7-30-2025

The Problem With Consumer Affordability of Prescription Medications in the United States

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This is to certify that the doctoral dissertation by

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Walden University
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Abstract

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Abstract

Consumer affordability of prescription drugs is an ongoing problem in the United States. This study was undertaken to research the financial, physical, and economic effects of drug prices on consumers and the methods used by consumers to address such effects. Rational choice and power and politics theories were used to explain the decisions consumers make when they could not afford their medications and the role policies and politics play in drug pricing. The research questions concerned the relationship between consumers' perceptions of drug pricing and their ability to purchase medications. The quantitative nonexperimental study involved the administration of a survey featuring selected questions from the 2019 KFF Health Tracking Poll. The sample size of 87 participants was comprised of individuals over 26 years old. All participants had to have their own medical insurance. Data was analyzed using chi-square test of independence to determine relationships between the categorical variables. Results showed no correlation between participants' opinions on the price of medications and whether they were generic or should be purchased from Canada; however, participants did not believe drugs were priced fairly. There was a positive correlation between the cost of prescription and the use of drug discount programs. Policymakers and other stakeholders should consider the patient's perspective when evaluating programs aimed at lowering the cost of medications, and they should seek to raise prescribers' awareness of such programs. By doing so, policymakers and other stakeholders may be able to foster positive social change by providing financial, economic, and physical relief to consumers.

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Acknowledgments

I would like to express my deepest appreciation to Dr. Daniel Jones for his support, patience and guidance through this experience. I am also grateful to Dr. Dale Brooker for his invaluable comments. Many thanks go to Dr. Reginald Taylor for his assistance in helping me understand statistics. I would also like to give special thanks to my sister Lachelle Bell whose assistance was crucial in helping me locate articles. Lastly, I would be remiss if I did not mention my other family members and my friends and doctors. Their continuous practical, emotional, and religious support during this journey was welcome during challenging times.

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Chapter 1: Introduction to the Study

There is an ongoing problem with consumer affordability of patented prescription medications. Because of the rising cost of prescription drugs in the United States, many consumers have difficulty affording their medications. Consumers in the United States spend more on prescription drugs than in any other developed country (Kantarijan et al., 2013; Kesselheim et al., 2016). According to Kesselheim et al (2016) increases in the unaffordability of prescription drugs result from increases in the price of brand-name drugs far beyond the consumer price index. As a result, consumers have devised methods of coping with this issue, including intentionally not taking their medications, not taking medications as prescribed, purchasing products from outside of the United States, or trying alternative therapies (Cohen & Villarroel, 2015; Doshi et al., 2016; Kantarjian & Rajkumar, 2015). These methods of coping may turn out to be detrimental to the consumer in the long run.

Given the rising drug prices, the overall effect of drug pricing on the consumer and whether the current system of pricing drugs support its sustainability are worth exploring. There was a need to address these issues. The literature contained examples of how the rising costs of drugs led to medication non-adherence, particularly among cancer patients and patients with diabetes. These issues are addressed in this chapter. However, this research focused on out-of-pocket (OOP) expenses for the insured consumer, including the effect of medication costs on their physical and financial well-being.

In this study, I examined the role that pricing of patented medications, discount drug pricing programs, and economics have on the consumer. In this chapter, I discussed

how the results could be used to discuss possible changes to the current policies associated with drug pricing to alleviate some financial hardship for the consumer. This chapter began with information on the history of drug pricing and its effect on diverse groups emphasizing cancer and diabetic patients. The problem statement, purpose of the study, and research questions (RQs) and hypotheses were also listed. I also explained the nature and significance of the research, the theories, and assumptions. Definitions of key terms are also provided.

Background

The increasing cost of prescription drugs in the United States can affect patients particularly those with chronic diseases such as diabetes or cancer. These patients are on life-sustaining medications and, therefore, may not necessarily be able to afford their medications if the price continues to increase. The continuing increase in drug prices in the United States presented a cause for concern, as in 2018, consumers in the United States spent approximately $476,000,000,000 on prescription drugs, with 80% spent on brand-name drugs (Rome et al., 2021). The manufacturers of these brand names set the price at whatever they chose, and over the past decade, these prices increased yearly by 9.1% (Rome et al., 2021). Sometimes these soaring prices could be offset by providing negotiated rebates through pharmacy benefit managers (PBMs) and insurers; however, the rebate levels varied depending on the drug class (Rome et al., 2021).

Approximately half of the individuals in the United States carry insurance through employer-based insurance plans, which charge flat rate copayments for prescriptions, however, insurance companies gradually transfer these costs to the patient through

deductibles and coinsurance (Rome et al., 2021). Recent studies have shown that from 2010 to 2016, the average OOP expenses increased by 53%, while the list prices for the 14 top-selling drugs doubled (Rome et al., 2021). The rising costs of prescription drugs have altered the behavior of consumers to the point of changing how they take their medications causing them to develop other methods of coping with the financial hardships that come with the rising costs of prescription medications (Rome et al., 2021).

Financial hardship has different acronyms, such as financial toxicity, financial burden, or financial problems, and combines three areas: material conditions, the psychological response, and coping behaviors (Hastert et al., 2019; Yabroff et al., 2020). Material conditions included OOP medical costs, productivity loss or limited ability to work, decreased income, assets, or net worth, increased medical debt, trouble paying medical and other household bills, and bankruptcy (Yabroff et al., 2020). Psychological responses included worries concerning paying medical bills and affording care, and the stress of such concerns (Yabroff et al., 2020). Coping behaviors included delaying medical care or non-adherence to medications for medical conditions (Hastert et al., 2019; Yabroff et al., 2020). Research suggests that financial hardship can lead to worse health outcomes, worse quality of life, and less satisfaction with health care (Hastert et al., 2019; Yabroff et al., 2020).

The cost of prescription drugs has risen over the past few decades and continues to do so. This increase in prescription drugs had placed an increased financial burden on the patient and contributed to cost-related non-adherence (CRN) to medication use (Lee et al., 2018). CRN can be associated with an array of adverse health outcomes for the

chronically ill, including decreased mental and physical functioning, stroke, increased use of emergency services, and earlier than expected deaths (Lee et al., 2018). High OOP spending affected adherence and patient outcomes, especially if the patient was poor, had a chronic illness, or was a member of a minority group (Gaffney et al., 2020).

Adhering to medication dosing depended on various factors, including the patient's character, family and culture, interactions with health care providers, and the health care system (McQuaid & Landier, 2018). Insufficient medication adherence was associated with health outcome disparities, especially for various racial and ethnic groups (McQuaid & Landier, 2018). With trends toward rising treatment costs, concentration on more effective treatment, and higher cost sharing, especially for oral medications, the cumulative risk of financial hardship would likely continue to increase in the future (Yabroff et al., 2020).

Because of the high pricing of drugs, individuals aged 65 and older have developed strategies to reduce their drug costs which could prove detrimental to themselves (Cohen & Boersma, 2019). In 2017, 86% of adults over 65 had been prescribed medications within the past 12 months, with most having prescription coverage either through Medicare, Medicaid, Veterans Administration, or some other source such as private health insurance (Cohen & Boersma, 2019). Despite being insured, consumers still devised strategies to reduce the cost of prescription drugs. Two of these methods included not taking their medications as prescribed or asking their physician for a lower-cost medication (Cohen & Boersma, 2019). The U.S. Food and Drug

Administration (FDA), which approves medications and medical devices for use in the United States, does not take part in the pricing of drugs.

Research has also shown a line between culture and adherence to medication (McQuaid & Landier, 2018). Adherence to prescription medication involved complex behaviors and decisions (McQuaid & Landier, 2018). Optimal adherence involved prescribing a medication, filling the prescription, and continuous use of said prescription if indicated (McQuaid & Landier, 2018). Studies have shown that adherence is less than optimal across disease and demographic groups (McQuaid & Landier, 2018).

Studies have also shown that medication adherence tended to be lower among patients with lower socioeconomic status and racial/ethnic backgrounds such as Blacks and Hispanics, and, as a result, one of the contributors to disparities in health outcomes (McQuaid & Landier, 2018). The patient, provider, culture, history, and the health care system all contributed to this problem (McQuaid & Landier, 2018). Discrimination, perceived or actual, was related to lower adherence among minorities (McQuaid & Landier, 2018). One study noted that in underserved communities, survivors of a stroke or TIA believed they were discriminated against and therefore were not adherent to their medications (McQuaid & Landier, 2018). The authors reported comparable results in adults with sickle cell anemia and HIV/AIDS who reported instances of discrimination and were, therefore, less likely to take recommended medications (McQuaid & Landier, 2018). Low income, limited insurance coverage, and high OOP costs contributed to low adherence (McQuaid & Landier, 2018).

Problem Statement

There are many problems facing the current health care system. One problem is the affordability of patented medications and their effect on the consumer in OOP expenses, and the decisions the consumer must make because of the rising costs. The effect of inflation on the rising cost of existing drugs versus new drugs is unknown; however, studies have shown that the cost of oral and injectable drugs for outpatients increased annually between 2008 and 2016 by 9.2% for oral drugs and 15.1% for injectables (Hernandez et al., 2019). Given the rising cost of prescription drugs, how did this affect the consumer's physical, mental, and financial well-being, and can consumer opinion affect changes in the social policies concerning drug pricing? The literature focused primarily on the consumer's financial burden; however, this research also focused on physical burdens and relief through drug-assistance programs.

New medications have come to market in recent years to treat chronic conditions, which one would assume would lower the cost; however, that was not the case (Liu et al., 2021). Liu et al. (2021) studied the trends of wholesale prices for brand-name medications from 2015 to 2020, with results showing the compound annual growth rates in costs ranged from 15% to 17% and outperformed the annual growth of the consumer price index at a rate of 2.1% over the same period. For specialty drugs such as cancer medications, orals and injectables increased by 20.6% and 12.5%, respectively with 71.1% and 52.4% attributed to the cost of new drugs entering the market (Hernandez et al., 2019).

As of 2018, it was estimated that worldwide, nearly half of all adults and approximately 8% of children (5–17 years of age) had a chronic condition (Cutler et al.,

2018). When factoring in the aging population, these chronic conditions and rising costs created a growing demand for resources used for health care, including medications (Cutler et al., 2018). The rising costs also contributed to the affordability of medications and may have resulted in non-affordability or non-adherence to medications. Estimations are that there was 50% non-adherence to medications for individuals with chronic illnesses (Cutler et al., 2018).

Cutler et al. (2018) indicated that annual costs of non-adherence to medications in the United States ranged from $100,000,000,000 to $290,000,000,000, with older adults comprising 10% of hospitalizations due to medication non-adherence. For the typical patient, this amounted to three extra annual medical visits and a $2000 increase in medical costs per year (Cutler et al., 2018). For diabetic patients, medication non-adherence costs ranged from $661,000,000 to $1,160,000,000 (Cutler et al., 2018). Adding together the various reasons for medication, one can comprehend how it has become a crucial clinical and economic issue (Cutler et al., 2018).

Cutler et al. (2018) conducted a comprehensive literature review to study medication non-adherence across 16 disease groups. The indicators for measuring cost non-adherence were total health care, pharmacy, inpatient, outpatient, emergency, medical, and hospitalization costs (Cutler et al., 2018). Higher costs, and disease-specific costs of non-adherence ranging from $949 to $44,190 (2015), were linked to lower non-adherence, while costs attributed to all causes ranged from $5271 to $52341 (Cutler et al., 2018). The authors concluded that research needs to be continued on the study of medication non-adherence, and the results used to inform policymakers to help patients

avoid costs associated with medication non-adherence as well as other issues within the health care system in the United States (Cutler et al., 2018).

Effectively addressing the financial hardships and non-adherence to medications that affect the consumer's day-to-day lives will require further research. Previous research has shown that factors contributing to financial hardships were employer-based health insurance for working age, spouses and dependents, health care providers, the health care system, and state and national health care policies (Yabroff et al., 2020). Socioeconomic and clinical traits also contributed to financial hardships in that lower household incomes, education, minority status, race, ethnicity, rural status, and unmarried were associated with difficulties and absence of insurance coverage (Yabroff et al., 2020).

Increased medical care costs factor in CRN, increasing OOP expenses (Lee et al., 2018; Yabroff et al., 2020). Individuals living with cancer paid more OOP expenses for their medical care than those without cancer, creating an increased financial burden for the cancer survivor and their families (Lee et al., 2018; Yabroff et al., 2020). As the cost increased, insurers shifted the cost of care to patients through copayments, higher deductibles, and coinsurance (Yabroff et al., 2020). Additionally, cancer survivors experienced loss of income and possible loss of health insurance through employers, which could result in worries concerning overpaying medical bills and delaying or skipping medical care because of the costs (Yabroff et al., 2020). In 2013, the President’s Cancer Panel recognized as a national priority the need to address the high cost of cancer drug pricing (Yabroff et al., 2020).

A concern for cancer survivors with a history of radiation and chemotherapy was financial stress, leading to an avoidance of prescribed medications (Lee et al., 2018). Lee et al. (2018) examined the prevalence of CRN in separate groups. They reported that female cancer survivors were more likely to report CRN, and older Hispanic and African American cancer survivors were also more likely to report CRN than non-Hispanic Whites. The researchers also reported that being African American, having a lower income, and having insurance that was not through an employer were risk factors for CRN (Lee et al., 2018). Approximately 10% of individuals on Medicare, whether they had cancer or not, reported CRN and decreased spending on basic needs to offset the high cost of medications (Lee et al., 2018). Examination of adult cancer survivors in the United States between the ages of 18 and 64 from the years 1998 and 2000 showed that CRN was likely to be found in the uninsured and those using public insurance programs, and 20% of cancer survivors reported missing or postponing care because of cost (Lee et al., 2018). More than half the cancer survivors in the United States experienced at least one area of hardship. and nearly one-third experienced multiple areas (Hastert et al., 2019; Yabroff et al., 2020).

There is evidence that financial hardships were more prevalent in racial/ethnic minority and low-income survivors, with distinct types of hardships having different implications (Hastert et al., 2019). The Detroit Research on Cancer Survivors (Detroit ROCS) conducted a study to explore the association of comorbidities between Black and White cancer survivors by studying medical history, health behaviors, social support, financial well-being, and health-related outcomes (Hastert et al., 2019). Participants were

between 20 and 79 years of age and diagnosed with either primary, invasive colorectal, lung, prostate, or female breast cancer (Hastert et al., 2019). Patients were asked if they had to do any of the following: refinance or take out a second mortgage, sell their home, sell stocks or investments, or withdraw from retirement accounts to pay bills related to their cancer treatment (Hastert et al., 2019). Additionally, they were asked if they had to borrow from friends or family, if their income had declined, and if they were in debt due to their cancer treatment (Hastert et al., 2019). Results from the study indicated financial hardship was more prevalent in Blacks (50.3%) than Whites (41%), with a decrease in income being the most common, followed by debt that was cancer-related, borrowing money from family or friends, and using assets to pay for care (Hastert et al., 2019). The findings showed that race makes a difference in financial hardship associated with care for cancer patients (Hastert et al., 2019). Previous research had focused on patients' non-adherence to study medications. This research focused on the physical burden and how consumers felt about the current insurance and drug pricing system.

Purpose of the Study

The purpose of this quantitative research was to study the overall financial and physical effect of drug prices on the consumer and to study the effect of the use of drug discount pricing programs on the ability of the consumer to purchase medications. Specifically, I studied (a) the overall effect of drug prices on the insured consumer's physical and financial status and (b) the effect of discount drug pricing programs on the consumer's ability to obtain and pay for their medications. I surveyed insured consumers to ascertain their opinions on whether they could afford their medications and what steps

they took if they cannot. The goal was to determine if there was a correlation between the cost of prescription medications and financial hardships, whether participating in a drug-pricing program helped alleviate some of the price, and whether there was a physical burden on the consumer if they could not afford their medications. Focusing the research on the effect of drug pricing on the consumer's ability to afford medications linked to the RQs as the data showed the consumer's opinions on drug pricing, affordability, variations, depending on the different types of insurances, and the effect of discount drug-pricing programs.

Research Questions and Hypotheses

For this quantitative non-experimental study, the main RQs and hypotheses were

RQ1: What is the association between the consumers' perception of the current drug pricing system with the consumer's ability to purchase medications because of cost?

$H_0$1: There is no direct relationship between the consumer's perception of the current drug pricing system and the consumer's ability to purchase medications because of cost.

$H_1$1: There is a direct relationship between the consumer's perception of the current drug pricing system and the ability to purchase medications because of cost.

RQ2: What is the relationship between the consumer's opinion whether the cost of prescription drugs is reasonable and favoring purchasing drugs from Canada?

$H_0$2: There is no direct relationship between consumers' opinions on whether prescription drug costs are reasonable and whether it should be easier to purchase medications from Canada.

$H_1$2: There is a direct relationship between consumers' opinions on whether the cost of prescription drugs is reasonable and whether it should be easier to purchase drugs from Canada.

RQ3: What is the association between the consumer's opinion on whether drugs are priced fairly and the government making it easier for generic drugs to come to market?

$H_0$3: There is no direct relationship between the consumer's opinion on whether drugs are priced fairly and if it should easier for generic drugs to come to market.

$H_1$3: There is a direct relationship between the consumer's opinion on whether drugs are priced fairly and if it should be easier for generic drugs to come to market.

RQ4: What is the relationship between consumers filling their prescriptions using a discount drug program and filling their prescription if they were not part of a discount drug program?

$H_0$4: There is no direct relationship between participating in a drug discount program and filling prescriptions.

$H_1$4: There is a direct relationship between participating in a drug discount program and filling prescriptions.

RQ5: What is the relationship between consumer's using a discount drug program and alternatives to filling the prescription if not in a program such as asking for less expensive drug, taking over-the-counter (OTC) drug, or skipping taking the medication?

$H_0$5: There is no relationship between participating in a drug discount program and alternatives to filling the prescription if not in a program such as asking for a less expensive drug, taking an OTC drug, or skipping taking the medication.

$H_1$5: There is a relationship between participating in a drug discount program and alternatives to filling the prescription if not in a program, such as asking for a less expensive drug, taking an OTC drug, or skipping taking the medication.

RQ6: What is the relationship between the consumer using a drug discount program in the past 12 months and alternatives to filling the prescription if not in a program such as not filling the prescription because of cost, cutting pills in half, or skipping doses because of cost and taking an OTC instead of filling the prescription because of cost?

$H_0$6: There is no relationship between participating in a drug discount program within the past 12 months and additional alternatives to filling the prescription if not in a program, such as not filling the prescription because of cost, cutting pills in half, or skipping doses because of cost and taking an OTC instead of filling the prescription because of cost.

$H_1$6: There is a relationship between participating in a drug discount program within the past 12 months and additional alternatives to filling the prescription if not in a program, such as not filling the prescription because of cost, cutting pills

in half, or skipping doses because of cost and taking an OTC instead of filling the prescription because of cost.

Theoretical and/or Conceptual Framework for the Study

This study focused on drug pricing and consumer opinion of drug pricing. Two theories were used for this exploration. For consumer opinion on drug pricing, the rational choice theory (RCT) was chosen. The power and politics and rational choice theories were used to explore drug pricing. Power and politics and RCT were used to supply a framework for decision making by corporations concerning how to set drug prices in the pharmaceutical industry. RCT explains criminal behavior; however, I used RCT to examine consumers' choices regarding how they purchased drugs. RCT was also used to examine consumers' choice of adhering to dosing directions when they could not afford their drugs. Rational choice and power and politics theories were also used to examine the motivation for setting drug prices.

Rational Choice Theory

RCT is used in criminology and behavioral research to explain criminal activity (Paternoster et al., 2017). RCT is a theory positing that people make what they consider to be sensible choices after viewing their options based on their beliefs and desires and will choose what meets their satisfaction at the time (Paternoster et al., 2017). While there was not much literature using RCT to describe how consumers buy medications or adhere to their usage, this researcher used the tenets of RCT to apply to consumer behavior based on the affordability of patented medications.

RCT is not just one theory but involves many disciplines, including economists, psychologists, behaviorists, and political scientists with varying definitions (Foy et al., 2018, Herfeld, 2020). People have reasons and motivations (whether good or bad) for their actions (Pogarsky et al., 2017). There are three elements to RCT when applied to crime: (a) the decision to commit a crime is rational and involves weighing the perceived costs and benefits, (b) the model should be specific to the crime committed, and (c) the action chosen is influenced by self-interest (Paternoster et al., 2017). There are also two assumptions necessary for RCT: (a) people are diverse when it comes to their preferences, and (b) the idea or rationale is not necessarily limited to one's self-interest but can also be towards the interest of others or other entities (Paternoster et al., 2017). While this research did not involve criminal activities, the RCT theory will compare the three elements to the consumer's decision to purchase or adhere to medication instructions. The consumer, who comes from a diverse population, makes a rational decision, weighing the perceived or actual costs of certain medications, and is influenced by self-interest, which could range from affordability to choosing an alternative to medication. RCT has also been used to analyze individuals and institutions and explain institutions' power (Hudik, 2019).

Power and Politics Theory

Organizational theories provided the framework for the second theory, specifically power and politics. The literature did not contain many articles on the intersection of politics, policy, and the pharmaceutical industry; therefore, this research examined this topic from the perspective of the pharmaceutical industry's influence on

setting drug prices. Shafritz et al. (2016) tells us that there is no one theory of organization but rather several theories to explain how people and leaders in organizations function. In looking at theories on democracy, the influence of corporations and their private interests on politics has always been a concern (Woll, 2019).

I selected power and politics theory because it views organizations (in this case, the pharmaceutical industry, and the political system) as systems where individuals influenced their interests, perspectives, and preferences (Shafritz et al., 2016). Each group gains influence through conflict and the power and political resources wielded (Shafritz et al., 2016). Influence results in the creation of goals through power and politics, and control dictates the organizational structure through bargaining and maneuvering among the individuals (Shafritz et al., 2016). This theoretical framework is rooted in theories of organizational theory and the distinct types of power available (Shafritz et al., 2016).

For years, power has been recognized as a driving force in creating and supporting public policies, and by extension, power is critical to addressing public policies concerning inequities (Harris et al., 2020). The dynamics between power, policy, and politics can be found in policy and political theory; however, navigating power and politics can be challenging because of the many nuanced and unseen layers (Harris et al., 2020). Power is sometimes visible and sometimes not and therefore is not always straightforward and has always exerted influence in policy making, but it may not always be obvious (Harris et al., 2020).

Suppose one reviewed the power relationship between individuals, collectives, systems, and life structures. In that case, the theory could open itself up to a broader array

of positions of influence on policies and choices (Harris et al., 2020). Most contexts can have moral, legal, political, and historical scopes on how power can be employed and where the exercise of power, whether locally or globally (Harris et al., 2020).

Nature of the Study

In this research, a quantitative approach was taken to examine how the pricing of patented prescription drugs affected the average consumer. The research involved utilizing a survey to solicit opinions on the physical and financial effects of drug pricing on the insured consumer. Finally, there was an examination of whether the use of discount drug pricing programs assisted in the affordability of medications for the consumer.

The data collected was analyzed and compared to data collected from the KFF Health Tracking Poll from February 2019. KFF public opinion and survey research is a charter member of the Transparency Initiative of the American Association for Public Opinion Research. The KFF (n.d.)is the leading organization in policies affecting health care in the United States. The public opinion and survey research team performs original research on attitudes, knowledge and experiences of Americans pertaining to the health care system. Their objective from the polling is to amplify the voice of the public in debates on national issues, particularly those are often overlooked such as the disenfranchised, low income, and those without insurance.

The original KFF Health Tracking Poll was designed by public opinion researchers (KFF, 2019) and was conducted by phone interview. The abbreviated version used for this research was posted on the internet and accessed through SurveyMonkey

and was conducted over a 9-month period. SurveyMonkey is an online program that helps users create, send, and analyze surveys (Kimball, 2019.). I was blinded to which participants made which survey responses. The data were analyzed using a bivariate statistical analysis program and assessed for statistical significance and predictive values. SPSS Statistics Version 28.0.1.0.1 was used for all data analysis, and statistical significance was assessed at less than 0.05.

Definitions

Affordable Care Act (ACA): The comprehensive health care reform law enacted in March 2010 (sometimes known as ACA, PPACA, or "Obamacare"). (healthcare.gov, n.d.)

American Diabetes Association (ADA): The organization that funds research to prevent, cure and manage diabetes by supplying credible information and delivering service to communities (diabetes.org).

Complementary and Alternative Medicines (CAM): Term used for medical products and practices that are not a part of standard medical care or treatment. (cancer.gov).

Cost-related medication non-adherence (CRN): Taking less medication than prescribed because of cost, such as delaying or not filling prescriptions or skipping or lowering medication doses (Google.com, 2021).

Drug Manufacturer: Anyone engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling a prescription drug. (FDA.gov, n.d.).

Financial hardship (Financial toxicity, financial burden): An inability to meet basic living expenses for goods and services necessary for the survival of the debtor and their spouse and dependents. (Legal Information Institute Cornell Law School).

KFF: The Kaiser Family Foundation is an independent, nonprofit organization that focuses on national health issues and the U.S. role in global health care policy. KFF runs its policy analysis, journalism, and communications programs and sometimes partners with other major news organizations (kff.org/about-us/, n.d.).

Limited English Proficiency: Language assistance for individuals who do not speak English as their primary language and have difficulty or limited ability to read, speak, write, or understand English. These individuals may need an interpreter or document translation to have meaningful access to programs funded by the U.S. Department of Health and Human Services (hhs.gov, n.d.).

Out-of-Pocket (OOP) expenses: A payment an individual makes with their own money, even if they will be reimbursed. (Kagan, 2021).

Pharmaceutical Research and Manufacturers of America (PhRMA): A trade group representing companies in the pharmaceutical industry in the United States. Founded in 1958, PhRMA lobbies on behalf of pharmaceutical companies – (Wikipedia, n.d.).

Pharmacy Benefit Managers (PBMs): Pharmacy benefit managers, or PBMs, are companies that manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers (Explainer, 2019)

Quality of life: The degree to which an individual is healthy, comfortable, and able to participate in or enjoy life events (Britannica, n.d.).

Socioeconomic status: The social standing for classes of individuals or groups measured as a combination of education, income, and occupation (APA.org, n.d.).

U.S. Food and Drug Administration (FDA): A U.S. federal agency that protects the public's health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices (FDA.gov, n.d.). The FDA also ensures the safety of the nation's food supply, cosmetics, and products that emit radiation.

Veterans' Health Administration (VHA): The most extensive integrated health care system in the United States, providing care to over 9,000,000 veterans enrolled in the Veterans Administration health care program (va.gov, n.d.).

Assumptions

I had several assumptions when conducting this study. I assumed that all participants had access to the internet and would respond truthfully to the questions in the survey. Another assumptions was that participants were on an insurance plan that included prescription drug coverage and had OOP expenses for prescription drugs. The questions omitted from the original survey were assumed to not be relevant to the results needed for answering the RQs. I assumed that the sample size was sufficient to address the RQs. Furthermore, I assumed that the statistical methods utilized for this study were reliable, and the results could be used for further study. Finally, it was assumed that the participants in this study would like to see changes in the setting of drug prices and wanted to see changes in policies and laws to ease the burden on the consumer.

Scope and Delimitations

I used SurveyMonkey to collect data from volunteers who agreed to participate in the study. The survey was adapted from the instrument used by the KFF Health Tracking survey of 2019. Recruitment included participants with an insurance plan covering prescription medications and OOP expenses. I was blinded as to who completed which survey, and no monetary incentive was offered for participating in this research.

Limitations

Limitations to the study included representation of overall population, sample size, and participant's possible hesitation to share sensitive information. These limitations may affect the validity and reliability of the study. The sample may not be representative of the overall population. A large sample size was not collected. Participants may have been hesitant to share sensitive information such as their insurance information. If data could not be collected from a representative sample of the overall population it may be challenging to meet the study objectives (Rahman, 2023). Sample size was calculated using G*Power and was calculated at 129 participants. Recruitment was challenging and recruitment was closed with the final sample size being 87.

There could be concerns around privacy of information over the internet. A cross-sectional study used an online survey to determine personal concerns of releasing personal information to health care providers using electronic hospital records (Cherif et al., 2021). Results indicated private concerns were lessened depending on the level of trust in the health care providers and perceived benefits from releasing the information (Cherif et al., 2021). There were no known biases for this study.

Significance

The aim of this study was to examine the effect of prices of patented drugs and discount drug programs on the insured consumer. Also, the purpose was to determine if there was an association between drug prices and patient nonadherence and if nonadherence affected the health and financial well-being of the consumer. The findings from this research could potentially address changes needed in how drugs are priced in the United States. Several states have presented proposals for lowering the cost of prescription medications as they are also aware of the excessive burden it places on the average consumer, people of color, and minorities. The National Academy for State Health Policy (n.d.) provides a state-by-state analysis of what is being proposed for each state. It was unknown if pharmaceutical companies are open to seriously addressing such issues; however, as more definitive information is put forth from research, it might force the manufacturers to rethink their positions on deciding drug prices. The study may also provide a greater understanding for the health care provider and assist them in helping to find better ways to help their patients obtain medications for lower prices.

Summary

In this quantitative study, I explored how the rising costs of patented medications affect consumer behavior. This study examined drug pricing in the U.S and how consumer behavior was affected by non-adherence to their medications. The survey is adapted from the KFF Health Survey of 2019. The data were from participants who were insured patients and have prescription drug coverage. Chapter 1 offered background for the research, the issue to be studied and why, RQs, and their relationship to the proposal.

In Chapter 2, I comprehensively review current and relevant literature and the theoretical basis for the RQs. Chapter 3 includes an explanation of how the study was designed and how the data were collected and analyzed. In Chapter 4, I discuss the results and outcomes, and in Chapter 5 I discuss the results of the analysis of the data and any conclusions reached from the study, as well as offer recommendations for further research.

Chapter 2: Literature Review

Introduction

In the United States, there is an ongoing problem with consumer affordability of patented prescription medications. While there are published works examining the price and affordability of prescription medications (Frazier 2020; Luo & Gellad, 2020; Kesselheim et al., 2016; Thompson et al., 2021), the studies did not focus on the many systems that influence drug pricing including political and pharmaceutical. Nor was there much focus on the possible illicit activities surrounding drug pricing and the impact on the consumer.

Many older adults, when they cannot afford their medications, develop strategies for reducing drug costs, including not taking prescribed medications, which could involve skipping doses or taking less or a dose, or delaying filling a prescription (Cohen & Boersma, 2019). Kang et al. (2018) examined cost-related non-adherence to medications among people with diabetes and concluded that non-adherence was 16.5%, and consumers with annual incomes greater than $50,000 and better adherence than those with lesser incomes.

For Medicare patients, access to specialty drugs typically covered by Part D may be limited due to increases in drug prices requiring the patient to pay a percentage of the drug's price through their insurance (Dusetzina et al., 2019). One of the benefits of the ACA was to improve affordability by gradually decreasing coinsurance for patented drugs (Dusetzina et al., 2019). However, when the prices began to increase, the savings were nullified by the increase (Dusetzina et al., 2019). Nonetheless, patients with

Medicare coverage were more likely to take medicine as prescribed (Cohen & Boersma, 2019).

This chapter includes a review of the literature on the study topic. In the literature review, I discuss the impact of pharmaceutical companies on setting drug prices, the possible illicit activities associated with pricing, the results of those actions, the political influence pharmaceutical companies exert over the political machine and the ultimate effect on the consumer. The goal was to suggest social policy changes to alleviate the consumer's burden. The chapter also includes an overview of the literature search strategy and more information on the theoretical foundation and conceptual framework of the study.

Literature Search Strategy

The literature review was presented in three distinct ways. The first section focused on the theoretical framework (RCT as the main theory with organizational theory [power and politics] as a secondary theory). The second section of the review focused on the pharmaceutical industry's influence concerning drug pricing, the use of lobbyists and political systems in pricing drugs, and drug companies' questionable activities involving drug pricing. Finally, the third section of the review summarized the methodology.

The literature search consisted of peer-reviewed articles describing how pharmaceutical companies price patented drugs in the United States and the cost of prescription drugs, emphasizing use for cancer and diabetes treatments. The literature search also explored market exclusivity of prescription drugs, consequences of drug pricing, the effect of lobbying on setting drug prices, criminal activity of pharmaceutical

companies concerning drug pricing, and the impact of increased drug pricing on the consumer. Theoretical articles on RCT and organization theory, specifically power and politics organizational theory, were summarized.

I used the Google Scholar search engine and the following databases: ProQuest, EBSCO, and PubMed. Keywords and phrases used were *pricing of prescription drugs, drug pricing and criminal activity, the effect of drug pricing on consumers, lobbyists, and the pharmaceutical industry, disparities in the health care system, corporate social responsibility, power and politics*, and *rational choice theory*. As the articles were retrieved, they were organized according to drug pricing, criminal activity, ethics, and consumer opinion to support the research problem, design, theoretical framework, and RQs. Older references were used when describing the origin of theories. Adjustments were made to the search parameters while reviewing the content of the articles.

Theoretical Foundation

The theoretical framework for this research is the RCT and organizational theories involving power and politics. RCT has been used as a criminology theory to explain several types of crimes (Paternoster et al. 2017). RCT is a simple theory of criminal activity based on self-interest after weighing the costs and benefits of a course of action. The action taken is most effective for the offender (Paternoster et al. 2017). RCT means people make what they consider to be sensible choices after viewing their options based on their desires, likings, and beliefs and will choose what satisfies their preferences at that time, despite their ideals (Herfeld, 2020).

Conceptual Framework

Rational Choice Theory

RCT is not just one theory but comes in many versions and is used by many disciplines, including behaviorists, economists, psychologists, and political scientists, and its definition, along with its features, can vary from one research genre to another (Foy et al., 2018; Herfeld, 2020). Scholars disagree about RCT's concepts, methodological status, and the epistemic role and have linked it with accepted decision theories (Foy et al., 2018; Herfeld, 2020).

There are three elements to RCT when applied to crime: (a) the decision to commit a crime is rational and involves weighing the perceived costs and benefits, (b) the model should be specific to the crime committed, and (c) the action chosen is influenced by self-interest (Paternoster et al., 2017). There are also two assumptions necessary for RCT: (a) people are diverse when it comes to their preferences, and (b) the idea or rationale is not necessarily limited to one's self-interest but can also be towards the interest of others or other entities (Paternoster et al., 2017). RCT is also a methodological resource consisting of rational choices (Blakely, 2020). Its principles consist of the adages of completeness and transitivity (Blakely, 2020). The completeness axiom hypothesizes that rational actors rank their choices, and the transitivity axiom posits that preferences can be transferred from one object to another (Blakely, 2020). The cost of offending can be divided into legal (criminal justice, financial, conviction) or nonlegal such as the impact of being labeled or stigmatized (Pogarsky et al., 2017). Theoretically, the players consider certainty, severity, and celerity (how fast one can

perform something) and the consequences before attempting to commit a crime (Pogarsky et al., 2017).

RCT has proven to be a valuable theory for analyzing individuals and institutions explaining the power of institutions; however, behavioral economists argue that RCT has unrealistic assumptions, and its predictions are false (Hudik, 2019). They contend that the theory does not stand up to scrutiny when considering psychological factors (Hudik, 2019). Rational choice shows the logic of human reasoning and can predict outcomes for how humans will behave and act (Blakely, 2020). When people make decisions under duress and uncertainty, they begin to rely on heuristics (Raue & Scholl, 2018). A heuristic decision allows someone to make judgments without all the available information (Raue & Scholl, 2018). This decision is especially true for complex situations and situations where people have limited capacity to cope with the information (Raue & Scholl, 2018).

Throughout the years, political scientists and sociologists have tried to build theories around the concept that before engaging in actions, individuals participate in what they consider 'rational' actions after calculating the costs and benefits of those actions (Scott, 2000). This theoretical approach is known as RCT. RCT premises are based on assumptions that one can explain social phenomena in elementary terms: human action and interactions with other individuals (Scott, 2000). Theorists can also apply the same principles in producing, consuming, and distributing goods to RCT (Scott, 2000). The resources are time, information, approval, and prestige, as individuals are motivated by their goals and desires (Scott, 2000). After studying the information and conditions,

individuals will act (Scott, 2000). A rational choice will be made based on an expected outcome; choosing what they have concluded will give them the most significant reward (Scott 2000).

From a psychological perspective, George Homans argued that rewards and punishments influence human behavior (Scott, 2000). Therefore, behavior is not a free choice and is conditioned through the reward/punishment system (Scott, 2000). Looking at RCT through an economic lens, social interaction is a social exchange process of goods, services, approval, or other behaviors (Scott, 2000). An individual might engage in activity for opportunities, monetary, or non-monetary rewards (Scott, 2000).

Heuristics

People have reasons and motivations (whether good or bad) for their actions (Pogarsky et al., 2017). As a result, one could surmise that offending is related to the perceived threat of being punished, with the rational choice being most likely to address the reasons for making the decisions (Pogarsky et al., 2017). Pogarsky et al. (2017) posited that the principles of heuristics when considering psychological and behavioral aspects might improve the accuracy of RCT in accounting for decisions in committing crimes (Pogarsky et al., 2017). Heuristics is a strategy where the individual ignores part of the information to make a quicker decision (Pogarsky et al., 2017). This concept could be beneficial to decision making as it takes less effort to make decisions when ignoring part of the information but making decisions this way could decrease accuracy and bias the decision-making process (Pogarsky et al., 2017).

Because most individuals aim to seek pleasure and avoid pain, various forms of information and perceptions about the consequences of their actions, including offending, are integrated, and weighed when making decisions (Pogarsky et al., 2017). Individuals and corporations may pursue potential criminal opportunities when they expect benefits that could be monetary in value, possible status, or political advantage (Pogarsky et al., 2017). Using RCT, an individual's perception of certainty, speed, and severity of punishment should drive the decision as to whether to engage in the crime with a lower perceived certainty, celerity, or severity leading to a better likelihood of committing the crime (Pogarsky et al., 2017).

Power and Politics Theory

The second framework for this research was organizational theory, specifically power and politics theories. The literature did not have many articles on the intersection of politics, policy, and the pharmaceutical industry. Therefore, this research examined the topic from the perspective of the pharmaceutical industry's influence on setting drug prices. In looking at theories on democracy, the influence of corporations and their private interests on politics has always been a concern (Woll, 2019). Lobbying and the impact of lobbyists was one of those concerns. U.S. democracy allows individuals, groups, and corporations to influence political outcomes (Woll, 2019). However, financially stronger companies could more efficiently promote their interests at an unfair advantage than companies with lesser means (Woll, 2019). While there is the outrage over the influence of lobbyists, the current regulatory system does not seem equipped to

prevent corporate power, even though the United States has one of the most developed sets of regulations to combat such actions (Woll, 2019).

Shafritz et al. (2016) tell us that there is no one theory of organization but many theories to explain how people and leaders in organizations function. Methods of an organization have two significant themes: applying systems of general approaches to organizations and using quantitative tools and techniques to understand the complex relationships between organizations and the outside environment (O'Sullivan et al., 2017). Keeping that in mind, the power and politics organization theory was a secondary theoretical framework for this dissertation topic.

This theory was selected because it views organizations (in this case, the pharmaceutical industry, and the political system) as systems where individuals influence interests, perspectives, and preferences (Shafritz et al., 2016). Each group gained influence through conflict and power and political resources wielded (Shafritz et al., 2016). Influence resulted in the creation of goals through power and politics, and control dictated the organizational structure through bargaining and maneuvering among the individuals (Shafritz et al., 2016). This theoretical framework is rooted in theories of organizational theory and the different types of power available (Shafritz et al., 2016).

Rationale for Selection of Rational Choice Theory

RCT relates to the study because of the activities engaged by individuals within the pharmaceutical company. It could help explain the power of institutions, corporations, and individuals (Hudik, 2019). Rational choice was also recognized as a resource in economics as it ranks preferences that can be transferred to other concepts (Blakely,

2020). In the case of pharmaceutical companies, the industry could exercise power through involvement with politicians, lobbyists, and Patient Advocacy Groups (Edgar, 2013). These were sound decisions made by assessing some of the following, the cost of their actions based on loopholes in the law, lobbyists ensuring politicians are on their side, insurance companies, the health care system, and PBMs (Edgar, 2013). These decisions were designed to convince politicians and the public that they were doing nothing wrong, and this is just the cost of business (Edgar, 2013).

For years, power had been recognized as a driving force in creating and maintaining public policies and by extension, was critical to addressing action on public policies to address any inequities (Harris et al., 2020). The dynamics between power, policy, and politics can be found in policy and political theory; however, navigating power and politics can be challenging because of the many nuanced and unseen layers (Harris et al., 2020). Power is sometimes visible and sometimes not and therefore is not always straightforward and has always exerted influence in policy making, but it may not always be obvious (Harris et al., 2020). Harris et al. (2020) described four methods of expressing power:

- *Power over* is the best-known expression of power. This method implies control and coercion and would be considered part of a win-lose relationship. This form of power is associated with domination and disenables those over whom the power is exerted.
- *Power with* centers around building coalitions and collective strength. *Power with,* is based on building allies to change the power relations together.

- *Power to* is individual responsibility where each person has the power to shape their world and open the possibilities for power.
- *Power within* emphasizes self-worth and self-knowledge and is the capacity to imagine and have hope.

Edgar (2013) suggested that regardless of industry, they will use their economic power to ensure any regulations enacted are to their advantage. This influence would more than likely result in the interest of corporations clashing with federal and state rules leaving corporations to supply what they believe are rational explanations for their behavior (Edgar, 2013). Suppose one reviews the power relationship between individuals, collectives, systems, and life structures. In that case, the theory can open itself up to a broader array of positions of influence on policies and choices (Harris et al., 2020). Most contexts can have moral, legal, political, and historical scopes on how power can be employed and where power can be exercised locally or globally (Harris, 2020). Power is not inherently good or bad, but it can be about manipulation and coercion or empowering and transformative, depending on the motives of the individuals wielding it (Harris et al., 2020).

When applying power and politics to political science, the focus is on the importance of power, which highlights the balance between structure and organization (Harris et al., 2020). Themes of policy and power centered around “actors” were considered ‘rational choices’ with the actors being the various stakeholders, which can be industry, government, regulators, communities, or other groups (Harris et al., 2020). These different actors bring different perspectives, which can change the value or

position of other actors (Harris et al., 2020). Communicating the construction of power within policy institutions is crucial in understanding the policy dynamics, actions and decisions that create or maintain the status quo and can show how to take actions to disrupt those dynamics in the interests of equity (Harris et al., 2020). The concept of rational choice was applied to the responses made by participants concerning drug pricing. I then examined the tenets of power and politics to determine their influence on drug pricing and whether there was any consideration for the consumer or only profit. The outcomes were applied to answer the RQs.

Literature Review Related to Key Variables and/or Concepts

Big Pharma

The pharmaceutical industry is highly regulated because of the products they produce and must prove their product's safety and efficacy (Edgar, 2013). The industry is banned from selling products directly to the consumer but not directly advertising to the consumer (Edgar, 2013). Pharmaceutical companies must show that the benefits of their products outweigh the risks and must work to minimize the risks to the consumer if they misuse of their product (Sanchez Alonso, 2021). The marketing of pharmaceutical products is regulated, and companies have exclusive rights through patents overproducing and selling their product for a limited time (Edgar, 2013). It is essential to understand that the process of bringing a drug to market is expensive to develop, with an estimated price of over $2,500,000,000 in 2018 (Gabaldon, 2018).

Big Pharma is the term given to collectively describe some of the largest drug companies in the world (Sekerka & Benishek, 2018; Sekerka et al., 2018). Big Pharma

also has a trade group known in the United States as PhRMA. Big Pharma has considerable economic and political influence and power over consumers' lives (Sekerka & Benishek, 2018, Sekerka et al., 2018; Edgar, 2013).

While the name "Big Pharma" can evoke a less than favorable response from the public, it is essential to note that the pharmaceutical industry produces new drugs and provides a much-needed service while also allowing the institutions to make substantial profits (Sanchez Alonso, 2021). However, certain companies can have ulterior motives which motivate them to prioritize profit over the health and safety of the consumer (Sanchez Alonso, 2021). To comprehend the magnitude of Big Pharma's impact, one must understand how Big Pharma attempts to use its power to influence (Sekerka & Benishek, 2018). By intervening in government health policies, manipulating patient advocacy groups (PAGs), physicians, patients (through direct-to-consumer [DTC] advertising), the media, and others by interacting with all relevant stakeholders involved in the process of influencing selling prescription drugs, the pharmaceutical industry influences several aspects of drug regulations (Edgar, 2013).

Patient advocacy groups were formed to assist in the interest of individuals suffering from specific diseases or conditions such as cancer or HIV/AIDS by providing information and support to members, lobbying on their behalf, funding research, and consulting on government policies (Edgar, 2013). Because the interests of the PAGs overlap with the interests of the pharmaceutical companies, the drug companies would provide funding to the PAG (Edgar, 2013). In return, the PAGs could be used to communicate with the patient, and government and drug companies benefit from

perceived credibility and integrity (Edgar, 2013). While the drug companies make themselves out to be "ethical" with this alliance, it may, in the long run, harm the PAG by tarnishing them with the same suspicions as the drug companies because of the close relationship (Edgar, 2013).

Pharmaceutical companies have also been accused of disease-mongering or creating diseases or awareness of medical conditions by presenting risk factors as diseases and overstating the importance of minor illnesses or ailments, making any medical condition a rationale for the need for medication (Edgar, 2013). All industries use economic power to influence regulatory regulations to their advantage; therefore, the interests of corporations will, in some way, always clash with federal and state rules, and corporations will need to offer rational explanations for their behavior (Edgar, 2013). There is even a theory, the "Big Pharma conspiracy theory," which suggests that pharmaceutical companies, regulators, politicians, and others are working together secretly against the public's interest (Andrade, 2020; Blaskiewicz, 2013). In this theory, the enemy is an abstract entity formed of corporations, regulators, politicians, physicians, and others for their slice of the trillion-dollar prescription drug pie (Blaskiewicz, 2013). No one expects that pharmaceutical companies will publicly admit that they want to increase their drug prices to increase profits; that is for the other side to argue and prove (LaPira & Holyoke, 2017). However, conspiracy theories range from pharmaceutical companies withholding harmful information about medications to withholding cures for certain diseases to make profits (Andrade, 2020).

While images of draining the swamp invoke thoughts of insect infestations, it is essential to note that swamps and wetlands are vital to the ecosystem (LaPira & Holyoke, 2017). The same can be said for the "swamps" in the government (LaPira & Holyoke, 2017). While the existing system is flawed concerning the balance between competing interests, and the current ethical guidelines and regulations seem insufficient to resolve the problem, LaPira & Holyoke (2017) believe there are ways to make the "swamp" healthy wetlands. Over the past 40 years, developing drugs has become a contest to see which company could produce the next "blockbuster drug," which would generate billions of dollars in sales which has caused critics of the industry to believe that the consumer is secondary to profits (Sekerka & Benishek, 2018; Sekerka et al., 2018)).

The pharmaceutical industry spends millions of dollars yearly on DTC advertising (Sekerka & Benishek, 2018). It is the second-fastest-growing market competing with providers such as the fast food, insurance, and automotive industries (Sekerka & Benishek, 2018). Estimations are that in 2011, the average American household watched approximately 111 advertisements per month for prescription drugs and that there are around 80 drug ads for every hour of television in America (Sekerka et al., 2018). People watch around 5 hr of television a day but see their physician approximately four times a year, spending only 15 min with them, and the FDA has not done much to address the issue (Sekerka et al., 2018). While the drug companies' returns have been lucrative from DTC advertising, that advertising has not always benefited the consumer (Sekerka & Benishek, 2018).

One example was Jublia, a toe fungus treatment. Jublia was one of the most advertised drugs in 2016, proved effective in less than 20% of the users, and cost around $600 a bottle (Gabaldon, 2018; Sekerka et al., 2018). Consumers will likely spend more time listening to and watching pharmaceutical advertisements than speaking with their physicians (Sekerka & Benishek, 2018). Additionally, many of these ads can be a tax deduction for drug companies (Sekerka & Benishek, 2018).

Legislation has been introduced to eliminate the tax deduction; however, lobbying groups backed by industry continually apply their power to challenge any changes (Sekerka & Benishek, 2018). Government regulations are designed to serve the good of the public, not the shareholders of a company; however, there is much discussion about whether this is true (Sekerka & Benishek, 2018). Pharmaceutical companies contribute to the FDA as they must pay the agency to review their product applications for approval (Sekerka & Benishek, 2018). These contributions have created a symbiotic relationship between the two entities, blurring the government's line of protecting its citizens (Sekerka & Benishek, 2018). Interest groups represent patients and company rights; however, the pharmaceutical company's wealth and influence far outweigh the impact of groups with fewer finances, with approximately 80% of the patient advocacy groups taking money from Big Pharma. (Sekerka & Benishek, 2018).

The 21st Century Cures Act (Cures Act) passed in 2016 was designed to help fast-track the development of new medical products, advances, and innovations for patients quicker and more efficiently (Sekerka & Benishek, 2018). However, the Cures Act has served to weaken the FDA approval process since approximately 1,400 industry lobbyists

worked on the bill amounting to significant financial advantages to drug and medical device companies (Sekerka & Benishek, 2018). Other entities that profited from prescription drug sales in addition to the pharmaceutical companies included insurers, PBMs, pharmacies, and wholesalers, with the consequence being that the pharmaceutical company can corner the market on a drug that is on patent and charge whatever they want (Sekerka & Benishek, 2018). Patient advocacy groups are supposed to be independent; however, many have PhRMA leaders, the Biotechnology Innovation Organization (BIO), and executives from drug companies sitting on their boards (Sekerka & Benishek, 2018).

According to the nonprofit company MapLight, which tracks the influence of money in politics, drug companies contributed over $70,000,000 fighting California's Proposition 61, which was supposed to limit the price states pay for prescription drugs (Sekerka & Benishek, 2018; Sekerka et al., 2018). The drug industry often backs politicians who agree with their approach toward the shareholder (Sekerka & Benishek, 2018). In 2016, the PhRMA spent $7,000,000 on a campaign that gave millions to politicians who were up for election and more than $2,000,000 on groups representing patients with various diseases (Sekerka & Benishek, 2018). The result was higher drug prices and hiring government employees connected to those politicians who agreed with them, allowing big Pharma an advantage (Sekerka & Benishek, 2018). Also, legislation passed that allowing the National Institutes of Health to enter deals with drug companies, allowing the industry to own all their discoveries (Sekerka & Benishek, 2018; Sekerka et al., 2018). Furthermore, doctors, scientists, research organizations, medical journals,

teaching hospitals, and medical schools accept money from the drug industry (Sekerka & Benishek, 2018; Sekerka et al., 2018).

Big Pharma often sponsored clinical trials paying researchers, academics, physicians, and scientists to conduct the research, collect the data, and prepare and analyze the findings (Sekerka & Benishek, 2018). However, the drug companies, called Sponsors, owned the data, prepared additional analyses, and reported what supported their agenda (Sekerka & Benishek, 2018). The pharmaceutical industry has used its power and influence over Congress, the FDA, research centers, academia, and the medical profession to market medications in the United States to gain the most significant degree of profit while leaving the consumer frustrated, feeling like they have no options or anyone to help them (Sekerka & Benishek, 2018)

The price of prescription drugs has overtaken the cost of inflation for years (Sekerka & Benishek, 2018). The industry explained that extra profit was needed for research and development (R & D) to produce better treatments, fund patient access programs that provide free or low-cost medications to the uninsured and reduce copayments for certain medications (Sekerka & Benishek, 2018). Although drug companies insisted the high cost of drugs was R & D, pharmaceutical companies allocated more money for advertising than R & D (Sekerka & Benishek, 2018). As a result of the effectiveness of advertising, Big Pharma is known for its political and social influence over its stakeholders, which includes the federal government, health care systems, insurance companies, practitioners in the medical field, administrators, medical facilities, and consumers (Sekerka & Benishek, 2018; Sekerka et al., 2018). The industry

has become so large that it influences how consumers and Western medicine think about their health and well-being (Sekerka & Benishek, 2018). Big Pharma, like most companies, produces what will increase earnings for its shareholders (Sekerka & Benishek, 2018).

Over the years, Big Pharma has been involved in billion-dollar lawsuits stemming from fraudulent marketing practices, kickbacks to physicians for prescribing certain medications, and aligning with generic companies to keep the cost of drugs higher (Sekerka & Benishek, 2018). In 1967 the sugar industry paid scientists at Harvard to downplay the link between sugar and heart disease, misleading the public for decades (Sekerka et al., 2018). Researchers believed this withholding of the negative effect of sugar had contributed to the rate of increase in heart disease (Sekerka et al., 2018). Additionally, some of the largest drug companies in the United States have been sued by the U.S. Drug Enforcement Administration for their participation in plans to distribute opioids (Gabaldon, 2018).

Unfortunately, drug companies do not seem to be deterred by the fines, fees, and settlements and look at it as the cost of doing business; however, it is the consumer that ultimately pays through tax dollars (Sekerka & Benishek, 2018; Sekerka et al., 2018). Pricing decisions like these are not uncommon or confined to greedy or unethical firms, as pricing decisions are based on maximizing profits (Sekerka & Benishek, 2018, Gabaldon, 2018). Between 2009 and 2014, there were five significant settlements between Big Pharma and the U.S. Department of Justice totaling more than

$13,000,000,000 (Sekerka et al., 2018). Four more examples are the cases of Turing Pharmaceuticals, Valent Pharmaceuticals, Mylan Pharmaceuticals, and Purdue Pharma

Turing Pharmaceuticals

Turing Pharmaceuticals was the maker of Daraprim, a 60-year-old drug used to treat parasitic infections in HIV/AIDS patients. The CEO of Turing, Martin Shkreli, calculated that he could make $1,000,000,000 in 3 years by raising the price of Daraprim, a generic drug costing pennies per pill to manufacture (Carrier, 2019; Sekerka & Benishek, 2018, Gabaldon, 2018; Sekerka et al., 2018). As a result, he raised the price by 5000%, from $1700 per bottle to $75,000 per bottle, with almost all of it becoming profit (Carrier, 2019; Sekerka & Benishek, 2018, Gabaldon, 2018; Sekerka et al., 2018). Shkreli also changed drug distribution from local pharmacies and hospitals to a single source of purchase (Carrier, 2019). As a result, patients could no longer find the drug at local pharmacies, and hospitals could no longer purchase the drug from a general wholesaler, making it impossible for anyone other than registered clients to obtain the drug creating monopoly power over the drug (Carrier, 2019).

Because of the public's outrage, the House Government Reform and Oversight Committee investigated how such an increase could occur and determined and confirmed that Shkreli raised the price as high as he did because, legally, he could (Sekerka & Benishek, 2018; Sekerka et al., 2018). Because of the backlash against him, he was forced out of the company, charged with fraud, and in 2018, sentenced to 7 years in prison (Sekerka & Benishek, 2018). Part of his strategy was hiding the cost from the patient and avoiding confrontations with HIV/AIDs advocates and hospitals (Sekerka &

Benishek, 2018). Despite his sentencing, there was no relief to the patients in desperate need of the medication (Sekerka & Benishek, 2018).

Valent Pharmaceuticals

In 2015 Valent Pharmaceuticals bought two heart medications, allowing them to take ownership of the company (Sekerka & Benishek, 2018; Sekerka et al., 2018). Once purchased, they raised one medicines price by 525% and the other by 212% profiting $351,000,000 in a year from the two drugs alone (Sekerka & Benishek, 2018, Gabaldon, 2018; Sekerka et al., 2018). Valent received complaints about the price of their medication and, as a result, set up a patient access program meant to assist patients who could not afford the drug; however, only a few benefited from the programs (Sekerka et al., 2018). As a result of a subsequent U.S. Attorney's office investigation, Valant's stock price decreased, resulting in short-lived success (Sekerka & Benishek, 2018; Sekerka et al., 2018).

Mylan Pharmaceuticals

Mylan Pharmaceuticals is the maker of EpiPen, a life-saving device used in emergency cases to deliver epinephrine to treat anaphylaxis (Carrier, 2019). Between 2009 – 2016, Mylan raised the price of EpiPen 15 times, increasing the price by over 400% even though the medicine costs only pennies per dose (Carrier, 2019). These price increases affected approximately 15,000,000 Americans and 1 in 13 children with allergies such as peanuts, shellfish, and other products (Carrier, 2019). Despite the reasons given for the price hikes, Mylan eventually eliminated all competitors through legal actions such as litigation through settlements which delayed competition from

entering the market (Carrier, 2019). Mylan also used citizen petitions (to stall the introduction of generics) and exclusive contracts with schools to create laws requiring auto-injectors on the premises (Carrier, 2019).

The company had to pay nearly half a billion dollars to settle a Medicaid complaint about misclassifying the drug and other complaints that it overcharged consumers (Dewey, 2018; Sekerka & Benishek, 2018; Sekerka et al., 2018). Mylan was indicted for increasing the price of a drug that had been on the market for over 20 years (albuterol sulfate tablets) by 4000% (Cohen, 2016; Dewey, 2018). Mylan was also indicted for raising the prices of lorazepam and clorazepate by 2000% (Dewey, 2018). Finally, there were lawsuits against the company for attempting to prevent competition and implementing illegal price increases (Cohen, 2016; Dewey, 2018).

Purdue Pharma

OxyContin, initially approved for end-of-life cancer care or other chronic pain conditions, should have been prescribed every 12 hr (Sanchez Alonso, 2021). Purdue Pharma began advertising OxyContin as a safe and non-addictive medication which they knew to be untrue, disregarding the company's bioethics standards (Gabaldon, 2018, Sanchez Alonso, 2021). The company used outdated and biased studies as evidence, cited articles out of context, did not inform the public of the risks, and hid data that would have proven the long-term exposed risks leading to an abundance of prescriptions by physicians (Sanchez Alonso, 2021). Purdue Pharma refused to take responsibility for its complicity in the opioid epidemic and did not try to reduce the harm caused by opioids (Sanchez Alonso, 2021).

Purdue Pharma marketed OxyContin using brochures that stressed the chance of addiction was low or did not exist and proceeded to email doctors, encouraging them to prescribe higher doses (Sanchez Alonso, 2021). The company used as proof one paragraph from a letter-to-the-editor from 1980 saying that there were low rates of addiction in closely monitored, hospitalized patients using OxyContin. The article was not a research article and had no empirical data, methodology, or discussion on how the study was conducted (Sanchez Alonso, 2021). Furthermore, the letter was published 15 years before OxyContin's approval by the FDA (Sanchez Alonso, 2021). The drug was studied in controlled hospital settings as opposed to consumers using the drug at home (Sanchez Alonso, 2021). Purdue Pharma made $35,000,000,000 dollars from selling OxyContin (Sanchez Alonso, 2021). After launching an investigation, Purdue Pharma eventually pleaded guilty to charges of fraud and kickbacks, admitting its role in the opioid epidemic, settling for $8,.300,000,000 (Sanchez Alonso, 2021). Purdue Pharma also provided evidence that the company did not work according to ethical principles and profited from peoples' pain rather than helping them alleviate it (Sanchez Alonso, 2021).

Professionals in the industry argue that because the medications bought by Turing and Valeant were for rare illnesses or so-called orphan drugs, and because there was little incentive to produce them or no competition, they could do what they did (Sekerka & Benishek, 2018). However, the actions of these companies leave blemishes on the pharmaceutical industry, practitioners of medicine, and the country, as these acts were not conducted in a bubble (Sanchez Alonso, 2021). Several players contributed to these companies' greed, fraud, and deceit.

Lobbyists

The editors of the Encyclopedia Britannica define lobbying as any attempt by individuals or private interest groups to influence the decisions of government (Britannica, T. Editors of Encyclopedia, 2020). In its original meaning, lobbying referred to efforts to influence legislators' votes generally in the lobby outside the legislative chamber (Britannica, T. Editors of Encyclopedia, 2020). For this study's purposes, *lobbying* is the transfer of information in private meetings and venues between interest groups, politicians, their staff, and agents (De Figueiredo & Richter, 2014, p. 164). Lobbying is inevitable in any political system. In the U.S. capitalist system, the assumption is that the government should not interfere and legislate the behavior of corporations, however no one envisioned how the money would influence the options available to consumers (Berg, 2017).

In the United States, both organizations and individual citizens have the right to appeal to politicians individually or collectively through interest groups to influence their decisions on policies, and those interest groups may vary across political and national territories (De Figueiredo, & Richter, 2014; LaPira & Holyoke, 2017; Wouters, 2020). One way to exert this influence is through hired lobbyists who distribute information to politicians in favor of their clients (LaPira & Holyoke, 2017; Wouters, 2020). Although individuals and organizations can contribute money to political campaigns, lobbyists must abide by a separate set of rules (Wouters, 2020). Lobbying is quite prevalent within the U.S political system, outspending contributions made by political action committees

by 5 times in 2000, with corporations and trade associations making up over 84% of the lobbying expenditures (De Figueiredo, & Richter, 2014).

If one assumes the goal of a politician is to get elected and reelected, they will seek information on how their position on different issues will affect that goal (De Figueiredo & Richter, 2014). One of the promises from candidate Donald Trump in 2016 was to "drain the swamp" in Washington, D.C., and he indicated he meant special interests and lobbyists for their perceived corruption (LaPira, & Holyoke, 2017). He was not the first to state this as Minority Leader Nancy Pelosi said the same thing in 2006 during the midterm elections, and Ronald Reagan also promised to do so in 1984 when he was running for President (LaPira, & Holyoke, 2017).

Few studies have been published on the influence of lobbying on legislative outcomes by the pharmaceutical industry. Most research is from 2009 or earlier (Wouters, 2020). Wouters (2020) examined the spending of lobbyists and contributions by the drug and health industry from 1999 to 2018 to answer the question of how much money the pharmaceutical and health care industry spent on lobbying and contributions to campaigns by analyzing public data. In 2018, the United States spent 17.6% of its gross domestic product on health care, including $345,000,000,000 on prescription drugs obtained from retail pharmacies amounting to an increase per person from $520 in 1999 to $1025 in 2017 (Wouters, 2020). While both Democrats and Republicans insist that lowering drug prices is a priority, lobbyists and those in the pharmaceutical industry who donate to political campaigns run interference in the efforts of state and federal governments to do so (Wouters, 2020). Wouters (2020) concludes that understanding the

enormous amounts of money the pharmaceutical industry spends on lobbying and contributing to campaigns can influence health care and drug policies. Companies also use lobbyists to gain exclusivity in selling their products.

A study was conducted in Denmark to study the lobbying effects of the pharmaceutical company Roche, the manufacturer of Tamiflu; an antiviral medication stockpiled before the 2009 A(H1N1) flu pandemic (Vilhelmsson & Mulinari, 2018). Roche lobbied directly and through what was to be an independent third party to convince hospitals that Tamiflu reduced hospitalizations and serious complications from the flu, resulting in institutions engaging in pandemic stockpiling (Vilhelmsson & Mulinari, 2018). Afterward, Roche accused governments and institutions of intentionally allowing themselves to be misled as the drug had little efficacy (Vilhelmsson & Mulinari, 2018). Results from subsequent clinical trials indicated that Tamiflu lessened flu symptoms by less than a day and only if treated within 48 hr, and the evidence of reducing hospitalizations was limited (Vilhelmsson & Mulinari, 2018). Additionally, some of the guidelines were written by key World Health Organization experts whom Roche paid for other projects creating a possible conflict of interest (Vilhelmsson & Mulinari, 2018).

The results also revealed that the company used two tactics and two arguments for its actions. Tactic 1 - Roche directly lobbied health and political leaders urging them to sign the procurement agreement claiming that the drug would be delivered on a first-come, first-served basis (Vilhelmsson & Mulinari, 2018). Argument 1 - The implications were that without the agreements, they could not guarantee that enough drugs would be

available, and medicine would be dispersed to the countries that acted more quickly (Vilhelmsson & Mulinari, 2018). Tactic 2 - certain doctors, who argued in favor of stockpiling, were acting on behalf of Roche (Vilhelmsson & Mulinari, 2018). Argument 2 - Denmark was at a higher risk because it would have fewer drugs in the event of a significant outbreak (Vilhelmsson & Mulinari, 2018). Roche attempted to influence these discussions using a third party (Vilhelmsson & Mulinari, 2018). These tactics and arguments are just two examples of how lobbyists and outside actors can unduly influence legislators (who are supposed to act on citizens' behalf) decision-making process. Similarly, Vilhelmsson & Mulinari (2020) noted that during the current COVID-19 epidemic, the quest to obtain adequate amounts of vaccine might have presented an analogous situation in that there may have been efforts by the pharmaceutical companies to control once again the rules on obtaining the vaccine. Their concern was that the tactics used by Roche in 2009 may once again have been used when countries were negotiating to obtain vaccines for COVID-19 (Vilhelmsson & Mulinari, 2020).

Prescription Drug Pricing

Compared to countries with national health programs, the United States is the only primary market where pharmaceutical prices are not regulated, with patients, insurers, and the government paying more than the same prescribed medicines in other countries (Sekerka et al., 2018). Because of the continually rising costs of prescription drugs, many consumers cannot afford their medications, and the prediction is that by 2025 retail prescription drug sales in the United States will be almost $600,000,000,000 (Kantarijan et al., 2013; Kesselheim et al., 2016; Mattingly et al., 2018). All prescription

drug pricing is not equal. Eighty percent of all prescription drugs are generic and have lower prices than brand drugs; however, even these prices are beginning to change (Cohen, 2016).

The inflated cost of a new drug had caught the attention of activists and political interest, sparking debate over the continual increase in drug prices (Mattingly et al., 2018). Currently, few laws and policies prevent pharmaceutical companies from charging whatever price the market will allow, and companies have come under scrutiny and federal prosecution for their pricing. Pricing, and other issues, resulting in a burden on the health care system and the consumer, and drug transparency is lacking in the industry on price setting (Mattingly et al., 2018).

Consumers must now deal with pharmacy pricing variations for the same drug as pharmacies and their price increases (Sekerka & Benishek, 2018). When consumers use their insurance, they may discover the insurance company no longer covers the medication, and they must pay OOP, leaving consumers to shop around to find the best deals with no transparency from the drug companies or pharmacies (Sekerka & Benishek, 2018). As a result, states have introduced legislation to address price increases using a variety of processes, from allowing Medicare to negotiate drug prices to greater transparency (Mattingly et al., 2018). Mattingly et al., 2018, evaluated the manufacturer net price of drugs compared to the price set by the U.S. Veterans Administration to help better understand how discounts may help researchers decipher cost-effectiveness analysis. The sales of the top 10 pharmaceutical products for three companies were analyzed. The National Drug Code was used to identify the wholesale acquisition cost

and the Federal Supply Schedule for each product (Mattingly et al., 2018). The manufacturer net price was estimated, and the conclusion was that the manufacturer net price was close to the Veterans Administration price and could be used as a proxy for what is paid by the PBM or third parties (Mattingly et al., 2018).

Attempting to analyze national data on prescription drug pricing has many challenges because many players lack transparency (Cohen, 2016). Drug costs and policies depend on the payer, and each payer (e.g., Medicare, Medicaid, government programs, private insurers) has its own set of policies surrounding eligibility, deductibles, and covered drug copayments (Cohen, 2016). Other factors in prescription drug pricing include how states choose to do exchanges under the ACA and federal exchanges (Cohen, 2016).

Pricing of brand-name drugs generates enormous profits for pharmaceutical companies who sometimes use aggressive tactics to protect their monopoly (Cohen, 2016). In a political context, drug companies worry about changes in regulations and often place the costs of any new laws on the patients by increasing the price of drugs (Cohen, 2016). Drug prices are routinely estimated using an economic tool called wholesale acquisition cost; however, it does not consider rebates and discounts offered to PBMs (Mattingly et al., 2018).

Cancer Drug Prices

The ACA was signed into law in 2014 to provide more low-income adults with health insurance coverage. Levine et al. (2018) examined the effect of the ACA on CRN with medications for adult stroke survivors. Levine et al. (2018) examined stroke

survivors between 45 and 64 years of age before and after the implementation of the ACA (Levine et al., 2018). From 2011 to 2016, Medicaid increased, and uninsurance decreased among those who survived a stroke (Levine et al., 2018). CRN increased before implementation of the ACA and decreased after implementation of the ACA, revealing that after execution of the ACA, CRN decreased among adult stroke survivors (Levine et al., 2018). Another group affected by CRN is individuals who have cancer. (Lee et al., 2018). Many cancer patients have chosen to deal with the increased financial burden by not adhering to their medications as prescribed (Lee et al., 2018).

Clinical progress has been made in the last few decades around advances in anticancer medications, representing a substantial benefit to patients and health care providers (Bennette et al., 2016). However, these advances have also added to the high cost of cancer treatments in the United States. The high cost of oncology drugs threatens patients' ability to afford the medication (Bennette et al., 2016: Shih et al., 2017)

Targeted oral cancer medications (TOAMSs) have been in development for the past 20 years as they not only improve patient survival but improve the delivery of cancer care where patients no longer must have chemotherapy in the office but rather at home (Shih et al., 2017). Nonetheless, there continues to be a growing concern over the affordability of these drugs as studies have shown that price of the oral medications has increased over intravenous medications (Shih et al., 2017). The financial burden on the patient has been recognized as a significant danger to cancer treatment due to loss of productivity, OOP expenses, bankruptcy, and increased medical debt (Shih et al., 2017).

When Shih et al. (2017) examined the trends in TOAM prices and OOP payments in Medicare Part D and estimated the effects of OOP payments on the patient, the assumption was that because of the increase in prices, the patients did not experience any financial relief. The authors concluded that policymakers should look for ways to increase competition in pricing for Medicare beneficiaries (Shih et al., 2017).

The cost of cancer drugs has been soaring out of control lately, threatening whether patients can continue to sustain the cost of cancer treatments (Workman et al., 2017). Cancer or antineoplastic drug costs were more than 50% of total health care costs in 2018, are expected to be nearly 70% of total costs in 2025, and over 80% in 2030 (Polite et al., 2020) if nothing changes.

In 2012, 12 of the 13 newly approved cancer drugs were priced above $100,000 annually, and the situation has only worsened since (Workman et al., 2017, pg. 579). The problem is even more exacerbated by the fact that many of the medications need to be combined with other medications, which in 2016 could exceed $250,000, and there is nearly a 40% chance of developing some cancer in one's lifetime (Workman et al., 2017).

The industry defends these costs as the costs of doing registration trials (Workman et al., 2017). However, cancer drugs tend to be targeted and no longer require Phase III trials with thousands of patients (Workman et al., 2017). Research has shown little correlation between drug pricing and the clinical benefit to the patient (Workman et al., 2017). Instead, it is thought that cancer drug pricing is based on what the market will bear (Workman et al., 2017). As with other drug pricing one reason prohibiting the United States government from negotiating drug prices is the law, which means there is a

lack of competition, making drug prices in the United States some of the highest in the world (Workman et al., 2017). There is little evidence that introducing new products will decrease the price of anticancer drugs (Bennette et al., 2016). One must understand the market's influence to decrease prices to develop effective policies to address the growing costs (Bennette et al., 2016).

Effect of Increased Drug Prices on Cancer Patients

In a study of lung cancer and colorectal cancer survivors, lower quality of life was reported for those with less than 12 months of financial reserves (64% and 68%, respectively) than for those with at least 12 months of financial reserves (Yabroff et al., 2020). A study of cancer survivors in the state of Washington showed that cancer survivors who filed for bankruptcy significantly increased for mortality concerns than those who did not file bankruptcy (Yabroff et al., 2020).

Zhao et al. (2019) studied the relationship between cancer history and CRN and the cost coping strategies used by patients. The National Health Interview Survey (2013–2016) was used to identify adults 18 to 64 years old with and without a cancer history (Zhao et al., 2019). The researchers studied whether the patients requested lower-cost medications or used alternative therapies as cost-saving measures. Results showed that cancer survivors were more likely to report CRN and cost-coping strategies than those without a cancer history (Zhao et al., 2019). Those with private insurance, high deductibles, and no health savings plans experienced the greatest CRN (Zhao et al., 2019). However, regardless of cancer history, CRN and cost-coping strategies were most significant for the uninsured and those without prescription drug coverage under their

health plan, with cancer survivors more prone to CRN (Zhao et al., 2019). They would probably use cost-coping strategies (Zhao et al., 2019). Because individuals with cancer in the United States are surviving longer, addressing this problem is essential to developing practical solutions to the issue of CRN (Yabroff et al., 2020).

In the United States, in 2017, OOP costs for medications were 14% of a patient's income per capita (Beer et al., 2019). There is supporting documentation in the literature that increased OOP expenses will lead to medication nonadherence due to cost concerns and can significantly affect morbidity and mortality (Beer et al., 2019). A study of persons with HIV showed that nonadherence was related to the cost of prescription drugs (Beer et al., 2019). As a result, 14% of patients who developed strategies to help with the cost had a 7% cost-saving related nonadherence and nonadherent patients were more likely to visit the emergency room and need hospitalization (Beer et al., 2019). The researchers concluded that reducing the cost of medications might help decrease nonadherence and improve the health outcomes of people with HIV (Beer et al., 2019).

Effect of Drug Pricing on Cancer and Race

In another study, Knight et al. (2018) studied financial toxicity, identify rates, and the reasons for noncompliance in cancer patients. The definition of *financial toxicity* is financial harm due to cancer treatment. For this study, the definition of *financial toxicity* is paying for more medical care than one could afford (Knight et al., 2018). With responses taken from a Patient Satisfaction Questionnaire-18, patients reporting financial toxicity were younger than 65, female, non-White, non-English speaking, not married, less educated, and recently had received their diagnosis (Knight et al., 2018). These

patients were noncompliant with their medication due to their inability to afford the prescription drugs and passed up on mental care, doctor's visits, and medical tests (Knight et al., 2018). The most used reasons for the delay in treatment were no insurance coverage, and the inability to cover their household expenses, making financial toxicity a chief issue in care for cancer patients (Knight et al., 2018).

Williams et al. (2018) examined the effect of nonadherence to medication by race for people with hypertension dividing groups into White men, White women, Black men, and Black women. Results indicated low adherence in White women (22.9%) versus Black women (40.7%) and 26.3% in White men versus 37.2% in Black men (Williams et al., 2018). Across groups, medication cost reduction was associated with low adherence, duration, and comorbidities (Williams et al., 2018). Unwed and depression were also associated with low adherence for Whites but not Black people (Williams et al., 2018).

Effect of Drug Pricing and Diabetes

High prices and underuse of insulin due to cost have become a frequent problem for patients and health care providers (Luo & Gellad, 2020). Many stakeholders are interested in the increasing price of insulin, including large public and commercial payers of prescription drugs, patients and their families, and health care providers (Luo & Gellad, 2020). Public and commercial payers are interested because rising prices drive up the overall cost of spending on health care (Luo & Gellad, 2020). In contrast, patients, their families, and health care providers are concerned because higher prices can lead to rationing of insulin, which can lead to worsening clinical outcomes such as poor glycemic control and death (Luo & Gellad, 2020).

As of 2018, over 20,000,000 Americans had diabetes at the cost of more than $327 per year (Cefalu et al., 2018). Health care providers have several classes of medications and formulations of insulin to manage the issues associated with diabetes; however, whether patients can afford these medications is a concern to diabetics, their families, health care providers, insurance companies, and employers (Cefalu et al., 2018). Access to insulin is a matter of life and death for people with Type I diabetics; however, the average price of insulin has nearly tripled between 2002 and 2013 (Cefalu et al., 2018). One of the reasons for the cost of insulin is the drug pricing system and its complexities (Cefalu et al., 2018; Luo & Gellad, 2020). If insulin prices continue to rise, those living with the disease may be forced to choose between purchasing medications and paying for other living expenses, which could impact their long-term and short-term health (Cefalu et al., 2018). Estimations are that approximately 25% of Americans with diabetes use less insulin than prescribed because of the high cost (Luo & Gellad, 2020).

Rajkumar (2020) relates the case of a male diagnosed with diabetes at age 23 and, once reaching the age of 26, could no longer remain on his mother's health insurance making him responsible for obtaining his insulin. Realizing he could not afford the $7600 annual deductible and $440 per month premium, he decided to pay cash, rationing the insulin use until more affordable insurance could be found (Rajkumar, 2020). He was discovered in his apartment, having died of diabetic ketoacidosis (Rajkumar, 2020). The death of the person is just one of numerous examples of deaths or disease progression contributing to the rising cost of prescription drugs in the United States (Rajkumar, 2020). Most forms of analog insulin used in the United States cost 10 times more than in

other developed countries (Rajkumar, 2020). Many other deaths are due to patients' unaffordability with insulin (Rajkumar, 2020). Because diabetes is a life-long chronic disease and Type 1 patients will die without insulin, addressing insulin affordability is an urgent issue (Rajkumar, 2020).

Pharmaceutical companies cite three main reasons for the high cost of prescription drugs (Rajkumar, 2020). I examine the three reasons using insulin pricing as an example. First is the high cost of drug development, even though insulin is over 100 years old, and the newer analogs are all over 20 years old (Rajkumar, 2020). Second, free market forces do not apply as there is limited competition (Rajkumar, 2020). Over the past 20 years, the price of insulin has risen higher than the rate of inflation, and the patient cannot negotiate the cost (Rajkumar, 2020). Third, continued innovation requires higher medication costs; however, there is little insulin innovation (Rajkumar, 2020).

Rajkumar (2020) posits the real reasons for the high cost of insulin are, firstly, a vulnerable population that requires insulin for survival and must do what they can to obtain the medication. Secondly, three companies, Novo Nordisk, Sanofi-Aventis, and Eli Lily, virtually control the insulin market, with no regulations to control the price (Rajkumar, 2020). The third is patent protection. Even though insulin was first manufactured in 1921, it is still under patent protection because of improvements in formulations (Rajkumar, 2020). Each formulation comes with new patent protections, which prolong the patient’s life, with companies filing multiple patents for the same drug (Rajkumar, 2020). Fourth, there is an issue with biosimilars which are not generics but rather are biological products almost identical to the patented compound (Rajkumar,

2020). Generic formulations of insulin would fall under this category. The approval process results in fewer insulin biosimilars approved for the market and lawsuits from the three companies, many without merit, which also delays market entry (Rajkumar, 2020). Fifth, some intermediaries who stand to gain from a high price can exert control over the market share (Rajkumar, 2020).

Most drugs, including insulin, move from a drug manufacturing company to a wholesaler and then to a retailer with markups in price at each step (Rajkumar, 2020). Because there are no regulations, the wholesaler and the retailer also gain from a higher price, passing the cost on to the patient and the insurance companies (Rajkumar, 2020). Insurance companies use PBMs, who negotiate the price of insulin with the retail pharmacy and drug company in the form of rebates (Rajkumar, 2020). While the rebates pass back to the insurance companies, they are also a significant source of income for the PBMs because the higher the list price, the bigger the rebate and the more revenue for a PBM (Rajkumar, 2020). The result is that everyone who is a part of the drug pricing system benefits except the patient. Finally, there is the power of the PhRMA – the lobbying group for the pharmaceutical industry that spends substantial amounts of money on lobbying and advertising to prevent changes to the current system (Rajkumar, 2020).

Cohen & Boersma (2019) examined these strategies with data from a Nation Health Interview Survey on this topic. They found that 4.8% did not take their prescribed medications, and 17.7% requested a lower-cost prescription from their doctor. Women were more likely not to take their drugs than men, and adults aged 65–74 were more likely not to take their medications and ask for a lower-cost prescription than those 75

and over (Cohen & Boersma, 2019). Adults with private insurance were more likely to take their prescribed medications than those on Medicare and Medicaid, and poor adults were more likely to ask for a lower-cost medication (Cohen & Boersma, 2019). The strategies used by these adults have implications for their health and have resulted in increased use of emergency rooms and hospitalizations (Cohen & Boersma, 2019).

In the 1970s, the FDA created a citizen petition program for ordinary citizens to voice concerns about the FDA and its regulations (Feldman et al., 2017). There are suggestions that pharmaceutical companies use the citizens' petitions to delay generic competitors (Feldman et al., 2017). These delays can be worth hundreds of millions of added revenues to the companies, with consumers and government agencies bearing the bulk of the cost through higher drug prices (Feldman et al., 2017). Today more than 80% of prescriptions are filled with generics at a discount 80%–85% below their brand names (Feldman et al., 2017).

Kang et al. (2018) examined the factors affecting CRN in people with diabetes, defined as taking less medication than prescribed because of cost for adults with diabetes. to find people with diabetes and their CRN, researchers used data from the Behavioral Risk Factor Surveillance System from 2013 and 2014. (Kang et al., 2018). Using dominance analysis, diabetes care, lifestyle, and health factors were ranked (Kang et al., 2018). Results indicated that 16.5% of respondents with an annual income of $50,000 reported CRN compared to those with incomes ≥$50,000 and insurance (Kang et al., 2018). Participants who used insulin had a 1.24 times greater risk of CRN than those not on insulin. Factors affecting CRN included diabetes care, lifestyle, depression as

comorbidity, arthritis, and COPD/asthma (Kang et al., 2018). The Dominance analysis showed that health insurance was the most important factor for respondents less than 65 years old, and depression was the most crucial factor for those 65 years old or older (Kang et al., 2018). Results also indicated that policies and social support addressing the related factors might help improve CRN (Kang et al., 2018).

Karter et al., (2018) conducted an observational study on the effect of OOP costs on nonadherence among diabetic patients using electronic health records. Adherence was decided based on dispensing records from the pharmacy. Primary findings suggested that as OOP expenses increased, some patients were never dispensed medications, with 7% of the new medications never being dispensed if the OOP was $\geq$\$11. Five percent were never dispensed medications if the cost was between \$1 - \$10, and 3% of the medications were not dispensed if the medication was free (Karter et al., 2018).

Nelson et al., (2018) studied the barriers to nonadherence to medications for diabetics based on the information-motivation-behavioral skills model. Participants were asked to identify barriers to adherence. The most frequently reported barriers were forgetting their doses, preferring brand-name medicines over generic medicines, no benefit from medications, and being burnt out with taking medications (Nelson et al., 2018).

Luo and Gellad (2020) studied the factors contributing to the high prices. They noted three features, including the list price had increased over the past 15 years by more than 300% between 2002 and 2013; insulin manufacturers follow the pricing practices of their competitors; and cost-sharing practices are passed along to the patient in the form of

either high copays, higher deductibles, or both (Luo & Gellad, 2020). Three factors can explain the excessive cost of insulin: A complex pricing system, allegations of price-fixing by the three major manufacturers of insulin, and lack of generic competition (Luo & Gellad, 2020).

Pricing System of Insulin

Representatives from the insulin companies blame the other players when asked about the high cost, saying they are forced to increase prices because of PBMs and sponsored health plans and need the rebates to get preferred formulary placement (Luo & Gellad, 2020). Since health plans use rebates to reduce premiums, manufacturers insist the current system allows those with chronic health problems to support the healthy (Luo & Gellad, 2020). However, since product-specific rebate data are private, the data on insulin prices could not be verified by researchers or those making policy decisions (Luo & Gellad, 2020). These arguments do not explain the root cause of the higher prices. The PBM system is the same for all medications, not just insulin, so it could not be used to explain the higher prices (Luo & Gellad, 2020). Second, even if the manufacturers are correct, high list prices will continue to harm those with high-deductible insurance plans, the uninsured, and those with a gap in their coverage (Luo & Gellad, 2020). Manufacturers insist that lower prices are not concerned with the high prices but with regulating how PBMs can use rebates and pass the savings on to the patients (Luo & Gellad, 2020).

While some payers have produced voluntary caps on OOP spending for insulin, potentially saving lives, these caps are limited to patients with only certain types of

insurance. Still, they exclude the underinsured or those on Medicare or Medicaid (Luo & Gellad, 2020). In response, the three major manufacturers have produced "authorized generic" insulins, the same drug but relabeled as a different drug at a lower price to avoid rebates (Luo & Gellad, 2020). These methods, while intended to help address the issue of affordable insulin, will not change the existing system (Luo & Gellad, 2020).

Drug companies manufacturing insulin are not unique in elevating list prices to generate profit; however, insulin pricing was not viewed the same because insulin was one of the more regularly used medicines in the United States (Luo & Gellad, 2020). In 2017 alone, approximately 1,100,000 Medicare Part D payees filled a prescription for Lantus, a long-acting insulin pen (Luo & Gellad, 2020). While several manufacturers are marketing insulin products, there may be only one or two competitors for that product resulting in reciprocal price increases with manufacturers taking part in what is called shadow pricing (Luo & Gellad, 2020). Between 2007 and 2017, total Medicare Part D spending on insulin increased 840%, from $1,400,000,000 to $13,300,000,000 (not including rebates), while OOP spending doubled from $324 to $588 (Luo & Gellad, 2020).

As a result, a class action lawsuit was filed in 2017 in New Jersey against the three major insulin manufacturers, alleging a conspiracy with the PBMs to raise the list price of insulin way beyond the production cost; however, the lawsuit was dismissed (Luo & Gellad, 2020). The judge did indicate that the pricing practices might run afoul of the state’s consumer protection laws (Luo & Gellad, 2020). Additionally, the three manufacturers received subpoenas from the New York Attorney General’s office

requesting documents on how insulin pricing was determined, along with determination of discounts and sales practices (Luo & Gellad, 2020). Potentially fraudulent practices still do not explain why the current prices are so high (Luo & Gellad, 2020). Next is an examination of the lack of generic competition to explain the higher prices.

The three prominent manufacturers of insulin (Novo Nordisk, Sanofi, & Eli Lilly) control almost 100% of the U.S. insulin supply even though the first use of insulin was almost 100 years ago (Luo & Gellad, 2020). Because of price-fixing and the government grants monopolies in the form of patents to companies, drug companies have very few limitations when pricing their products (Luo & Gellad, 2020). Shareholders expect manufacturers to price their products to what they think the market will bear (Luo & Gellad, 2020). There are no regulations to prevent manufacturers from increasing the price of insulin several times during the year (Luo & Gellad, 2020). Companies can also use the excuse of innovation by changing the delivery systems rather than the actual insulin, thus extending or receiving more patents (Luo & Gellad, 2020).

The American Diabetes Association (ADA), through its Insulin Access and Affordability Working Group (Working Group), has been looking for ways to provide relief for patients and their families who cannot afford insulin (Cefalu et al., 2018). The Working Group met with various stakeholders concerning the complex pricing of insulin including drug companies, wholesalers, PBMs, pharmacies, insurers, and employers, as well as the distributors of payments (Cefalu et al., 2018). There is no agreed-upon price for insulin, and what the person with diabetes pays depends on the prices, rebates, and

negotiated prices with the stakeholders who have varying degrees of power to negotiate (Cefalu et al., 2018).

The three major insulin manufacturers set the list price (the price the drug companies set for their drugs) for each product and sell that product to wholesalers, who then distribute the insulin to pharmacies (Cefalu et al., 2018; Luo & Gellad, 2020). Occasionally, a pharmacy chain will deal directly with the drug company (Cefalu et al., 2018; Luo & Gellad, 2020). Wholesalers purchase the medications for around the same amount as the list price and receive a handling fee, a fixed percentage of the list price (Cefalu et al., 2018). Wholesalers then sell to pharmacies with minimal markup, but they can charge the pharmacies the higher list price (Cefalu et al., 2018). Pharmacies dispense the medication to patients, and if the individual has a health care plan, collect the negotiated price, and submit the bill to the insurer to be reimbursed for the cost minus any cost-sharing collected and a dispensing fee (Cefalu et al., 2018). If a patient does not have insurance, the pharmacy usually charges a price close to the price purchased plus a markup (Cefalu et al., 2018).

Data also show that when one manufacturer increased its price for insulin, the other manufacturers would respond in kind and increase their prices similarly (Cefalu et al., 2018; Luo & Gellad, 2020). One also cannot forget the PBM role. PBMs manage the pharmacy benefit portion of a health plan for their clients, large employers, pharmacy providers for Medicare participants, insurers covering Medicaid, or health plans sold to individuals (Cefalu et al., 2018) Another factor contributing to the high cost of insulin is

using more expensive human insulin analogs from the less expensive human insulins (Cefalu et al., 2018).

Drug companies negotiate with PBMs for rebates and discounts between stakeholders, design the formularies for their clients, and therefore have more input into which medications are on the formulary and what tier sets the rules for patient access (Cefalu et al., 2018). Manufacturers negotiate with the PBMs to have their medications on a lower cost-sharing tier or, to avoid constraints on the formulary, by paying fees and price concessions to the PBMs after the patient receives the manufacturer's discount (Cefalu et al., 2018). These rebates are in addition to the fees paid to provide the formularies (Cefalu et al., 2018). Nationally, three major PBMs, CVS Caremark, Express Scripts, and OptumRx, manage about 70% of all prescription claims (Cefalu et al., 2018; Luo & Gellad, 2020). The Working Group found one major issue: the lack of transparency throughout the insulin supply chain (Cefalu et al., 2018).

Drug companies claim they are at a disadvantage in determining insulin prices by not knowing the negotiations between PBMs and health plans and not knowing where the dollars from increased rebates go (Cefalu et al., 2018). Other stakeholders want transparency on how drug companies set their list prices as public, and private payers pay for the bulk of the costs as list prices continue to rise (Cefalu et al., 2018). Payers would like more transparency in prices and the therapeutic benefits of the more expensive drugs as opposed to the less expensive ones (Cefalu et al., 2018).

Park et al. (2021) examined the effects of OOP on diabetic Medicare recipients by race/ethnicity and income level compared to nondiabetics on Medicare. Results indicated

that total OOP costs were $3,609–$5,283, gradually increasing until leveling off in 2005 (Park et al., 2021). A higher burden of OOP was noted (57%–72%) at the 10% income level and 29%–41% at the 20% level (Park et al., 2021). Non-Hispanic Whites had the highest OOP costs and occurrences of high OOP burden, while those with diabetes were more likely to have higher OOP costs than those without diabetes (Park et al., 2021).

Provigil

The marketing of Provigil by Cephalon Provigil demonstrates how companies can produce multiple forms to prevent competition. Provigil is a medication used for sleep disorders and was initially approved for sleepiness associated with narcolepsy and obstructive sleep apnea (Carrier, 2019). The drug is considered a gold standard for treating excessive sleepiness, and sales in the United States increased from $25,000,000 in 1999 to $475,000,000 in 2005 and $800,000,000 in 2008 (Carrier, 2019). Cephalon filed a New Drug Application for the active ingredient in Provigil (modafinil) in 1996, and the FDA approved the application in 1998 (Carrier, 2019). The U.S. patent for modafinil was issued in 1979 and expired in 2001, after which Cephalon submitted and received a second patent in 1997 (Carrier, 2019). The second patent covered a new modafinil formulation (Carrier, 2019). This new approval extended the patent until 2014, when Cephalon received an additional 6 months of exclusivity until April 2015 for pediatric use (Carrier, 2019).

The FDA accepted applications from four companies to manufacture a generic version of modafinil (Carrier, 2019). Cephalon, realizing generic companies could distribute less expensive generic versions of modafinil, introduced a second product,

Nuvigil, in 2006 (Carrier, 2019). Nuvigil was like modafinil but longer lasting; patients could take one pill a day instead of two (Carrier, 2019). The FDA had not approved Nuvigil by 2005. Cephalon was unsure if they would have approval from the FDA before the generic versions were on the market, so they decided to pay the four generic companies to forgo their entry until April 2012.

The company was charged with violating antitrust laws as they knew generic versions of Provigil would lead to a substantial decrease in revenues, with the vice president predicting a decrease in revenues of more than $400,000,000 within a year and the generic firms would take over 90% of the prescriptions (Carrier, 2019). The settlements with the four generic companies increased sales by $4,000,000,000 because of 6 more years of patent protection Further review of Cephalon indicated the company had no intention of competing with the generics but delaying the generic competition guaranteed no challenge to the Provigil patent (Carrier, 2019).

With that information, Cephalon could market its new drug Nuvigil which was approved in 2007 and is on patent until 2023 (Carrier, 2019). The company then decided to make Provigil less desirable and Nuvigil more desirable. Their plan was accomplished by ceasing marketing and raising the price of Provigil while marketing Nuvigil as a better drug, thereby ensuring that when Provigil was off patent, the price would be too high for the generic companies to compete (Carrier, 2019).

Drug Pricing Nonadherence

Drug Pricing and Nonadherence Across Other Disease and Cultural Groups

In the United States in 2017, OOP medication costs were 14% of patients' income per capita (Beer et al., 2019). There is documentation that increased OOP expenses will lead to medication nonadherence due to concern about costs and can significantly affect morbidity and mortality (Beer et al., 2019). A study of persons with HIV suggested that nonadherence was related to the cost of prescription drugs (Beers et al., 2019). Fourteen percent of patients who developed strategies to help with the cost had a 7% cost-saving related nonadherence, and nonadherent patients were more likely to visit the emergency room and need hospitalization. The researchers concluded that reducing the cost of medications might help decrease nonadherence and improve the health outcomes of persons with HIV.

Access to health care, including medications, can vary between different citizens, the various ethnicities of those citizens, and different immigrant groups. Sharif et al. (2020) examined how the use of the ACA affected how different immigrant groups were able to receive health care. Mainly, they studied non-White Latinos, born in or outside of the United States and aged 18–64, using data from the National Health Interview Survey 2011–2016 (Sharif et al., 2020). The researchers measured currently uninsured, insured via Medicaid, people visiting the emergency department, visiting a doctor at least once, delaying care due to costs, not getting care due to costs, and being told by doctors that they would not be accepted (Sharif et al., 2020). While there were variations across the groups, overall, the ACA was associated with better access to health care across all

groups (Sharif et al., 2020). This study underscores the need for understanding how current health care and social policies affect immigrants (Sharif et al., 2020).

The belief that medication is not necessary also differs across cultural groups. This lack of belief can be attributed to several factors, including history, culture, family experiences, and individual preferences (McQuaid & Landier, 2018). There are well-documented concerns among ethnic groups regarding participating in medical research and medical care, particularly for African Americans (McQuaid & Landier, 2018). While these concerns are rooted in historical medical abuse, it has fomented an aura of mistrust which plays a role in medication adherence and the possibility among all groups of alternatives to their prescribed medications (McQuaid & Landier, 2018).

Alternative Medication Use

Complementary and alternative medicines (CAM) are used in conjunction with or as an alternative to conventional medicine by approximately 30% of U.S. adults (McQuaid & Landier, 2018). CAMs include natural products such as herbal medicines, yoga, massage, acupuncture, spirituality, and energy therapies (McQuaid & Landier, 2018). CAM also varies by race and ethnicity, with minorities tending to be less forthcoming to their health care provider about their use because of concerns of a negative response or, in many instances, the provider not inquiring (McQuaid & Landier, 2018).

CAM was used more by Mexican Americans with type 2 diabetes than other Hispanic Whites, with Mexican Americans and Vietnamese patients describing CAM as being more in line with their cultural traditions (McQuaid & Landier, 2018).

Additionally, CAM may be preferable for those with limited medication access (McQuaid & Landier, 2018). CAM was also used every day among HIV/AIDs patients but was not associated with lower adherence (McQuaid & Landier, 2018).

Language Barriers to Adherence

Individuals with limited English proficiency, combined with difficulty or resistance to acclimating to the American culture, a lower socioeconomic status, and limited insurance, may experience barriers in communication with their health care providers (McQuaid & Landier, 2018). Additionally, patients with limited English proficiency may not have access to interpreters (McQuaid & Landier, 2018). When there is access, studies show that the interpreters may spend less time with the patient as more time is needed to explain and ensure their understanding of the information (McQuaid & Landier, 2018). A study of older adult Latino asthma patients with limited English proficiency showed less medication adherence than adolescent Latinos with asthma, who were often relied upon as interpreters for older adults (McQuaid & Landier, 2018). Adolescents related to older adult patients intentionally altered the information from the physician to the patient, which accounted for miscommunication (McQuaid & Landier, 2018).

The public has long been concerned about nonadherence to long-term therapies as a public health issue, especially for the uninsured in the United States, as the subject has not been widely studied (Fernandez-Lazaro et al., 2019). Fernandez-Lazaro et al. (2019) studied patients from Community Health Centers in Georgia. They had been prescribed medications for two or more chronic conditions and had started a new

medication regimen assessing medication adherence and potential barriers to adherence (Fernandez-Lazaro et al., 2019). Nonadherence was reported by 52% of the participants, with nonadherence being lower for participants who used pillboxes, had help from a caregiver, and included dosing into their daily routines (Fernandez-Lazaro et al., 2019). The researchers concluded that medication nonadherence was lower among low-income, uninsured patients with chronic conditions with opportunities to address the issue through interventions and changes in social policies (Fernandez-Lazaro et al., 2019).

The placement of pharmacies may be an overlooked issue in drug adherence and medication affordability. A study of the availability of pharmacies in urban areas found that there were consistently fewer pharmacies in Black and Hispanic/Latino neighborhoods than in White or diverse neighborhoods (Guadamuz et al., 2021). The VHA provides medications at a minimal cost which would reduce the CRN for vets (Gaffney et al., 2020). Gaffney et al. (2020) examined CRN for vets as these individuals tended to be older, in worse health, and had lower incomes than others with coverage. Results showed that VHA patients had a nonadherence rate of 6.1% versus 10.9% for non-VHA patients. CRN was especially so with VHA patients who had chronic illnesses, were in minority groups, and had socioeconomic disparities that generally contribute to CRN (Gaffney et al., 2020). These results imply that the VHA benefit model for medications can be an excellent model to address the affordability of prescription drugs (Gaffney et al., 2020).

Summary and Conclusions

In this chapter, I described the strategy of the literature and the theoretical framework. The theoretical framework for this research consisted of the RCT and organizational theory involving power and politics). RCT was chosen because it posited that drug pricing was based on the self-interest of the pharmaceutical company and not the best outcome for the consumer. RCT has been used by social scientists and psychologists and is recognized as a methodological resource. The literature did not contain many articles concerning power and politics theory. The articles examined the influence of power (organizations) and its interaction with the political system to serve different interests.

Relevant literature reviewed included the pharmaceutical industry, its product marketing, and drug pricing. The review included the players, including the role of lobbyists, advocacy groups, DTC advertising, the media, other stakeholders, and government health policies. Also examined were examples of the tactics and what, if any, repercussions. Explanations were given for prescription drug pricing, the effect of higher drug prices on the consumer, and what steps some states were implementing to combat the higher drug prices.

Finally, the methodology was discussed for this research. The methodology consisted of using an online survey. The survey was taken from the KFF Health Tracking Poll, which determined participants' opinions on prescription drug pricing and the use of discount drug pricing services. In Chapter 3, I explain the research study design, and in Chapter 4, I discuss the data collection and analysis and present the study results. Chapter

5 includes discussion of the findings, conclusions, and recommendations for future research and social policy changes.

Chapter 3: Research Method

Introduction

The rising cost of medications continues to add an increased financial burden to the consumer, affecting other aspects of their lives, including their health. The purpose of this research was to examine the insured consumer's concerns with the affordability of patented medications. This research intended to survey insured consumers to ascertain their opinions on whether they could afford their drugs and what steps they took if they could not. I studied the effect of drug prices on the insured consumer's physical and financial status and the effect of discount drug pricing programs on the consumer's ability to obtain and pay for their medications.

The purpose was to determine whether there was a correlation between the cost of prescription medications and financial hardships. I also examined whether participating in a drug-pricing program helped alleviate some OOP expenses. Finally, I examined whether there was a burden on the insured consumer if they could not afford their medications. The results may suggest possible changes to current policies associated with drug pricing to alleviate some of the financial hardships the consumers face. This chapter focused on research design, sample population, procedure for collecting samples, instruments, and data collection and analysis. Research approaches can be qualitative, quantitative, or a mixture of both. This study used a quantitative design to analyze survey results.

Research Design and Rationale

The research design used quantitative method. *Quantitative research* describes variables systematically using a formal and objective approach and tests the relationships or cause and effect processes between them (Bloomfield & Fisher, 2019). Numerical data is generated and strengthened by assumptions including beliefs in a single reality or truth, objectivity, and interpretations (Bloomfield & Fisher, 2019). Quantitative research seeks answers by testing hypotheses using impartial scientific methods (Bloomfield & Fisher, 2019). These hypotheses are evaluated by obtaining a representative sample from a population, measuring independent and dependent variables, and using statistical analyses to test the hypotheses (Bloomfield & Fisher, 2019). Usually, the null hypothesis is that there is no relationship between the dependent and independent variables and is either accepted or rejected based on the results of the statistical analyses (Bloomfield & Fisher, 2019). The research design must be reliable and have internal and external validity to generate confidence in generalizing the population from the results (Bloomfield & Fisher, 2019).

There were several quantitative methods for approaching this study; however, this study used the survey method. Internet-based surveys have been around since the early 2000s, and today, virtually all main players involved in global market research use some form of online survey research (Evans & Mathur, 2018). Using surveys as a research tool is well-known in social research and involves a series of questions centered on a particular theme (Braun et al., 2020). Survey research collects behaviors, opinions, and attitudes and is descriptive (Burkholder et al., 2016). It is a self-reporting method that

uses interviews and, in this case, a questionnaire to describe and explain various behaviors (Burkholder et al., 2016). It is a popular method used within the social sciences (Burkholder et al., 2016). Survey research explores a topic, explains a relationship between two or more variables, and describes a population's characteristics (Burkholder et al., 2016).

Questionnaires and surveys provide some of the easiest methods for collecting data; however, care must be taken in developing these surveys (Younas & Porr, 2018). This study used a self-administered, online questionnaire allowing for privacy and anonymity when answering personal or sensitive questions (Burkholder et al., 2016). One of the advantages of an online survey is the flexibility to speak to a wide range of questions of varying interests with possible access to people from different experiences (Braun et al., 2020). Other advantages of online survey research are the potential global reach, flexibility in the availability of online survey programs, speed and timeliness, convenience for the user, ease of data analysis, and the ability to obtain a large sample size (Evans & Mathur, 2018). Some disadvantages of online surveys include perceiving surveys as junk mail or spam, thereby ignoring them, instructions may not be apparent if the survey is poorly designed, privacy issues, and possible low response rates (Evans & Mathur, 2018).

Survey research uses a quantitative approach to health and social sciences research (Creswell & Hirose, 2019). In survey research, a survey or questionnaire is administered to a sample of people to find opinions, behaviors, or perceptions on a topic (Creswell & Hirose, 2019). Surveys can provide evidence on attitudes, practices, and

awareness (Story & Tait, 2019). Data is collected and statistically analyzed to describe trends, evaluate hypotheses, and include qualitative and quantitative questions (Creswell & Hirose, 2019). Surveys can be conducted over a period or at one point (longitudinal vs. cross-sectional) and grouped as questionnaires or interviews (Creswell & Hirose, 2019). The ideal survey should ask important questions, have a high response rate, precise results, and have systematic answers (Story &Tait, 2019).

Frazen et al. (2020) used quantitative methods to examine proposals to existing policy to reduce drug prices at a market launch and the basis for the proposals. The researchers reviewed articles on oncology policy proposals and chose six proposals concerning transparency, isolating profits from sales, 2-part pricing, public research, reforming orphan drugs, and public clinical trials (Frazen et al., 2020). Their findings indicated that additional research was needed as insufficient evidence supports the proposals for lowering drug prices (Frazen et al., 2020).

The survey used for this research was based on the KFF Health Tracking Poll designed by public opinion researchers (KFF, 2019). The survey determined respondents' opinions on prescription drugs and their prices. KFF public opinion and survey research is a charter member of the Transparency Initiative of the American Association for Public Opinion Research. A survey for this study was conducted over 9 months. Some participants were familiar to me; however, all respondents' answers were anonymous to me.

Phenomenology

Phenomenology is the collecting and analysis of described or lived experiences of people's perceptions or beliefs (Burkholder et al., 2016). It is an event or something that happens to someone and can be defined and finite (Burkholder et al., 2016). As part of a research design, phenomenology can help the researcher understand how people perceive an event and can help one to understand the human perspective more clearly (Burkholder et al., 2016). The questions for phenomenological research ask how and why people feel the way they feel, do what they do, or act how they act (Burkholder et al., 2016). The researcher should ask questions that can be answered by the participant (Burkholder et al., 2016). The researcher is interested in the participants' accounts and statements of their lived experiences (Muzari et al., 2022). The sample size for a phenomenology study is usually between 5 and 15 participants (Burkholder et al., 2016). Because participants were to describe their experiences with the drug pricing system and purchase of medications, phenomenology fits well for this study.

Hermeneutics

The definition of *hermeneutics* is a theory of the experience of thinking (Tomkins & Eatough, 2018). It is constantly and always evolving as the dialogue of history continues to evolve and change (McCaffrey et al., 2018; Tomkins & Eatough, 2018). Understanding and interpretation are two aspects of hermeneutic thinking (Muzari et al., 2022; Tomkins & Eatough, 2018). Interpretation addresses how researchers explain issues and generate rules and standards, which can directly influence the method (Tomkins & Eatough, 2018). At the same time, understanding concerns how researchers

come to their conclusions and how they try to formulate principles that indirectly influence methodology (Tomkins & Eatough, 2018). The research examined the participants' actual experiences and involvement in purchasing prescription medications.

Ethnography

Ethnography studies the culture of groups intending to understand specific characteristics and behaviors of the group (Muzari et al., 2022). The findings from the studies can be assumed to be part of the participant's real-life experiences (Muzari et al., 2022).

Role of the Researcher

The role of the researcher in this study was to collect, analyze, and interpret the data gathered from the survey. The survey was administered and collected through SurveyMonkey. I retrieved the responses in a blind manner; I was not aware of the responses from any participant as data were coded with a unique random code to which I did not have access. I had knowledge of some of the participants but had no influence over their responses and did not know which participants completed which form. There were no power relationships.

Methodology

Several methodologies are available when designing a research study. Choosing the research design that best aligns with answering the RQs was essential. Designing research can be qualitative, quantitative, or a combination of both, and there were several approaches to each design, including field research, case studies, evaluation, and survey. Field research involves observing and interacting with people to understand how they

perform in their natural environment (QuestionPro, n.d.). The advantages of field research are that the researcher can get incredibly detailed data and emphasize the role and importance of social context health (Queiros et al., 2017).

Case studies are a form of field research that thoroughly reviews data and data collection methods to make conclusions from the data (QuestionPro, n.d.). Case studies can be used to study complex situations having multiple variables and are a popular tool used in researching the social sciences, education, and health (Queiros et al., 2017). Case studies can provide detailed information, offer opportunities for changing theoretical assumptions, and can be a suitable alternative to focus groups (Queiros et al., 2017). When researching drug pricing, case studies have been used to study transparency in drug pricing (Ahmad et al., 2020), comparing the prices for drugs from different state boards (Bendicksen et al., 2021). Silver and Hyman (2020) used case studies of two expensive drugs to study the price paid and determine the importance of both private and public support.

There are disadvantages to both field research and case studies. Field research can be time-consuming and may take many years to complete. It may be difficult for the researcher to separate themselves from biases in the study and to control internal and external variables (QuestionPro, n.d.). One disadvantage of case studies is that showing a cause-effect relationship for conclusions can be difficult to generalize, mainly if a small number of case studies are used (Queiros et al., 2017). It may be challenging to create a case study that will satisfy all subjects (Queiros et al., 2017).

Surveys can be administered in person, by mail, over the phone, or online. Advantages of online survey methods include minimal cost, possible fast response time, access to large populations if needed, more direct questions can be asked, and there is no interviewer bias (Story & Tait, 2019). There are disadvantages of using a survey approach as a research method, particularly an online survey approach. Those disadvantages include concerns over confidentiality, possible low response rates, and technical issues while using the internet (Story & Tait, 2019).

Examples of survey studies include Dong et al. (2021), who conducted a retrospective, cross-sectional analysis of the 2017 Medical Expenditure Panel Survey – Household Component. This survey analyzed household data on health issues such as access, cost, use of services, insurance, income, and health status to determine the association between health care access and financial burden (Dong et al. (2021). In another study, a survey of economists was used to explore the fairness in the U.S. prescription drug market (Karmarker et al., 2020). Finally, Khubchandani et al. (2021) used an online questionnaire to find what Americans thought about immunizing themselves with the COVID-19 vaccine to study vaccine hesitancy.

The survey used for this research was based on the KFF Health Tracking Poll designed by public opinion researchers (KFF, 2019). The survey determined respondents' opinions on prescription drugs and their prices. KFF public opinion and survey research is a charter member of the Transparency Initiative of the American Association for Public Opinion Research. A survey for this study was conducted over 9 months. Some

participants were familiar with me; however, all survey responses were anonymous to me.

The sample population included African Americans, European Americans, Pacific Islanders, Asians, Hispanics, those currently employed, and those on Medicare. The survey was given online for the participant to complete. The age range was 27 years of age and older; there was no upper limit. Not all questions in the original KFF survey were applicable or were not needed (such as political affiliation) and, therefore, were not used in this research.

Population

This study's target population was individuals enrolled in some health insurance programs and were responsible for the costs. All volunteers were over 26 years old, could be male or female, and of any race or ethnicity. The cutoff of over 26 years was chosen because younger people could be on their parents' insurance until after the age of 26. There was no upper age limit. The estimated sample size was calculated by G*Power to be approximately 129 participants. Due to recruitment issues the final sample size was 87 participants. Explanation is given in Chapter 4 in the Data Collection Section.

Sampling and Sampling Procedures

Individuals who were assumed to be from different levels of society comprised the sample size. I was given permission to use the Walden student population, individuals known to me, and individuals from Facebook. I did not know which responses belonged to any individual or participant in the study. This research looked at the effect of the drug pricing system in the United States, discount drug pricing programs, the consumer

opinion on drug pricing policies, and the effect of the pricing and policies on the consumer's ability to purchase prescription medications. The sample size was calculated using G*Power, and based on that calculation, approximately 129 volunteers would be needed (Htway, 2020).

Procedures for Recruitment, Participation, and Data Collection (as Appropriate)

Recruitment for this study involved contacting individuals known to me to determine their interest in participating in the study, as well as participants from the Walden student body if given permission. The inclusion criteria for this study consisted of the following:

- adults 27 years of age or older. There was no upper age limit.
- male or female
- any race or ethnicity
- have medical insurance
- willing to provide a workable email address
- willing to consent to take part in the research.

Potential participants were informed that I would not know who completed the survey, as surveys were assessed via SurveyMonkey. The data were retrieved by me in a blinded fashion such that I was not aware of anyone's specific answers. No names or ages were collected. All participants had to give informed consent before being allowed to access the survey. Participants were informed that they would not be allowed to participate if they did not consent. Volunteers initially had 4 weeks to complete the survey. SurveyMonkey gathered the responses and posted in a blinded fashion on SurveyMonkey

for the research to retrieve so that I would be unaware of any specific volunteer's answers. Participants finished the study when they completed and submitted the survey. There were not any follow-up procedures for the participants.

Instrumentation and Operationalization of Constructs

The survey instrument used for this study was adapted from the KFF Health Tracking Poll from February 2019. The KFF public opinion and survey research is a charter member of the Transparency Initiative of the American Association for Public Opinion Research. The original KFF survey was designed and analyzed by public opinion researchers at the KFF. It was conducted from February 14 to– 24^{h}, 2019. Original findings from that study can be accessed on the KFF website, and methodology can be accessed on the same website under the methodology section. Per email communication, (A. Kearney, personal communication, June 21, 2022), permission is not required to use the survey.

All original KFF survey elements were not used for this study as all questions did not apply to the research. Researchers conducted the original survey through telephone interviews. The abbreviated version used for this study was conducted online through SurveyMonkey. This change allowed the participants to select from a list of answers rather than verbally responding to answers over the phone.

Most of the questions were measured using Likert scales, designed to measure the attitudes or opinions using fixed choices (McLeod, 2008). A Likert provides possible answers to a question (usually no more than five possible answers) which allows a person to indicate their level or strength of agreement (McLeod, 2008). Appendix A contains the

complete adapted KFF survey that I intended to field; it includes insurance coverage and demographics. Due to difficulty with SurveyMonkey, some questions from the survey did not transpose correctly and therefore were not used in the final analysis. The study used a confidence interval of 95%.

Operationalization of Each Variable

Shuttleworth (2008) noted that operationalization is the process of defining variables such that they can be measured. Defining the variables increases the results' quality and strengthens the study design (Shuttleworth, 2008). An independent variable is the cause, if the variable is manipulated, and as the name implies, its value is independent of the other variables in the study (Bhandari, 2023). The dependent variable is the effect and depends on changes in the independent variable (Bhandari, 2023). It was expected that if the independent variable changed, depending on the change, the results of the dependent variable would be more beneficial to the consumer. The RQs with dependent and independent variables are defined in Table 1.

Table 1

Research Questions and Associated Dependent and Independent Variables

Research question	Dependent variable	Independent variable
1. What is the association between the consumers' perception of the current drug pricing system with the consumer's ability to purchase medications because of cost?	Consumer ability to purchase medications	Drug pricing system
2. What is the relationship between the consumer's opinion whether the cost of prescription drugs is reasonable and favoring purchasing drugs from Canada?	Cost of prescription drugs reasonable	Purchasing drugs from Canada
3. What is the association between the consumer's opinion on whether drugs are priced fairly and the government making it easier for generic drugs to come to market?	Drugs are priced fairly	Easier for generic drugs to come to market
4. What is the relationship between consumers filling their prescription using a discount drug program and filling their prescription if they were not part of a discount drug program?	Filling prescription without use of drug discount program	Use of discount drug program
5. What is the relationship between consumer's using a discount drug program and alternatives to filling the prescription if not in a program such as asking for less expensive drug, taking OTC drug, or skipping taking the medication?	Alternatives to filling prescription if not using drug discount program	Use of drug discount program
6. What is the relationship between the consumer using a drug discount program within the past 12 months and alternatives to filling the prescription if not in a program such as not filling the prescription because of cost, cutting pills in half, or skipping doses because of cost and taking an OTC instead of filling the prescription because of cost?	Additional alternatives to using drug discount program	Use of drug discount program

Data Analysis Plan

Data Collection

I obtained approval from the Walden University Institutional Review Board before uploading the survey to SurveyMonkey. Email addresses were sent to SurveyMonkey and a link to the survey was sent by SurveyMonkey to the participants, which they could complete by accessing anonymously. The survey was initially conducted for approximately 4 weeks to reach the target sample of 129 completed surveys. Recruitment was slower than expected and permission was given by the IRB to post on Facebook, and recruitment was extended to 9 months. When recruitment was terminated, 87 surveys had been completed.

Data Analysis

The software used for analyses was SPSS Version 28.0.1.0.1. I used the chi-square test to analyze the data to answer the RQs. The data generated were ordinal, and a nonparametric test such as chi-square to evaluate for independence was used. The questions were designed to assess the relationship between the affordability of prescription medication and drug pricing in the United States and the use of discount drug programs. If there was no correlation, the answered responses should have been equally distributed. There are several chi-square tests; however, the chi-square goodness of fit test was initially chosen for this study but was changed to the chi-square test for independence. The reasoning will be explained in Chapter 4's Treatment and/or Intervention Fidelity section.

The assumptions of the chi-square Test are

- The X^2 assumes the data is obtained through random selections.
- The categories are mutually exclusive.
- The data will be in the form of frequencies and not percentages.
- Observations will be independent of each other.
- If more than 20% of the expected frequencies have a value of less than 5, then chi-square cannot be used (Suresh, 2019).

Questions concerning insurance coverage included the type of coverage, prescription drug plan, and issues with their plan. Demographics covered included participant's opinion on their health, preexisting conditions, chronic health conditions requiring medical treatment, marital status, employment status, education, race, place of birth, and income. All categories were analyzed using descriptive statistics.

Threats to Validity

Internal and external validity shows how much one can trust the study results (Siedlecki, 2020). One factor affecting internal validity includes how rigorous the study has been constructed since the more demanding the study, the more reliable the results will be (Siedlecki, 2020). External validity involves being able to generalize the findings beyond the study sample (Siedlecki, 2020) or determining whether the study results can be used and applied to other than those enrolled in the study (Murad et al., 2018).

For internal validity, the survey was taken from a validated survey that KFF has used for years. All the questions used in the original survey were not used for this study, and the questions used were not altered and were verbatim. The printed responses were in

Likert form as the original survey was conducted over the phone, but responses were also in Likert form.

There can be threats to the external validity of survey research. One such threat is participants' bias depending on age and whether they have long-term disabilities. Chen et al. (2022) studied the sampling bias of aging individuals as to whether they would prefer phone calls or internet survey-based formats. The survey results indicated that if the participant was less educated, older, and had worse self-reported physical health, they preferred the phone interview. Participants who earned less than $10,000 annually and lived alone also preferred the phone interview (Chen et al., 2022). The researchers concluded that sociodemographic was associated with the type of survey format participants preferred (Chen et al., 2022).

Additionally, if the sample was not representative of the general population, it may not be easy to generalize the results (Siedlecki, 2020). There was representation of individuals 27 years old and above for this study. However, it was unknown how many of each age group would be included. Finally, there was always the possibility that respondents would not complete the survey, or answer all the questions (external validity), or would not answer truthfully (internal validity)

Ethical Procedures

Before data collection, I applied to Walden's IRB for approval to conduct the research. The approval was subsequently granted (approval no. 04-05-23-0744790). It is vital to protect human participants when they participate in research, obtain their informed consent to participate in the research, and ensure their confidentiality will be

preserved. Each participant in this study was given detailed information regarding the study's purpose, potential risks, and benefits, how the data would be collected and stored, and how it would be used.

Before signing the informed consent, each participant could take as much time as needed to decide if they wanted to participate. The consent form informed each participant that their participation was voluntary, and they could refuse, or omit to answering any question they did not want to respond to and withdraw from taking part at any time before or during the completion of the survey. To ensure the participants' identities were protected, surveys were distributed through SurveyMonkey. No identifying questions were included in the survey, such as name or email address, so that I would remain blind to the respondents' answers.

Summary

In this study, I aimed to determine the effect of drug pricing on the consumer's ability to pay for their prescription medications and determine how consumers feel about the current drug pricing rules and regulations. This chapter included discussion the quantitative research design, including the type of survey used. The RQs were presented along with the independent and dependent variables. The survey questions were also provided. The methodology was described, including the statistical tests used for analyzing each variable as well as demographics. I will present the results of the study in Chapter 4.

Chapter 4: Results

Introduction

In this quantitative study, I investigated the association between consumers' perceptions of the drug pricing system and whether those perceptions affected their ability to purchase medications. Additionally, the study examined the association between discount drug pricing programs and the consumer's ability to buy medications. Six RQs were the facilitator to explore the association with the drug pricing system, discount drug pricing programs, and the consumer's ability to purchase medications. The RQs were as follows:

RQ1. What is the association between the consumers' perception of the current drug pricing system with the consumer's ability to purchase medications because of cost?

RQ2. What is the relationship between the consumer's opinion whether the cost of prescription drugs is reasonable and favoring purchasing drugs from Canada?

RQ3. What is the association between the consumer's opinion on whether drugs are priced fairly and the government making it easier for generic drugs to come to market?

RQ4. What is the relationship between consumers filling their prescription using a discount drug program and filling their prescription if they were not part of a discount drug program?

RQ5. What is the relationship between consumer's using a discount drug program and alternatives to filling the prescription if not in a program such as asking for less expensive drug, taking OTC drug, or skipping taking the medication?

RQ6. What is the relationship between the consumer using a drug discount program within the past 12 months and alternatives to filling the prescription if not in a program such as not filling the prescription because of cost, cutting pills in half, or skipping doses because of cost and taking an OTC instead of filling the prescription because of cost.

To address these questions. individuals were invited to participate through SurveyMonkey, the Walden research website and Facebook. Criteria for participating included being willing to sign the informed consent, having health insurance, and age 27 or over. The initial recruitment period was extended as recruitment was slower than anticipated. Additionally, Facebook was used as a method to recruit additional participants.

There were no exclusions based on race, sex, income, marital status, work status, or education if the original criteria were met. Participants were primarily born in the United States and indicated they were either in good or very good health; and no one thought they were in poor health. Most subjects were White and non-Hispanic, with the next highest being Black/African American.

I collected data by administering an adapted KFF survey (see Appendix B) that was distributed online through SurveyMonkey. The data were presented as individual and

summary data in SurveyMonkey and retrieved as such. Only summary data were analyzed using the statistical program SPSS Statistics Version 28.0.1.0.1. Although there was a smaller- than-expected sample size, I am confident in the data, interpretation and methods used. The responses correspond to similar studies from literature. I am convinced that I was blinded to the results and that no participant was aware of other participants' responses as only I had access to the survey on SurveyMonkey.

Of the six RQs, only the analysis of RQ4 indicated a statistically significant correlation between participating in a drug discount program and the likelihood of filling a prescription. I could not reject the null hypotheses for the other questions. Because of the small sample size, further research should be considered, especially considering the price of drugs, which has been getting more attention at the state and federal levels and has become a more significant issue than when this study was initiated.

Data Collection

I collected data online using a survey I adapted from the KFF Health Tracking Poll from February 2019. Not all questions on the original KFF survey were used for this study. The questions that were excluded were concerning opinions on whether consumers thought they paid higher or lower prices for the same medications than those in Canada, Mexico, and Western Europe, whether they favored or opposed various actions that would keep Medicare prices down, political affiliations, and opinion on the job the president (at the time Donald Trump) was doing. I thought that the participants would not be familiar with the cost of medicines in other countries and I did not want politics to be a part of the study. After receiving IRB approval, the survey was posted on

SurveyMonkey. and the link to the survey was sent to Walden University for uploading to their participant pool website. Participants received the survey link via email from SurveyMonkey, allowing them to complete the survey anonymously.

Initially, the survey was intended to be available for 4 weeks; however, recruitment progressed slower than anticipated, resulting in only 19 responses from 55 emails after the first 4 weeks. Consequently, I requested and received IRB approval to post the survey on my Facebook page and to have individuals share the link, maintaining participant anonymity. By the end of recruitment (52 weeks), 74 surveys had been sent through SurveyMonkey, with 27 responses. Additionally, 20 individuals participated via Facebook, and 40 participated through the Walden participant pool.

The target sample was intended to be 129 volunteers, and recruitment continued for an additional 9 months. ending with 87 participants. SurveyMonkey collected the responses which I retrieved and analyzed with SPSS Version 28.0.1.0.1. using the chi-square test of independence to test the hypotheses. The data generated were ordinal, and a nonparametric test such as chi-square was thought to evaluate the relationship between categorical variables best. Statistical significance was also assessed.

The survey included 59 questions addressing opinions on the ACA (Obamacare), trust in pharmaceutical companies, drug pricing policies, purchasing generic drugs and drugs from Canada, prescription medications, government regulations and policies on drug pricing, Medicare, drug costs, insurance coverage, and discount drug pricing plans. Demographic and socioeconomic factors were also assessed. Not all the questions on the survey were intended to be used to analyze the hypotheses. Additionally, there was a

technical issue in transposing Questions 12b, 12c, 12d, and 21from the adapted survey to SurveyMonkey leading to unusable responses; therefore, these questions were also excluded from the analyses.

As part of the research design, phenomenology, hermeneutics, and ethnography, as noted in Chapter 3, were revisited through examining the responses to the RQs. The responses were applied to the tenets of the RCT to examine whether the choices were in line with rational choices given the participants' situation in paying for medications and the consequences for not doing so. According to Creswell (2013), a good sample size for a phenomenological research study is 3-25 participants, and this study had 87 participants. Hermeneutics, or the theory of experienced thinking, was explained when the RCT was applied to consumers, the pharmaceutical industry. and ethnography. The study was open to all ethnicities that wanted to participate provided the met the other inclusion criteria.

The sample size was a smaller representation of the larger population of interest. The group of interest was the group of consumers who believe the cost of medications is too expensive and the steps they take when they cannot afford their medication. The literature indicates this is an issue that crosses sex, race, ethnicity, religion, and political views and is an essential issue for most people in the United States.

Demographics

The survey was available for approximately 10 months. There was a total of 87 participants. The descriptive statistics are presented in Table 2. Most participants were born in the United States, 84 (96.55%), with 2 individuals (2.3%) indicating they were

born in another country and one refusing to answer. Most volunteers noted they were either in very good or good health, 37.21% and 43.02%, respectively. Nine (10.47%) indicated they were in fair health, 8 (9.3%) indicated they were in excellent health, and no one thought they were in poor health.

Most of the participants, 56 were White, non-Hispanic (65.12%) ,with the next highest group being Black/African American, non-Hispanic 18 (20.93%). Three (3.49%), were Hispanic, 5 (5.81%), indicated they were other or mixed/race, non-Hispanic, and 4 (4.65%), were undesignated. Interestingly, six individuals (6.98%) indicated they were Hispanic when asked as a stand-alone question. Still, only three indicated they were Hispanic when the question was asked, along with other questions concerning race.

Most of the participants, 49 (57.65%), were married. The remainder were divorced 14 (16.47%), never married 13 (15.29%), lived with a partner, 7 (8.24%), and widowed 2 (2.35%). Most participants were employed, with 58 (67.44%) employed full-time or part-time. The second highest group were retired individuals, 17 (19.77%). Four participants (4.65%) were disabled and could not work, 3 (3.49%) were students, 2 (2.32%) were unemployed, and 2 were stay-at-home parents.

Many of the volunteers, 46 (53.49%), had a postgraduate or professional degree, 10 (11.63) had some postgraduate education but no postgraduate degree and 10 also had a 4-year college or university degree. Seven (8.14%) had a 2-year associate degree, while 8 (9.3%) had some college but no degree, and 3 (3.49%) indicated that they were a college graduate +. There was no explanation for graduate +, so I assumed this meant they graduated and took additional classes after graduation but did not pursue any

postgraduate degree. One person had less than a high school education, and no participants indicated they had no formal schooling, left high school with no diploma, or just a high school graduate/GED certificate.

Total family income for 2022 indicated 31 (36.47%) participants made $100,000 or more, 16 (18.82%) made between $50,000 and less than $75,000, 14 (16.48%) made between $75,000 and less than $100,000. Six (1.06%) made between $20,000 and less than $30,000, 5 (5.88%) made between $40,000 and less than $50,000, 2 (2.35%) made between $30,000 and less than $40,000 as well as less than $20,000, and 9 (10.59%) refused to answer the question.

Table 2

Descriptive Statistics for Participants

Characteristic	*n*	%
Marital status		
Married	49	57.65
Living with a partner	7	8.24
Widowed	2	2.35
Divorced	14	16.47
Separated	0	0
Never been married	13	15.29
No response	2	2.35
Employment		
Employed	22	25.58
Full-time	34	39.53
Part-time	2	2.33
Unemployed (seeking employment)	1	1.16
Unemployed (not seeking employment)	1	1.16
Student	3	3.49
Retired	17	19.77
Disability (cannot work)	4	4.65
Homemaker/stay-at-home parent	2	2.33
Refused to answer	1	1.16
Education		
High school grad or less	1	1.16
Less than high school (Grades 1-8 or no formal schooling)	0	0
High school complete with no diploma	0	0
High school graduate (Grade 12 diploma or GED certificate)	0	0
Some college	7	8.14
Some college, no degree (includes community college)	1	1.16
2-year associate degree from college or university	7	8.14
College graduate +	3	3.49
4-year college or university degree	10	11.63
Some postgraduate or professional schooling, no postgraduate degree	10	11.63
Postgraduate or professional degree, including Master's, doctorate, medical or law degree	46	53.49
Don't know/refused	1	1.16
Skipped	1	1.16
Race		
White, non-Hispanic	56	65.12
Black Hispanic	0	0
Black or African American, non-Hispanic	18	20.93

Characteristic	*n*	%
Hispanic	3	3.49
Asian, non-Hispanic	0	0
Other/mixed race, non-Hispanic	5	5.81
Undesignated	4	4.59
Skipped	1	1.16
Hispanic/Latino ethnicity (Mexican, Puerto Rican, Cuban, or other Spanish background)		
Yes	6	6.98
No	78	90.7
Don't know/refused	2	2.33
Skipped	1	
Country of birth		
United States	84	96.55
Puerto Rico	0	0
Another country	2	2.3
Don't know	0	0
Refused	1	1.15
Health self-rating		
Excellent	8	9.3
Very good	32	37.21
Good	37	43.02
Only fair	9	10.47
Poor	0	0
Skipped	1	
Total family income, 2022		
< $20,000	2	2.35
$20,000–$29,999	6	7.06
$30,000– $39,999	2	2.35
$40,000–$49,999	5	5.88
$50,000–$74,999	16	18.82
$75,000–$89,999	7	8.24
$90,000–$99,999	7	8.24
$100,000 or more	31	36.47
Don't know/refused	9	10.59
Skipped	2	2.35

Note. GED = general equivalency diploma.

Treatment and/or Intervention Fidelity

The original recruiting plan used participants from individuals known to me and the Walden University student body. Recruitment progressed slowly, so permission was granted to use Facebook as an additional recruitment tool. Individuals known to me were allowed to share the survey with others, either by directing them to my Facebook page or by having them send their email addresses to me. I then entered these email addresses into SurveyMonkey to send the survey link. For Walden University students, the link was sent to the Walden Participant Pool administrator, who posted it on the Participant Pool website, allowing interested individuals to access the survey.

The initial recruitment period was planned for 4 weeks but was extended to nine additional months due to slow progress. The target was to recruit 129 participants, but at the end of the extra 9 months, only 87 participants completed the survey. The survey took approximately 16 min to complete. I accessed SurveyMonkey to retrieve the data. All participant responses were blind such that I was unaware of individual responses when the data were retrieved.

The original plan was to use the chi-square goodness of fit test to determine how observed data fit a specific probability distribution. However, it was determined that the chi-square goodness of fit test was not the appropriate test for this study because it required known frequency distributions which were not available for the variables. Instead, I used the chi-square test of independence to assess the relationship between the categorical variables. Additionally, I added four RQs, for a total of six, to better address the study's topic. The chi-square test of independence used cross-tabulation, where data is

classified according to two categorical variables, with one variable appearing in the column and the other in the row. There were no known adverse events connected to this study. Participants were free to avoid answering any questions they did not want to; in some responses that was the case.

Results

The statistical assumption was that the Chi-square test of independence results would show if there was a correlation between the independent and dependent variables that compose the RQs and whether the null hypotheses could be rejected or not rejected. The chi-square test of independence was conducted for each RQ to examine the relationship between the two variables. The chi-square test of independence assumes that the sample is random, variables are nominal or ordinal, data is frequency or counts, categories are mutually exclusive, no cell should have a value less than one, at least 80% of the cells should have a value of 5 or more, and no counting more than once (McHugh, 2013). The chi-square results for each RQ are discussed. Statistical significance for all RQs was assessed at less than or equal to 0.05.

Research Question 1: Drug Pricing System and the Ability to Purchase Medications

Survey Questions 6 and 26 answered RQ1: What is the association between the consumer's perception of the current drug pricing system and the consumer's ability to purchase medications because of cost? The intent was to determine if there was a direct relationship between whether the drug pricing system influenced their ability to purchase their medications because of the cost.

A chi-square test of independence was conducted using a three-by-three contingency table. The independent variable was the consumer's perception of the drug pricing system, and the dependent variable was their ability to purchase medications because of cost. The results indicated no significant association between consumers' perceptions of drug pricing and their ability to purchase medications due to cost. X^2 (4) = 7.829, p = 0.098, Cramer's V = 0.274. Therefore, I failed to reject the null hypothesis; the alternative hypothesis was not supported. I expected all 87 participants to respond to the question concerning purchasing medications because of cost including not purchasing the prescription, cutting pilis in half or skipping doses, or taking OTC medications instead.

However, only 52 (59.7%) responded to this question while all participants answered the question about trusting the pharmaceutical companies to price their products fairly. Of the 52 responses 44.2% did not fill their prescriptions because of cost, 13.5% cut their pills in half or skipped doses because of cost, and 42.3% took OTC medications because of cost. The low response rate led to five cells in the contingency table having fewer than the recommended minimum count of five responses, which may have affected the chi-square test results as Garness (2019) noted that 8% of consumers in the United States do not take their medications because of cost and 25% pay more OOP today than they did in the previous year.

Research Question 2: Cost of Prescription Drugs and Purchase of Drugs From Canada

Survey Questions 4 and 9b addressed RQ2: What is the relationship between the consumer's opinion of whether the cost of prescription drugs is reasonable and favoring

purchasing drugs from Canada? Participants were queried to determine if there was a direct relationship between if they thought the cost of medications was reasonable and if it would be easier for them if they could purchase their medications from Canada.

The chi-square test of independence was conducted using a two-by-two contingency table. The independent variable was the ability to purchase medications from Canada and the dependent variable was the reasonableness of the price of medications. The results indicated no statistical significance in the relationship between consumers' opinions on the reasonableness of drug costs and whether they favor purchasing drugs from Canada. X^2 (1) = .160, p = 0.690, Cramer's V = 0.043. Therefore, I failed to reject the null hypothesis indicating no direct relationship between the drug pricing and the preference for buying drugs from Canada. It is important to note that chi-square tests require a minimum of five expected responses per cell. In this case, one cell had only two responses, which could affect the reliability of the results. Specifically, only nine respondents (10.5%) opposed buying drugs from Canada, with six opposed, one strongly opposed, and two somewhat opposed, while the majority, 77 respondents (89.5%), favored, strongly favored, or somewhat favored purchasing drugs from Canada.

Research Question 3: Fair Pricing of Prescription Drugs and Ease of Bringing Generics to Market

Survey Questions 6a and 9c addressed RQ3: What is the association between the consumer's opinion on whether drugs are priced fairly and the government making it easier for generic drugs to come to market? I wanted to study whether participants thought there was a correlation between whether they thought drugs were fairly priced

and if the government should make it easier for generic drug to become available to the public. The independent variable is the time it takes generics to come to market and the dependent variable is whether drugs are fairly priced.

The chi-square test of independence was conducted using a four-by-three contingency table. The results indicated no statistically significant association between consumers' opinions on whether drugs are priced fairly and whether they believe the government should make it easier for generics to come to market. X^2 (6) = 8.176, $p <$ 0.225, Cramer's V = 0.218. Therefore, I failed to reject the null hypothesis indicating no significant relationship between the opinion of drug pricing fairness and support for government action to facilitate the market entry of generic drugs. While it has been noted that consumers had problems with the cost of medications and would like to be able to purchase more generics, the two do not seem to be correlated.

Notably, five cells in the contingency table had an expected count of less than five. This issue might have influenced the results. Specifically, the survey question on making it easier for generics to enter the market showed a strong favor, with only three of the 86 respondents (3.5%) opposing it in any way, while the remaining 83 (96.5%) favored or somewhat favored the idea. On the question on trusting the pharmaceutical companies to price their drugs fairly, responses of a lot and somewhat were 17.2%, and those who thought drugs were not fairly priced was 82.8%.

Research Question 4: Use vs. Lack of Use of a Discount Drug Program to Fill Prescriptions

Survey Questions 29 and 30 addressed RQ4: What is the relationship between consumers filling their prescriptions using a discount drug program and filling their prescriptions if they were not part of a drug discount program? The independent variable is filling prescriptions, and the dependent variable is participating in a drug discount program. The chi-square test of independence was conducted using a 2x3 contingency table to examine the relationship between participating in a drug discount program and the likelihood of filling prescriptions. The results showed a statistically significant association between participating in a drug discount program and the ability to fill their prescriptions if in the program, X^2 (2) = 13.557, p = 0.001, Cramer's V = 0.428 . Therefore, the null hypothesis was rejected, indicating a significant correlation between using a drug discount program and consumers' ability to fill out their prescriptions.

It was observed that 43 (50%) of the participants indicated they participated in a drug discount program and would have still filled their prescription even if they were not in a program. 42 (48.8%) indicated that they were not in a drug discount program and 1 person was unsure. Of the participants not in a drug discount program 22 (29.7%) indicated they would not have filled their prescription, 12 (16.2%) did not know if they would have filled the prescription and 3 participants did not respond. These results suggest that while drug programs are beneficial, approximately half of the participants would still fill their prescription without the program but results also indicate they could possibly benefit by participating in such programs.

Research Question 5: Use of a Discount Drug Program and Alternatives to Filling Prescriptions

Survey Questions 29 and 31 addressed RQ5: What is the relationship between consumers using a discount drug program and alternatives to filling the prescription if not in a program, such as asking for less expensive drug, taking OTC drug, or skipping taking the medication? The independent variable was the drug discount program, and the dependent variable was the use of alternatives to filling the prescription. The chi-square test of independence was conducted using a 2x3 contingency table to examine the relationship between participating in a drug discount program and using alternative methods for acquiring medications. The results indicated no statistical significance, with X^2 (2) = 1.73, p = 0.421, Cramer's V = 0.149. Therefore, I failed to reject the null hypothesis, meaning there is no significant relationship between participating in a drug discount program and the alternatives consumers use to fill their prescriptions.

Consequently, the alternative hypothesis was rejected. Eighty-six (98.9%) participants answered the question positively, indicating they had participated in a drug discount program. The alternatives to using the drug discount programs included 43.6% indicated they would ask their doctor for a less expensive drug, 5.1% would take OTC medications, 11.5% would skip taking the medication altogether, 15.4% indicated they would do something else but did not state what that would be, and 18% did not know what they would do. It is unknow whether the participants using alternative methods were aware of the drug discount programs.

Research Question 6: Use of a Drug Discount Program and Additional Alternatives

Survey Questions 29 and 26 addressed RQ6: What is the relationship between consumers using a drug discount program and their choice of alternatives to filling the prescription if not in a program, such as not filling the prescription because of cost, cutting pills in half, skipping doses because of cost, or taking an OTC medication instead of filling the prescription? The independent variable, the drug discount program and the dependent variable was additional alternatives to using the discount drug programs.

The chi-square test of independence was conducted using a 2x3 contingency table to examine the relationship between participation in a drug discount program and alternative methods for managing prescription costs. The results indicated no association between participating in a drug discount program and using alternative methods for managing prescription costs with X^2 (2) = 2.382, p = 0.304, and Cramer's V = 0.214. Therefore, I failed to reject the null hypothesis. Two cells had an expected count of less than five, which may impact the reliability of the results. As noted for question 5, 86 (98.9%) participants answered the question positively for participating in a drug discount program. However, there were only 52 responses for alternatives methods. Of those 52, 44.2% responded they did not fill a prescription because of cost, 13.5% cut pills in half or skipped doses because of cost and 42.3% took an OTC drug instead of their prescription because of cost.

Summary

I conducted this study to better understand the relationship between the cost of prescription medications and their effect on the consumer. The consumer's opinions on

various facets of the drug pricing system were solicited through a survey. Consumers were asked to give their perceptions of the drug pricing system and how and if it affected their ability to purchase their medications. Participants were also asked about buying generic drugs, purchasing drugs from Canada, and participating in a discount drug program. The responses were analyzed to determine possible correlations between drug pricing and purchasing generic drugs or drugs from Canada and the effect of the drug pricing program on purchasing their medications.

Initially, I sought to understand if there was a correlation between consumer's perception of the drug pricing system and their ability to purchase their medications. The results indicated that while the participants were concerned about the price of medications and did not trust the drug pricing system, there was no correlation between the consumer's perception of the drug pricing system and their ability to purchase medicines because of cost. The U.S. health care system in general is a self-interest and profits system which affects all sectors including drug companies, insurers, hospitals, investors and physician practices (Berwick, 2023). The assumption is made that consumers do not understand the intricacies of drug pricing and it is doubtful if knowing so would change their minds about how they view drug pricing. While consumers were concerned about the difficulty in affording medicines and the OOP costs and were frustrated with the high costs of their medications, they did not believe the two had any significance when compared.

Participants were also surveyed as to whether they thought drugs were reasonably priced and if they favored buying drugs from Canada. While most of the participants'

thought drugs were not priced fairly and favored being allowed to purchase drugs from Canada, there was no correlation between the two. Reducing drug prices has bipartisan support from policymakers and the public (George, 2024) and currently Florida is the only state cleared to import drugs from Canada to reduce drug prices. A study by KFF on drug importation from Canada indicated over 78% of Americans favored buying prescription drugs from Canada (Freed, Neuman & Cubanski, 2024). A larger sample size might generate different results as Congress now allows states to import certain drugs from Canada with approval from the FDA because of their reduced cost and it is not understood why participants would not correlate paying less for medications coming from Canada if they believe prices are too high in the United States. Although Florida estimates the plan would save the state up to $183,000,000 for the 1st year of implementation it is unclear how much, if any savings, there would be for Floridians (Freed et al., 2024).

When questioned as to whether participants thought drugs were fairly priced and if the government should make it easier for generic drugs to come to market; there was no correlation between the two. Again, most participants thought the government should make it easier to bring generics to market, but there was no correlation with their opinion of the price of drugs, even though most of the participants thought the price was too high. Research by KFF found that the cost of prescription drugs was an important area of public interest, that most people take at least one prescription drug, see the benefits of taking drugs, and the majority believe the cost is too expensive (Sparks et al., 2024). While generic drugs accounted for 90% of prescriptions filled, they accounted for only

20% of the total spending (Lalani et al., 2024). Costs were lower for insured patients with individuals ensured through their employer-sponsored paying an average of $11 for their first generic medications (Lalani et al., 2024). Findings indicate the consumer sees the value in being able to purchase generic medications.

Drug discount programs are being utilized by the consumer and this research sought to examine the effects of using a drug discount program and what consumers saw as options if they did not participate in such a program. Looking at discount drug programs and their impact on the consumers filling their prescriptions there was a correlation between utilizing a drug discount program and the likelihood of filling their prescriptions. However, only half of the participants had taken advantage of a drug discount program even though many of these programs offer significant savings to patients. The Mark Cuban Cost Plus Drug Company (MCCPDC) is one such company. In studying the cost of 30-day prescriptions of the top nine oral urology drugs under Medicare in 2020 the cost incurred was $1,565,000,000 (Cortese et al., 2023). Under the MCCPDC, the cost savings for 30-day prescriptions ranged from 16.0% to 98.9% and for 90-day prescriptions savings ranged from 48.7% to 99.2% (Cortese et al., 2023). All drugs studied were generics and results indicate that by changing the price scheme of drugs MCCPDC had been able to pass on savings to the customer and decrease the financial anxiety that accompanied being able to afford prescription drugs (Cortese et al., 2023). Results such as these should encourage providers to consider MCCPDC or other drug discount programs when advising patients on how to pay for medications.

Examining the consequences of not using a drug discount program, the nonuse of a drug discount program did not stop participants from filling their prescriptions but did cause them to use other cost-cutting methods such as asking the doctor for a less expensive drug, trying an OTC drug, or skipping taking the medication altogether. A KFF survey conducted in July 2023 researched public opinion on prescription drugs and their prices. From that survey just over half (55%) of adults were concerned about affording prescription drugs for themselves or family members with Blacks (61%) and Hispanics (69%) exhibiting more concern about affording their medications than Whites (Sparks et al., 2024). According to Sparks et al. (2024), results from the survey also indicated that three in ten adults reported they did not take their medications as prescribed including not filling a prescription (21%), took OTC medication (21%) and cut pills in half or skipped a dose (12%). That number increased to four out of 10 for those not filling a prescription, taking an OTC, or cutting pills in half or skipping a dose for adults ages 18–29, (40%), Hispanic adults (39%), those taking four or more prescriptions (37%) and 37% for households with annual incomes of less than $40,000 (Sparks et al., 2024).

Finally, participants were asked about what additional alternatives were used if they did not utilize a drug discount program. There was no correlation between being in the program and options such as not filling the prescription, cutting pills in half, or skipping doses. Medication nonadherence can result in progression of diseases, increase in cost of care, and undue drains on the health care system (Aremu et al., 2022). Stewart et al. (2023) indicated that self-reporting of medication nonadherence ranged from deliberately not taking medication to forgetting. A study was conducted in 2020 in

diabetic patients on the association between nonadherences because of cost. Participants were asked if they employed any of the following because of cost, took less medications, skipped doses, delayed or did not fill a prescription, and delayed or decided not to see a health care provider (Chiang et al., 2023). The prevalence of nonadherence ranged from 52 to 63% (Chiang et al., 2023). Chiang et al. (2023) noted that among those with comorbidities nonadherence was the highest in patients with liver issues (63%) and anemia (61%), and lowest in those with cancer (52%) and kidney disease (54%). The most prevalent nonadherence was delaying prescriptions filled (Chiang et al., 2023).

The results of the study indicated that except for using the drug discount program and purchasing medication, there was no correlation between the other issues and purchasing, although consumers are concerned about the price of their medications. However, the literature indicates that the economic burden placed on individuals who cannot afford their medications needs to be addressed.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The cost of prescription medication continues to be a growing concern for consumers in the United States. Research has shown that when the price of medications is too expensive, consumers develop alternative means of coping which could further endanger their health. The affordability of prescription medications has not only become a concern to the consumer and health care providers but has also become a concern for politicians as well. This quantitative study was designed and initiated to study the association between the consumers' perceptions of the drug pricing system, whether drugs were priced fairly, and whether those perceptions affected their ability to purchase medications as well as what alternatives, if any, were initiated if they could not afford their medications. Additionally, the study examined the association between participating in discount drug pricing programs and the consumer's ability to buy medications.

Drug affordability is challenging for consumers and physicians who must prescribe the medications and speak to patients about the cost and alternatives (Dusetzina et al., 2023). The elevated price of drugs in the United States can be harmful to patients and the similar countries (Tarazi et al., 2022). Spending on pharmaceuticals in the United States is at its highest cost and prices continue to climb while people struggle to pay for those medications (Swank, 2023). In 2020, spending on prescription drugs in the United States was approximately $350,000,000,000 and was expected to increase 3%–6% annually (Rajkumar, 2020). It was estimated that due to the cost of drugs, 25% of Americans have difficulty affording prescription because of high OOP costs that drug

companies indicate are necessary for innovation (Rajkumar, 2020). However, the most critical reason stated most often for the high cost of prescription drugs the drugs are on patent and there are no new medicines, no alternatives, and no real competition (Rajkumar, 2020).

The extreme and continually rising costs of prescription drugs have become not only a problem for consumers, but a policy problem as well, and several aspects of the issue make it problematic to solve (Mello, 2020). Among those problems is the agreement on balancing the tradeoff in regulating prices from a moral perspective (affordability versus innovation) and what consumers believe is a fair price (Mello, 2020). Marketing issues include a lack of transparency in price and a system with dogged incentives on how prescriptions are provided to patients. Finally, current policies are inhibited by political negotiations and scandals focusing on instances of price gouging, making it difficult to fix the system (Mello, 2020). The high price of drugs mainly affects Medicare patients and patients of color.

The National Health Interview Survey (NHIS) estimated that in 2019, 3,500,000 adults 65 and older and 1,800,000 Medicare recipients under 65 struggled affording their medications (Tarazi et al., 2022). Compared to White adults over 65, Black and Latino adults over age 65 had difficulty affording their medicines at a rate of 1.5 to 2 times greater (Tarazi et al., 2022). Beneficiaries under 65 who qualified for Medicare due to a disability or end-stage renal disease had much greater rates of affordability than adults over 65 (Tarazi et al., 2022). Finally, people with lower incomes, and those diagnosed with chronic conditions such as diabetes showed more difficulty affording their

medications than other groups (Tarazi et al., 2022). The high cost and OOP expenses paid for drugs, particularly for those with chronic illnesses, can cause a delay in patients taking medications or patients skipping taking their prescriptions altogether (Tarazi et al., 2022). A poll conducted indicated that 79% of participants believe the cost of prescription drugs is unreasonably high, and 29% of adults reported taking less medication because of price (Shumway, 2024). Additionally, 70% of adults in the United States think Congress should make lowering the cost of prescription drugs a top priority (Shumway, 2024). Because of the difficulty in affording medications, consumers have developed methods of coping with this issue, with some of the methods possibly endangering their health (Cohen & Villarroel, 2015; Doshi et al., 2016; Kantarjian & Rajkumar, 2015). The pharmaceutical industry could generate more innovative medications with their current resources and affordably prices, but that would require action from the government (Angelis et al., 2023).

In this quantitative study, I examined how medications are priced and to determine how drug pricing affects consumers physically, financially, and economically. The theoretical frameworks for this research were the RCT and the organizational theory involving power and politics. The RQs were developed to address the consumer's perceptions of how drugs are priced, what actions they take if they cannot afford to purchase their medications, their opinion about generic drugs, and buying drugs from Canada and whether participating in a drug discount program influenced how they purchased their medications. Data were collected through SurveyMonkey using an

adapted survey from the KFF Health Tracking Poll from February 2019 and analyzed using descriptive statistics and the chi-square test of independence.

According to the study results, there was no significant relationship between (a) consumers' perception of the price of medications and their ability to purchase because of cost, (b) whether drugs were reasonably priced and favored purchasing drugs from Canada, (c) whether drugs were fairly priced and whether the government should make it easier for generic drugs to come to market, and (d) using a drug discount program versus alternatives to filling the prescription. Regarding whether participating in a drug discount program made a difference in purchasing or using their medications, the results indicated a statistical significance between participating in a drug discount program and filling their prescriptions. However, there was no statistically significant difference in participating in a drug discount program, and alternatives if they did not participate, such as taking less expensive drugs, taking OTC meds, skipping medications, or cutting pills in half. Because of the small sample size, future research should be conducted as these issues are becoming more important in society today.

Interpretation of the Findings

The concept of rational choice was applied to the responses made by participants concerning drug pricing. I then examined the tenets of power and politics to determine their influence on drug pricing and whether there was any consideration for the consumer or only profit. The concepts of both theories were applied to the results of the analysis of the RQs to further explain the results.

Over the past decade, there has been a growing concern over the price of new medications, with net prices of new drugs estimated to have increased from a median of around $1,400 in 2008 to over $150,000 in 2021 (Angelis et al., 2023). From 1999 to 2018, the 15 largest pharmaceutical companies in the world spent approximately $2,200,000,000,000 on selling, general, and administration of prescriptions than they did on R & D, which was $1,400,000,000,000 (Angelis et al., 2023). Most of these companies also spent more on dividends and buybacks than R & D (Angelis et al., 2023). The drugs developed during this time provided little added advantage, over the current treatments (Angelis et al., 2023). Given that the pharmaceutical industry is one of the most profitable industries, it becomes problematic for the companies to argue that the high prices are needed to develop more effective medications (Angelis et al., 2023). It appears it is a rational choice for the pharmaceutical companies to charge as much as they can for their product to maximize profits for their shareholders. Given the power of pharmaceutical industries to control the cost of medications, many consumers are having difficulty affording their medications.

Prescription Drug Pricing

Spending on prescription drugs is a growing topic of interest not only to the public but also the health care industry as well policymakers from both sides of the aisle who are pursuing options on how to lower drug prices (Freed et al., 2024; Dusetzina et al., 2022; George, 2024). There are many reasons given for the high cost of prescription drugs. Sertkaya et al. (2024) looked at the estimated cost of pharmaceutical drug R & D across 18 years from 2000 to 2018. In 2018, it was estimated that the average cost of

developing a new drug was approximately $172,700,000, ranging from $72,500,000 for genitourinary medications to $297,200,000 for pain and anesthesia medications (Sertkaya et al., 2024). When adding studies where the results indicated a failure to generate capital that would allow the drugs to come to market, the cost increased to $515,800,000, and factoring in additional capital, the cost further increased to $879,300,000 (Sertkaya et al., 2024). Pharmaceutical company's sales increased by 10.0% (from $380,000,000,000 to $418,000,000,000) between 2008 and 2019, while the cost of R & D remained steady, or in some instances, decreased (Sertkaya et al., 2024).

Past assessments concentrated on medications covered by Medicare Part D but not drugs administered by clinicians (Medicare Part B) or focused on Medicare fee-for-service beneficiaries regardless of their drug coverage (Dusetzina et al., 2022). A valuation by Dusetzina et al., (2022) showed that in 2019, roughly 27% of the overall spending for Medicare beneficiaries enrolled in Part D was spent on prescription drugs, even after taking rebates into account through the pharmaceutical companies (Dusetzina et al., 2022). How do consumers feel about these prices?

When looking at the consumer's perception of how drugs were priced and their ability to purchase medications, the adapted KFF study's findings indicated that there was no association between the perception of drug pricing and purchasing medications. In determining consumer awareness of how drugs were priced, a separate consumer survey conducted by the KFF showed that most respondents (95%) understood that drug prices could vary from pharmacy to pharmacy, but 85% said they would like to know the cost of medications ahead of time to help with the experience (Gordon, 2022). Findings

from the adapted KFF study as well as a reporting of a separate KFF study by Gordon, (2022) also indicated that consumers would like more visibility in the cost of drugs as that might help them take their prescription as prescribed. KFF reported that one-quarter of adults reported having difficulty paying for prescription drugs and that they or a family member avoided filling a prescription, skipping, or cutting drugs in half because of cost with the figure being higher among people of color, women, and lower-income people (Gordon, 2022).

The high cost of prescription drugs for consumers may also cause an increase in medication nonadherence. Using a survey, Dusetzina et al. (2023) assessed CRN and coping strategies for adults 65 years old and older in the United States from June 2022 to September 2022. According to the authors, among 2005 participants, CRN was reported by 20.2% of the participants (Dusetzina et al., 2023). Methods for coping with non-affordability included forgoing basic needs to afford the medication (8.5%) or going into debt (4.8%) to afford medications (Dusetzina et al., 2023). Many respondents (89%) indicated being comfortable or neutral conversing with their physician about whether the prices were accurate and indicated they would be upset if the cost were more than the physician reported (Dusetzina et al., 2023). Many respondents reported that if the price were higher than initially reported, it would affect their decision to start or continue taking a medication (Dusetzina et al., 2023). The authors concluded that real-time conversations with the physician and benefit tools would help patients make better decisions and possibly become more enthusiastic about taking their medications (Dusetzina et al., 2023).

Results from a survey by Prescryptive Health (a health care technology company) indicated that 73% of consumers were more likely to speak with their prescriber about lower-cost options if they were aware of the cost of prescriptions in advance (Gordon, 2022). Speaking with the physician might prevent skipping or altering prescriptions because of financial hardships, as knowing the price beforehand would allow patients to find an affordable alternative (Gordon, 2022) proactively.

Zhang et al. (2022) studied the effect of medication nonadherence in a population of older American specifically baby boomers (between 50 and 54 years old), the silent generation (65–69) and 80 and above labeled the greatest generation who were followed from 2024 to 2014. Demographics, income, insurance status, daily living limitations, instrumental activities of daily living, and comorbidity of CRN were measured over time. As age increased, the likelihood of reporting CRN decreased across all three cohorts and all three cohorts had higher prevalence of diabetes, cancer, heart conditions, and stroke. The researchers concluded that CRN changed (i.e. decreased as Americans aged which is an implication for social policy changes).

I examined whether there was a relationship between consumers' opinions on whether drugs were reasonably priced and if they favored purchasing medications from Canada. There was no significance between the two. When the respondents were asked whether they favored buying prescription drugs from Canada, 89.5% either favored, strongly favored, or somewhat favored doing so. However, this did not produce a significant response between purchasing medications from Canada and the current price of drugs even though 81.6% did not think drugs were reasonably priced. Despite these

results, some agencies are taking action to allow medications to be purchased from Canada.

In 2020 during President Trump's first term, he issued an executive order allowing for the import of drugs from Canada (Shumway, 2024). Several states had already passed laws, without authorization from the U.S. Department of Health and Human Services, to develop programs for importation of drugs from Canada (Scheckel & Rajkumar, (2021). While several states filed the petition, as of 2022, the order still needed approval (Shumway, 2024). The FDA finally authorized Florida to buy less expensive prescription medications from Canada. On January 5, 2024, Florida because the first state authorized by the FDA to import certain prescription drugs from Canada (Freed et al., 2024). These programs excluded expensive drugs such as biologics (Scheckel & Rajkumar, (2021). This program was the first of its kind in the United States, with 2 years of approval (George, 2024). Included in the application were drugs to treat HIV, mental health, and prostate cancer for individuals on Medicaid or state government health care, and it was expected to save Florida up to approximately $183,000,000 during the 1st year (George, 2024). However, the savings would not impact consumers who bought their medications from retailers or mail-order pharmacies (George, 2024).

These programs had bipartisan support (Freed et al., 2024) however it is unclear if the public, other than those in Florida were aware of these programs. However, there are several ethical and safety concerns for policymakers and prescribers when analyzing the cost and benefits of such programs (Quasba & Vice (2024). There is concern over

whether Canada can supply the demand given it has a population one-tenth that of the United States and Canada is opposed to the United States, encroaching on its drug supply (Quasba & Vice, 2024). There is also the possibility of counterfeit drugs entering the U.S. market, so the onus is on the United States to ensure the drugs are safe (Quasba & Vice 2024).

In this study, I further examined whether the consumer thought drugs were priced fairly and if the government should make it easier for generic drugs to come to market with no significance between the two. DTC pharmacies, which allow patients to fill prescriptions without insurance, offer lower prices than traditional retail pharmacies (Lalani et al., 2024). DTC pharmacies buy from generic manufacturers or wholesalers and sell to patients in-store or by mail at much lower prices. (Lalani et al., 2024).

From the adapted KFF survey, 83 (96.5%) favored, strongly favored, or somewhat favored making it easier for generic drugs to come to market, and 72 (82.8%) either did not trust too much or not at all that pharmaceutical companies priced their drugs fairly. However, when comparing the two, there was no significance. It may be possible that the consumers did not see a relationship between the two or were unaware of DTC generic pharmacies because they do not trust the pharmaceutical company and would prefer to have generic drugs.

Using a cross-sectional study, Lalani, Tessema, Kesselheim, and Rome (2024) examined the cost and availability of expensive and generic drugs for DTC pharmacies. The authors analyzed 118 expensive generic drugs and found that 94 (80%) were available at one or more DTC pharmacies (Lalani et al., 2024). Out of fifty-two common

generic drugs, 51 (98%) were available in DTC pharmacies, and out of eighty-eight expensive generics, 42 (47%) could be purchased at a lower cost through DTC pharmacies such as Amazon, MCCPDC, Health Warehouse, or Costco (Lalani et al., 2024). While many of the more expensive generic drugs were unavailable through DTC pharmacies, less expensive medications were available, however the prices vary, and the consumer must shop for the lowest prices (Lalani et al., 2024).

A study was conducted in Houston Texas to examine the consumer's attitudes towards generic substitutes for their drugs (Sansgiry et al., 2011). Results indicated consumers had favorable perceptions of generic drugs (Sansgiry et al., 2011). However, there were some consumers who were skeptical of the quality and effectiveness of generics (Sansgiry et al., 2011). The FDA has been making affordability of medications a public health priority (Conrad et al., 2024). The most recent study estimated savings from 742 generic drug applications approved in 2022 (Conrad et al., 2024). The generic drugs approved in 2022 yielded an estimated $18,900,000,000 in total savings following the first 12 months of their approval, which is in line with previous years (Conrad et al., 2024).

The Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Act has been the source for regulating generic drugs in the United States for almost 40 years (McElwee, 2023). The purpose of the Hatch-Waxman Act was twofold: (a) to increase the use of generic drugs and marketing competition and (b) to incentivize innovation for brand-name companies (McElwee, 2023). The Act was initially successful as, by 1990, approximately 40% of prescriptions were filled with

generic drugs versus brand-name drugs (Encarnacion, 2023). However, part of the Hatch-Waxman Act allowed pharmaceutical companies longer patent monopolies on their branded drugs increasing the prices on the top branded drugs while price-gouging on newer drugs to offset their losses (Encarnacion, 2023).

The Generic Drug User Fee Act was created and passed in 2012 by the FDA to bring generic drugs to market in a shorter period (Singh et al., 2023). Singh et al. (2023) studied the impact of the Act on the price of generics, concluding that in recent years, since the passing of the Act, the cost of generic drugs had fallen partly because of increased competition. In 1984, only 35% of off-patent medications had a generic equivalent marketed; however, by 2023, more than 90% of brand-name drugs no longer on patent, had a marketed generic counterpart (McElwee, 2023). While some issues remain, the Generic Drug User Fee Act has been able to allow challenges to brand name companies (McElwee, 2023; Singh et al., 2023). Nevertheless, new treatments are still needed for diseases with unmet medical needs or without safe and effective treatments (McElwee, 2023). Despite these issues, generics have provided safe, effective, and affordable access to drugs that would otherwise be unaffordable to the consumer and have challenged brand manufacturers to become more inventive to compete with generic drugs (Encarnacion, 2023).

Finally, this study examined the significance of participating in a consumer drug program and filling prescriptions. There was no significance in participating in a drug discount program and finding alternatives to the expensive medications. Many consumers in the United States use prescription drug discount programs or coupons to reduce their

OOP expenses (Curran et al., 2024). Curran et al. (2024) examined data on pharmacy claims representing 65% of the country's chain pharmacies and approximately 67% of the independent pharmacies, including data from retail, specialty mail order, and long-term care pharmacies, and transactions covered by all payers. including commercial consumers, public insurers, and cash payers. Data were examined from October 1, 2017, and September 30, 2019 (Curran, 2024). They included the dose, quantity, day's supply of the prescription, and costs, including OOP cost after discount, if a discount was applied (Curran, 2024). Data did not include OOP costs before a discount or the discount amount (Curran, 2024). Most of the products were for chronic diseases or neuropsychiatric conditions. The author's findings indicated that while pharmacy PBM discounts such as GoodRx are commonly used, little is known about the association or interactions between these programs, patient's use, and OOP expenses (Curran, 2024). In many cases, these discounts were associated with higher OOP expenses even after the discount was applied, which may be attributed to the design of the prescription benefit program and may not generate the savings many consumers believe (Curran, 2024).

Another examination was conducted to determine how frequently patients use discount coupons for chronic conditions and frequency of use using patterns of manufacturer coupon use for prescription drugs in the United States between 2017 and 2019 (Kang et al., 2023). The study examined 238,474 drug chains and 35,352 patients (Kang et al., 2023). Ninety-five percent used their first coupon within the first four prescription refills, 65% used a coupon for an individual incident, 70% of patients used

the coupon, and many discontinued the drug after the last coupon was used (Kang et al., 2023).

Another way for consumers to lower the cost of drugs is through the 340B Drug Pricing Program. The 340B Drug Pricing program was created in 1992, which requires pharmaceutical manufacturers to sell outpatient drugs at a discount to specific health organizations, particularly to treat low-income patients such as those with sole hospital communities, rural areas, and public, nonprofit hospitals (Fact Sheet: The 340B Drug Pricing Program, 2023). The Health Resources and Services Administration (HRSA) is responsible for administering the program which has attained average savings of 25% to 50% in drug purchases, decreased government spending, and increased access to patient care. (Fact Sheet: The 340B Drug Pricing Program, 2023). Some want to reduce the patient benefits from the program (Fact Sheet: The 340B Drug Pricing Program, 2023). The Inflation Reduction Act of 2022 allows Medicare the authority to negotiate prices for certain prescription drugs (Rome et al., 2023). However, it does not indicate which drugs would be selected nor the negotiated price (Rome et al., 2023).

In rural–urban areas where one would find cancer disparities, it was noted that there were greater mortality rates, which could be attributed to limited oncology services (Owsley & Bradley, 2023). Without these services, the residents may have experienced delayed treatment and were less likely to receive their recommended care (Owsley & Bradley, 2023). The 340 Drug Pricing Program on oncology services in rural areas allowed patients to purchase covered oncology drugs at discount prices (Owsley & Bradley, 2023). Owsley & Bradley (2023) assessed the assoiciation between new

enrollment in the 340B program and oncology services initiated in rural areas that lacked oncology services using data from 2011 through 2020 compared with hospitals that did not enroll in the program. Hospitals enrolled were more prone to have added oncology services, with most of these hospitals in states with Medicaid expansions and counties with noninsurance rates (Owsley & Bradley, 2023). Findings indicated that the 340B program enabled hospitals to expand oncology access, however additional work still needs to be done to address the disparities in areas that lack sufficient services (Owsley & Bradley, 2023).

There was a statistical significance in participating in a drug discount program and filling prescriptions. From the survey administered, approximately the same number of respondents, 43 (50%), participated in a discount drug program as did not use the program 42 (48.84%), in the past 12 months. When asked if they would have filled the prescription without the discount program, 37 (50%) said yes, and 34 (49.95%) said no, or they did not know.

The Staff News Writers (2023) of the AMA reported that there were 8 reasons people reported why people would not take their medications including fear, cost, misunderstanding, too many medications, lack of symptoms, mistrust, worry, depression. Prescribing medications on a discount list would be one way of decreasing the cost to the patient (Staff News Writers, 2023). Hung et al. (2021) studied the impact of financial assistance programs on medication adherence and concluded there was a positive effect on all levels of medication adherence however some OOP expenses were higher among the users of the voucher. If medication adherence due to cost could be improved this

would lead to better health outcomes (Peasah et al., 2024). Peasah et al. 2024 investigated the impact of financial incentives as well as refill reminders to increase medication adherence. Results indicated both the financial incentives, and the reminders improved medication adherence, reduced emergency visits and lowered medication costs.

One of the ways consumers pay for prescriptions is with cash because it allows them to save money through pharmacy discount programs (Gordon, 2022). A Prescryptive Health survey indicated that approximately one-third of the survey respondents paid for prescriptions OOP (Gordon, 2022). Among those with health insurance, 61% still paid cash despite having coverage (Gordon, 2022). The respondents indicated this was done because it was less expensive to use the discount card than it would have been if they had used the discount card, which would have been cheaper than using their insurance (Gordon, 2022). However, there can be issues. Paying OOP does not count towards their deductible, and it took longer for the consumer to reach it (Gordon, 2022). While many knew they would not meet their deductible, they felt it was better to save money in any way possible. It is doubtful that discount programs will go away since independent pharmacies have seen an increase in their use as consumers will continue to search for ways to decrease the cost of prescription drugs (Gordon, 2022).

A cross-sectional analysis was performed to determine what portion of OOP payments exceeded the discount pricing for Amazon Prime and GoodRx Gold programs for common generic medications (Patel et al., 2023). Data from the 2020 Medical Expenditure Panel Survey (MEPS), which is a national survey collecting responses from Americans who are not institutionalized, matched OOP payments to corresponding

Amazon Prime and GoodRx Gold prices (Patel et al., 2023). The National Drug Code numbers, drug name, dosage, day's supply, and quantities were examined for the twenty most prescribed generic medications, excluding controlled substances (Patel et al., 2023). Findings indicated that OOP payments by patients exceeded Amazon prices by about 20% and GoodRx prices by approximately 43% (Patel et al., 2023). OOP expenses for prescriptions in the deductible phase surpassed Amazon prices by 40% and GoodRx prices by 79% (Patel et al., 2023). The cumulative cost savings for patients using the discount drug program was approximately $969,000,000 for Amazon and $1,830,000,000 for GoodRx, with most of the savings coming from 90-day prescriptions (Patel et al., 2023). The findings concur with the survey results that patients can benefit from drug discounts programs.

Medicare and Drug Pricing

In the United States, prices of cancer medications are causing economic hardships for consumers even though the higher prices do not indicate evidence of clinical benefits (Furlow, 2022). Findings such as these stimulated a renewed importance of value-based pricing aligning with the drug's clinical benefits (Furlow, 2022). Medicare plans must cover all cancer drugs, so companies have no limits on what they can charge, making them very expensive (Furlow, 2022).

For cancer and other high-priced drugs, many Medicare Part D beneficiaries ineligible to obtain a subsidy based on income must pay a portion of the drug's price (Dusetzina et al., 2022). The OOP expense for these medications may amount to hundreds or thousands of dollars for one refill (Dusetzina et al., 2022). Dusetzina et

al. (2022) examined 17,076 new prescriptions issued between 2012 and 2018 for beneficiaries of Medicare Part D with and without subsidies to determine the prescriptions that were filled. Results indicated that individuals receiving subsidies were nearly twice as likely to obtain prescriptions as those without subsidies (Dusetzina et al., 2022). It was also observed that 30% of the prescriptions were written for anticancer drugs, 22% for hepatitis C treatments, and more than 50% for therapies for immune system disorders or hypercholesterolemia (Dusetzina et al., 2022). The findings support legislative efforts to increase these expensive medications' associability and to reduce OOP expenses, especially for people without subsidies (Dusetzina et al., 2022).

Theoretical Perspective on the Findings

Rational Choice

Rational choice shows the logic of human reasoning and can predict outcomes for how humans will behave and act (Blakely, 2020). People sometimes make decisions under duress and must make judgments without all the available information (Raue & Scholl, 2018). These decisions are especially true for complex situations and situations where people have limited capacity to cope with information such as balancing paying for an expensive medication with other financial responsibilities (Raue & Scholl, 2018). The framework for looking at the decisions consumers make regarding their prescription medications is RCT. Is it rational to look for alternatives to medication adherence for the high cost of drugs? Is it rational to try different methods, some of which might harm the patient?

From the consumer's perspective, rational choice was used to decide whether to purchase expensive medications, weigh the costs and benefits, and explore other options specific to certain drugs. It is assumed to be motivated by the self-interest of remaining healthy. For pharmaceutical companies' perspective, because the market allows them to charge whatever they want, the decision to continually raise prices is rational, involves weighing the costs and benefits, and is specific to the interest in the company's profits. Regarding the two assumptions for RCT, the consumers have diverse preferences, and their reasoning may involve helping others with their medication adherence. For the pharmaceutical companies, the interest is not only in the company and its profits, but also in the shareholders and other partners.

How does RCT stand up when used to examine medication nonadherence from a consumer's perspective and can medication nonadherence be a rational optional choice for the consumer. Medication nonadherence continues to be a challenge in health care, which can impact treatment outcomes and the effectiveness of medical interventions (Muiruri et al., 2023; Stewart et al., 2023). Approximately 30-50% of adults with chronic illnesses do not take their medications as prescribed (Liddelow et al., 2021). Medication nonadherence has been known to be associated with an increase in hospital visits, risking deterioration of disease or death (Liddelow et al., 2021). It costs the economy in the United States approximately $100,000,000,000–$300,000,000,000 annually due to hospital visits and medical interventions (Liddelow et al., 2021).

There is a rise in the aging population, with approximately 117,000,000 people in the United States with long-term health conditions and an estimated 15,000,000 people

living with a chronic physical illness (Stewart et al., 2023). Prescription medication is one of the most common remedies for these conditions, however, nonadherence continues to present a significant barrier affecting the outcomes, with around half of the medicines prescribed for long-term conditions not taken as directed (Stewart et al., 2023). In addition to the effects on the patient, medication nonadherence is also costly for the health care system (Stewart et al., 2023).

How can one understand and predict medication nonadherence? Part of the rationale and figuring into the rational choice for patient decisions involves their beliefs, expectations, and costs (Muiruri et al., 2023). Nonadherence was studied in patients to determine causes, focusing on side effects and how well the patients perceived the medicine worked (Muiruri et al., 2023). The results indicated that patient adherence consisted of minimizing the side effects without compromising the efficacy and that if efficacy were compromised, patients would take the medicine as required (Muiruri et al., 2023). This concept aligns with the first element of RCT which is weighing the perceived costs and benefits. The benefit of taking medication as directed outweighed the cost of not taking the medication as directed which, would have resulted in more side effects (Muiruri et al., 2023).

Traditional barriers to medication nonadherence aside from cost include social barriers such as inadequate social support for coping, patient barriers such as demographics (race, age, and sex), behavior, stress, comorbidities, health status, and lack of knowledge (Krousel-Wood et al., 2021). Additional barriers include poor perception of the health care system, lack of motivation to take care of themselves, and barriers to

treatment, such as the complexity of the disease and side effects (Krousel-Wood et al., 2021).

Often, patients do not tell their doctors if they have used their medication as prescribed which has caused self-management of adherence to medication directions as one of the most crucial factors influencing the safety and efficacy of medications (Kvarnström et al., 2021). Results from the adapted KFF survey (my survey) indicated that 33.33% of the respondents told their doctor if they did not take the medication as prescribed, 21% did not, while 38% took the medication as prescribed. Medication nonadherence may be intentional or nonintentional, and patients may have rational reasons for modifying their doses (Kyarnstrom et al., 2021). Treatment adherence can be complex and requires the patient to adhere to the treatment for the best outcome voluntarily; however, multiple factors may contribute to nonadherence, including the patient's values, beliefs, attitudes, and willpower (Amdie et al., 2022).

Do patients genuinely have free will to make choices regarding their prescriptions? They certainly have no control over the cost of mediation, which is a factor in their decision-making process. Free will implies the ability to choose one action over another, and it is anticipated that free will allows people to take control of their own lives and accept accountability for their actions (Amdie et al., 2022). A patient’s mental state also plays a role in decision making as they determine their goals, needs, and desires, which will factor into their decision making when receiving care and taking medications as prescribed (Amdie et al., 2022). Additionally, health care providers’ role is essential in promoting medication adherence, noting the importance of integrating a patient’s values,

attitudes, and intentions (Amdie et al., 2022). It is vital to recognize what factors, including mental, socioeconomic, and financial aspects, influence the patient's free will when making a well-informed decision for medication adherence actions (Amdie et al., 2022).

Power and Politics

The second framework for this research was organizational theory, specifically power and politics theories. This research examined the effect of the cost of drugs on the consumer from the perspective of the pharmaceutical industry's influence on setting drug prices.

When examining power and politics theory, pharmaceutical companies exert *power over*, which implies using control and coercion which is associated with exercising power over the government (Harris et al., 2020).The pharmaceutical industry also exerts *power with*, which encompasses building coalitions and allies to change or maintain the power relations. *Power with* is exhibited in their relationships with the government, politicians, and the medical industry through sponsoring and controlling the results of clinical trials.

The government is making efforts to lower the costs of drugs through legislative and regulatory initiatives; however, campaign donors and lobbyists for the pharmaceutical industry continue to attempt to interfere with those efforts (Wouters, 2020). Federal and state-level data were analyzed using data from the Center for Responsive Politics and the National Institute on Money in Politics (Wouters, 2020). These are nonpartisan entities tracking federal and state campaign contributions, and spending on lobbying by individuals and organizations to influence legislative and

election outcomes (Wouters, 2020; Rajkumar, 2020). The analysis showed that from 1999 to 2018, the pharmaceutical industry spent $4,700,000,000 on lobbying efforts federally, which was more than any other industry (Wouters, 2020). The breakdown of the payments was $422,000,000 by PhRMA and $2,200,000,000 by the 19 top companies in the industry (Wouters, 2020). The industry also spent $414,000,000 on contributions to political candidates in presidential and congressional elections, national party committees and outside parties (Wouters, 2020). Additional spending breakdowns include presidential and congressional candidates, senators, committees influencing health-related issues, and state candidates (Wouters, 2020).

The pharmaceutical industry spends more on lobbying than any other industry in the United States (Van de Vrande et al.,2024). The literature recognizes the benefits of lobbying, but the criticism of the unethical aspects of lobbying causes the industry to devise unique ways to strategize their lobbying activities (Van de Vrand et al., 2024). The pharmaceutical industry has almost unrestricted power when pricing drugs because of the many numbers of lobbyists and lack of restrictions on corporate donations to politicians (Swank, 2023). This power has allowed the industry to extinguish most attempts at price negotiations allowing them to continually increase prices even on older drugs (Swank, 2023).

Spending on prescription drugs in the United States exceeded half a trillion dollars in 2020, propelled by the high cost of brand-name drugs whose prices are set by the manufacturers (Rome et al., 2022). Increasing the prices translates to restricting access by payers, increased premiums, or unaffordable OOP costs for patients (Rome et

al., 2022). From 2008 to 2021, prices for introducing new drugs increased by 20% per year, and from 2020 to 2021, 47% of new medications had an initial price of over $150,000 per year, with prices increasing 11% per year (Rome et al., 2022). Even after drugs were marketed, manufacturers regularly increased the prices by 4.5% per year from 2007 to 2018 (Rome et al., 2022). The United States could prevent manufacturers from freely setting prices by following the example of other industrialized countries, allowing for the negotiation of drug prices (Rome et al., 2022).

Big Pharma's influence can be seen everywhere as large companies have become incorporated into many parts of the health care industry (Shumway, 2024). The industry giants maintain their influence by targeting patients, providers, and consumers resulting in fewer companies having enormous control over the systems and the quality of care (Shumway, 2024). Big Pharma works with the government to effect decisions concerning the industry, creating a conflict of interest that could negatively affect the consumer (Woelful, 2023). This influence has created an oligopoly, which has caused some policymakers to implement more regulations; however, while the United States is a global leader in pharmaceutical innovations, consumers pay more than people in other countries (Shumway, 2024). Destruction of business ethics has led to decision making by the pharmaceutical industry that can be both corrupt and illegal, negatively impacting the consumer, harboring distrust, weakening democracy, and hindering economic development (Woelful, 2023). A study showed that while drug companies received additional funding and tax cuts, spending on prescription drugs ($535,000,000,000)

increased 50% from 2010 to 2018, surpassing yearly inflation at that time (Woelful, 2023).

The Trump administration claimed it would stand up to Big Pharma, but no action was taken against them during his time in office (Woelful, 2023). Instead, some drug company insiders were placed in top administrative positions which could encourage corrupt behavior and a conflict of interest between the government and the industry (Woelful, 2023). These are examples of the influence of power and politics over the pricing of medications in the United States. However, politicians, social groups, and consumers are fighting these tactics.

U.S. lawmakers enacted a new drug pricing law, the Inflation Reduction Act of 2022 (IRA), which empowers Medicare to negotiate the price of high-priced drugs, in August 2022 despite aggressive lobbying by the pharmaceutical industry (Baron & Twinamatsiko, 2023). The pharmaceutical sector was pursuing ways to prevent the implementation by using the courts, spending hundreds of millions of dollars lobbying Congress in 2022 to influence and successfully block the passage of the legislation (Baron & Twinamatsiko, 2023). Some of the drug companies and PhRMA, the pharmaceutical lobbying group, sued the head of the U.S. Department of Human Services, claiming the IRA violated their first, fifth, and eighth amendment rights (Tanne, 2023).

The Congressional Budget Office estimated the IRA would save Medicare $100,000,000,000 over 10 years with insignificant impact on the innovation of new drugs coming to market (Baron & Twinamatsiko, 2023). How much patients will save depends

on numerous issues, including which drugs are chosen and the amount of the price reduction (Baron & Twinamatsiko, 2023). It is suggested that the initial list of drugs will include treatment for blood clots, diabetes, autoimmune diseases, and breast cancer (Baron & Twinamatsiko, 2023). When new laws that will bring significant reforms to the health care system, such as the ACA or the No Surprise Act are passed, the industry is motivated to try and weaken the extent of the legislation, and the IRA is no different (Baron & Twinamatsiko, 2023). When the industry cannot undermine the laws through Congress or the Executive branch, the pharmaceutical industry will look to the courts as a last resort (Baron & Twinamatsiko, 2023).

One of the legal challenges proposed by the pharmaceutical industry is that negotiating prices is a taking of property and violates the Constitution's Takings Clause (Bhargava et al., 2023). The Fifth Amendment prevents the government from taking private property unless it is for public use, and drug manufacturers attempted to assert that price negotiation is taking their property without just compensation (Bhargava et al., 2023). The drug makers argued that if the government imposed a 50% discount on one of their products, which would be like seizing 50% of their inventory (Bhargava et al., 2023). The drug companies are basing their argument on profits, not products as they are not against the selling of their products but the cost (Bhargava et al., 2023).

The U.S. government currently purchases goods and services and regularly engages in price negotiations without raising any "taking" issues in the past (Bhargava et al., 2023). Courts have held that no one is entitled to sell to the government by the constitution (Bhargava et al., 2023). However, as a purchaser, the government is allowed

to select its partners and negotiate the terms and conditions of the contracts including, the price (Bhargava et al., 2023). As a result, pharmaceutical companies' negotiations with the government do not violate the Takings Clause even if the negotiations reduce profit, and prescription drugs are no different (Bhargava et al., 2023). The pharmaceutical industry has also implied that brand-name drugs on patent should be treated differently to no avail (Bhargava et al., 2023). Drug manufacturers can sell to the government, which already negotiates drug prices with them for several programs, including VHA and Medicaid, as well as the 340B program (Bhargava et al., 2023). The courts have repeatedly upheld that the requirements of the IRA program do not violate the Takings Clause (Bhargava et al., 2023).

Limitations of the Study

One limitation of this study was the sample size. The goal was to have 129 participants for the study. However, recruitment was slower than expected, ending with only eighty-seven participants. Had 129 participants been recruited, this would still have been a small sample size. A second limitation was that the sample size may have differed from the overall population. Generalizability was limited as the study relied on the Walden University participant pool and SurveyMonkey participants who responded to an invitation to participate or access the survey from my Facebook page. There may have also been an underrepresentation of various racial/ethnic groups because of the sample size and recruitment strategy. Out of eighty-seven participants, 65% were White, non-Hispanic, 18% Black/African American, 3% Hispanic, and 5% mixed race, and there was

no indication of participation from the Asian population. Most of the participants answered all the questions, some refused to answer some of the questions.

Internal validity is how confident the researcher and reader can be that the results are unbiased (Kamper, 2020). I adapted and used a previous survey by a credible institution (KFF), and I was not aware of the responses from any individual participant, eliminating any bias in the conduct of the study. As there are other studies in literature similar to this one, while the sample size was small, the results of this study can be added to the body of work researching the subject of drug pricing and its effect on the consumer.

Trustworthiness implies that something is worthy of trust, and it is justified or rational to trust the findings of a study (Peels & Bouter, 2023). The findings of a survey are trustworthy if one has a good reason to believe the conclusions are close to the truth or true (Peels & Bouter, 2023). The findings from this study were not compared to the original KFF study conducted in 2019. However, results of the individual responses support what is found in the literature and several KFF studies conducted since 2019. Because there was no literature comparing the relationships between the sets of variables in the study, further research will need to be conducted to determine the trustworthiness of the results.

Recommendations

Much has changed since this project was undertaken. When this study began, the COVID pandemic had not occurred. Since the pandemic and the reporting on the number and types of people who were not able to get the vaccine, there has been much talk on

health care and the cost of medications. Medication prices have continued to be a topic kept alive through the media, and continuous consumer complaints. Also, the head of an insurance company has been murdered, the result of frustration with insurance companies.

As a result of the IRA, by law, Medicare has begun negotiating drug prices which will become affective in 2026 (Hernandez et al., 2023). The cost cannot be higher than that of Medicare plans after discounts or a higher premium, based on how long the drug has been on the market (Hernandez et al., 2023). The discounts will produce an estimated savings of $1,800,000,000 (Hernandez et al., 2023). These estimated savings show the importance of current rebates and encourage competitiveness for the maximum discount process (Hernandez et al., 2023). By 2028, 40 drugs, thirty-eight dispensed in pharmacies and two dispensed in doctor's offices, will have prices negotiated by Medicare to benefit patients with diseases such as cancer, diabetes, respiratory conditions, and cardiovascular diseases (Dickson & Hernandez, 2023). Once initiated, this price negotiation could help Medicare beneficiaries by making drugs for common diseases more affordable (Dickson & Hernandez, 2023). Many drug companies that manufacture insulin have already lowered the price (Dickson & Hernandez, 2023).

Thanks to the IRA, the price of insulin for Medicare participants has been capped at $35 a month for diabetes treatment through price caps and savings programs (Croft, 2024). One example is Sanofi, who, because of the complaints and criticisms of the insulin drug manufacturers by analysts, politicians, and patient advocates, cut the price of

Lantus by 78% and Apidra by 70% (Croft, 2024). The other manufacturers of insulin, Novo Nordisk, and Eli Lily have also cut their insulin prices by 75% and 70%, respectively (Croft, 2024). Before this change, the American Diabetes Association noted the money spent by patients on insulin tripled from $8,000,000,000 in 2012 to $22,300,000,000 in 2022 because of the rising prices, even though insulin is cheap to produce and is over 100 years old (Croft, 2024).

President Biden indicated that the law should apply not only to Medicare patients, saving older adults hundreds of dollars per month, but everyone (Fact Sheet: White House Briefing March 02, 2023). This change will disproportionately effect communities of color s such as Black, Hispanic, American Indian, and Alaska Native as these groups have higher rates of diabetes in the United States than White Americans (Fact Sheet: White House Briefing March 02, 2023).

There is no easy solution to fixing the high drug prices. Compared to the rest of the Western world, there are complex reasons unique to the United States for the high drug prices (Rajkumar, 2020). Some of these issues are monopolies by the drug companies, the seriousness of the disease, the high cost of drug development, and the power of the lobbyists on behalf of the drug companies (Rajkumar, 2020). Possible solutions could be faster approval of generics and biosimilars, shorter duration of patents, the user of nonprofit generic manufacturing companies set up by the United States, and policy changes (Rajkumar, 2020). Drug companies will inevitably continue to challenge many of these solutions. Citizens in the United States overwhelmingly support the efforts

on the part of the federal government to reduce drug prices, including having Medicare negotiate prices directly with the manufacturer (Sullivan, 2023).

This study focused on the effect of drug pricing on the consumer and their ability to purchase their medications. The study also examined the impact of using a discount drug program and buying medications. The results showed that while consumers had a distrust of how drugs were priced, there was no correlation between drug pricing and their ability to purchase medications. The study also showed that while participants thought that drugs were not reasonably priced there was no correlation between the price and being allowed to purchase drugs from Canada or whether the government should make it easier to bring generic drugs to market.

When asked about drug discount programs and determining if there was a correlation between using the programs and filling their prescriptions, there was significance in using the program and the likelihood of purchasing medications. However, only half of the participants took advantage of the drug-purchasing programs. Finally, not using the drug pricing program did not stop participants form purchasing their medications but did cause some to try alternatives such as cutting pills in half, taking OTC meds, asking for less expensive drugs, or skipping doses.

Future researchers can address the limitations of this study and the changes in drug pricing by developing a larger sample size that is not limited by individuals known to me. Future researchers may also need to create a new survey based on the changes in drug prices and how the IRA has affected the consumer's ability to purchase, including the change in cost and savings to the consumer. Research can also be conducted to

determine how lowering the price of certain drugs affects the use of the drug discount program and if more people are aware of the drug discount program. Only half the participants took advantage of the drug discount programs, but it was unknown whether those who did not utilize them were aware of the programs.

Implications

A significant issue of concern in the health care system is the ability of consumers to afford prescription medications because of the cost. There was interest from the federal, state, and local levels as well as with the consumer in lowering drug prices. Although the participants in this study did not believe drugs were reasonably or fairly priced and wanted the U.S. government to allow drugs to be purchased from Canada as well as have a procedure for having medications come to market more quickly, they did not equate these issues with one another with any level of significance. However, the study showed that there was a statistical significance in utilizing drug pricing programs and purchasing prescription medications. Further study of this result could lead to positive social change. Drug assistance programs and the 340B Drug Assistance Program are discussed regarding their medical and social change benefits.

Access to medications is an essential aspect of the health care system; however, many patients, specifically those with chronic conditions, find themselves challenged with the reality of the financial burdens placed on them because of having to fill their prescriptions (Wilkinson, 2024). Drug assistance programs and the 340B Drug Pricing program have become and continue to be a viable source of some relief for the consumer by not only aiding in affording medications, but also reducing hospital readmission rates

(Wilkinson, 2024). Hospitals can reallocate their resources to other needs with fewer readmissions to reduce health care costs and efficiency (Wilkinson, 2024).

These programs also reduce medication nonadherence as patients will be more likely to take their medications as directed if they are affordable. (Wilkinson, 2024). An additional perk of the programs is to lessen the stress and anxiety of the patient by reducing the financial barriers of access to medications (Wilkinson, 2024). While drug assistance programs are a positive force, there are still many challenges to the program, such as patient awareness of and accessibility to the programs. The health care team and pharmacists should actively engage with patients to advise them of the programs (Wilkinson, 2024).

The 340B Drug Pricing Program is also another program that provides discounted drug prices for patients. The program is designed to provide a safety net to help with drug pricing and expand across-the-board services for patients (Wagner et al., 2023). Of the $4,300,000,000,000 spent on health care in the United States, $1 out of every $100 is spent on the 340B Drug Pricing Program (Levengood et al., 2024).

A qualitative study of people with diabetes was undertaken to determine whether the 340B Drug Pricing Program is accomplishing what it was intended to do, as there have been criticisms of the program (Wagner et al., 2023). The participants in the study had positive remarks concerning the 340B program, with some describing it as a lifesaver, making their injectable diabetes medications affordable where otherwise they would have to resort to other means (Wagner et al., 2023). The program has benefited underserved communities (Wagner et al., 2023).

However, there are questions about whether hospitals effectively use drug discounts to improve access for vulnerable populations which was a comment from a study using chronic asthma patients (Tripp et al., 2023). Levengood et al. (2024) reviewed the literature to assess the program's impact. They determined that nonprofit DSHs may be using the 340B program in ways that are conflicting with an increased safety net, consistent with other hospitals and public health clinics.

A study of the effect of the 340B Program on the health care for patients with chronic obstructive pulmonary disease indicated that access to medications at a reduced cost was associated with a substantial reduction in visits to the emergency room as well as a decline in hospitalizations of patients with COPD which resulted in a decrease in the use of resources saving money across the board (Taliaferro et al., 2023).

It is still being determined whether health care providers in vulnerable communities understand how the 340B program best works to help their patients (De La Riva, Gray et al., 2024). Health care providers who could prescribe medications were surveyed about the program and agreed that the patients benefited from the pharmacies participating in the 340B program but had limited knowledge of the program or which drugs were available on the program (De La Riva et al., 2024).

The results of this study and the literature indicate that drug prices concern consumers, health care providers, policymakers, stakeholders, and those associated with social policy. Policymakers and other stakeholders should consider the patient's perspective when evaluating the importance of the 340B program as a program that can provide much-needed social change for the health care system (Wagner et al., 2023). In

addition, there should be a focus on training the prescribers to make them aware of the 340B program (De La Riva et al., 2024).

The implications of this methodological (survey) and theoretical (rational choice and power and politics theory) noted in this study are appropriate to contribute to the body of research concerning the effect of drug pricing on the patient. The impact of using the drug pricing program and the 340B program can ease the financial burden of the individual as well as the family. Given the current state of rising prices in the United States for all products, these programs are easing the financial burdens of the consumer in prescription drugs, which can only create a more satisfied population.

Conclusion

The cost of medication has been and continues to be an issue in the United States. Patients believe drugs are not priced fairly or reasonably and sometimes need help to afford their medications. As a result, patients who cannot afford their medication are finding ways to compensate, which may lead to more hospitalization and possibly more severe illnesses. While patients would prefer to be allowed to purchase medicines from reputable pharmacies in Canada and would like to the government to make it easier for generics to come to market, they did not correlate the high cost of medications with either of these situations. Patients did benefit from participating in a drug assistance program and the 340B Drug assistance program which significantly correlated with purchasing medications. Patients were more likely to buy their medication, adhere to their medication schedule and only look for alternatives if the cost was reasonable.

Since this study was conducted, the KFF has conducted additional studies on consumers' opinion of drug pricing, negotiation drug prices with Medicare, the IRA, and transparency in drug costs. Consumers will continue to shop for the best price for their medications comparing the costs from their insurer and using drug discount programs (Gordon, 2022). A KFF Health Tracking Poll from 2021 indicated that prescription drug costs are at the top of health care priorities with most of the public indicating of the many proposals for changes in health care, lowering prescription drug prices should be a top priority for lawmakers and Congress (Kirzinger et al., 2021).

Nearly 88% of the public was in favor of allowing the federal government to negotiate with the pharmaceutical companies for lower prices on medications including 77% of Republicans, 89% of Independents, and 96% of Democrats (Kirzinger et al., 2021) However the public can become concerned when pharmaceutical companies state that lowering prices could lead to a decrease in R & D of new drugs causing the public to consider opposing the proposals (Kirzinger et al., 2021). However, according to a KFF study, most adults do not believe drug companies need to have high drug prices to invest in new research and that the companies would still make money after lowering drug prices (Kirzinger et al., 2021).

Around nine in 10 adults believe the federal and state governments should negotiate with drug companies to get lower prices on prescription drugs with 92% and 89% respectively (Kirzinger et al., 2021). A majority (88%) also believe the government should place a cap on how much OOP costs older adults should have to pay for

prescription drugs (Kirzinger et al., 2021). Because of a new prescription drug law enacted in 2023, negotiations and changes have already begun.

People with Medicare Part D will have no OOP expenses for more vaccines, meaning no copayment or deductibles (Medicare.gov, n. d.). In addition, a 1-month supply of insulin cannot cost more than $35 and there is no deductible (Medicare.gov, n. d.). For OOP expenses, there will be lower copays for certain drugs and biologics if the price of increase is higher than the rate of inflation (Medicare.gov, n, d.). Beginning in 2025, yearly OOP expenses for medications will be capped at $2,000 with the option of paying monthly, spreading the cost over the year rather than when the prescription is filled (Medicare.gov, n. d.). This change is especially helpful for HIV, chemotherapy drugs and other expensive drugs. In addition, Medicare will continue to negotiate for 15 additional drugs in 2025, 15 drugs in 2026, 20 drugs in 2027, and 20 drugs in 2028 and manufacturers who do not negotiate will be subject to paying a tax and penalties (Medicare.gov, n. d.).

These efforts may help people with Medicare, but a better job needs to be done to make the public aware. While many voters are aware that insulin in capped at $15 for a month's supply, a KFF study found that many voters were not aware of the Medicare negotiations or the IRA (Sparks, 2024). Research, especially from KFF, which does numerous health surveys, indicates that prescription drug pricing is an issue at the public forefront. Consumers continue to be challenged financially by the high and rising costs of medications and expect their elected officials at the federal and state level to provide methods of relief. That relief has started for Medicare patients with a cap for the price of

insulin, and Medicare negotiation with the pharmaceutical companies to lower the price of certain drugs. Under the IRA, this process will continue for at least the next 4 years.

According to Lieneck et al. (2023), recent analysis of the literature indicates that the social impact of the IRA and drug assistance programs provides financial, economic, and physical relief to the patient. Studies indicate it will take policymakers, patient advocates, and stakeholders working with and listening to the consumer to ensure meaningful changes continue to be enacted to help the consumer deal with the effect of high drug prices and the industries that will challenge any changes to their bottom line (Lieneck et al., 2023). If the policymakers listen to the will of the people and continue to make progress in pricing drugs, many consumers may benefit not only physically, but mentally and financially as the literature has indicated that lower prices will result in less stress on the consumer (Lieneck et al., 2023).

Researchers will need to conduct additional studies to explore the impact of the IRA and similar policies. Dramatic changes to several government departments including those that affect health care are being implemented by the current U.S. president and it is unclear what effect these changes will have on the populace as they navigate the many moving pieces of the health care system. Researchers should consider adding a follow-up study to determine the effect of these changes on the consumer.

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Appendix A: Adapted KFF Survey

Q1. As you may know, a health reform bill was signed into law in 2010, known commonly as the Affordable Care Act or Obamacare. Given what you know about the health reform law, do you have a generally (favorable) or generally (unfavorable) opinion of it?

a) Favorable

□ Very favorable

□ Somewhat favorable

□ Don't know/refuse to answer

b) Unfavorable

□ Very favorable

□ Somewhat favorable

□ Don't know/refuse to answer

Q2. Do you favor or oppose having a national health care plan, sometimes called Medicare-for-all, in which all Americans would get their insurance from a single government plan?

□ Strongly favor

□ Somewhat favor

□ Somewhat oppose

□ Strongly oppose

□ Don't know/refused to answer

Prescription Drugs

Q3. Do you think prescription drugs developed over the past 20 years have generally made the lives of people in the US?

a). Better

□ A little better

□ A lot better

b.) Worse

□ A little worse

□ A lot worse

□ Haven't made much difference

□ Don't' know

□ Refused to answer

Q4. In general, do you think the cost of prescription drugs is reasonable or unreasonable?

□ Reasonable

□ Unreasonable

□Don't know

□ Refused

Q5. Overall, how confident are you that prescription drugs sold in the United States are safe?

□ very confident,

□ somewhat confident,

□ not too confident,

□ or not at all confident?

Q6. How much do you trust pharmaceutical companies to:

a. Offer reliable information about how well their drugs work

□ A lot

□ Somewhat

□ Not too much

□ Not at all

b. Offer reliable information about side effects and safety of their drugs

□ A lot

□ Somewhat

□ Not too much

□ Not at all

c. Develop new, effective drugs

□ A lot

□ Somewhat

□ Not too much

□ Not at all

d. Price their products fairly

□ A lot

□ Somewhat

□ Not too much

□ Not at all

e. Inform the public quickly when they learn of a safety concern with one of their drugs

□ A lot

□ Somewhat

□ Not too much

□ Not at all

Regulations and Government Policies

Q7. Is there too much regulation in Regulations and Government Policies for prescription drugs, not as much as there should be, or about the right amount of regulation?

a. Making sure prescription drugs are safe for people to use

□Too much regulation

□Not as much as there should be

□About the right amount of regulation

b. Limiting the price of prescription drugs

□ Too much regulation

□ Not as much as there should be

□ About the right amount of regulation

Q8. Which of the following do you think would do a better job at keeping prescription drug costs down?

□ More government regulation of drug and insurance companies

□ More competition among drug and insurance companies

□ Both

□ Neither

□ Don’t know

□ Refused to answer

Q9. Would you favor or oppose?

a. Requiring prescription drug companies to include the list price (the price the drug companies set for their drugs) of the drug in their advertisements

□ Favor

□ Strongly Favor

□ Somewhat Favor

□ Oppose

□ Strongly Oppose

□Somewhat Oppose

b. Allowing Americans to buy prescription drugs imported from licensed Canadian pharmacies

□Favor

□ Strongly Favor

□ Somewhat Favor

□Oppose

□ Strongly Oppose

□ Somewhat Oppose

c. Making it easier for generic drugs to come to market in order to increase competition and reduce costs

□ Favor

□ Strongly Favor

□ Somewhat Favor

□ Oppose

□ Strongly Oppose

□ Somewhat Oppose

d. Ending the tax break given to drug companies for their spending on television ads and other marketing expenses

□ Favor

□ Strongly Favor

□ Somewhat Favor

□ Oppose

□ Strongly Oppose

□ Somewhat Oppose

e. Increasing taxes on drug companies whose drug prices are too high

□ Favor

□ Strongly Favor

□ Somewhat Favor

□ Oppose

□ Strongly Oppose

□ Somewhat Oppose

Q10. The federal government does NOT currently negotiate with drug companies to get a lower price on medications. Would you (favor) or (oppose) allowing the federal government to negotiate with drug companies to get a lower price on medications for people on Medicare?

□ Favor

□ Strongly Favor

□ Somewhat Favor

□Oppose

□ Strongly Oppose

□ Somewhat Oppose

Medicare

Q11. Some people have made arguments for or against having the federal government negotiate prescription drug prices for people on Medicare. Would you (favor) or (oppose) allowing these negotiations if you heard that:

a. As a result, Medicare might not cover some prescription drugs

□Favor

□ Strongly Favor

□ Somewhat Favor

□Oppose

□ Strongly Oppose

□ Somewhat Oppose

b. It could lead to seniors saving money on their prescription drugs

□ Favor

□ Strongly Favor

□ Somewhat Favor

□ Oppose

□ Strongly Oppose

□ Somewhat Oppose

c. As a result, Medicare could save the federal government money by paying less for prescription drugs

□ Favor

□ Strongly Favor

□ Somewhat Favor

□ Oppose

□ Strongly Oppose

□ Somewhat Oppose

d. It could lead to less research and development of new drugs

□Favor

□ Strongly Favor

□ Somewhat Favor

□Oppose

□ Strongly Oppose

□ Somewhat Oppose

e. Experts say these types of negotiations won't be effective at keeping drug costs down

□Favor

□ Strongly Favor

□ Somewhat Favor

□Oppose

□ Strongly Oppose

□ Somewhat Oppose

Costs

Q12. Listed below factors that some people say contribute to the price of prescription drugs. For each, I'd like you to tell me if this is a major factor, a minor factor, or not a factor contributing to the price of prescription drugs.

a. The cost of research and development

□ Major Factor

□ Minor Factor

□ Not a Factor

b. The cost of marketing and advertising

□ Major Factor

□ Minor Factor

□ Not a Factor

c. Profits made by pharmaceutical companies

□ Major Factor

□ Minor Factor

□ Not a Factor

d. Profits made by companies that serve as middlemen that manage prescription drug benefits for health insurance plans

□ Major Factor

□ Minor Factor

□ Not a Factor

Coverage 13 – 21 Part of Demographics

Q13. COVERAGE. Are you, yourself, now covered by any form of health insurance or health plan or do you not have health insurance at this time? A health plan would include any private insurance plan through your employer or a plan that you purchased yourself, as well as a government program like Medicare or (Medicaid/Medi-CAL])?

□ Yes

□ No

□ Don't know

□ Refused

Q14. COVTYPE. Which of the following is your MAIN source of health insurance coverage?

□ Plan through my employer

□ Plan through your spouse's employer

□ Plan you purchased either through an insurance company or a state or federal marketplace

□ Covered by Medicare or Medicaid

□ If Medicaid, State-Specific Medicaid name

□ Health Insurance from somewhere else

□ Please describe (I added this)

Q15. Which is more important to you?

□ Having the option to choose from different prescription drug plans and change your plan if you want

□ Keeping your overall spending on prescription drug premiums and co-pays as low as possible

□ Neither of these

□ Both of these

□ Don't know

□ Refused

Q16. Thinking about prescription drug plans for seniors, adults 65 and older. Which is more important to you?

□ Giving seniors the option to choose from different prescription drug plans and change plans if they want

□ Keeping senior's overall spending on prescription drug premiums and co-pays as low as possible

□ Neither of these

□ Both of these

□ Don't know/refused

Q17. As far as you know, does your plan cover all prescription drugs or only some prescription drugs?

□ All

□ Only Some

□ Don't know/refused

Q18. Listed below are a list of problems some people experience with their health insurance plan. Please tell me if you have had any of these problems in the past 12 months, or not.

a. You were told your plan would not cover a drug prescribed by our doctor

□ Yes (If yes, proceed below)

□ No

□ Not applicable/haven't used services yet

□ Don't' know/refused

b. You had to wait more than 2 days to fill your prescription because the pharmacy needed additional approval from your insurance plan

□ Yes (If yes, proceed below)

□ No

□ Not applicable/haven't used services yet

□ Don't' know/refused

c. Your plan required you to try a less expensive drug before you could get the more expensive drug prescribed by your doctor

□ Yes (If yes, proceed below)

□ No

□ Not applicable/haven't used services yet

□ Don't' know/refused

Q19. Thinking about your prescription drug coverage, which is more important to you,

□ Paying a lower premium each month

□ Having a lower co-pay at the pharmacy when you get your prescriptions filled

□ Neither of these

□ Both of these

□ Don't know/refused

Prescriptions Maybe 20 & 21 part of demographics

Q20. Do you currently take any prescription medicine or not?

□Yes

□No,

□Don't know/refused

Q21. How many different prescription drugs do you take?

_____

Q22. When your doctor writes a prescription for a drug you haven't taken before, do you usually talk to him or her about it?

□The cost you will have to pay for the new medication

□ The safety and potential side effects of the drug

□Whether there is a less expensive alternative available

Q23. When you fill a new prescription at the pharmacy, do you usually talk to your pharmacist about (Check all that apply)

□ Whether there is a less expensive alternative available

□The safety and potential side effects of the drug

Q24. On average, how much do you spend each month on all of your prescription drugs, including any co-pays or other out-of-pocket expenses?

□ Less than $25

□ $25 to less than $100

□ Between $25 and $50

□ More than $50 but less than $100

□ $100 or more a month

□ Don't know/refused

Q25. In general, how easy or difficult is it for you to afford to pay the cost of your prescription medicine?

□ Very easy

□ Somewhat easy

□ Somewhat difficult

□ Very difficult

□ Don't have to pay

□ Don't know?

Q26. In the past 12 months, have you:

□ Not filled a prescription for a medicine because of cost

□ Cut pills in half or skipped doses of medicine because of cost

□ Taken an over-the-counter drug instead of getting a prescription filled because of cause

Q27. Did you tell your doctor or health care provider that you did not take your prescription as recommended because of the cost?

□ Yes, did tell doctor

□ No, did not tell doctor

□ Took prescription as recommended

□ Don't know

□ Refused

Q28. Did your condition get worse as a result of not taking your prescription as recommended, or did it not get worse?

□ Condition got worse

□ Condition did not get worse.

Q29. In the past 12 months, have you received a discount on a prescription drug, either through a coupon, a copay card, a drug company patient assistance program, or some other kind of prescription discount?

□ Yes

□ No

□ Don't know

□ Refused

Q30. If you hadn't received the discount for the prescription drug, would you still have chosen to get the prescription filled, or not?

□ Yes

□ No

□ Don't know

□ Refused

Q31. Instead, would you have (asked your doctor for a prescription for a less expensive drug), (taken an over-the-counter drug), or skipped taking medication entirely?

□ Asked your doctor for a prescription for a less expensive drug

□ Taken an over-the-counter drug

□ Skipped taking medication entirely

□ Something else

□ Don't know

□ Refused

Demographics

Q32. HEALTH. In general, would you say your health is

□ Excellent

□ Very good

□ Good

□ Only fair

□ Poor

Q33. The term pre-existing condition is used to describe a medical condition that a person had before they got health insurance like a history of asthma, diabetes or high blood pressure, or cancer. Would you say that you or someone else in your household have a pre-existing condition of some sort, or not?

□ Yes

□ No

□ Don't know/refused

Q34. CHRONIC. Do you or anyone in your immediate family have a chronic health condition that requires ongoing medical treatment?

□ Yes

□ No

□ Don't know/refused

Q35. MARITAL. Are you currently married, living with a partner, widowed, divorced, separated, or have you never been married?

□ Married

□ Living with a partner

□ Widowed

□ Divorced

□ Separated

□ Never been married

Q36. EMPLOY What best describes your employment situation today?

□ Employed

□ Employed full-time

□ Employed part-time

□ Unemployed and currently seeking employment

□ Unemployed and not seeking employment

□ A student

□ Retired

□ On disability and can't work

□ Homemaker or stay-at-home parent

□ Don't know/refused

Q37. EDUC: What is the highest level of school you have completed or the highest degree you have received?

A. High school grad or less

□Less than high school (Grades 1-8 or no formal schooling

□High school incomplete (Grades 9-11 or Grade 12 with no diploma)

□High school graduate (Grade 12 with diploma or GED certificate)

B. Some College

□Some college, no degree (includes some community college)

□Two-year associate degree from a college or university

□College Graduate +

□ Four-year college or university degree/Bachelor's degree

□ Some postgraduate or professional schooling, no postgraduate degree

□ Postgraduate or professional degree, including master's doctorate, medical or law degree

□ Don't know/refused

Q38. Are you, yourself, of Hispanic or Latino background, such as Mexican, Puerto Rican, Cuban, or some other Spanish background?

□Yes

□No

□Don't know/refused

Q39. What is your race? Are you white, black, Asian or some other race?

□ White, non-Hispanic

□ Black Hispanic

□ Black or African American, non-Hispanic

□ Hispanic

□ Asian, non-Hispanic

□ Other/mixed race, non-Hispanic

□ Undesignated

Q40. Were you born in the United or in another country?

□ United States

□ Puerto Rico

□ Another country

□ Don't know

□ Refused

Q41. INCOME. Last year – that is, in 2021– what was your total family income from all sources, before taxes?

□ Less than $20,000

□ $20,000 to less than $30,000

□ $30,000 to less than $40,000

□ $40,000 to less than $50,000

□ $50,000 to less than $75,000

□ $75,000 to less than $90,000

□ $90,000 to less than $100,000

□ $100,000

□ Don’t know/refused