2021

The Place and Role of Pharmacy Benefit Management (PBM) Companies in US Healthcare System

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The Place and Role of Pharmacy Benefit Management (PBM) Companies in US Healthcare System

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A Thesis

Presented to

the Faculty of the College of Arts, Humanities and Social Sciences

University of Denver

In Partial Fulfillment

of the Requirements for the Degree

Master of Arts

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by

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August 2021

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Title: The Place and Role of Pharmacy Benefit Management (PBM) Companies in US Healthcare System
Advisor: Henning Schwardt
Degree Date: August 2021

Abstract

On average, prescription drugs cost US consumers more than any other developed country in the world. US drug makers claim that intermediaries in the prescription drug supply chain, companies called pharmacy benefit managers (PBM), are forcing them to increase their drug prices. PBMs counter that the discounts they receive from drug makers are channeled to insurers. This thesis will examine the role that PBMs play in the prescription drug supply chain and determine what effect they have on drug prices. This thesis will utilize a comparative static model, Structure, Conduct, Performance (SCP) framework to analyze the pharmaceutical manufacturing and the PBM markets. Given the limitations of comparative static analysis, this thesis will critically evaluate the conclusion of the SCP framework and provide a more contextualized alternative. While the PBMs profit from high drug prices, drug manufacturers are the leading cause behind increasing drug costs in the US.

Acknowledgements

I want to thank my advisor, Dr. Henning Schwardt, for his insight, knowledge, and patience, which helped me through this process. I would also like to thank Dr. Yavuz Yasar, who suggested the theoretical framework and provided a general outline for this thesis to take shape. Additionally, I am forever grateful to all the Economics professors at the University of Denver for their hard work and dedication, especially during difficult times. They have changed my life forever by giving me the gift of purpose, insight, and a drive to succeed in life. I would also like to thank the committee members who reviewed my thesis, Dr. Yavuz Yasar, Dr. Chiara Piovani, and Dr. Alejandro Ceron Valdes. Finally, I would like to thank my friends, family, and co-workers who supported me and encouraged me to do my best throughout school.

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List of Abbreviations

ACA	Affordable Care Act
CMS	Centers for Medicare and Medicaid Services
CR4	Concentration Ration (4 firms)
DIR	Direct and Indirect Remuneration
DOJ	Department of Justice
DUR	Drug Utilization Review
FDA	Food and Drug
FTC	Federal Trade Commission
HHI	Herfindahl-Hirschman Index
HHS	US Dept of Health and Human Services
IP	Intellectual Property
M&A	Merger and Acquisition
MAC	Maximum Allowable Cost
NIH	National Institute of Health
NME	New Molecular Entities
OTC	Over the Counter
PBM	Pharmacy Benefit Management
PCMA	Pharmaceutical Care Management Association
PCP	Personal Care Physician
P&T	Pharmacy and Therapeutics
R&D	Research and Development
SCP	Structure, Conduct, and Performance
US	United States

Chapter One: Introduction

On average, prescription drugs in the United States (US) cost consumers more than any other developed country in the world. It is estimated that the US per capita spending on prescription drugs in 2019 was $1,229. The next closest countries were Switzerland with $894 per capita, Germany with $883 per capita, and Canada, with $879 per capita (Mikulic 2021). US drug makers claim that intermediaries in the prescription drug supply chain, companies called pharmacy benefit managers (PBM), are forcing them to increase their drug prices. PBMs counter that the discounts they receive from drug makers are channeled to health insurers, and ultimately the consumer (Commonwealth Fund 2019).

This thesis will examine PBM companies' role in the prescription drug supply chain and determine what effect they have on drug prices. This research will also discuss the component that make up the prescription drug supply chain and analyze how each piece affects drug prices. Additionally, determining whether those components are outside the control of PBMs' ability to manage costs to consumers. This research will also provide some historical context to PBM concentration and vertical integration with other members of the prescription drug supply chain over the years. While also discussing how the interaction between prescription drug supply chain participants affects drug prices and access.

PBM companies serve as an intermediary role in the current US prescription drug supply chain between health insurers, pharmaceutical manufacturers, and pharmacies. Primarily PBMs manage prescription drug benefits on behalf of health insurers for an administrative fee. PBMs also develop and maintain lists of medications that health insurers agree to cover on their health plans. These lists of medications are called formularies, and they influence which drugs consumers have access to and ultimately determine patients' out-of-pocket costs for their medicines. PBMs can leverage enrollee buying power to negotiate rebates and discounts from pharmaceutical manufacturers through their ability to pool together various health insurance plans, passing the savings onto health plan insurers and consumers. Furthermore, PBMs develop networks of pharmacies for health plan enrollees to conveniently pick up prescriptions while also administering reimbursement fees to pharmacies for prescription delivery services (Commonwealth Fund 2019).

The US prescription drug costs have persistently been above general inflation for the last forty years (Bureau of Labor Statistics 2021). While the price of generic drugs has seen steady decreases over time to the extent that they are approximately 60% cheaper today than they were ten years ago. The cost of brand-name medications has grown approximately 150% during the same period (Cox, Kamal, and McDermott 2019). Brand name prescription drugs have become so expensive in the US that nearly 1 in 5 Americans have reported skipping a dose to prolong their prescriptions and delay paying for refills. While nearly 1 in 4 Americans also reported that they did not fill a prescription because of the out-of-

pocket costs associated with their prescriptions (Porter 2021, 2). These decisions by consumers have tremendous consequences for their quality and quantity of life. As mentioned earlier, pharmaceutical manufacturers argue that the rebates they pay to PBMs are forcing them to increase drug prices to maintain the profitability of their products. This thesis will examine the interactions between drug manufacturers and PBMs to determine whether it is possible to ascertain who is the main culprit behind increasing drug costs.

Traditional methodologies used to evaluate economic outcomes often use comparative static models to examine the impact that a change of an exogenous parameter has on equilibrium. The methodology used in this thesis is the Structure, Conduct, and Performance (SCP) model, which is itself, a comparative static model. The purpose of the SCP model is to trace the cause of an industry's performance back to its competitive market structure. Following the microeconomic theory, industries characterized by many small firms and low barriers to entry create competitive market conditions where each firm is a price-taker and cannot influence the market price of their products. This pricing behavior informs firms' conduct to not price their products above or below competitors for risk of losing market share or profit. As a result, the industry's performance is such that the economic profit of individual firms is reduced to zero, and each firm has an equal market share (Strategic Toolkits, n.d.).

However, comparative static models present specific challenges to analysis and policy recommendations as these models lack historical context between the

events of interest. While an industry's structure can be measured in many ways, this research used readily available data on the market shares of individual firms to calculate their market structure. SCP relies on the microeconomic assumption that industries with fewer firms and thus higher market shares are inherently analyzed as less competitive. As a result, there exists the possibility that this research has overemphasized the importance of market concentration and therefore has overlooked other factors that contribute to an industry's performance (StudyMoose 2016). For example, the SCP framework used in this research does little to explain the market power accrued by pharmaceutical manufacturers through government-granted monopolies of patent-protected medications. It also totally lacks any consideration of the creation or evolution of PBM companies in the prescription drug supply chain over time. Therefore, this research will try to add contextualization to the SCP model to understand better the causes behind increasing drug prices in the US.

The following chapter—Chapter Two—examines the US pharmaceutical industry according to the SPC framework, with particular attention given to the market conditions that affect prescription drugs' delivery and pricing behavior. This thesis will assess what aspects of the prescription drug supply chain other than those roles associated with PBMs, impact drug prices. In Chapter Three, there is an analysis of the formulary-rebate scheme that characterizes the negotiations between PBMs and pharmaceutical manufacturers. The SCP framework is again utilized to evaluate the PBM market and draw certain conclusions regarding the

research question, keeping in mind the limitations of the methodology. Additionally, this thesis will explore the pricing behavior and market implications of PBM concentration and vertical integration into health insurance companies and pharmacy chains. Lastly, Chapter Four provides a summary of the findings and a set of policy recommendations.

Chapter Two: The US Pharmaceutical Industry

This chapter summarizes the US pharmaceutical industry according to the SCP framework while considering the role that PBM companies have in the delivery of pharmaceutical products. The first of the three aspects of the SCP model examines the market structure of the US pharmaceutical market. It helps establish the overall market environment that firms are operating. Some essential market structure characteristics discussed are the number and size of the sellers and buyers, the type of products offered for sale, barriers to entry, and whether any asymmetry of information exists between buyers and sellers. The second aspect of the SCP model examines the conduct of firms and how they price, promote, and develop their products. Whether a firm decides its policies independently or in conjunction with other firms in the market has a crucial impact on the conduct of the industry. The third aspect examines the performance of firms, which is illustrated in the allocative efficiencies, equity, and technological progress of the industry (Santerre and Neun 2010, 208-211).

Market Structure of the Pharmaceutical Industry

The first part of this section covers the supply of prescription drugs and explores drug manufacturer firm size and distribution and their relative market power in the US prescription drug market. The second section covers the demand for prescription drugs, which delves into demographic usage and induced demand. While the last section covers third-party influences that either promote or reduce the supply and demand of prescription drugs in the US.

Number and Size Distribution of Sellers

The pharmaceutical industry in this research is defined as those companies who develop, produce and market pharmaceutical drugs for use as medications with the explicit purpose to cure, treat or alleviate symptoms of disease (McGuire, Hasskarl, Bode, Klingmann, and Zahn 2007). The table below shows the total revenue of the top 17 pharmaceutical companies whose revenue was generated within the US in 2018. These figures were taken from the various companies' 2018 annual fillings for net revenue based on the US geographic area. Furthermore, all the numbers are in 2018 averaged USD.

Entity	2018 U.S. Revenue in Billions of USD	% of total U.S. Revenue	HHI for Entity
Pfizer Inc.	25.32	9.017	81.306
Johnson & Johnson	23.28	8.291	68.741
Roche	22.76	8.106	65.707
AbbVie	21.52	7.664	58.737
Amgen	18.28	6.51	42.38
Novartis	17.56	6.254	39.113
Merck & Co.	16.6	5.912	34.952
Gilead	16.2	5.769	33.281
Eli Lilly	13.87	4.94	24.404
Sanofi	13.15	4.683	21.93
Novo Nordisk	12.64	4.502	20.268
Bristol-Myers Squibb	12.58	4.48	20.07
Bayer	8.29	2.952	8.714
AstraZeneca	6.87	2.447	5.988
Takeda	5.41	1.927	3.713
Allergan	5.32	1.895	3.591
CSL	5.22	1.859	3.456
Total:	**244.87**	**87.208**	**536.351**

The left-most column lists the pharmaceutical company name, and the second column lists the 2018 US revenue for that company. The 2018 revenue is then used to calculate the percentage of that company's contribution to the $280.79 billion total US pharmaceutical revenue (Statista 2019). These percentages are then used to calculate the market concentration of the US pharmaceutical market.

The four-firm concentration ratio, or CR4, is a common technique used to measure market concentration. The CR4 equals the sum of the market shares of the four largest firms and ranges between 0 and 100 percent, with a higher value reflecting that the largest four firms account for a larger share of industry output. An industry with a CR4 of 60 percent or more is considered tightly oligopolistic. An industry with a CR4 between 40 and 60 percent is labeled as a loose oligopoly.

Industries with a CR4 of 40 percent or less are treated as being reasonably competitive (Santerre and Neun 2010, 234). If we add the four largest US market shares of the pharmaceutical firms, we obtain a CR4 of 33.078 (9.017 + 8.291 + 8.106 + 7.664), which is well within the range of being reasonably competitive.

Another way to measure market concentration is the Herfindahl-Hirschman index (HHI). This measure of market concentration is calculated by summing the squared market shares of all the firms in the relevant market, where S_i stands for the percentage market share or percentage of industry output produced by the i^{th} firm and HHI = $0 < HHI \leq 10{,}000$ (Santerre and Neun 2010, 235).

$$HHI = \sum_{i=1}^{N} S_i^2 = S_1^2 + \cdots + S_N^2$$

The above table is not a comprehensive list of all the US pharmaceutical firms and only accounts for 87.208% of the total $280.79 billion US pharmaceutical market. However, we can make a close approximation of the level of concentration given the information available. The above table has already calculated the HHI contribution for each entity and has summed those figures for a total HHI score of 536 for the pharmaceutical industry.

The Department of Justice (DOJ) has established some guidelines concerning the level of market concentration that the agency believes triggers concern about the potential exploitation of market power. The DOJ, therefore, believes that reasonably competitive conditions hold when the HHI is less than 1,000. The DOJ treats an industry as being mildly concentrated when the HHI falls

between 1,000 and 1,800. While an HHI above 1800 is considered highly concentrated (Santerre and Neun 2010, 236).

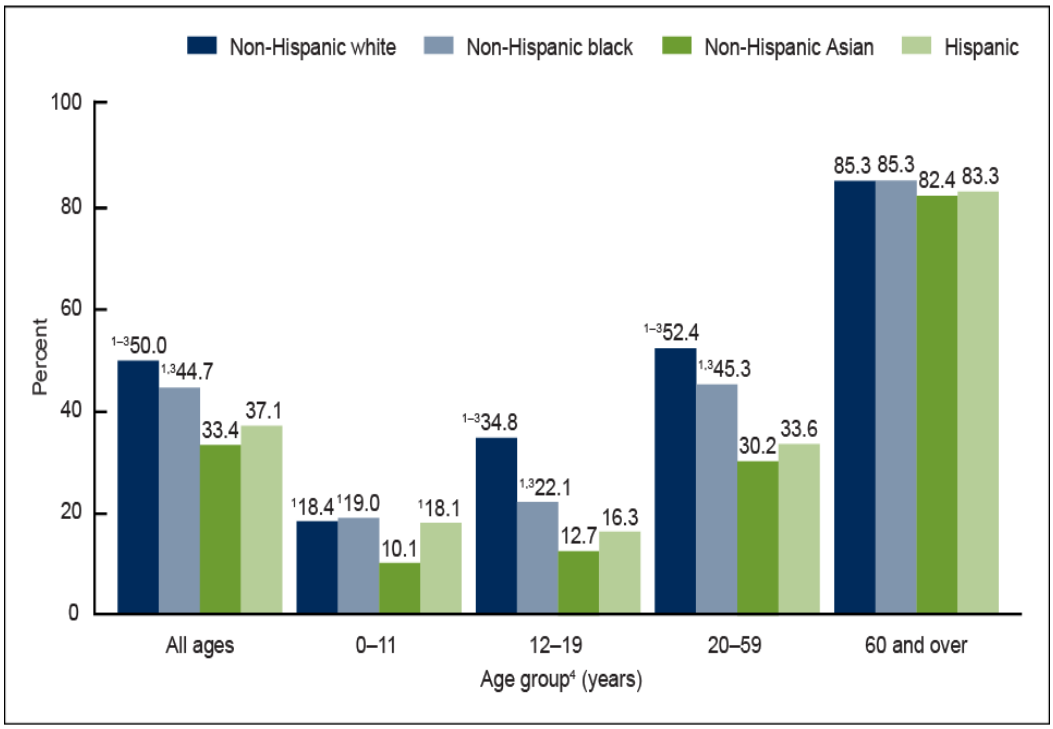
With this research's calculated HHI of 536.351 based on US revenue in 2018, the US pharmaceutical industry appears to be reasonably competitive. However, as we shall see in further sections, there are other factors besides the number and size of firms that help explain the market competitiveness of the US pharmaceutical industry and, ultimately, its' market performance.

The Buyer Side of the Pharmaceutical Market

Demographics and Usage

Now that we have defined and identified the supply side of the pharmaceutical industry, we need to examine the buyer side. In the US, nearly 50% of the population has taken a prescription drug in the past 30 days. Furthermore, this trend of prescription drug usage has not changed very much over the last 15 years (Martin, Hales, Gu, and Ogden 2019).

Figure 2. Use of one or more prescription drugs in the past 30 days, by age and race and Hispanic origin: United States, 2015–2016



[1]Significantly different from non-Hispanic Asian persons.
[2]Significantly different from non-Hispanic black persons.
[3]Significantly different from Hispanic persons.
[4]Significant increasing trend with age.
NOTES: Estimates for all ages were age adjusted by the direct method to the 2000 projected U.S. population using age groups 0–11, 12–19, 20–59, and 60 and over. Access data table for Figure 2 at: https://www.cdc.gov/nchs/data/databriefs/db334_tables-508.pdf#2.
SOURCE: NCHS, National Health and Nutrition Examination Survey, 2015–2016.

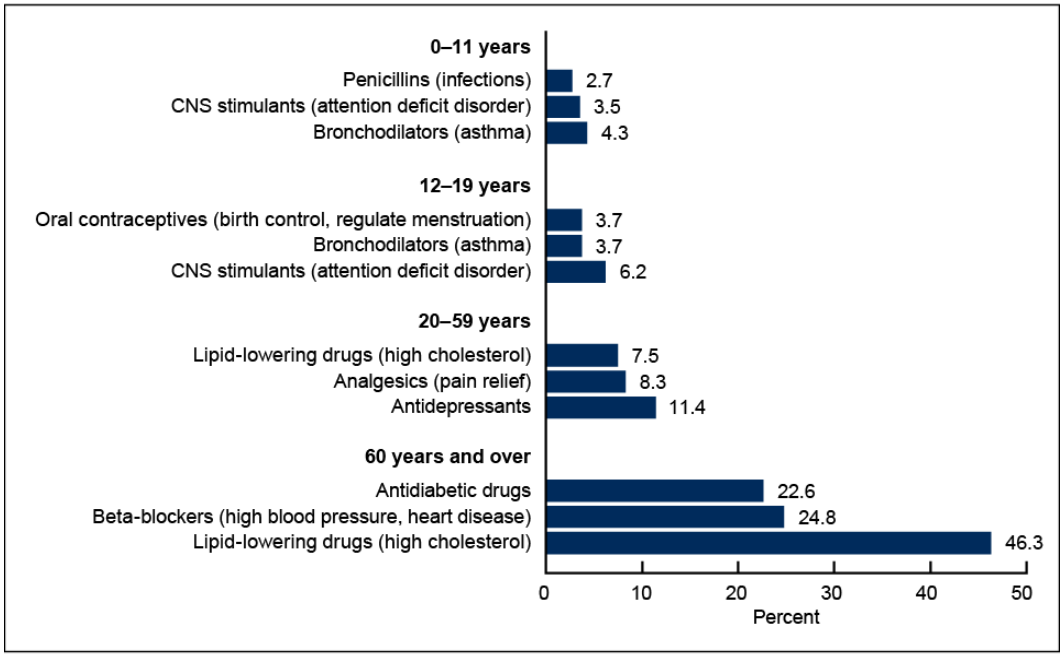
Let us analyze the Martin et al. findings in Figure 2, which has been reposted above. Older age groups are prescribed prescription drugs at a higher rate than younger age groups at every level. Regarding age and race, there is an interesting trend where prescription drug usage is consistent among all races ages 0-11 years old except for non-Hispanic Asian Americans who are about 8% less likely to be prescribed drugs in this range. From ages 12-19, there is a slight increase of no more than 3% of prescription drug usage among non-Hispanic black, Non-Hispanic Asian, and Hispanic Americans. However, among non-Hispanic white Americans, there is nearly a doubling of prescription drug usage in the 12-19

age range, 18% for ages 0-11 to 35% for ages 12-19. It is not until the 20-59 age range there is a similar doubling in prescription drug usage among non-Hispanic black Americans, Hispanic and non-Hispanic Asian Americans. Non-Hispanic white Americans in the 20-59 age range have the highest prescription rates among all Americans at 52.4%. However, the discrepancy in prescription drug usage vanishes when considering prescription drug usage among all Americans 60 and older. Non-Hispanic black, Hispanic, non-Hispanic Asian and non-Hispanic white Americans all have a similar prescription rate of about 85% when considering 60 and older (Martin, Hales, Gu, and Ogden 2019).

Below is Figure 3, taken from the Martin et al. research, illustrates the top three therapeutic areas prescribed to each age group. Among Americans 60 and older who are prescribed drugs, 46% are prescribed lipid-lowering drugs used to treat high cholesterol, 25% are prescribed beta-blockers, which are used to treat high blood pressure and heart disease, and 23% are prescribed antidiabetic drugs (Martin, Hales, Gu, and Ogden 2019). The average American 60 and older may be prescribed two or more of the drugs mentioned above to treat their illness. Also, the number one killer of Americans aged 65 and older in 2018 is heart disease (Center for Disease Control and Prevention, n.d.). Lipid-lower and beta-blocker drugs are directly used to treat and prevent heart disease. Diabetes itself, while not a leading cause of death in the US, does contribute to heart disease deaths as complications with diabetes do lead to various cardiovascular aliments (Center for Disease Control and Prevention 2021). Recall that antidiabetic drugs are the third-highest

prescribed drug to Americans aged 60 and older after medications used to treat cardiovascular ailments.

Figure 3. Use of the most commonly used prescription drug types in the past 30 days, by age group: United States, 2015–2016



NOTES: The primary indication for use of the drug type is in parentheses. Other drug types may also be used for the same indications as those shown. CNS is central nervous system. Oral contraceptives were used by 7.5% of girls aged 12–19. Access data table for Figure 3 at: https://www.cdc.gov/nchs/data/databriefs/db334_tables-508.pdf#3.
SOURCE: NCHS, National Health and Nutrition Examination Survey, 2015–2016.

Similarly, there is a connection between the leading causes of death in the US and the type of prescription drugs prescribed for younger ages. Instead of medications used to treat cardiovascular diseases in older Americans, we see a shift in prescriptions drugs used to treat illnesses like pain and depression. Interestingly, the leading cause of death for Americans 15-44 years old is unintentional injuries, of which unintentional poisoning to include drug overdose, is the leading cause (Center for Disease Control and Prevention. n.d.). Over 11% of Americans are prescribed antidepressants while 8.3% are prescribed pain relief, the first and second most prescribed drug to Americans 20-59 years old (Martin, Hales, Gu and

Ogden 2019). The above connection is quite striking because studies have shown that patients somaticize their economic and social disadvantages into physical pain. Researchers agree that the lack of economic opportunity, poor working conditions, and eroded social capital in depressed communities, accompanied by hopelessness and despair, are root causes of the misuse of opioids and other medications (Beletsky, Cirrarione, and Dasgupta 2018).

Payment for Prescription Drugs

Health care coverage in the US is not a guarantee. Several different entities assist consumers with payment for medical expenses. Private insurance can either be through an individual's employer or purchase private health insurance on their own. Either way, the individual pays monthly premiums to the plan provider in exchange for health insurance benefits that help reduce the out-of-pocket costs to the consumer. Federal and state-funded programs either reduce or eliminate out-of-pocket costs for some consumers who qualify, such as Medicare, Medicaid, and the Office of Veterans Affairs (Commonwealth Fund 2020).

According to the US Department of Health and Human Services (HHS), of all the drugs purchased in 2014, private insurances companies purchased a little over 35%, with about 30% purchased by Medicare, 15.6% purchased by Medicaid, 13.9% purchased by patients and the remaining 5.5% purchased by other public programs such veterans' aid programs, workers' compensation, and community clinics (Langreth 2020). Other than the 35% paid by private insurance, prescription

drug costs are either paid by the patient at 13.9% or are paid by the US federal government and other state governments through such programs like Medicare, Medicaid, and the Office of Veteran Affairs. Collectively, federal and state governments pay more than 51% of all prescription drug costs in the US.

Induced Demand

The market for pharmaceutical drugs creates peculiar market interactions because the consumer/patient is not the one who decides on what type of drugs are used in their treatment. Pharmaceutical drugs are defined into two broad categories, either prescription or over-the-counter (OTC). Prescription medications must be prescribed by a doctor to an individual and bought at a pharmacy. In contrast, an OTC drug does not require a doctor's prescription and can be used by multiple people, and can be purchased almost anywhere (US Food & Drug Administration 2017).

This research will focus only on prescription drugs for which the demand is highly dependent upon physician prescriptions in addition to consumer tastes and preferences. The market interaction between the patient and the gatekeeper physician creates a principal-agent problem due to the asymmetry of information available to the patient and the physician. The patient, a layman in medicine, needs to seek relief from an illness and seek out a physician's knowledge. The physician can diagnose and prescribed medication to the patient, which the patient has no control over. It is expected that physicians are to act utterly devoid of economic or

personal motive when seeing a patient. Depending on the incentives and regulations governing physician's duties, there have been reviews that have found variations in the quality and cost of care given to patients (Santerre and Neun 2010, 371).

When we consider the tremendous expectations placed on physicians to balance the economic and medical outcomes of patients, those expectations become almost impossible to manage given the overall shortage of personal care physicians (PCP) in the US. The lack of primary care in the US is because PCPs face longer work hours and lower pay on average than their medical specialist counterparts (Bodenheimer and Grumbach 2012). In addition, the biomedical model of medicine focuses purely on the biological factors to identify and treat disease. This overreliance on the physical aspects of healthcare, in effect, excludes other important factors that contribute to health, such as psychological, environmental, and social factors (Beletsky, Cirrarione, and Dasgupta 2018). The more a physician is overworked, the easier it becomes to prescribe a medication to a patient to treat the symptoms of their aliment versus a more time-intensive holistic evaluation of the patients' needs that more adequately addresses the underlying causes of illness and thus reducing overall healthcare costs and utilization of prescription drugs.

Third-Party Influence on Supply and Demand

Pharmacy Benefit Management Companies

An influential agent in the prescription drug supply chain and the principal party of interest for this thesis, PBMs, specializes in managing prescription drug

benefits on behalf of health insurers such as large employers, Medicare Part D plans, and other payers. PBMs serve as intermediaries in the distribution chain between drug manufacturers, pharmacies, and health insurance companies (Commonwealth Fund 2019). This intermediary role is meant to reduce prescription drug costs by channeling the needs of different actors of the prescription supply chain into a single point-of-contact, the PBM company.

Health insurers pay a fee to PBM companies, which may be based on the number of covered individuals or on a fee-for-service basis to develop and maintain a list of covered medications on behalf of the insurance plans. These lists are called formularies, and they influence which drugs individuals use and determine the out-of-pocket costs paid by the consumer at the pharmacy. If a patient is prescribed an expensive brand-name medication by their doctor, the formulary allows the PBM to identify cheaper biosimilar generic medications for dispensing at the pharmacy (Santerre and Neun 2010, 465-6). Having the ability to place products on a health plan's formulary allows PBM companies to negotiate retrospective discounts or rebates from drug manufacturers. PBM companies also arrange prescription drug access by developing networks of pharmacies for prescription pick-up services (Commonwealth Fund 2019).

Food and Drug Administration

Another important entity that defines the market structure of the US pharmaceutical industry is the Food and Drug Administration (FDA), which acts as

a barrier to entry due to its enforcement of drug rules and regulations. Pharmaceutical manufacturers argue that the FDA is a severe impediment to the development of life-saving therapies because of the increased research and development (R&D) costs associated with stringent regulations on product safety. It is also argued that the bureaucratic red tape that the FDA forces drug makers to go through contributes to unnecessary testing and long wait times for new drug approvals (Santerre and Neun 2010, 468-9).

The perception that government is inefficient is a self-fulfilling prophecy where government cutbacks create heavy workloads requiring longer hours for federal employees and ultimately loss of knowledgeable, talented individuals to the private sector. If left unchecked, government cutbacks would continue to unravel any government agency. In response to gradual defunded over the years, the first law was passed in 1992, allowing drug developers to pay the FDA a portion of a new drug's approval process (Hawana 2020). Over the years, the FDA's budget has increasingly been funded by these payments by drug manufacturers, with an estimated 32% of the FDA now funded by "user fees" (Dabrowska and Green 2020). With the growth of "user fees," there appears to be a conflict of interest as a drug manufacturer can pay for a quicker drug approval process and potentially get their product to market faster and possibly capture a greater share of the market before their competitors.

Conduct of the Pharmaceutical Industry

This section covers the conduct of the pharmaceutical industry. The first section explains the patent process for pharmaceutical drugs. The second section details the distinction between innovator and generic pharmaceutical manufacturers and their respective emphasis on R&D. The third section examines the motives behind research and development and calls into question the pharmaceutical industry's claim that high drug prices are used to recoup expensive R&D projects. The fourth section analyzes the marketing and promotion of pharmaceutical products and the resilience of branded drugs over cheaper generics to generate revenue. The last section examines various studies conducted over the years comparing the pricing behavior of drug manufacturers regarding branded versus generic products.

Patent Protection

Patents are awarded to pharmaceutical manufacturers and give the firm the right to be the sole producer of a particular drug for a maximum of 20 years (DeShong 2004). Given that pharmaceutical products require years and often billions of dollars to create a viable medication, it is argued that to incentivize new drug develop, drug manufacturers need to be protected from cheap imitators like generic manufacturers. Otherwise, there would be no economic incentive to undertake risky and expensive R&D projects when a competitor can easily replicate

the novel chemical compound without incurring the massive R&D costs associated with the new drug's development (DeShong 2004).

While the patent system does confer monopoly power to the patent holder, the economic rationale is that it is better to have a monopolist selling a smaller than socially desired quantity of a drug than not to have any drug at all. However, this monopoly power can quickly become eroded because pharmaceutical patents are granted for a drug's chemical composition and not for its therapeutic novelty (Santerre and Neun 2010, 466-7). Meaning that when a new drug enters the market or is made public, it can be analyzed by a competitor's chemist to identify the active chemical chain or enzyme used to treat an illness. Once the enzymatic reaction is found, the competitor chemists can add a non-enzymatic chain of chemicals to the larger chemical compound, thus altering the chemical composition and developing a new compound that can be patented (Lowe 2015).

The 1984 Hatch-Waxman Act has hastened the approval process for generic drugs. Generic drug manufacturers do not have to prove the safety and effectiveness of their generic medications like novel drug manufacturers. Instead, generic manufacturers only need to show that their generic products contain the same active ingredient or enzymatic compound as a brand-name product. Consequently, once a patent on a pharmaceutical drug expires, competition between generic manufacturers drives the price of generic medications very low (Santerre and Neun 2010, 467 and 472).

Innovator and Generic Manufacturers

There are two kinds of prescription drug manufacturers: innovators or novel manufacturers and generic or biosimilar manufactures. The difference is that innovator manufacturers spend a large portion of their resources developing a new or better prescription drug. In contrast, generic manufacturers produce non-novel drugs and do not spend nearly the same amount of resources on R&D (DeShong 2004).

The difference between an innovator and generic drugs becomes important when considering how pharmaceutical drugs are priced. Novel prescription drugs are much more expensive than generics. Innovator manufacturers argue that the reason behind this price discrepancy is that it is costly to create and market a new or better prescription drug. The time and resources required to develop a new drug could take a decade and cost millions of dollars in personnel, tests, and side projects. Therefore, when a new drug is approved for use by the FDA, the manufacturer of the novel compound would like to recoup their R&D costs which require a high price per pill (DeShong 2004).

Once a novel drug is discovered, generic manufacturers who are not burdened with the overhead cost of research and development like their innovator counterparts can produce the drug at a much lower cost. It stands to follow that an innovator manufacturer who spent millions of dollars on a new drug would not be incentivized to develop the new drug if a generic competitor could sell the same compound at a lower price. Therefore, to incentivize innovator firms to develop

new medications, the US government passed several legislative measures that allow innovator firms to have exclusive rights to the intellectual property (IP) associated with their drug patents. However, there are time limits that an innovator has exclusivity over a novel compound. Those time limits are intended to balance economic profits with societal benefits (Santerre and Neun 2010, 466-7).

Even if an innovator loses its patent exclusivity, there are still other strategies that they may employ to restrict the supply of generics. Pay-for-delay is a common strategy used by large innovator firms who pay their competition, in this case, generic manufacturers, to not produce their novel compound (Federal Trade Commission 2010). The price that the innovator must pay the generic manufacturer must be high enough to incentivize the generic manufacturer that not producing the drug is more profitable than producing it. Fundamental market economics teaches us that a restriction of the supply will increase demand and, therefore, price. If the prescription drugs companies are restricting necessary medications, then people are going to buy them regardless of the price increase, which harms consumer wellbeing.

Another strategy used by innovator manufacturers is to sell an authorized generic version of the brand-name drug. By law, the first company to market a generic version of the branded drug gets 180 days of exclusivity, during which no other companies can sell a generic product. Innovator firms merely market their brand name product under the generic name, extending the patent exclusivity for

another six months and building product familiarity with the authorized generic over its competitors (Fox 2017).

Research and Development

The claim that it is expensive to bring a new drug to market may be true. Still, there are strategies that the pharmaceutical industry uses to lessen the risk of investment in new pharmaceutical products. The most common strategy involves shifting the burden of financing to either the federal government or shifting the risk of development to smaller innovator firms. As a result, many of the advancements in prescription medications do not come from the privately-owned R&D labs of large pharmaceutical companies, but rather from public research universities and research programs that receive grants from government institutions such as the National Institute of Health (NIH) (Mazzucato 2015, 75-7).

While there has been a long trend of increased R&D spending in the pharmaceutical industry over the years, with $50.7 billion in 2010 to $79.6 billion in 2018, that spending on R&D as a percentage of total revenues has remained consistently around 15-20% per year, for the last 15 years (Statista 2019). However, this trend is overshadowed by the fact that from 2008-2018, large pharmaceutical companies spent more on stock buybacks and dividends to CEO pay than they did on R&D (Mazzucato 2015, 32).

While total R&D spending and patent applications for drugs have trended upwards together, the classification of new molecular entities (NMEs), drugs

containing as their active ingredient a chemical never marketed in the US before, has not seen the same upward trend. Of the 1,072 drugs approved by the FDA between 1993 and 2004, only a fraction, 357, was NMEs compared to the remaining approved drugs that were mere variations of existing medications (Mazzucato 2015, 72). We would expect that the number of NMEs would be increasing over the years from an industry that likes to self-promote itself as innovative. On the contrary, between 2000-2010, there was only a slight increase in NMEs compared to the 1980s despite having tremendous technological progress in medical science (Porter 2021, 5).

There is a distinction that should be made regarding the size of pharmaceutical firms, as empirical evidence shows that most novel research into NME is conducted by smaller firms. These firms are often spun-off from publicly funded sources like university research programs and funded by the NIH to help develop truly innovative products in critical therapeutic areas. It is estimated that 75% of the NMEs discovered have had their origin in publicly funded research institutions or some funding support from the NIH (Mazzucato 2015, 72).

Despite the public source of the funds, the innovation and technology developed by these small firms do not stay in public hands or even within the small firm itself. An established strategy by large pharmaceutical companies will be to purchase the small firm once a marketable product becomes apparent. In 2009, only 31% of drugs launched that year were discovered by small firms. By 2018 that number had increased to 64% (Porter 2021, 8).

Large pharmaceutical companies have in effect side-stepped the financial burden of R&D and are merely engaged in the marketing and promotion of pharmaceutical products. This strategy is so common that it even has its own name, the Fast-Second Strategy. A large firm will let a smaller innovator firm deal with the costs and risks, then respond quickly with a 'fast second' merger and acquisition (M&A) if the new drug seems promising (Santerre and Neun 2010, 482). Other than acquiring IP, large pharmaceutical companies purchase smaller firms to boost stock prices as the M&A of a smaller business is seen as growth for the larger firm, thus incentivizing stock buys. Or sometimes, M&As are even used to prevent competitors from deploying better quality drugs or alternatives (Porter 2021, 3).

Marketing and Promotion

Due to the range and scope of different kinds of drugs available on the market, drug manufacturers invest heavily in marketing and promotional activities, given that a prescribing physician must know the appropriate medication, correct dosage, and the properties of the drug for different patients, classified by various characteristics, such as age, weight, general health status. It is no surprise that drug marketers try to influence physicians' prescription decisions by handing out short, easy-to-read promotional material on new drugs. It is estimated that around 20-30% of drug sales are used for marketing and promotional purposes, of which 70% is spent on personal promotion by pharmaceutical salespeople, with 27% spent on

journal advertising and the remainder accounting for direct mail advertising (Santerre and Neun 2010, 474).

Depending on whether the new drug is entering a market with increased generic competition, the innovator firm tends to devote fewer resources to advertising, suggesting that the purpose of product promotion is more motivated by information dissemination than by persuasion. However, evidence indicates that persuasive advertising of new drugs by pharmaceutical salespeople target physicians who have recently graduated from medical school are meant to create brand loyalty and thus reinforce prescribing habits. Furthermore, leading firms' promotion expenditures of their products appear to demonstrate market share resilience when presented with generic competitors even when generic drugs are sold at a considerable discount (Santerre and Neun 2010, 474-5).

Due to the effect that marketing and promotion activities have on consumer and physician preferences for brand names over generic drugs, pharmaceutical products are considered inelastic goods. Therefore, we could characterize the information environment of pharmaceutical drugs as being one where persuasive promotional activities induce habitual buying, less elastic demand, and higher prices. When it comes to the demand for prescription drugs, several studies have shown that the price elasticity of demand for branded medications is less than 1, ranging anywhere from -0.18 to -0.60. For example, a 10% increase in the price of a drug could expect a 1.8% to 6% decrease in the drug's usage by patients (Cox 2009).

Pricing Behavior

The cost of prescriptions drugs in the US is so high that nearly 1 in 5 Americans reported skipping a dose, and nearly 1 in 4 Americans did not fill a prescription because of prescription costs. Conversely, profits in the pharmaceutical industry today are the highest they have ever been (Porter 2021, 2). The relatively high barriers to entry through the national regulatory agency and patent exclusion rights imply that pharmaceutical companies possess a relatively high degree of market power to price their products above the marginal costs of production and generate larger economic profits. Furthermore, the first-mover advantage may mean that firms that develop a new drug first can maintain a larger market share over generic competitors given years of cultivated brand loyalty.

These non-competitive pricing practices have encouraged numerous studies meant to examine the pricing practices of pharmaceutical manufacturers. One such study conducted in 1988 analyzed 56 brand name drugs between 1978 through 1983 and compared how generic entrants of those 56 brand name drugs affected post-patent protection pricing practices. The results of the 1988 study affirmed the hypothesis that with generic entry into the market, brand name drug prices did see a decline, but at less than a one-to-one ratio suggesting that buyers are relatively insensitive to price changes. The authors go on to surmise that a possible explanation is that product familiarity built-up during the patent exclusivity period extends the high price of the brand-name drug for longer as physicians and patients continue habitual prescribing and buying practices (Caves and Hurwitz, 1988).

Another study conducted in 1991 examined the effect of generic entry on brand name and generic prices. The study analyzed the post-patent protection competition for 30 brand-name drugs and several generic entrants between 1976 through 1987. Once a generic drug enters that market, the brand-name drug price increases initially but then declines over time. The authors conclude that with every generic entrant into the market, the brand name drug price declines 4.5% on average. Furthermore, as more generic alternatives enter the market, the price between generic products falls faster than the brand-name product. Lastly, despite significant discounts, generic manufacturers often gained little market share (Caves, Hurwitz, and Whinston 1991, 1-66).

However, a more recent study in 2008 by Tracy Regan has shown contradictory results with the 1988 Caves and Hurwitz, and the 1991 Caves, Hurwitz, and Whinston studies. The 2008 study did find similar results regarding increase generic competition leading to lower overall generic prices. The Regan study also found that each generic entrant is associated with a 1% increase in the brand name drug price on average (Regan 2008). The literature review discusses that the previous works to include Caves et al. (1991) and others, have estimated a negative relationship while other studies by Frank and Salkever (1997), Grabowski and Vernon (1996, 1992) have found a positive relationship between brand name price and generic entrants. Using a newly constructed data set, Regan's study finds that brand name producers prices increase in response to generic competition (Regan 2008).

The most common explanation for this behavior is the generic competition paradox. This paradox is a contradiction between the economic rationale that theorizes that an increase in competition is associated with a decrease in equilibrium price as more price-sensitive consumers switch to buying generics over brand name. However, empirically we see the opposite. Regan's work concludes that innovator firms with branded products may forego the cross-price elasticity segment of the market in favor of the brand-loyal segment suggesting that price competition in the prescription drug market is confined only to the generic market (Regan 2008).

Performance of the Pharmaceutical Industry

This section covers the performance of the pharmaceutical industry. The first section examines the price inflation of prescription drugs in the US and discusses possible causes. The second section considers the motive behind the creation of new pharmaceutical products. The last section analyzes the profits in the pharmaceutical industry.

Price Inflation

One method for analyzing the performance of an industry is to examine how the price of its products change over time. It is expected that the product's price will fluctuate over time due to imbalances in supply and demand and may even rise a little to keep pace with general inflation. However, a product characterized by

persistent above-average general price inflation is seen as potentially harmful to consumers as their incomes are relatively fixed compared to high inflation products (Santerre and Neun 2010, 483). As we will see, brand-name pharmaceutical products have been scrutinized by policymakers for their above-average price inflation for a long time (US House Oversite Committee 2020, 2).

Historically, between the 1970s through about 1975, the price inflation rate of prescription drugs was below the general inflation rate. Specifically, general inflation averages 7.4%, while prescription drugs averaged 3.9%. However, this trend reversed quite dramatically around 1980 when prescription drug price inflation continued to grow while the general inflation declined sharply during this period. Drug prices grew at an average rate of 9.6%, while the average general inflation rate only increased at 5%. During the 1990s, drug price inflation matched more closely with general inflation, which averaged 3%, while drug price inflation averaged 5%. More recently, drug price inflation has outpaced the general price inflation but at a lower rate than in the 1980s and 1990s, at only above 1-2% and with few spikes that exceed 2% (Bureau of Labor Statistics 2021).

However, these statistics combine the average price of cheaper generic drugs and branded drugs, obscuring that branded drug prices contribute much more to the overall price inflation. While the price of generic drugs has seen steady decreases over time to the extent that they are approximately 60% cheaper today than they were ten years ago. The price of brand-name medications has increased approximately 150% during the same period (Cox, Kamal, and McDermott 2019).

One such example of the public's concern over drug prices leads to the 2020 Congressional Oversite Committee that oversaw the drug pricing investigation into Celgene, the owner of Revlimid, a medication used to treat types of cancer. The investigation uncovered that at launch in 2005, Revlimid was $215 per pill, but after more than 20 price hikes, the drug now costs $763 per pill. Furthermore, the committee concluded that those price hikes were not intended to cover R&D expenses but rather improve Celgene's quarterly earnings to maintain and attract investors. Unsurprisingly, the committee also found that the company's executive compensation system incentivized these price hikes by tying CEO pay to quarterly earnings reports (US House Oversite Committee 2020, 4-5).

While the Revlimid case is an extreme example, there are countless others where pharmaceutical firms routinely increase the list price of many of their products. Drug companies typically increase the list price of their drugs at the beginning of the year and again six months later, often by double-digit percentages. The average price hike being 10.5%, or about five times the rate of inflation (Hopkins 2019). Furthermore, 41 drugs have had their prices increased by more than 100%, with a few drugs pushed past 300% like Mometasone, a topical steroid, increased 381%, and Promethazine/Codeine, a pain reliever, increased 326% both in 2019 (Picchi 2019).

Output of New Pharmaceutical Products

Another measure of an industry's performance is its level of output and how well products are distributed amongst members of society. Regarding pharmaceutical products, there appears to be quite a large distribution of medications to the general population. Recall that nearly 50% of Americans have taken a prescription in the last 30 days (Martin, Hales, Gu, and Ogden 2019). However, due to structural conditions such as patents and marketing, the development of new pharmaceutical products may be burdened by legislative action meant to accelerate drug innovation.

The introduction of the Hatch-Waxman Act in 1984 was meant to incentivize innovation by extending a new drug's patent life by five years, but no more than 14 years in total (Santerre and Neun 2010, 487). This legislation, coupled with the industry's tendency to repackaging already existing drugs by slightly modifying their chemical composition, refiling for patent protection, and securing patent exclusivity, has not seen the development of many NME, but rather the reselling of existing drugs just under different dosages and therapeutic areas (Lowe 2015). As mentioned before, most groundbreaking work in NMEs comes from publicly funded sources, which are later acquired by large pharmaceutical firms that patent and profit from the publicly funded discovery. Any innovation that would have been shared publicly is instead locked up in privately owned corporate IP holdings.

Profits in the Pharmaceutical Industry

As mentioned before, what is seen as excessive profits in the pharmaceutical industry have attracted concern from consumers and politicians alike. Inelastic demand, brand loyalty, and patents are cited as some of the main theoretical causes of exuberant profits in the pharmaceutical industry. Historically, after-tax return on equity in the pharmaceutical industry has been at least twice as high compared to the same measure for all other manufacturing sectors in the US (Santerre and Neun 2010, 488).

When it comes to the sources of revenue generation in the industry, we see that for the last 15 years, around 80% of drug revenues in the US have come from branded drugs, while the remainder comes from generics. Interestingly, the proportion of branded drug prescriptions dispensed in the US during the same period has seen a decline from a 40% high in 2005 to an all-time low of 10% in 2018 (Statista 2019). Suggesting that within the pharmaceutical industry as a whole, larger firms with branded products account for the majority of revenue generated and are increasingly relying on their monopoly power to maintain profitability.

Chapter Three: Pharmacy Benefit Manager (PBM) Companies in the US Healthcare System

No one would blame you if you never heard of a PBM company or knew precisely their role in the US healthcare system. The important and prevalent role that PBMs play in the delivery of prescription medications is often overlooked, probably due to their opaque and bureaucratic status as middlemen in the US prescription supply chain. While PBMs never physically handle prescription drugs, they serve as the intermediaries between insurers, pharmaceutical manufacturers, and pharmacies. More generally, PBM companies are third-party administrators of prescription drug programs for employer-sponsored commercial health plans, self-insured plans, Medicare Part D plans, and other state and federal government health plans. The primary role of any PBM company is to develop and maintain a list of drugs known as a formulary, build networks of pharmacies to create convenient access to medications for patients, negotiate drug discounts with pharmaceutical manufacturers, and process prescription drug claims (Commonwealth Fund 2019).

Before PBMs fulfilled their role as specialist intermediaries, insurance companies often handled their own prescription drug processing claims in-house. However, as more Americans began to utilize prescription drug services, the need for cost-effective drug processing rose among insurers. Eventually, insurance companies realized that it would be more cost-effective if they just eliminated their in-house processing departments and instead outsourced the processing duties to a third party, thus the rise of the PBM company. While initially, PBMs were meant to reduce administrative costs by handling prescription medication claims for insurance companies and plan sponsors for a small fee. PBM's duties quickly expanded to include such services as validating patient eligibility, performing drug utilization reviews, deciding reimbursement fees for pharmacies, while in some cases even operating mail order and specialty pharmacies themselves (Hoffman-Eubanks, 2017).

Given PBMs' central role in delivering prescription drug services, other companies in the prescription drug supply chain have sought to vertically integrate PBMs into their own business. During the 1990s, companies began to acquire an ownership interest in PBMs, but regulators at the Federal Trade Commission (FTC) blocked such M&As for pharmaceutical manufacturers, fearing they would exclude competitors from the formulary. However, insurance and pharmacy companies successfully managed to avoid regulator's suspicion by being less involved in formulary decisions (Feldman 2017). As a result, today there are few independently

operated PBM companies with most PBMs being owned by either an insurance company or a pharmacy chain.

Economic Perspective of PBM Companies

From an economic perspective, PBMs role in the US healthcare system is somewhat controversial. One view that supports PBMs in the US healthcare system argues that PBM's specialization in the administration and processing of prescription claims allows other entities in the prescription supply chain to focus on the delivery of their healthcare products and services. This process of specialization allows more resources to be devoted to their respected areas of expertise, which in theory generates greater output and reduced costs to consumers. Additionally, if drug manufacturers, health insurance providers, and pharmacies individually eliminate the economic costs of their administration services and hypothetically amass those administration costs together into a new entity, the PBM. The expected result would be greater economies of scale for administrative services in the prescription drug supply chain and an overall reduction in the costs of prescription drugs.

Furthermore, there may be an economic justification for a vertically integrated organization like the large corporate entities we see today that are not only insurance providers but also contain PBM and pharmacy subsidiaries. An insurance company may combine with a PBM company to minimize the transaction costs associated with market transactions. By producing internally, the combined

firm avoids the transactions costs of negotiating, writing, and enforcing contracts (Santerre and Neun 2010, 466). If vertical integration is compatible with market competition, there may be justification for such clustering of prescription drug delivery companies as consumers will benefit from the resulting lower prices.

However, there is another view that is much more critical of the PBMs role in the prescription drug supply chain. This alternative view shared by pharmaceutical manufacturers is that PBM companies are taking advantage of the formulary-rebate scheme as a strategy for extracting excess profits by favoring higher-priced medications over more cost-effective alternatives. By pooling insurance enrollee medication needs together, PBMs can leverage that buying power against pharmaceutical manufacturers and receive rebates on medications by purchasing prescription drugs wholesale. The PBM keeps a portion of these rebates while the rest pass through towards the insurance plan provider (Commonwealth Fund 2019).

Drug manufacturers claim that PBM companies have an incentive to favor higher-priced medications over more cost-effective alternatives because the rebates received by PBM companies are often calculated as a percentage of the drug manufacturer's list price. For example, suppose two medications that treat the same disease, the first drug costs $100 and the second costs $200, and the PBM keeps 10% of any rebates it negotiates with drug manufacturers. The PBM negotiates an 80% rebate for the cheaper $100 drug while negotiating a 50% rebate for the more expensive $200 drug. The out-of-pocket cost to the consumer for the cheaper drug

is $20 versus $100 for the more expensive drug. The PBM only receives $8 of the negotiated rebate from the cheaper drug versus $10 of the negotiated rebate from the more expensive drug. It would be in the PBM's financial interest to favor the higher-priced drug but doing so would push consumers away as the out-of-pocket cost for the more expensive drug is $80 more than the cheaper alternative.

Now assume we still have two drugs, one that costs $100 and another that costs $200, but the negotiated rebate for the cheaper drug is 50% while the negotiated rebate for the more expensive drug is 80%. In this scenario, the out-of-pocket costs to the consumer for the cheaper drug is $50, while the out-of-pocket cost for the more expensive drug is $40. The PBM receives $5 of the negotiated rebate from the cheaper drug versus $16 of the negotiated rebate from the more expensive drug. Both the consumer and PBM benefit from this arrangement of a higher-priced drug with a high rebate. Therefore, illustrating the drug manufacturers' argument that PBMs leverage formulary placement and market access to obtain higher rebates, forcing drug makers to increase drug prices to maintain revenue.

How do PBM Companies Interaction with Other Healthcare Service Providers

PBMs and Health Insurance Providers

As mentioned earlier, PBM companies primarily manage drug benefit plans on behalf of insurance providers who may be contracted through an employer or plans purchased separately by an individual and their family, or even a plan

provided by the state or a federal government agency such as Medicare or Medicaid. Either way, the PBM's job is to control prescription drug costs for the health plan provider (Pharmaceutical Care Management Association, n.d.). Besides establishing and maintaining the formulary, PBM companies also manage patient adherence programs and implement utilization management tools such as prior authorization and tiering to steer enrollees toward certain drugs on the formulary, which is meant to reduce costs through generic substitution of branded drugs (Santerre and Neun 2010, 465-6).

PBM companies also monitor the prescribing, dispensing, and administering of medications. This process is known as a drug utilization review (DUR) and is meant to improve the allocation of health resources to ensure positive patient outcomes while maintaining effective costs measures. If a DUR concludes that a prescription is inappropriate, the PBM will intervene on behalf of the insurance provider and the patient to correct the medication's dosage avoiding unnecessary adverse side-effects (Santerre and Neun 2010, 464).

PBMs and Drug Manufacturers

Pharmaceutical manufacturers keen to sell their products and tap into the pool of enrollees requiring medication seek to negotiate with PBM companies for formulary placement of their products. Drug manufacturers offer rebates to the PBM companies to guarantee that their products are being sold on various health

plans. PBMs keep a portion of these rebates and pass through the rest of the rebate to the health plan provider (Commonwealth Fund 2019).

PBMs and Pharmacies

To achieve convenient access to prescriptions for health plan enrollees, PBMs contract with pharmacies to build robust networks for dispensing medications. Given the PBM's purchasing power through their control over drug utilization, PBMs can make pharmacies compete on service and quality measures within a particular health insurance plan (Carrier 2018). Once a health plan enrollee purchases a prescription, the PBM will reimburse the pharmacy for the physical cost of the medication and provide a small dispensing fee for their service (Santerre and Neun 2010, 465).

Not Just an Intermediary

While PBMs are traditionally characterized as the middlemen of the prescription supply chain, PBM companies are also involved in several other services to maintain cost-effective prescription drugs. One such area is disease management which consists of the construction of databases on current prescription practices and health outcomes to determine cost-effective treatment methods. PBM companies are even known to operate mail order and specialty pharmacies, given their industry knowledge of pharmacy practices and health insurance plans (Santerre and Neun 2010, 465).

Market Structure of the PBM Market

This section will examine the number and size distribution of PBM firms in the US prescription drug supply chain and discuss the potential impact that a highly concentrated PBM market may have on drug prices. Additionally, this section will discuss PBMs' subsidiary status within larger prescription supply chain companies and evaluate their economic impact.

Number and Size Distribution of PBM Firms

Over the last 15 years, the number of independent PBMs has fallen, and the size of individual PBM firms has grown. Not only have PBMs themselves consolidated but insurance and pharmacy companies have been acquiring larger PBM companies and vertically integrating them into their own business structures. Today the PBM market is dominated by only three large PBM companies, Express Scripts, OptumRx, and CVS Caremark (Carrier 2018). These PBMs themselves are not totally independent companies but rather corporate subsidiaries of larger healthcare corporations. Express Scripts is a subsidiary of Cigna, an insurance provider, while OptumRx is a subsidiary of UnitedHealth Group, also an insurance provider. CVS Caremark is a subsidiary of CVS Health, which owns CVS Pharmacy and the insurance provider Aetna (National Association of Insurance Commissioners 2021). The market concentration of the PBM market is illustrated by the market share of these three PBMs by total equivalent prescription claims managed in 2018, where CVS Caremark held 30% of the market, with Express

Scripts and OptumRx each holding 23%. While the next closest competitor Humana Pharmacy Solutions, only had 7% (Paavola, 2019).

It is important to note that the market shares reported above are reported for prescription claims and not revenue. That being the case, +95% of revenue generation for the three largest PBMs are derived from the delivery of prescription drugs through the PBMs contracted network of retail, home delivery, and specialty pharmacies as stated in Express Scripts, OptumRx, and CVS Caremark 2018 annual 10-K filings. Furthermore, previous studies on the market share of PBM companies find that of the $22.6 billion in gross profits in 2016, each PBM's market share roughly corresponds to their share of the prescription claims managed (Atteberry, Bach, and Yu 2018).

Using these figures, we can calculate the degree of market concentration reflected in the market concentration measures CR4 and HHI. Recall that CR4 equals the sum of the market shares of the four largest firms and ranges between 0 and 100 percent. In the case of the PBM market, we obtain a CR4 of 83% which is well above the 60% threshold to be considered tightly oligopolistic (CVS Caremark 30% + Express Scripts 23% + Optum Rx 23% + Humana Pharmacy Solutions 7% = 83%) (Paavola 2019). Likewise, when we consider the HHI to measure market concentration of the 2018 US PBM market, we find a HHI of 2095 ($30^2 + 23^2 + 23^2 + 7^2 + 6^2 + 6^2 + 4^2 = 900 + 529 + 529 + 49 +36 + 36 + 16 = 2,095$) (Paavola 2019). Note that the remaining 4% of the market share calculated here comprises all other PBMs in the market, so the actual HHI should be slightly less than the calculated

HHI of 2095. Nevertheless, an HHI score of 2095 is well above the 1,800 threshold that the DOJ regards as a highly concentrated industry.

PBM Companies Subsidiary Status and Market Concentration

One dimension of the PBM market that we should consider a little more closely is the degree to which PBM companies are vertically integrated into other healthcare service providers and consider how this integration affects the market for prescription drugs. First, let us consider the PBM companies like OptumRx and Express Scripts, which are subsidiaries of insurance companies UnitedHealth Group and Cigna Corporation. PBMs' ability to leverage enrollee buying power against pharmaceutical manufacturers creates an incentive for both the PBM and their corporate parents to favor high-priced drugs with large, negotiated rebates as these rebates are passed through towards the health insurers. In the case of the PBM company like CVS Caremark, where their in-network pharmacies, CVS Pharmacy, is also owned by the same parent company CVS Health. There exists a financial incentive to steer patients away from non-chain pharmacies in which CVS Health does not have an ownership interest by charging lower reimbursement rates for non-CVS pharmacies. This practice would reduce patient access to affordable medications by increasing the transaction cost of out-of-network pharmacies (Carrier 2018).

However, there may be an economic justification for the vertical integration of PBM companies into other prescription drug service providers like insurance

companies and pharmacies. By producing internally, the combined firm avoids the transactions costs of negotiating, writing, and enforcing contracts. If vertical integration is compatible with market competition, there may be justification for such clustering of prescription drug delivery companies as consumers will benefit from lower prices.

Conduct of PBMs in the US Prescription Supply Chain

This section covers the promotion of pharmaceutical products through formulary placement. Additionally, this section separately examines the pricing behavior between PBMs and drug manufacturers, PBMs and pharmacies, and PBMs and health insurers.

Promotion of Pharmaceutical Products

To determine which drugs to cover at what price, PBMs develop a formulary that uses panels of experts called Pharmacy and Therapeutics or P&T Committees to determine the most clinically appropriate medications for a given drug class and indication. Based on the P&T Committee recommendations, PBMs design their formularies that factor in several cost-saving components such as biosimilar availability and negotiated rebates with drug manufacturers. Health insurance providers can adopt PBM-developed formularies or develop their own custom formularies, which are governed by their own P&T Committees (Pharmaceutical Care Management Association, n.d.).

Some examples of PBM formularies include open, closed, and tiered. In an open formulary, the health insurer pays a portion of the cost for all drugs, regardless of formulary status. Although, a plan sponsor may choose to exclude certain products, such as lifestyle drugs, from coverage. In a closed formulary, the plan sponsor will only cover drugs listed on the formulary. Drugs not listed on the formulary are not covered unless approved through a formulary override process. Lastly, in a tiered formulary, the plan sponsor offers different copays or other financial incentives to encourage participants to use preferred formulary drugs but will also pay a portion of the cost of the non-preferred drugs. For example, when a plan sponsor offers a three-tier benefit design, it may cover non-preferred, non-formulary products on its third tier with the highest copay (Pharmaceutical Care Management Association, n.d.).

Formularies are also constantly updated by P&T Committees who analyze a broad range of topics, including new drug evaluations, new FDA-approved indications for existing drugs, new clinical line extensions, and newly published or clinical practice trends that may impact previous formulary placement decisions. In cases where more than one product has been determined to be therapeutically equivalent, PBMs may use the leverage provided by formulary placement in negotiations with drug manufacturers to receive discounts on drug purchases. PBMs argue that the therapeutically equivalent drug that offers the best value for clients will be given preferred status on a formulary (Pharmaceutical Care Management Association, n.d.).

Pricing Behavior of PBMs and Drug Manufacturers

One of the main ways in which PBMs reduce the costs for consumers is through rebates from drug manufacturers in exchange for drug placement on formularies. A rebate in this context is a refund given to the PBM by the drug manufacturer after the PBM has paid the full price for prescription drugs. By altering the amounts of rebates offered, pharmaceutical manufacturers can price their prescription medications differently for different segments of the market and increase their profit overall. Practice is known as price discrimination.

For example, in the case of a closed formulary where certain drugs are excluded, and consumers face the full price of off formulary products, drug makers can effectively outbid their competition by offering higher rebates than their competitors. The Express Scripts 2019 closed formulary lists Austedo as the preferred medication to treat Tardive Dyskinesia, a neurological disorder, while its competitor Ingressa is marked as excluded. We would expect that the pharmaceutical manufacturer of Austedo offered a higher rebate amount to Express Scripts for preferred formulary placement than Ingressa manufacturer (Express Scripts - 2019 Preferred Formulary Exclusions).

This type of arrangement may generate conflicts of interest between pharmaceutical manufacturers, PBMs, and patients. As the PBM company Express Scripts in 2015 agreed to pay $60 million to settle allegations of accepting kickbacks from the drug-maker Novartis for preferred formulary placement of its iron chelation drug Exjade to Medicaid patients instead of a less expensive

alternative. Given the secretive nature of rebate negotiations, it is difficult to determine whether kickbacks are offered willingly by pharmaceutical manufacturers or overtly demanded by PBMs (Gray 2015). However, what is clear is the number of drugs that are being placed on formulary exclusion lists has been increasing over the years, with CVS Caremark alone increasing the number of excluded medications to 124 in 2016, raising the possibility of more kickbacks and pay-to-play schemes (Fein 2015).

In the case of a tiered formulary, the stakes are not so dire for competitors as drug makers can offer various rebate amounts and still receive drug placement on a tiered formulary. However, there is an economic incentive to try and offer higher rebates than competitors to obtain the top-tier position for that therapeutic area. The higher the tier, the lower the out-of-pocket cost to the consumer, which builds product familiarity, habitual buying practices and cements market share for that therapeutic area. Additionally, rebates in a tiered formulary system also can capture a larger segment of the therapeutic market by offering different prices to distinct price-sensitive segments of the demand market for medications. For example, a drug manufacturer can offer a high rebate in exchange for a top-tier placement to capture a very price-sensitive segment of the demand market, while offering slightly less of a rebate to another plan to capture a slightly less price-sensitive segment of the demand market.

Lastly, in the case of an open formulary where the insurer pays a portion of the medication cost regardless of formulary status, we would not expect to see a

drug maker offer rebates because their product would be covered by the insurance provider regardless of formulary status. Unfortunately, information on the negotiations between PBMs and pharmaceutical manufacturers regarding rebates is not public knowledge and is considered a trade secret (Carrier 2018). Therefore, it is unknown as to the prevalence of certain types of formularies and the size and distribution of rebates offered by drug manufacturers.

Pricing Behavior of PBMs and Pharmacies

The first PBM company was started in Scottsdale, Arizona, in 1968 and was called Pharmaceutical Card Systems. The importance of such entities in the delivery of prescription drug services became evident as PBMs were able to pool their patient networks together and independently negotiate lower reimbursement rates with pharmacies and drug manufacturers. Being independent meant that PBM companies had an incentive to pass along those negotiated savings back to their health plan sponsors, which was ultimately passed on to consumers. However, early in the 1990s, pharmaceutical manufacturers lured by the profit potential began to acquire PBM companies. The FTC worried that combining PBMs with pharmaceutical manufacturers would enable drug manufacturers to observe competitors' sensitive pricing information, coordinate pricing policies, and favor their own drugs over their competitors (Feldman 2017). Empirically it would seem that the FTC's concerns were merited as, during the 1990s, there was a dramatic increase in prescription drug prices (Cox Kamal, and McDermott 2019). Motivated

by double-digit price inflation of prescription drugs, the FTC brought anti-trust complaints against pharmaceutical manufacturers that eventually saw the break of these drug-maker/PBM super-businesses (Feldman 2017).

Today we see a different kind of super-business between PBMs merging with insurers and pharmacies. This scenario creates a new set of issues as a PBM merged with a pharmacy would have an incentive to steer health plan enrollees toward its affiliated member pharmacies instead of contracting with as many pharmacies as possible to increase convenience and other quality care measures for patients. These concerns appear not unfounded either. When the FTC allowed the large pharmacy conglomerate CVS to acquire Caremark, a PBM company, in 2007, only 12% of CVS's retail prescription revenue came from Caremark. However, by 2014, CVS's retail prescription revenue had increased to 35% (Feldman 2017).

Implicitly this creates significant business concerns for small independent 'mom-and-pop' type pharmacy businesses. An in-network pharmacy is charged differently than an out of network pharmacy. Specifically, PBMs pay independent pharmacies lower reimbursement rates and can expel pharmacies that complain about their pricing techniques. A common practice known as spread pricing occurs when a pharmacy bills a health plan for the cost of dispensing a prescription. The PBM will keep a portion of the reimbursement in the form of a processing fee and delivers the remainder of the difference to the pharmacy. For example, a recent report on Medicaid in Ohio found that CVS Caremark and OptumRX billed health

plans $2.5 billion while only reimbursing pharmacies $2.3 billion, pocketing the $200 million difference (Carrier 2018).

Not only is spread pricing a concern for independent pharmacies, but increasingly PBMs require that independent pharmacies pay direct and indirect remuneration (DIR) fees. These fees are imposed after-sale and are meant to reconcile any costs associated that were not initially captured during the transaction. Another retroactive payment scheme used by PBMs is 'clawbacks,' which can lead patients to pay more in copayments than the drug costs. For example, a University of Southern California study found that by charging a $50 copay for contraceptive and acne-treating Sprintec, a drug that costs $11.65 for a 28-day prescription, one PBM enjoyed a $38 windfall per prescription (Van Nuys, Joyce, Ribero, and Goldman 2018).

Pricing Behavior of PBMs and Insurers

We have mentioned the straightforward way that a PBM company and a health plan provider operate within the prescription drug delivery context. The insurance provider pays the PBM an administration fee. In return, the PBM manages the whole drug benefit plan while also trying to contain costs from drug manufacturers through rebates, which the discounts are shared with the insurance provider. However, there are other more complicated ways that a PBM and insurance provider may want to manage high-dollar medications.

Certain patients with particularly costly medication regimens are often offered copayment offset programs or copay cards from pharmaceutical manufacturers. These copay programs are meant to cover some of the cost associated with the beneficiary's out-of-pocket cost for a brand-name drug. With the growth of expensive medications, there has been a corresponding increase in manufacturers' copay programs along with insurance plans that strongly favor high deductible and coinsurance spending. In 2019, there were double-digit growth rates for copay programs that are estimated to have cost pharmaceutical manufacturers $15 billion (Fein 2020).

Usually, the payments from a copay program are counted towards a patient's deductible or maximum annual out-of-pocket cost. However, under a copay accumulator policy, the insurance plan or the managing PBM does not include the copay program or other third-party assistance such as a charitable assistance program towards the patient's deductible. Thus, reducing the cost that the insurance provider must pay while increasing the out-of-pocket expenses that the patient must pay. In response to this predatory pricing practice, The Center for Medicare and Medicaid Services (CMS) implemented a rule that prohibited these copay accumulator plans for brand name drugs that did not have a generic equivalent. However, expensive medication regimens for illnesses are often packaged in high deductible plans that offer no generic alternative (Fein 2020).

After being outed for shifting prescription drug costs towards patients, insurance providers and their PBM subsidiaries developed another more subtle

payment scheme. Copay maximizer policies that evenly divide the maximum value of the copay program across the year. The result is that a patient's out-of-pocket costs are more predictable and do not vary month to month. A copay maximizer policy has the advantage over an accumulator policy because it reduces or can potentially eliminate the out-of-pocket expenses paid by the patient when they purchase their medication. However, this payment policy effectively shifts the costs to the drug manufacturers by increasing the number of average monthly copays paid by the drug manufacturer versus the fewer, larger payments paid earlier in the year (Fein 2020).

Performance of PBMs in the US Pharmaceutical Market

High drug prices have been a persistent problem in the US. Even though the rate of drug price inflation has declined in the last few years, the US still spends the most on prescription drugs than any other advanced industrial nation (Mikulic 2021). This section will examine what role PBMs have at increasing drug prices in the US.

PBMs Role in Higher Drug Prices

There have been numerous studies to determine whether there is any merit to pharmaceutical manufacturers' claim that PBMs are the cause behind increasing drug costs in the US. These studies have primarily analyzed manufacturer's rebates and have neglected to review other transaction costs and mark-ups. Given the

complex and round-about nature of US health care in general, it is difficult to determine exact cause and effect. However, a 2018 study analyzed the purchase, distribution, and payment of prescription drugs throughout the US supply chain. The authors' analysis provides estimates of the revenue retained by each actor in the process (Atteberry, Bach, and Yu 2018).

Developing a consistent and reliable dataset on estimated prescription drug spending can be difficult because the data collected from various government agencies and private research firms have varying criteria for what they consider in their measurements. Therefore, the authors of the study used five different datasets and logged what each dataset measured, and compared the dataset's total estimate of expenditures to others. Using financial disclosures and third-party market data, the authors were able to quantify the overall market size based on retained revenues of the supply chain participants (Atteberry, Bach, and Yu 2018).

The study's results offer a striking conclusion, of the $480 billion estimates for gross profits in the entire prescription drug supply chain, pharmaceutical manufacturers' share is close to 67%, with the rest divided between wholesalers with 4%, pharmacies with 15%, providers and hospitals with 7%, insurers with 2%, and lastly PBMs with only 5% (Atteberry, Bach, and Yu 2018). It would appear that PBM companies themselves do not make nearly as much money compared to pharmaceutical manufacturers. Even if we consider the vertical integration between PBM companies, pharmacies and insurers, the total does not even reach 25%. While PBM companies are vilified by pharmaceutical manufacturers, it is the drug

manufacturers who are profiting the most off the current system. This intuition can be observed by two data sets that analyze the proportion of branded versus generic prescription drug revenues in the US and the proportion of branded versus generic drug prescriptions dispensed in the US over the last 15 years.

Revenues for generic and branded drugs have stayed relatively consistent over the last 15 years, where generic drugs comprise anywhere from 10-15% of revenues and branded drugs accounting for 70-80% of revenues. However, the proportion of branded drugs dispensed has fallen from about 40% in 2005 to only 10% in 2018 (Statista 2020). Therefore, we are forced to conclude that pharmaceutical companies are increasing prices for their branded drugs to maintain their record-high profitability (Porter 2021, 2).

The rebate system between PBMs and pharmaceutical manufacturers helps facilitate this trend of increasing prices for already high-priced branded drugs as PBM companies receive a percentage of the rebate based on the drug's price. PBMs who accept pharmaceutical manufacturers' rebates claim they pass along the savings to insurers which are intended to be shared with enrollees. However, from the 2018 Atteberry, Bach, and Yu study, the insurance company is not receiving much profit from prescription drug claims. Recall insurance providers only receive 2% of the revenue share in 2016. Additionally, to counter the claim by PBMs that they pass rebates through to insurers, it has been documented that many small health insurance providers and employers claim that they do not receive any of the

savings from rebates when contracting with larger PBM companies (Commonwealth 2019).

PBMs Role in Reducing Pharmacy Access

Recently there has been a flurry of legal and legislative actions meant to reign in drug costs with a specific emphasis on PBM companies. In December 2020, the US Supreme Court ruled unanimously that states can regulate PBMs operating in their jurisdictions. The suit was filed on behalf of 45 states and independent pharmacies who claimed that PBM companies kept reimbursement rates low for generic drugs, which have resulted in the closure of thousands of small independent pharmacies, particularly in rural areas. The ruling allows states to regulate the rates at which PBM companies can reimburse pharmacies (Wolf 2020).

This decision by the US Supreme Court is an encouraging sign that more market transparency regarding the operations of PBMs and their rebates schemes will lead to cost reduction in the private prescription drug market. With the passage of the Patient Protection and Affordable Care Act (ACA), new rules dictated PBM transparency when dealing with state and federal health plans. Additionally, in 2016 the CMS mandated that Medicare Part D plans and their administering PBMs must provide all contracted pharmacies the reimbursement rates for drugs under the maximum allowable cost (MAC) program (Hoffman-Eubanks 2018). As a result of these transparency mandates by the federal government, the CMS has seen drug

prices decline in their Part D plans over the last three years (Commonwealth Fund 2019).

Chapter Four: Conclusion and Policy Recommendations

This research sought to answer the question of what role do PBMs have on drug prices in the US. After analyzing of the pharmaceutical and PBM markets through an SCP framework, we can conclude that the main driver behind the US' high per capita costs for prescription drugs is derived from expensive brand-name medications. The claims made by drug manufacturers who assert that PBMs are forcing them to increase drug prices to pay for the rebates do not appear accurate. Empirically, drug manufacturers generate most of the prescription drug supply chain revenue, specifically through expensive brand name medications, while simultaneously reporting record-high profits (Atteberry, Bach, and Yu 2018), (Porter 2021, 2). If PBMs were the cause behind persistently high drug prices for brand-name medications, we should not expect record-high profits for drug manufacturers. Moreover, we would expect PBMs' share of the revenue generation in the prescription drug supply chain to be much more than 10%, especially compared to the 67% share by drug manufacturers (Atteberry, Bach, and Yu 2018). Therefore, drug makers claim that PBMs are the cause behind increasing drug costs seem spurious.

However, PBMs are not innocent either. Their claim that rebates are channeled to health insurers and consumers in the form of savings also appears to be bogus. As health insurance premiums increase in the US, more consumers opt to enroll in high-deductible health plans to avoid expensive monthly premiums. It is estimated that in 2019, 51% of the workforce is enrolled in a high-deductible plan, the highest it has been in five years (Price 2021). Under a high deductible plan, the cost of expensive medication regimens is shifted towards the consumer, or in the case of government health plans, the taxpayer. In 2017, it was estimated that insurance companies only paid for 42% of the cost for prescription drugs while together consumers, state, and federal governments paid nearly 54% (Cubanski, Rae, Young, and Damico 2019). If PBMs were creating savings for consumers through drug manufacturer's rebates, we should expect premiums and the proportion of high deductible plans to decrease, not increase.

What does appear to be happening in the US prescription supply chain is that US drug manufacturers are unilaterally increasing drug prices to meet quarterly revenue projections to maintain stock prices for their investors (US House Oversite Committee 2020, 4-5). Almost equally important is the absence of the prescription drug supply chain's price control mechanism, the PBM, and the purpose of the formulary. PBMs were designed to control costs by leveraging enrollee buying power to negotiate discounts on prescriptions and utilize generic substitution of more expensive brand name medications. However, the industry practice by PBMs of withholding a percentage of the negotiated rebate engenders a conflict of interest

between the PBM and health plan enrollees. As PBMs are incentivized to favor higher-priced medications over less expensive alternatives (Commonwealth Fund 2019). While drug manufacturers are the cause behind increasing drug costs, PBMs are being all but being bribed from enforcing reasonable price controls on medications through the formulary-rebate scheme.

Limitations of SCP and its Conclusions

PBM market concentration is often cited as a significant cause of increasing drug costs in the US (Carrier 2018). As PBMs have consolidated and become vertically integrated, drug prices have gone up. The straightforward conclusion is to break up PBM concentration and expect drug prices to become lower. However, this analysis is predicated heavily on the importance of market concentration and is ultimately misguided. Using the SCP framework to analyze the PBM market, we could come to the traditional conclusion that PBMs are leveraging their market control to extract higher profits from drug manufacturers. On the contrary, empirically, we see the opposite. Drug manufacturers, whose market was determined to be much more competitive, leverage their patent monopolies to extract record-high profits (Porter 2021, 2).

This discrepancy highlights the difficulty in evaluating the importance of specific market competition parameters such as market concentration or barriers to entry on the overall analysis. In this case, patent monopolies are a more critical factor in determining market power than firm concentration. Additionally, the SCP

framework does not help explain how the industry has developed over time and provides little predictive capabilities of future changes. The importance of the market competition parameters is largely unknown and constantly changing.

Therefore, any public policy meant to increase competition among PBMs through antitrust legislation may prove to be less effective in the long run as these measures are ultimately predicated on a single assumption that competition will reduce drug prices. As we have seen in the past, when the FTC successfully forced drug manufacturers to divest their ownership of PBMs, drug prices were expected to fall. However, other agents in the prescription drug supply chain who avoided FTC scrutiny, health insurers, and pharmacies began to successfully vertically integrated PBMs into their business structures. While drug prices continued to increase, most of the revenue generation did not go to the oligopolistic vertical integrated firms like SCP would predict, but rather to drug manufacturers who had been forced to divest their PBM businesses. Calling into question the assumption that market competition reduces prices and giving credence to the critique of SCP that is difficult to determine the respective importance of various market competition parameters.

As such, any regulation that is meant to increase competition is effectively a one-time static solution. In contrast, firms in free-market competition are dynamic and are allowed to develop alternative business strategies to circumvent any fixed policy solution. Subsequently, regulation based on increasing competition is relatively limited and ineffective as firms will navigate around any business

impediment just as drug manufacturers began to rely more heavily on their monopolies over brand name medications to generate their revenue and exploit the formulary-rebate scheme to side-step any oversite by PBMs.

Policy Recommendations

Leaving the production and allocation of prescription drugs to free-market competition is a never-ending cat-and-mouse game where private firms accrue market power over their competitors and exploit imperfect market competition to the extent that government regulation is required to 'correct' market imbalances. The new set of rules establishes a temporary status quo among firms. To become only then exploited by a new entrepreneurial firm or business strategy requires another round of government regulation.

If the US is serious about controlling drug prices, then the federal government should heavily regulate the health insurance and drug manufacturing industries and implement tight price controls for prescription medications. Such measures would have to be so extreme as to ensure that firms cannot innovate their way out of regulations and would need to be implemented in such a way to affect all participants in the prescription drug supply chain. Therefore, the US should implement a German or Swiss-style multi-payer system where health insurance is mandatory, insurers are non-profit, and all participants in the prescription drug supply chain are tightly regulated (Department of Professional Employees 2016).

Under a Swiss system, responsibilities to manage the health care system are divided among federal, provincial, and municipal authorities. The federal government regulates financing, ensures the quality and safety of pharmaceuticals and medical devices. While provincial governments are responsible for licensing providers and insurers, coordinating hospital services, and subsidizing individual premiums. Municipal governments are responsible for organizing and providing long-term care and social support services for vulnerable populations. The entire system is funded through enrollee premiums, provincial taxes, social insurance contributions, and out-of-pocket payments. (Tikkanen et al. 2020).

There are three aspects to the Swiss system that the US should implement. The first is universal coverage. Individuals without medical insurance are more likely to go to work even when sick, prolonging pandemics, reducing productivity, and increasing healthcare costs for all (Harbage and Furnas 2009). Additionally, a universal mandate would eliminate the issue of paying the higher costs associated with the uninsured who utilize emergency services more often due to the lack of access to preventative care (Tikkanen et al. 2020). The second aspect the US should implement is non-profit health insurance via sickness funds which are used to pay physicians and hospitals at uniform rates (Tikkanen et al. 2020). Having insurance be non-profit and managed by state governments would significantly reduce health care costs as the motivation for providing health insurance would provide affordable health care services for the public and not generate profit at the expense of enrollees. Lastly, the US should heavily regulate health insurers and drug

manufacturers to ensure drug prices are kept in check. In Switzerland, the Federal Office of Public Health is the primary national regulator and is tasked with setting price controls to include insurance premiums, pharmaceuticals, and medical devices (Tikkanen et al. 2020).

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