest that, from 2018 to 2024, there has been a rising trend in the seizure of counterfeit and unapproved pharmaceuticals at Florida ports, which is reflected in the present study's finding that a greater number of individual counterfeited items were seized from Florida schemes than the overall national estimate. This study states that US Customs and Border Protection (CBP) has increasingly intercepted shipments containing opioids, erectile dysfunction pills (a fact borne out by the Sullivan, 2018 study), and other controlled substances, which not only pose health risks but also generate substantial illicit revenue for traffickers (National Institute on Drug Abuse, 2023) as evidence by the three times greater amount of illicit revenue generated by Florida schemes. From a human services point of view, these operations underscore the ongoing challenges faced by law enforcement in addressing the nexus between pharmaceutical fraud and drug trafficking, highlighting the need for continued vigilance and enforcement efforts (Gordon & Maloney, 2022).

Research Question 2

The second research question was: *What are the differences between the individual offenders associated with pharmaceutical counterfeiting schemes in the State of Florida when compared to individual offenders in a national estimate?* Two differences emerged from the analysis of the individual offender data. The first difference

was evidenced in offenders racial and ethnic distribution. Although the offenders in both the Florida and national estimates were mostly White (67.2% in Florida and 61.7% in National) there were particularities in the Florida data showing less racial diversity (as evidenced by the absence of Black and Asian offenders), but a higher percentage of Hispanic offenders. This corroborates 2020 US Census data that shows that Hispanics are an important minority group that represents 18.7% of the population (US Census, 2020).

A second difference evidenced in this study for offender's data is the intellectual property protection status of the pharmaceutical products being counterfeited. A protected product means that a company has paid for the product to be registered thus placing it under copyright protection. Offenders participating in Florida counterfeiting schemes were more frequently involved in counterfeiting non-protected products, whereas offenders participating in schemes from the wider national estimate were more involved in counterfeiting protected products. These findings could have two implications. The first might be that Florida operations are specifically targeting non-protected products on purpose given there are less legal protections afforded for such products. Another explanation could relate back to the fact that Florida is a conduit for the aforementioned 30% market share of counterfeit drugs from the Latin American and Caribbean region.

Research Question 3

The third and final research question was: *What are the differences between the conviction rates associated with pharmaceutical counterfeiting schemes in the State of Florida when compared to conviction rates in a national estimate?* A higher conviction rate was noted in Florida schemes when compared to the national estimate.

The overall results in this study showing particularities in Florida counterfeiting schemes and offenders' demographics that may be likely associated with Florida's geographic location and higher percentage of Hispanic offender's participants may be consider as facilitators for this type of illicit operations. According to the U.S. Department of Justice (2022), "demographic trends in drug-related offenses show significant variations by state, with Florida exhibiting a unique profile." The unique diversity distribution in Florida schemes is supported by this Department of Justice (DoJ) report and underscores the need for targeted law enforcement interventions.

Another insight these results provide involves the strategy of offenders, when choosing which products to counterfeit. The intellectual property protection status of counterfeited pharmaceutical products plays a critical role in this issue. The fact that Florida offenders engage in the counterfeiting of non-protected drugs indicates that these individuals are aware of the protection status and view them as easier targets. A protected product indicates that a company has invested in registering it, thereby affording it trademark and copyright protection. Bansal (2021) notes that "the enforcement of intellectual property laws is crucial in combating the prevalence of counterfeit pharmaceuticals," emphasizing that robust protections can deter offenders and safeguard public health. The fact that Florida schemes generate three times more revenue than national schemes could be evidence that the strategy of targeting unprotected products is lucrative for these individuals and their schemes and that from a Human Services perspective greater collaboration between pharmaceutical firms, law enforcement, and intellectual property agencies is needed to mitigate this key source of illegal drugs and revenue. These insights highlight the complex interplay between demographic factors and

intellectual property rights in the fight against pharmaceutical counterfeiting and illustrate the role a human services professional can play in the fight against counterfeit drugs.

Our results indicate that law enforcement in the State of Florida is more effective in identifying pharmaceutical counterfeiting schemes compared to the national estimate. The ICPSR 37177 indicates that the prosecutorial jurisdiction of most schemes is federal, however, Florida state law enforcement has a reputation for valuing collaboration and cooperation with federal agencies thus indicating a possible source for the higher conviction rates. The U.S. Department of Justice (2022) indicates that "Florida's legal framework, combined with focused law enforcement efforts, has resulted in a greater likelihood of successful prosecutions in cases of pharmaceutical counterfeiting." This heightened conviction rate can be attributed to the state's proactive measures, including collaborative efforts between local, state, and federal agencies to dismantle organized crime networks involved in these schemes. Furthermore, Gordon and Maloney (2022) highlight that "increased public awareness and regulatory scrutiny have created an environment where offenders are more likely to face legal consequences." Leveraging dynamics will only serve to deter future offenses but also highlight the importance of continued vigilance and resource allocation to combat the ongoing challenge of counterfeit pharmaceuticals in Florida.

Contributions

This study contributes significantly to the Human Services field by illuminating the intricate relationship between pharmaceutical counterfeiting and public health awareness of the consequences of pharmaceutical counterfeiting. By analyzing the trends specific to Florida, it provides a comprehensive understanding of how counterfeit

medications affect vulnerable populations, particularly those reliant on consistent and safe access to pharmaceuticals. This research study underscores the critical role of human services professionals in recognizing the signs of counterfeit medications and advocating for policy changes that strengthen consumer protection. By enhancing their knowledge of these trends, future professionals can be better equipped to address the challenges posed by counterfeit pharmaceuticals and develop targeted interventions that protect community health.

Furthermore, this study emphasizes the importance of interdisciplinary collaboration among human services professionals, law enforcement, healthcare providers, and regulatory agencies. It highlights how such partnerships can foster a holistic approach to combating pharmaceutical counterfeiting, ultimately leading to stronger regulatory frameworks and increased public awareness. Future human services professionals can take these insights and implement proactive measures in their practice, contributing to community resilience against the threats posed by counterfeit medications. By integrating these lessons into their training, they will be better positioned to advocate for vulnerable populations and work towards safeguarding the integrity of pharmaceutical supply chains, enhancing overall community well-being.

Limitations

Some limitations emerged from the use of a protected, secondary data set. From a research design point of view, a key limitation is that any study is bounded and constrained by the data contained within the secondary source. Although the ICPSR 37177 data provided a codebook that outlined all the variables contained therein, upon receipt of the data, it was clear that many of the variables were impoverished and had a

high degree of missingness. In addition, the separate nature of the scheme, individual offenders, and victim data made it difficult to make a combined dataset in which individual offenders and victims could be linked to specific schemes. These limitations made it difficult to construct a quantitative model that looked at deeper relationships between the scheme, offender, and victim data.

Another limitation that arose as a function of the high degree of missing data was that it reduced the power of the statistical analyses performed. When comparing the Florida and national estimates data some differences variables did not reach statistical significance because of i) the differences in sample size (i.e., Florida had much fewer data points) and ii) the high degree of data missing within both the Florida and the national estimates.

Future Research

Future research should explore the motivations and behaviors of individuals involved in the pharmaceutical counterfeiting supply chain. Understanding the socio-economic and psychological factors that drive counterfeiters can provide insights into how to develop more effective prevention strategies. Qualitative studies, such as interviews or focus groups with law enforcement officials, pharmacists, and even individuals caught in the counterfeit trade, could illuminate the complexities of this issue. Additionally, examining the role of organized crime in pharmaceutical counterfeiting in Florida could reveal deeper connections and strategies used by these groups, informing targeted law enforcement efforts.

Another important area for future research is the evaluation of existing technological interventions aimed at combating pharmaceutical counterfeiting. As

advancements in serialization, blockchain technology, and authentication methods continue to evolve, it is essential to assess their effectiveness in real-world applications. Future studies could conduct longitudinal analyses to determine the impact of these technologies on reducing counterfeit incidents in Florida. Furthermore, research could investigate consumer awareness and attitudes toward counterfeit medications, identifying gaps in knowledge that could be addressed through public health campaigns. This multifaceted approach will contribute to a more comprehensive understanding of the landscape of pharmaceutical counterfeiting and enhance the efficacy of interventions.

Recommendations

The infiltration of counterfeit pharmaceuticals poses a critical threat worldwide. The results of this study suggest that Florida is a microcosm of the trends that have emerged both in the wider United States and internationally. As a gateway for international trade and tourism, Florida acts as a conduit into the United States for the influx of counterfeited medications, thus making it an important locus of study to better understand how to mitigate pharmaceutical counterfeiting and how human services professionals can better inform their practices. By collaborating with law enforcement, healthcare providers, and regulatory agencies, they can enhance awareness, strengthen regulatory frameworks, and ensure the integrity of pharmaceutical supply chains. Through proactive measures and interdisciplinary cooperation, human services professionals can mitigate the impact of counterfeit pharmaceuticals, safeguarding communities in Florida and across the United States from this pervasive threat.

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APPENDIX A

BRANY SBER IRB

BRANY

BRANY SBER IRB

DATE: 04/12/2023
TO: Maria Perez, MD, PhD
CC: Study-Site Contacts
FROM: Raffaella Hart, MS, CIP, BRANY SBER IRB (IRB00010793)

SUBMISSION TYPE: SBER-Initial Review (#212054)
PROTOCOL NUMBER: 23-066-447M
SITE(S): Carlos Albizu University - Miami Campus
STUDY TITLE: Understanding Trends in Pharmaceutical Counterfeiting in Miami Dade Florida: A Quantitative Descriptive Study Using Secondary Data

IRB DETERMINATION: **NOT HUMAN SUBJECT RESEARCH**

DETERMINATION DATE: 04/12/2023
EXPIRATION DATE: NA
REVIEW TYPE: Not Human Subject Research

Thank you for your submission for the above-referenced study.

1. **BRANY SBER IRB Determination**
   The BRANY SBER IRB has determined the activity mentioned above **does not constitute research involving human subjects** that is regulated by DHHS or FDA regulations and is therefore not subject to further BRANY SBER IRB review.

   This determination requires that all procedures and activities are performed in accordance with relevant state law.

2. **Documents Acknowledged with this Submission**
   a. Approval from ICPSR (Submitted Item(s))
   b. BRANY LRC Form_20210720 03302023.docx (Local Research Context)
   c. citiCompletionCertificate Gorka Meneses_11834407_53425752 (2).pdf (Human Sub. Prot. Training)
   d. Conflict of interest Form GM 0330202314..pdf (COI Disclosure Form)
   e. Explanation of Data Analytic Sheet Secondary Data Gorka I Meneses 03292023.docx (Data Collection Tool)
   f. Funding Data_The data will be obtained from the ICPSR 37177 database.docx (Funding documentation)
   g. ICSPR #37177 Study Letter Signed by Director AJ Million 02032023.pdf (Data Collection Tool)
   h. IRB Certificate Gorka Meneses (3).pdf (Human Sub. Prot. Training)
   i. IRB Conflict of Interest M Perez Abalo signed 2023-03-08.pdf (COI Disclosure Form)
   j. Protocol Gorka I Meneses 03252023.docx (Protocol)
   k. Protocol Gorka I Meneses 03252023.docx (ICF/Assent/Adden Submitted)
   l. SBER Study Application-2023-03-31-23-10.pdf (Application)
   m. Secondary Data from Data Base_Excel Analytic Sheet G.Meneses.xlsx (Data Collection Tool)
   n. VITA Gorka I Meneses 03252023.docx (CV)

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BRANY SBER IRB

3. **Provisions of BRANY SBER IRB's Determination**
   Although BRANY SBER IRB determined this activity is not research involving human subjects and the activity does not require for IRB review, any proposed changes must be reviewed by the BRANY SBER IRB prior to implementation. The BRANY SBER IRB will evaluate the proposed change(s) and determine whether the changes constitute human subjects research.

If you have any questions or require any additional information, please call me at 516-470-6909 or send an email to me at rhart@brany.com. Thank you.

APPENDIX B

JOURNAL SUBMISSION

From: notifications@email.scholasticahq.com <notifications@email.scholasticahq.com> on behalf of Scholastica Notifications <notifications@email.scholasticahq.com>
Sent: Tuesday, December 10, 2024 9:54 PM
To: Meneses, Gorka <gmeneses102@albizu.edu>
Subject: Successful submission of manuscript Trends in Pharmaceutical Counterfeiting in Florida: A Quantitative Study Using Secondary Data to Journal of Human Services

Your modern academic journal management platform

Hello Gorka Meneses,

"Trends in Pharmaceutical Counterfeiting in Florida: A Quantitative Study Using Secondary Data" has been **successfully submitted** to *Journal of Human Services*. **The editors have been notified**.