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U.S. Patented Medication Prices Too High to Warrant Affordable Costs by Patients

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This is to certify that the doctoral dissertation by

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Abstract

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by

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Master of Philosophy, Walden University 2021

MBA, Fontbonne University, 2013

BS, University of Missouri, 2011

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Management

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11 December 2024

Abstract

Optimal pricing of patent medicines is needed to ensure profitability of pharmaceutical companies while managing ease of access to these medicines for patients. The general problem that necessitated this study was that the prices of most patent medications in the United States are too high to warrant affordable costs by patients while simultaneously fostering drug innovation. The purpose of this qualitative multiple case study was to explore the best practices for ensuring equal access to patent medicines while maintaining profitability of pharmaceutical companies to pursue needed innovation and development of new drugs. This study was underpinned by Bandura’s social cognitive theory and the self-efficacy concept and guided by a qualitative methodology with a case study design. Data sources were semistructured interviews conducted online via Zoom, and document analysis of relevant reports and written manuals about the phenomenon. Participants were 17 pharmaceutical industry experts with 10 years of experience and at least 3 years in a managerial-level position in the departments of research and development, marketing, and/or finance and who also held at least a master’s degree. Thematic analysis led to the identification of three themes: (a) implementing strategic and operational practices, (b) policy and regulatory reforms, and (c) pricing and accessibility strategies as best practices in ensuring equitable access to patent medicine while maintaining profitability. The results of this study have potential implications for positive social change that include reducing the high prices of patent drugs, which could lead to improved access to medications, and improved access to medications would enhance health for all.

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Dedication

This study is dedicated to my parents who passed away. I wish they were here to witness the outcomes of the sacrifice they made sending me to the United States to pursue education with the last money they had. I also dedicate this study to those most affected by the phenomenon of the study: patients who are unable to access patent medications due to high prices.

Acknowledgments

I would like to thank my committee chair, Dr. Hyuk Kim. Without you, I would not be here. I am very grateful for your support and guidance during this process. Your prompt feedback in the process was very helpful, and I am glad that you accepted to be my chair in this process. I would also like to thank my second committee member, Dr. Stephen Tippins. Your guidance and feedback on my content was very helpful. I also thank you for accepting to be my second committee member in this process. Finally, I wish to thank my family and friends for their support and understanding throughout this dissertation journey.

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Chapter 1: Introduction to the Study

The topic of this study was balancing access to patent medications with the profitability of pharmaceutical companies. Patent medicines are known to be expensive, especially those for treating rare diseases (Cherla et al., 2021). Two major opposing factors affect the dynamics of patented drugs distribution, sales, and consumption: drug prices and accessibility. Having significant inclination to one factor as opposed to the other may lead to extremely negative results for the individuals and parties involved. The potential social implications of this study stem from the need to balance initiatives to keep prices reasonable and drugs accessible to patients while maintaining profitability for pharmaceutical companies, maintaining patent protection and simultaneously protecting patients from unreasonable prices.

The contents of Chapter 1 are focused on the development and presentation of the problem, purpose, and research questions of the study, which are the foundation of the subsequent chapters of the study. The themes discussed in this chapter encompass the background, in which I provide a brief overview of the problem under study. Next, I present the problem and purpose of the study followed by the research questions. I then describe the theoretical foundation followed by the nature of the study in which a quick recap of the methodology is provided. After defining the key concepts of the study, I provide a discussion of the assumptions, scope and delimitations, limitations, and significance of the study. At the end of the chapter, a summary is provided.

Background of the Study

Different policies govern the patenting of drugs for the protection of the manufacturer and the consumer (Cherla et al., 2021). Patent medicines are usually priced higher than generic and more common medicines (Cherla et al., 2021; Gøtzsche, 2018a; Pandey & Paul, 2019; Stiller et al., 2022). Patented drugs are priced higher to recoup the costs of research and development for the drugs (Gøtzsche, 2018a). The implication of such high prices of patent medicines is the increased monopoly of some pharmaceutical organizations (Pandey & Paul, 2019). Because of the high prices of patent medicines, patients' access to these drugs is lower (Boggio & Ho, 2018). Boggio and Ho (2018) highlighted that higher prices of patent medicines may be a hindrance to the right to access science and technological advancements, including these patent medicines. In other cases, anomalies have been uncovered, wherein pharmaceutical companies were blamed for manufacturing patented drugs that were not different from the existing drugs during the patent duration (Stiller et al., 2022). Aggarwal et al. (2020) added that corruption through patent pricing has been on the rise without impeded innovations. Pharmaceutical companies are manufacturing drugs that have no extra benefits compared to the existing drugs (Stiller et al., 2022).

Ensuring equal access to patent medicines while maintaining profitability has remained a challenge. The high prices have been reported in both developing and developed countries where cases of patient exploitation and other medical malpractices are high (Inotai & Kaló, 2019; Jenei et al., 2022). Simmons et al. (2019) explained this phenomenon further, noting that the practice of selling drugs and vaccines in developing countries at prices substantially lower than in industrialized countries has been rampant in recent years. This trend can be attributed to the widespread support received over the past 2 years from policymakers, academics, and civil societies in a bid to enhance access to medicines for people living in poverty. Despite these efforts, several shortcomings have been tied to tiered pricing (Burrone et al., 2019). For instance, this model is not only inferior when competing firms are allowed to attain the lowest sustainable prices, but it also often involves arbitrary divisions of markets and/or countries, especially for patented drugs (Inotai & Kaló, 2019). This outcome explains why in many developing countries, resources are often so stretched that medicines can only be affordable by selling them at or near the cost of production (Burrone et al., 2019).

In this study, I explored the balance between pricing of patent medicines to ensure the profitability of pharmaceutical companies while promoting patients' access to these medicines in the United States. Based on Bandura's (2000) social cognitive theory, the concept of self-efficacy was used to explore experts' views on how to reduce the high price of patent medications sold by pharmaceutical companies. Yılmaz et al. (2019) stated that social learning occurs mostly through others and experience through observation. The findings of this study may reveal the best practices that could lead to equal access to patented drugs in the United States.

This study may bridge the research gap on the best practices for ensuring consumers' improved access to patent medicines, while maintaining profitability for pharmaceutical companies to pursue needed innovation and development of new drugs. By demonstrating the research problem and the possible impact associated with high prices of patented drugs in the United States, this study may serve as a learning paradigm for experts in the pharmaceutical industry in terms of understanding how to reduce the high prices of patent medications. Cherla et al. (2021) affirmed that the patent, which is meant to promote innovations, also impedes innovations because of the exclusive rights associated with unjustifiable broad scope of protection of the patentee. In this area, researchers have often focused on the exclusive rights that impede the innovations and competition that could have been provided by generics. Yılmaz et al. (2019) highlighted that social learning occurs through observation and the experience of others.

This study may bring a positive social change to the community by providing information that U.S. Congress can use as basis to enact effective laws for controlling the overpricing of drugs to enhance patients' access to medications at reasonable prices. This study may provide information on workable approaches the United States can apply to innovate and develop new drugs in cost effectively, thereby addressing the issue of high pricing of the patent medicines sold by the pharmaceutical companies. The findings may help future researchers explore further the high pricing of patent medicines. Reducing the high prices of these drugs could help foster positive social change by impacting the community through patients' improved access to medications. The findings from this study may enhance health for all through improved access to medications.

Problem Statement

The general problem that necessitated this study was that the prices of most patent medications in the United States are too high to provide affordable costs for patients while fostering drug innovation (Gøtzsche, 2018a; Saluja et al., 2018). The situation or issue that prompted the search of the literature was the high prices of some patent medications within the United States, which affect society by being unaffordable to patients and causing problems with balancing and easy access to these medications (Saluja et al., 2018; Stiller et al., 2022). The specific research problem addressed in this study encompasses the best practices for ensuring equal access to patent medicines while maintaining profitability to pursue needed innovation and development of new drugs (Prager et al., 2018; Saluja et al., 2018). Saluja et al. (2018) stated that high prices of patent medicines may harm patient health through increased out-of-pocket expenses, which decrease patients' access to these medications and possibly reduce patient outcomes that the medication may provide.

Stiller et al. (2022) echoed the public outcry against pharmaceutical companies for manufacturing and marketing drugs that do not provide significantly improved benefits compared to existing drugs but retain patent protection. Pharmaceutical companies argue that patents and high drug prices are needed to recoup the costs of research and development and to ensure a sufficient supply of new drugs to the market (Gøtzsche, 2018a). Pharmaceutical companies further argue that reducing the prices of patented drugs could decrease their profit margins, potentially affecting the development and innovation of new drugs (Saluja et al., 2018).

Purpose of the Study

The purpose of this qualitative multiple case study was to explore the unknown best practices for ensuring equal access to patent medicines while maintaining the profitability of pharmaceutical companies to pursue needed innovation and development of new drugs and ensure business sustainability. Bandura’s (2000) concept of self-efficacy served as a lens for understanding the high pricing of patent medications sold by pharmaceutical companies. This concept helped me explore the ways to improve access to patent medicines by patients while maintaining optimal profitability for pharmaceutical companies based on data from pharmaceutical company experts, in-depth semistructured interviews, and document analysis. The analytical tool used for processing the data was thematic analysis.

Research Question

The following research question guided the current study:

RQ: What are the best practices for ensuring equal access to patent medicines while maintaining profitability of pharmaceutical companies to pursue needed innovation and development of new drugs and ensure business sustainability?

Theoretical Foundation

The theories and/or concepts that grounded this study include Bandura’s (2000) social cognitive theory and the concept of self-efficacy. The high prices of patent medicines could slow innovation in the pharmaceutical industry if there is no quick response to concerns related to the current patent system. The industry is monopolized by a few companies with patents, which discourages potential innovators because of the unbalanced rights of copying versus exclusive economic benefits.

Social Cognitive Theory

This theory helped further understand the study phenomenon. Bandura (2000) defined self-efficacy as the belief in one’s capability to organize and execute the courses of action required to manage prospective situations. Boggio and Ho (2018) emphasized that the government should ensure that intellectual property rights, such as patents, do not hinder access to scientific knowledge. Based on Bandura’s concept of self-efficacy, experts may explore how to reduce the high prices of patent medications sold by pharmaceutical companies. The self-efficacy concept references an individual’s belief they can initiate the course of action required to produce a desired outcome (Bandura, 2000). The perceived patent efficacy is defined in the study as a pharmaceutical expert’s belief or judgment about their capabilities to organize and deliver the results related to the high prices of the patent medications. It was important in this study to discuss the issue of having access to essential, life-saving medications. Talevi and Bellera (2020) found that over half a billion people do not have access to medications due to the monopoly caused by patent rights. In the United States, 12.4% of uninsured adults do not have access to the prescription drugs they need due to cost (Tolbert et al., 2022).

Self-Efficacy

Self-efficacy enhances and plays a significant role in influencing people’s daily lives. Unnikrishnan et al. (2018) stated that valuing patients’ rights is the backbone of providing good healthcare. This self-efficacy concept helped me to explore the views of participants from pharmaceutical companies through semistructured interviews, which may contribute to establishing effective pathways to reduce the high prices of patent medications. Bandura’s (2000) social cognitive theory has been used extensively in business research. An example is Wang et al. (2019), who used social cognitive theory to explore the motivations of business owners in the field of tourism. In the current study, this theory helped understand the knowledge acquisition process and rationale for deriving best practices from pharmaceutical experts' responses to ensure consumers' improved access to patent medicines, while maintaining profitability for pharmaceutical companies to pursue needed innovation and development of new drugs. Therefore, the theory served as the foundation for proposing structural changes in the patent medication pricing system.

Nature of the Study

To address the research question for this qualitative study, I used a case study design. This qualitative study involved an exploration of the perceptions of pharmaceutical company experts to identify the best practices for ensuring consumers' improved access to patent medicines while maintaining profitability for pharmaceutical companies to pursue needed innovation and development of new drugs. To gather data, I conducted online semistructured interviews with experts in the pharmaceutical industry via Zoom and performed document analysis of relevant reports and written manuals about the phenomenon. I expected to interview 10–15 participants with the necessary experiences, knowledge, and expertise, a sample that is enough to reach data saturation for case studies (Yin, 2017). The documents analyzed for this study included company publicly available annual reports, company newsletters, and newspaper articles related to drug innovations, drug pricing, medicine patents, and patient usage of patented drugs.

To attain the appropriate sample, I used purposive sampling. The criteria for inclusion of pharmaceutical experts were as follows: (a) pharmaceutical experts with 10 years of experience and at least 3 years in a managerial-level position in the departments of research and development, marketing, and/or finance and (b) pharmaceutical experts with a master's degree or higher. Recruiting pharmaceutical experts with higher education as participants in the study helped enhance the rigor of the research process. The idea was to analyze the collected themes and patterns from the experts and identify themes emerging from the data regarding the best practices for pricing patent medicines in the pharmaceutical industry.

This research approach was based on the work of Yin (2017) regarding case studies. The case study design involves the exploration of a phenomenon in the real-world context, which is bound by a predefined time or space (Yin, 2017). Researchers often use case studies when exploring participants' perceptions about a phenomenon rather than the lived experiences or storied events about the said phenomenon (Yin, 2017). These descriptions are aligned with the requirements of fulfilling the purpose and addressing the research question of this study.

Definitions

Essential medicines: Drugs that "satisfy the priority healthcare needs of the population" and, according to the World Health Organization, they are selected based on their estimated current and future public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness (Urias & Ramani, 2020). Medicines that meet these principles are published in the World Health Organization's model list of essential medicines, an inventory updated every 2 years and tailored to national or regional health needs in a national essential medicines list. Countries can use national lists as a tool to prioritize their most pressing public health needs by focusing on public sector procurement and treatment of a limited and high priority set of medicines (Simmons et al., 2019).

Innovation of drugs: Relative to innovative medicinal products, the activity of coming up with completely new or partially active, or an amalgamation of drug agents that act against a disease, relieve symptoms, or prevent a disease through pharmacological or molecular mechanisms and developed and made available as patented products (Urias & Ramani, 2020).

Intellectual property rights: The rights given to a person or a firm regarding their creation (Angural, 2019).

Patent medicine: A drug sold by a pharmaceutical company under a specific name or trademark protected by a patent (Pensabene & Gregory, 2013).

Patents: A temporary property right on an invention (Chattopadhyay & Bercovitz, 2020). A patent confers so-called *negative rights* that allow the patent holder to exclude others from using their invention. Granted by the state, patents allow companies to control the production, distribution, and use by others and importation and, therefore, the price of the product in question.

Trademark: A distinctive sign, name, symbol, or word that identifies certain goods or services as those produced or provided by a specific person, company, or enterprise (Sharma, 2018).

Assumptions

Assumptions are concepts considered true but cannot be completely proven as such (Theofanidis & Fountouki, 2018). The first assumption for this study was that all the participants for this study would give honest and complete answers during the data collection process. This assumption was necessary because I could not be certain that the participants would give honest answers during data collection. Nevertheless, I reminded the participants to provide accurate and honest answers before conducting data collection. Another assumption was that the data collected would enable me to identify emergent themes relevant to the research question for this study. This assumption was necessary because I could not be certain of the exact information and data to collect from the participants.

Qualitative methodological assumptions consist of the assumptions made by the researcher regarding the methods used in the process of qualitative research (Creswell, 2003). The procedures used by the researcher are inductive and based on their experience in collecting and analyzing data. The research for this study was the product of researcher values. Further, an inductive approach, when used, implies that raw textual data are condensed into a brief summary format to ensure that concise links are established between research objectives and summary findings derived from raw data. In adopting this approach, the research question might be changed in the middle of the study so that the research problem is better understood (Creswell, 2003). Due to this aspect, the strategy for collecting data, which is usually developed before the study begins, may need to be modified to accommodate new questions.

Scope and Delimitations

Delimitations are aspects of a study that a researcher controls to define the scope and boundaries of the research (Theofanidis & Fountouki, 2018). The first delimitation of this study related to the phenomenon of interest: the best practice for ensuring equal access to patent medicines while maintaining pharmaceutical companies' profitability to pursue needed innovation and development of new drugs. This phenomenon aligns with the problem and purpose of the study. No other phenomenon was explored in this study. The second delimitation was the focus on experts' knowledge, perceptions, and experiences about the phenomenon of interest. This delimitation was aligned with the problem of the study. The importance of the experts' opinions and knowledge was established at the beginning of this study. Only by understanding the perceptions and experiences of the chosen sample was I able to answer the research question.

Another delimitation was the collection of data from a small sample of experts. Qualitative research, such as this study, does not require large samples. The important characteristic of data for this type of research is the depth of data collected. Therefore, I ensured data saturation and collection of thick and rich data to improve the transferability of the study. The last delimitation of this study was that the expert participants were volunteers and did not receive compensation for taking part in the study. The data collected were confined to attitudes, knowledge, and experiences of the experts. I anticipated that perceptions and attitudes would vary regarding equal access to patent medicines, given the need to sustain the profitability of pharmaceutical companies to pursue the needed innovation and development of new drugs.

Limitations

Limitations are aspects of a study that are beyond the control of the researcher but may influence the findings of the study (Theofanidis & Fountouki, 2018). This study's findings were limited to the pharmaceutical companies that agreed to participate in the study. Therefore, the current findings may not be relevant to companies from other industries (e.g., medical instrument industry and healthcare services), thus possibly constraining the generalization of the results. The potential limitations and challenges that would be encountered during this research and that may potentially interfere with the validity of the study and its outcomes included the following: (a) difficulty in obtaining the site agreement, (b) recruitment of pharmaceutical experts, (c) the willingness of participants to give information, and (d) the participants' own biases, which were out of the researcher's control. However, the techniques and tools employed to collect the data for this study helped foster a fair process free of bias. The interview guide was field-tested before conducting data collection to minimize bias. I also listed potential sources of personal biases to prevent these from possibly affecting the results of the study. Another potential limitation is the response bias of the pharmaceutical managers.

Research studies are subject to certain limitations that may influence the outcomes. This study was limited in that the COVID-19 pandemic led to certain mitigation measures, such as lockdowns and social distancing. Thus, some challenges were likely in gathering firsthand insights from the target participants and in deciphering the data. Analyzing data from a secondary source was another possible challenge, as I did not have access to the questions or answers provided during the survey.

Significance of the Study

The purpose of this qualitative multiple case study was to explore the best practices for ensuring equal access to patent medicines while maintaining profitability of pharmaceutical companies to pursue needed innovation and development of new drugs. Achieving this purpose may have a positive impact to practice, theory, and social change. In the following sections, the significance of the study is detailed.

Significance to Practice

The significance of this study relates to exploring the high prices of patent medications and making them accessible to consumers at a reasonable price while maintaining profitability for pharmaceutical companies. Upon patent expiration, companies report billions of dollars in losses, thus justifying the claim that patents help in profit generation (Gholiagha et al., 2020). Gholiagha et al. (2020) gave examples of numerous active ingredients, including fluoxetine, wherein the expiration of this drug in 2001 corresponded to an 80% drop in the profits of Prozac in the United States. However, the high price of the patented medications undermines pharmaceutical companies' efforts to support health for all because many people cannot afford the medications.

This study may serve as a learning paradigm for the pharmaceutical industry experts in terms of understanding how to reduce the high pricing of patent medications. Cherla et al. (2021) stated that a patent, which is meant to promote innovations, also impedes innovations because of the exclusive rights that come with an unjustifiably broad scope of protection to the patentee. In this area, researchers have often focused on the exclusive rights impeding innovations and competition that could have been provided by generics.

Significance to Theory

Theoretically, drug development and improved access to patented drugs face two challenges. According to Urias and Ramani (2020), these are double challenges of increasing costs and increasing pressure on pricing, on one hand, and the need for pharmaceutical companies to make profits and stay afloat on the other. The lack of appropriate commercial perspectives among pharmaceutical companies has resulted in unmet medical needs, prompting stakeholders to discuss ways to improve the efficiency of drug research and development (Mignani et al., 2019). The current study adds to the theory of balancing drug development with pricing by introducing the component of private-public partnerships. According to Seoane-Vazquez et al. (2019), this component is worth being introduced in its many different forms with regard to scope, duration, and type and number of participants to ensure a balance between the desires of pharmaceutical companies and the need for accessing patented medical products. The current study may provide a wide range of information that will help put into perspective project-specific collaborations ranging from strategic alliances to large multiparty consortia (Seoane-Vazquez et al., 2019). This information will only be gained by considering large volumes of investigator-initiated studies in the literature review. This research may also bridge the research gap on the best practices for ensuring consumers' improved access to patent medicines while maintaining profitability for pharmaceutical companies to pursue needed innovation and development of new drugs.

Significance to Social Change

Pharmaceutical companies tend to attain more than one patent, which extends the life of the patent as well as the market value of the drug (Gholiagha et al., 2020). This study may bring a positive social change to the community by providing empirical evidence that could be used by Congress as a basis to enact laws that are effective in controlling the overpricing of drugs so that patients can access medications at reasonable prices. This study may provide much-needed answers to the high pricing of patent medications sold by pharmaceutical companies. This information may add to the knowledge and assist future researchers in exploring the high pricing of patent medications. Reducing the high prices for patent medications could foster positive social change in the community through patients' improved access to these medications, enhancing health for all.

This study may generate positive social change by providing information that may help override the influences of disappointing returns in the social sector, particularly in healthcare. The current state of healthcare is characterized by high costs of patented pharmaceutical products, a social justice issue. According to Lubberink et al. (2019), throughout the world, affluent nations, institutions, and individuals generously fund social services that fail to fully deliver on their promise. The aim of the current study was to deliver on this promise by focusing on appropriate investments rather than solutions, as has previously been the case (Burrone et al., 2019). Although advocating for positive social change, the study deviates from the norm of using fiscal resources to maintain the status quo of pharmaceutical companies that have become fixated on their long used delivery, innovations, solutions, and patients or recipients (Lubberink et al., 2019). Instead of focusing on the provision of inaccessible and sophisticated patented drug products, this study focused on understanding approaches that may bring innovative and simpler offerings that would be accessible to a wider range of patients. Advocating for the necessity of a study that would achieve such as positive social feat, Lubberink et al. (2019) suggested that emerging studies on drug innovation should approach social-sector problems in a fundamentally new way and inform the creation of scalable, sustainable, and systems-changing solutions by facilitating catalytic innovation.

Summary and Transition

The topic of this study was balancing access to patent medications with profitability of pharmaceutical companies. In Chapter 1, I established that the specific research problem is the unknown best practices for ensuring equal access to patent medicines while maintaining profitability of pharmaceutical companies to pursue needed innovation and development of new drugs (Prager et al., 2018; Saluja et al., 2018). The purpose of this qualitative study was to explore the best practices for ensuring equal access to patent medicines while maintaining profitability to pursue needed innovation and development of new drugs. To address the problem and purpose of the study, the research question was: What are the best practices for ensuring equal access to patent medicines while maintaining profitability of pharmaceutical companies to pursue needed innovation and development of new drugs? The theories and/or concepts that grounded this study include Bandura's (2000) social cognitive theory and the concept of self-efficacy. In Chapter 2, the literature relevant to this study is presented and reviewed. The gap in existing research is also established and explained in detail.

Chapter 2: Literature Review

This study was intended to address the general research problem that the prices of most patent medications in the United States are not affordable to patients, which simultaneously hinders drug innovation (Gøtzsche, 2018a; Saluja et al., 2018). The specific research problem is that best practices for ensuring equal access to patent medicines while maintaining profitability to pursue medical innovation and the development of new drugs remain unknown (Prager et al., 2018; Saluja et al., 2018). The purpose of this qualitative study was to explore the best practices for ensuring equal access to patent medicines while maintaining profitability, medical innovation, and the development of new drugs. This research addressed the research gap pertaining to the best practices for balancing the need to ensure consumers' improved access to patent medicines with the profitability of pharmaceutical companies, which may indirectly benefit the process of pharmaceutical innovation and development.

The high price of many patent medications not only affects consumers' access to medications but also incentivizes monopolistic behavior within pharmaceutical companies (Gøtzsche, 2018a; Saluja et al., 2018). Pharmaceutical companies that pursue multiple patents can extend the period of exclusivity granted by patents to enhance the market value of a drug. Exploring the high prices of patent medications and the accessibility of these medicines for consumers could lead to the development of solutions that maintain the profitability of pharmaceutical companies. Findings from this research may produce knowledge that pharmaceutical professionals and leaders can use to reduce the high prices of patent medications. The findings can also be used to inform policy changes to control pricing surges on both patent and non-patent medication. The literature search strategy that guided the development of this chapter is discussed in the following section.

Literature Search Strategy

I developed this literature review using resources identified and accessed through Google Scholar, EbscoHost, and ProQuest research databases. The following key terms and phrases were used to locate existing research relevant to the topic of this study: *social cognitive theory, self-efficacy*, *patent medicines*, *patent on medicines*, *patent medications, comparing patent and non-patent medicines*, *patent and non-patent medicine differences*, *medicine patenting process*, *patenting policies*, *patent medicine in the United States, patent medicine pricing*, *patent medicine profits*, *patent medicine access*, *medical patent process*, *balancing accessibility and profitability*, *healthcare access and profit*, *patent medicine corruption*, and *patent medicine ethical issues*. A limited number of historical or dated articles are included in this review for their foundational theoretical or empirical contributions. Most of the research included in this review, however, was published between 2017 and 2021 to ensure it is relevant to the research problem at the time of this study.

This literature review is organized into categories based on concepts and themes relevant to the current study. Sections of this review address key elements of the research problem and purpose of the study, including patents on medicines; the distinct qualities, controversies, processes, and policies associated with patents on medicines that distinguish them from non-patent medicines, as well as the best means of balancing patents on medicine accessibility, profitability, innovation, and development. Sections of this review are organized so that broad topics are discussed first, whereas more specific and nuanced discussions of the primary research topic are addressed in the second half of the review.

The theoretical framework is discussed in the following section. Subsequently, existing literature on patents on medicines is discussed within the context of the current study. Subsections of this review address the drug patenting process; the role of patenting policies; the significance of balancing patent medicine accessibility, profitability, innovation, and development; and corruption and ethical issues that affect the patenting process. I conclude Chapter 3 with a summary.

Theoretical Foundation

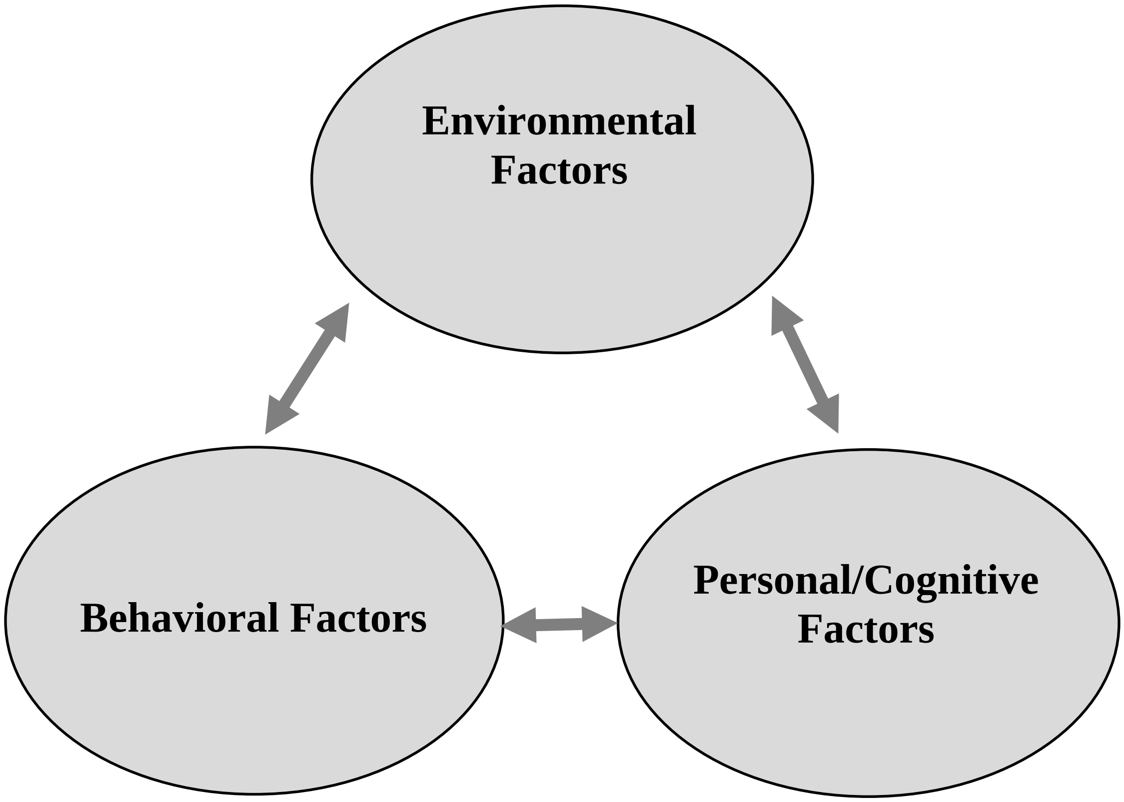
The theories and/or concepts that grounded this study included Bandura's (2000) social cognitive theory and the concept of self-efficacy. Key principles and concepts associated with social cognitive theory are discussed in the first subsection. Subsequently, Bandura's notion of self-efficacy is explained in the following subsection.

Social Cognitive Theory

Social cognitive theory describes the nature of how personal, behavioral, and environmental factors shape human behavior in different contexts (Bandura, 2000). This theory addresses the intersection and interaction of personal, environmental, and behavioral factors and how the relationships among these factors shape social-cognitive processes (see Figure 1). Within this theory, the concept of self-efficacy is regarded as a personal or cognitive factor.

Figure 1

Social Cognitive Theory



Note. Three domains of factors that are thought to influence social-cognitive processes through interactions and relationships with other social cognitive factors according to Bandura’s (2000) social cognitive theory.

Bandura’s (2000) social cognitive theory has been used extensively in research on organizations in different business sectors to understand behavior and decision making. For example, Wang et al. (2019) used social cognitive theory to explore the motivations of business owners in the field of tourism. For research within the healthcare sector, most social cognitive theory research involves predicting or changing patients’ behavior (Annesi, 2021; Smith et al., 2020). Social cognitive theory, however, has also guided the understanding of workplace behaviors and decision making of leaders and members of healthcare organizations (Ho & Lawrence, 2021; Sabbah et al., 2021; She et al., 2021).

Social cognitive theory is a prominent theory in existing research on the behaviors and decisions that guide pharmaceutical sales and the operations of pharmaceutical companies (Alssageer & Kowalski, 2021; Miller, 2018). Miller (2018) investigated the ethical decision making of pharmaceutical sales professionals from a social cognitive theory perspective. The researcher specifically investigated the effects of entertainment education in comparison to e-learning approaches for educating pharmaceutical sales professionals. Miller's (2018) research was predicated on the lack of existing research on how e-learning influences "employees' (a) awareness of unethical sales practices, (b) ability to judge a selling practice as unethical, and (c) intentions to speak up about unethical sales practices have had the desired effects" (p. 2). Miller separated 64 pharmaceutical sales professionals into e-learning and entertainment-education groups. At the conclusion of their respective training programs, surveys and scenario-based questions were administered to participants to evaluate their ethical decision making. Miller found that though both groups experienced increased behavioral intentions to speak up when confronted with unethical sales practices after training, a moderate difference was observed between the two groups in regard to their behavioral intentions when confronted with patient safety issues. These findings exemplify the influence of social cognitive theory concepts and principles in the context of how training shapes pharmaceutical professionals' decision making involving professional ethics.

More recently, Alssageer and Kowalski (2021) used a social cognitive theory framework to guide their content analysis of persuasive techniques employed during pharmaceutical representatives' promotional visits to doctors. In pursuit of profitability and competitiveness in saturated markets, pharmaceutical companies employ various marketing strategies, including meeting with doctors to promote their pharmaceutical products (Alssageer & Kowalski, 2021; Miller, 2018). Further, extensive evidence from social cognitive theory research indicates that promoting a positive consumer attitude toward a product through marketing tactics can directly influence consumers' behavior or behavioral intentions (Bandura, 2000).

Although these principles are well-established in many business sectors, the unique ethics environment in the healthcare sector discourages many healthcare providers from admitting that representatives selling pharmaceuticals or other medical products persuade their professional decisions. Thus, Alsageer and Kowalski (2021) conducted a content analysis of meetings between pharmaceutical representatives and doctors. The researchers found a high degree of similarity between marketing strategies used by pharmaceutical representatives and representatives selling nonmedical products. Pharmaceutical representatives, however, were more inclined than other representatives to emphasize how their product or brand was superior to alternative brands and products. Further, doctors were more likely to be misled by pharmaceutical representatives who displayed overconfidence toward the products they were marketing.

Self-efficacy is a concept central to social cognitive theory. Bandura (2000) defined self-efficacy as the belief in one's capability to work toward goals and manage situations by planning and organizing the course of action required to produce an outcome. In the context of this research, perceived patent efficacy refers to a pharmaceutical expert's belief or judgment regarding their ability to plan, organize, and achieve high profitability while selling patent medications at affordable prices. By discussing and researching the issue of access to essential, life-saving medications in this way, the role of pharmaceutical experts' best practices may become clearer. The construct of self-efficacy, as described by Bandura, was particularly central to the current study. Bandura's notion of self-efficacy is discussed in the context of the topic of the current study later in the review.

Social cognitive theory was used in the current study to frame the exploration of the knowledge acquisition process and rationales of pharmaceutical experts for deriving best practices for ensuring consumers' improved access to patent medicines while pursuing profitability for pharmaceutical companies, medical innovation, and the development of new drugs. This theory was also used in this research as a foundation for proposing aspects of development and structural change within the patented medication pricing system. Following the proposed recommendations may benefit multiple stakeholders.

Literature Review

Patents on Medicines

This section focuses on the topic of patent medicines. Definitions of patent medicines and differences in comparison to non-patent medicines are discussed.

Subsections address the medicine patenting process, the role of patenting policies, the significance of balancing accessibility and profitability, and corruption and ethical issues.

Patent medicine is a drug sold by a pharmaceutical company under a specific name or trademark protected by a patent (Pensabene & Gregory, 2013). Patent medicines have distinct histories and origins in different countries and cultures, which consequentially evolved to be regulated by different regulations and policies (Amijima, 2019; Luan et al., 2020; Mackintosh, 2017; Saks, 2020). Further, in some countries, patent medicines are considered largely ineffective, or limited in their effectiveness; whereas in others, they are regarded as being integral to health and wellness as prescription medications (Zhuang et al., 2020). In the United States, patent medicines are held to the standards of relevant trademark regulations and policies, as well as the standards of approval from the U.S. Food and Drug Administration (FDA; Petty, 2019).

Another key distinction between patent medicines and off-patent medications relates to their respective histories and marketing practices of the companies that make them (Mendelová, 2018; Petty, 2019). Many patent medications are only available under the direct guidance and allocation of medical professionals, ultimately rendering medical providers the target consumers. Patent medicines originated, and continue to exist, as products marketed to the general public through various forms of advertisement (Mendelová, 2018). Many authors, including Kim (2019), Mendelová (2018), Wixson (2018), have cited patent medicines as some of the first examples of organized and strategic product marketing in the United States. Patent medicines became a widespread phenomenon in the United States in the 19th century; however, at the time, the term *patent medicine* was used to describe any product designed to relieve health ailments that were readily available to the public without a doctor's visit, regardless of whether a patent had been obtained (Mendelová, 2018). According to Urias and Ramani (2020), ingredients in patent medicines were not regulated for safety reasons in the United States until the early 1900s; therefore, many early patent medicines were dangerous concoctions of ingredients now regarded as narcotics.

Advertising practices for early patent medicines were notorious for making loaded promises, or for touting short-term health benefits, but failing to mention potentially dangerous long-term health effects (Mendelová, 2018). Over time, consumers became wary of the efficacy and potential health consequences, including worsening symptoms that could occur from taking patent medicines. Once the term *snake oil salesman* became a ubiquitous reference describing patent medicines and other products advertised with substantial claims about benefits that could not be proven, the patent medicine industry and other industries that relied on false advertising shifted tactics (Mendelová, 2018). Rather than exaggerating or fabricating the benefits of patent medicines entirely, marketers of patent medicine began seeking to distinguish these brands from competitor products by promoting a level of professionalism and expertise that consumers had come to expect from trained medical professionals and prescription pharmaceuticals (Mendelová, 2018). In this way, the evolution of patent medicines sold in the United States mirrors the evolution of the marketing industry. The distinct combination of ingredients in a patent medicine is trademarked by the inventor so that others cannot replicate their product (Petty, 2019; Zhuang et al., 2020).

Although patent medicines have some distinct disadvantages that make them an unfavorable choice in comparison to off-patent alternatives, they can offer innovative solutions whereas other available medicines may not substantively address symptoms associated with a particular ailment or condition. In a review of existing literature, Zhuang et al. (2020) offered a globally relevant example in the context of patent medicine use. Specifically, the researchers examined the use of patent medicines in the treatment of COVID-19 in China. At the time of their study, no antiviral off-patent medication was available that would adequately treat the underlying virus rather than its symptoms. Thus, patent medicines, off-label prescriptions, forms of traditional Chinese medicine, and combinations of these treatment options were the primary options available to Chinese medical professionals treating COVID-19 at the time of this review.

Zhuang et al. (2020) also highlighted key differences in COVID-19 treatment guidelines at the time of their study in comparison to national treatment guidelines in the United States at the same time. Many patent medicines and forms of traditional Chinese medicine are included in national treatment guidelines for their antibacterial, antipyretic, analgesic, anti-shock, pulmonary functionality, antiviral, anti-inflammatory, anti-acute lung injury, and immune regulation properties. Patent medicines with these properties showed significant therapeutic efficacy in Chinese clinical settings, particularly when used in conjunction with forms of Western medicine (Ni et al., 2020; Zhuang et al., 2020). By contrast, patent medicines have largely been regarded as ineffective as treatments for COVID-19 in the United States, with many prominent health officials warning against common proprietary treatments (Rogosnitzky et al., 2020). More commonly in the United States, physicians have used the off-labeling option to prescribe existing medications that adhere to prescription drug regulations for symptoms and conditions other than what they were originally developed to treat. Rogosnitzky et al. (2020) specifically cited famotidine/cimetidine, bezafibrate/fenofibrate, dipyridamole, and sildenafil citrate as viable, effective, and affordable treatment options that have been prescribed off-label for COVID-19 treatment and offer promising evidence that warrants further investigation in clinical trials (Rogosnitzky et al., 2020).

Medicine Patenting Process

In the United States, medicines are patented by the U.S. Patent and Trademark Office (USPTO). The patenting process is pursued to provide medicine manufacturers with a legal mechanism for preventing or excluding other manufacturers or merchants from selling a medicine (Shadlen et al., 2020). In the United States, patent medicines are categorized under utility patents. The patenting process can take multiple years with no guarantee that the resulting patent will be granted. Patents can, however, financially benefit pharmaceutical manufacturers, as they can often sell patent medicines at a higher price than non-patent medicines.

The patenting process begins with ensuring that a medicine meets the four general criteria of patentability: (a) the medicine is considered patentable subject matter; (b) the medicine is novel in relation to existing medicines; (c) the nature or function of the medicine is nonobvious; and (d) the medicine is fully enabled to work in accordance with how it is described in the patent (Shadlen et al., 2020). If a medicine meets these requirements, a provisional or nonprovisional patent application is submitted.

Subsequently, the USPTO conducts a process of examination, or prosecution, over the course of approximately 1 to 6 years, resulting in approval or denial of the patent.

The patenting process occurs separately from the FDA approval process, which can also take multiple years (Shadlen et al., 2020). Regardless of if or when the patent is granted, companies cannot begin to sell patent medication until FDA approval is granted. Some medicine manufacturers hire specialized attorneys or patent professionals to facilitate the process. For some manufacturers, the costs and resources necessary to pursue the patenting process outweigh the benefits. For larger pharmaceutical manufacturers with significant resources at their disposal, however, patenting medicines is a key source of funding for regulatory approval processes, research and development, and other key expenses (Shadlen et al., 2020).

Role of Patenting Policies

Numerous country-specific policies govern the patenting of drugs for the protection of the manufacturer and the consumer (Cherla et al., 2021). Although some researchers contend that there has been a shift toward the politicization of patenting policies in recent decades, Mertha (2018) argued that patents that cover medical products have always been political in nature. Mertha particularly emphasized how ideologies, historical context, and political culture have shaped key medical patent controversies surrounding products related to human genealogy, biology, stem cells, and medicines.

The medicine patenting landscape is ever-changing in the United States and globally, as governing bodies are constantly shifting aspects of the patenting process, production regulations, and which facets of medicines can be patented (Kumar et al., 2018). Innovations in medicines necessitate policy updates to ensure a fair and development-oriented policy landscape, as new developments can render existing patent policies irrelevant or ineffective as a form of regulation (Mertha, 2018). For instance, the development of pharmaceutical co-crystals created new regulatory hurdles, with regulatory bodies holding significantly different opinions on whether pharmaceutical co-crystals can be patented. The primary contention regarding pharmaceutical co-crystals is that regardless of the manufacturing process, whether based on co-crystals or salt formulations, the ultimate product must meet the required safety standards (Mertha, 2018). This example of patenting policy conflict highlights interactions between many individuals and factors involved in medicinal breakthroughs and seeking legal protections for revolutionary medicines.

Patents, as they are defined in USPTO regulations, do not offer absolute or infinite protection from competitors seeking to create similar products (Shadlen et al., 2020). Patenting policies governing product attributes, such as biosimilarity, and exclusivity are subject to constant change, which shapes how patenting influences the healthcare sector. Shadlen et al. (2020) discussed changes to medical patent policies, specifically those that govern biological medications, stating that the recently introduced controversial Congressional bill would shorten the exclusivity period for expensive biologic medications from 7 to 12 years. Representative Janice Schakowsky (D-IL) introduced the bill on June 23, 2016, in an effort to allow drug manufacturers to market lower-cost versions of drugs more quickly to help reduce healthcare expenses (Shadlen et al., 2020). Biosimilar versions of the drugs are predicted to cost between 10% and 30%

less. Representative Schakowsky cited data from the U.S. Department of Health and Human Services showing that reducing the exclusivity period for biologic medications would save taxpayers nearly $7 billion over the next 10 years. The 12-year exclusivity period was initially introduced as part of the Affordable Care Act, and the White House has routinely proposed shortening the period to 7 years to save federal healthcare dollars.

In the United States, patent medicine manufacturers can sell their medicines at high prices when granted legal monopoly rights that provide protection from competitors producing generic alternatives; these rights can be divided into two categories (Beall et al., 2019). The first category includes patents that apply to medicines during the initial period characterized by brand-name-only sales. The second category refers to patents granted when approval is given by the U.S. FDA. These patents typically define the minimum period of exclusivity before generic alternatives can be manufactured and sold (Gupta et al., 2019).

Exclusivity periods and other specifications in medicine patenting policies have significant implications for the dynamics and priorities that define the patent medicine market (Gupta et al., 2018; Hoen et al., 2018). The emergence of generic alternatives at the end of exclusivity periods is traditionally associated with significant changes in drug prices in the United States. Specifically, Gupta et al. (2019) noted that “the greater the number of generic manufacturers’ versions in a market, the steeper the price decline, with prices decreasing to less than 20% of the original drug’s price,” and that “low-cost generic drugs generated $253 billion in savings to the U.S. healthcare system in 2017 and more than $1 trillion in the past decade” (p. 64). Reliance on generic alternatives to patent medicines has increased significantly and consistently since the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (Gupta et al., 2019). Gupta et al. also noted that "in 2016, generic drugs accounted for only 27% of overall U.S. drug spending yet constituted 89% of drug prescriptions in the U.S., a dramatic increase from just 19% of prescriptions in 1984" (p. 52). These findings highlight the significant role of policies dictating exclusivity periods, generic drug availability, and drug pricing in the United States.

Despite the clear relationship between policies that regulate generic drugs and drug pricing, concerns have grown in the past decade regarding increases in generic drug pricing and decreases in generic drug availability (Gupta et al., 2018, 2019). An accountability report that was recently released by the U.S. government indicated that "315 of 1,441 (22%) generic drugs sold in the U.S. experienced price increases of 100% or more from 2010 to 2015, many of which were older, small-market medicines," and that "shortages of generic drugs in the U.S. have also risen, quadrupling between 2005 and 2011, from 61 to 250 drugs" (Gupta et al., 2019, p. 42). These changes in prices and supply defy traditional expectations of a linear association between the availability of generic drugs and pricing, a phenomenon for which Gupta et al. (2019) offered a partial explanation:

> These specific drug markets often continue to lack sufficient generic competition, face supply limitations due to concentration of manufacturers, or experience market exit of individual manufacturers due to low profits. Complicated arrangements between drug manufacturers, pharmaceutical benefit managers, and

> insurance companies can also result in the use of brand-name drugs even though generic alternatives are available. A recent report from the Office of the Assistant Secretary for Planning and Evaluation found that Medicare Part D plans spent almost $9 billion on brand-name drugs when therapeutically equivalent generics were available, and the program could have saved $3 billion had generic versions been dispensed instead. (p. 71)

Although the initial patent period for most patent medicines is 20 years in the United States, this period may be extended due to contextual factors, such as the length of the regulatory review process and the time needed to complete clinical trials (Beall et al., 2019; Hoen et al., 2018). In some instances, other regulations prevent the approval of off-patent medicines for approximately 6 to 7 years. Concerning new biologics, specifically, the initial patent period is 12 years. On average, current patent policies grant manufacturers market exclusivity for approximately 12 to 16 years based on the protections afforded by both categories of monopoly protection (Beall et al., 2019).

Once a patent expires and a patented drug's market exclusivity is terminated, competing companies can pursue the regulatory process needed to develop, manufacture, and sell similar versions of the drug (Hoen et al., 2018). In the U.S. drug market and many others globally, new off-patent drugs are sold at a discount in efforts to increase market share. Over time, this process drives the off-patent medicine price toward its marginal cost. Gupta et al. (2019) noted that many manufacturers decide to cease selling the drug, or "will only continue to make that product if the cost of its production remains low or if there are strong synergies with that firm's other product lines" (p. 360). Thin profit margins earned before this point in the process deter many prospective competitors that lack the incentive to invest the time, money, and other resources necessary for regulatory approval. Drugs tailored to the needs of small populations of patients are particularly likely to reflect this process once market exclusivity has expired, as revenue potential is already relatively low in comparison to the revenue potential associated with drugs used by many patients, or for many purposes (Gupta et al., 2019).

Numerous critics have taken sides on this issue, where policy changes are perceived to benefit some stakeholders over others. Shadlen et al. (2020) indicated that the process of medical patenting and use of policies is delicate and requires balancing manufacturer's rights and interests with those of the public. Cherla et al. (2021) suggested providing an option to extend the period of protection allotted to patentees so that the revenue from patent extensions can be used to fund medication development and intervention in regions or countries with limited medical access.

Although fostering innovation and addressing other key concerns through policy changes should be a direct means to address these issues, Pandey and Paul's (2019) suggested that some policies designed to foster innovation have been counterproductive, leading researchers to continue searching for more effective policy solutions. The researchers specifically cited the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement enacted by the World Trade Organization as an example.

By giving monopolistic rights to holders of patents associated with new medicines, the World Trade Organization assumed that technology transfer to countries lacking in medical innovation and access to healthcare would improve. Analysis of a panel data set that included the 65 signatories to the TRIPS Agreement from 1995 to 2016 revealed significant evidence of a decrease in new patents being filed for low- and middle-income countries included in the agreement (Pandey & Paul, 2019). The most significant decrease in filed patents was for upper-middle and low-middle income countries, rather than middle-income countries. The researchers concluded that strengthening the rights of medicine patent holders did not increase the innovative potential of the countries included in the TRIPS Agreement; instead, the opposite of the intended effect was observed.

Among the medicines and products made possible through research and development funding, manufacturers are more likely to focus their resources on medicines for treating conditions that require chronic care than medicines that provide fast and relatively inexpensive solutions for consumers (Gøtzsche, 2018b). Beyond the cost of medicines, Gøtzsche (2018b) further asserted that patent medicine policies that unintentionally encourage or allow companies to prioritize profits over everything else could push them to develop new drugs to treat conditions that affect significantly fewer people if affordable lifestyle interventions are readily available. Thus, the researcher proposed a radical shift that would make patent medicines outdated. Key ideas proposed in Gøtzsche's new system are as follows:

> Once fully implemented, the new system will abolish the patenting of drugs and devices. In the transition period, all regulations that impede the introduction of generic medicines and biosimilars to the market should be removed, and new patents for minor changes, for example the removal of the inactive part in a

> stereoisomer, should not be allowed. The bar for launching lawsuits against generic competitors with claims that they have broken a patent should be raised substantially, and the time limits for lawsuits and patent exclusivity shortened. Companies that launch frivolous lawsuits should be subject to stiff penalties, as the mere threat of such lawsuits often stifles innovation in start-up companies. (p. 24)

Within this new system, the primary strategy Gøtzsche (2018b) proposed to address the lack of innovation and affordability in patent medicine was strengthening regulations surrounding marketing tactics, spending, and claims. The researcher also proposed establishing an independent organization responsible for developing and researching new medicines so that the motivation of pharmaceutical industries to maximize profit over public health would be reduced. Gøtzsche provided a dynamic perspective on ways to radically change policies surrounding patent medicines to benefit consumers.

Corruption and Ethical Issues in Patenting

Certain concerns about sources of corruption and unethical conduct surrounding patent medicines are prevalent in existing literature. One central concern is that patenting medicines impedes the development and diffusion of medical innovations because it leads to a focus on maximizing profit instead of contributing to public health and well-being (Babalola, 2018; Bloom et al., 2019; Myloneros & Sakellariou, 2021; Stiller et al., 2022; Vogler, 2019; Vogler et al., 2018). Some firms that produce patent medicine are more likely to struggle to balance product innovation and profits over others. For instance, Stiller et al. (2022) and Arnold and Troyer (2016) found a significant association between marketing expenditures and a lack of drug innovation as well as between increased research and development spending and increased drug innovation. Their findings suggest that a firm's expenditure priorities are direct determinants, influences, and reflections of the extent to which they prioritize innovation or medical progress over profits.

Policies that shape the development and sale of patented medical products are primarily intended to ensure that a product fulfills the requisite features and functions of a unique object with medical value, rather than evaluating products on the basis of medical innovation (X. Chen et al., 2019; Deshko, 2018). Researchers such as Bloom et al. (2019), Golan et al. (2019), and David and Halbert (2017) have emphasized, however, that policies can encourage innovation through strategic allocation of key resources, rather than assuming that offering direct funding will directly contribute to the production of innovations. The researchers emphasized that direct funding may contribute to the development of new medicines that are technically unique enough to qualify for patents, and yet do not represent substantial innovations or improvements upon existing products. Thus, although direct funding can contribute to short-term innovation, Bloom et al. emphasized that pro-innovation policies should focus on allocating resources or enabling changes that foster human capital growth, such as changing college admission requirements or incentivizing interdisciplinary collaboration during professional development programs.

An additional issue relates to medicine manufacturers' role in choosing and promoting their research agendas, regardless of unmet health needs or areas of drug development that require attention for the benefit of public health (Gøtzsche, 2018a, 2018b). Patent medicine manufacturers are inclined to invest their research and development funding in medications for the management of the symptoms of chronic conditions, rather than developing drugs for short-term health problems or for treating an ailment so that, eventually, no more medication is required. Although developing such drugs can still represent medical progress, key areas of research and public need can be ignored entirely, as drug companies do not receive incentives or suffer penalties for setting wrong priorities in their research agendas (Gøtzsche, 2018b).

Key evidence of this issue was raised by Gøtzsche (2018b) in the context of medical advancements that are published in medical journals. Specifically, Gøtzsche referenced *Prescrire*, a French medical journal that, unlike many other journals that publish medical advancements, stringently evaluates authors' connections to the drug industry and does not publish any papers that appear to be influenced by conflicts of interest. Concerning a key distinction and accolade associated with the journal, Gøtzsche wrote:

> Since 1981, Prescrire's Pilule d'Or (Golden Pill) has been granted to drugs that constitute a major therapeutic advance in a field in which no treatment was previously available. There was no worthy candidate for 1982, 1984, 1985, 1990, 1991, from 1993 to 1995, for 1997, from 1999 to 2005, from 2008 to 2013, and for 2015. (p. 31)

This point emphasizes the significant lack of therapeutic advancement and innovation in treatment areas where innovation is needed most (Gøtzsche, 2018b). Specifically, researchers hired by drug companies appear unmotivated to address key weaknesses in entire classes of drugs, including cancer drugs and antibiotics. By contrast, research and development for drugs that address symptoms of chronic conditions, such as hypertension and diabetes, continue to result in new products that offer little to no innovative value in comparison to other products in the market (Gøtzsche, 2018a).

Medical innovation can also be stalled due to patent disputes that occur before medicines enter the market, thus further delaying market entry (Bloom et al., 2019; Gupta et al., 2019), particularly for biosimilars (Zhai et al., 2019). The phenomena of protecting medicines with a patent thicket was described by Zhai et al. (2019), wherein drug manufacturers file a multitude of patents for the same drug in efforts to prevent competitors from producing medicines that are remotely similar to their formulations. Patent thickets extend the protections of medicine patents beyond the unique features of specific products, thus contributing to disputes that can disrupt the development of multiple drugs. Zhai et al. provided a practical example of the effects of the patent thicket phenomenon:

> Arguably, the most notable case of patent litigation leading to the delayed entry of biosimilars involves adalimumab, the top-selling drug in the world. In 2017, adalimumab had $18.4 billion in global sales, more than double the second best-selling drug, lenalidomide. AbbVie, adalimumab’s manufacturer, procured over 100 patents on the product. Although AbbVie’s active ingredient patent on

> adalimumab expired in 2016, it was granted a series of patents protecting everything from the manufacturing process to new formulations of the drug. One 2018 report found that 89% of these patent applications were filed after adalimumab was on the market, and 49% were filed after the first patent expired in 2014. (p. 668)

A problem similar to patent thickets, known as product hopping, can have a comparable effect on drug pricing and the availability of generic alternatives (Gupta et al., 2019; Zhai et al., 2019). Product hopping refers to another strategic approach by companies with exclusive rights to a drug but are anticipating the emergence of generic alternatives in the market. Specifically, product hopping occurs when “the brand-name manufacturer precludes automatic switching of its drug for a generic version by launching a branded reformulation at the time of generic entry and simultaneously discontinuing its original version” (Gupta et al., 2019, p. 53). Gupta et al. (2019) emphasized that product hopping can effectively delay the launch of alternatives that could be available to patients at lower prices. The researchers exemplified this phenomenon by referencing the drug fenofibrate, noting that “Abbott Laboratories engaged in a serial switching strategy in which at the time of generic entry it launched multiple sequential branded reformulations without demonstrated superiority to the original product, which prevented their substitution with generics of the older products,” and “Abbott also simultaneously filed patent litigation to delay the approval of generic versions” (p. 72).

Another key concern is patent trolling, wherein legal entities or organizations acquire a patent for a product they do not intend to produce. Rather, they acquire the patent under the assumption that their product would be of interest to their competitors and thus would infringe on their patent in a way that gives them the legal ability to pursue damages (Bloom et al., 2019). In theory, this phenomenon could be of significant concern to medical innovation, as companies may avoid producing products that are remotely similar to patented products. The ultimate effect is the hindered development of innovations that could benefit public health due to not only competitors' lack of production rights but also the patent owner choosing not to produce the product. Despite the potential for this issue, Bloom et al. (2019) emphasized that there is insufficient evidence to suggest that patent trolling is a significant hindrance to innovation among patent medicine manufacturers.

The other central concern and implication of such high prices of patented medicine is the increased risk of a small number of pharmaceutical organizations monopolizing the production of some medicines to their benefit and the public's detriment (C. Chen et al., 2020; David & Halbert, 2017; Finkel, 2018; Ijomah, 2019; Kendrick, 2019; Pandey & Paul, 2019; Yongbo et al., 2019). Legal entities, including those that signed the Anti-Counterfeiting Trade Agreement, have attempted to prevent monopolies by changing legal distinctions and characteristics of monopolies. These efforts have, however, had some unintended consequences and may have the opposite effect on monopolization as intended. David and Halbert (2017) noted:

> The failed Anti-Counterfeiting Trade Agreement (ACTA) sought to abolish the legal distinction between counterfeit and generic drugs, a move supported by 'big pharma' in efforts to eliminate competition from generics and make access to medicine possible only under the terms of strong patent protection… In reality, patents create the monopoly rents that incentivise counterfeiters; generic medicines, meanwhile, in reducing prices, eliminate scope for profiteering by patent holders and counterfeiters alike. Generics do not undermine creative incentives. Most innovative drugs research is government/ charity/university funded.... The predominant commercial contribution is in clinical and post-clinical trials. Costing between two and four times the price of publicly funded trials, this 'contribution' allows patents, increases conflicts of interest, but serves no wider interest. (p. 5)

In other cases, anomalies have been uncovered, wherein the pharmaceutical companies were blamed for manufacturing patented drugs that are not different from the existing drugs during the patent duration (Stiller et al., 2022). Aggarwal et al. (2020) added that corruption through patent pricing was on the rise, as impeding innovations are lacking. These pharmaceutical companies are manufacturing drugs that have no extra benefits compared to the existing drugs (Stiller et al., 2022).

A key defense that deters patent medicine manufacturers from pursuing patents that fail to contribute to innovation is comparative effectiveness research (C. Chen et al., 2020; Guan et al., 2020; He et al., 2020; Sun et al., 2021; Zhao et al., 2021). Jiang et al. (2022) recently conducted one such study. Comparative effectiveness research provides objective evidence for the effectiveness of patent medicine in comparison to similar medicines available in the market. The researchers conducted their study at four hospitals in China and included a sample of 144 patients. The patent medicines they examined were compound danshen pills and QishenYiqi pills.

Participants were split into four groups, with two groups receiving the patent medicines intended to treat coronary heart disease and angina pectoris and the other two groups receiving placebos. Jiang et al. (2022) found distinct advantages to each of the two patent medicines that were studied. Although neither pill was determined to be generally superior, QishenYiqi was found to be most beneficial for patients with qi deficiency and blood stasis syndrome that presented spontaneous perspiration or asthenia as well as for patients with qi stagnation and blood stasis syndrome that presented distending chest pain. By contrast, compound danshen pills were more beneficial for patients with qi deficiency and blood stasis syndrome that experienced shortness of breath as well as for patients with qi stagnation and blood stasis syndrome that present palpitations. The researchers' findings highlight how comparative effectiveness research can clarify distinct benefits and effects associated with a patent medicine in comparison to other patent medicines that are used to treat the same conditions and ailments.

This section included insights into how the histories and marketing practices associated with the sale of patent medicines and off-patent medications vary considerably. Advertising practices are notoriously unethical among sellers of early patent medicines sold in the United States, which were associated with loaded promises and claims about product benefits, despite ample evidence of potentially dangerous long-term health effects. The patent medicine industry and other industries that relied on unsupported, or outright fabricated, product claims shifted tactics by using marketing strategies to distinguish themselves from competitors through professionalism and expertise that consumers associated with trained medical professionals and prescription pharmaceuticals.

Concerning today's patent medicine, some distinct disadvantages of patent medicines position them as an unfavorable choice in comparison to off-patent medicines. When other available medicines are not effective for addressing symptoms associated with a particular ailment or condition, patent medicines can offer innovative solutions. The multitude of patenting policies that govern product attributes, such as biosimilarity and exclusivity, are constantly changing in a way that significantly influences innovation and other facets of the healthcare sector. Policies governing exclusivity periods granted to patent medicine manufacturers have particularly significant implications for the dynamics and priorities that characterize the patent medicine market. Due to the significant implications of patent policies for innovation and other key concerns, policy change should be a direct means of addressing issues. Evidence, however, suggests that some policies designed to improve access for patients and foster innovation are ineffective, leading researchers to continue searching for more effective policy solutions.

Balancing Patented Medicine Accessibility, Profitability, Innovation, and Development

In most cases, patent medicines are priced higher than generic and non-patent medicines (Cherla et al., 2021; Gøtzsche, 2018a; Pandey & Paul, 2019; Stiller et al., 2022). The prices of patented drugs often far exceed the value of the product itself. The high prices are often attributable to companies seeking to recoup the costs of research and development, marketing, and other costs associated with successful market entry (Gøtzsche, 2018a). In markets where generic, or off-patent, medicines are widely available, many consumers avoid patent medicines entirely to save money. In the United States, 89% of purchased medicines are generic drugs. By contrast, spending on generic drugs in 2016 represented only 27% of the drug budget (Gupta et al., 2018). These statistics underscore the difference between patent and non-patent medicine prices in the U.S. drug market.

The relatively high prices of patent medicines can limit patients' access to these drugs in many countries (Boggio & Ho, 2018; Oluwasanu et al., 2021; Onah, 2018; Wong et al., 2018). Many researchers, including Boggio and Ho (2018), emphasized that high prices of patent medicines can limit people's right to access the benefits of scientific progress and technological advancements. Luna (2019) considered the affordability and accessibility of patent medicines as factors that cannot coexist. Specifically, Luna emphasized that either affordability or accessibility will always emerge as superior in different markets, depending on socioeconomic conditions and other factors. From this perspective, manufacturers of patent medicines may consider balancing accessibility and profitability a futile effort that will always leave either the manufacturer or the consumer at a disadvantage.

Conversely, patent medicines allow access to healthcare for many individuals living in rural regions or who otherwise lack reliable access to formal healthcare services

(Adam & Aigbokhaode, 2018; Durowade et al., 2018; Uneke et al., 2021). Although patent medicines are thought of as relatively expensive in many parts of the world where formal healthcare services are easily accessible, they are considered the most affordable option for those without access to formal healthcare. For instance, Uneke et al. (2021) found that patent medicines were the only accessible and affordable option for many mothers and young adults living in rural areas of Southeastern Nigeria. Using cross-sectional descriptive methods and purposive sampling, the researchers surveyed a sample of 159 nursing mothers and 148 young adults. Their findings were that the vast majority of participants would turn to patent and proprietary medicine vendors before other healthcare options when they experienced a health concern or symptom. Products that were commonly bought by participants from patent and proprietary medicine vendors included antibiotics, analgesics, and antimalarials. These findings highlight how patent medicines serve different roles and purposes in different countries depending on the healthcare context of the region, particularly the healthcare infrastructure and ease of access to formal treatment.

Although it may be reasonable to conclude that patent medicines are more expensive in countries where there is limited access or generic options are lacking, Morgan et al. (2020) documented that despite more effective drugs being developed, due to the patents, patients may not access them due to their high prices. Similarly, Goldstein et al. (2017) came to this conclusion after conducting a comparative study of the price of patent cancer medications in seven different countries representing varying income levels. Income levels were estimated based on countries’ gross domestic product and average annual salaries. Upon comparing cancer medicine pricing in China, Israel, the United Kingdom, Australia, India, South Africa, and the United States, the researchers determined that the cancer medicines were more affordable in high-income countries than middle-income countries. Specifically, the patent cancer medicines were disproportionately and significantly less affordable in India and slightly less affordable in China and South Africa, than in the United States, Israel, the United Kingdom, and Australia. Based on this finding, Morgan et al. recommended differential pricing as a potential policy strategy to enhance the affordability of patent anti-cancer therapies globally.

Morgan et al. (2020) emphasized a point that has not received significant attention in the existing literature. Numerous researchers have brought attention to the high cost of pharmaceuticals in many countries, as well as the significance of the conflict between the profitability of pharmaceutical companies and the price of their products (Wouters et al., 2017). These issues, however, are typically referenced in terms of prices or price comparisons to other drugs or markets, rather than affordability in the context of residents' earnings and socioeconomic conditions in a given region. For instance, Wouters et al. (2017) recently compared drug markets in Europe to the U.S. drug market based on drug prices, spending, and volume. Through a review of existing literature and surveys of previously collected data sets in existing studies, Wouters et al. found a significant variation in drug pricing and market shares across different countries in Europe. Concerning specific countries, Wouters et al. determined that generic drug manufacturers in Switzerland charge approximately 2.5 times more than manufacturers in

Germany and over six times more than manufacturers in the United Kingdom. Further, non-patent drugs accounted for only 17% of prescriptions in Switzerland in 2013 compared to 83% and 84% of prescriptions in the United Kingdom and the United States, respectively, in the same year.

Although Wouters et al. (2017) lent insight into the nature of differences between the drug markets in European countries and the United States, the price comparison between countries was conducted by calculating Laspeyres price indexes. This calculation method is associated with significant limitations that Wouters et al. acknowledged, particularly the assumption that prescription generic drug pricing does not influence demand. By contrast, Morgan et al. (2020) emphasized and accounted for potential limitations, including the significance of global currencies and exchange rates in studies that provide global price comparisons of patent medicines:

> There is a clear difference in drug prices depending on whether prices are converted from local currency to US dollars using exchange rates or purchasing power parity. The reason for this difference is driven by the difference in conversion rates. While the foreign exchange rates and purchasing power parity rates are similar for high-income countries they are considerably different for middle-income countries ... We see that although prices may appear somewhat comparable between countries using foreign exchange rates, when we incorporate purchasing power parity, there are significant differences. These differences essentially relate to the difference in the value of US currency between countries. (p. 16)

Most existing comparative research does not address the significance of purchasing power parity. However, Morgan et al. (2020) indicated that purchasing power parity significantly influenced the relative affordability of the patent cancer therapies that were compared. Thus, Morgan et al. provided a nuanced understanding of the implications of patent drug pricing in the context of what patients can afford to pay.

The significance of balancing access to and profits from patented medicines is apparent in all stages of the development and production process (Godman et al., 2018; Haque et al., 2020; Imasuen & Nwajana, 2021). A number of studies have emphasized the need to balance accessibility and profitability. For example, Godman et al. (2018) concluded that balancing accessibility and profitability for patented medicine can be attained if there is selection and implementation of an appropriate model.

Based on a review of existing literature on the entry of new patent medicines designed to treat cancer, Godman et al. (2018) found evidence for the use of many different entry models when new patent medicines are released for sale. The researchers emphasized the effectiveness of entry models and strategies guided by “the growing role of horizon scanning activities starting up to 36 months before launch, managed entry agreements and post launch follow-up” (Godman et al., 2018, p. 328). Godman et al. also emphasized that patent medicines introduced to the market at a relatively high price point in comparison to alternative products are more likely to be heavily scrutinized to determine how the effectiveness of new patent medicines compares to existing products. Specifically, they emphasized the likelihood of scrutiny involving “establishing minimum effectiveness targets for premium pricing along with re-evaluating prices as more medicines for cancer lose their patent" (Godman et al., 2018, p. 328). These findings highlight how the process of balancing the profitability and accessibility of patent medicines begins well before medicines are released for sale.

It is important to note that even in markets where off-patent, or generic, medications are widely available, there is no guarantee that these alternatives to patent mediations that have a reputation for affordability will have stable or justifiable prices (Calcagno et al., 2019; Fukumoto et al., 2017; Manchikanti & Dias, 2021; Vogler et al., 2018). Graber (2017) emphasized that medications that have not been covered by a patent for years can suddenly increase in price by up to 10,000%. Thus, although many researchers have identified the issue of balancing profits with access to medication as a key ethical concern that characterizes the patent medicine industry, firms involved in the sale of off-patent medications can be just as likely to raise prices exponentially, depending on market conditions. Graber categorized exponential price increases in medicines, or *price ratcheting*, as resulting from one of two causes. The first type of price deviation is a natural occurrence due to organic market deviation, whereas the second type occurs when drug market vulnerabilities are taken advantage of by drug manufacturers.

Although Calcagno et al. (2019) noted that increasing competition in the drug market is a frequently proposed solution to reduce price ratcheting, they provided three distinct examples of medicines characterized by recent price ratcheting that illustrate how increased competition did not correct price ratcheting immediately or over time. The examples provided by Calcagno et al. in the context of the United States drug market were Daraprim, doxycycline, and EpiPen. All three drugs were initially released with little or no competing products. However, once comparable products became available at a lower price, the prices of these drugs did not decrease, and over time, they stabilized. Further, although Daraprim and EpiPen were patent medicines, doxycycline was an off-patent medicine and displayed comparable changes in price as the patent medicines. Calcagno et al.'s findings highlight how some proposed solutions to the high cost of patent and non-patent medications fail to address the complexities of the factors that contribute to price ratcheting and other changes in medicine pricing.

Off-patent medications that are regulated by the FDA are often produced by many manufacturers to ensure the accessibility of medical innovations and breakthroughs (Petty, 2019; Zhuang et al., 2020). By contrast, Cherla et al. (2021) argued that patenting medicine, which is intended to promote innovation, also impedes innovations because the exclusive rights granted to the patent holder gives them an unjustifiably broad scope of protection in the event that a competitor creates a product that is, to some extent, similar. To address this issue through research, researchers have often focused on changes that enhance the balance of exclusive rights that may impede innovations and the innovation that may result from the availability of competing products (Cherla et al., 2021).

Although many researchers have proposed changes to medicine patenting policies as an approach to address key issues related to innovation and scientific progress, others, including Cherla et al. (2021), Gøtzsche (2018a), and Z. Chen et al. (2020), have asserted that more radical changes are necessary to address key concerns and restore innovation in patent medicine. Gøtzsche supported his argument by identifying myths and false assumptions that fuel the patent medicine industry. The researcher emphasized that key innovations and progress are often stalled or lost entirely due to intense competition and efforts to stop competitors from producing similar medicines that could be potentially more beneficial and/or less expensive to consumers. Further, Gøtzsche noted that a minute percentage of drug industry revenues are used to fund new research and development.

Compulsory licensing is another solution that has been proposed to enhance access to lifesaving medications in some contexts (Inotai & Kaló, 2019; Urias & Ramani, 2020). Urias and Ramani (2020) noted, however, consensus is lacking on the final impact of compulsory licensing on access "because the agreement housed instruments to address this challenge" (p. 70). Compulsory licensing that facilitates price reductions on medications has been considered an influential measure to counter inaccessibly expensive medicines. Accordingly, Urias and Ramani conducted a systematic review of existing research to address how compulsory licensing influences medication prices. The researchers identified and analyzed 51 observations of medication prices before and after compulsory licensing prices and determined that compulsory licensing has a significant likelihood of contributing to price reductions on patented drugs, though there were some limitations to this finding. Urias and Ramani also found that "compulsory licensing procurement from the international market is likely to be more effective in reducing drug prices than contracts to local companies" (Urias & Ramani, 2020, p. 70). Urias and Ramani affirmed their findings by bringing attention to the need to improve access to Remdesivir for treating COVID-19.

Similarly, Inotai and Kaló (2019) reviewed solutions to address the challenge of covering patent medicines from resources with significant restrictions in countries with significant unmet medical needs, as well as the associated financing gap. They noted that enacting volume restrictions on patent medicines in efforts to foster financial sustainability may have the unintended effect of increasing inequity and access issues for patients. However, the researchers promoted financial risk-sharing agreements and confidential price discounts as more effective approaches for improving the cost-effectiveness of pharmaceuticals without significantly impacting the floor price of pharmaceuticals. They also emphasized that narrowing the group of patients who are eligible for specific pharmaceuticals can result in targeted improvements to medicine access among patients, potentially improving the health benefits of medicines while reducing costs for patients. Inotai and Kaló concluded "that transparent and sustainable pharmaceutical policies aiming to improve the allocative efficiency of scarce resources should be implemented in CEE" (p. 45) to reduce gaps in patient financing and access to high-cost pharmaceuticals.

Research reviewed in this section confirmed that most patent medicines are priced higher than generic and non-patent medicines, rendering patent medicines' affordability and accessibility as central concerns in many countries where access to generic medication is limited. Patent medicines are thought of as relatively expensive in many parts of the world where medication and other aspects of healthcare are easily accessible. They can also be the most affordable option for those without easy access to formal healthcare. Although it may be reasonable to conclude that patent medicines would be the most expensive in countries where there is limited access, or a lack of generic options, evidence suggests that some patent medicines that represent key medical progress toward treating serious illnesses are more expensive in countries where patients are least able to afford them.

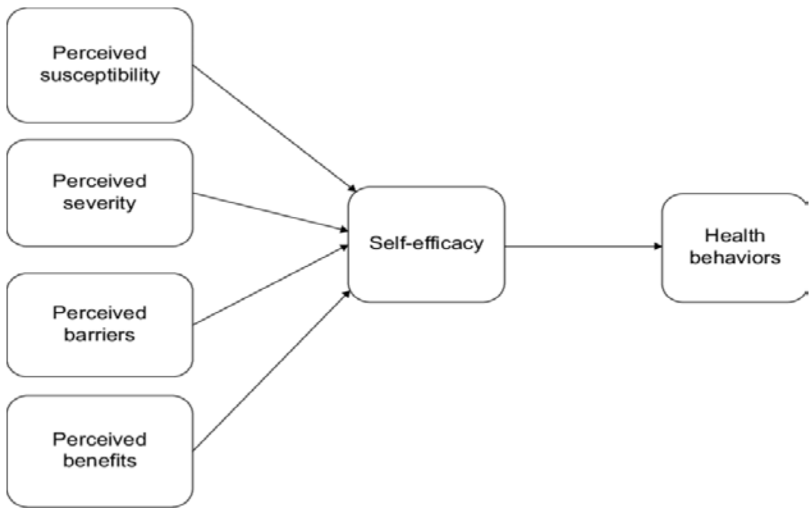
Role of Self-Efficacy

Self-efficacy is a central concept in many studies on facets of the healthcare sector and the behaviors of healthcare stakeholders (Boggio & Ho, 2018). Perhaps the most common application of self-efficacy in healthcare research relates to how self-efficacy influences health behaviors (Rosenstock et al., 1988). Particularly, researchers have used Bandura's (2000) notion of self-efficacy in tandem with the health belief model, resulting in an explanatory model of health behaviors to develop best practices for treatment approaches and behavioral interventions. Rosenstock et al. (1988) proposed that self-efficacy is an independent variable that shapes health behaviors in the same way that the variables of perceived severity, barriers, susceptibility, and benefits shape health behaviors. The researchers also included an incentive to behave, or health motivation, in their model, but did not explicitly include locus of control because its influence was thought to be indirect.

In a more recent study, Tshuma et al. (2017) emphasized the role of self-efficacy as a factor that shapes health behaviors in tandem with factors that shape health beliefs. Rather than positioning self-efficacy as an additional independent variable that has a similar influence as health belief factors, Tshuma et al. determined that it shapes health behaviors as a mediating influence. Specifically, they determined that self-efficacy mediates the influence of the health belief factors of perceived susceptibility, perceived severity, perceived barriers, and perceived benefits (see Figure 2).

Figure 2

Conceptual Health Behavior Model



Note. A conceptual model developed by Tshuma et al. (2017) to describe relationships between individual health beliefs, self-efficacy, and health behavior.

The model depicted in Figure 2 was tested by Tshuma et al. (2017) among 2,277 adult residents of Johannesburg, South Africa. Based on a cross-sectional survey of the participants, they found that the most significant predictors of participants' self-efficacy were perceived barriers and perceived benefits. Self-efficacy was also determined to fully mediate how perceived benefits and perceived susceptibility influenced health behaviors. Further, perceived barriers and perceived severity had a significant influence on health behaviors and were partially mediated by self-efficacy. Tshuma et al. concluded as follows:

> Perceived susceptibility and perceived benefits did not affect health behavior unless associated with self-efficacy. In contrast, individual perception of the seriousness of [non-communicable diseases] and perceived barriers might still have a direct influence on health behavior even if the person does not feel able to prevent [non-communicable diseases]. However, this influence would be more significant when perceived severity and perceived barriers of NCDs are associated with self-efficacy. (p. 29)

Research that improves understanding of how self-efficacy shapes health behaviors is also useful for healthcare providers and organizations that sell medical products, as organizations can use such research to enhance alignment between public health needs and available products and services (Ozumba et al., 2019; Rosenstock et al., 1988). The association between public health service utilization and public perceptions was investigated by Ochonye et al. (2019) in a qualitative study conducted in different Districts of Nigeria. The researchers highlighted that health perceptions reflect the interaction of numerous factors, including risk perception, self-efficacy, action-outcome expectancies, and precautionary motivation. Ochonye et al. found that public health service utilization was significantly predicted by health system status and locality. Further, ratings of public health systems and public health service use were significantly predicted by respondents' perceptions as well as variables, such as self-efficacy, that contribute to health perceptions. Facilities that offered a larger array of health services had higher service utilization and ratings from participants. These findings highlight how healthcare organizations and manufacturers of health products can use research insights into the role of self-efficacy and other factors that shape health behaviors to better meet the health needs of the public.

Valuing patients’ rights and perceptions of their ability to improve their health are core principles of ethical healthcare (Unnikrishnan et al., 2018). Accordingly, the concept of self-efficacy is a key feature of several studies on the role of pharmaceutical companies in patient outcomes (Boggio & Ho, 2018; Talevi & Bellera, 2020). Researchers, including Boggio and Ho (2018), have asserted that representatives from pharmaceutical companies may contribute to establishing effective pathways to reduce the high price of patent medications if they possess the self-efficacy to enact best practices. Further, Boggio and Ho noted that the government should ensure that intellectual property rights, such as patents, are not a hindrance to access to scientific knowledge. Boggio and Ho’s research highlighted how Bandura’s (2000) concept of self-efficacy can be harnessed by experts to find solutions to the high price of patent medications sold by pharmaceutical companies.

Talevi and Bellera (2020) emphasized that many people did not have reliable access to medications at the time of their study due to high costs associated with monopolies on certain patented medications. Despite clear evidence of the role of self-efficacy in the professional practices of doctors, nurses, and other medical professionals (Pietrzak et al., 2020; Tobzhanova et al., 2019), the role of self-efficacy in the professional practices and decisions of pharmaceutical professionals is unclear. In the current study, the role of self-efficacy was explored as a factor that shapes practices by pharmaceutical companies to balance equal access to patent medicines with profitability.

Summary and Conclusions

In summary, the aim of this research was to explore best practices for ensuring equal access to patent medicines while maintaining profitability, medical innovation, and the development of new drugs. Patent medicines are sold under a specific name or trademark that is protected by a patent. A medicine patent from the USPTO provides medicine manufacturers with a legal mechanism to prevent or exclude other manufacturers or merchants from selling a similar medicine during the period of exclusivity. Ensuring that a medicine meets the four general criteria of patentability is the first step in obtaining a patent. Subsequently, a provisional or nonprovisional patent application is submitted if the medicine meets the patentability criteria. An examination, or prosecution, is then enacted that results in the approval or denial of the patent. However, patent medicine manufacturers' ability to sell their medications depends on the FDA approval process.

Under the current U.S. patent policies, a manufacturer is granted approximately 12 to 16 years of market exclusivity, during they have monopoly protection. Patent policy changes are often controversial for medical products, as they are perceived to benefit some stakeholders more than others. Many researchers have proposed changes to medicine patenting policies as the most effective strategy to address the key issues of ethics, innovation, and scientific progress, though some contend that changing foundational aspects of the medicine patenting system and process are necessary to address key concerns. Practices that contribute to balancing access to and profits from patent medicines are influential at all stages of the development and production process; however, best practices for ensuring accessibility and profitability remain unclear.

This study addressed the gap in the existing research concerning knowledge of the best practices that balance the need to ensure consumers' access to patented medication with pharmaceutical companies' profits. Addressing this research gap may also indirectly benefit pharmaceutical innovation and development processes. The methodology selected to address this gap in the existing research was discussed in further detail in this chapter. Key details of the methodology are addressed in Chapter 3, including the research design, sampling method and size, data collection and analysis strategies, and ethical considerations. A summary is provided to transition to Chapter 4.

Chapter 3: Research Method

The ease of access to patent medication and the profitability of pharmaceutical companies are two factors found on the opposite ends of a spectrum. As established in Chapter 1, the specific research problem is the unknown best practices for ensuring equal access to patent medicines while maintaining profitability to pursue needed innovation and development of new drugs (Saluja et al., 2018). Based on the problem, the purpose and phenomenon of interest of this qualitative study were to explore the best practices for ensuring equal access to patent medicines while maintaining profitability to pursue needed innovation and development of new drugs.

In Chapter 3, the details of the methodology and research design are discussed. I used a qualitative methodology with case study research design for this study. The details of choosing a case study and the procedures implemented to fulfill the purpose and answer the research question of the study are discussed further in Chapter 3. The sections included in this chapter are as follows: research design and rationale; role of the researcher; participant selection logic; instrumentation; procedures for recruitment, participation, and data collection; data analysis plan; and ethical procedures.

Research Design and Rationale

The research question addressed in this study was: What are the best practices for ensuring equal access to patented medicines while maintaining profitability of pharmaceutical companies to pursue needed innovation and development of new drugs? To address this question, I used a qualitative case study. A qualitative methodology is often used when exploring a phenomenon through experiences, beliefs, perceptions, and behaviors of individuals (Mohajan, 2018; Senyo et al., 2018). The phenomenon explored in this study was the best practice for ensuring equal access to patent medicines while maintaining profitability to pursue needed innovation and development of new drugs. When implementing the qualitative method, the major objective is to explore and make sense of the perceptions, subjective experiences, and behaviors of individuals as the basis for the human aspect of an issue within a phenomenon (Harrison et al., 2017; Whitaker & Atkinson, 2019). For this study, the exploration was focused on the perceptions and knowledge of experts in the pharmaceutical field. Based on these descriptions, the qualitative method was aligned with and appropriate for the requirements of fulfilling the purpose and addressing the research question for this study.

A case study is appropriate for exploring phenomena because the design is used to draw upon in-depth data collection to paint a comprehensive, contextual picture of a study's subject that depicts the phenomenon and the context surrounding it (Yin, 2017). Case studies are used when the purpose of research is to understand an individual, group of individuals, or a specific event or phenomenon (Yin, 2017). The phenomenon of interest for this study was the best practice for ensuring equal access to patent medicines while maintaining profitability to pursue needed innovation and development of new drugs. Due to the contextual aspect of the issue under study, the case study was appropriate.

I also considered other research designs but found them inappropriate for this study. Phenomenology is a design used to explore human participants' lived experiences to make sense of a phenomenon (Moustakas, 1994). The focus of this study was the best practices for ensuring equal access to patented medicines while maintaining profitability to pursue needed innovation and development of new drugs. Conducting phenomenology would require deep immersion into the lived experiences of individuals related to the phenomenon of interest. Such strategy would require significant time, which was not feasible for the given timeframe for this study. I also considered narrative inquiry, which involves the use of data on events in a chronological order of occurrence (Barkhuizen, 2019). The aim of the current research was not to explore and identify best practices through storied data that have to be presented and analyzed in chronological order. Therefore, the narrative design was not appropriate, and the alternative research designs were found to be inappropriate for this study. A case study was the most appropriate design for this research.

Role of the Researcher

The major role of the researcher in this study was to serve as the main instrument of data collection. In qualitative studies, it is common for researchers to be the main data collection instrument by serving as interviewers or observers as well as data analysts (Bimrose et al., 2019). During data collection, I performed open-ended interviews and conducted document reviews. Aside from the role of the researcher as the main instrument for data collection, participant recruitment and data organization and analysis are also included in the responsibilities of the researcher.

In the recruitment phase, my role was performing purposive sampling to identify and recruit eligible participants for this study. Purposive sampling involves recruiting participants based on a set of characteristics aligned to the requirements and topic of the study (Campbell et al., 2020). As part of my role as a recruiter of participants, I obtained site permission before conducting purposive sampling. I also initiated contact with potential participants through email.

The role of the researcher is to provide and ensure professionalism and integrity regarding the study (Mozaffor et al., 2019; Parasidis et al., 2019). Another responsibility of the researcher is minimizing the influences of personal biases (Triplett, 2019). As a researcher, it is common to have deep knowledge about the research topic. In the exploration of the topic, even before arriving at a specific problem to be addressed, I had already gained significant knowledge of the topic, developing beliefs about the topic, which could have influenced the findings from this study. An important means of addressing personal biases is to acknowledge these possible sources of bias (Bero, 2017). To minimize bias, it is important to acknowledge all personal opinions, perceptions, and beliefs, including expected findings about the study. All interpretations and conclusions must have corresponding support based on the actual data collected from the participants.

During data collection, it is part of the researcher's role to conduct different methods of gaining information about the topic from relevant participants (Umanailo et al., 2019). For this study, the multiple data sources were semistructured interviews, open-ended questionnaires, and document review. I used an expert-reviewed interview protocol during data collection to avoid asking irrelevant, biased, or leading questions, which could have led to invalid results.

One of the main considerations when recruiting participants is minimizing conflict of interest with the target population (Goodrum et al., 2021). To avoid conflict of interest, it is imperative that family members, relatives, friends, colleagues, and subordinates of the investigator be excluded as participants in the study. Specifically, I did not include colleagues, especially subordinates at work or in other organizations, as participants in this study. This step was important in ensuring that power differentials would not be a consideration when assessing the credibility of the findings. Gaining participants' informed consent was also part of the role of the researcher to ensure minimization of conflict of interest.

My personal drive to pursue this research on patent medicines was the significant price increase of the EpiPen. I manage the EpiPen line and thus may have bias and empathy for poor people who need to purchase patent medicines but cannot afford such expensive medications. My aim for pursuing this study was to benefit society by serving as a learning paradigm for the pharmaceutical company experts in terms of understanding how to reduce the high pricing of patent medications. To avoid any influence of these personal beliefs and perceptions, I ensured that the study was based on actual data from participants using the bracketing approach, and discussions and interpretations in Chapter 5 are accompanied with actual data from the participants and research support from relevant literature, where applicable. The bracketing technique encompassed setting aside my biases, beliefs, and assumptions and focusing on the participants' experiences. To do this, I engaged in journaling and mindful meditation on my biases and assumptions and then set them aside.

Methodology

Participant Selection Logic

The target population for this study included experts from the pharmaceutical industry. This chosen target population was appropriate because of the knowledge and expertise these individuals possess regarding the phenomenon of interest. These experts in the pharmaceutical industry had the relevant knowledge needed to address the research questions of this study. Recruiting experts in the field of study as participants enhances rigor and allows the attainment of rich data in the process (Hayashi et al., 2019). Therefore, this chosen population was aligned with the requirements for this study.

I used purposive sampling to recruit participants in this study. Purposive sampling is a technique used to select samples based on a set of characteristics aligned with the requirements of research (Klar & Leeper, 2019). This technique enables a researcher to select participants who have the relevant background to provide information for addressing the research questions for a study (Etikan et al., 2016; Klar & Leeper, 2019). Based on this description, purposive sampling was appropriate for this study because of the need to include only participants with expert knowledge in the pharmaceutical industry, specifically regarding the phenomenon of interest. With this sampling technique, I could align the sample and the phenomenon by recruiting those who had a direct interaction with the phenomenon. Therefore, using the purposive sampling technique was appropriate for this study.

When using purposive sampling, the eligibility of participants must be ensured. The inclusion and exclusion criteria for the participants in this study included the following: (a) participants should be pharmaceutical experts; (b) have 10 years of experience in the pharmaceutical field; (c) with at least a 3 years managerial level position in the departments of research and development, marketing, and/or finance for them to provide insights regarding to the costing and profitability issues; and (d) with a master's degree or higher. Recruiting pharmaceutical experts with higher education as participants in the study helped enhance the rigor of the research process. These eligibility criteria were aligned with the research question.

I asked a set of screening questions based on these criteria to ensure only eligible individuals participated in this study (see Appendix C). I sent an email to the participants enumerating all the inclusion criteria. Potential participants replied to the email stating whether they satisfied each item on the criteria. Eligible individuals were those who satisfied all the criteria.

In qualitative studies, researchers often recruit a small sample, while achieving data saturation ensures that the appropriate sample size was reached (Etikan et al., 2016). Data saturation is a point during collection and analysis wherein no new codes or themes can be identified despite adding more data obtained from the data collection sources (Braun & Clarke, 2021). For this study, I aimed to recruit a minimum of 10 experts in the pharmaceutical industry to be participants in the semistructured interviews. Yin (2017) claimed that a sample of six for case studies is acceptable, provided data saturation is achieved and the targeted samples are from the social group aligned with the case. My plan was to recruit more participants if the initial sample did not yield data saturation.

Instrumentation

The main instrument for data collection for this study was me, the researcher, and I conducted the interviews and document reviews. To aid in data collection, however, I used an interview guide as I collected information from the experts in the pharmaceutical industry. I personally developed this interview guide to address the research question for this study. The items in the interview guide were based on relevant literature in the context of the research question of this study. The interviews were audio-taped, and participants were made aware of this recording through the informed consent form.

Conducting an expert review of a researcher-developed interview protocol for the data collection of a study is helpful in improving a study's credibility (Maidin & Rahman, 2020; Young et al., 2018). I conducted an expert review to improve the validity of the interview guide. In this procedure, I asked a panel of three professionals to evaluate the items in the interview. The members of the review panel were different from the actual participants in the study. The panel members were composed of three individuals from each of the following fields: (a) pharmaceutical industry, (b) academic research, and (c) qualitative research. Each panel member had to have at least 5 years of experience in their respective field. The panel members provided feedback about the interview guide items based on the following: (a) usage of words and sentences are appropriate for the interviewees; (b) the sentence structure is understandable and fit for interviewees; and (c) the scope of the questions is sufficient to address the research question for this study completely. Based on the feedback from the panel members, I made the necessary changes to the questions before conducting any data collection.

Procedures for Recruitment, Participation, and Data Collection

To gain access to the participants, I contacted the association of pharmaceutical companies in the United States to seek their permission to conduct the data collection of the study with their members. I asked for email addresses of known experts in the pharmaceutical field who were eligible and interested in participating in this study. As an alternative measure, I intended to use social media pharmaceutical groups, targeting experts in this field as a source of participants.

Participants had to meet the following inclusion criteria: (a) participants should be pharmaceutical experts; (b) have 10 years of experience in the pharmaceutical field; (c) with at least a 3 years' managerial level position in the departments of research and development, marketing, and/or finance for them to provide insights regarding to the costing and profitability issues; and (d) with a master's degree or higher. Participants also had to be involved in financial planning analysis, budgeting, cost accounting, and other financial management functions in healthcare. They also had to be knowledgeable about costing in patented products and its impact on pricing of products.

I emailed potential participants inviting them to participate in this study. I discussed the scope of the study, participation procedures, and the criteria for eligibility in the invitation and included a copy of the informed consent form to ensure potential participants underwent the consent process before participating in this study. The informed consent also included information about member checking, wherein participants received copies of their interview transcripts and the researcher's initial interpretation of the corresponding participant's interview data. Participants were allowed 7 days to respond and provide comments regarding possible mistakes and inaccuracies in the documents. Those who read and agreed to the contents of the consent form were asked to sign the consent. Therefore, only those who gave a signed copy of the consent form through email participated in this study.

I conducted data collection using semistructured interviews and document reviews. All interviews occurred online via Zoom to minimize physical contact between myself and the participants. The decision to conduct data collection online was to ensure the safety of the parties involved amidst the COVID-19 pandemic. Each interview was expected to last 60 minutes. I provided each participant with the Zoom meeting details through email at least 1 day before each scheduled interview. The email contained instructions for installing Zoom as well as the meeting ID and password. The use of Zoom for online interviews is aligned with the study of Son et al. (2020). I assigned each participant a unique meeting ID and password to allow them to access the virtual meeting room.

On the day of the interview, I opened the meeting room 5 minutes earlier than the scheduled time. I welcomed the participant to the interview once they entered the virtual meeting room. Once the interviewee and I were settled, I began with an introduction, which included an overview of the topic and flow of the interview. I asked participants about their expectations for the interview and addressed any misconceptions that they had at this point.

After the introduction, I began asking questions based on the interview guide. Whenever needed, I asked follow-up questions to collect deeper explanations for their initial responses. Asking follow-up questions is a useful attribute of semistructured interviews to aid researchers in gaining deeper insights and explanations to participants' initial answers (Roulston & Choi, 2018). Using the follow-up questions, I investigated more about the participants' answers and gained more data for this study. After exhausting the questions in the interview protocol, I asked them for the documents that would be used for the document review. I then thanked the participant for their time and reminded them about the member-checking process, wherein a review of the accuracy of the initial interview data interpretations would be conducted. Each participant had 7 days to respond with any changes that could be made ensure accurate information and interpretation. I also planned to conduct follow-up interviews to seek for clarifications from specific participants regarding the data collected in their respective interviews. These follow-up would occur via Zoom and the session recorded to document the conversation. After conducting follow-up interviews, I would finalize the transcripts and initial interpretations to finish the member-checking phase. The conclusion of member checking marked the end of the participants' participation in the study.

A contingency plan was in place for participant recruitment so that if the initial recruitment did not yield data saturation, more eligible participants would be recruited. If a participant exited the study before analysis, they would have been replaced by another eligible individual. Therefore, recruitment would be repeated. If there were excess eligible participants in the sampling phase who were not included in the data collection, these individuals would be contacted for an interview. If more participants would still be needed, I planned to continue emailing individuals who belonged to the target population to continue the recruitment procedures.

I also conducted a document review. The purpose of the secondary data source was for triangulation, which was needed to improve the credibility of the data and findings. Examples of the documents included were company annual reports, company newsletters, newspaper articles related to drug innovations, drug pricing, medicine patents, and patient usage of patented drugs. I chose these documents because they had information relevant to the phenomenon of interest for this study. From the documents, I identified relevant information for addressing the research question for this study. I highlighted the words, phrases, and sentences that I found to be relevant to the study. I converted these words, phrases, and sentences into a word document for data analysis. These steps were derived from the descriptions of Bretschneider et al. (2017) on document review.

Data Analysis Plan

Organization and processing of the data collected preceded the analysis of the data collected. After each interview, I transcribed the data and wrote a report on the initial interpretation of the findings from each interview. Using the transcript and my initial interpretation, I conducted member checking.

Member checking is a common process in qualitative studies for ensuring the credibility of the findings (Candela, 2019; Carlson, 2010). This process is accomplished by allowing participants to review the interpretations of the data they provided (Candela, 2019). I performed member checking by providing each participant with a copy of their respective interview transcripts and my initial interpretation of the data they provided in the interviews through email. Each participant had 7 days to review the information in the transcript and initial interpretations file. Participants could provide clarifications or corrections to the information found in the two documents. These clarifications or corrections had to be disclosed to the researcher through a reply to the email containing the interview transcript and the initial interpretation. If after 7 days a participant had not sent any response to the email, I assumed that the information in the transcript and initial interpretation documents was accurate and required no corrections. After member checking, any new data were loaded into the NVivo software and subjected to thematic analysis.

I analyzed the data using Braun and Clarke's (2019) thematic analysis. The steps of thematic analysis are: (a) data familiarization, (b) code development and coding, (c) theme development, (d) theme revisions, (e) theme finalization and theme definition development, and (f) report generation (Braun & Clarke, 2019). In the data familiarization step, I began reading the interview transcripts and documents to become familiar with the data. According to Braun and Clarke, reading and rereading information are useful to become familiar with the data. Therefore, I read the transcripts at least two times. Starting from the second round of reading, I highlighted descriptive texts as I read the data collected for the study. Descriptive texts were words, phrases, and sentences aligned with the research question for this study. If necessary, I would complete a third and fourth round of reading to ensure all relevant descriptive texts were highlighted.

In the second phase of thematic analysis, I began open coding. In open coding, an analyst identifies distinct concepts and themes for categorization depending on the data collected, rather than having a preconceived set of codes to be followed (Williams & Moser, 2019). I developed a coding scheme, wherein the codes (e.g., prompt response to complaints, courteousness, listening to customers, etc.) were based on the data collected through the interviews and document reviews. I grouped texts with similar meanings under one code. As I went through the descriptive texts, however, I added more codes into the coding scheme, if necessary, to facilitate coding in the NVivo software. In the software, each code was represented by a node.

The third step of the analysis entailed grouping similar codes to form a theme. The themes provide a direct answer to the research question of this study. To facilitate theme development in NVivo, I grouped related codes to form trees or groups of nodes. I also showed the relationship of the codes through the NVivo software hierarchy of relationships using nodes and trees.

In the fourth step, I finalized the themes by ensuring their relevance to the research question of this study. I determined the final list of themes by identifying the themes from the answers of the majority of the participants. These themes were the major themes, whereas the remaining themes were considered minor themes.

In the fifth step, I defined the themes in relation to the research question. Theme definitions were written to be parallel with the terms used in the research question to ensure themes addressed the problem of the study. In the sixth and final step, I wrote the report of the findings, which makes up part of the content of Chapter 4.

Issues of Trustworthiness

Trustworthiness refers to the qualitative counterpart of validity and reliability (Cloutier & Ravasi, 2021). Addressing issues of trustworthiness is important in qualitative research (Cloutier & Ravasi, 2021). Trustworthiness is composed of four elements: (a) credibility, (b) transferability, (c) dependability, and (d) confirmability. I addressed each component for this study as explained in the following subsections.

Credibility

Credibility refers to the extent to which the data interpretations are true and similar to the intended meanings of the participants (Lincoln & Guba, 1985). I ensured credibility by conducting member checking, which entailed participants' reviewing their transcripts and corresponding initial interpretations to confirm the accuracy of the information in the document, as Candela (2019) advised. The participants offered any corrections that had to be made to the interpretations. I also used two data sources for triangulation, which was also a means of improving data saturation.

Transferability

Transferability is the external applicability of qualitative research beyond its current context and boundaries (Lincoln & Guba, 1985). I ensured transferability by providing thick and rich descriptions of the procedures and findings of the study, per Lincoln and Guba (1985). Through rich and thick descriptions, future researchers and readers can replicate the study with ease and assess the applicability of the findings to another context or population. I also provided all data in the original description form to enable future researchers to use the data, should they wish to do so.

Dependability

Dependability refers to the reliability of the study (Lincoln & Guba, 1985). I improved dependability by conducting an audit trail. In the audit trail, I documented all the steps followed in fulfilling this qualitative case study for an easier review by readers and future researchers, should the need for such a review arise. Triangulation through multiple data sources also aided in improving the dependability of this study.

Confirmability

Confirmability is the objectivity of the findings (Lincoln & Guba, 1985). I ensured confirmability by acknowledging personal beliefs, experiences, and preferences in relation to the topic to minimize researcher bias. An expert review of instrumentation is an effective means of improving confirmability (Amin et al., 2020). Therefore, I also conducted an expert panel review of the interview guide. These initiatives reduced subjectivity, thus enhancing the confirmability of the study. To prevent bias, I used bracketing, a useful tool for recognizing and setting aside any possible personal biases, assumptions, and preconceptions that may have an influence on the data (Emiliussen et al., 2019). In this technique, I identified and acknowledged my biases and assumptions relating to the topic and wrote them down in a notebook so that I could make note when they came up during the research process. Subsequently, I set them aside during collection, analysis, and interpretation. The final process of bracketing entailed reflection, where I recapped the process and documented how it helped me eliminate bias.

Ethical Procedures

When using human subjects for a study, a researcher should address ethical issues that may compromise the rights of the participants. The first ethical procedure is the institutional review board (IRB) process. I obtained approval from the university's IRB to ensure that the study's procedures were ethical. I also ensured all participants underwent the informed consent process before conducting data collection for this study. Through the informed consent form, I disclosed the arrangements and understanding between the participant and myself as the researcher in conducting this study. All participants in a study must be volunteers and agree to the contents of the consent form before participating in the study. Participants could withdraw from this study at any time. If any participant decided to withdraw from this study, I would have respected their decision without any consequence. I kept the identity of the participants confidential using pseudonyms for the participants or organizations. I kept all information and documents in a locked cabinet inside my home office to which only I have access. I will keep these files for 5 years and destroy them thereafter.

An investigator must also uphold the rights of human participants based on the elements of the Belmont report: (a) justice, (b) beneficence, and (c) respect for persons (Belmont Report, 1979; Fell et al., 2020; Lantos, 2020). To ensure justice in research, I ensured all procedures were reasonable and nonexploitative, as Fell et al. (2020) noted. Second, to uphold benevolence, I ensured the risks related to participating in this study were minimal (Fell et al., 2020; Lantos, 2020). When upholding respect for persons in a research study, it was important for the participants to undergo the informed consent process, which ensured they had prior knowledge of what they would be doing in the study before deciding to participate (Fell et al., 2020; Parasidis et al., 2019). I considered each of these procedures in my role when dealing with human participants in this study.

Summary

In Chapter 3, I established that a qualitative methodology with a case study design was the appropriate choice for this research. This choice was aligned with the purpose and research question for this study. The purpose of this qualitative study was to explore the perceptions of pharmaceutical company experts to identify best practices for ensuring consumers' improved access to patented medicines while maintaining profitability for pharmaceutical companies to pursue needed innovation and development of new drugs. To facilitate this purpose, I collected data from 10 experts in the pharmaceutical industry through online semistructured interviews via Zoom and a document review. I then analyzed the data using thematic analysis. The findings for this study are presented in Chapter 4.

Chapter 4: Results

The purpose of this qualitative multiple case study was to explore best practices for ensuring equal access to patent medicines while maintaining the profitability of pharmaceutical companies to pursue needed innovation and development of new drugs and to ensure business sustainability. The specific research problem addressed in this study was the best practices for ensuring equal access to patent medicines while maintaining profitability to pursue needed innovation and development of new drugs (Prager et al., 2018; Saluja et al., 2018). The following research question guided this study:

RQ: What are the best practices for ensuring equal access to patented medicines while maintaining the profitability of pharmaceutical companies to pursue needed innovation and development of new drugs and ensure business sustainability?

This chapter includes a discussion of the demographics of the participants who consented to participate in the study. The data collection and data analysis used to generate the results of the study are also discussed. The evidence of trustworthiness is given, followed by a discussion of the results obtained from the data analysis process using NVivo 14 software. The chapter concludes with a summary and a transition statement to Chapter 5.

Demographics

To attain an appropriate sample for this study, I used purposive sampling to recruit eligible participants. Using the inclusion and exclusion criteria, I was able to obtain 17 participants who consented to participate in the study. All the participants were pharmaceutical experts with 10 years of experience, including at least 3 years at managerial-level positions in the departments of research and development, marketing, and/or finance. The participants also had master's degrees, which helped enhance the rigor of the study.

Data Collection

Data were collected through interviews and document reviews as indicated in the plan presented in Chapter 3. In total, 17 participants were interviewed. All the interviews were conducted online via Zoom, and each took about 60 minutes. The interviews were conducted from different locations because the participants joined from their respective homes or offices. A day in advance, each participant was emailed the installation instructions for Zoom, the meeting ID, and the password for the interview so that all interviews could be held as scheduled. With participants' consent, all interviews were recorded to ensure accurate data collection.

All interviews were conducted according to the schedule, and participants did not experience technical problems related to entering virtual meeting rooms. One of the interviews did not occur as scheduled due to an internet connectivity problem on the part of the participant. This interview had to be rescheduled for the next day. Further, I conducted follow-up interviews with three participants to allow clarification of some of the issues raised in the first interviews. The follow-up interviews were also conducted on Zoom and recorded for purposes of accuracy. Document review was performed as planned with no remarkable deviations from the outlined procedures.

Data Analysis

From the data organization and processing plan discussed in Chapter 3, the interviews were carefully transcribed before undergoing preliminary interpretation. Member checking by the participants was done by sending each transcript, together with a preliminary interpretation of the data, to the respective participants. The participants had a 7-day review period to provide clarifications or corrections where necessary. I collected comments from 17 respondents who gave their feedback. In the cases of those who did not reply within the given time, the documents were considered accurate as they initially appeared. All the changes proposed from member checking were applied in the final data set before thematic analysis.

The thematic analysis was conducted using Braun and Clarke’s (2019) six-step framework. Initially, I familiarized myself with the data by thoroughly reading and rereading the transcripts, which allowed an immersive understanding of the content. During the coding process, I identified significant phrases and concepts and systematically coded them. The next step was reviewing the codes to identify overarching themes, which were refined and revised through an iterative process to ensure they accurately represented the data. The final themes were clearly defined and contextualized within the framework of the research questions. This process culminated in the generation of a comprehensive report with details of the emergent themes and their relevance to the study’s objectives. The NVivo software facilitated the organization and analysis of the data, ensuring a rigorous and methodical approach to thematic analysis.

Step 1: Familiarization With the Data

The immersion into data involved reading several times and listening to the audio files that had been recorded after all Zoom calls. This process also included some preliminary note making on what seemed to be the response of the particular participants on the issues to be addressed. This step helped me generate some ideas and create a preliminary feel of the data. Initial notes from the process captured the particular thoughts of the participants in the study. I focused on the description given by the participants to understand the best practices for ensuring equal access to patent medicine while maintaining profitability.

Step 2: Generation of Initial Codes

Upon familiarization with the data, codes were generated from the original notes, and labels were made for the participants' unique responses. Here, codes referred to brief notes and phrases that captured the participants' reactions to the elimination of the recycling programs. These codes provided a basis for the categorization and analysis of qualitative data, whereby I identified themes and patterns pertaining to the participants' views regarding the best practices of ensuring equal access to patent medicine. Such a systematic analysis of these coded responses allowed an in-depth understanding of the various perspectives within the study. Table 1 shows how the initial codes were formulated in clusters in response to the research question.

Table 1

Codes and Categories for RQ

Codes	Categories
Better planning and intentionality Collaboration with other institutions Contract manufacturing of medicines Investing in quality infrastructure Investing in research and development Transparency in pharmaceutical companies	Strategic approaches to enhance efficiency, innovation, collaboration, infrastructure, and transparency within the pharmaceutical industry
Advocating for policy reforms Government integrations Having a universal healthcare system Not extending patents Subsidization of commodities	Policy reforms and government actions to improve healthcare access and affordability
Establishing patient assistance programs Ethical considerations during research Having tiered pricing strategies Market segmentation Ensuring cost-effectiveness during production	Ethical pricing, targeted assistance, and efficient production to enhance patient access

Step 3: Searching for Themes

There was the need to identify similar codes and those that related to others and bring them together in agglomerated clusters. For each group, I aggregated codes that exhibited a pattern. This step involved the identification of similar and different aspects in description by the participants to establish general patterns. Clusters that were identified informed the formulation of possible themes.

Step 4: Review the Identified Themes

At this stage, I examined the themes formulated to ensure they captured the correct perspectives of the participants. In this process, some formed clusters were combined with the rest of the themes and new themes were formulated. This iterative process was important to relate each theme to the research question.

Step 5: Defining and Naming of Themes

Step 5 entailed cross-examining each theme and defining them in relation to the research question. For the themes generated in Step 4, I developed names for each of them, which were in line with the research question. Through this process, resulting themes captured what participants responded regarding the best practices of ensuring equal access to patent medicine while maintaining profitability in pharmaceutical companies. Table 2 shows themes that were developed from the codes generated.

Table 2

Codes, Categories, and Themes

Codes	Categories	Themes
Better planning and intentionality Collaboration with other institutions Contract manufacturing of medicines Investing in quality infrastructure Investing in research and development Transparency in pharmaceutical companies	Strategic approaches to enhance efficiency, innovation, collaboration, infrastructure, and transparency within the pharmaceutical industry.	Theme 1: Strategic and operational practices
Advocating for policy reforms Government integrations Having a universal healthcare system Not extending patents Subsidization of commodities	Policy reforms and government actions to improve healthcare access and affordability.	Theme 2: Policy and regulatory reforms
Establishing patient assistance programs Ethical considerations During research Having tiered pricing strategies Market segmentation Ensuring cost Effectiveness during production	Ethical pricing, targeted assistance, and efficient production to enhance patient access.	Theme 3: Pricing and accessibility strategies

Step 6: Writing the Report

This step entailed presenting the findings in a narrative manner that captured the responses of the participants. In this step, I wrote a detailed description and included quotes from the participants illustrating every theme. The report captured themes coupled with the participants' narrations. By following the six thematic analysis steps, three themes that addressed the research question were identified. Table 3 contains a summary of the themes identified and the research question.

Table 3

Research Question and Themes

Research question	Themes
What are the best practices for ensuring equal access to patent medicines while maintaining the profitability of pharmaceutical companies to pursue needed innovation and development of new drugs and ensure business sustainability?	Theme 1: Implementing strategic and operational practices Theme 2: Adopting policy and regulatory reforms Theme 3: Pricing and accessibility strategies

Evidence of Trustworthiness

Trustworthiness is a measure used to ensure that the data collected in qualitative research is rigorous. According to Lincoln and Guba (1985), trustworthiness refers to the degree to which a qualitative study reflects the participants' perspective as well as the context under investigation, which is based on the design of the study. Ensuring trustworthiness involves four criteria: credibility, transferability, dependability, and confirmability.

Credibility

According to Wood et al. (2020), credibility reflects the strategies employed by the researcher in an effort to ensure that the results that are presented align well with what they purport to be with regard to the researched phenomenon. The trustworthiness can be enhanced by the researcher's judgment on whether the study has rightly followed the established qualitative procedures along with the proper cause. In this study, I employed a member-checking method, wherein the participants were allowed to check their transcripts for correctness. Transcripts were sent to all 17 participants who submitted feedback signifying that the findings are correct.

Transferability

Transferability is the degree to which findings can be generalized or applied to other contexts or populations (Kyngäs et al., 2020). I gave a detailed account of the methodology as a way of ensuring that the findings would be transferrable. This process involved an accurate description of the participants, how they were selected, and what made them inclusive or exclusive, so as to enable the audience to relate with how the respondents were drawn and how population transfer would have been possible. The detailed description of the methodology allows the reader, on reading findings, to determine in which contexts the given conclusions are applicable or transferable (Kyngäs et al., 2020). In view of the methodology employed, the findings from this study are applicable to other similar research settings.

Confirmability

Confirmability is the level at which data collected truly reflect reality, free from any researcher bias or assumptions. According to Stahl and King (2020), a researcher has to prove that the qualitative research conducted was objective and free of any bias or assumption. In the current study, I conducted data analysis, which involved repeatedly reading the data and coding, identifying patterns, and developing themes. This approach ensured a process that was objective rather than subjective throughout the research. To ensure confirmability, I maintained reflexivity by critically reflecting on personal biases and assumptions made throughout the research process.

Dependability

Dependability refers to the degree of generalization, meaning that if another researcher replicates a study at a later time, they should be able to achieve consistent and reliable results (Stahl & King, 2020). This criterion further refers to how long-term consistencies retain relevance in research findings. In this study, I used an audit trail to enhance dependability of this study. The audit trail involved recording the history of the entire process of this study, for example, field notes, audio recordings, and files used during data analyses. With open accountability in data as achieved using an audit trail, the dependability of the study can be judged, as put forward by Stahl and King (2020).

Results

The research question for this study was: What are the best practices for ensuring equal access to patent medicines while maintaining the profitability of pharmaceutical companies to pursue needed innovation and development of new drugs and ensure business sustainability? I aimed to investigate the best practices for ensuring equal access to patent medicines while maintaining the profitability of pharmaceutical companies to pursue needed innovation and development of new drugs and ensure business sustainability. Three themes were identified that help answer the research question: (a) implementing strategic and operational practices, (b) adopting policy and regulatory reforms, and (c) pricing and accessibility strategies.

Theme 1: Implementing Strategic and Operational Practices

Theme 1 addresses the strategic and operational practices that companies use to ensure there is equal access to patent medicines for everyone irrespective of their income level. Six codes were aggregated to form this theme. The codes included better planning and intentionality, collaboration with other institutions, contract manufacturing of medicines, investing in quality infrastructure, investing in research and development, and transparency in pharmaceutical companies.

Regarding better planning and intentionality in ensuring equal access to patent medicine, Participant DW talked about companies having to be deliberate and plan to provide better, quality, and accessible patent medicine. Companies have to face the challenge of profitability head-on and be deliberate about it. Participant DW said, “To maintain profitability again requires deliberate thought and planning to provide better. Quality and access to patent. You just have to face those head-on and then be very deliberate and intentional in what you’re trying to accomplish and achieve.” Participant JE also mentioned that drug manufacturers need to be deliberate about implementing the best practices in their companies to maintain profitability, saying, “Then you know drug manufacturers can implement. I think those are some of the best practices that we can utilize to maintain profitability while making sure that patients have access to those branded drugs."

Collaboration with other institutions was mentioned as a practice that companies producing patent medicine should embrace. Participant EC said they believed that companies should not work in silence but rather collaborate with other institutions, including governments and nongovernmental organizations, to address the issue of profitability. Working with other organizations would make every stakeholder understand what is happening on the ground. Participant EC said:

> Yeah, I believe pharmaceutical companies should not work in silence. They should make sure that there is a collaboration with other institutions, including governments or even nonprofit organizations and other stakeholders to address, systemic issues. You know, when you work with other stakeholders, you can easily understand, like what? The issues on the ground and how can we as a pharmaceutical company come in to help address those issues.

Participant PK emphasized that it is important for companies to involve both the government and other nongovernmental institutions to ensure a widespread availability of patent medicine. The partnerships also need to be strategic because companies want to collaborate with partners they can share costs of production with, hence lowering the cost of the medicines. Participant PK said:

> We cannot do it without involving the government involving nongovernment organizations to ensure the widespread availability over the country within and

> also beyond the border, so as to ensure that all those people are able to access it. Strategic partnership—you're trying to make sure that you bring in partners and to make sure you're combining hands to do this, and you're not alone, so where you would incur, would be too much cost, when you have partners in place, you might distribute the cost between the different partners and that lowers how much you would spend as an individual. So that lowers your production cost and makes sure you're selling now.

Investing in quality infrastructure was also mentioned by the participants as another best practice that companies could employ to ensure equal access to patent medicines. Participant GM said that investing in infrastructure would ensure efficient special networks and accessible healthcare procedures even in remote areas. Companies are expected to ensure compliance with all requirements set out for development. Participant GM said:

> Investments in … infrastructures pay tribute to the role of ensuring efficient special networks and accessible healthcare procedures, even in remote areas … And support for the skills for its infrastructure development in and in different regions actually compliance and having to regress the great standards and compliance requirements in all aspects of the development, manufacturing, and marketing, comparing medicines to ensure safety quality.

Participant JV also mentioned that companies should strike a balance between fostering innovation through intellectual property protection and ensuring equitable access to essential treatments. They should also invest and embrace technology, especially in developing countries to enhance access while potentially reducing production costs. Participant JV said:

> Best practices in the industry regarding patents and medicine strike a delicate balance between fostering innovation through intellectual property protection and ensuring equitable access to essential treatments … Embracing technology transfer initiatives and supporting local manufacturing capabilities in developing countries can enhance access while potentially reducing production costs—ultimately, a multifaceted approach that considers both financial viability and social impact, essential for achieving the dual goal of profitability and equal access to patent medicine.

Theme 1 demonstrates companies' strategic and operational practices in their attempt to access patent medicines regardless of income. Principally, the major practices include purposeful planning, collaboration with governments and nongovernmental institutions, strategic partnerships for cost reduction, investment in quality infrastructure, innovation, ensuring access, and embracing technology for improved distribution and reduced production costs. These practices shed light on the multifaceted approach to balance profitability with giving accessibility to essential medicines to all.

Theme 2: Adopting Policy and Regulatory Reforms

Theme 2 captures the policy reforms suggested by the participants that companies could undertake to ensure equal access to patent medicine while maintaining profitability. Eleven participants said that policies should be regulated to ensure profitability and equal access to everyone. Five codes were aggregated to come up with Theme 2: (a) advocating for policy reforms, (b) government integrations, (c) having a universal healthcare system, (d) not extending patents, and (e) subsidization of commodities.

Regarding advocating for policy reforms, Participant JV said that companies should advocate for policies that enhance openness and fairness in the healthcare system. The policy reforms should promote competition, transparency, and equitable access to healthcare resources. The resources will then help create a more conducive environment for innovation while addressing affordability. Participant JV said:

> They can push for rules that encourage fairness and openness in the healthcare system. Making sure that everyone has a chance to get the treatment they need further … Advocating for policy reforms that promote competition, transparency and equitable access to healthcare resources can create more conductive, conductive or conducive environments for innovation while addressing affordability. Talk to my lead pharmaceutical companies. They must balance their business objective with their social responsibility to ensure that innovative medicine is accessible to all who need it.

Participant JO, though not working in the production department, said that they would follow the FDA rules and regulations. Regulatory control, which is shared among the national regulatory authorities, pharmaceutical producers, distributors, and other actives, was mentioned as a best practice of ensuring fairness. Participant JO said:

> So this is a tricky question because I work in production and I don’t make regulations, but the one thing. What I can say we do is follow the FDA rules and regulations … Some of the best practices would include things like regulatory

control, which is a shared responsibility of the national regulatory authorities, pharmaceutical producers, distributors, and also other activities.

Nine participants talked about involving the government as the major policymaker in the process of ensuring equitable access to patent medicines. Participant JE mentioned that the government should come up with incentives such as tax exemptions. These incentives would then help companies reduce their cost of production, hence reducing the prices of patent medicines for low-income earners. Participant JE said:

> They're getting some type of government incentive that may potentially offset somewhere the research cost. For the drug, or if they can, some of the government, senator or they can get extradited approval and get it to market. To pass it. Those are some of the things I think would have, you know, gotten equal access to these medications … They're kind of missionary early is that if the information comes we have more incentive. To you know, to develop new drugs, more incentives such as, you know, the government, you know, giving us some type of, you know, tax, you know, incentives or something, you know, where they're reducing the cost of the research and development where they offer them incentive, where they can. You know they can get. Do you know the drug to market?

Participant SL also said that the government should raise its funding either through government grants or private funding. Once the government has offered funds, companies should then develop drugs and set fair prices for people who may not be able to afford patent medicines. Participant SL said:

> So you know, I think somehow the funding for the development should be raised, you know whether it's through the government grants through private funding, so on and so forth but not transferred into the prices of the product. Raise the money, do your development, and then set a fair price afterward.

Another best practice suggested by the participants was that companies manufacturing patent medicines should not seek an extension of expiration dates. Participant AC said that the expiration dates for patents should be short to control pharmaceutical greed of setting high prices. By not extending expiration dates, other companies could also join the market and offer competition. Participant AC said:

> The best practice would be to not seek extended patents on medicines. Patent expiration dates should be based on a shorter length of time to control pharmaceutical greed with high prices for favorite and popular patented medicines. Also, by not extending patents, companies would not be solely the only ones that the Med could be.

Theme 2 addresses the call for policy and regulatory reforms that would ensure equitable access to patented drugs without affecting the manufacturers' profitability. The participants mentioned the need for advocacy of policy changes to increase fairness, transparency, and healthcare competition. The involvement of governments through incentives in the form of tax breaks and funding is important. Limiting patent extensions was also mentioned as necessary to prevent high prices and promote competition in the market. Such reforms, they added, are necessary to strike a balance between the interests of big pharmaceuticals and the broader goal of access to medicines.

Theme 3: Pricing and Accessibility Strategies

Theme 3 addresses the pricing and accessibility strategies suggested by the participants as best practices for ensuring equitable access to patent medicine while maintaining profitability. Five codes were aggregated to form Theme 3. The codes were as follows: (a) establishing patient assistance programs, (b) ethical considerations during research, (c) having tiered pricing strategies, (d) market segmentation, and (e) ensuring cost-effectiveness during production.

To ensure profitability, 11 participants said that companies should embrace differential pricing to cater to low-income earners. For example, Participant EC said that one of the ways in which profitability can be achieved is through implementing differential pricing based on income level or purchasing power. Companies should consider low-income earners when setting prices for their patented medicines. Participant EC said:

> So yeah, I feel there are various ways in which this can be achieved and this includes differential pricing based on their income levels or price purchasing power. So, you know there are different people with different income levels and we can have actual prices based on how much each person is. Maybe how much is targeting market mix and we can target that with the differential pricing.

Participant JV talked about a responsible pricing strategy to ensure that patent medicines are accessible to those who need them. These include adopting pricing strategies that balance profitability with affordability, such as differential pricing models based on a country's economic status or negotiation of fair prices with healthcare systems. Participant JV said:

> We continue to focus on a responsible pricing strategy. To ensure that patented medicines are accessible to those who need them. These include adopting pricing strategies that balance profitability with affordability, such as differential pricing models based on a country's economic status or negotiation of Fair prices with healthcare systems. Firstly, pharmaceutical companies can implement higher price strategies based on the country's economy level offering lower prices in low-income regions while containing a higher price in wealthier markets. This helped balance affordability with revenue generation.

Market segmentation was also another best practice suggested by the participants. Participant GM said that companies should implement market segmentation whereby they would charge higher prices to high-income countries and lower prices to low-income countries. This participant also said that markets should be segmented based on income levels, healthcare infrastructure, and disease prevalence, saying:

> Market segmentation companies may implement different pricing strategies, charging higher prices in high-income countries while offering prices in lower-income countries. These can help of community by maximizing revenue in different market segments … Market segmentation. Segmenting markets based on factors such as income levels, healthcare infrastructure, and disease prevalence allows the companies to tailor the pricing and distribution strategies to each market in its needs.

Participant HS said that pharmaceutical companies should look for ways in which they can reduce their cost of production so that medicines can be sold at low prices. A best practice would be to expedite the lead time to market, reduce the cost, and expedite developing testing and regulatory filings for the products. Eventually, the cost of production would reduce. Participant HS said:

> For pharmaceutical companies to be able to produce medicines and sell them at a low cost while maintaining profitability. In my opinion, they must establish lean manufacturing processes. Expedite the lead time to market, reducing the cost, expedite development testing and the regulatory filings for the products and the manufacturing processes established manufacturing processes that are robust, consistent, and reliable. Even at large scale and also utilizing value engineering this can drive the overall cost of the product down.

Participant SL also suggested subsidizing the production cost as another way of ensuring profitability and maintaining equal access to everyone. To achieve profitability and equitable access to patent medicine, companies can even discount some of their products to cater to low-income earners. Participant SL said:

> I mean it's in order for, you know, profitability to be maintained from the company that produced the drugs. You know they have to, you know require they'd have to discount or lower the prices or you know somehow. That's subsidized. So you know, until that happens. They're only going to get the profitability they're charging, they're only going to be profitable by charging the high prices, but that's not going to allow everyone to have access to it.

Theme 3 focuses on pricing and accessibility strategy for better access to patent medicines with a profitable business model. The participants suggested implementing differential pricing, using market segmentation, lowering production costs by using lean manufacturing, and subsidizing in economic contexts. These approaches would allow companies to balance their interest in profitability with an ethical commitment to making essential medicines accessible to each level of income.

Summary

The purpose of this qualitative multiple case study was to explore unknown best practices for ensuring equal access to patent medicines while maintaining the profitability of pharmaceutical companies to pursue needed innovation and development of new drugs and ensure business sustainability. I aimed to investigate the best practices for ensuring equal access to patent medicines while maintaining the profitability of pharmaceutical companies to pursue needed innovation and development of new drugs and ensure business sustainability. Three themes were identified that helped answer the research question: (a) strategic and operational practices; (b) policy and regulatory reforms; and (c) pricing and accessibility strategies. NVivo 14 software was used as an organizational tool to help in the coding process. The coding and thematic process followed the six thematic steps as suggested by Braun and Clarke (2019). In the next chapter, I discuss the recommendations and conclusions from the findings.

Chapter 5: Discussion and Conclusions

The purpose of this qualitative multiple case study was to explore best practices for ensuring equal access to patent medicines while maintaining the profitability of pharmaceutical companies to pursue needed innovation and development of new drugs and ensure business sustainability. It was essential to explore the balance between the pricing of patent medicines to ensure the profitability of pharmaceutical companies while managing the ease of access of patients to such medicines in the United States. Bandura's (2000) social cognitive theory and the concept of self-efficacy were the guiding frameworks for this study. One research question was formulated. A qualitative methodology with a case study research design was used. I used purposive sampling to recruit 17 pharmaceutical experts with 10 years of experience and at least 3 years at managerial-level roles. Data were collected using semistructured interviews and analyzed using Braun and Clarke's (2019) thematic analysis and NVivo 14. Three themes emerged.

The findings for Theme 1 regarded the strategic and operational practices that companies use to ensure equal access to patent medicines for everyone irrespective of their income level. The outcomes for Theme 2 suggest that companies can adopt policy and regulatory reforms to ensure equal access to patent medicine. The results for Theme 3 indicate that pricing and accessibility strategies could be adopted as best practices in ensuring equitable access to patent medicine while maintaining profitability.

Interpretation of the Findings

Theme 1: Implementing Strategic and Operational Practices

The findings for Theme 1 regard implementing strategic and operational practices to ensure equal access to patent medicines for everyone irrespective of their income level. The practices include planning and intentionality, collaboration with other institutions, contract manufacturing of medicines, investing in quality infrastructures, investing in research and development, and promoting transparency in pharmaceutical companies. These findings support research outcomes by Stiller et al. (2022), who noted an association between increased investment in research and development and increased innovation. Assertions by Inotai and Kaló (2019) that transparent and sustainable pharmaceutical policies intended to enhance the allocative efficiency of rare resources should be implemented to reduce gaps in patient financing and access to high-cost pharmaceuticals aligned with the current study's outcomes. However, the findings contrast with research results by Gøtzsche (2018a), who noted that investment in research and development for drugs for treating symptoms of chronic conditions, such as hypertension and diabetes, continue to lead to new products that offer little to no innovative value compared to other drugs already in the market. Pharmaceutical companies can ensure equal access to patent medicines for people of all income levels by implementing strategic and operational practices such as contract manufacturing and investing in quality infrastructure and research and development.

Drug manufacturing companies should be deliberate and plan to provide better quality and access to patented medicines. The challenge of profitability has to be faced head-on. Best practices should be adopted to maintain profit margins, including streamlining operations, negotiating better deals with suppliers, diversifying products, and using cost-effective strategies. Strategic partnerships with other institutions should be embraced to achieve the bigger goal of cheaper patented drugs and availing patent medicines to everyone. Investing in infrastructures can ensure efficient special networks and accessible healthcare procedures even in remote regions. Companies can also strike a balance between fostering innovation through intellectual property protection and equitable access to treatment.

Theme 2: Adopting Policy and Regulatory Reforms

The outcomes for Theme 2 suggest that companies can adopt policy and regulatory reforms to ensure equal access to patent medicines. Some of the needed reforms include government integrations, having a universal healthcare system, not extending patents, and subsidizing commodities. This finding aligns with the research results by Gøtzsche (2018b), who proposed strengthening regulations surrounding marketing tactics, spending, and claims, and establishing an independent organization to bear all responsibility for developing and researching new medicines. However, the current study’s findings do not support research outcomes by Beall et al. (2019) and Hoen et al. (2018), who noted the effect of contextual factors such as the time needed to complete trials in extending the initial patent period in the United States. Research results by Cherla et al. (2021) suggested providing an option to extend the period of protection allotted to patentees so that revenue from patent extensions can be used to fund medication development and interventions in regions or countries with limited resources, which is not supported by the current study's findings. The concept of patent thickets presented by Zhai et al. (2019), in which the patent protections of medications are extended by covering features beyond the unique aspects of a product, also does not align with the current study's outcomes. Pharmaceutical companies can adopt policy and regulatory reforms to ensure equal access to patent medicine by encouraging a universal healthcare system, not extending patents, and subsidizing drug manufacturing-related commodities.

Drug manufacturing companies should advocate for policies that enhance openness and fairness in the healthcare system. These policies should promote competition, transparency, and equitable access to healthcare resources that can help create a more conducive environment for innovation while addressing affordability. Regulatory control by agencies such as the FDA is an excellent way of ensuring fairness in access to patented drugs. The government can provide incentives such as tax exemptions that can help drug manufacturing companies lower their production costs. Another role the government can play is increasing funding to drug manufacturing companies through grants and private funding. Drug manufacturers should stop seeking patent extensions after expiry to allow the entry of other companies, allowing competitive forces to lower drug prices.

Theme 3: Pricing and Accessibility Strategies

The results for Theme 3 indicate that pricing and accessibility strategies could be adopted as best practices in ensuring equitable access to patented medicine while maintaining profitability. Some of the strategies mentioned by participants include establishing patient assistance programs, ethical considerations during research, having tiered pricing strategies, market segmentation, and ensuring cost-effectiveness during production. This outcome supports research findings by Morgan et al. (2020), who recommended differential pricing as a potential policy strategy to enhance the affordability of anti-cancer therapies. Research results by Wouters et al. (2017) indicated a difference in the pricing of generic drugs between different countries in the European market, which aligns with the current study's findings. Godman et al. (2018) found evidence of premium pricing and price reevaluations among pharmaceutical companies in a bid to balance the profitability and accessibility of patent medicines, which is by supported the current study's outcomes.

Inotai and Kaló (2019) promoted financial risk-sharing agreements and confidential price discounts as effective approaches for enhancing the cost-effectiveness of pharmaceuticals, which agrees with the current investigation's findings. Research results by Miller (2018) indicated that through training, pharmaceutical professionals could make ethical decisions when confronted with unethical sales practices, which aligns with the current research's outcomes. According to Petty (2019) and Zhuang et al. (2020), many manufacturers often produce off-patent medications that are regulated by the FDA to ensure the accessibility of medical innovations and breakthroughs, which supports the current study's findings. Pharmaceutical companies can adopt pricing and accessibility strategies to ensure equitable access to patent medicine while maintaining profitability, including establishing patient assistance programs, following ethical considerations during research, having tiered pricing strategies, adopting market segmentation, and ensuring cost-effectiveness during production.

Patented drugs should be available to all who need them. Drug manufacturers can work toward adopting pricing strategies that balance profitability and affordability. Drug manufacturing companies can offer differential pricing based on income level or purchasing power to ensure people at all socioeconomic levels have access to patented drugs. Market segmentation can be used to charge higher prices to high-income countries and lower prices to low-income countries. Market segmentation can also be based on disease prevalence and the availability of healthcare infrastructure. The cost of producing patent medicines can be reduced by expediting the lead time to market, reducing the cost, and expediting development testing and regulatory filings for the products. Companies can subsidize their production costs or discount some products to cater to low-income earners.

The concept of self-efficacy, as described in Bandura's (2000) social cognitive theory, was central to the current study. Self-efficacy is the belief in one's capability to work toward goals and manage situations by planning and organizing the steps needed to arrive at a desired outcome (Bandura, 2000). Pietrzak et al. (2020) and Tobzhanova et al. (2019) presented evidence that self-efficacy plays a role in the professional practices of doctors, nurses, and other medical professionals. The current study's outcomes highlight the role of self-efficacy among pharmaceutical experts. The findings indicate that pharmaceutical companies use various unknown best practices to balance equal access to patented drugs and profitability. Some of the strategies highlighted by the respondents include collaborating with other institutions, advocating for policy reforms, tiered pricing of patented drugs, and ensuring cost-effectiveness by subsidizing drug prices.

Limitations of the Study

One of the limitations of this study is the use of purposive sampling to recruit pharmaceutical experts. This recruitment strategy helped recruit participants whose background, experience, knowledge, and skills aligned with the requirements of the research. However, purposive sampling is a nonprobabilistic respondent recruitment technique that may result in a nonrepresentative sample (Klar & Leeper, 2019). Therefore, the study sample might not have adequately represented the pharmaceutical experts in the general U.S. population, which may limit the transferability of the findings. I mitigated this shortcoming by recruiting 17 participants, a sample size large enough to capture the relevant themes and characteristics related to the phenomenon under investigation as suggested by Yin (2017).

Conducting this study exclusively in the United States is another shortcoming. Pharmaceutical firms have operations in other countries, including Switzerland, the United Kingdom, and Germany (Wouters et al., 2017). According to Cherla et al. (2021), different countries have distinct policies governing drug patents for the protection of the manufacturer and the consumer. The findings of the current study may thus not be transferable to other countries due to differences in local practices and other conditions such as legislation and prevailing economic conditions (Morgan et al., 2020).

Interviewing exclusively pharmaceutical experts is another limitation of this research. The experts provided rich and useful details regarding the strategies that pharmaceutical firms in the United States use to make patent medicines affordable to people of all income groups while maintaining profitability. However, pharmaceutical experts are only one of many stakeholders in the field of drug patents, which also includes regulatory bodies, patients, doctors, insurance agencies, and pharmaceutical traders (Pietrzak et al., 2020; Tobzhanova et al., 2019). The views obtained in this study were thus limited to one stakeholder, making them potentially similar.

The self-efficacy concept of the social cognitive theory used in this study presented some key limitations. According to Bandura (2000), self-efficacy is the individual belief that one possesses the capability to coordinate the actions needed to produce a desirable outcome. This concept helped understand how pharmaceutical experts working for pharmaceutical firms contribute to establishing effective strategies for reducing the high prices of patent medications. However, relying on the concept meant that the role of patents in inducing innovation was largely not considered. This overreliance on a single theory led to tunnel vision for this research in an attempt to explore pharmaceutical companies' best practices for ensuring equal access to patent medicines.

Recommendations

Using purposive sampling to recruit participants likely reduced the representativeness of the sample obtained. Klar and Leeper (2019) noted that purposive sampling is a nonrandom sampling technique that often results in a biased sample. The potentially nonrepresentative sample could have affected the transferability of the study findings to the general population of pharmaceutical experts in the United States. In future investigations, researchers should recruit a representative sample using probabilistic sampling techniques such as random sampling.

Undertaking the current investigation exclusively in the United States is a significant limitation of the current study. The findings obtained are only transferable to other pharmaceutical experts and firms in the United States. According to Lincoln and Guba (1985), transferability is the external applicability of qualitative research findings beyond the current investigation's context. People in other parts of the world where formal healthcare services are easily accessible also find patent medicines expensive and would benefit from research on strategies for reducing the cost of drugs. Patent drugs serve different roles and purposes in different countries depending on the healthcare context of the region, including the healthcare infrastructure and ease of access to formal treatment. In rural Southeastern Nigeria, patent medicines are the only accessible and affordable option for many mothers and young adults (Uneke et al., 2021). Therefore, research is needed in different parts of the world to obtain findings applicable to most countries. To increase transferability, future investigators can consider conducting their investigations in multiple countries to enhance the transferability of their findings to other countries around the world. Multiple case studies can be done in developed and developing countries to achieve this goal. Multiple case studies are research designs that allow researchers to conduct in-depth, multifaceted explorations of complex phenomena in their real-life settings (Yin, 2017), and thus can help investigators focus on differences and similarities between countries in terms of affordability and access to patented drugs.

Collecting data exclusively from pharmaceutical experts is a major limitation of the current investigation. Drug manufacturing and patenting is a wide field with many stakeholders, including healthcare economists, doctors, patients, regulatory authorities, insurance agencies, and pharmaceutical traders (Pietrzak et al., 2020; Tobzhanova et al., 2019). Collecting data from various stakeholders would have enriched the findings obtained because experts from different fields may have differing views on ways of reducing patented drug prices. Insights from healthcare economists can help understand whether the solutions suggested in this study are workable and can lead to more equitable, accessible, and affordable drugs for all. Doctors and nurses can offer their input by helping researchers identify populations that should receive maximum benefits in terms of subsidies as well as ways of minimizing the high costs of drugs. Through regulatory alignment, regulators can help investigators understand the steps that can be taken to ensure public health is protected and promoted throughout the process of ensuring equitable and affordable access to patented drugs. Future researchers can interview other stakeholders, such as healthcare economists, patients, doctors, nurses, and regulatory authorities, to enrich the depth and quality of their findings.

The use of the self-efficacy concept of the social cognitive theory limited the assessment of the drug patent landscape in this investigation. I failed to consider the impact of patents in inducing motivation for useful inventions among inventors and investments from willing investors. Research findings by Cherla et al. (2021) and Pandey and Paul (2019) indicated that patents do not increase the innovative potential of drug manufacturers, but instead they reduce the motivation for innovation. Patents and small profit margins deter innovators who often lack the resources and time to invent patented drugs (Gupta et al., 2019). The role of patents in keeping drug prices high needs to be investigated from multiple perspectives for a more comprehensive view of the research landscape. Relying on the views of pharmaceutical workers alone resulted in a one-sided view of the research landscape in the current study. In future investigations, researchers should consider triangulating the social cognitive theory with other theories that consider the powerful impact of patents in driving or curtailing innovation and encouraging the disclosure of new inventions. Such theories include the invention-inducement theory, the disclosure theory, and the development and commercialization theory.

The findings of the current study suggest that having a tiered pricing strategy for patented drugs can ensure equal access to patent medicines while maintaining the profitability of pharmaceutical companies. Godman et al. (2018) found evidence of a similar pricing strategy in the form of premium pricing and price reevaluations among pharmaceutical companies. However, Burrone et al. (2019) found several shortcomings of tiered pricing, including inferiority in addressing competition for companies that used the practice given the need to attain the lowest possible sustainable prices. This inability to compete results in resources being so stretched that affordability is only possible through selling medicines at or near the production cost (Inotai & Kaló, 2019). There should be a delicate balance between ensuring access to drugs for the lowest earners and the need for drug manufacturers to remain in business through reasonable profit margins. Most pharmaceutical companies maintain that patents and high drug prices are necessary to recoup research costs and ensure efficient drug supply (Gøtzsche, 2018a). Merely reducing the prices of patented drugs can lower profit margins for companies and affect the ability of drug manufacturers to innovate and develop new drugs (Saluja et al., 2018).

According to Luna (2019), affordability and accessibility of patent drugs cannot coexist because one of the two factors will always emerge superior in different markets depending on socioeconomic conditions and other factors. More research is needed to determine whether the current tiered pricing strategies are optimal or whether more still needs to be done to make the model more profitable to drug manufacturers and at the same time make drugs more affordable to everyone. Future investigators should aim to establish the effectiveness of a tiered pricing strategy in enabling equal access to patent medicines, particularly in light of the price discrimination laws of the United States.

Implications

The findings for Theme 1 suggest that drug manufacturing firms implemented strategic and operational practices to ensure equal access to patent medicines for everyone irrespective of their income level. This outcome implies that it is possible to make strategic plans and operational adjustments to existing practices to enhance the likelihood of low-income earners accessing expensive drugs. To achieve this goal, managers of pharmaceutical companies can take various strategic and operational steps, including investing in research and development, creating transparent systems, engaging in contract manufacturing, and investing in quality infrastructure.

The outcomes for Theme 2 suggest that companies can adopt policy and regulatory reforms, including having a universal healthcare system, not extending patents, and subsidizing commodities to ensure equal access to patent medicines. This finding implies that policy interventions to lower the cost of production of patented drugs can help in reducing the drug price burden on low-income earners. Healthcare authorities can contribute to equal access to patent medicines by adopting policies that enable the firms to provide affordable drugs while still maintaining profitability, including subsidizing drug production commodities, failing to extend patents beyond the typical initial 20-year period, and having a universal healthcare system.

The results for Theme 3 indicate that pricing and accessibility strategies could be adopted as best practices in ensuring equitable access to patent medicines while maintaining profitability. The strategies proposed by the participants included establishing patient assistance programs, ethical considerations during research, having tiered pricing strategies, market segmentation, and ensuring cost-effectiveness during production. This finding implies that strategies for better pricing and accessibility of patented drugs are some of the best means of achieving access to expensive patented drugs. Managers of pharmaceutical companies can consider establishing patient assistance programs, using a tiered pricing system (market segmentation), lowering production costs by using lean manufacturing, and subsidizing the production cost.

Positive Social Change

Pharmaceutical companies will find the findings of this study valuable in various ways. First, pharmaceutical companies can consider implementing strategic and operational practices by taking various steps, including investing in research and development, creating transparent systems, engaging in contract manufacturing, and investing in quality infrastructure. Companies should deliberately plan to provide better-quality drugs that are accessible to people of all social and economic classes. Drug manufacturers should deliberately implement best practices that will allow them to maintain their profitability while making the drugs affordable to the lowest-earning Americans.

Second, drug manufacturers should learn to collaborate with competitors and other institutions. Pharmaceutical companies should stop working in silos thinking they are protecting their interests and learn that collaboration is more likely to lead to better benefits for all stakeholders. Such collaboration should go beyond private entities and include governmental and nongovernmental agencies that are engaged in the healthcare sector. Such agencies are crucial in information sharing and pushing forward beneficial legislation. With many agencies and firms on board, pharmaceutical companies would be in a better position to know exactly what is happening on the ground and make more tailored decisions. Some partners may be even willing to share the cost of production to make patent medicines cheaper.

Third, pharmaceutical companies should understand the value of investing in quality infrastructure. Such investments can ensure efficient networks and reliable and accessible healthcare procedures even in remote areas. Support for the skills needed to expand and maintain the infrastructure is equally vital to ensure it does not crumble over time. Drug delivery networks can be sustained through efficient and reliable networks.

Fourth, pharmaceutical companies can also learn to strike a balance between fostering innovation through intellectual property protection and ensuring equitable access to vital treatments. Drug manufacturing companies can embrace and invest in technology locally and in other countries to enhance access to patented drugs while reducing production costs. It is crucial to support the local manufacturing capabilities of developing countries where labor is cheaper and production costs can be lowered, hence reducing the prices of drugs. Following this multifaceted approach would ensure financial viability for firms and much-needed social impact in other countries, especially developing countries.

Drug manufacturing companies can also adopt policies that enhance openness and fairness in the healthcare system. The adopted policies should promote competition, transparency, and equitable access to healthcare resources. These resources can then be used to create more conducive environments for innovation while addressing affordability. Pharmaceutical companies can achieve this goal by pushing for rules that encourage fairness and openness and ensuring that everyone can access the drugs they need. Such steps will ensure a widespread approval of the drug manufacturing firms' efforts in the wider society.

Another lesson gained from the current findings is the value of following FDA rules and regulations. The FDA prescribes best practices for drug manufacturers to ensure the drugs that are released to the market are safe for human consumption (Petty, 2019). Regulatory control is vital in guaranteeing that pharmaceutical producers do not sell dangerous products (Zhuang et al., 2020). Adhering to FDA regulations as well as the regulations of other state and national authorities can increase trust and usage of the drugs produced, enabling manufacturers to focus on fine-tuning the economies of scale that come with a large market and mass production, which can lead to lower costs of drugs.

The findings can also benefit pharmaceutical companies by underscoring the need to involve the government as a major policy maker. The government plays a major role in ensuring equitable access to patent medicines through incentives such as tax exemptions (Gøtzsche, 2018b). Such favorable incentives can help pharmaceutical companies reduce their cost of production, hence reducing the prices of patent medications. Governments can also expedite the approval process for essential drugs to ensure they reach the market more quickly, if needed. Some participants cited the need to expedite the lead time to market as a means of reducing the cost of drugs.

Drug manufacturing companies can embrace the novel approach of not seeking patent extensions for the greater good. In the literature review phase, it was revealed that some pharmaceutical companies used various means to extend their patents so that they could use the revenue generated to fund other drug developments (Cherla et al., 2021). However, patents do not offer absolute or infinite protection from competitors (Shadlen et al., 2020). Social learning is a vital shared quality as firms can learn through observation and experience from others (Yılmaz et al., 2019). By not extending the expiration dates, other pharmaceutical firms are motivated to join the market and help reduce the prices of the drug through competitive forces. Instead of seeking to use patents to safeguard profit margins, drug manufacturers can seek to collaborate with competitors, the government, and other stakeholders to develop new drugs and allow drugs for which patents have expired to be mass-produced by new entrants to lower their cost and increase their availability to low-income households.

Drug manufacturers can adopt pricing measures that will enable low-income earners to afford and access patented drugs. One such measure is differential pricing, which is based on the income level and purchasing power of consumers. Leaders of pharmaceutical companies should consider low-income earners when setting prices for patent medicines. Different prices can also be set for different countries based on each country's level of development and purchasing power.

The government of the United States might find the results of this study useful. The findings underscore the need for more funding to pharmaceutical firms to help them lower the cost of production of patented drugs. The government can avail more funds through grants and use its power to ensure that drug manufacturers that receive such grants set fair prices. An affordable price would ensure the most vulnerable members of society can access drugs, contributing to their overall well-being.

Conclusion

The purpose of this qualitative multiple case study was to explore unknown best practices for ensuring equal access to patent medicines while maintaining the profitability of pharmaceutical companies to pursue needed innovation and development of new drugs and ensure business sustainability. Based on the social cognitive theory that guided this study, I anticipated that most of the pharmaceutical experts who took part in this study would be self-efficacious and would suggest novel ways of reducing the prices of patented drugs while simultaneously maintaining profitability. These expectations were confirmed as the study's outcomes highlight several best practices for balancing equal access to patented drugs and maintaining profitability.

The findings from this study underscore the need for healthcare authorities and drug manufacturers to collaborate to ensure equal access to patent medicines. The government and pharmaceutical firms should adopt policies that enable firms to provide affordable drugs while still maintaining profitability. The authorities can play their role by subsidizing the production costs of patented drugs through tax exemptions and creating a universal healthcare system. Strategies for lowering the pricing and accessibility of patented drugs are among the best means of achieving equal access to these medicines. The leaders and owners of pharmaceutical companies can consider establishing patient assistance programs, using a tiered pricing system, adopting market segmentation, and lowering the cost of production by switching to lean manufacturing. Owners of pharmaceutical firms can help reduce the prices of patented drugs by not seeking to extend drug patents beyond the initial 20-year period, which would allow new entrants into the market and subsequently lower prices due to competition. Drug manufacturers can also invest in research and development, create transparent systems, engage in contract manufacturing, and invest in quality infrastructure for the long-term sustainability of their operations.

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Appendix A: Interview Questions

RQ: What are the best practices for ensuring equal access to patented medicines while maintaining profitability of pharmaceutical companies to pursue needed innovation and development of new drugs?

1. How do you describe equal access to patented medicines?
2. How do you think equal access to patented medicines is achieved?
3. What are the practices of your organization on patented medicines?
4. What do you think are the best practices in industry in terms of patented medicines?
5. Is profitability maintained when equal access to patented medicines is achieved? Why or why not?
6. How do you think it is best to maintain profitability while ensuring equal access to patented medicines?
7. What do you think are the challenges of ensuring equal access to patented medicines?
8. How do you think can these challenges be mitigated by pharmaceutical companies to pursue the needed innovation and development of new drugs?

Appendix B: Recruitment Flyer

Interview Participants Needed

There is a new study about the equal access on patented medicines that could help maintain profitability to pursue needed innovation and development of new drugs in pharmaceutical companies. For this study, you are invited to describe your experiences on best practices for ensuring equal access to patented medicines.

This survey is part of the doctoral study for KisaMwenelupembe, a Ph.D. student at Walden University.

About the study:

- One 60-minute audio-recorded online interview via Zoom
- Review and validate transcribed interview responses (30 minutes)
- To protect your privacy, no names will be collected

Volunteers must meet these requirements:

- 18 years old or older
- A pharmaceutical expert with 10 years of experience in the pharmaceutical field
- With at least a managerial level position in the departments of research and development, marketing, and/or finance; and
- With a master's degree or higher

To confidentially volunteer, email the researcher at:
[insert researcher's email]

Appendix C: Pre-screening Questions

1. Are you working in the Pharmaceutical industry as an expert?
2. Kindly state your working experience in the pharmaceutical field.
3. Have you held a managerial level position in the departments of research and development, marketing, and/or finance, if yes. And for how long?
4. Are you a master's degree or higher holder?
5. Are you willing to take part in this study and share insights and knowledge regarding costing and profitability issues in pharmaceutical industry, relating to patented drugs?