Spring 2023

Pre-existing Illness Discrimination in Healthcare: How Barriers to Specialty Medication Effect Public Health Costs and Access

Charles M. Coryell
Bard College, cc7090@bard.edu

Pre-existing Illness Discrimination in Healthcare: How Barriers to Specialty Medication Effect Public Health Costs and Access

Senior Project Submitted to

The Division of Social Studies

of Bard College

by

Charles Coryell

Annandale-on-Hudson, New York

May 2023

Acknowledgements:

Mom - For what you have done to help me navigate a life that hasn't always given me the best hand. Thank you for visiting me when I was recovering from surgery. Amid the million other things you have to do every day, it means more to me than you will ever know that you still make the time to make sure I am doing okay. There is nobody I know who works harder than you and it's a trait that I am working towards emulating in my own life.

Dad – Thank you for showing me that it is okay to authentically be yourself. Through you I learned how to feel comfortable talking with anyone about anything. My natural inclination of wanting to learn and improve myself comes from you. You have also shown me the fulfillment that can be gained from making a career out of your passions and that is something I am keeping in my mind as I decide this next chapter in my life.

Jackson – There is no other person on this Earth I'd prefer to be my brother. Thank you for being someone I can talk to and goof off with, and most of all being a genuine friend. You are a joy to everyone when you want to be, and I want more people to see that side of you. Whenever you are willing to do that, you will do great things and I cannot wait to see it.

Table of Contents

Introduction……..5

Chapter 1 : Supply Side……..……12

Chapter 2 : Demand Side……30

Chapter 3 : Policy Proposal……53

Conclusion…….75

Bibliography……..82

Abstract: *Rising costs in specialty meds are at the center of the problems in healthcare. Pharmaceutical companies have grown to have nearly unchecked pricing power with specialty medications. Insurance companies have responded to rising prices in specialty medications by making these medications difficult to access for patients who need them. Policies to address the problems in healthcare have failed because they do not recognize the impact that the specialty medicine market has on the overarching story. Healthcare policy will be effective if it directly addresses specialty med costs and accessibility. This paper proposes an expansion of Medicare part D to the chronically ill and further leverage of Medicare's newfound ability to negotiate prices. This policy is projected to not only improve the plight of the chronically ill, but also to improve the private market because it will restore the fidelity of core assumptions originally made in the consumer demand for health insurance.*

Introduction:

In 2010, with the landmark passage of the Affordable Care Act, many thought that America had finally made a monumental step towards a more equitable health care system. It was created with the intent to improve access to affordable health coverage and protecting consumers from the abusive practices of insurance companies. One of the major achievements touted in the Affordable Care Act was the official end to the discrimination of those with preexisting conditions. The law was written such that, under the Affordable Care Act, health insurance companies cannot refuse to cover or charge more simply because the subscriber has a preexisting condition. More than a decade has elapsed since the Affordable Care Act was signed into law but what has not changed is the bevy of issues that still exist in the issuance and deliverance of healthcare. The Affordable Care Act was created with the good intention of trying to end discrimination in healthcare, but the new environment has created certain conditions where discrimination is even more deeply embedded. There are many more reasons for the problems that are still faced in healthcare and certainly not all of them are attributable to the passage of the Affordable Care Act. However, with over a decade's worth of information it is worth examining the limitations that the Affordable Care Act has had on achieving a healthcare system the United States can be happy with. This paper will evaluate the efficacy of the Affordable Care Act in ending the discrimination against those with preexisting conditions and where further reform needs to be directed to improve healthcare for those who need it most.

There are still marked deficiencies in the affordability and accessibility in the market for specialty medications. Specialty medications lack a universally agreed upon definition but oftentimes they are characterized by their expense to produce and that they require special storage and handling requirements. They are used to treat rare conditions and are largely found

within the biologic class of medications which are either injectable or require an infusion. This is opposed to the typical medications picked up at pharmacies like small molecule drugs which are often taken orally. Instead, specialty medications have their own system with specialty pharmacies.

Specialty medications have in recent years come to dominate the healthcare market and is at the center of the rapid rise in health spending that the United States has been experiencing for the past several decades. Prescription drugs have been the largest growing expense over the last 40 years and in 2020-2021 retail prescription drugs were still the fastest growing healthcare cost in the United States (Telesford, Rakshit, McGough, et. al 2023). The largest pharmaceutical companies use their specialty products as a core revenue generator. One example being Humira, the marquee product of the pharmaceutical giant AbbVie. Humira's story can be a conduit in which to explain the specialty med story, as it has enjoyed a monopoly for treatment on an array of inflammatory diseases. This is one of the more mature markets in the specialty medication space, and through its lifespan as a monopoly power has utilized and even pioneered many of the strategies that are common in the market today in its path to becoming the highest grossing drug of all time (Walker, Gorenstein 2023). To understand why Humira has been so successful is integral in crafting a solution to put the "health" back into healthcare.

The specialty medicine market has been often overlooked and understudied because there are very few people who are directly exposed to it. Nonetheless, it plays an integral role in the effectiveness of healthcare to function affordably. One example illustrating the size of this monster is that in 2018 a whopping 50% of total U.S. national drug spending was for specialty medication. What makes this number even more astounding is that specialty medications only constitute 1% of all prescriptions issued. The US market for specialty medications totals $87

billion and is growing at double the rate of the overall prescription drug market at 8.8% annually (Hirsch, Balu, Schulman 2014).

These growing statistics in drug spending do not just affect those who are prescribed these specialty medications, but they also impact anybody who pays a health insurance premium. Bradford Hirsch, a health economist, created a simple but telling model illustrating the relationship between specialty drug spending and the increase in the yearly cost of health insurance premiums. What the model revealed is that premiums would increase $1000 for every 1% additional utilization of specialty medications (Hirsch, Balu, Schulman 2014). The model is not an exact projection yet what it does show is the impact that specialty medications have on the overarching healthcare story. Therefore, to truly address the rapidly rising costs of healthcare one must be able to find an effective and enduring solution to the cost crisis found in the specialty medications market.

When health economists traditionally introduce the sheer volume of healthcare spending in the United States, the statistics most often presented are ones like how healthcare spending now contributes to nearly 20% of the entire U.S. GDP or how, on average, a person in the United States spent $12,500 on healthcare in 2020. These numbers are a good starting point to identifying the problem, but they lack and even obscure the explanation for these costs by making the misleading assumption that everyone bears these costs equally. The reality is that a small population accounts for a large percentage of the total healthcare spending. The Kaiser Family Foundation conducted a study and found in 2019 that just 5% of the population accounted for nearly half of all health spending (Peterson-KFF 2021).

The population that constitutes the 5% that consume the most health care is primarily two populations: those who are over the age of 65 and those with chronic illness. The former group

has been absorbed into the Medicare program. This happened because Lyndon B. Johnson identified that those over the age of 65 were chronically uninsured or underinsured. Prior to Medicare only 60% of people over the age of 65 had health insurance coverage. They were identified by insurance companies as a high-risk group and health insurance was either unavailable or unaffordable to them. Thus, with the passage of Medicare in 1965 the elderly population was saved from the realities of a risk pooling business in a free market.

Now the latter group of the chronically ill are not eligible for Medicare and thus are a tribe without a home in the world of healthcare. This is a population that is at the whims of a highly but poorly regulated and uncoordinated health insurance market. They also are likely to belong to a health insurance company which, to exist, is motivated to minimize costs. Many insurance companies, like Blue Cross Blue Shield, are not for profit but this does not mean that they do not care about the costs they incur. Insurance companies are still businesses and are revenue driven, otherwise they would not be businesses for long. Therefore, these health insurance companies, though compelled by law to not deny on the basis of preexisting conditions, do not want to shell out money to the regular claims that are submitted by those who are in need of expensive biologic medication. Insurance companies have since adjusted to the new rules put in place by the Affordable Care Act and have found novel ways in which to reduce their exposure to high-cost patients by both raising costs on everyone in their system or targeting those with pre-existing conditions by creating high barriers to approval for medication that is essential to a life without illness.

The consolidated market structure of specialty medications demonstrates cracks in the overall system that regulation has failed to correct, or worse, exacerbated the flaws already prevalent in the economic environment of healthcare. While the problems of insurance have been

acknowledged, they are made in response to conditions where pharmaceutical companies have been able to monopolize their control over treatments for certain chronic illnesses.

Ultimately, this paper seeks to be a reevaluation of the current interplay between the private and public sector of healthcare and how it works to the benefit or detriment of those with preexisting conditions and public health as a whole. The central character used in presenting this story will be specialty medications since they are new, have fundamentally changed the landscape, and face a clear mismatch in the healthcare industry. There is such a mismatch that they are subject to an almost entirely different system than any other medication. This has become an increasingly expensive exercise of trying to get a square peg to fit into a round hole. Specialty medications can and occasionally in this paper will interchangeably be described as biologic medications due to their strong overlap. Like specialty medications, biologics are complex treatments that often require specific storage and transfer.

This paper finds that the current structure of healthcare is inadequate in achieving the necessary goals of accessibility and affordability for medications. Legislation did succeed in guaranteeing health coverage for those with preexisting conditions, but the problems of reliable coverage for specialty medications run deeper and continue to persist. The reasons for this can be boiled down to a few factors that can be separated by the supply and demand side of this industry. On the supply side the problems lie in the drug manufacturers operating in monopolistic models. This has been achieved through a crafty use of patent laws to block out competitors, massive advertisement campaigns to persuade potential consumers, and an FDA approval process that is not built for the specialty medicine market to be competitive. On the demand side insurance companies have acted as a barrier to access specialty medications through cost containment strategies. These strategies consist of specific arduous approval processes. Prior

authorization and step therapy have quickly been adopted as a foundational part of the ecosystem. The other strategy has been a trend towards high deductible health plans (HDHP's) that shift the burden of cost of medication more to the consumer. Since specialty medications currently do not have a visible path to becoming dramatically cheaper the specialty med market has been playing a very expensive game of hot potato to see who is the one who must foot the bill.

This paper ends with an exploration of possible policy options and then a suggested prescription to make insurance finally work for those with pre-existing conditions. That suggestion is a plan to get those with preexisting conditions out of the risk pooling system operating with assumptions that do not fit the chronically ill population. Health insurance functions the way it is supposed to when subscribers face uncertainty in the amount of healthcare they are expected to consume. Insurance companies charge a premium for security against uncertainty of care, but because the chronically ill face certain costs each year they do not fit the behavioral model. When health insurance was popularized in the aftermath of World War II, this is how insurance operated. Since the introduction of extremely complex and expensive drugs the problem of regular and predictable medical claims now exist in the scope that it never did previously. Though insurance companies are now legally bound to accept those with preexisting conditions, the market incentives in a competitive industry force them to act contrary to the healthcare needs of a patient.

Therefore, this paper finds that moving those with preexisting and chronic conditions away from the private sector and to the public sector is the best solution for the health of not only those with chronic illness but for the integrity of the health insurance market as a whole. To find a proper home for those with chronic illness may improve the private insurance market by

reversing the adverse selection problem and reducing premiums overall among private insurance. This could be a key method to address the United States' epidemic of the uninsured that continues to exist even after the passage of the Affordable Care Act. 10.2% of the U.S. population under the age of 65 are uninsured and 69.6% responded that they were uninsured because coverage is unaffordable (KFF 2022). Figuring out a solution for the chronically ill could have an immense impact on saving private health care without requiring a radical upheaval of the current system.

Finally, to introduce a more robust degree of competition there should be legislation addressing the supply side issues of an abuse of patent law by drug companies producing biologic medication as well as an adaptation to the antiquated FDA approval processes to include a more expedited approval process for biosimilar drug formulations than the systems that currently are in place. The U.S. healthcare system is not irreparably broken but the longer that the current issues persist, the greater the danger will be that the American people forever lose confidence in it being fixed.

Chapter 1:

Supply Side of Specialty Drugs

Intro to Supply Side Issues:

To understand the very idiosyncratic market structure of specialty medications it is important to break down even more specifically what is entailed within their definition. It has already been said that specialty medications are a class of drugs that are expensive, yet one may logically ask: what makes these drugs expensive? The answer lies in their formulation.

Specialty medications are predominantly biologic drugs, which are a class of drug that differ from traditional small molecule drugs because they are created from the cells and tissue of living organisms. The structural complexity in producing biologics is much more involved than the simple formulations of oral medications; many of them simply being held together with starch and water. The complex structure of biologics is necessary because it plays a complex role in regulating a patient's immune response. What biologics are attempting to do is reengineer the proteins in the human body that are deficient in chronically ill patients.

The important takeaway from the production of biologics, and what will help illuminate the reason as to why competition is so sparse, is that many of the supply side issues stem from the complexity of their formulation. The unique science behind biologics is important to its economic story to the extent that there are specific regulatory measures that govern their approval process before they can be bought and sold. Biologics, and certainly their rapid rise in demand, are a rather new era in the history of healthcare. It is perhaps the defining problem of the modern healthcare system. At this point, the country has, despite several attempts to neatly adopt biologic medications into its sphere of influence, failed to adapt to these new conditions. This paper finds that the current regulatory environment in the United States has been inadequate at balancing the goals of making biologics affordable and accessible for the consumer. This

chapter will focus on explaining the deficiencies that exist on the supply side. What is evident in the present environment is a failure to create an effective fast-tracked approval process for biosimilars and the abuse of patent law by large pharmaceutical manufacturers. These two market deficiencies have resulted in large pharmaceutical producers to be sheltered from external competition. Addressing these problems would improve the competitiveness of the biologics market, make biologics more affordable, and downstream from that make them more accessible.

Supply Side of Specialty Drugs:

The development of biologics is one of the great achievements of medicine in recent history, but accessibility to these medications can be tenuous due to their cost and how intimately affordability is tied to insurance approval. Those who are diagnosed with a chronic illness require a greater consumption of healthcare than the average consumer. This poses a problem because the private insurance market is geared towards being best for the average consumer of healthcare. However, the average consumer does not regularly require health care. The consequence is that health insurance underexposes, or underinsures, those with chronic illness. One study published by Duke University helps to connect how the high cost of medications is downstream of accessibility by finding that "the presence of a chronic illness decreased the probability of having adequate coverage by about 10 percentage points among all individuals and by about 25 percentage points among single individuals" (Stroupe, Kinney, et. al 2000). The insurance they are on is not adapted for their specific context since unaffordability of medications is something that insurance companies also must navigate, not just patients. With specialty medications often costing thousands of dollars per month without insurance, patients need insurance to be on their side in order to handle the cost, limiting their autonomy in the private market. Furthermore, this statistic published by Duke could also feasibly be an

underestimate of patients who regularly use specialty medications, since not every individual with chronic illness requires specialty medicine as a part of their treatment regimen. With regular and persistent high costs, underinsurance has become a significant problem to those who need healthcare the most.

When examining the supply side of specialty drugs, the primary problem that many economists point to is the limited number of biosimilars on the market. Presently, there is little in the way of the federal government directly influencing the costs of prescription drugs. Biosimilars are currently used as the main economic input on the supply side to control the costs of medication. Many believe that introducing more biosimilar medications has the potential to force downward price pressures by making the market more competitive. The ideal market environment for the consumer is one of perfect competition because the price of goods in a perfectly competitive structure must be sold at marginal cost if a firm wants any share of the market. Therefore, theory holds that as more biosimilars are introduced firms will be more apt to reduce their price closer to the marginal cost it requires to produce one unit of medicine. The environment right now is far from a competitive one. For example, Humira's price has been increasing every year since 2003 (Brennan 2021). What is significant from this price increase is that it has been rising faster than inflation, meaning that Humira has increasingly been able to sell their medication at a higher and higher price than the marginal cost to produce it. One of the reasons this can be explained is because of the dearth of biosimilar competition. Using the chronic illness of irritable bowel disease (IBD) as our focus of analysis, "as of January 2020, there are 12 biologics approved for IBD use in adults" (Al-Bawardy, Shivashankar, et. al 2021).

One may assume that this is a moderately healthy number of options for the patient to choose from, but this would be an uncritical analysis of the true outlook. Each of these 12

formularies are distinct from one another, and more importantly face little direct competition from one another. This is because there is a hierarchy that is governed by what insurance covers. In other words, someone with IBD is having their choices decided by what step they are at in step-therapy. The first option offered for them would be infliximab (brand name Remicade). If that doesn't work, then the typical next tier up is the formulation adalimumab, and if that doesn't work then one would attempt to get coverage for the next cheapest drug and the process continues until the patient finds a drug that works. These are drugs that may exist in the same disease space, but do not actually interact with each other in the market because insurance places strict limits on the kinds of medications available to the ultimate consumer. In each of these cases, from infliximab, to adalimumab, and so on, patients encounter distinct monopolistic markets. With this in mind, the 12 biologics available for patients with IBD shrinks in term of the downward price pressure these drugs have. Insurers have little in the way of negotiating massive reductions for the medications that they are required to cover and therefore pursue step-therapy as its strategy to reduce the quantity supplied.

The problems evident show that the current supply side story still has a long way to go before achieving a picture of something resembling perfect competition. Though biosimilars have already been expounded upon, there are a few specific reasons why they still struggle to be introduced as competitors. The primary issues on the supply side can be condensed down to three main deficiencies. The first problem is the failure for the federal government to craft an adequate framework for biosimilar approval in the way that the Hatch-Waxman act exists for small molecule generic drugs. The second problem is a patent system that has been structured in such a way that it can be easily abused, and it has been by pharmaceutical companies for years to extend their monopolistic control on developed biologic drugs. The third problem is the overwhelming

marketing advantage that large pharmaceutical companies can enjoy and leverage to sustain a high-cost environment for their biopharmaceutical medication. Reform in these three key areas would lead to a more robust, competitive marketplace.

The Hatch-Waxman Act and Lack Thereof for Biologics:

In 1984, congress passed the Drug Price Competition and Patent Term Restoration Act, or more colloquially known as the Hatch-Waxman Act. Since its implementation, the Hatch-Waxman act has been integral setting the stage for a healthy supply side market for prescription drugs. It serves as one of the rare cases where there is bipartisan agreement regarding the success of this legislation in driving down the costs of prescription drugs. The Hatch-Waxman act was effective because it was able to utilize two tools to lower drug costs: an abbreviated approval pathway for generic drugs, and the ability for pharmacists to use generics interchangeably with the brand name drug when dispensing prescriptions for patients. Once the path for generic drugs to be approved was created the floodgates opened and a much more competitive market formed. Today, about 90% of all drugs now have a generic equivalent and 90% of all prescriptions dispensed in the United States are generic drugs themselves (Ampaabeng 2022). This has been a great boon in making many prescription drugs more affordable. Competition spurred by the introduction of generic drugs have resulted in price reductions for many small-molecule drugs by 80% or more and has saved the US trillions of dollars in healthcare spending over the last decade (Sarpatwari, Berenie, et. al 2018). However, caught in the 10% of drugs without a generic equivalent are the specialty medicines. Even with the passage of the Hatch-Waxman act there was no legitimate framework to introduce more affordable generic alternatives.

The healthcare landscape changed yet again with the passage of the Affordable Care Act. What emerged from the most robust health reform of the 21st century was the first attempt to grant an abbreviated approval process to biosimilar drugs, with the hope that biologics would have their own Hatch-Waxman framework in which to birth a more competitive pricing structure. Dubbed the Biologics Price Competition and Innovation Act of 2009 (BPCIA), it created an abbreviated pathway for biologics to avoid costly clinical trials. What this legislation also did is create two separate standards upon which a prospective biosimilar could apply for. The first is a standard biosimilar. The FDA defines this a biosimilar as having no clinically meaningful differences in safety, purity, and potency compared to the brand name drug it is copying. The second standard is for interchangeability. The FDA defines a biosimilar as interchangeable if it achieves the same clinical result in any given patient as the brand name drug it is replicating. All biosimilars must meet the first standard, but as of 2022 there are only three biosimilars that have the interchangeability designation: one insulin product, one Humira biosimilar, and one for treatment of a rare condition in the retina with all of them being introduced within the last couple of years (Pfizer 2022). The BPCIA has not yet been the same catalyst that the Hatch-Waxman act has been on prescription drugs, with prices remaining stubbornly high.

The difficulty in introducing market competition to brand name biologics stems from the substantial regulatory barriers that need to be met before competition can be introduced to market. To make a true "bioidentical" where each unit of medication is exactly the same down to its molecular structure would be exceedingly difficult if not impossible. A truly identical generic is quite feasible for small molecule drugs, but in the class of biologics there are more complex systems at play. Biologic drugs are made using living systems and because there are natural

variations in amino acid sequences, proteins will in the most technical sense be different even if they are functionally identical. This is even the case between medications from the same batch and manufacturer.

Biosimilars will always contain the same active ingredient as the reference drug, but their "recipe" differs in minor ways regarding the inactive ingredients. Therefore, since the active ingredient is the same the biosimilar drug serves the same primary function as the drug that it is copying, thus making it similar. However, it must be noted that being "similar" and not "identical" is an incredibly important and unique distinction to prescription drugs. This minor change lays the foundation of the issues underlying the creation of a competitive market for biologics. Similarity makes it so there are much higher standards when compared to small molecule drugs for biosimilars to be labelled as interchangeable. Without this designation, even when biosimilars are introduced to a market, the price reductions that follow are only modest at best. Infliximab has one of the most mature markets among biologics, having widespread use since 1998, but Remicade still controls 63% of the market even though there are now multiple biosimilar competitors (Joszt 2022). These are the signs that the biologics market in the BPCIA, while gradually improving, is still struggling to generate rapid downward price pressure from the development of a robust and competitive environment in a field that so desperately needs price reductions.

Economist Henry Grabowski used an economic model to estimate that the prices for biosimilars would only be a rather modest cost savings of 12-20% depending on the product in question (Grabowski 2007). The cost estimates for Anti-TNF products (Adalimumab, Infliximab, etc.) have been compared over multiple studies, and even these products have been found to generate slightly higher cost savings to the average product. The RAND corporation conducted a

study and discovered a potential 21% in cost savings when biosimilars are introduced anti-TNF products (Mulcahy, Predmore, Mattke 2014). Furthermore, when looking at Europe as counterexample to the United States one sees the degree to which a more robust biosimilars market can have on reducing prices for specialty medications and aggregate health care costs more broadly. The EU constitutes 80% of the global biosimilar market and, based on a 2013 study, biosimilars are on average 30% less expensive than the brand name drug (Blackstone, Joseph 2013). While it is hardly the same impact on prices that generics have had with prescription small molecule drugs this would go a long way in reducing the copays that consumers currently must pay.

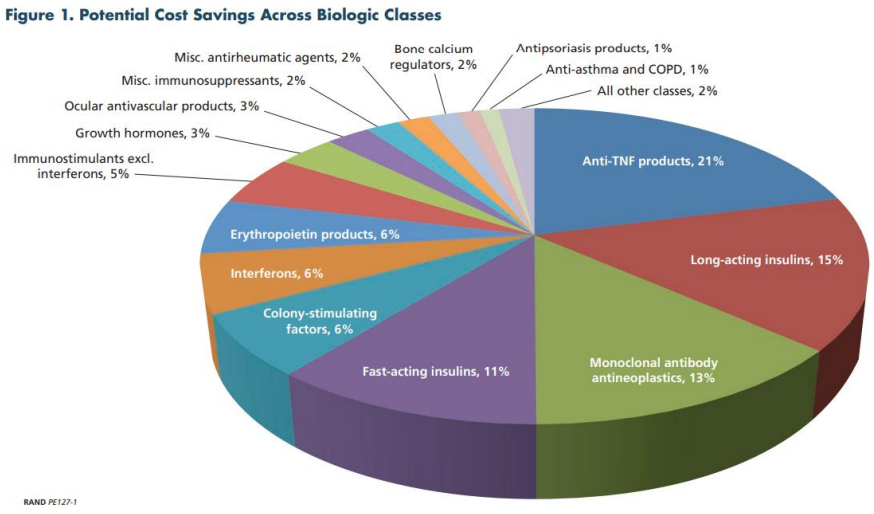

Figure 1: Mulcahy, Predmore, Mattke 2014

FDA and interchangeability:

High barriers to entry in the biosimilars market start with the onerous and ill-fitting standards that are established by the FDA for approval. This especially pertains to biosimilars as they face high costs upfront since, as previously referenced in this paper, there are only three drugs in the entire class of biologics that is permitted to be used interchangeably by the FDA. The costs for companies wishing to produce their own biosimilar include having to conduct their own clinical trials to prove that their drug is safe and effective, which oftentimes may feel banal because it is nearly identical to the reference drug since the active ingredient remains the same. The FDA regulations on approval of biologics are different and, as has been explained, more stringent than that of conventional drugs.

Even with the passage of the BPCIA manufacturers still have to go through expensive clinical trials to ensure their safety meaning that "the costs and time to obtain FDA approval are likely to be dramatically higher for biosimilars than for generic drugs" (Grabowski, Guha, Salgado 2013). Since the biosimilars are not identical they cannot be fast-tracked through the Hatch-Waxman act. The primary advantage of the Hatch-Waxman act as a fast-tracked approval process for small molecule generics is that they need not perform their own clinical trials to obtain approval from the FDA. Instead, they can reference the results of a previous clinical trial of the drug in which they are copying because they are identical products. The divergent systems of approval culminate in substantial differences of price for the development of a biosimilar drug compared to a generic. According to one analysis, "developing a biosimilar could cost more than $100 million and take more than five years. This compares to a cost of $2–$5 million and a time span of two to three years for generic drugs" (Grabowski, Guha, Salgado 2013).

An additional problem which exists is that the rules for drugs to qualify for interchangeability are strict and make it cumbersome for biosimilars to qualify for this class as compared to generic drugs. It is important for a biosimilar to be considered interchangeable because it opens avenues that are readily available for cost reduction. In economic terms, interchangeability is substitutability, and without this designation biosimilars are a sizeable distance away from being able to function as perfect substitutes for the brand name drug. The power of interchangeability comes from the ability of pharmacists to substitute the name brand drug with its generic counterpart as a cost saving measure. This can be done without a physician's approval because the same clinical outcome is achieved in either case.

Biosimilars face greater hurdles and a greater burden of proof to be definitionally considered interchangeable, and once again biosimilars must engage in clinical trials to provide proof of bio similarity but also that "it can be expected to produce the same clinical result as the reference product in any given patient" (FDA.gov 2016). In the United States the burden of proof that a biosimilar drug must meet to qualify for interchangeable is uniquely high. For example, the drug Omnitrope is approved as an interchangeable drug for somatropin in Europe but has been denied that classification in the United States. This potentially brings up the microeconomic concept of substitutions, and by classifying biosimilars as substitutes for the base product, one would be able to see the potential effects through microeconomic models. While rare, there is an example that demonstrates the effect of being approved as interchangeable. The drug enoxaparin, which is a biosimilar drug for lovenox, is used to treat deep vein thrombosis. Enoxaparin was approved as an interchangeable drug and since it has been introduced to market enoxaparin and lovenox have gone in opposite directions in terms of percentage of market control. As seen in figure 1, the impact was observed very quickly as "Enoxaparin earned over a

billion dollars in its first year on the market and captured more than half of the market" (Grabowski, Guha, Salgado 2013). Instead, it is more likely that under current conditions the expected typical story is that biosimilars will not act as substitutes like generic drugs, but rather as an alternative "name-brand" medication. Meaning that price is not the exclusive factor in determining market power but that other factors will matter, such as quality, provider trust in the biosimilar, and promotion.

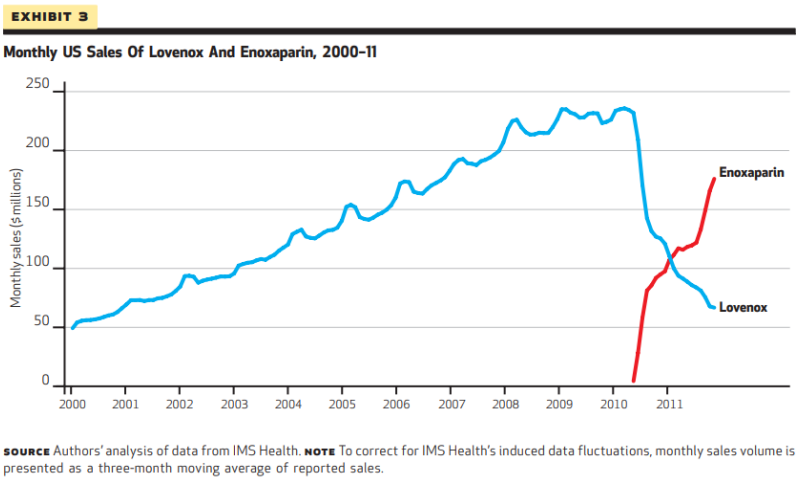

Figure 2

Patents:

The biologics market cannot be explained without delving into the abuse of patent law and how it is intimately connected to the reason as to why biosimilar medications have been delayed in their entry. In the research and development industry, which biologics belong to, innovation is a high priority behavior to incentivize. Patents are the method used by the government to encourage companies to develop novel and useful drugs. Patents act as that incentive, by giving the innovative manufacturer exclusive intellectual property rights of their invention for a certain period. The consequence of this is that, for a period (typically 10-15

years), the manufacturer holds monopoly power. While this does encourage innovation, monopolies distort markets since they are without competition and, because they have greater pricing power than in competitive industries the consequence is an inefficient market with a significant portion of deadweight loss. However, in the actual market for specialty drugs the trade-off is unbalanced. Humira has been able to sustain its market exclusivity from its launch in 2002 until 2023 (Campanelli 2022). Even if one wishes to keep the patent system intact as the kindling for innovation, it is not working. One core part of the analysis found in this paper is that the trade-off for innovation is not properly balanced with the alternative option of affordable and, *ipso facto*, accessible medications.

The use of patent law is something that drug manufactures have historically tried to maximize to their own advantage. One such practice that economic policy analysts focus on is one that some have colloquially and critically termed as "patent thickets." These pose a threat in allowing patents to get to market. The reason is because the original biologic manufacture can apply for patents beyond simply the patent for the drug itself. This in effect increases the length of their exclusivity on certain treatments beyond the time that is allotted on the main patent on the formulation. These are called 'subsidiary patents', and the consensus view for economists is that subsidiary patents serve in the market as a method for the reference product to protect itself from competition. For example, this can include the manufacturing process which may not be something that biosimilar manufactures are able to work around, which would effectively extend the original biologic's monopoly power on the product. The consequence of applying and receiving approval for several subsidiary patents is that they could delay biosimilars' entry into the market (Grabowski, Guha, Salgado 2013).

This can be seen unfolding in the real world. Once again, Humira serves as a good example of this behavior. Although the original patent for the "recipe" of Humira expired in 2016, it was able to extend its market exclusivity an additional seven years through subsidiary patents. They created what is colloquially referred to as "patent thickets", and though biosimilars have finally been introduced to compete with Humira, the patents that still exist impose barriers towards interchangeable entry. AbbVie, the supplier of Humira, placed patents on the manufacturing process of the drug. It is also acknowledged that these patents tie the hands of companies that want to produce an interchangeable biosimilar. An analysis by the University of College Cork, Ireland found that "due to the nature of their larger molecules, it is generally not possible to make an identical copy of a biological substance using a different manufacturing process" (O'Callaghan et. al 2019). The last of the patents for Humira will expire in 2039 (Gibbons, Laber, Bennett 2023).

When testing the validity of patent thickets affecting price Jeffery Wu in the Georgetown Law journal believes it is a contributing factor in driving up costs. While patents also exist with small molecule drugs, there are more patents that biosimilars face than generics in the small molecule field. As a result, "These patents, or 'patent thickets,' has… resulted in a lower launch to approval ratio for biosimilars compared to small-molecule drugs" (Wu 2019). The problem he identifies is that there is bevy of patents that are not really novel, which he classifies as type II drugs. He states "Type II Patent Thickets, on the other hand, are …. non-inventive patents that are prone to double patenting" (Wu 2019). The critical way to look at the construction of patent thickets is that they are an attempt to maintain an economic advantage. Therefore, patents transition away from being used primarily as a tool to protect intellectual property. This use of

patents, not in line with the spirit of the patent system, is referred to by some as ‘evergreening’, meaning to extend the life of intellectual property beyond the life of the original patent.

A lawsuit has been launched against AbbVie by several drug companies where they purport that AbbVie has been using the strategy of patent thickets to block out competition. The briefing states that, regarding AbbVie’s top selling biologic Humira, the patents AbbVie has applied for “share common specifications and have overlapping and nearly identical claims” (AbbVie Inc. et al v. Boehringer Ingelheim International GMBH et al 2019). Humira is a prime example of the debate surrounding the merits and legality of patent thickets since they have

> “75 patents covering formulations, treatment uses and manufacturing processes of the drug. Furthermore, in 2019, Richard Gonzalez, CEO of AbbVie, acknowledged the company's success on securing 136 patents on Humira” (Wu 2019).

To examine the validity of the claims that patent thickets impede market competition it is necessary to compare the story between small molecule drugs and biologics since patents also exist in the small molecule competitive environment. For the purposes of this paper the comparison will be limited to the top selling biologic manufacturer (Humira) to the top selling small molecule manufacturer (Revlimid). Jeffery Wu categorizes the patents by the general intellectual property they are intended to protect. On the left side is Revlimid’s patent portfolio and on the right side is Humira’s patent portfolio (Wu 2019). The inner circle of this chart contains the core patents while the outer donut represents peripheral patents. Something that is striking when comparing these two companies’ core patents is that 29% of the core patents in Humira’s portfolio are for protecting the method of manufacture. However, there are no core patents at all relating to the manufacture of Revlimid. This is certainly a piece of information to

keep in mind as to the different market environments that are created as patents are used in distinct ways. Furthermore, biologics generally have a higher volume of patents. For example, Humira is covered by 154 patents and the most patented small molecule drug is Revlimid with 74, less than half of Humira. Of course, one must examine this with more scrutiny to determine the degree to which this disrupts the market but, in any case, it is worth raising an eyebrow at.

The other thing to examine critically is not just the raw number of patents that companies have in stock but how many are type II patents. Jeffery Wu defines type II patents as those "that are less inventive and more prone to double patenting" (Wu 2019). This poses a problem because patents are supposed to be protecting intellectual property instead of protecting firms from competition. Reexamining Humira and Revlimid, Wu finds that Humira has many more type II patents than Revlimid. Additionally, when factoring in time one can see how many patent thickets (the life spans of patents clustered around the same period) each drug company has. According to Wu, Humira has 9 type II patent thickets compared to Revlimid which has 5 type II patent thickets. Neither is good, but the scale of patents blocking market entry is significantly greater with Humira.

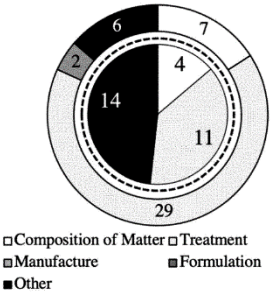

Figure 3 (Revlimid)

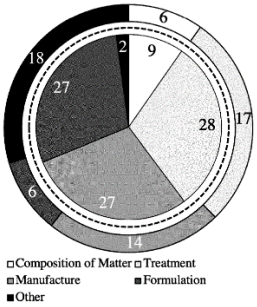

Figure 4 (Humira)

While it may be easy for economists to point out patents as the primary source of high costs with respect to biologics it is important to recognize that patents play a vital role in this ecosystem. Patents and exclusivity rights are the primary lever which the United States pulls in order to spur innovation and incentivize companies to pursue the creation of novel solutions to solve long-standing problems. This trade-off has been a such a central topic of discussion that William Nordhaus developed a model which measures the optimal trade-off between price competition and innovation. That being said, it is equally important to evaluate the landscape of this market and strike a balance between innovation and competition.

In the current structure of the healthcare market for specialty medications, pharmaceutical companies have been able to successfully maintain a profit margin of 15-20 percent above revenues (Dickson, Ballreich 2019). This is well above the market standards and speaks to who currently controls the most power in the market. The counterargument regularly made by pharmaceutical companies is that to target their profits would reduce innovation. This paper finds that claim to be unconvincing, and that drug price reform can, in fact, be had with little consequence to innovation. Pricing reform could be done by reforming the patent protection system and creating a higher standard for what qualifies as a real innovation. Less patents would make it easier for competition to be introduced to markets that desperately need it. This would require increasing the staff of the United States and Trademark Office. Currently, due to understaffing it is not possible for this office to be able to review patents in both a critical and timely manner. The lack of patent reviewers has made is such that pharmaceutical companies have been able to take advantage of ‘secondary patents’, which contributes to delayed entry for biosimilars (FTC 2019; National Academies Press 2018; Kesselheim 2016; Amin and Kesselheim 2012). The patent process faces a backlog and as a consequence of trying to address

that backlog they are not able to give adequate time to review these subsidiary patents. Patent examiners, and the amount of time they can commit to reviewal is determined by pay-scale. For example, While GS-11 examiners reviewing pharmaceutical patents are allocated nearly 25 hours on average to review each application, GS14 examiners are allocated less than 18 hours on average to review the same application. One analysis finds "upon a given GS-level promotion, examiners experience a roughly 10 percentage-point drop in the near-term in the rate by which secondary pharmaceutical patents issued in the U.S. are likewise allowed at the European Patent Office" (Frakes, Wasserman 2022). The European Patent Office is considered by many to be the gold standard of examining the validity of patents, and the United States is falling short of them. This study finds great benefits for biosimilar entry by modestly increasing the time to review patent applications. It states that "increasing time allocations by 50% over just one year of reviews of secondary drug patents will result in an aggregate acceleration of generic entry of 16.9 years among the set of FDA-approved drugs" (Frakes, Wasserman 2022).

Chapter 2: The Demand Side of the Specialty Drug Market

Demand Side of the Specialty Drug Market:

Manufacturers dominate control of the supply side. Through the maintenance of monopoly power and, until recently, the inability of Medicare to negotiate drug pricing, drug manufactures have freely been able to set their prices in the United States. However, the demand side has pressures that can act against drug manufacturers. The demand for any drug prescription is mediated by a third-party payer. In the simplest conception of an insurance model, a third-party payer is liable to contribute to the payment of prescription medication. Every claim is a cost to insurance. Therefore, insurance has a profit incentive to minimize the number of claims that they will approve. In a microeconomic sense, this translates to the insurance companies forcing downward pressures on the demand (and price) for prescription drugs, while drug manufacturers are forcing upward pressure. Microeconomic models in the specialty drug market are abstracted from the ultimate consumer. Since the affordability of specialty medications are dependent on insurance, they have little influence over the functions of the demand side outside of patients who are diagnosed with a chronic illness. The other reason patient autonomy is forfeited on the demand side is because these drugs are lifesaving or life-altering medications, making the demand for the ultimate consumer highly inelastic.

Thus, the war that is waged between the pharmaceutical industry and insurance companies is who will control the demand curve. Both parties have strategies in this regard. The method that the pharmaceutical industry uses is to dominate the airwaves with advertising, offer copay assistance programs for consumers, and leveraging the inelastic demand of their customers. Insurance companies have constructed ways to counter these measures. This is primarily through negotiating prices with the drug manufacturer, raising the burden of cost-sharing, or requiring an extraordinary burden of proof that delays the approval of essential

medicines. There is a disease that permeates in all these methods that makes the outcome of the demand side suffer. There is a constant push and pull but what is lost in the chaff is the consumer. A conflict of interest between producer and insurer has exacerbated the public health crisis in the United States. The reason that this is the case is because public policy does not play an active enough role in either demand model. Drug manufacturers view the chronic consumer as a cash cow and can take in immense profits. Insurers and employers look at the same person as one who could destroy the sustainability of the health insurance market if left unchecked. This chapter will examine the landscape and strategies used regarding the demand for specialty medication in the United States.

Theories of Demand for Health Insurance and how specialty medications affect them:

There is a robust amount of modeling that has been done to explain healthcare behavior on the demand side in an economical way. Economists envision that healthcare demand, with a few minor tweaks, can closely align with the same behavior as one's demand for fruit. The market for health insurance has conventional microeconomic models to help explain consumer behavior. Employer sponsored insurance is the most common type of private health insurance in the United States. The origins of employer sponsored health insurance were as a fringe benefit borne out of World War II. In 1942 the Stabilization Act was passed, which was designed to limit the freedom of employers to raise wages to combat inflationary pressures. Health insurance was offered as a way to skirt around these regulations as a substitute for an increase in wages and has become a mainstay in potential compensation packages ever since.

Health insurance was offered as a supplement to the wage, and this is still how economists view sponsored insurance today. Therefore, for neoclassical economists, it still fits within the labor market where the marginal productivity of a worker is the determining factor of

their wage. If total compensation is offered in excess of an employee's productivity, this will force firms to raise their prices and then their firm will no longer be operating at a competitive price point. If it is too low, then employees will go somewhere that compensates them at their marginal productivity level. In a reasonably competitive marketplace for employment, employees will be hired at close to or around their marginal rate of productivity. In the United States, employers are also responsible to share payments for the premiums of the health insurance that employees choose. Depending on state law, employers may be required to cover at least 50% of an employee's premium.

When someone is hired at a firm that offers health insurance there are two philosophies that can be pursued depending on what the consumer deems their healthcare needs to be: anticipating that they will be a high consumer of healthcare or a low consumer of healthcare. Consumers demonstrate this behavior based on how they balance their deductible and premium when selecting a health insurance plan. A deductible is the price that a consumer must pay before insurance kicks in. The reason that deductibles exist in healthcare plans is to prevent moral hazard. Insurance companies want the patient to be responsible for their own health and making them meet a deductible before insurance is accessible makes it, so claims are only made when they are truly necessary. Healthcare consumption by consumers is made to the point where the marginal cost of care is equal to the marginal benefit the consumer receives from it. With insurance the consumer is protected from the financial consequences of healthcare consumption, thus shifting their marginal cost for an additional unit of care lower. Insurance companies do not want to grant more healthcare consumption than the subscriber would consume on their own, so they have used deductibles to expose the subscriber to the cost of their own healthcare. This is a strategy that has been proven to work, with one meta-analysis finding that "individuals, on

average, consume less healthcare when they are required to pay more for it out of pocket" (Einav, Finkelstein 2018). For those that are chronically ill, and expect to use their insurance frequently, it is in their best interest to limit their exposure to health insurance plans with high deductibles.

The problem of moral hazard for economists naturally introduces the question of if it is present in the United States healthcare system. The answer is simple: according to the rules of how healthcare is determined it, in the most classical sense, must be inefficient consumption because marginal cost exceeds marginal benefit. However, this paper views healthcare as a unique good that is distinct from the consumer behavior that governs more traditional commodities. This is because the demand for healthcare is determined by needs and not by economic factors. For lifesaving and life-altering drugs the demand is extremely inelastic. The alternative to not consuming is, in many cases, death. There is value in meeting the demand for specialty medications because it will lead to a healthier chronically ill population because they will not be forced to forgo a dose of their medicine due to its cost. It is more valuable to ensure that their care is managed because it avoids costly, and often inefficient, trips to the emergency room (Einav, Finkelstein 2018).

Premiums are a flat monthly fee that subscribers must pay to insurance companies. Since people have different levels of health, finding the right plan is often an idiosyncratic process. The trade-off traditionally made is between an insurance with high premiums and a low deductible or an insurance with high premiums and a low deductible. This is the dilemma that any health theory of consumer demand for health insurance outlines. It is acknowledged that the choices individuals make at the consumer level are filled with uncertainty about the future. This is the same case with the insurer as well since they cannot predict when claims will be made.

Insurance is, fundamentally, intended as a pooling of risk for unexpected events. This is the case for car insurance, home insurance, life insurance, and other forms of insurance. Nobody expects to get in an accident, have their house burn down, or die. In fact, to intentionally destroy insured property is illegal, and considered insurance fraud. The same holds true in health insurance. Health insurance in the United States originated when Baylor offered 50 public school teachers access to medical services on a monthly subscription basis. In the very beginning, American health insurers limited coverage to a hospital's medical services. Generally, it was meant to cover catastrophic health and cost events like breaking a leg.

Insurance coverage continued along these lines for a few decades and economic theory builds its foundation on, and explains most behavior, using this environment as the backdrop. Conventional theory holds that people do not like assuming risk and will pay a premium to avoid it. This makes payments more regular rather than a large spike in expenses when one does, for example, break a bone. Health insurance is of course more complex than managing the risk for the breaking of bones, with people requiring coverage all the time for various reasons. Some people also consistently consume more healthcare than others. In a competitive marketplace this would make insurers judicious about who they extend healthcare coverage to. Life insurance providers have reasons to deny or increase their premiums based on preexisting conditions, car insurance increases premiums for new drivers, and so on. Optimally, a health insurer's desire would be to have as many people as possible who consume little or no units of healthcare, and for those who consume more, the price they pay will be higher. Consumers of health insurance come in many forms. There are those who are close to perfectly healthy individuals who do not require healthcare and there are also those who are chronically ill who have persistent and high costs. A diverse group of possible consumers for the same good, who purchase the good for

sometimes different reasons, poses a problem known by economists as adverse selection. This is the idea that people who require the most healthcare consumption will benefit the most from insurance, and because they benefit the most, they will have the least incentive to be uninsured. The consequence is that this forces upward price pressure which makes the healthiest people decide to exit the health insurance market because they no longer receive enough utility from it. When the healthiest people exit the insurance market this causes the risk pool to shrink causing further upward price pressures which makes the next healthiest group of people exit. This cycle continues until only the sickest population is insured.

There is an alternative approach to understanding why people purchase health insurance called the Nyman model. John Nyman proposed this model because he saw deficiencies in the conventional approach to understanding health care, particularly with the idea that people purchase insurance to guard against uncertainty. He states that "the demand for insurance has nothing to do with the demand for certainty, because uncertainty exists with or without insurance" (Kelman, Woodward 2013). The Nyman model is different from the conventional model by conceiving of health insurance as a purchase people make so there is the ability to transfer income from their healthy state to their ill state where it is more valuable to them. The reason income transfer works in the private market is because paying out claims on the risk pool is less than the cost of insurance. For example, a hip replacement surgery may be a $30-$50 thousand dollar procedure but someone can purchase insurance to have the income available to them in a state that is most valuable to them. If there were 100,000 people on this insurance plan and the odds of someone needing hip replacement surgery was 1 in 100,000, then the 99,999 people who did not need hip replacement surgery would be transferring their income to the one person on the plan who did need it.

The Nyman demand model can be used as an explanation for consumer behavior. The insurance system is built on these assumptions and the Nyman model of demand perceived as a sustainable behavior for private insurance to work around because though those 99,999 people did not receive an income transfer in this example, they can rely on an income transfer if they were to fall ill. There are assumptions built within the health insurance system that income transfers are ultimately uncommon and that subscribers are more likely to be contributing more to income transfers than be receivers of income transfers.

Income transfers can work within the private insurance framework if people generally face the same risk, or even if they face different risk, the income transfers to accommodate those risks are relatively minor. It also requires that subscribers and insurance providers are mutually entering into a gambling relationship:

> "Paying the premium and receiving the payoff are uncertain: the former happens only if the event that triggers the payoff does not happen and the latter occurs only if the event that triggers the payoff happens" (Nyman 2020).

The problem is that our current healthcare reality does not reflect these assumptions for everyone who is subscribed to a private insurer. The Nyman demand model can show how demand is more explained by a desire for income transfers than the conventional model of paying a premium to avoid uncertainty. However, both the conventional and Nyman theories of demand demonstrate the problems that occur when a population like the chronically ill can operate without uncertainty. It seems that to have health insurance "work" as a competitive idea, either insurers must be granted the right of denial, or nobody is allowed to exit the insurance market.

How specialty medications and the Affordable Care Act have changed insurance:

In 2010, with a rare senate supermajority, the Democratic party were finally able to pass the Affordable Care Act. It was decided that the way to solve the pressing healthcare crisis was to expand the risk pool and require the healthiest individuals to be enrolled on a health insurance plan or else face a financial penalty. 10 years later, and the problems it was intended to solve persist. The reason is that the healthcare market and its interested actors have rapidly evolved to the new context in which they operate. It is now a much more complex system than the classical conception of healthcare. The Affordable Care Act was obviously not a market-oriented solution, but its ideas for why reform would be successful operated within the structure of an insurance market that could be solved by reestablishing the integrity of a private health insurance market. This was done by passing legislation that expanded the risk pool to the entire insurable U.S. population that was not covered by a public program. However, the problems of insurance are more embedded than what was initially conceived. One of the core assumptions of both demand models is that consumers operate with uncertainty about the costs of their care. However, this breaks down when considering the chronically ill who use specialty medications. In this case, they have close to perfect information about the cost of care for their condition. Consumers of specialty medications the frequency in which they receive this care, down to the day. A broken leg typically costs between $17,000 to $35,000 without insurance (Abels & Annes 2023). Sovaldi, a specialty medication used to treat hepatitis C, has a normal retail cost of $28,000 for a one-month supply if uninsured. What this effectively means from an economic standpoint is that the consumer knows that they will do the financial equivalent of breaking their leg every single month. Market failures can be managed in some instances, but the financial scale of this

particular market failure is dire. It poses a huge problem because it undermines one of the core assumptions of how private health insurance is allocated in the market.

The odds are near certain that those with chronic illness will need medications that cost tens of thousands of dollars per year. Therefore, they are constantly going to be the beneficiary of income transfers and will always be the first purchasers of insurance because they are always in a "sick" state. Insurance has responded by increasing everyone's premiums to compensate for the chronically ill population. The Affordable Care Act may have ameliorated the problem of a shrinking pool of the insured, but it did not curtail the high and rapidly rising health care costs in the United States. Measured in inflation-adjusted dollars, health care spending grew at an average annual rate of 2.7 percent between 2003 and 2010, and 2.8 percent between 2010 and 2018 (Antos, Capretta 2020).

The sheer scale and consistency of the income transfers and coming from common source of people make it such that private insurance is poorly adapted for this health context, and it is largely because they are not gambling on their care. It can be likened to knowing that one will purchase home insurance knowing that the home will be swept away by a tornado every month. A way to adjust for this is to recognize the adverse selection bias that is uniquely present in the chronically ill population and instead move this group to an area that is better able to accommodate them, because markets cannot work if core assumptions in which they operate are incorrect.

Insurance companies are legally barred from discriminating against those with pre-existing conditions by denying or charging them more for care. This would be seen almost universally as an ethically sound decision but what has happened is a transmutation of a health

insurance that was originally based on a logic of risk pooling now becoming something else. It has essentially been obligated to operate as a social program for the chronically ill, as well as an insurer with a profit motive. Since the reforms in the Affordable Care Act did not solve the underlying crisis of growing healthcare expenditures insurance companies have prioritized finding ways to minimize their exposure to costs. They have since adjusted to the new landscape and discovered ways that they can continue to discriminate against those with pre-existing conditions. Private companies act as poor mode of delivery for social programs, but this is exactly the system that the chronically ill, non-elderly population find themselves in.

Cost Containment Strategies:

One of the problems bubbling up, particularly with biologic and specialty medications, is that insurance companies have increasingly pushed cost sharing onto the purchasers of the insurance, or put in other words, the patients. The explanation for this is found in the divergent interests between purchaser and insurer. Health economic theory holds that the purchaser wants to consume health care to the point where the marginal benefit they receive from consuming one additional unit of healthcare equals the marginal cost of that consumption. However, in a world of scarcity not all health needs and desires will be met. The health insurer inherently wants to avoid reimbursement of any care considered excessive, believing that people will engage in an inefficient consumption of care, called moral hazard. Moral hazard is the concern that subscribers, when not having to burden any portion of cost, will engage in inefficient consumption of healthcare because to do so is at no, or minimal, consequence to them. As a result of this understanding, health insurance has implemented tools to guard against the overconsumption of care. In terms of higher cost sharing insurance companies have introduced higher deductibles for insurance plans, coinsurance, and copayments.

High deductible plans are becoming increasingly popular as a proportion of employer-sponsored plans that patients are enrolled in. Pinning down what exactly constitutes a high-deductible plan can be a tricky exercise because most definitions define it as a health insurance plan with deductibles higher than a traditional insurance. This definition makes a high-deductible health plan a moving price target because it is always done regarding the average deductible, and this number has been rising. What is understood is that deductibles are undoubtedly rising. The average deductible for a single coverage plan has nearly doubled from $1,025 in 2010 to $2,004 in 2021 (Center for American Progress 2022). An alternative, though limited, definition comes from the IRS who defines a high-deductible health plan as "a health insurance plan with a deductible of at least $1,500 if you have an individual plan" (Bank of America 2023). Using this definition, from 2013-2021 national enrollment in high deductible health plans has increased from 30.3% to 55.7%, climbing every single year in that span (Woolridge 2023). A high-deductible health plan in less than a decade has become the insurance for the majority of people on private insurance plans. Yet, the health of the nation has remained stable in this time.

Discussion around patient deductibles is rich with varied perspectives but this paper poses that the rising rates of patient deductibles is a response to the Affordable Care Act barring the denial of customers based on pre-existing conditions. In other words, insurance has adjusted to a post-ACA environment by shifting greater cost-sharing to not only high consumers of health care but also to the system as a whole. This is being done because health insurance firms act as an economic unit and are trying to minimize their own costs. With deductibles and other cost containment strategies health insurers can shift these cost responsibilities onto the patient. Deductibles were founded as a protection against moral hazard that may have been legitimate in its origin, but now insurance companies have been exploiting cost-sharing mechanisms to

minimize potential losses. There is no system in place right now to judge the merits of a deductible increase. This is an especially important topic because it targets the difficulties patients face in trying to access what is touted as the best health care in the world. Cost has always been a barrier to access, but it is now becoming more difficult to ignore. Rising deductibles are an apt example since patients bear 100% of health care expenses until they fulfill their deductible requirement, and only then will they finally have assistance.

When examining deductibles in this way there is clarity on the possible difficulties that arise for those who are high consumers of healthcare. For expensive medication, as biologics are, people on high deductible health plans would need to meet the full cost of that medication, or up to the full cost of the deductible. However, because these are high deductible plans patients may have to saddle the full cost of two to three months of their medication just to fulfill their deductible if a family has the average deductible for a family plan of $2800.

Coinsurance is something that finds its origins within the high-cost specialty drug market as a way to shift costs to consumers compared to copays. Coinsurance is different than the typical copayment because instead of a fixed cost of services rendered coinsurance is a charge of some percentage cost of the medication. Logically, coinsurance has been a strategy that has found its way into the prescription drug market, and especially specialty medications. This is because requiring a percentage of the total cost is often more expensive for the patient-consumer. Subsequently, this leads to the patient burdening more of the cost of their medication. Specialty medications are often put on the highest cost-sharing tier, with one study having shown that 49% of beneficiaries had a coinsurance of 29% (Claxton et al, 2014). This can become expensive very quickly. For example, the $300,000 a year cystic fibrosis medication KALYDECO, at a 29% coinsurance rate, leaves the patient with a cost of $87,000 (Rozario 2019). High cost-sharing

does make patients susceptible to decreasing their adherence on the medication that had been prescribed to them. Even for a condition with symptoms as severe as cystic fibrosis, it was found that "25% of patients with private insurance abandoned their medication when out-of-pocket cost per claim was greater than $200 for specialty medications" (Doshi et al 2016). While one could conceivably argue that this is an attempt to limit wasteful spending, the more convincing conclusion is that insurance companies are intentionally discriminating against patients in order to minimize their own costs.

The third-party system in the United States has grown in its influence to dictate treatment decisions. As reimbursement becomes more of a necessity for consumers to manage the costs of medication, third-party payers are tending to wield more power over treatment decisions than even the patient's primary physician. Additional frictions emerge at the expense of the consumer when biologic drugs not only need regulatory approval from the FDA but also requires a third-party payer to be willing to reimburse the patient. These factors have been demonstrated to restrict a patient's accessibility to drugs like biologics. One example of cost being a restriction to reimbursement is with the oncology drug rituximab. The most common reason for why treatment with rituximab has to be delayed, reduced, or cancelled outright are due to cost. In the U.S. 21% of the time the insurance refused to fund the treatment and 33% of the time the patient could not afford the copayment (Baer, Maini, Jacobs 2014). For the vast majority of patients, a biologic that is not reimbursed will be too expensive even if the drug passes all the other hurdles (regulatory approval, prescribed by physician, etc.) but as can be seen even when insured the copayments still can be too burdensome for patients.

For third-party payers to make their reimbursement decision, they often rely on testing a drug's "relative efficacy." The European Health commission defines relative efficacy "as the

extent to which an intervention does more good than harm, under ideal circumstances, compared to one or more alternative interventions" (Hans-Georg Eichler, Bloechl-Daum, Abadie, et. al 2019). This is an important measure for third-party payers as they have to be conscious of their budget and ensuring that funds are being allocated efficiently. Payers will also conduct an evaluation of need for individual patients regarding the drugs they take. This can include some or all of: "formulary tiers, step therapy [and] prior authorization" (Crespi-Lofton, Skelton 2017). However, this practice has problems arise on the consumer side as this can be a considerable roadblock in getting access to expensive treatments. From the patient's perspective who has to navigate this labyrinthian system by themselves, it can seem overwhelming to keep track of. To ensure a delivery and approval of a drug that is affordable the patient has to coordinate between many different parties that may not seem intuitively connected.

Employer Sponsored Insurance as a barrier to Accessibility

The cost of production that defines the market for specialty medicine has caused a crisis of affordability. The natural progression of this has also ultimately converged into an accessibility crisis as well. For the average specialty drug, the annual cost totals $84,442. Someone has to burden most of this cost and one group that has imposed a barrier to access has been employers. Tying health insurance to employment has been a practice particular to the United States, and even with health insurance reforms 56.6% of people under the age of 65 have employment-based insurance (Cha, Cohen 2020).

Hiding away in a corner, far from the front-page news, employers are trying to figure out how to manage the unmanageable: the chronically ill. Employers are still readily relied on by employees as their ticket to the best healthcare the world can offer but the cold reality is that

employers, in the sake of self-preservation, are obligated to impede the amount of healthcare employees can consume. When employers go shopping for health insurance they are willing to sponsor, there are two objectives on their mind: the cost of premiums and the appeal of the plan to potential employees. In both of these considerations, the chronically ill suffer.

The inclusion of coverage for specialty meds significantly increases the premiums of a health insurance plan. Employers bear a large responsibility for premium payments, with Humana gathering "employers typically cover about 82 percent of single employee premiums and 70 percent of family premiums. Therefore, employers are incentivized to limit the coverage options if the cost of inclusion is too high. With this in mind, there has been a transition by employers to carve out coverage of specialty meds into its own category, excluded from the standard plan. Another option increasingly being explored by employers is through excluding specialty meds from the pharmacy benefit altogether (EBN 2021). Oftentimes, the only way for employees to access have access to prescription drug coverage is by paying for it individually. Thus these patients are directly having to pay more to have insurance work for them due to their preexisting or chronic condition.

The contradictions at play are clear. To manage the rising costs of health insurance premiums, employers are cutting out the benefits that are responsible for this cost. The perpetrator that they have identified has been the prescription medicine benefit. According to a study published by Pharmaceutical Strategies Group (PSG), 70% of plans in 2021 tracked specialty meds separately as medical benefit, up from 50% in 2019. The reality is that employees on specialty meds are far more expensive than the average employee. The PSG study continues, and finds the cost of a specialty drug claim billed under the pharmacy benefit is $5,555 for the plan sponsor. Just one claim already brushes up against what an employer would expect to pay

for the average employee for the *entire year* ($6,894). When taking into account that specialty meds are administered multiple times per year, the comparison becomes silly. When PSG annualizes the cost of care for someone who uses at least one specialty drug, the cost of the health plan on behalf of the sponsor totals up to an average of $58,157.

The funny thing about this whole ordeal (if there is any humor to be found) is that employers are just as disgruntled about finding a solution to the specialty medicine crisis as the patients are in cutting through the red tape to have access to vital treatments. One benefits executive who was interviewed about the state of employer sponsored healthcare directly stated, "if there's a place where companies feel comfortable with government stepping in, it's specialty drugs" (The Commonwealth Fund 2023). What this executive verbalizes is a sentiment that has been shared by many employers who have found health insurance increasingly unmanageable. If nobody is satisfied with the system, and both are clamoring for government to ameliorate the problems, the logical next step is to examine what exactly our options are.

Marketing:

Everyone in the United States who owns a television set has seen advertisements for medication. Companies are aware of their target audience, so advertisements for Humira, Rinvoq, and Dupixent have become a ubiquitous part of the evening news, Jeopardy, or Wheel of Fortune. According to an analysis conducted by the Department of Medicine at Emory University, "via television alone, the average American is exposed to more than 30 hours annually of DTC advertisements for drugs" (Brownfield et. al 2004). To put this statistic into perspective, it dwarfs, by multiple magnitudes, the amount of time the average American spends with his/her physician each year (Tai-Seale et. al 2007). Advertising has also grown

tremendously in recent years. From 1997 through 2016 “DTC prescription drug advertising increased from $1.3 billion (79 000 ads) to $6 billion (4.6 million ads [including 663 000 TV commercials])” with the advertisements shifting towards expensive biologics and cancer immunotherapies (Schwartz, Woloshin 2019).

While the sheer volume of advertising may have been normalized in the United States, it is important to recognize that this is a unique landscape. Europe, for example, is completely absent of advertisements spending 30 seconds listing the possible side effects of a niche new medicine. However odd, this does not mean advertising is unimportant to pharmaceutical companies. In fact, it is a substantial part of their strategy for them to build up a firewall against potential competitors when they do enter the market. From 2016 to 2018 there was a total of $17.8 billion spent on direct-to-consumer advertising for a total of 553 different medications, with two-thirds of all the spending being dedicated to just 39 different drugs. Humira alone accounted for $1.4 billion of ad spending in that time frame (Torres 2021). It is important to scrutinize the purported benefits of advertising in improving public health since it constitutes a substantial portion of aggregate health spending in the United States.

To understand advertising, it is worth exploring when and how it can be a healthy tool for the consumer. There are demonstrable benefits in a world of robust advertising because it can potentially foster a competitive environment. One example being a landmark study examining the cost of eyeglasses across different states and seeing if there was a significant difference between the states who permitted optometrists to advertise versus states who prohibited advertising. The study found that in states which permitted advertising, the average price of eyeglasses was about 25% lower than in states restricting advertising (Benham 1972). Opticians advertised their prices to consumers, and this came closer to fulfilling the standard of perfect

information that is integral to a perfectly competitive market. Effectively, advertising is a low-cost way for consumers to become more educated in the choices they make by having the advertisers explain the benefits received if one purchases their product.

While this is the idealized story of advertising, it is much more different in the advertising space for specialty medications. Drug companies may advertise everywhere but the information that is shared is very specific. The primary problem in the advertising space for consumers is that they are bombarded with a positive assessment of a brand name drug without having additional information to compare to the advertisement itself. Biologic drugs are a good example of this problem. These are complex medications, and they go through very specialized processes and research to meet standards approval. There may be a ton of information out there, but the cost to the consumer in accessing and learning to understand the underlying facts is much higher than the minimal cost it takes for them to watch an advertisement. These facts have resulted in an asymmetric information system, or in other words an information failure.

Pharmaceutical advertisements sometimes provide information on what the consumer can expect in terms of price, but the way in which price is divulged is able to shield drug companies from price competition. The way that this is done is through rebates, drug coupons, and copay assistance programs. In essence, the drug manufacture offers discounts directly to the consumer of the medication, circumnavigating insurance so it is not a barrier to potential revenue. All of these tactics serve to reduce the price that the direct consumer has to pay for the drug that is advertised. This also makes direct-to-consumer advertising for specialized medicines a viable venture as well, because affordable programs are offered for people who have insurance. Studies have generally found that DTC advertising is a valuable tactic to increase the volume of outpatient visits to increase the number of prescriptions (Iiuzika, Zhe Jin 2007). Based on the

growing market for specialty medications this strategy has been highly favorable for the goals of pharmaceutical companies.

Humira is one of the original drugs to have its owner offer a copay assistance program to make the drugs more accessible for patients. AbbVie offers a savings card for this medication where patients can purchase Humira for as little as $5 a month. It is worth acknowledging that programs like this do clearly benefit the consumer in the short run. However, copay assistance programs have become quite controversial, and are heavily regulated in states such as California and Massachusetts, with several others considering legislation to curb the use of these programs.

What could be the problem that these states have with a program that looks like such a boon to patients? The problem paradoxically comes from the patients themselves. With these copay assistance programs, many having minimal and even free copays, consumers are no longer sensitive to the price changes happening behind the scenes. Since Humira launched in 2003 the price has risen 470% but these increases are invisible to consumers. This matters because the tab still needs to be paid by insurance companies and the costs of healthcare are forced to rise in other areas. Namely, with greater degrees of cost sharing such as higher deductibles, out of pocket maximums, and premiums. Copay assistance cards also have long-term implications in terms of the barriers they pose to biosimilar competition. This has turned into an economically unhealthy symbiosis where patients have strong brand adherence to the medication since they pay little while drug companies have a degree of freedom to charge the prices they want with minimal resistance. This overall reinforces the bloated health spending system in the United States, with specialty medications being a substantial part of the reason as to why.

Advertising is not limited to just drug competition, but it is also a tool to compete for the ears of potential patients. In this sense, not only are drug companies competing with each other,

but they are also competing with doctors to convince the patient what medication to take. In a study of 454 U.S. family physicians, nearly 80% shared the belief that direct-to-consumer-advertising was "not a good idea" (Lipsky, Taylor 1998). This is because it takes medical care out of the hands of experts. One could see direct to consumer advertising as a boon to patient autonomy, but this is only helpful to the extent that the patient has perfect information in both their condition and the products available. This is often not the case, and it is not uncommon for advertising to mislead the patient by omission. Most advertisements did not contain the basic elements of information a person might need to judge the usefulness of a treatment, such as "how a drug works (missing in 64%) or the likelihood of treatment success (missing in 91%). Only 29% of advertisements mentioned any treatment alternatives" (Lexchin, Mintzes 2002). Healthcare does not yet have the tools in place for patients to consistently make the correct healthcare decisions entirely autonomously.

Ideally, the role of the patient's doctor is to act as a more informed purchaser than them, and fill in the information asymmetry gap, but there are difficulties in achieving this. Physicians are also exposed to the advertising of large pharmaceutical firms, and this has compromised their ability to operate as an independent expert that acts on behalf of the patient. As figure 1 shows, while consumer advertising has grown the most, the majority of funds are still directed towards marketing towards physicians. Large pharmaceuticals are major contributors to medical journals. They also commit a large number of resources towards detailing, which is what pharmaceutical companies do to help educate physicians on their product in the hope that the physician will prescribe it more often. One econometric analysis of prescription drug advertising found that direct-to-physician advertising has long-lasting effects on prescription drug choice (Iiuzuka, Zhe

Jin 2007). This is a technique to go to physicians directly and build brand loyalty. It is not a stretch to conceive of this as operating with the same purpose as lobbying in Washington.

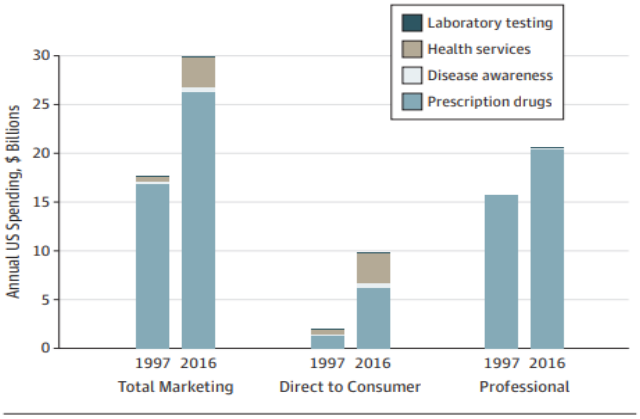

Figure 1: The total marketing for prescription drugs has grown substantially from 1997 to 2016. Direct to Consumer advertising has grown the most during this time but advertising to professionals still makes up the bulk of the total marketing for prescription drugs. (Schwartz, Woloshin 2019)

In all of these strategies, the goal of pharmaceutical companies' investment is to gain the trust of physicians and patients. The central decision makers in deciding what to prescribe are the physicians, rather than the ultimate consumer of the product. The effect that advertising has on physicians can be seen by using biosimilar uptake as a proxy. A 2014 survey of 81 Canadian rheumatologists found that 72% were unlikely or very unlikely to offer a biologically naive patient a biosimilar over an originator biologic (Sarpatwari, Berenie, et. al 2018). Even with clinical trials showing minor, ineffectual differences there is still skepticism about biosimilar products. Another possible reason for biosimilar hesitancy is due to the FDA's naming convention. Biosimilars are required to add a random four-letter suffix to the chemical name of the biologics. The argument follows that this may have an implicit psychological effect where

people conclude that there are greater differences between a biosimilar and its reference drug than actually exist.

Advertising prescription drugs is a contradiction in terms. Prescriptions are made available to those with specialized training to determine if certain kinds of treatments are appropriate. In today's environment, direct-to-consumer advertising is implicitly presented as arming the consumer with their own expertise in the treatment that is most effective for them. The reality is that the education provided through prescription drug advertising, especially specialty medications, is inadequate to substitute for the knowledge that physicians provide patients. The miscomprehension of medical information by consumers has been something that has been widely documented, as people often struggle to weigh the benefits and risks of medicinal products (Wilkes Bell, Kravitz 2000). Right now, the advertising campaigns of drugs is an aggressive method to strip the independent decision-making power of physicians which ultimately hampers the competitiveness of biosimilars. This can be restored, but it would have to come from deliberation on how, or if, advertising can be used to the benefit of public health.

Chapter 3:

Policy Solutions

Policy Proposal:

This paper identifies multiple issues that are present and persistent from the production to delivery of healthcare. There are problems of insurance companies who are using cost-sharing tools not to eliminate wasteful spending, but to minimize their own bottom line. Pharmaceutical companies monopolize essential medications by abusing the patent system. Patents have moved beyond the protection of intellectual property, and instead are being used to secure monopolies, with a not insignificant portion of these patents having no true innovative contribution despite being approved. In both instances, the health of the consumer is not part of their calculus, which has resulted in chronic price and accessibility problems. Given these details, it seems that the healthcare in the United States is irreparably broken. However, one does not need to throw the baby out with the bathwater as there are reasonable solutions that can be had without compromising the healthcare system that 86% of Americans are satisfied with (PRI 2022).

This paper has repeatedly identified the population on specialty medications as a key group in need of reform in order to depress the costs of healthcare. Even when there are options to make medications affordable, such as copay assistance programs, this does not force downward price pressure on the treatments themselves. The total cost of medication is instead being spread across the entire insured population through rising premiums, deductibles, and copays. It is no coincidence that these are the main qualms that subscribers have with their insurance. 46% of people said insurance premiums were too high, 45% said that deductibles were too high, and 39% said copays were too high (PRI 2022). Therefore, an essential problem that must be addressed to restore the integrity of the private healthcare system is managing the problem of cost.

The tool that is at our disposal that has the potential to address both of these concerns simultaneously is the government. Medicare was created for the purpose of being the insurance for those who the private market either charges exorbitant premiums or refuses to cover. These reasons are why the U.S. population over the age of 65 are eligible for Medicare.

Once United States citizens turn 65 years old, they are eligible for Medicare. However, it is important to note that the basic Medicare package does not cover everything that can be considered healthcare. Rather, the package is only limited to part A and part B benefits. This paper's policy proposal will be centered around reforming Medicare part D, which was established in 2006. Medicare part D is supplemental coverage in addition to Medicare that handles what its part A and B does not pay. Medicare part A is hospital insurance which includes coverage for inpatient hospital, hospice, and nursing home care. When insurance was first introduced in the United States this is what was offered as things that may be covered. Medicare part B covers medical services. This includes ambulance services, mental health, outpatient durable medical equipment, and some prescription drugs. These prescription drugs include but are not limited to those that are administered with durable medical equipment (such as an infusion pump), osteoporosis if one meets three specific criteria, end-stage renal disease drugs, and infusion and injection drugs that are administered by a licensed medical provider. Part B does not cover most immunosuppressive drugs because they can be, and often are, self-administered injections.

Medicare part D fills in this gap by being the additional coverage one could purchase for prescription drugs as a whole. This becomes a necessity for those over 65 to opt into if they need specialty medications. Medicare part D can operate as the solution to the problems present in U.S. healthcare if it includes the chronically ill and has robust negotiating power.

The chronically ill population meet the health standard that was set for the federal government to have an obligation to extend Medicare as an option. In many instances they may even exceed this standard, because the over 65 population is still faced with uncertainty regarding when and the amount of healthcare they will consume. This is unlike the chronically ill population, who, especially with their prescription medication face little to no uncertainty regarding when and how much they will need each year. The government has the capacity to grant chronically ill patients a source of affordable and accessible medication. Even more so, by extracting the most expensive subscribers of insurance out of the private market it is possible to stymie and even decrease the rising cost of premiums, deductibles, and copays.

In crafting a policy solution concerning specialty medication, this paper considers how to properly balance the interests of insurance, pharmaceuticals, and patients. This paper also operates under the assumption that with any policy decision there will be necessary trade-offs. One healthcare economist, Arnold Kling, refers to this as the "healthcare trilemma". This is a concept stating that the trade-offs in healthcare revolve around three primary goals: access, affordability, and insulation from risk. If a world of scarcity is to be assumed as true, then any policy must trade-off one of these goals for the benefit of improving the others. Access, affordability, and insulation from risk are the terms that this paper will work with when explaining the policy proposal, but we seek to expand upon the definition of what access really is in healthcare. Access is most commonly measured by the amount of people who are uninsured. However, access is much more than that and, as this paper has demonstrated, is inseparable from the issue of affordability.

Power dynamics in the healthcare market for specialty medications are such that increased costs flow down disproportionately to the consumer. There is high pricing for

prescription drugs and cost-containment strategies used by insurance companies, but the normal individual who relies on their medication does not the leverage to push for a system that works for them. Their outlet is to have those who possess greater to advocate for their needs on their behalf. This is normally the responsibility of a government or their doctor, but insurance and pharmaceutical companies are embroiled in an effort to for these consumer lifelines to prioritize their interests over that of the patient.

Based on the evidence outlined in this paper it is that the deliverance of healthcare suffers because patients on specialty medications do not have enough of a voice in the health insurance market to generate momentum for a healthcare system that works for them. The solution to this problem can be readily obtained, and it ought to be pursued by recommitting the federal government to its goal of being run by the people and for the people. Institutional fractures have made it such that congress has allowed, through inaction, for an affordability problem to grow into a crisis. The reason that this has happened is because the pharmaceutical industry has had the power to freely operate as a monopoly power over many rare illnesses and diseases. This excess is a fundamental market failure that bleeds into accessibility issues for the consumer because insurance is able to partially circumvent the imposition of increased costs to the system by leveraging their cost-sharing mechanisms such as deductibles, premiums, and copays.

The proposal that this paper advocates to address the affordability crisis is one that has been readily made more effective as a result of Medicare Part B and D being able to negotiate drug prices. The proposal is an expansion of Medicare Part D to those who are chronically ill. The WHO has a list of essential medications that it finds important to make readily accessible, but this paper believes that a list of essential illnesses is a better format to address conditions specifically. This guarantees that treatments will be accessible because of one's actual illness

instead of it being accessible because one is fortunate enough that their specific prescribed treatment is on the list.

For this expansion to be effective, it is also necessary that Medicare Part D be permitted to maintain its negotiating power in order to act as a powerful advocate for the consumer of care. The healthcare market breaks down because of the several monopolies on treatment that are controlled by pharmaceutical companies. Where any reform is directed, it must be addressing this as the primary solution to be solved. Otherwise, policy would fail to address the problem of affordability and even the federal government cannot absorb the inflated costs of specialty medications without completely being overwhelmed by its current budget. This next section will explore the possible avenues for reducing the costs of specialty medications while also addressing the common retort from the pharmaceutical industry that reducing their revenues would cripple innovation.

Drug Price Negotiation:

Many of the United States healthcare programs can negotiate medical costs. Medicaid, VA healthcare, and the IHS have this provision. However, as odd as it may seem, Medicare is not granted this privilege. Medicare's ability to negotiate drug prices has been advocated for as a tool for reducing the cumulative costs of prescriptions but this idea has been met with resistance. Opponents of price negotiation will point out that negotiation for prescription drugs does happen, except it does not happen directly with the federal government. Unlike part A and B which is provided by the government directly. Medicare part D is contracted out and provided by private companies. Humana is the main private company that offers Medicare Part D as a purchasable plan. The negotiation process is done by Humana instead of the government itself.

Nevertheless, Humana as the negotiator is not sufficient on its own to move the bulk of specialty drugs away from a monopoly system. Drug price negotiation in its current state can only negotiate prices 20% lower than the list price, which is still magnitudes larger than the marginal cost (Kesselheim, Avorn, Sarpatwari 2016). What this means is that the drug manufacturers effectively act as price setters rather than price takers. Medicare, being legally forbidden from directly negotiating prices, has essentially bestowed pricing power to the major biopharmaceutical companies. Therefore, pharmaceutical companies will also be able to control output by only selling up to the point where the marginal cost to produce an additional unit of their drug is equal to the marginal revenue that they receive from selling an additional unit of that drug. The assessment of the social damage of a monopoly is done by comparing this system to one of perfect competition. A monopoly, comparatively, has lower output at a higher cost. The consequence of this is that there is a market failure because this is not an efficient outcome.

Nevertheless, studies have found that negotiating power would have a major impact in its ability to reduce prescription drug spending in Medicare. One policy analysis by NBER found that there is great public welfare potential in having an expanded part D program that can negotiate drug prices:

> ‘‘Enrolling an additional 100,000 Part D beneficiaries enables an insurer to negotiate 2.5-percent lower prices on average. Our evidence suggests that most of the savings negotiated by insurers are, on the margin, passed on to enrollees as lower premiums. These results do not account for savings from improved bargaining power in negotiations with drug manufacturers, and thus provide a lower bound of the enrollment effect on total drug costs” (Lakdawalla, Yin 2009)

Though recently the Inflation Reduction Act had a provision beginning to set the stage for negotiating specialty medications, the provisional number of 10 negotiable drugs ought to be

expanded. A Medicare program that has the ability to negotiate can absorb the chronically ill into its system. However, to make drug negotiation even more robust this paper believes that Medicare part D should be the single payer for specialty drugs.

This is because Medicare Part D as the sole negotiator has the potential to correct the market failure that currently defines the market for specialty drugs. The reason for this is because the monopoly power of the pharmaceutical companies can be counteracted by Medicare as a monopsony. A monopsony is an economic actor who is the only buyer of a product being sold. Monopsonists behave similarly to the inverse of a monopoly where they are also a price setter but as the sole consumer of a good rather than the sole producer. Both the monopolist and the monopsonist are fighting over control of the demand curve and these two competing interests will help to lower the price to more competitive rates than the ones that currently exist. Figure 2 further shows why introducing a monopsonist power can lead to a more competitive outcome.

The demand schedule for a system where Medicare part D operates as a single payer for the chronically ill would have immediate market effects. It would generate a market structure where the high-priced specialty drug makers (a monopoly power) are negotiating with the government (a monopsony power). The result of this is difficult to quantify exactly but the settled price will be one based on who has greater bargaining power and skill. If a product has already been produced by a drug manufacturer, then the government will have greater leverage since drug companies only have one firm that will purchase their product. It is better to sell at a low price than to never sell it at all.

It is possible to get a basic conception of what monopsony negotiation could look like with a drug product that is a monopoly by looking at Europe, though there are limitations to this method. Admittedly, there is no country that produces an incentive structure for innovation to the

degree of the United States, and Europe is a beneficiary because they do not have to trade-off innovation for the benefit of low prices. The United States spending the most in the world on healthcare also means it is the greatest contributor to the revenues of companies that create health products. The United States market makes up 30-40% of the revenues for pharmaceutical companies across the entire world (Ellis 2016). This is despite accounting for 24% of the global GDP (Bhutada 2021). There is a disparity in importance of the US market compared to the rest of the world. This is especially evident with specialty medications because the vast majority of their revenues come from the United States. One study published found that Humira, Biktarvy, Ocrevus, and Enbrel made at least 77% of their total revenues in the United States alone (Claypool, Rizvi 2021). These are all specialty medications that are used to treat conditions like HIV, multiple sclerosis, and autoimmune diseases. This is of course an indication that something in the specialty medications needs adjustment if the US market is so radically different from the rest of the world, but it is also one explanation for why Europe can afford to do the policies it chooses to implement.

That being said, it is important to examine the European countries that use a single payer system to see how their monopsonist systems interact with these monopolistic products. To be blunt, there is little that separates the European system of price negotiation from a price control other than giving the pharmaceutical manufacturers the choice to opt into the price that is set. Despite this, the cost controls are not low enough to where no pharmaceutical company wants to sell to Europe. Europe enjoys both reliable accessibility to specialty medications and at a reduced cost. European countries almost uniformly participate in some form of value-based pricing. This means that the price is assessed based on the clinical benefit of the drug.

There are two main approaches that are used in Europe. One way that prices are decided is by evaluating a drug's comparative clinical effectiveness. In other words, this is a comparison between the drug that is being assessed and observing how much more effective it is than the other treatments that are already available. The better it is compared to the next best drug the higher its price will be set. This approach has been applied in France, Switzerland, and Germany. The other method used assesses a drug's comparative cost-effectiveness compared to existing treatments already available. This method is used in England where the drug's value is determined by "considering the additional cost required to generate an additional unit of health from the new drug" (Vokinger, Naci 2022).

These are methods trying to uncover what is a fair price to pay for a new medication on the market as opposed to pharmaceutical companies having the freedom to set the prices themselves in the United States. With either method, the result is the same in the sense that the monopsonist possesses greater power than the monopolist in this market. Though there is a distinct difference with the government acting as the drug price negotiator that is different from the typical monopsonist. The difference is that the government is dictating its price to maximize public welfare whereas most monopsonist's are motivated to choose a price that maximizes its profit and its individual welfare. In both price negotiating methods that are implemented across Europe there is indeed an effort to drive the cost of medication down, but this is being done to limit the deadweight loss that is felt when monopolistic pricing exists. Rather, the federal government is trying to set prices such that they resemble what a more competitive market environment would look like. Figure 1 below presents how the market for many specialty medications is allocated when able to operate in a monopolistic market and figure 2 shows how

Medicare part D negotiating power will be used to increase the allocative efficiency of prescription medications while also reducing costs.

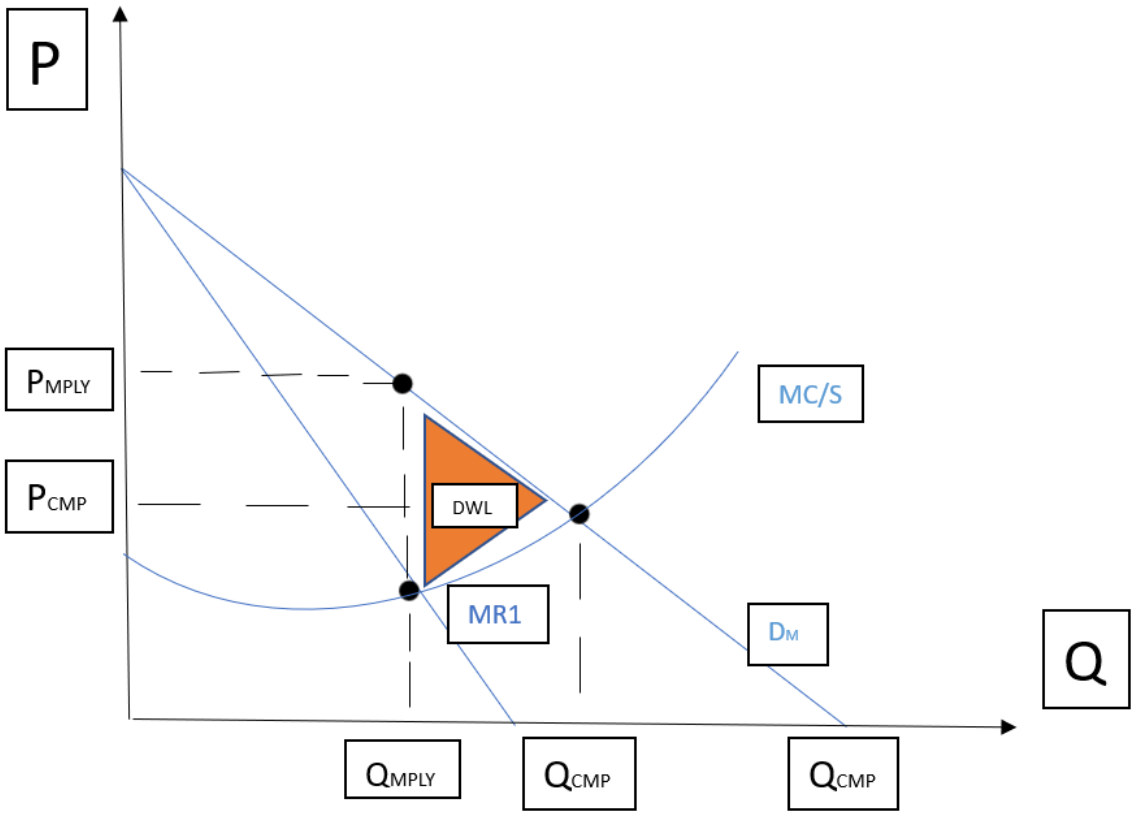

Figure 1: This is a general picture of many drugs in the specialty meds market. A monopoly model makes it such that the firm is a price maker rather than a price taker. Monopolistic firms operate along the demand curve and will pick their price on the demand curve where marginal cost (the supply curve) is equal to the marginal revenue curve. This pricing power means monopolies can charge above the competitive rate and supply a quantity below the competitive rate. This efficiency deficit compared to a competitive market is marked by the orange triangle labeled DWL (Deadweight Loss).

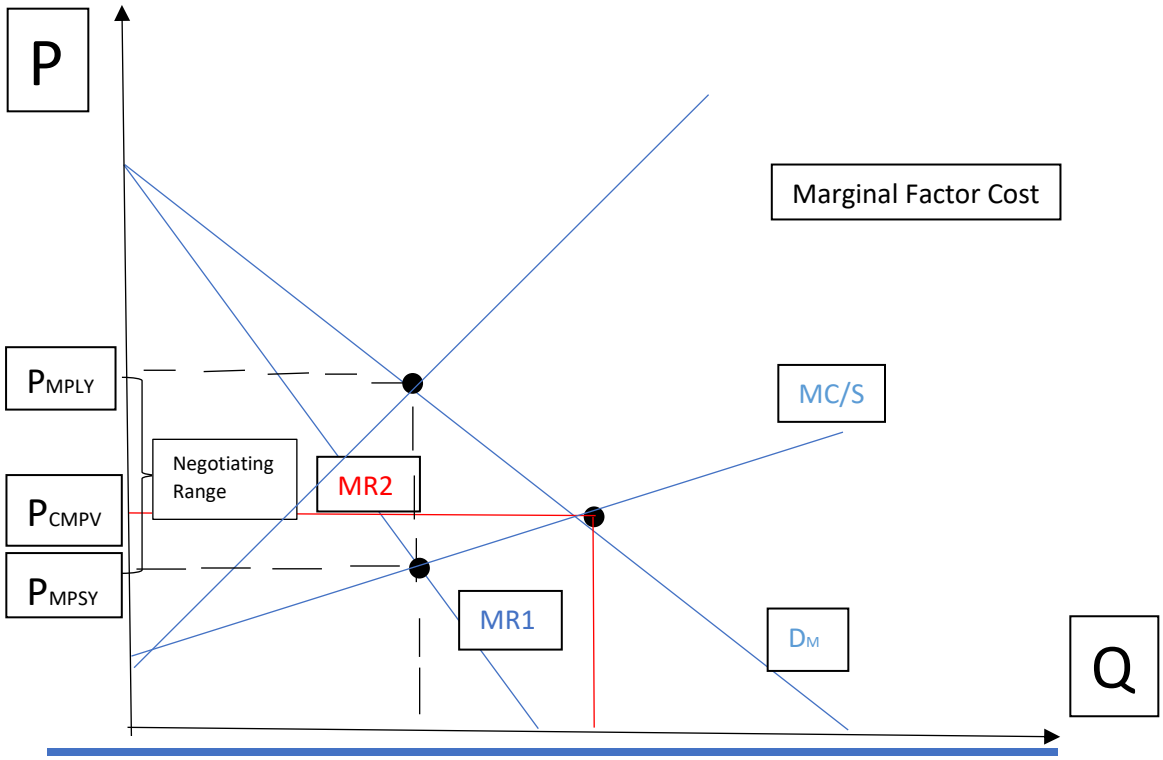

Figure 2: Based on the current legislative language Giving Medicare the ability to negotiate prices would lead to reduced deadweight loss and grant greater allocative efficiency than the current monopolistic pricing model of many biopharmaceutical companies. A single payer Medicare part D model for specialty drugs would resemble a monopsonist buyer. When a monopsony is given pricing power, they select the point on the marginal cost (supply) curve where marginal factor cost equals demand. Therefore, the model that takes shape is a monopoly (a price maker) vs. a monopsony (a price maker). In these two competing interests, a negotiating range opens and the outcome is determined by who has more market power. If both have equal levels of power, then theoretically one would arrive at the competitive rate as represented by MR_2. If the monopolist has more power than price will be set above the competitive rate. If the monopsonist has more power than the price will be set below the competitive rate. Medicare negotiating power is made in such a way where its goal is not motivated purely by monopsony interest but in reducing the deadweight loss that results from monopolies. The logic of this market structure mirrors that of many European countries that have the power to negotiate drug prices.

In any sort of single-payer legislation, one must be able to respond to the counterclaim that a monopsonist buyer will make it such that pharmaceutical firms will withdraw their investment from research and development for specialty drugs. This is an important question to answer because the world relies on innovation to improve the health of the population and find treatments for rare diseases. Thankfully, there are multiple data points one can point to where innovation is not unduly affected by bringing drug prices down.

The countries in Europe operate with a single payer system yet they still have access to prescription drugs with the added benefit that they obtain them at a lower cost than the United States. The system in the United States has become a cash cow for large companies because of the fractured process of price negotiation. In the United States large-branded pharmaceuticals can charge multiples more than the marginal cost to produce them (Dranove, Hermosilla, Garthwaite 2014). Several countries in Europe, as previously referenced in this paper, can purchase drugs at a rate more in line with traditionally competitive markets.

The power of negotiating prices is something that congress has long been demanding, and in 2022 we saw the first measures passed to introduce Medicare's ability to negotiate drug prices. Right now, the scope of this legislation is limited to 10 Medicare part D drugs that will be selected for negotiation by the Center for Medicare and Medicaid Services (CMS). The 10 drugs up for negotiation have yet to be officially selected but CMS will publish them by September 1, 2024. The criterion for selection is centered around three questions: clinical benefit, the extent to which it fulfills an unmet medical need, and its impact on people who rely on Medicare (HHS 2023). Negotiation will then expand further with CMS selecting up to 15 more part-D drugs by 2027, up to 15 more part-B or D drugs for 2028, and up to 20 more part-B or D drugs for each

year after that (HHS 2023). This will feel like a small step in its initial rollout but as the program expands it will be a boon to reducing spending by the government in the healthcare sector. The Congressional Budget Office (CBO) estimated that the drug pricing provisions in the Inflation Reduction Act will reduce the federal deficit by $237 billion over a 10-year time period from 2022-2031. This is especially notable since the first negotiated prices won't actually be applied until January 1st, 2026 at the earliest.

The effects of the legislation stemming from the previous legislation directed at reducing the prices for essential drugs have already paid early dividends. Recently, multiple insulin products have been reduced drastically in price. One example being Eli Lilly, which is the top producer of insulin. The firm reduced their price by 70% starting in May 2023. This drop in prices was not done out of altruistic reasons but rather because the government compelled Eli Lilly to adjust to new regulations. Namely, this comes from new Medicaid rules that penalize drug makers for raising prices faster than the rate of inflation (Los Angeles Times 2023). These are simple measures that are taken that can radically change the story of rising costs in the prescription drug market.

Benefits of Chronically Ill in Public Care

An expansion of Medicare Part D where it acts as the single payer for specialty medications would not just have the effect of granting affordable access to essential treatments, but it would also unburden private health insurance companies from their most expensive customers. There are many healthcare economists who, even while being advocates of market-driven reform in healthcare, readily admit that insurance is poorly adapted to prescription drug coverage (Hooper, Henderson 2018). This is especially relevant to this paper because insurance covers a monthly prescription of someone's illness for something like rheumatoid arthritis or

Crohn's disease. It does not take an actuary to measure that the event of this occurring approaches a probability of 100 percent. This is pre-paying for a known expense, and insurance does a poor job of this because paying for an event that has certainty is no longer insurable in any practical way. What is proposed by market driven reformers to address this problem is a transition to an insurance system that looks more like car or life insurance, where the events that fall under insurance ought to be the ones that are genuinely unexpected events. Expected events like picking up a prescription or a routine checkup should not be subject to insurance, but instead the consumer should be able to cover these small out-of-pocket costs themselves.

Though free market economists have been able to identify the problem with modern health insurance, this paper diverges from their solution. The specialty medicine market is unique in the sense that these are events that are entirely expected but also have extremely high out-of-pocket costs. In the context of this situation, it is unreasonable to expect that solving the healthcare system is as simple as separating the expected events from unexpected events, though this structure can work if the expensive expected events are not so directly exposed to the free market. This is where the proposed reformed Medicare Part D can act as an elegant solution to address the needs of the traditional and chronically ill population. For the chronically ill Medicare Part D can make specialty medications more affordable while maintaining a commitment to accessibility. The traditional population's premiums and deductibles would be reduced as insurance companies no longer have to guard against the rising costs of healthcare. This policy proposal not only aims to make drug prices cheaper, but also envisions a pathway towards eliminating the market failure in the health industry that is attributable to patients who do not face uncertainty in their care.

Policy exploration on regulating the increase of deductibles by insurance:

To make this a reality there must be some pressure for insurance companies to reduce their premiums because it is naïve to expect companies to reduce prices when there is no imperative. This would instead have to come from the government in the form of assessing the actual validity of raising premiums or deductibles. The ideal standard that an assessment policy would want to achieve is to ensure that premiums and deductibles are rising on the basis of reducing moral hazard in health care and not on the basis of reducing their own exposure to costs. One basic standard that could be as a tangential measurement is that deductibles and premiums would not be allowed to rise above the rate of inflation.

Insurance companies have also been burdened with a new role since the Affordable Care Act. Without the right to deny coverage the agency of insurers to avoid costs outright has been blocked. Since these are patients who are chronically ill, who do not face uncertainty of claims when assessing their own health, the harmony of the insurance-patient relationship is disrupted. Now, insurers have to effectively operate with two roles: one as a profit seeker and managing a social program for the chronically ill. These two jobs are at odds with one another, and make private insurers poorly adapted to take on chronically ill patients. The Affordable Care Act may have prevented those with preexisting conditions to be denied entry, but insurance companies are not prevented from burdening patients with high cost-sharing or placing significant barriers before approving a patient's medication. The outcome of this is a recognition that chronically ill patients not only need an insurance company that is a true advocate for their health needs, but also one that is powerful enough to exert downward price pressure on pharmaceutical companies.

Patent Reform:

Since the bulk of the problem with specialty medications on the supply side has been based on the abuse of the patent system, it is reasonable to look at options for innovation that can

be reimagined beyond the patent system. One can look at the development process of Operation Warp Speed to see how the government can compel the behavior of firms to invest in the drugs that Americans had a demand for.

Additionally, South Korea is an example of how government can direct private investment instead of pure market forces. This was a series of policy choices adapted towards the rapid development of their nation after the Korean war to reach highly developed status but the techniques that were used to achieve this could be applied to healthcare. What South Korea did was help assist with the financing of "infant" industries. These industries were selected for investment based on the government identifying a need in the economy. Notable examples of industries that benefited from non-neutral industrial policy were producers of concrete, steel, petroleum, and chemicals (Westphal 1990). This was done because these are the core ingredients that were needed to be able to build infrastructure, but there is reason to believe that this can also be applied to research and development. Companies that are investing into drugs that the government sees as worthwhile could have expanded investment subsidized. In the common situation of a monopolistic firm selling specialty medications the government could also be compelled to help along biosimilar products that wish to enter the market but face high-cost barriers to entry. The clinical trials are still necessary to ensure the fidelity and safety of a new treatment, but at least in this case the government could assist biosimilar products through this process through a grant approval process.

Alternatively, as has also been used in East Asia with success has been the government setting a reward for developing something that the government demands. This was actually recently seen in the United States during the pandemic. The government made several promises to companies were they able to develop a vaccine for COVID-19. The United States made

extensive use of advanced purchase commitment contracts to ensure that there would be a sufficient enough demand for the vaccine. There was also a push by the government to absorb the bulk of the cost for clinical trials (Frank, Dach, Lurie 2021). The government essentially stepped in to subsidize the risks of entering the market for COVID-19 vaccines. The vaccines for the initial rollouts wound up being free for the ultimate consumer, because the government was again aiding in subsidizing the cost.

This was a moment where central government coordinated with private enterprise in a fast, efficient, and effective manner. The total cost of this project by the government has been estimated between $18-$23 billion. One does not need to invest that much into creating a more robust market for specialty medications. Biosimilar products and their tracking to approval could be aided by having the government alleviate some of the risk that makes it such that firms are hesitant to enter the biosimilars market.

The problem with Operation Warp Speed was that large pharmaceuticals, the very sector that already has been identified by this paper as having excessive power, would be the beneficiary of subsidized costs. This also would do little in reducing the real costs of specialty medications since this merely shifts the costs from the private sector to the public sector. There are serious questions about the sustainability of government's role in healthcare spending, and this policy does not address it but perhaps exacerbates it. However, this problem exists because the federal government did not negotiate aggressively enough with the pharmaceutical companies to reduce the prices of the vaccine. This is forgivable because leverage was not with government because the pandemic created a state of emergency but in instances that are less pressing, the government has the capacity to control the amount of revenue that a pharmaceutical company is able to make with the product that they create.

Exploring policy proposal also poses an opportunity to explore what this paper refers to as the "diminishing marginal rate of return on the profit motive." In other words, it is worthwhile to find out the efficient point where profit is a motivating factor to innovation. This is the intention of the policy that this paper proposes. Every policy proposal that has momentum in the public sphere has some method in which to attempt to toe the line between the making prescription drugs affordable while not adversely affecting innovation. Instead, it may be fruitful to objectively identify the point where there is minimal non-innovative innovation without losing any of the meaningful innovation. There is most certainly wiggle room available right now where profits can be reduced in the pharmaceutical industry without adversely impacting innovation in a significant way. According to the CBO a 15-25% reduction in revenues for the drugs in the top quintile of expected returns (which specialty medications are) would only lead to a 0.5% average annual reduction of new drugs in the first decade and increasing to maximum rate of 8% in the third decade. This is certainly a manageable percentage, and it is even more so when considering many of these "new" therapies that are projected to be lost would most likely be neither novel or an improvement on a preexisting drug. Marcia Angell, the former editor of the *New England Journal School of Medicine,* contextualizes the innovative contribution of private pharmaceuticals stating,

> "The big drug companies now concentrate mainly on … producing variations of top-selling drugs already on the market —called 'me-too' drugs. There is very little innovative research in the modern pharmaceutical industry, despite its claims to the contrary" (Angell, 2010).

In other words, they would not be innovative in the sense that innovation is traditionally understood. The way that pharmaceutical companies primarily contribute to innovation is by creating new formularies or delivery processes to impose barriers to biosimilar entry and making

bioequivalent entry close to impossible. Though the question of innovation is important to address with any policy that targets the pharmaceutical industry, evidence points to there being enough leeway where a reduction in profits does not necessarily have the consequence of less meaningful innovation. Given this information, it is feasible that large-advanced purchase orders by the government can help alleviate some of the market risk for pharmaceutical companies to continue to operate in an innovative capacity even in an environment with reduced revenues.

Investment in infant industry and a reimagining of Operation Warp Speed are two possible policy options that through positive reinforcement could continue to encourage innovation in an environment while simultaneously having lower list prices and lower profit margins. A government-industry partnership is a conducive path towards sustained innovation at an affordable cost for Medicare, Medicaid, and the patients themselves. This may sound like a massive change on paper, but it is perhaps more modest than it sounds. The reason for this is because the government and universities already play a vital role in research and development. Additionally, while research and development are a component for private companies it is often relatively minor. This has already been explained regarding the minimal actual innovation that is borne out of private research and development, but private companies also demonstrate a lesser role in the innovative process with their budgeting. Programs such as advertising and lobbying garner a greater percentage of a pharmaceutical company's overall budget.

The research done by the National Institute of Health and universities has been able to shoulder most of the investment made in the medical sector. This evidence is significant when one calls concern to the possible trade-off of a less favorable market for medicines resulting in less innovation. Much of the science surrounding mRNA development did not occur on the campus of Pfizer or Johnson & Johnson but rather it came from the National Institute of Health

and the laboratories of institutions such as MIT and the University of Pennsylvania (Blumenthal, Miller, Gustaffson 2021). Research and Development for the big pharmaceutical corporations come in the end-stages of development such as conducting clinical trials for their products and figuring out how to manufacture their product so it can be sold as a commodity good. This is an essential step, but it proves that the research and development process for firms operates in very specific realms. Their research is not beyond the scope of how to turn the science of the NHS into a marketable product.

This policy analyzes the current landscape of healthcare and concludes that of the major actors, it is the pharmaceutical industry dominates. To improve the healthcare system, it must begin with a policy to curtail the nearly unchecked pricing power of biopharmaceuticals. This paper recommends that the most prudent course of action is to absorb the chronically ill into Medicare Part D because they fundamentally do not fit the private market assumptions of consumer demand. Medicare part D's newfound negotiating power ought to be robust and it can become the single payer for specialty medications if those that require them are all part of the same insurer. This will force price pressures downward to a more competitive rate. Pharmaceutical companies will be able to tolerate this reduction in profits without a significant reduction in new drug innovations. Lower prices are the norm in every other developed country, and there is little reason to suspect that the United States would not be able to adopt similar measures. Even if the prices following this policy are still above the international average this would still be a boon in comparison to current situation of persistent rising healthcare costs.

Chapter 4: Conclusion and Expansion of Discussion on Specialty Medications

Conclusion:

Those who are looking for solutions to reduce the aggregate spending of healthcare in the United States are often looking in the wrong places. There are many who believe that the reason healthcare is swallowing up GDP is because of inefficient moral hazard that is pervasive in consumer behavior. This paper proposes a contrary perspective: that the groups meeting the catastrophic care threshold are at the center of the healthcare spending crisis. This is a conclusion supported by others who have found "the majority of healthcare spending… is accounted for by a small share of high-cost individuals whose spending is largely in the "catastrophic" range where deductibles and co-payments no longer bind" (Einav, Finkelstein 2018). The focus on moral hazard is a misdirection that has been repeatedly applied to excess in a reckless quest to achieve efficiency while missing the context of what is being threatened in a framework that punishes people for pursuing their healthcare needs. Our current system of healthcare punishes people who need it the most, people with rare and complex diseases, cancers, and diabetics.

Specialty medications are at the center of our health care ills and in desperate need of a cure. The current sustainability of our current healthcare system requires insurance companies to make accessibility as difficult as possible for patients. Over time, pharmaceutical companies have built leverage in this space to set and raise the prices for their products with little resistance. The patent system currently in place has little recourse to prevent its abuse by biopharmaceutical companies. This has downstream effects and bleeds into the rest of the problems that are present on the supply side of the specialty drug market. Patents are the source of monopoly power for firms, and if this is the impetus America chooses for innovation there at minimum has to be ways to lessen the impact of patent thickets. Excessive patents have overwhelmed the patent offices in being able to effectively analyze their true innovative capacity with sufficient scrutiny. Patents

have also made it such that the introduction of competition has been both delayed and limited in their capacity to generate downward price pressures. Competitors have to work around several different drug formularies and manufacturing processes that are patented by a single firm, and this makes truly substitutable products such a burdensome process that it is hardly ever pursued. Biosimilars, even when they are introduced, still face more disadvantages because the major biopharmaceutical players have multiple strategies to dominate control over the demand curve with advertising and creating patient loyalty for their product.

The ability of biopharmaceutical companies to sustain their high prices is the reason that insurance companies are prompted to make claims on specialty drugs difficult to get consistent approval for. Each claim made is a potential cost to the insurer and specialty medications are high-cost claims that are regularly being made each day. Insurers have responded by imposing barriers and utilizing tools such as the widespread use of prior authorization forms and the utilization of step therapy. What is evident is that there is an adversarial relationship that is inherent between the insurer and the subscriber, and this is only made worse by both parties trying to avoid as much exposure to the high cost of specialty medications as possible. However, the almost inevitable result that we see today is the one where the consumer loses. Currently, the chronically ill must navigate a healthcare environment where the means to receive care is ultimately dictated by the insurers and not by themselves.

Despite legislation attempting to ameliorate these problems, private health insurance has repeatedly failed to be a tool that works for the chronically ill in effectively and reliably delivering them healthcare. The reason legislation has failed is because it does not address the root of the problem. In order to enact meaningful and lasting change in the specialty drug market the power of the major biopharmaceutical players must be curtailed. What this paper has

proposed is not a novel solution, but merely borrowing from European countries that have identified and addressed this same problem. Medicare part D has the power to negotiate prices to reduce them down to a level that is comparable to the rest of the West, and more reflective of a competitive market. Therefore, including the chronically ill as beneficiaries of an effective negotiation process will result in the reduction of prices and there will also be a subsequent reduction in the total amount of spending on one of the fastest growing markets in the United States: prescription drugs.

The novel contribution that this paper does contribute to the conversation is that this is a policy that can be passed without placing additional burden on any specific group of people. This is because there is a simultaneous benefit in moving the chronically ill to public care because it also improves the efficacy of the private healthcare sector. By admitting that the chronically ill are not an insurable group and moving them to a social program, private health insurers would no longer have to compensate for their inclusion by raising premiums and deductibles for everyone. So long as there is a standard in place to evaluate the necessity of raising premiums and deductibles, there would be a pause in the upward trajectory of health insurance costs. It is even possible that premiums and deductibles could decrease for the insurers to capture a broader market of people who opt not to subscribe to insurance specifically because of their current high-cost structure. This sequence of events means that an expansion of Medicare part D to include the chronically ill could be had at a minimal increase in taxes. It is feasible that this tax increase could also be offset by the benefit that private subscribers will get in the reduction of their premiums and deductibles.

This paper sets out to make clear that the chronically ill population does not make sense in the private insurance system for any party other than the biopharmaceutical industry. The

Nyman demand theory for healthcare reflects how patients consume healthcare, and it also shows why the chronically ill population are a population pool that does not interact well with the general population that consumes healthcare. The chronically ill are, over their lifetime, going to be net receivers of income transfers and this is known by the chronically ill with certainty. This violates John Nyman's own definition of insurance which is that "Insurance is a contract between an insurer and a consumer that exploits the uncertainty of some future event that would trigger a payout" (Nyman 2020). This is the problem with the chronically ill population on an insurance plan: since they know that they will need medication regularly, they are operating with certainty in the kind of healthcare they will consume in an environment where uncertainty is the core assumption of insurance. This is a group that for all intents and purposes best fits the criteria to have a social program established for them. The market has had some modest success in reducing the prices for specialty drugs, but these are still limited in the price pressures due to the difficulty in building the capital to establish new participants in the market as well as the necessary but restrictive regulations required to ensure that new drug products are both safe and effective. The government is the most effective tool at our disposal to speedily, consistently, and securely lower drug prices for a healthcare system that desperately needs it.

This is not just an economic problem but also a question of moral obligation posed at Americans to people who needs their country to have their needs in mind. The reason why Medicare was created in the first place was to help vulnerable groups who are exposed to the harsh realities of the market. Market exposure is not inherently bad, but the outcomes of the elderly in receiving adequate care prior to Medicare were. They were too much of a risk for insurance without blatant price discrimination because the information the elderly possessed for their demand for healthcare was approaching certainty. The story of the elderly population

navigating private insurance is one that lines up with the chronically ill today, but the way that private insurance treats them is perhaps even more pernicious, because their cost of care is known with even greater certainty.

The story that is presented in this paper is not strictly contained within the boundaries of the specialty medicine market. The problems that are shown are evident in several different contexts. For example, the power of companies to wield power over the direction of funding is a barrier to progress that exists in research for other fields of research. Many non-profit organizations compete for grant funding to continue their research in a space that is very competitive. Who determines what is worthy of research is often lost in the background, but this is a highly normative process because it shapes the sphere of what is objectively known. One example is the persistent racial bias that is present in research funding. In the research space, comparing racial minorities in the United States to white Americans they have fewer social networks that enable connections to the philanthropic community as well as an overall lack of funding capacity to meet the preconditions for funding from philanthropic sources (Dorsey, Kim, Daniels, et. al 2020). If only one perspective is receiving the funding to explore their hypothesis, then they will necessarily be armed with a greater base of knowledge than other competing perspectives. This can result in certain perspectives winning out in the marketplace of ideas with the force of money alone.

The health insurance system needs saving, and the solutions are readily available to us right now. This paper serves as an example that there need not be a radical overhaul of the current status quo to make real improvements in people's lives. Medicare for All may be a laudable goal, but in the meantime, it is worth exploring other ways to deliver progress to the people. A platform must be flexible and cannot sustain itself on a single policy alone. The goal

of legislation is to look for solutions. Political gridlock does nothing but prolong the duration of problems that need solving today. This paper is an exercise in looking for creative contributions to the larger discourse of how to address the healthcare crisis in the United States and it would be prudent to see more widespread momentum to look for novel solutions to novel problems.

Bibliography:

[1] Imani Telesford, Shameek Rakshit, Matthew McGough, Emma Wager, and Krutika Amin. "How has US spending on healthcare changed over time?." *Peterson-KFF health system tracker* (2023).

[2] Walker, L., & Gorenstein, D. (2023, January 31). *AbbVie's blockbuster drug Humira finally loses its 20-year, $200 billion monopoly*. NPR. Retrieved April 15, 2023, from https://www.npr.org/sections/health-shots/2023/01/31/1152513058/abbvies-blockbuster-drug-humira-finally-loses-its-20-year-200-billion-monopoly

[3,4] Hirsch, B. R., Balu, S., & Schulman, K. A. (2014). The impact of specialty pharmaceuticals as drivers of health care costs. *Health Affairs*, *33*(10), 1714-1720.

[5] Jared Ortaliza, Matthew Mccough, Emma Wager, Gary Claxton, Krutika Amin "How has US spending on healthcare changed over time?." *Peterson-KFF health system tracker* (2023).

[6] Jennifer Tolbert, P. D. (2023, February 7). *Key facts about the uninsured population*. KFF. Retrieved April 15, 2023, from https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/

[7] Stroupe, K. T., Kinney, E. D., & Kniesner, T. J. (2000). Does chronic illness affect the adequacy of health insurance coverage?. *Journal of Health Politics, Policy and Law*, *25*(2), 309-342.

[8] Brennan, Z. (2021, May 18). *House committee uncovers how Humira's price spiked by 470% as AbbVie execs cashed bonuses tied to the hikes*. Endpoints News. Retrieved April 15, 2023, from https://endpts.com/house-committee-uncovers-how-humiras-price-spiked-by-470-as-abbvie-execs-cashed-bonuses-tied-to-the-hikes/

[9] Al-Bawardy, B., Shivashankar, R., & Proctor, D. D. (2021). Novel and emerging therapies for inflammatory bowel disease. *Frontiers in Pharmacology*, *12*, 651415.

[10] Kofi Ampaabeng, O. C. (2022, December 9). *How the new Congress can improve drug pricing reform*. The Hill. Retrieved April 15, 2023, from https://thehill.com/opinion/healthcare/3768561-how-the-new-congress-can-improve-drug-pricing-reform/

[11] Sarpatwari, A., Barenie, R., Curfman, G., Darrow, J. J., & Kesselheim, A. S. (2019). The US biosimilar market: stunted growth and possible reforms. *Clinical Pharmacology & Therapeutics*, *105*(1), 92-100.

[12] Wednesday. (n.d.). *Article*. Pfizer. Retrieved April 15, 2023, from https://www.pfizer.com/news/articles/5_things_worth_knowing_about_biosimilars_and_interchangeability

[13] Joszt, L. (2022, May 13). *The US is entering round 2 of biosimilar activity, says Cardinal Health's oskouei*. Center for Biosimilars. Retrieved April 15, 2023, from https://www.centerforbiosimilars.com/view/the-us-is-entering-round-2-of-biosimilar-activity-says-cardinal-health-s-oskouei

[14] Grabowski, H. G., Ridley, D. B., & Schulman, K. A. (2007). Entry and competition in generic biologics. *Managerial and Decision Economics*, *28*(4-5), 439-451.

[15] Mulcahy, A. W., Predmore, Z., & Mattke, S. (2014). The cost savings potential of biosimilar drugs in the United States. *Perspectives*, *1*, 1-16.

[16] Blackstone, E. A., & Joseph, P. F. (2013). The economics of biosimilars. *American health & drug benefits*, *6*(8), 469.

[17,18,20,22] Grabowski, H. G., Guha, R., & Salgado, M. (2014). Regulatory and cost barriers are likely to limit biosimilar development and expected savings in the near future. *Health Affairs*, *33*(6), 1048-1057.

[19] US Food and Drug Administration. (2016). Implementation of the Biologics Price Competition and Innovation Act of 2009.

[21] Campanelli, Gina. 2022. Feeling Evergreen: A Case Study of Humira's Patent Extension Strategies and Retroactive Assessment of Second-Line Patent Validity. Master's thesis, Harvard University Division of Continuing Education.

[23] Gibbons, J. B., Laber, M., & Bennett, C. L. (2023). Humira: the first $20 billion drug. *The American Journal of Managed Care*, *29*(2), 78-80.

[24,25,27,28,29] Wu, J., & Cheng, C. W. C. (2019). Into the woods: a biologic patent thicket analysis. *Chi.-Kent J. Intell. Prop.*, *19*, 93.

[26] *AbbVie Inc. et al v. Boehringer Ingelheim International GmbH et al, no. 1:2017CV01065 - document 471 (D. del. 2019)*. Justia Law. (n.d.). Retrieved April 15, 2023, from https://law.justia.com/cases/federal/district-courts/delaware/dedce/1:2017cv01065/62839/471/

[30] Dickson, S., & Ballreich, J. (2019). How much can pharma lose. *West Health Policy Center*.

[31] Amin, T., & Kesselheim, A. S. (2012). Secondary patenting of branded pharmaceuticals: a case study of how patents on two HIV drugs could be extended for decades. *Health Affairs*, *31*(10), 2286-2294.

[32,33] Frakes, M. D., & Wasserman, M. F. (2020). *Investing in ex ante regulation: Evidence from pharmaceutical patent examination* (No. w27579). National Bureau of Economic Research.

[34,35] Einav, L., & Finkelstein, A. (2018). Moral hazard in health insurance: what we know and how we know it. *Journal of the European Economic Association*, *16*(4), 957-982.

[36] Kelman, S., & Woodward, A. (2013). John Nyman and the economics of health care moral hazard. *International Scholarly Research Notices*, *2013*.

[37] Nyman, J. A. (2020). The theory of insurance and gambling. *Available at SSRN 3599273*.

[38] Antos, J. R., & Capretta, J. C. (2020). The ACA: Trillions? Yes. A Revolution? No. *Health Affairs. https://www. healthaffairs. org/do/10.1377/hblog20200406*, *93812*.

[39] Abels, D. (2023, February 23). *Broken bones can result in thousands of dollars in losses*. Abels & Annes, P.C. Retrieved April 15, 2023, from https://www.daveabels.com/broken-bones-can-result-in-thousands-of-dollars-in-losses/

[40] Director, S. N. A., Nadeau, S., Director, A., Shepherd Director, M., Shepherd, M., Director, E. L. A., Lofgren, E., Rapfogel, N., Ross, J., Nelson, D. A., Buchanan, M. J., & Donald, K. (2022, July 28). *Health insurance costs are squeezing workers and employers*. Center for American Progress. Retrieved April 15, 2023, from https://www.americanprogress.org/article/health-insurance-costs-are-squeezing-workers-and-employers/

[41] *What is a high-deductible health plan and how does it work?* Bank of America. (2023). Retrieved April 16, 2023, from https://healthaccounts.bankofamerica.com/how-an-HDHP-works-with-an-HSA.shtml#:~:text=Per%20IRS%20guidelines%20in%202023,before%20your%20insurance%20pays%20anything.

[42] Wooldridge, S. (2023, February 20). *HDHP enrollment reaches more than 50% of American private-sector workers*. BenefitsPRO. Retrieved April 16, 2023, from https://www.benefitspro.com/2023/02/20/hdhp-enrollment-reaches-more-than-50-of-american-private-sector-workers/?slreturn=20230316121442

[43] Siracusa, C. M., Ryan, J., Burns, L., Wang, Y., Zhang, N., Clancy, J. P., & Drotar, D., Claxton (2014). Electronic monitoring reveals highly variable adherence patterns in patients prescribed ivacaftor. Journal of Cystic Fibrosis, 14(5), 621-626.

[44] Rozario, N. L. (2019). *Price Elasticity of Demand for Patients with Select Diseases Using Specialty Medications and Their Association to Total Healthcare Costs* (Doctoral dissertation, The University of North Carolina at Charlotte).

[45] Doshi, J. A., Li, P., Ladage, V. P., Pettit, A. R., & Taylor, E. A. (2016). Impact of cost sharing on specialty drug utilization and outcomes: a review of the evidence and future directions. *Am J Manag Care*, *22*(3), 188-197.

[46] Baer, W. H., Maini, A., & Jacobs, I. (2014). Barriers to the access and use of rituximab in patients with non-Hodgkin's lymphoma and chronic lymphocytic leukemia: a physician survey. *Pharmaceuticals*, *7*(5), 530-544.

[47] Eichler, H. G., Bloechl-Daum, B., Abadie, E., Barnett, D., König, F., & Pearson, S. (2010). Relative efficacy of drugs: an emerging issue between regulatory agencies and third-party payers. *Nature reviews Drug discovery*, *9*(4), 277-291.

[48] Crespi-Lofton, J., & Skelton, J. B. (2017). The growing role of biologics and biosimilars in the United States: Perspectives from the APhA Biologics and Biosimilars Stakeholder Conference. *Journal of the American Pharmacists Association*, *57*(5), e15-e27.

[49] Cha, A. E., & Cohen, R. A. (1922). Demographic variation in health insurance coverage: United States, 2020.

[50] Schiavo, A. (2021, August 30). *As the cost of specialty medications increases, employees want employers to bear the financial burden*. Employee Benefit News. Retrieved April 16, 2023, from

https://www.benefitnews.com/advisers/news/as-the-cost-of-specialty-medications-increases-employees-want-employers-to-bear-the-financial-burden

[51] *What employers say about the future of employer-sponsored health insurance*. What Employers Say About Future of Employer-Sponsored Insurance | Commonwealth Fund. (2023, January 26). Retrieved April 16, 2023, from https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/what-employers-say-future-employer-health-insurance

[52] Brownfield, E. D., Bernhardt, J. M., Phan, J. L., Williams, M. V., & Parker, R. M. (2004). Direct-to-consumer drug advertisements on network television: an exploration of quantity, frequency, and placement. *Journal of health communication*, *9*(6), 491-497.

[53] Tai-Seale, M., McGuire, T. G., & Zhang, W. (2007). Time allocation in primary care office visits. *Health services research*, *42*(5), 1871-1894.

[54] Schwartz, L. M., & Woloshin, S. (2019). Medical marketing in the United States, 1997-2016. *Jama*, *321*(1), 80-96.

[55] Torres, L. (2021, June 17). *Medicare spent bulk of drug cash on advertised products*. Bloomberg Law. Retrieved April 16, 2023, from https://news.bloomberglaw.com/health-law-and-business/medicare-spent-bulk-of-drug-spending-on-advertised-products

[56] Benham, L. (1972). The effect of advertising on the price of eyeglasses. *The Journal of Law and Economics*, *15*(2), 337-352.

[57,58] Iizuka, T., & Jin, G. Z. (2007). Direct to consumer advertising and prescription choice. *The Journal of Industrial Economics*, *55*(4), 771-771.

[59] Lipsky, M. S., & Taylor, C. A. (1997). The opinions and experiences of family physicians regarding direct-to-consumer advertising. *Journal of Family Practice*, *45*, 495-499.

[60] Lexchin, J., & Mintzes, B. (2002). Direct-to-consumer advertising of prescription drugs: the evidence says no. *Journal of Public Policy & Marketing*, *21*(2), 194-201.

[61] Sarpatwari, A., Barenie, R., Curfman, G., Darrow, J. J., & Kesselheim, A. S. (2019). The US biosimilar market: stunted growth and possible reforms. *Clinical Pharmacology & Therapeutics*, *105*(1), 92-100.

[62] Wilkes, M. S., Bell, R. A., & Kravitz, R. L. (2000). Direct-To-Consumer Prescription Drug Advertising: Trends, Impact, And Implications: Aiming drug ads at consumers means big business for drug companies, but its effect on clinical care is not yet known. *Health affairs*, *19*(2), 110-128.

[63,64] Pacific Research Institute. (2022, September 27). *Americans are overwhelmingly satisfied with their health coverage, finds new PRI National Survey*. Pacific Research Institute. Retrieved April 16, 2023, from https://www.pacificresearch.org/americans-are-overwhelmingly-satisfied-with-their-health-coverage-finds-new-pri-national-survey/?utm_source=rss&utm_medium=rss&utm_campaign=americans-are-overwhelmingly-satisfied-with-their-health-coverage-finds-new-pri-national-survey

[65] Ellis, L. (2015). Snapshot of the American Pharmaceutical Industry. *Harvard. edu. Inside Health newsletter. Recuperado de https://www. hsph. harvard. edu/ecpe/snapshot-of-the-american-pharmaceutical-industry*.

[66] Lakdawalla, D., & Yin, W. (2009). *Insurer bargaining and negotiated drug prices in Medicare Part D* (No. w15330). National Bureau of Economic Research.

[67] Bhutada, G. (2021, January 14). *The U.S. share of the global economy over time*. Visual Capitalist. Retrieved April 16, 2023, from https://www.visualcapitalist.com/u-s-share-of-global-economy-over-time/

[68] Claypool, R., & Rizvi, Z. (2021, October 4). *For 20 top-selling drugs worldwide, Big Pharma Revenue from U.S. sales combined exceeded revenue from the rest of the world*. Public Citizen. Retrieved April 16, 2023, from https://www.citizen.org/article/united-we-spend-big-pharma-us-international-revenue-report/

[69] Vokinger, K. N., & Naci, H. (2022, December). Negotiating Drug Prices in the US—Lessons From Europe. In *JAMA Health Forum* (Vol. 3, No. 12, pp. e224801-e224801). American Medical Association.

[70] Dranove, D., Garthwaite, C., & Hermosilla, M. (2014). *Pharmaceutical profits and the social value of innovation* (No. w20212). National Bureau of Economic Research.

[71] https://www.latimes.com/business/story/2023-03-17/column-eli-lilly-announced-a-huge-cut-in-its-insulin-prices-heres-why-it-doesnt-deserve-your-praise

[72] Charles L. Hooper and David R. Henderson, RELATED CONTENT By Charles L. Hooper, Novak, M., Carden, A., Salinas, A., & Candela, R. (2018, September 28). *A cure for our health care ills*. Econlib. Retrieved April 16, 2023, from https://www.econlib.org/library/Columns/y2018/HooperHendersoncure.html

[73] Westphal, L. E. (1990). Industrial policy in an export-propelled economy: lessons from South Korea's experience. *Journal of Economic perspectives*, *4*(3), 41-59.

[74] Frank, R. G., Dach, L., & Lurie, N. (2021). It was the government that produced COVID-19 vaccine success. *Health Affairs*.

[75] Angell, M., & Reading, K. (2005). *The truth about the drug companies: How they deceive us and what to do about it* (p. 319). New York: Random House Trade Paperbacks.

[76] Blumenthal, D., Miller, M., & Gustafsson, L. (2021). The US can lower drug prices without sacrificing innovation. *Harvard Business Rev*.

[77] O'Callaghan, J., Barry, S. P., Bermingham, M., Morris, J. M., & Griffin, B. T. (2019). Regulation of biosimilar medicines and current perspectives on interchangeability and policy. *European journal of clinical pharmacology*, *75*, 1-11.

[78] Dorsey, C., Kim, P., Daniels, C., Sakaue, L., & Savage, B. (2020). Overcoming the racial bias in philanthropic funding. *Stanf Soc Innov Rev*.