An Analysis of The Drug Pricing System in the United States

STS Research Paper
Presented to the Faculty of the
School of Engineering and Applied Science
University of Virginia

By

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May 13, 2021

On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

At just three years old, doctors diagnosed Jack Hogan with Duchenne Muscular Dystrophy (DMD), a genetic disorder characterized by progressive muscle degeneration and weakness. By age 7, Jack was wheelchair bound and struggled to hold his head up on his own. By 12, Jack's respiratory and cardiac systems were severely comprised. With the help of corticosteroids and anti-angiotensin enzyme inhibitors to prevent muscle degradation and heart damage, his condition began to stabilize. In late 2018, doctors informed Jack's parents of a newly approved gene therapy for DMD called golodirsen that could address the mutation in Jack's dystrophin gene that caused the disease. This new gene therapy could reverse the effects of Jack's genetic mutation, addressing the cause of his medical issues rather than the symptoms. However, with an annual price tag of $300,000, and Jack's condition relatively stable, his parents decided to delay the use of the therapy until the need was more dire. Unfortunately, on March 31, 2019, Jack's lungs suddenly failed in his sleep. Without any prior indication that his health was worsening again, Jack passed away at just 14 years old.

Like Jack's family, so many Americans must factor cost into the decision to use a potentially live saving drug. Unfortunately, these decisions are not limited to Americans who require rare specialty drugs. In a 2017 issue brief, the Commonwealth Fund reported findings that the United States pays significantly more for the same prescription drug than any other country studied. The American drug pricing system is extremely complex, with two to four 'middlemen' between the drug manufacturer and the patient (Glied, 2020). Each of these middlemen may sell the drug for a price higher than their acquisition cost in order to turn a profit. Despite government intervention to reduce the impact of these middlemen, there has been a constant increase in prescription drug prices for decades. The healthcare systems of the United States foster environments where profit supersedes patient health, more so than any other developed country.

This paper seeks to determine which political and economic factors fostered the rapid growth of prescription drug prices in the United States.

Current Drug Pricing in the United States

New medications, such as golodirsen, rely on millions of dollars in general research, development, and technological advancement, and enter markets without any reasonable competition. Sarepta Therapeutics, who obtained FDA approval to manufacture and sell golodirsen in 2019, estimated the average annual cost of the therapy to be about $300,000 per patient (Figueiredo, 2019). Because the medication is a therapy and not a cure, this is an annual cost for every DMD patient's lifetime. According to the 2019 Census, the cost of golodirsen is approximately 336% higher than the median household income in the United States (U.S. Census Bureau, 2019). With price tags this high, many Americans must decide between life-saving medication and necessities like food and housing. Furthermore, evidence suggests that companies are listing new, introductory drugs at prices much higher than would be required to make profit (Waxman, 2020). Thus, the money spent by American to save the lives of their loved ones pads the pockets of the drug manufacturers and the middlemen.

While specialty drugs are introduced at extremely high prices, this price gauging seems to be occurring across the pharmaceutical industry. Americans face rising prescription drug prices for commonplace drugs already on the market, as "the median net cost of the 49 highest-volume brand drugs increased 76 percent between January 2012 and December 2017" (Waxman, 2020). Net price growth has been significantly above inflation for all brand name drugs in recent years (Aitken, 2015). As prices for prescription drugs continue to rise, under- or uninsured patients are faced with higher and higher copays that are often unaffordable. In a 2017 issue brief, the Commonwealth Fund reported findings that the United States pays significantly more for the same

prescription drug than any other country studied. Due to these unreasonably high prices, Americans are more likely to leave a prescription unfilled than a citizen of nine other high-income countries (Glied & Zhu, 2020). The drug supply chain is facing growing pressure from citizens and the federal government to restructure, but any change could result in higher drug prices or higher insurance premiums (Entis, 2019).

In order to fully understand the price of prescription drugs in the United States, one must first understand the distribution channels through which patients receive their prescriptions. There are a significant number of steps, and the chain is illustrated in Figure 1 below. By following the flow of drugs, it appears that manufacturers sell to wholesalers, wholesalers to pharmacies, and pharmacies to patients. However, other entities influence the price of these sales. Pharmacy Benefits Managers (PBMs) lie at the center of drug distribution channels. They are responsible for developing lists of covered medications, negotiating rebates from manufacturers, and reimbursing pharmacies for dispended drugs (Seeley & Kesselheim, 2019). Thus, the flow of money through the distribution channel is far more complex than the flow of drugs. While PBMs' negotiating power provides them the opportunity to slow price growth through the use of rebates, they are also incentivized to favor high-cost drugs over ones of better value. Additionally, the rebates and discounts make for an exceedingly complex system that most citizens cannot understand. To understand how and why PBMs have come to hold such a vital role in the drug distribution and pricing system, the Social Construction of Technology will be used to understand the benefits to each of the key stakeholders.

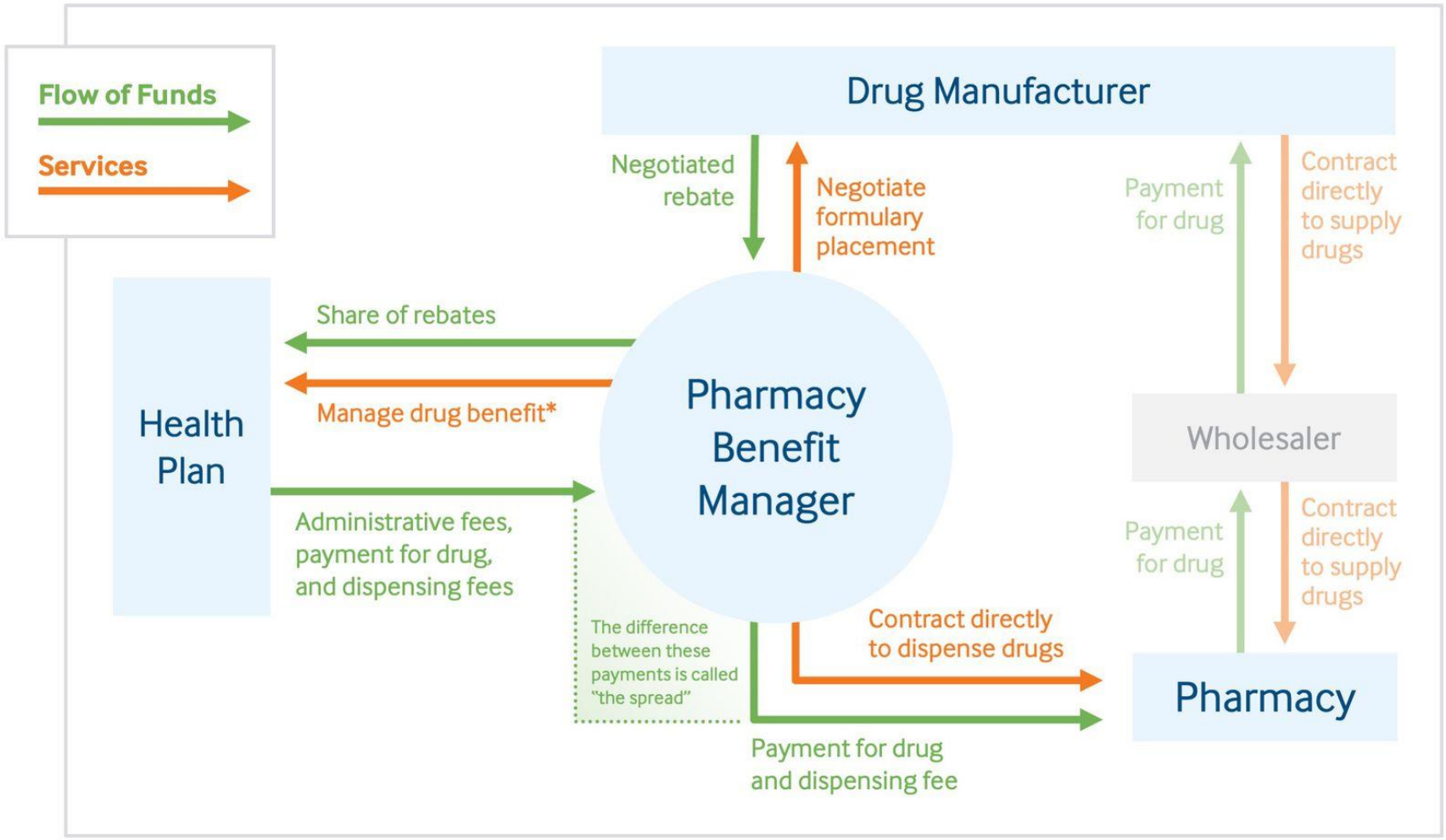

Figure 1. The current drug distribution and pricing system in the United States. Drugs flow from drug manufacturers to wholesalers to pharmacies to patients. The flow of funds is much more complex, as money flows in and out of PBMS to each unit of the system. (Image Source: Seeley, E. & Kesselheim, A.S. 2019)

Social Construction of Technology Framework

The Social Construction of Technology (SCOT) framework will be used to analyze the impact of the different institutions in the drug distribution chain on the list price of prescription drugs. SCOT emphasizes the role of social groups in the development and use of technology. Social groups are defined as institutions, organizations, and organized and unorganized groups of individuals that share values or meanings as attached to a technology (Pinch & Bijker, 2008). I will study the key social groups United States (U.S.) residents, private health insurance companies, the federal government, PBMs, and large pharmaceutical manufacturers and how the interaction between these groups has led to the current drug pricing system.

I will examine proposed solutions to the issue and how these solutions impact different social groups, offering an explanation of why potential solutions have not yet been employed. The multidirectional model, as proposed by Pinch and Bijker (2008) will be used to understand how different stakeholders view different issues surrounding the pricing of drugs. The multidirectional model works to explain how social groups, problems, and potential solutions to those problems are related. This understanding can then be used to determine why certain technological artifacts survive while others do not. An initial visualization of this system is shown in Figure 2. I can then analyze the potential solutions to different issues to understand how the current system addresses or fails to address these issues. In doing so, I aim to determine why certain social group's interests prevailed over others and offer solutions that address the needs of each social group in a manner that does not result in unreasonably high prices for patients.

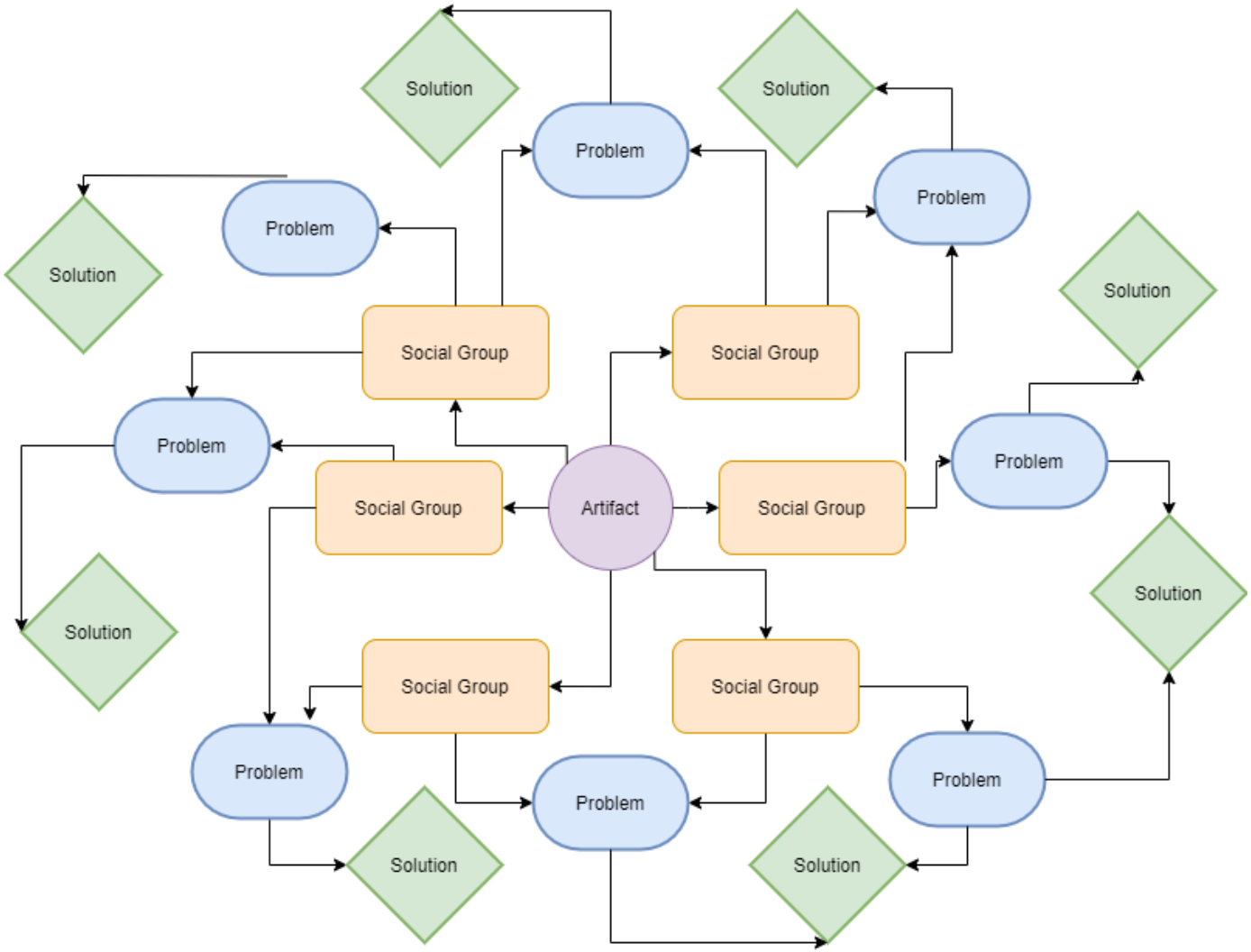

Figure 2. A visualization of the multidirectional model as proposed by Pinch and Biker. Different social groups interpret artifacts differently, and thus see different problems with that artifact. Different problems require different solution. The power and influence of the different social groups influence which solutions are adopted. (Image Source: Barton 2019)

Research Question and Methods

This paper seeks to determine which political and economic factors have fostered an environment that allows for the continuous growth of prescription drug prices in the United States to propose solutions that make prescription drugs more affordable for the average American. The analysis will focus on the impact of the government, major pharmaceutical manufacturers, PBMs, and health insurance companies on the determination of drug prices. The question to be answered here is: how have these major institutions in the pharmaceutical industry impacted the rapid growth of drug prices in the United States? Think tank reports and prior literature will be studied to gain an understanding of the current pricing system. Two case studies offer evidence to help address this question.

The first case study examined the price of human insulin over time and determined how government intervention has or has not been successful in regulating the price of a prescription drug used by 7.4 million Americans (Cefalu et al, 2018). The pricing model of insulin was examined in depth, providing evidence of how private insurance can leave many Americans without means to afford basic life-saving medication (Glied & Zhu, 2020). Government action and inaction in the market was analyzed to understand the government's role in the price of insulin. This analysis determined the most powerful social groups in the pricing of insulin.

In contrast, the second case study focused on orphan drugs, or specially designated drug products that treat rare diseases. Because the diseases these drugs treat are rare, their development would not typically be profitable as the market for the drugs is too small. Therefore, the United States government provides tax breaks and other incentives to produce these drugs. However, pharmaceutical companies have taken advantage of the financial incentives (America's Health Insurance Plans, 2019). I examined how and why intervention by the United States government failed in this case. This case also offered insight into how drug

companies establish prices for drugs with little to no competition. By understanding how these list prices are determined, I offer solutions that would successfully combat unnecessarily high list prices.

Perhaps the most interesting difference in these two cases lies in the way drugs are priced. Insulin is becoming less affordable over time due to changes in the price, while orphan drugs are introduced at unaffordable prices. These cases were chosen to explore this major difference. Due to the complexity of the system, each social group may have a very different role in the different processes. In order to ensure affordability, issues in both channels must be understood and addressed. Each case study was analyzed to understand the prominent social groups and stakeholders, the issues these social groups deem important, and the current and potential solutions to these issues. Think tank reports, government documents, and prior literature was used to understand the cases and the drug pricing system as a whole. The multidirectional model was employed to understand how the interests of each social group and their interactions impact the current system. Because the pricing model of insulin and orphan drugs fundamentally differ, the multidirectional models for each case include unique problems and solutions. These models were compared to find commonalities between the systems so that any proposed changes to the system adequately address all problems rather than focusing on one specific channel.

Results

First, the development and origins of PBMs were examined to understand how third parties rose to relevance in the drug pricing system. In the 1960's, health insurance companies began covering prescription drugs. Initially, patients would purchase their prescription drugs from a pharmacy and file a paper insurance claim for the cost of the drug. Health insurers were faced with a high volume of low value claims that were all individually processed (Strongin,

2019). Furthermore, many different drug manufacturers produced biosimilar products to treat the same ailments. Thus, manufacturers had to convince thousands of individual doctors or health systems to prescribe their drugs. Figure 3 shows the simple multidirectional model of the drug pricing system at the time.

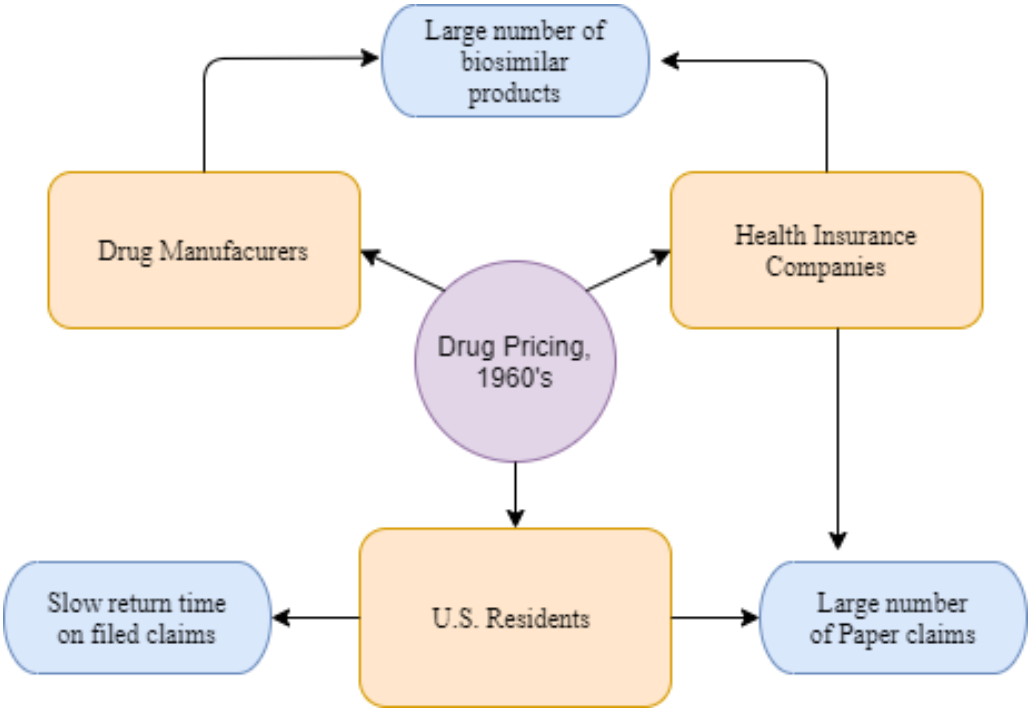

Figure 3. A simple model of the drug pricing system in the United States in the 1960's. Multiple problems existed, and solutions to those problems had not yet been developed. (Image Source: Barton 2021)

PBMs originated in the early 1970s to streamline the prescription drug process. Pharmaceutical Benefit Management was the *solution* to the major problems in the drug payment process in the 1960's. Patients no longer had to file paper claims, and insurance companies left the processing of prescriptions to the PBMs. When similar brand-name drugs existed, PBMs would select one to the lists of drugs they would be willing to cover, called formularies. Insurance companies that employed PBMs could only offer coverage on these selected drugs. Drug manufacturers could now focus on negotiating with PBMs, who often represented multiple insurance companies, to

ensure their drugs would be prescribed. As PBM's grew, however, they became one of the largest social groups involved in the pharmaceutical pricing process.

The multidirectional models for insulin and orphan drug pricing can be seen in Figures 4 and 5, respectively. In both cases, the U.S. government regulates the activity of each social group, and as such is the most powerful social group in the system. However, drug manufacturers and pharmaceutical benefit managers spend millions of dollars each year on lobbies to influence the federal government. As such, these two entities hold the greatest power in the system, despite the fact that the government *should* act in the best interest of the American public. Government action has largely failed because of the heavy influence of social groups who benefit at the expense of the public. The power in both systems lies with social groups that share little to no common problems with U.S. residents. As such, both models reveal that the current drug pricing in no way addresses the problems of the American people. Instead, the problems of large corporations are considered and remedied, often at the expense of U.S. residents. The models differ due to the power structure in each system.

Insulin

With about 7.4 million Americans using it each year, insulin is one of the most commonly prescribed drugs in the United States (Cefalu et. Al, 2018). This has not prevented drug manufacturers from raising its list price, as the average price on insulin nearly tripled from 2002 to 2013. In more recent years, the list prices of newer, more effective forms of insulin have increased by an average of 15 to 17% each year (Hua et al, 2016). These price increases have serious consequences for those who use insulin, as at least 4 Americans have died each year for the last 4 years while trying to ration their insulin (Popken, 2019). The Federal and State

Governments have taken action to attempt to keep the price of insulin affordable, but prices continue to grow.

U.S. residents face more problems than any other social group in the insulin pricing system, as shown in Figure 4. However, very few of these issues are shared by other social groups. In fact, the solutions to problems faced by manufacturers and PBMs often result in problems for U.S. residents. Because PBMs have focused on common drugs like insulin, the rebates manufacturers pay to PBMs continue to grow, with no guarantee that the benefit of these rebates reaches the American people. In turn, manufacturers raise the list price of insulin to ensure a profit. Both PBMs and manufacturers benefit when more expensive forms of insulin are used, causing undue financial stress on patients who could be treated by cheaper versions of the drug. The model reveals that the problems faced by the public have largely been ignored and left unaddressed because their interests contradict the interests of the more powerful social groups.

Insulin was first introduced in 1923, so one might assume that most insulins are generic and no longer under patent. However, continuous innovation in the industry has led to renewal of patents. Drug manufacturers claimed that the short patent period caused them to introduce new innovations at very high prices to ensure a comfortable profit margin before the patent expiration. Thus, the U.S. Government has extended existing patents and granted new patents for minor technological advancements (Rajkumar, 2020). These extended patents have allowed 3 companies to maintain a virtual monopoly over the market: Eli Lilly, Novo Novartis, and Sanofi. These three companies produce various types of insulin, but very few are true competitors as they address different needs, age ranges, and conditions. The lack of biosimilars frees the companies to sell each of their products at essentially any price (Hua et al., 2019). While price

gauging has long been a conversation at every level of government, the Federal government has taken little action to reduce its impacts.

PBMs, who claim to be the general public's "advocates in the healthcare system" (Pharmaceutical Care Management Association, 2021), have focused on getting rebates from the three major players in the insulin market. In fact, *Eli Lilly pays more in rebates to PBMs than they make in profit each year (*Weinstein & Schulman, 2020). PBMs claim that these large rebates get passed on to the consumer through their health insurers, but the lack of transparency in the system makes it nearly impossible to verify. Furthermore, there is evidence that suggests rising rebate rates correlates strongly with rising list prices (Seeley & Kesselheim, 2019). Demanding higher rebates may actually harm the patient, as co-pays for insured patients are sometimes determined as a function of list prices, while uninsured patients must always pay the full list price. More comprehensive insurance coverage, where co-pays and out of pocket costs are limited, would protect insured Americans from high list prices. However, those that struggle to pay for insulin cannot afford to purchase more comprehensive coverage. Medicaid patients have access to similar formulations as privately insured individuals and rarely pay significant out of pocket costs, but many Americans who struggle with high insulin prices still do not qualify for Medicare. According to a study by Sherry Glied and Benjamin Zhu, continuing the expansion of Medicare may be the most effective way to protect Americans from rising out-of-pocket costs (2020).

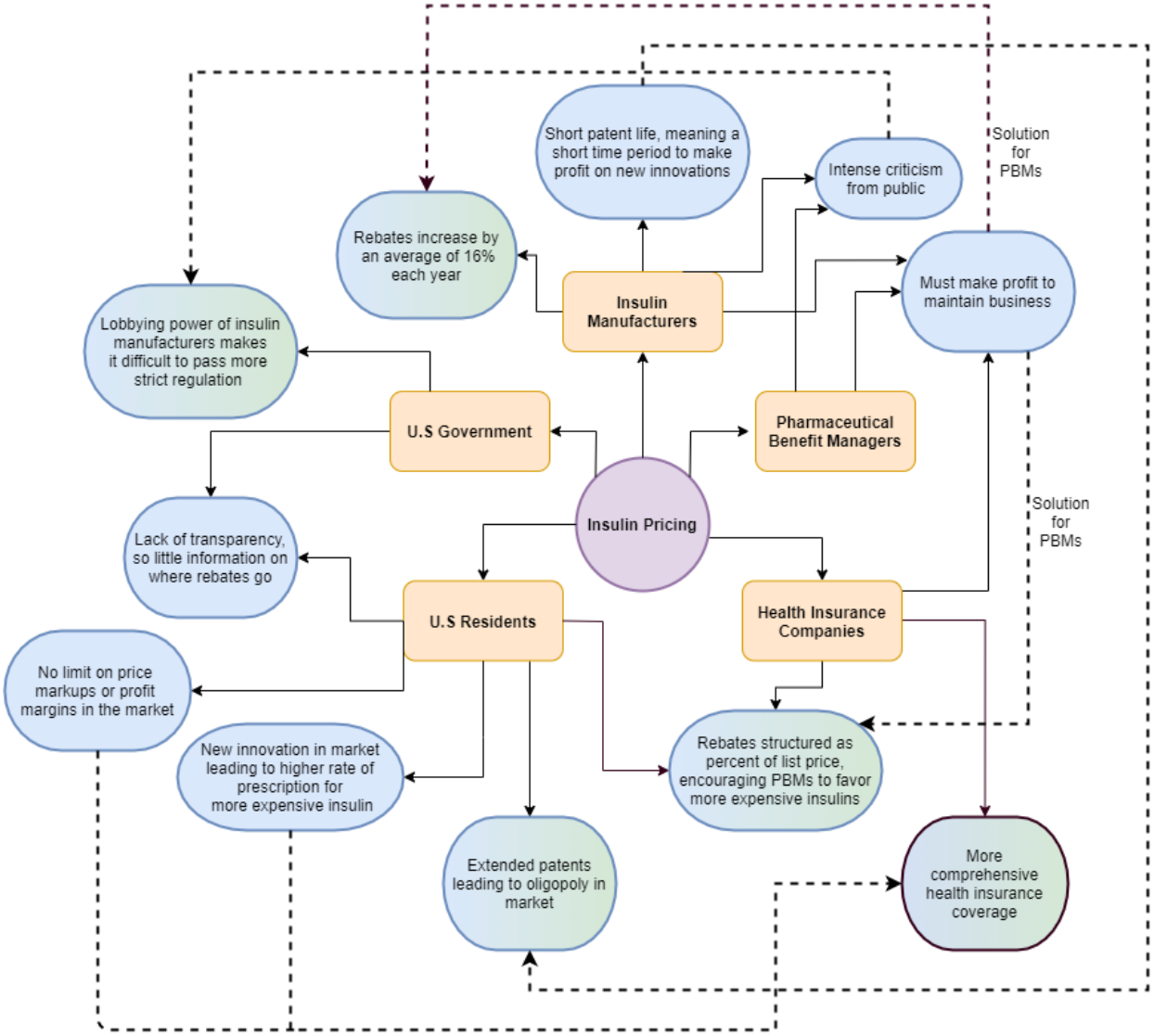

Figure 4: Multidirectional Model for the current Insulin Pricing system. Orange Rectangles represent social groups and blue ovals represent problems. Ovals that are both blue and green represent solutions for one group that causes a problem for another. Solid lines connect social groups to the problems they face. Dotted lines connect problems to their current solutions. All current solutions also create issues for other groups. U.S residents face more issues than any other social group. PBMs face fewer issues that any other social group. Drug Manufacturers and PBMs do not share any common problems with U.S. Residents. (Image Source: Barton, 2021)

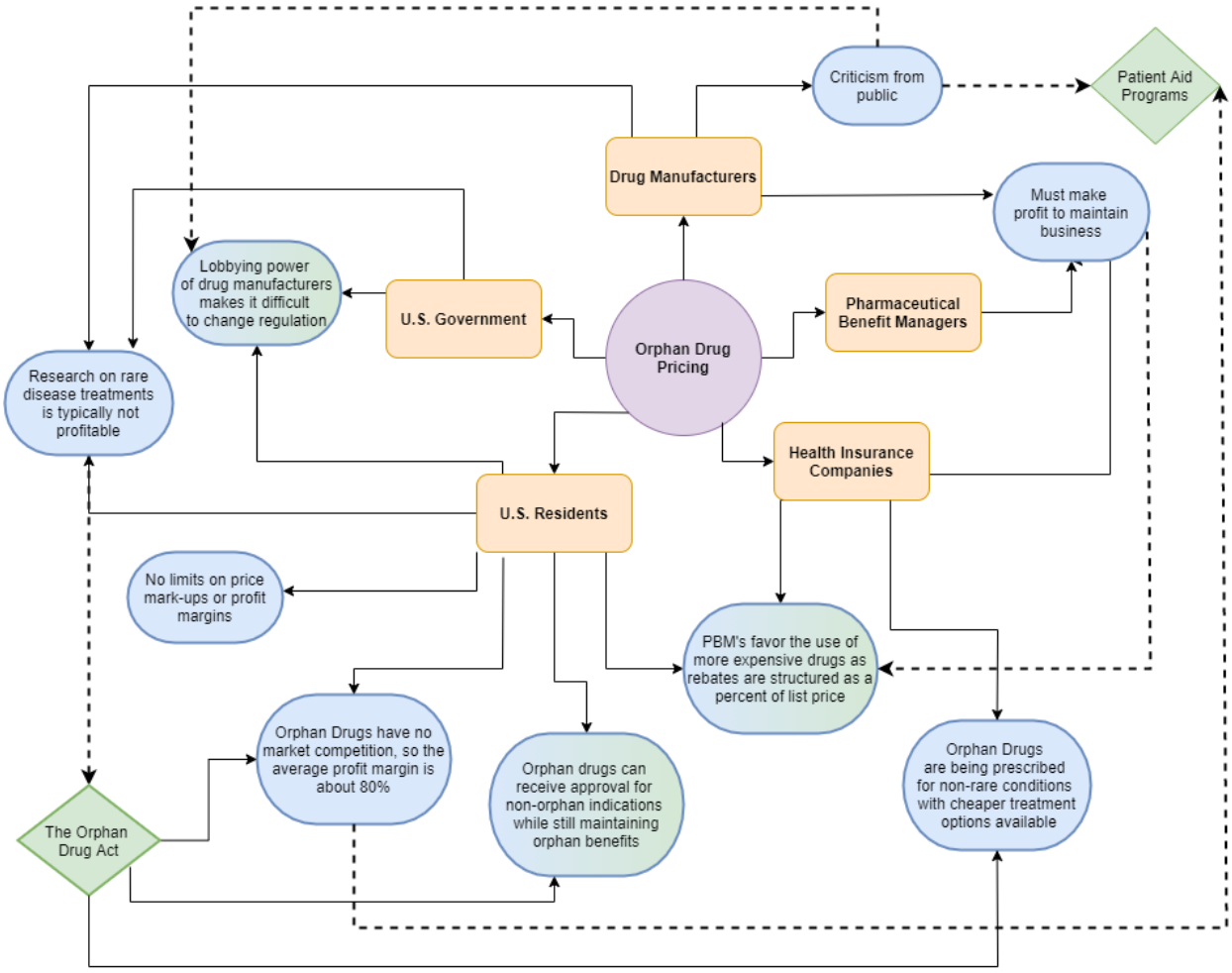

Figure 5. Multidirectional Model for the price of Orphan Drugs in the United States. The key is the same as above. The most powerful institution in the market, drug manufacturers, shares only one common problem with the public. The lack of research on rare diseases has been addressed, but the solution has created even further problems for the American public. Because many proposed solutions to the issues faced by the American public are not shared by manufacturers, they have largely been unaddressed. Because the only current solution relies solely on the charity of large companies, it is not long-term solutions to every issue. Many Americans will still be forced to pay extremely high prices for life-sustaining medications. (Image Source: Barton, 2021)

Orphan Drugs

The multidirectional model for orphan drug pricing is shown in Figure 5. Again, U.S. residents face more issues than any other social group in the system. PBMs' role in the orphan drug pricing system differs notably from their role in the insulin pricing system. Because these drugs are rarer and used by a smaller portion of the American public, PBMs have exerted less effort in this market. Thus, the power in this system lies almost solely with drug manufacturers. Manufacturers are then free to set prices as they wish, often with profit margins of over 80%. The only common issue between manufacturers and U.S. residents, the lack of research on uncommon diseases, has already been addressed. Its solution, unfortunately, has generated a plethora of other issues for the public. Because solutions to the root causes of resident's issues would negatively impact the profits of manufacturers, the solutions will not be implemented.

In 1983, the U.S. government passed the Orphan Drug Act to encourage the development and manufacture of treatments for diseases that impact less than 200,000 Americans. Because the patient pool for these drugs is relatively small compared to other pharmaceuticals, drug companies saw the market as unprofitable, so very little research had been done on prospective treatments. The act provided the following incentives to pharmaceutical companies (The United States Food and Drug Administration, 1983):

1. *Tax credit for 25% of expenses related to clinical trials.*
2. *Waiver of FDA application fee for the drug.* Pharmaceutical companies are typically charged a fee when submitting a drug for approval from the FDA. In 2018, these fees total $2,421,495 for applications requiring clinical data, and $1,210,748 for applications not requiring clinical data (Prescription Drug User Fee Rates for Fiscal Year, 2018).

3. *Market Exclusivity for a 7-year period after approval.*

These incentives allowed pharmaceutical companies to actually gain returns on investment in rare disease research. This rare disease research as proved invaluable, as more knowledge on the causes of these rare diseases can translate into a deeper understanding of the function of the human body, and a more robust knowledge base for treating both common and rare diseases (Institute of Medicine Forum on Drug Discovery, 2009). Gene therapies, for example, owe much of their development and success to the orphan drug program. Many consider the act successful as over 326 orphan drugs were approved in the first 25 years of the program, and the scientific advancement behind these drugs would not be possible without the Act (ibid).

However, pharmaceutical companies can abuse the orphan drug program. There are currently a number of drugs on the market with orphan designations that physicians commonly prescribe for non-rare diseases. As pharmaceutical companies did more research on rare diseases, they developed products that could in fact treat rare diseases, but could also enter more lucrative markets. When seeking FDA approval, companies can seek orphan indication, guaranteeing tax cuts, waived fees, and market control for the drug. Companies can ask the FDA for a second or third indication for the drug, which allows the company to market the drug for a different use, most likely for a much more common disease or ailment. Pharmaceutical companies can ask for orphan designation during any round of new indication approval, so drugs that are first approved for a mass market can later receive orphan status, and vice versa (Padula et al., 2020). Drugs do not often differ in price regardless of indication, so partial-orphan drugs are still sold at extremely high prices.

Humira, for example, was originally approved for the treatment of Rheumatoid Arthritis, which impacts millions of people in the United States. Abbvie, Humira's manufacturer, sought a

secondary indication for juvenile rheumatoid arthritis, which only impacts about 50,000 Americans. Since then, Humira has gained 4 more orphan-status indications, extending its patent until 2023 (America's Health Insurance Plans, 2016). Because of this patent extension, no company can produce a generic version of Humira for any indication, leaving millions of Americans with costly prices to treat an extremely common disease. Due to protections under the Orphan Drug Act, Humira costs about $69,295 per patient per year, even though less than 10% of its prescriptions are for orphan use (America's Health Insurance Plans, 2021). Abuse of government programs like this allow for high profit margins for drug manufacturers at the expense of U.S. residents.

Discussion

While the drug pricing system was relatively simple in the 1960's, the generation of formularies gave large PBMs an unprecedented amount of power to negotiate with drug manufacturers (Seeley & Kesselheim, 2019). If PBMs decide to not add a drug to their formulary, the number of patients with access to the drug decreases greatly. To ensure their drug gets prescribed, drug manufacturers will offer PBMs substantial rebates on drug prices to ensure as many people as possible have access to their drug. PBMs will then share a portion of this rebate with health insurers, which should decrease the patient's co-pay. Today, the drug pricing system centers around these rebates. Drug manufacturers set prices and otherwise operate knowing they will offer substantial rebates to PBMs. This complicated and often confidential system is at least in part responsible for the rise in drug prices in the U.S.. Now, cases of insulin and orphan drugs will be used to demonstrate this responsibility.

Insulin

Clearly, U.S. residents are faced with more problems than any other social group in the system. Furthermore, no social groups face more than one problem in common with U.S.

residents. Notably, PBMs and manufacturers have no common problems with U.S. residents. Furthermore, current solutions to the problems faced by both drug manufacturers and PBMs create further problems for U.S residents. Both PBMs and Drug Manufacturers spend large amounts of capital each year lobbying the government to protect their interests. Thus, laws that would protect U.S. residents from high drug prices are extremely difficult to pass because they would negatively impact the profit margins of drug manufacturers and PBMs.

In a system meant to deliver life-saving medication to U.S. residents, U.S. residents have the least amount of power to change the pricing process. Instead, private corporations that benefit financially from high list prices have controlled the insulin pricing system. Because these institutions hold the most power, the solutions to their problems are implemented much more rapidly than solutions to problems faced by the American public. The model displays the lack of connection between patients and powerful organizations. Concrete government action would be the most comprehensive solution to many of the issues faced by the American public (Waxman et. Al, 2020). Table 1 lists examples of regulations on PBMs and drug manufacturers that would likely impact list prices directly. Each of these regulations would in some way prevent large corporations from unjustly profiting off necessary life-preserving medication.

Table 1: Potential Solutions in the insulin pricing system, and the social groups that would be benefitted or harmed by these solutions. (Source: Barton, 2021)

Potential Solution	Social Group Harmed	Social Group Benefitted
Patent Reform	Large Manufacturers	U.S. residents, Small Manufacturers
Non-Profit Manufacturing	Manufacturers, PBMs	U.S. residents
Legal Maximum Mark-Up	Manufacturers, PBMs	U.S. residents
Public Rebate Information	PBMs	U.S residents, U.S. Government
Regulation on Price Increases	Manufacturers	U.S. residents

However, lobbyists of drug manufacturers and PBMs reduce the ability of the government to take this sort of drastic action. As long as the government is tied closely to PBMs and manufacturers, little will be done to address the root cause of high insulin costs. Instead, the government can expand Medicare and other means of public insurance so fewer Americans are exposed to increasing list costs. Improvements to insurance coverage will not reduce the number of issues in the system, but rather mask them so residents are no longer impacted by them, and insulin becomes widely affordable. Because the most powerful entities in this system, manufacturers and PBMs, do not have any common problems, U.S. residents are not properly represented in the model. The public's problems are not addressed because their problems do not impact the most powerful social groups influencing drug pricing.

Orphan Drugs

A multidirectional model for the pricing of orphan drugs in the United States can be seen in Figure 5. As with insulin, U.S. residents bear the burden of the problems in the system. The Orphan Drug Act itself solved a major problem for residents: the lack of medications and therapies for rare diseases. However, the abuse of orphan drug status by certain pharmaceutical companies has led to further issues, including profit margins exceeding 80% in the rare disease market (Phillips, 2019). To maintain the potential profitability of rare-disease research and development to pharmaceutical companies, no limits on these profit margins currently exist. Additionally, orphan drugs are prescribed to treat conditions that have other, cheaper treatment options, as PBMs encourage the use of these higher cost solutions by favoring them over other treatments on their formularies. This exposes a much larger portion of U.S. residents to the high costs of orphan drugs.

PBMs are much less significant in the pricing of orphan drugs, as the issue with these drugs tends to be high initial list price rather than increasing list price in response to increasing rebate rates (Hyde & Dobrovolny, 2010). Drug Manufacturers, thus, play the most significant role in maintaining unpayable prices. Once again, the most powerful player in the system shares no common problems with residents of the United States. However, general public pushback and action by patient advocacy groups, some drug manufacturers offer patient relief programs, in which they reimburse patients in need for the cost of the drug. While these programs are extremely beneficial and offer a partial solution to the issue, it only protects certain Americans who qualify for aid. Action by the government is the only reasonable way to protect the majority of U.S. residents from the high prices set by of drug manufacturers. Because the power in the system lies in the hands of these large companies, the interests of U.S. residents will not otherwise be protected. At the very least, government action can be taken to ensure that patients seeking life-saving medication do not pad the pockets of multi-million-dollar pharmaceutical companies. Increased public health insurance, such as Medicare, would likely shield patients from the cost of medications without impacting the incentives on pharmaceutical manufacturers. This ensures continued development of treatments for rare diseases, but could minimize the financial impact on U.S. residents.

Eliminating the Orphan Drug Act entirely should not be considered as an option. Overwhelmingly, the Act has successfully allowed for the generation of hundreds of treatments for rare diseases, including genetic disorders and cancers. The Act should be reworked, however, to ensure that orphan protections cannot be unfairly applied to drugs used to treat non-orphan conditions. New government regulations on orphan drugs with other indications could allow generics to be produced and prescribed for non-orphan ailments. These regulations will be met

with stark opposition from large pharmaceutical lobbies. In order to pass more stringent regulation, the government will have to overcome the influence of the most powerful entity in the system, which will prove difficult. Because large scale reform is difficult to implement, more robust healthcare is the most probably solution to protect the public from high drug prices. While action should be taken to prevent abuse of the Orphan Drug Act, it is much more likely that mitigative measures are implemented to protect Americans from that abuse.

Conclusion

The multidirectional models indicate that the needs of U.S. residents are largely ignored because powerful institutions do not face the same problems as residents, and can often benefit by worsening the public's issues. From this, two possible solutions arise, one more complicated than the other. To address the root cause of the issue, the power must be removed from the hands of PBMs and drug manufacturers. Both models reveal the contradictory nature of problems and solutions between these large corporations and U.S. residents. Only when this contradiction is resolved can the pricing structure be rebuilt in a manner that benefits the public. However, this large of a reform is highly unlikely, especially in today's divided political climate. Thus, a second solution is proposed: the implementation of public healthcare that shields the American public from high list prices and rising costs. Again, passing large reforms proves difficult in today's climate, but by ensuring the appeasement of large pharmaceutical lobbies, this type of solution is much more likely. Better health insurance coverage guarantees patient protection in both cases, whereas other solutions may only influence the insulin market or the orphan drug market individually. Overall, the most efficient solution at the moment only masks the issues to the consumers, but does not fix the root cause of extremely high drug prices. Until the most powerful social groups in the system reflect the needs of the public, the public's needs will not be fully addressed.

Social groups in the multidirectional model could be constructed differently to study the effects of different subsets of society. Further research could be done on the impact of the drug pricing system on insured and uninsured Americans. Uninsured Americans are disproportionately impacted by high list prices, and further models could be built that distinguish two social groups of U.S. residents: insured and uninsured. “U.S. residents” applies broadly to those living in the United States of America, as the health care system impacts all who seek medical treatment here. Future work could distinguish between citizens of the United States and non-citizens, as non-citizens are even less protected by the United States government. Furthermore, research could make a distinction between large pharmaceutical companies and smaller biotech firms, which can play vastly different roles in the orphan drug market.

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