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# An Analysis of State Level Legislation Aimed at Reducing Pharmaceutical Prices: Are They Enough?

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## *An Analysis of State Level Legislation Aimed at Reducing Pharmaceutical Prices: Are They Enough?*

By

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## ***Table of Contents***

## ***Abstract***

The rising cost of pharmaceuticals has been an issue of growing concern in many countries both developing and developed. In the United States, high pharmaceutical prices cause significant financial stress to patients and create barriers to access, causing treatable conditions to deteriorate. Many legislative attempts have been attempted on various levels to control prices, but in the United States it has been mostly left to states to address the issue. In this comparative case study, pharmaceutical utilization data and sentiment data are analyzed from three states to represent various approaches: South Dakota to represent states with little legislation, Rhode Island to represent states with average amounts of legislation, and New Jersey to represent states with high levels of legislation. This analysis will provide insight into whether current legislative efforts being undertaken at the state level are proving to be sufficient to tackle an ongoing and worsening problem.

## ***Glossary***

- Pharmacy Benefits Managers (PBMs): third-party administrators of prescription drug programs that negotiate rebates and discounts for patient groups they represent. They are also primarily responsible for the development of the formulary for pharmacies, and represent a major interest group in the pharmaceutical industry with significant financial and social power.
- List Price: the price of a product or service (in this case, pharmaceuticals) that would be listed on the product were it viewed in a traditional commercial environment. Also referred to as sticker price, it is the price which sellers set for their products before any discounts or other modifications are applied.
- Actual/True Price: the actual cost paid by a consumer for a good or service. This consistently differs heavily from list price in the case of pharmaceuticals due to the many layers of rebates, discounts, insurance, and other modifications that are the norm in the industry.
- Drug: another term for pharmaceutical, used interchangeably in this thesis. Both of these terms represent chemical entities consumed or utilized for their therapeutic benefit - for example, insulin is a pharmaceutical/drug because it is a chemical entity used in the treatment of diabetes.
- (Unique) Chemical Entity: a term used in patent law and the sciences to delineate chemical products of a specific molecular composition. Chemical entity is therefore the blanket term used to describe the category of pharmaceutical goods in order to differentiate between the molecular compositions of various products. New chemical entities are often developed by major pharmaceutical companies, and are the “product”

which is protected under patent law as having the exclusive right to be produced by the company which developed it.

- Generic Drug/Brand: the equivalent of "store brand" as opposed to "name brand" with regards to pharmaceuticals, in which a manufacturer markets a chemical entity under the scientific name of the entity after that entity has surpassed its patent period. The generic form of the Epipen is referred to as an epinephrine auto-injector, just as the generic form of Advil is known as ibuprofen.
- Legislative Effort: throughout this thesis, this term will be used to refer to any actions initiated directly by state legislatures which are in some way meant to address high drug prices (as determined by the National Academy for State Health Policy). These efforts did *not* need to be successful or result in enacted legislation in order to be considered for this thesis.

## ***Introduction***

The rising cost of healthcare in the United States has been a topic of heated debate for much of the 21st century. As many countries in the developed world and beyond establish systems of socialized, single-payer healthcare, the United States' system of individual payers has been the topic of much critique, as it has become increasingly clear that a significant portion of the population slips through the cracks. These patients, whether they be uninsured, underinsured, or high cost, have often been left financially harmed by rising medical costs, often to the point of facing a choice between bankruptcy and prolonged illness. Despite having access to arguably the best medical technology in the world, United States citizens routinely suffer and die under the burden of treatable illnesses due to prohibitive costs. These costs have become especially notable in the pharmaceutical industry, as the nature of pharmaceuticals is such that they are perhaps the most widely interacted with facet of medicine to the average citizen. Thus rising costs of pharmaceutical products are an issue of key concern when considering how to keep the citizens of the United States healthy.

The circumstances of these rising costs are, in certain examples, mystifying. Many products currently exist on the market in a state of rising costs which traditional market economics fail to explain. Chief among this category are injectable insulin, used in the treatment and management of diabetes, and the Epipen, the epinephrine auto-injector owned and produced by Mylan (now Viatris after a merger with Pfizer subsidiary Upjohn) and used for emergency treatment of anaphylactic shock. The unique context of these cases are similar to each other; each pharmaceutical has been on the market for decades, with the first use of insulin occurring in 1922 and the first epinephrine auto-injector coming to market in 1983 (Vecchio et al, 2018 and FDA, 1987). Since their inception, the pharmaceutical products themselves have undergone very

few changes, i.e. the form in which they entered the market is largely the same as that which can be found in the modern day. Both products have become ubiquitous to United States citizens, with insulin treatment being an everyday consideration for diabetic patients and almost every person with severe allergies being recommended to carry an Epipen at all times for emergencies (Energy and Commerce Committee, 2019 and GOP Oversight Committee, 2015). And finally, both products have undergone massive price increases post-2000, such as insulin tripling in price between 2002 and 2013 and the Epipen doubling in price between 2014 and 2018 (Hua et al, 2016 and Marsh, 2018).

These price increases have come steadily over the course of years. This combination of facts yields some confusion. A basic understanding of economics would state that steady price increases would result from reduced supply, increased demand, or a change in the quality or production of the product. However, neither insulin nor the Epipen exhibit these changes. The products themselves have remained largely the same with some minor exceptions, such as optimizations of the Epipen's delivery mechanism, and both remain comparatively cheap and easy to produce, with both drugs costing pennies to manufacture (Energy and Commerce Committee, 2019 and GOP Oversight Committee, 2015). While demand has increased in proportion to the population, this has been matched by increases in supply due to the ease of manufacturing each pharmaceutical. Even if it is assumed that increased demand would increase price, it fails to explain the sheer magnitude of the price's rise. Other pharmaceuticals, such as those with small markets, have well understood confounding variables which conspire to create similar price rises. In addition, if demand has risen so dramatically, then the market size has also risen dramatically, which should incentivize competition in the form of other companies producing the same products for lower prices. The question thus remains: what causes

pharmaceutical products such as insulin and the Epipen, which are well understood, easy to produce, and applicable to a massive market, to rise in price?

Addressing this issue is imperative for a country like the United States. One does not need to look far to see the massive impact that high costs of healthcare can have on everyday citizens. News stories abound of people rationing their supply of insulin due to being unable to afford additional doses, leading to injury and death (Cefalu et al, 2018). Similar accounts circulate of people left destitute paying for medical treatment, with bills for treatment reaching hundreds of thousands or even millions of dollars (Amadeo, 2021). Crowdfunding websites such as GoFundMe have seen massive increases in utilization for emergency medical funds, with as many as a third of all campaigns being used for such needs (McClanahan, 2018). Taken together, these factors form a bleak picture of the United States as a place where citizens die from treatable illnesses, not because the treatment is complex or dangerous, but because it is inaccessible.

Some may argue that allowing the free market to self regulate is the proper response to this sort of issue, as the problem is excessive prices. Theoretically, a competitive environment would encourage another producer to enter the market, especially if the products are easy to produce. However, there are multiple reasons that this problem cannot be left to its own devices. First, the trend of prices has been steadily upwards, despite controversies over high prices being consistent over the past decade or more (Cefalu et al, 2018 and Chua and Conti, 2017). This implies that the problem might not correct itself if given time. When considered economically, this idea is reinforced - medications are an incredibly inelastic good, as the alternative to purchase in the case of conditions such as diabetes is injury or death. With this fact ensuring a constant demand, there is a power imbalance in which the consumer cannot exercise their usual

ability to stop supporting excessive prices. Second, with regards to competition, the main competitive forces present in the pharmaceutical industry are generic manufacturers. However, evidence has shown that generic manufacturers have proven to be some combination of ineffective, unable to intervene, or unwilling to intervene, leading to circumstances in which singular producers may go uncontested in pharmaceutical markets, a phenomenon which will be explored more in depth later in this thesis (Wouters et al, 2017 and Drake et al, 2014).

Another note on the limitations of the free market is that it has been widely agreed that a rigorously regulated pharmaceutical industry is desirable to ensure the quality of the goods produced. With this being the case, a truly free market is impossible, as some level of quality assurance oversight is necessary. While it is certainly possible that a perfectly free market would succeed in driving down drug prices, it is unlikely that such a market could feasibly exist.

Herein lies the impetus for this issue to be considered a problem of policy. A variety of groups *could* theoretically intervene in this matter, those groups mostly consisting of pharmaceutical companies, the public, healthcare providers, insurance companies and pharmacy benefit managers, and state or federal intervention. However, each of these bodies, with the exception of governmental bodies, has factors that either disincentivize them from intervening or prevent them from doing so:

- The pharmaceutical industry, just like any other industry, is profit motivated on a basic level. That is to say, financial considerations are the only factors of relevance when determining a corporation's behavior. As has been outlined previously, the inelastic demand for pharmaceutical products maintains relatively constant levels of demand in the market, allowing high prices to remain in place without relevantly reducing sales. In

addition, competitive forces cannot drive prices down due to the unique nature of intellectual property as it pertains to medical products as well as due to the issues in efficacy present in the generic manufacturer niche (Kesselheim et al, 2016). In essence, there is no financial motivation for companies to lower prices, and to the contrary, they instead enjoy financial incentives to *maintain* high prices. With the only currently existing incentive to lower prices being moral, there is effectively no impetus for a strictly profit motivated body to change its behavior when that behavior yields rewards.

- Traditionally, the public has intervened when confronted with potentially imbalanced financial situations via methods such as boycotting or changing purchasing behavior. However, two primary factors prevent the public from exercising this power in the pharmaceutical market. The touched upon inelasticity of medical goods means that boycotting and similar methods cannot be implemented without yielding massive amounts of harm to the patients who use these medicines, as even momentary breaks in treatment can be potentially fatal. Meanwhile, the nature of the pharmaceutical industry as one of high barriers to entry and strictly regulated (and therefore expensive) developmental processes yields a consumer market comparatively bereft of competition, as small businesses cannot enter the market (Morgan et al, 2011). In addition, intellectual property barriers can prevent even potential competitive entities from intervening and offering patients choice (Kesselheim et al, 2006 and 2016). Thus the public is left in a position where they both must purchase the product and are unable to "shop around" for lower prices.
- Healthcare providers are, in many ways, equivalent to the public in that they are unable to avoid consumption of medical goods and cannot notably influence the source of those

goods. While the public maintains a personal safety need to consume medical goods, healthcare providers instead maintain a moral imperative to offer care to their patients.

- Insurance companies, much like pharmaceutical companies, are, on a basic level, profit motivated. Whereas pharmaceutical companies enjoy direct benefits from high prices, insurance companies enjoy a more indirect one: high list prices allow insurance companies the opportunity for large discounts, which both engenders a sense of gratitude from the public and artificially creates a *need* for insurance. Thus high list prices for pharmaceuticals are, in part, responsible for the thriving of insurance companies, creating financial incentive for insurance companies to maintain them. Pharmacy benefit managers are in a similar position where negotiating larger discounts helps maintain both their public image and their necessity from a financial perspective.
    - Many proponents of both the insurance and pharmaceutical industries point to the ubiquity of insurance as justification for high list prices, as if the actual price of a drug is affordable, the list price is irrelevant. However, the state of insurance in the United States, which leaves many under or uninsured, leads to some number of patients paying list price and being unable to afford treatment as such (HHS, 2021).

In the absence of any other actors with the ability or incentive to intervene in pharmaceutical pricing, policy is necessary to rebalance the playing field. The fact that only the government can intervene also serves to double down on the moral imperative mentioned earlier - if another entity could feasibly intervene, and had reason to do so, then there would be an argument for the government to remain uninvolved for the sake of neutrality. As the only actor in

that position, however, it becomes the government's responsibility to rectify the current situation so as to aid the health and wellbeing of citizens of the United States. Not only that, but many of the contributing factors to this problem stem from policy decisions made elsewhere, such as decisions regarding how to restrict and manage pharmaceutical companies, meaning the government bears some responsibility for the situation's existence in the first place.

Another factor which lends policy actors unique efficacy and impetus to intervene is the deeply rooted information asymmetry present in the pharmaceutical industry. It is well understood that the process of developing new pharmaceuticals and medical products in general, as well as the process of producing existing ones to high standards of quality and efficacy, is an expensive one (Morgan et al, 2011). What is *not* well understood is where those expenses come from in the supply chain. Major parts of the pharmaceutical supply chain are deeply obfuscated from public view such that it is often difficult to verify claims of the costs associated with a product's production (Glabau, 2017). The absence of this information creates a major informational asymmetry between producers and consumers which further separates the average patient from the agency of making informed decisions about their medicines. In addition, it prevents legislators from making informed decisions regarding policy in this sphere, as the veracity of claims from pharmaceutical manufacturers becomes more difficult to verify. That being said, in much the same way as policy is the only tool able to intervene in this matter overall, it is also the only tool which can enforce high standards of transparency, a key first step towards understanding the problem as a whole. Pharmaceutical companies benefit from this imbalance in power, and so despite being the only parties with access to the information necessary to rectify it, they cannot be expected to.

Overall the prior factors outline the fact that policy is not only the most effective response to the current crisis, but also the most warranted one, as a government bears a responsibility to not allow its citizens to languish under situations that it is equipped to solve (and in many ways responsible for solving). Indeed it can be seen that many policy actors have already been mobilized to attempt to rectify the situation - national attention has been paid to the healthcare crisis, with public officials at both the state and federal levels proposing a variety of solutions, and in fact many pieces of legislation or other action have been taken (examples of this legislation will be explored in detail later in this thesis). Currently, this action exists mostly on the state level, as the vastly different opinions on the best way to approach the situation, paired with the unique contexts of healthcare in each individual state, have conspired to prevent federal legislation from gaining traction (Padula, 2019). For example, the Affordable Care Act, known colloquially as Obamacare, is the most recent piece of landmark healthcare reform in the United States, and has been perhaps the most controversial piece of policy implemented in the past few decades. Therefore state level actors have sought their own routes to reducing the cost of healthcare.

Unfortunately, while costs of healthcare have been a hot button topic in the United States media for more than a decade, they remain inaccessibly high for many people, including for ubiquitous drugs such as insulin and the Epipen. Not only that, but many reports indicate that prices continue to rise. With so much attention being paid to reining in healthcare costs on the state level, the question must be asked of whether these efforts are wasted. While the justification for state level action (namely, more specifically tailored solutions to each state) is reasonable, it is possible that the roots of the problem are only addressable from a federal perspective, as they require more generalized changes to the operation of the pharmaceutical industry or its related

branches. In addition, federal legislation often carries more force, and while being "one-size-fits-all" is in many ways a downside, it does enforce nationwide standards that can reduce the complexity of the field as a whole.

This thesis will attempt to analyze the suitability of state level drug pricing regulations as they pertain to the examples of insulin and the Epipen, for the purposes of determining whether such actions are adequate for reducing prices and increasing accessibility. Thus there are three potential results for this research: analysis could determine that state level actions are effective, that state level actions are not effective and federal intervention is warranted, or that neither state nor federal intervention is effective or warranted. These results will depend largely on comparisons between states with low, middling, and high levels of legislative attention paid to controlling healthcare costs. These comparisons will be made between a variety of benchmarks of efficacy meant to specifically highlight the baseline accessibility of each pharmaceutical, i.e. how accessible those goods are to the lowest common denominator of patient in the state. In this way a qualitative comparative analysis of each state as a case study in its specific legislative approach to healthcare can be constructed to inform future policy decisions and more efficiently direct resources towards addressing the overall problem.

As an engineer, a student of policy, and a generally concerned citizen of the United States, I view the rising prices of pharmaceuticals to be one of the most egregious issues faced by the country's populace in the modern day. As an engineer, I have been taught that the free exchange of knowledge is key to the cultivation of progress and innovation, and yet in pharmaceuticals we see the field dominated by a few key players encouraging the market to allow them to be the only producers. As a student of policy, I have been taught that it is the government's duty to intervene on behalf of the people when situations arise which cause them

harm, and yet people continue to fall ill and die from conditions which we have known how to combat for decades. And as a concerned citizen, I see the state of my fellow residents of the United States as one in which they are being abused for profit, held at metaphorical gunpoint with an ultimatum: pay for the drugs, or die from the disease. There are many challenges facing us, and the world, in the modern day for which there are no current solutions. Therefore we cannot afford to waste time and resources addressing problems which are manufactured artificially for the benefit of a few key players and at the expense of society at large. The current circumstances of pharmaceuticals in the United States does nothing except enforce itself and keep medical treatment out of the hands of those who need it, and thus must be rectified as soon as possible.

# ***Literature Review***

If there is one thing that is well understood about the United States healthcare system, it is its complexity. To understand the suitability of various approaches to solving the problem of rising costs, it is thus necessary to have an understanding not just of what approaches are being used, but also of their reasoning and the general context of the problem as it exists. In addition, from there it is important to understand the possibilities and limitations of the potential federal responses such that it can be determined whether those alternatives would be more effective than current state level solutions. Reviewing literature which addresses each of these topics will allow for the creation and understanding of a narrative that will inform as to what questions are necessary to answer. This will therefore direct the creation of case studies which can be used to answer those questions.

## Rising Prices

While it is now a commonly known fact that the United States pays more for healthcare than other countries, it is nonetheless important to understand the severity of the problem as well as the factors that contribute to that cost. Proponents of the United States system argue that the high costs are reflective of efforts to encourage innovation from the corporate sector, as well as the systems of insurance which help most residents to cover medical costs (Tulum and Lazonick, 2019). Critics, meanwhile, argue that the high prices are indicative of predatory business practices taking advantage of vulnerable communities, and that the various systems meant to reduce list prices to palatable amounts still leave many people falling through the cracks (Energy and Commerce Committee, 2019).

To begin, evidence shows that the cost of medical care in the United States is dramatically higher than in other countries, even when accounting for potentially confounding variables. In a study conducted by Papanicolas et al (2018), it was found that the United States pays as much as twice the amount of money as other high-income countries on medical care, despite having similar rates of utilization, workforce, and other metrics of supply and demand. The key differences in cost, according to the researchers, came from administrative costs, labor costs, and costs of goods - goods such as pharmaceutical products, for which spending per capita was anywhere from two to three times as much as in other countries. The study also noted that rates of insurance in the United States were significantly lower than in other industrialized countries, at roughly 90% as opposed to 99-100%, with more than half of insured patients utilizing private insurance. This study thus shows that healthcare in the United States is both more expensive and less likely to have its cost reduced than in other countries.

Furthermore, price has not just increased in pharmaceutical products as a whole, but specifically in products which should theoretically be ripe for competitive price decreases. In their 2020 study, Alpern et al performed a cross-sectional analysis of three-hundred pharmaceutical products which were defined as sole-source (i.e. only produced by one manufacturer) and off-patent, looking specifically for price increases. They found that, even when adjusted for inflation, these products suffered from an on-average 8.8% price increase per year, with 66 drugs suffering from upwards of 50% price increases per year. Traditional economic wisdom would imply that competitive forces should drive these prices down, but the perverse incentives in pharmaceutical manufacturing instead enable the continuation of effective monopolies on these products. These monopolies subsequently allow those sole manufacturers to price their products with impunity.

**Why Prices Rise**

Among these perverse incentives are the complexities inherent in the United States pricing system. As has already been mentioned, the various layers of price modifiers in the United States are often used to justify high list prices. Pharmaceutical companies need to profit from their business, after all, and thus must account for layers of rebates and discounts. For example, in her 2002 brief for the National Health Policy forum, Gencarelli outlines the flaws inherent in the use of average wholesale price as a benchmark for drug pricing; specifically, she explains how the price is established not based on transaction costs, but on estimations of the expected rebates and discounts that will be applied to the cost before it becomes a true price. Average wholesale price is effectively equivalent to a drug's list price. These estimations, while not directly in the control of pharmaceutical manufacturers, are nonetheless informed by their pricing data, and so allow the opportunity for willful misrepresentations of true cost in pursuit of profit. In this case, the presence of an incentive to set prices to financially advantageous levels pushes prices for products up in the absence of other explanatory variables.

In addition to these perverse incentives are the variables which can potentially drive drug prices up in a more legitimate way. One of these is the high cost of development of drugs, both innovative and established. DiMasi et al (2003) found that, when accounting for the costs associated with failed pharmaceuticals, the developmental costs of innovative drugs measure in the hundreds of millions of dollars. While the production of known chemical entities is a significantly less expensive process, the rigorous processes of quality control and approval necessitated by the Food and Drug Administration nonetheless raise the barrier for entry into the pharmaceutical market, reducing competition. In addition, when considering innovative drugs, patient populations are often low, thus reducing the size of potential markets and further

disincentivizing the entry of competitive entities. These factors make the pharmaceutical industry in many ways a potentially high-risk, low reward market where manufacturers *must* make significant returns on each product. This phenomenon is illustrated in Figure 1.

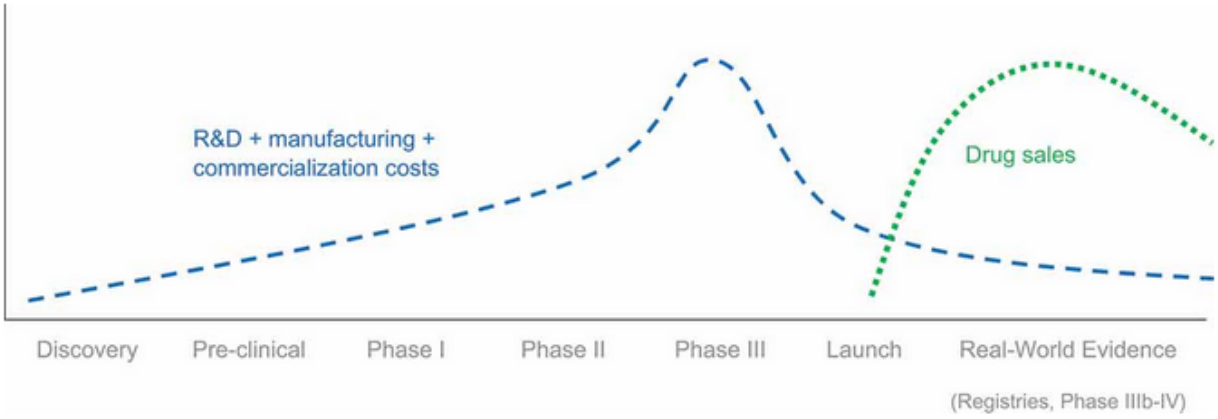



*Figure 1: a graph from Moreno and Epstein (2019) detailing the costs and revenues in the pharmaceutical development process. This graph displays one of the multiple factors that make pharmaceuticals a high risk market: high costs that are not recouped in revenue until late in the production process.*

This more "above-board" incentive for high prices nonetheless yields its own perverse incentives - for example, Drake et al (2014) outline the practice of "reverse payment" settlements between name-brand and generic pharmaceutical producers, in which it is more advantageous to generic manufacturers to accept settlement payments from name-brand manufacturers than it is for them to invest in a drug market as a producer. This allows the generic manufacturer a guaranteed profit and the brand-name manufacturer a continued monopoly, raising profits for both. These profits come at the expense of the patient, who is forced to continue purchasing from isolated manufacturers.

**What's the Problem?**

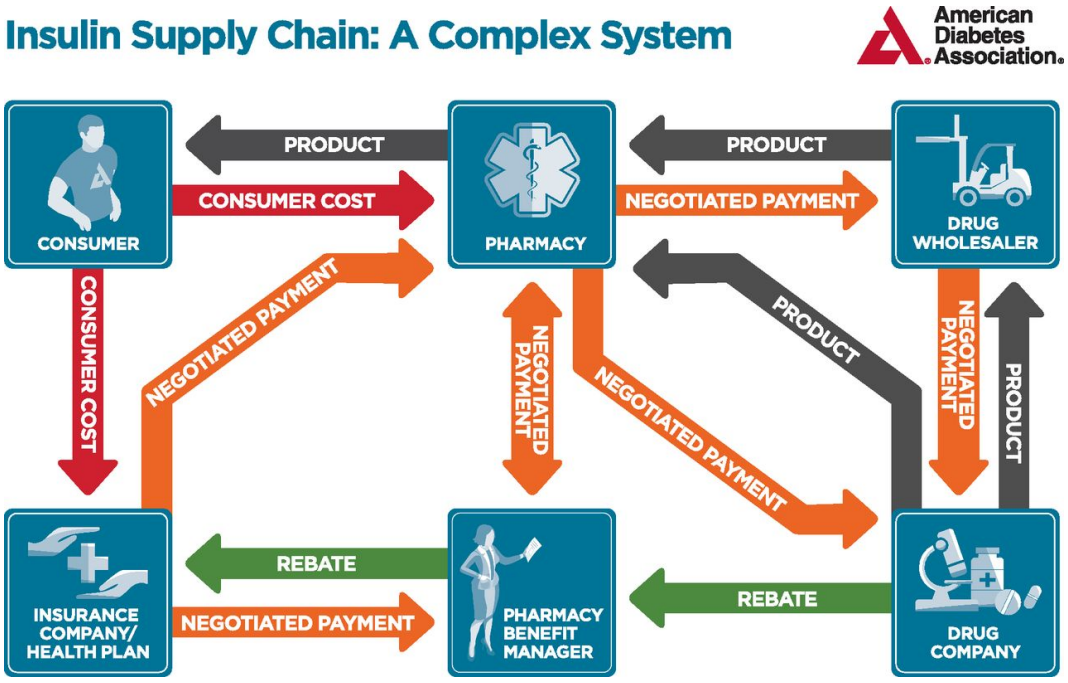
Even with these perverse incentives, proponents of the pharmaceutical industry argue that high costs are necessary in order to fund further research and development of innovative new drugs (Tulum and Lazonick, 2019). However, this may not be the case. Gagnon (2015) outlines the high rates of investment that the pharmaceutical industry maintains on fronts such as shareholder return and mergers and acquisitions - fronts more or less divorced from research and development. Evidence such as this implies that a greater than average portion of profits are being directed towards the enrichment of the company and shareholders as opposed to the development of new products.

Despite these issues, many tout the institution of generic drug manufacturers as the solution, and indeed generic drugs represent a powerful tool for the reduction of price of off-patent drugs. Wouters et al (2017) found that utilization rates of generic drugs in the United States far exceeded rates in other wealthy countries, while also exhibiting lower prices. That being said, they also note that many off-patent pharmaceuticals have experienced massive price spikes in recent years, reinforcing the previous idea that while generics are an effective tool when implemented properly, there are barriers to entry which prevent the system from being utilized to its full efficacy.

**Insulin and the Epipen**

With these factors and incentives established, we have now attained a reasonable understanding of the general problems facing the pharmaceutical market in the United States. As such we can move to focus on the specific cases of insulin and the Epipen. Insulin in particular has been a topic of much focus in the modern day due to its meteoric price rise. Hua et al (2016)

performed a study which found that the average list price of insulin products in the United States had more than tripled between 2002 and 2013. In part utilizing the data from this study, Cefalu et al (2018) analyzed the potential reasons for this price increase. They found that, between the three manufacturers of insulin, any price increase by one would be surreptitiously matched by the other two. In addition, the researchers noted that the pricing environment of insulin is as complex as any other pharmaceutical, if not more so due to the massive market size and the presence of multiple powerful entities in the market, as shown in figure 2a below. As the figure shows, money flows in many directions and between a multitude of parties, and every new actor adds new layers of complexity and pricing differences. This complexity lends itself to the aforementioned layers upon layers of price calculations, which in turn yields high list prices that are expected to be reduced before point of sale. This complexity further impacts pricing by obfuscating the mechanisms by which prices are established, allowing for practices such as egregious list price setting.



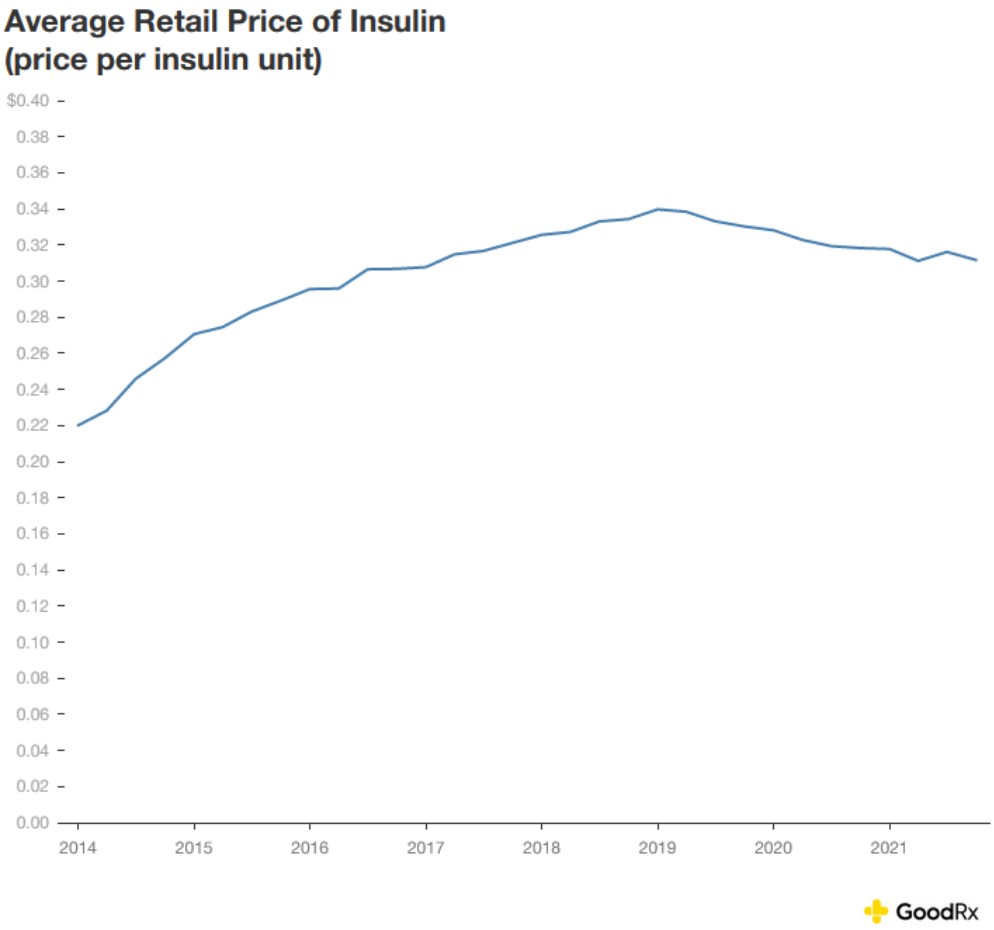



*Figure 2a: a flowchart from the American Diabetes Association detailing the flow of money in the insulin supply chain, meant to illustrate the complexity of the system.*

*Figure 2b: data from GoodRx detailing average retail price per unit for insulin from 2014-2021. The data shows a roughly 50% price increase followed by a plateau.*

These high prices have demonstrable impacts on the health and wellbeing of diabetic patients. T1International (2018) performed a survey in which they polled diabetes patients regarding their use of insulin. They found that, of the 627 respondents in the United States, 162 (or 25.9%) had rationed or forgone their insulin dose in the past year, a practice which physicians acknowledge as incredibly dangerous to the health of the patient. Herein lies the crux of the

problem: people with a treatable illness are being forced to delay, or even cancel, treatment that is known to be safe and effective, not because of a physician's recommendation or a circumstance unique to the patient, but because of the high list prices that many are forced to pay.

The Epipen, meanwhile, has experienced similar price increases over the same amount of time. In a study performed by Chua and Conti (2017), private insurance enrollees were analyzed to determine out-of-pocket expenditures on Epipen prescriptions. They found that out-of-pocket spending per patient more than doubled between 2007 and 2014, and furthermore, that the percentage of patients paying more than $250.00 annually for their Epipen prescriptions had increased from 0.1% of the population to 7.4% of the population (an increase of 5,631.7%). Given that the Epipen is a similarly ubiquitous medication to insulin (in large part due to the efforts from its manufacturer to promote it as the de facto response to anaphylactic shock), this meteoric price rise brings with it major issues of accessibility.

With the issues facing the United States with regards to prescription drug pricing outlined, and specifically the pricing practices involved in insulin and the Epipen, it is now necessary to outline the justification and approaches being used for state level interventions. The United States, being both geographically large and diverse in population, has utilized state legislation effectively for centuries to tailor solutions more specifically to local conditions. Therefore, we must analyze what is currently being done to determine whether it is an effective solution to the outlined problems.

## State Approaches

The rationale behind allowing states to implement their own legislative solutions to the issue of drug pricing is understandable. With the diversity of patient populations present in the United States, a one-size-fits-all solution implemented in a broad federal stroke could leave many with the same problem for different reasons. A solution that works for New Jersey, where an estimated almost 700,000 diabetic patients live, may not work in South Dakota, where only an estimated 50,000 live (American Diabetes Association, 2020). Major variables such as ease of access to care, proximity to pharmaceutical production centers, and urban population are all important considerations when crafting a legislative solution.

Riley and Lanford (2019) outline this rationale for state interventions, as well as some of the challenges that state legislators face. While these challenges will be addressed in the upcoming section of this literature review, what is currently of interest is their outlining of the approaches various states are taking to address the problem. Riley and Lanford mention six strategies in specific, alongside emerging approaches: pharmaceutical drug pricing transparency, pharmacy benefit manager oversight, drug importation, anti-price-gouging laws, drug affordability review boards, and Medicaid initiatives. Given the fact that this study was performed recently and outlines a variety of methods, it can serve as a guideline to understand the various approaches states are using, each of which will be expanded upon below.

## Transparency Legislation

Transparency legislation is an often discussed topic regarding reducing pharmaceutical prices. Researchers often describe pharmaceutical pricing as a “black box” of missing information, which makes it difficult to determine where, if anywhere, prices could be brought

down. Figure 3 below comes from Ryan and Sood (2019) who performed a study analyzing state level transparency initiatives from 2015-2018, and is similar in many ways to Figure 2a's description of the flow of money in the pharmaceutical supply chain, with the notable difference of highlighting areas in which the actual amount of money flowing is unknown. They found 35 drug pricing bills in 22 states which included a transparency component. Of these bills, they found only 7 to have "informative" requirements, or in other words, requirements which would make one or more links in the supply chain report net prices and profits. This follows a sentiment outlined by Riley and Lanford (2019) about the response in many states to transparency initiatives: pharmaceutical companies often lash back vigorously against such legislation, claiming that it violates trade secret law.

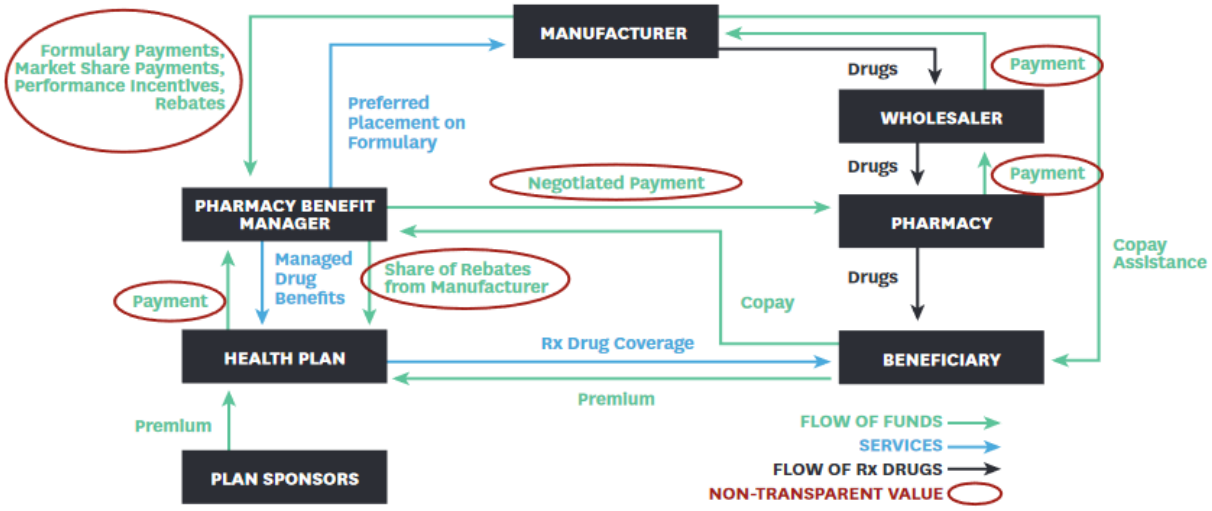



*Figure 3: a flowchart similar to that shown in figure 2a, with the notable difference of highlighting areas with non-transparent values of monetary exchange which can be targets for legislative attempts to foster transparency in pharmaceutical supply chains.*

**Pharmacy Benefit Managers**

Pharmacy benefit managers are, perhaps even more so than transparency in pricing, a hot button topic with regards to drug pricing. This comes in part due to the urging of pharmaceutical companies, which often point to pharmacy benefit managers as the source of the disparity in list and net price. Indeed, many legislative efforts target pharmacy benefit managers in an effort to simplify the situation and circumvent targeting influential pharmaceutical companies. Padula (2019) outlines how one area of state legislators' focus is on pharmacy benefit manager "gag" clauses, which prevent pharmacists from disclosing differences in costs between the various methods of drug acquisition to patients. Riley and Lanford point out that these efforts are often transparency initiatives in their own right, just focused on a different portion of the supply chain, which further reinforces the idea that this legislation is intended to reduce the complexity of the pricing process and clarify the "black box" of pricing. Ohio, for example, published a report in 2018 in which they revealed that they were terminating all contracts the state held with pharmacy benefit managers and renegotiating transparent ones to prevent the practice of spread pricing, in which the managers mark up the difference between reimbursement amount and the amount charged to health plans.

**Drug Importation**

Drug importation is self explanatory and represents a very economically focused approach to reducing drug prices. The concept is simple: import drugs from other countries where they are less expensive. Scheckel and Rajkumar (2021) found that multiple states have pursued drug importation initiatives in recent years, including Vermont. According to Riley and Lanford, Vermont's proposed system identified savings in the millions of dollars, even when

accounting for expensive markups. This potentially valuable amount of savings has attracted attention from various other states, with Scheckel and Rajkumar noting 11 states where drug importation legislation has been proposed. This method is somewhat complicated, as international importation requires federal approval in the form of an authorization from the Health and Human Services secretary, and the authors make note of this limitation among others.

**Anti Price-Gouging Laws**

Anti-price-gouging legislation takes a more direct approach to reining in drug prices, putting direct limitations on raising the prices of products. Riley and Lanford outline a bill passed in Maryland in 2017 which prohibited drug manufacturers from engaging in price-gouging of essential, off-patent, or generic drugs. According to Greene and Padula (2017), the criteria for an activity qualifying as price-gouging involved the action being defined as unconscionable, or in other words, being beyond all reasonable doubt tilted in the favor of the manufacturer. While the bill was challenged in court and struck down by 2018 due in part to the potentially vague definition of "unconscionable," it nonetheless has spurred other states to take more direct action in aggressively moderating the actions of pharmaceutical companies. Anti-price-gouging laws are, in many ways, the most combative approach, as the context of the term outright states that manufacturers are abusing their power, which differs from other strategies which are more conciliatory. That being said, Greene and Padula note that such measures are meant only to address the most egregious of practices. They thus represent an attractive option as a first step in reducing prices.

**Affordability Review Boards**

Still, the aggressive nature of anti-price-gouging legislation poses significant legal challenges, which has prompted some states to instead turn to affordability review boards. Riley and Lanford describe the efforts Maryland made in the years following the striking down of its anti-price-gouging law, which involved the establishment of a Prescription Drug Affordability Review Board. Enacted in 2019, Sklar and Roberston (2019) describe the process by which the board would require manufacturers to justify any proposed price increases and, should the increase be determined to be unreasonable, set its own price for the drug in response. This approach is similarly direct as anti-price-gouging laws, but circumvents some of the potential legal challenges which examples like Maryland have shown could be levied against such efforts. Instead, affordability review boards are more akin to the state determining what price it is willing to pay for a product - a prospect which is significantly harder to challenge as it is rooted firmly in the state's behavior as opposed to the behavior of the manufacturer.

**Medicaid Initiatives**

Finally, Medicaid initiatives involve the state attempting to leverage its position as a major purchasing power in the field of pharmaceuticals by regulating its purchasing habits. In this way, they hope to influence manufacturers economically by utilizing market forces to encourage lower prices. Hwang et al (2017) describe the efforts taken by New York to establish value-based pricing practices, in which the state would evaluate the therapeutic benefits of a pharmaceutical and determine a price target which it would then negotiate rebates and discounts in pursuit of. This approach is meant to focus on value for the patient, ensuring that high expense is only incurred for high utility. Riley and Lanford describe similar programs which seek to turn

pharmaceutical treatments into “subscription services” which patients could pay set monthly fees for enrollment in. Washington, for example, has explored such a model that would contract treatment to the lowest cost manufacturer, encouraging a competitive environment and reducing overall costs of treatment.

While this does not address all potential forms of state intervention in high drug pricing, it nonetheless provides a reasonable understanding of the legislative landscape as it currently exists. These efforts on the state level are among many which have attempted to rein in costs, both for the benefit of the patient and for the benefit of the state’s budget. While some of these efforts have borne significant dividends and savings, prices remain high, and the efforts to implement policy on the state level have revealed a number of challenges. These challenges may imply an inadequacy of state level intervention which could behoove a federal approach, and as such must be understood more fully before this thesis can proceed.

## Challenges to the State Approach: Specifics

The benefits of state level action are numerous, but so too are the downsides. The granularity offered by various state actions increases complexity on a national scale; the sensitivity to local politics can lead to unfair perspectives gaining influence; and the diversity of ideas can lead to dead end solutions wasting time and resources. In addition, state level action lacks some of the defining characteristics that help federal actions carry weight. Herein we will explore some of the challenges state level action has faced in its current form, both due to its specific form and due to its general qualities.

On an individual level, each of the approaches outlined above have weaknesses which limit their efficacy. As Ryan and Sood (2019) explain, transparency regulations often fail to force

companies to be truly informative as to their practices, and furthermore, even when successful transparency legislation usually does not include a mechanism to actually reduce prices. Drug importation suffers from restrictive regulations and the need to include federal actors, which often puts the decision to utilize it out of the hands of state actors, as Scheckel and Rajkumar (2021) outline. Meanwhile, regulation of pharmacy benefit managers and anti-price-gouging laws face similar issues of legal opposition from the bodies they target due to their more aggressive and directed nature according to both Padula (2019) and Greene and Padula (2017). And finally, while affordability review boards and Medicaid initiatives are often effective at their goals, they also tend to be limited in scope by virtue of the fact that they involve the state acting as a normal economic actor as opposed to a regulatory body. In other words, they may face fewer challenges, but are also more limited in impact, as explained by Sklar and Robinson (2019) and Hwang et al (2017). These varied challenges have similarly varied impacts, which range from limiting the efficacy of the approach to having the legislation struck down due to legal resistance.

**Challenges to the State Approach: in General**

On a broader scale, tackling the problem of drug pricing holds significant intrinsic challenges as well. One major issue that states face is a lack of information regarding the pricing practices of pharmaceutical companies. Glabau (2017) alludes to the "black box" of pharmaceutical pricing (as referenced prior in this thesis), as well as the myriad conflicting assumptions which many make regarding how pricing is formulated. These assumptions include the snowballing effect of high drug prices - high prices yield value to the manufacturer, which enriches it and enables it to acquire more products and investment, further enriching it, and so on. Transparency regulation is often directly intended to clarify this "black box," as the lack of

information prevents problem areas from being isolated. In addition, much of the confusion spawns from the aforementioned complexity of the pricing system, which means that even when information is available, it is difficult to compile. While this lack of information is widely acknowledged and understood as a major problem facing *any* effort to reduce drug prices, it is particularly problematic for state legislatures, who face legal challenges to their ability to demand information due to the often federal nature of the rights of corporations.

The topic of manufacturer value poses other significant challenges in regulating drug prices. In particular, it hints at a wider issue: the financialization of the pharmaceutical industry. Oftentimes high prices are justified by pharmaceutical corporations as necessary to fund innovation and high standards of quality, but recent trends suggest that high prices are not yielding dividends in that regard. Tulum and Lazonick (2019) collected data which showed that one of the primary areas of increase in the spending of pharmaceutical companies was in shareholder dividends. In addition, they found that the level of innovation in the United States pharmaceutical industry was rapidly being approached by the levels of innovation in other similarly wealthy countries - countries in which pharmaceutical costs are significantly lower. These factors point towards pharmaceutical production becoming more and more commodified and treated as any other good, a prospect which poses significant challenges for state legislators. To begin, governing pharmaceuticals as a trade good begins to edge into territories of interstate trade, which has already posed significant barriers to more aggressive legislation. Furthermore, this accumulation of wealth in pharmaceuticals poses a twofold problem: first, pharmaceutical interest groups gain significant lobbying power, and second, states have a vested interest in capitulating to that power due to the desire to enrich the state by enticing wealthy companies to base their operations there.

This influence cannot be overstated. In 2004, Landers and Sehgal performed a study analyzing lobbying expenditures in healthcare, and found that those expenditures accounted for 15% of the total federal lobbying expenditure between 1997 and 2000, an amount exceeding the share of every other field. They also found that pharmaceutical and health product companies spent the most on lobbying within this category, and that the growth of spending on lobbying was more pronounced in pharmaceutical companies than it was in physicians and other groups directly involved in patient care. Recent evidence shows that this trend has continued, and in doing so has lent more sway to the producers of pharmaceuticals than to the doctors that prescribe them. This reinforces the financialization of the pharmaceutical industry, thus strengthening the wall of legislative influence that corporations can erect to counteract aggressive state efforts.

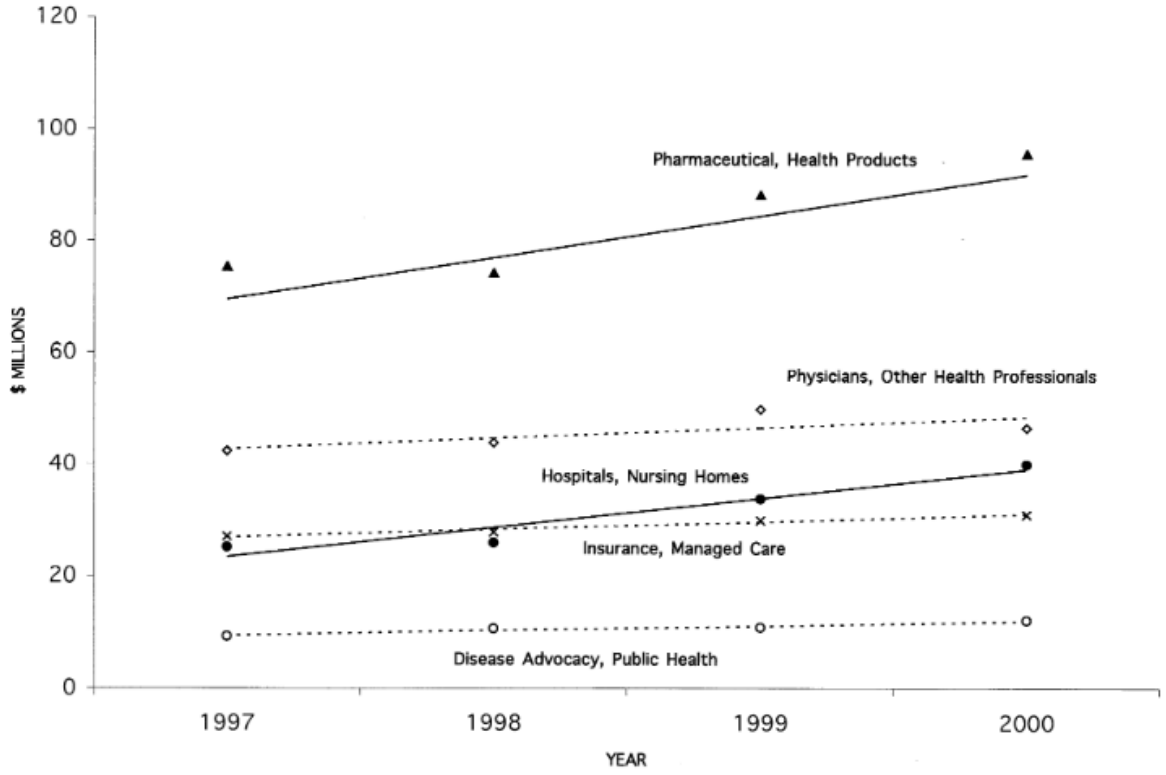


*Figure 4: a graph from Landers and Sehgal (2004) outlining the more rapid rate of increase in lobbying expenditures by pharmaceutical companies when compared to other stakeholders in the healthcare industry.*

However, the level of expenditure would not matter if it were not possible to justify the high prices in such a way as to not be explicitly price gouging. Herein lies another barrier posed by the complexity included in the setting of pharmaceutical prices. In the context of insurance, pharmacy benefit managers, rebates, discounts, and more, the concept of what constitutes a "fair" price for a drug is not simple. Calcagno et al (2019) outline this issue and expand upon it, citing the potential dangers of "false positives" where drugs are mistakenly said to have unfair prices. In this case, the downside would be potentially dissuading investors from contributing to the production of new pharmaceuticals. This danger creates a potential reason to not enforce price restrictions on a broad scale, which removes many of the most direct avenues for state intervention. It can also lead to loopholes in the enforcement of state laws, in that a corporation could argue that their prices do not fit whatever definition of "excessive" is established.

The issue of complexity is further exacerbated by the conflicts of interest present in the web of interactions involved in setting prices. Early in 2021, Senate Finance Committee Chair Chuck Grassley of Iowa and Ranking Member Ron Wyden of Oregon published a report investigating the high prices of insulin. They found not only that the major producers of insulin participate in "shadow pricing," or the practice of raising prices to match the price increases of other companies, but that they perform similar practices to be sensitive to the desires of pharmacy benefit managers. Pharmacy benefit managers base their business models on offering the best rebates and discounts to their constituents - manufacturers want to be on good terms with

managers, and so will at times decline price decreases to ensure that the managers can maintain attractive rebates. The debate on who is responsible for high prices often points to either manufacturers or pharmacy benefits managers, but this conflict of interest implies that the two may be on the same side. This creates a major issue for state legislatures by virtue of further obfuscating the proper target of legislation and, at the same time, creating potentially hidden barriers of influence that will push back against legislative efforts unexpectedly. While this is also an issue on the federal level, state action suffers from further restrictions of local focus and limited resources that make properly targeting legislation imperative.

**Challenges to the State Approach: Who's Driving?**

Even going beyond these systemic issues that plague state initiatives, there exist multiple issues of intention that cannot be evaluated from a state perspective without including federal perspective. For example, the financialization mentioned beforehand represents a trend towards business as a focus as opposed to healthcare as a focus - a shift that may not be the best for ensuring affordable access to healthcare. Also in this vein is the consideration of what should be encouraged by the pricing system. Currently, innovation is argued as the central focus of the United States system, with many high prices being justified as funding innovation. However, in Henry's 2018 case study on hepatitis C medication, she found that this focus on innovation was a key factor in driving prices upwards while removing care from many who would benefit from it. Further, she argues that the intense focus on innovation in the United States healthcare system has an effect of limiting the benefits of that innovation to those who suffer the most acutely - as the drugs innovate and become more expensive, only those who need them desperately can justify the cost either to themselves or to their insurance. This implies a problem at the very core

of the nation's pharmaceutical industry which cannot be addressed in individual states, in the form of a national focus on innovation that is not centered in the overall wellbeing of the wider patient population.

With these challenges laid out, it is finally pertinent to understand the legal grounds on which states can and have been challenged on their legislative efforts. Lee et al (2018) summarize three major legal challenges that can be levied against efforts at the state level, using laws in Maryland and Nevada as a baseline. The first is the "dormant" commerce clause, a constitutional doctrine that prevents states from interfering with interstate commerce, which in this case can be levied against states who attempt to restrict the actions of national corporations. Next is patent challenges, in which corporations can argue that price restrictions violate the exclusivity they are granted by patent periods. And third is trade secrecy challenges, which corporations use to counteract transparency legislation by claiming that it violates their intellectual property. Gudiksen et al (2018) expand on this by analyzing the challenges faced by a California effort to enact price transparency, which was argued against using not only the dormant commerce clause but also a citation of the First Amendment, a claim centered on the idea that requiring price disclosures *exclusively* from manufacturers was a violation of free speech. Gudiksen et al also cite the Employee Retirement Income Security Act Preemption (ERISA) as a legal barrier to state action, as it preempts any attempt by state legislators to regulate self-insured employee benefits, which applies to 60% of all citizens with employer sponsored insurance. In a later study, Gudiksen et al (2019) expand on these challenges, as well as the specifically challenging nature of ERISA as it applies to pharmacy benefit managers, citing multiple cases across a variety of states where efforts were preempted by the Act.

If the above evidence does nothing else, it demonstrates that the challenges facing state initiatives are myriad and diverse. With such a complicated legal environment which faces challenges due to federal overlap, powerful interest groups, and much, much more, the ability of states to effectively tackle the currently skyrocketing prices of many drugs in a timely manner is cast further and further into doubt. That being said, the final piece of this puzzle is to analyze the potential benefits of federal legislation and what it could offer to this problem.

## Federal Justification: the Hammer Falls

Just as state intervention carries many strengths, so too does federal intervention. What it loses in regional precision and granularity, it gains in potential strength of enforcement and standardization. In circumstances such as egregious drug prices, federal legislation can be an imperative first step in redirecting the intention of the nation's systems and establishing the foundation for state and local governments to expand upon. In this section, we will analyze some of the potential benefits that federal intervention could confer in reducing pharmaceutical prices, as well as seek examples from other countries as to what form that intervention could take.

One of the primary concerns many people have regarding any federal policy proposal is the difficulty involved in passing federal legislation in an increasingly polarized political environment. This is one of the reasons state intervention is often considered first. Dusetzina and Oberland (2019) emphasize this difficulty, mentioning as well that the powerful coalition of groups invested in high pharmaceutical prices represent a major roadblock to any federal effort where approval needs to approach unanimity to be sufficient. However, they also explicitly claim that, absent federal intervention, prices will continue to rise, as if the obstacles are difficult to overcome federally, they are nigh impossible to overcome in other ways. This reinforces the

assertion of the previous section - namely, that the primary justification for federal intervention is a failure of state intervention to effectively reduce drug prices. Given the general difficulty of procuring bipartisan support and contending with federal lobbying, federal policy is often a "last resort" option, especially in the United States where many prefer a more hands-off approach to governance. That being said, recent evidence implies that this last resort is quickly becoming necessary, as both the market and lower level government intervention have failed to address the problem.

Another major justification for federal intervention is that many of the supporting factors of high drug prices are federal in nature. We have already outlined the various legal challenges that states face that are grounded in federal legislation, but beyond that, one major consistent hurdle is intellectual property law, which is mandated strictly from a federal level. Kesselheim et al (2016) performed a study analyzing sources of high drug prices in the United States, and found that the primary factor contributing to them was twofold: first, the country allows drug manufacturers to set their own prices, and second, there are powerful protections implemented for periods of exclusivity, especially around pharmaceuticals. The researchers found that, due to accommodations created to counteract exclusivity lost during approval processes, the average widely used drug had a 12.5 year post-approval period of exclusivity, extending to 14.5 years on average for innovative products. In addition, as mentioned previously there are various factors that conspire to functionally extend periods of exclusivity even when on paper they have expired. With these monopolies, both sanctioned and unsanctioned, being a primary contributing factor to the high price of pharmaceuticals, federal intervention becomes necessary, as the regulation of intellectual property is firmly within the federal government's purview.

These extensions to the periods of exclusivity allowed by patent law cannot be overstated in their impact. Kesselheim et al performed a different study in 2006 analyzing the periods of extension found in certain drugs as well as the impact these extensions had on the product's price from a Medicaid reimbursement perspective. For example, they found that Augmentin, which was developed based on patents from the late 1970s, did not have its period of patent exclusivity end until January 2000, after which it was able to delay a generic alternative from reaching the market until 2002. This represents a period of exclusivity approaching or exceeding two decades - a period of exclusivity that the researchers found to have significantly increased Medicaid expenditures on the drug. They also cite the fact that these price increases have had a compounding effect on Medicaid, with many states' programs being forced into difficult decisions such as limiting coverage in order to account for high costs. This serves to emphasize the significance of intellectual property protections, as they are used as a tool to enable high prices which can only be impacted by federal intervention.

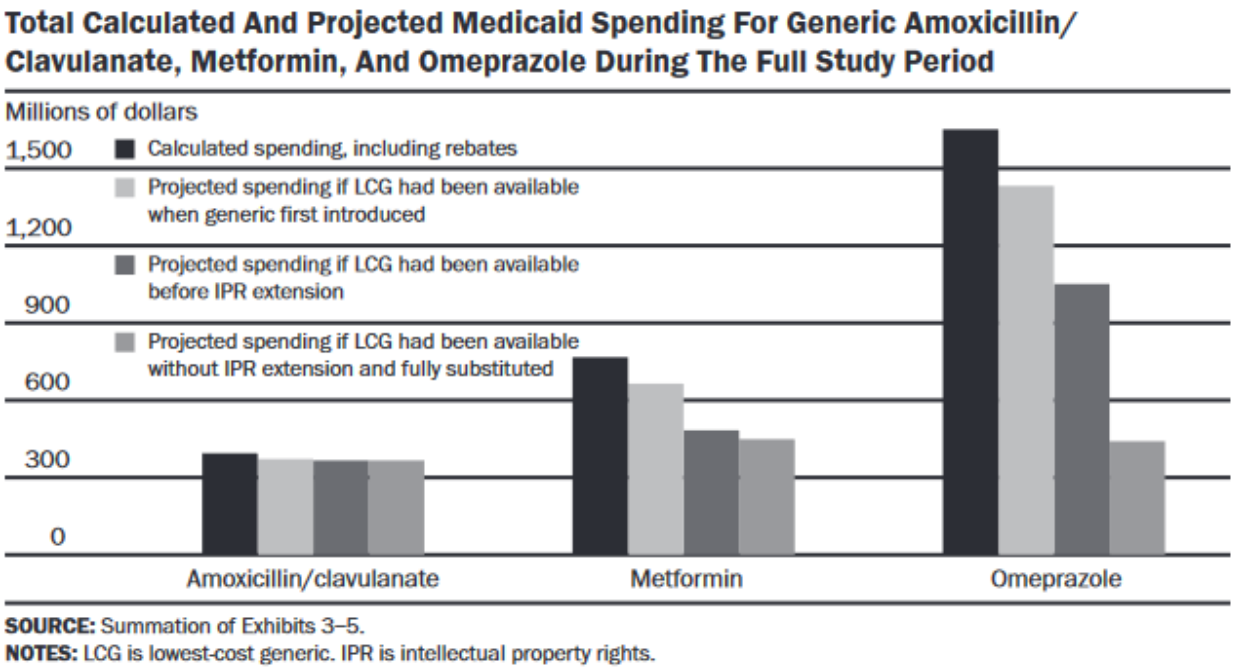



*Figure 5: a chart from Kesselheim et al (2006) showing both the variation in spending between drugs and the potential cost savings that could come from more aggressive introduction of low-cost generics. These charts highlight the fact that the delays in price decreases caused by intellectual property protection can contribute heavily to price increases.*

The federal government also simply has access to the most avenues of attack by which the problem of high drug prices can be approached, whereas states are more limited in their capabilities (a limitation which has allowed defendants of high prices to focus on blocking what avenues they have available). McEwen et al (2017) performed a review analyzing high drug prices and what can be done to lower them, and found that the most promising avenues involved the leveraging of market forces, more selective prescription methodology, and federal intervention. Regarding market forces, while Medicare and Medicaid carry significant weight, other factors and requirements in the programs prevent them from leveraging it. However, enforcing broad legislation that requires the prescription of less expensive, functionally

equivalent products can help to ensure better utilization of generics in treatment. From a strictly policy perspective meanwhile, the researchers again cite the barrier of intellectual property law as a primary hurdle in increasing accessibility. In other words, this review found that many of the most promising prospects for reducing drug prices are best implemented at the federal level due to the unique abilities present in that sphere of government.

**Federal Justification: Examples to Learn From**

While the theoretical justification is necessary, it is also important to consider the potential systems of pricing the federal government could establish in order to analyze whether they would be effective. In this regard, many analysts rightly look to other industrialized countries to provide examples that the United States could strive towards. Goldstein and Safarti (2016) performed a study comparing the systems utilized in various other countries, which are described here:

- Cost-effectiveness analyses are used in a variety of countries including the United Kingdom, and involve comparing economic input to health benefit output. To do so, a ratio is constructed of the amount of money that would need to be spent on a product in order to obtain one "quality-adjusted life year." This system allows the federal government to selectively support products that reach a threshold of value.
- Payment-by-results is a system used in Italy in which all premium-priced medicines are reimbursed at the same amount, and a rebate is subsequently determined based on the drug's performance. This system has the benefit of accounting for actual patient outcomes as opposed to a theoretical gauge of a drug's efficacy.

- Budget impact studies are used in Israel to analyze the raw potential costs involved in the coverage of a new drug, and are performed by taking into account the cost of the drug and the likely size of its patient population. While this method does not account for the efficacy of the drug, it does gain some measure of practicality by only considering the absolute baseline of the decision making process: is the drug affordable?
- External reference pricing is used by many countries and involves referencing a group of other countries in order to determine a regulated price for a product. While this technique relies heavily on the judgments of other countries, it does ensure that prices are consistent across countries and requires very little technical investment.
- Relative effectiveness is a model used in France and Germany. This method involves considering the potential benefit the new product would provide when compared to existing treatment methods. In other words, it asks the question "how much more effective would the new treatment be than what is currently used?" This is similar to cost-effectiveness analysis but involves a more holistic view of the drug benefits.

In addition to the options listed above, Kang et al (2019) cite the option of therapeutic or internal reference pricing, in which therapeutically similar products are referenced as opposed to other countries in order to determine a product's price. All of these methodologies provide ways for federal analysts to determine a more reasonable price for a product which can then be enforced via direct intervention in the market. It should be noted, of course, that models that work in other countries will not be directly transferable to the United States, as there are many unique contextual factors that would spell disaster were such a blind decision to be made. Still, these examples provide guidelines which could inform policy decisions and provide a basis of knowledge to operate from.

In addition to these options, some options exist by which the federal government could better leverage its existing systems so as to reduce prices in the intervening period while systemic change is enacted. Brennan et al (2016) published a report which outlines a method by which the federal government could utilize existing legislation to purchase generic alternatives to name brand products at a fraction of the cost that they are available on the market, such that they can subsequently provide that medication at low cost to patients. These strategies can form an important stopgap to ensure that people receive care while the benefits and detriments of more intensive federal interventions are considered.

With that, a reasonable understanding of the context of the United States and its practices regarding drug pricing has been established. There is clear evidence that state interventions may be insufficient for reducing drug prices, which behooves further analysis to understand whether this is indicative of a definitive failure or something more benign. From here we must determine what questions will be asked to be answered in this thesis.

## ***Research Questions***

The information outlined in the literature review has painted a picture of a system potentially in need of reshaping and improvement. Currently, the lion's share of efforts being made to contain spending on pharmaceuticals are made at the state level, under the justification of tailoring each state's response to the needs of its constituents. However, prices remain high, and reports from the public indicate that many are still suffering under the weight of drug expenditures. While approaching this issue from the state level has merit, these high prices could suggest that states lack the power (or perhaps inclination) to adequately address the problem and reduce the out-of-pocket spending of United States citizens. In addition, certain aspects of the pharmaceutical industry are strictly federal in nature, and as such are completely out of reach of states to regulate. While this issue has received a large amount of attention in the media, the public, and even in government of all levels, it is clear that the situation remains deeply detrimental to the health and wellbeing of a large portion of the nation's populace, which behooves further analysis to determine a better path forward.

Based on this information, the following series of questions is posed:

- **Is there a noticeable correlation between the number of legislative efforts a state undertakes to control drug prices and the accessibility of drugs in that state?**
- **If such a correlation exists, do greater numbers of efforts yield sufficient increases in accessibility, or if not, do they seem like they will in the near future?**
- **What major roadblocks do state legislators face in attempting to implement drug pricing policy, and are those roadblocks best addressed with a state, federal, or other approach?**

## ***Methods***

The methodology employed in this thesis involved the isolation of three states (South Dakota, Rhode Island, and New Jersey) as case studies to represent different approaches to legislation of drug prices. In order to determine which states would be focused on in this analysis, the quantity of legislative action taken in each state was used. For consistency of selection criteria, the data collected by the National Academy for State Health Policy of state-by-state legislative actions was referenced (National Academy for State Health Policy, 2021). This provided a standardized baseline for the categorization and recognition of legislative actions as pertaining to pharmaceutical pricing - in other words, ensuring that the same criteria was used to determine whether a law, study, or other action would be counted. This consistency allows for the quantity of actions to act as a baseline metric for each state's degree of focus on pharmaceutical pricing as a legislative issue. In addition, potential outliers were considered in state selection, such as ensuring the selected states were part of the contiguous United States, in order to ensure the selected states had as few other variables varying as possible.

Using this method, comparisons of each state's quantity of action, as well as the intended targets of those actions, were made. The charts of the compiled action quantities were compiled in a spreadsheet for ease of reference (see Appendix 1 for raw data). These charts were then compared against one another on two primary criteria: first, raw quantity of actions, and second, relative composition of actions, with the goal of isolating three states for analysis. These states would represent the highly legislated, averagely legislated, and scarcely legislated approaches to reducing pharmaceutical prices. Relative composition of actions, or in other words the breakdown of what each state was targeting with its legislation, was also considered in order to ensure that the selected states were reasonably representative of their respective quantity classes.

As the scope of this thesis is only meant to include a generalized view of each state with regards to a “hands-on” versus “hands-off” approach to pharmaceutical pricing, these confounding variables would harm the validity of the final results. For this reason, target composition was considered as part of the selection process. In addition, for ease of processing, the categories used by the National Academy for State Health Policy were utilized with minor modifications.

As a brief aside, it is important to mention that this metric (quantity of legislative action, which here is defined as any attempted bill, study, or similar measure) is meant only to provide a rudimentary metric of a state’s individual level of focus on the issue of pharmaceutical pricing. In this thesis we will be attempting to observe any potential correlation between this focus and lowering drug prices - effectively, in order to gauge the efficacy of current solutions, we are attempting to first gauge how aggressively these current solutions are being implemented in the states of interest.

Once states were isolated which seemed to be reasonably representative of their quantitative categories, the primary analysis was conducted. This analysis involved creating case studies of each of the three states to further understand the context of not only legislative action but also discussion and action among the general population pertaining to prescription drug pricing. The creation of these case studies involved the collection of newspaper articles and blog posts from the states in question. Collection of these articles was performed by utilizing similar search parameters on the collective databases of ProQuest and NexisUni, both of which compile news and blog sources which can be localized based on source. These search parameters used permutations of relevant search terms; for example, searching for the name of the state in conjunction with the terms “insulin” and “price.” These results were further manipulated by narrowing the source of the articles to the state in question, to ensure that local feedback was

being prioritized. Three hundred search results procured in this method were then manually combed through for relevant entries, as the broad net cast by these parameters often returned unrelated articles which tangentially mentioned the topics at hand. During this process, attention was paid to the quantity of results for each search as, in a similar way to the selection criteria, the incidence of such results was in and of itself relevant information. An article was considered relevant if it made specific reference to the issue of pharmaceutical pricing or to lack of accessibility of drugs.

With states selected and a basic understanding of the level of attention paid to pharmaceutical prices in each, a metric is needed to gauge the success of each approach in fighting rising prices. Unfortunately, this metric is somewhat difficult to obtain. One's first instinct would be to simply look at pricing data. However, there are two problems with this approach. First, list prices do not differ between states, as pharmaceutical manufacturers set standardized prices across state borders. Second, list price is not the price that most patients pay for their treatments, due to the complex layers of price changes that overlay the acquisition of pharmaceuticals (Gencarelli, 2002). The combination of these two facts complicates the acquisition of a worthwhile metric of price reduction in multiple ways. While list price is not the price that every patient pays, there still exists a significant population that *does* pay list price (namely the under- and uninsured). These layers, meanwhile, are so convoluted and disparate both between and within states that finding a reasonably rigorous "average" price for any product is almost impossible, a problem exacerbated by the opacity of the pharmaceutical supply chain and unavailability of information regarding patient payments.

In the absence of a reasonable price metric, it is necessary to pursue a method of benchmarking that can create a theoretical outline of level of success. In pursuit of this, other

metrics of accessibility can be considered, as the purpose of investigating price is to gain an understanding of whether and how many people are being kept from accessing medical care due to financial concern. Therefore finding other metrics of accessibility can extract similar utility as finding metrics of price. While information of this sort suffers from similar issues as price data (namely difficulty of collection and accessibility), there do exist standardized databases which collect relevant information which can be compared both over time and between states.

With all of the aforementioned factors outlined, one variable which can be compared both between states and over time is Medicaid utilization data. The Center for Medicare and Medicaid Services maintains databases of utilization information pertaining to covered outpatient drugs on the Medicaid Drug Rebate Program, delineated by year and by state (Center for Medicare and Medicaid Services, 2021). This data was collected for the years of 2015-2020 (the same year period for which legislation data was collected) in order to create timelines of utilization metrics for each state over time. These timelines would allow for a rudimentary understanding of how the state's spending on the drug in question has evolved. This will in turn allow for analysis of such trends in order to, at the very least, determine more specifically what gaps in existing knowledge exist, and potentially glean insight into whether the state has successfully reined in the price of that drug.

To compare between states, however, there must be some way to account for the differing populations in each, as while New Jersey may spend an order of magnitude more on insulin than South Dakota, it is also home to an order of magnitude more people. Luckily, the American Diabetes association retains statistics regarding the estimated populations of diagnosed diabetics in each state (American Diabetes Association, 2021). With this information, the utilization data from the Center for Medicare and Medicaid services can be normalized for patient population, in

order to obtain a metric of utilization per person. This can allow the information to be compared between states while controlling for the major differing factor.

When processing this data, one major roadblock was encountered in the form of selection of which data would be relevant. This difficulty came in two forms: too much data, and not enough data. Regarding insulin, there are three major types of insulin, each divided into multiple types and dosages. Meanwhile, the Epipen has only a few entries in any given year due to its brand name status. In addition, the formatting of the information from the Center for Medicaid and Medicare Services has some information suppressed, whether to support patient privacy or due to a low quantity of data that would be included in the entry. The Epipen data in particular has had many entries suppressed. This creates a general lack of information which weakens the body of data from a statistical standpoint. For these reasons, the decision was made to limit the scope of this analysis to rapid-acting insulin. Rapid-acting insulin represents one of the most commonly used forms of insulin, in addition to being the form of insulin most often referred to in common discourse (American Diabetes Association, 2021). The three types of rapid-acting insulin have data which have a somewhat limited amount of suppression, and when aggregated represent a significant amount of data that would not be skewed by any individual points of suppression.

The data from each of these sources is combined to create a case study in three parts for each state:

1. A profile of the state's legislative efforts is collected from the National Academy for State Health in order to provide information regarding the state's legislative focus both in quantity and direction.

   a. Targets for this analysis include determining which states pay the most legislative attention to pharmaceutical pricing, which states have particular targets for their legislation, and what the average levels of legislative intervention are on a national scale.
   b. The expected results are that there will be a widely varying number of legislative efforts between states, and that most states will have diverse targets for legislation.

2. A qualitative analysis of the state's news content is performed using ProQuest and NexisUni to flesh out the non-legislative side of the state's context on pharmaceutical pricing.
   a. Targets for this analysis include overall sentiment and outliers in public focus. As this analysis is qualitative, the results will not be easily quantifiable, but the quantity of relevant articles will be taken into consideration (and in addition, the relative size of each state will be considered when determining the relevance of its quantitative insights).
   b. The expected results are that public sentiment will correlate with legislative quantity, i.e. that in states with higher amounts of legislative focus, public sentiment will also be more focused on the issue. Outliers in opinion will likely be more common at the extremes.
3. Timelines of various metrics of the state's Medicaid utilization data from the Center for Medicare and Medicaid Services are created (and in some cases normalized using estimates from the American Diabetes Association) in order to track how the state's

utilization has changed over the period of time for which legislation has been included in the scope of this thesis.

a. Targets for this analysis include differences in spending over time, overall state level trends in utilization, and comparative insights regarding the trends observed between the selected states.
b. The expected results are that states with greater legislative focus will have reduced spending over time, and that this trend will be noticeably distinct from other states that employ less active methods.

These sources combine to inform as to the overall context and success of each state with regards to controlling pharmaceutical pricing, allowing for comparative analysis to follow.

# ***Results***

Analysis of the case studies is done by state, with each state's analysis proceeding through the three parts of the case studies that were created. For each section of results, any relevant graphs and charts will be included. This analysis will be conducted in the order of the data collection, i.e. beginning with the quantitative analysis of the state's legislative efforts from the National Academy for State Health Policy, continuing on to the analysis of NexisUni and Proquest news and blog posts, and finishing with a summary of the state's timeline of Medicaid utilization data. In addition, a final section will include any preliminary comparisons that were made between states, and each section will include qualitative descriptions of any roadblocks that were encountered during the process of data collection. For the purposes of this thesis, South Dakota, Rhode Island, and New Jersey were selected as representative case studies, representing a low legislation approach, middling legislation approach, and high legislation approach respectively. Further explanation of the qualities that each state presents such that it was selected will be provided in that state's section.

## **South Dakota**

South Dakota represents an example of a hands-off legislative approach to drug pricing. With a grand total of only five legislative actions relating to pharmaceutical pricing between 2015 and 2021 at time of writing, South Dakota beats only Alaska in volume of state attention. Given that Alaska is separated from the continental United States and, as such, has potentially significant differences in drug pricing from the norm, South Dakota was selected to represent the less legislated side of the drug pricing debate. This approach is one favored by many economically right-leaning political actors, who argue that the regulatory forces of the free

market should be allowed to force prices down “naturally.” The leeway and freedom this provides to industry actors makes this approach similarly attractive to pharmaceutical companies, pharmacy benefit managers, and others invested in the industry’s success, who often lobby to prevent governmental intervention in industry affairs at all levels.

As South Dakota has so little recent legislation directed at reducing drug prices, there is no distinct target for what efforts exist. The five pieces of legislation feature two targeting pharmacy benefits managers, one targeting transparency, one targeting coupons and cost sharing, and one falling into the catch-all “other” category. Such a small sample size implies that these efforts represent one-off attempts to address isolated problems as opposed to more focused ones meant to manage systemic issues. This also means that analysis of the ratio of successful versus unsuccessful legislation holds little value, although for posterity’s sake, all three of the legislative efforts from 2015 to 2020 passed. Overall, the quantitative analysis of South Dakota’s legislative landscape revealed very little focus on pharmaceutical pricing, making it a worthwhile example of the hands-off approach to this problem.

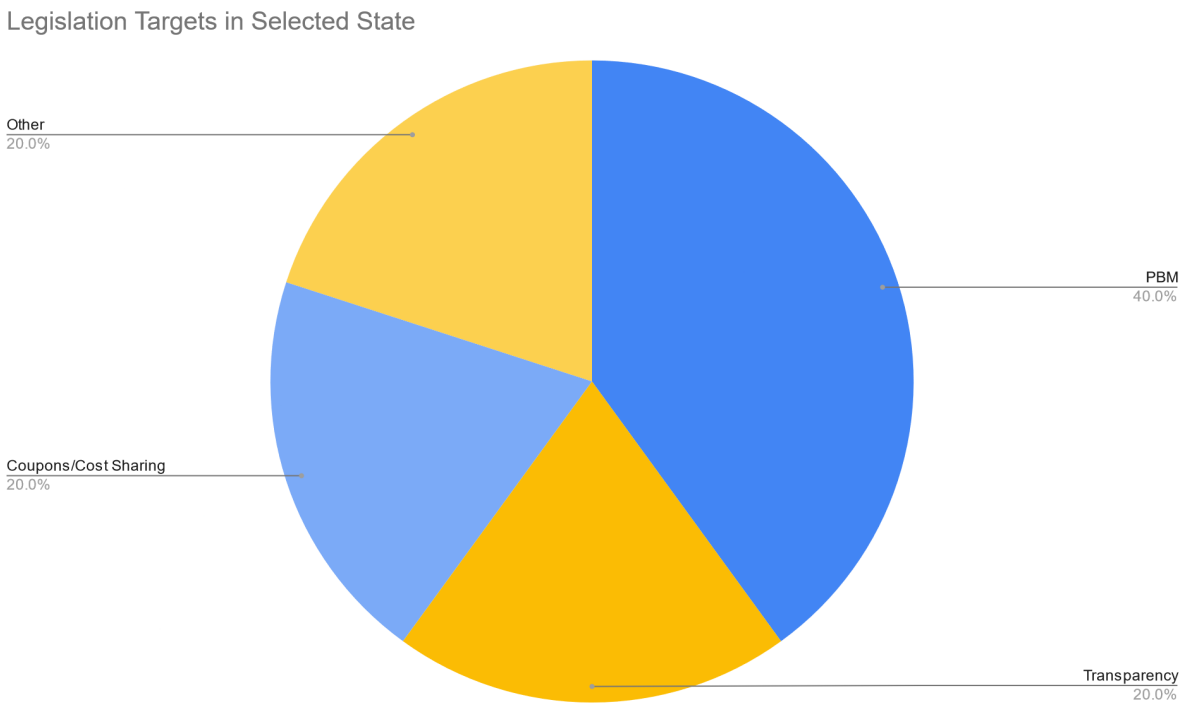



*Figure 6: a pie chart showing the split in targets of legislation meant to reduce pharmaceutical prices in South Dakota.*

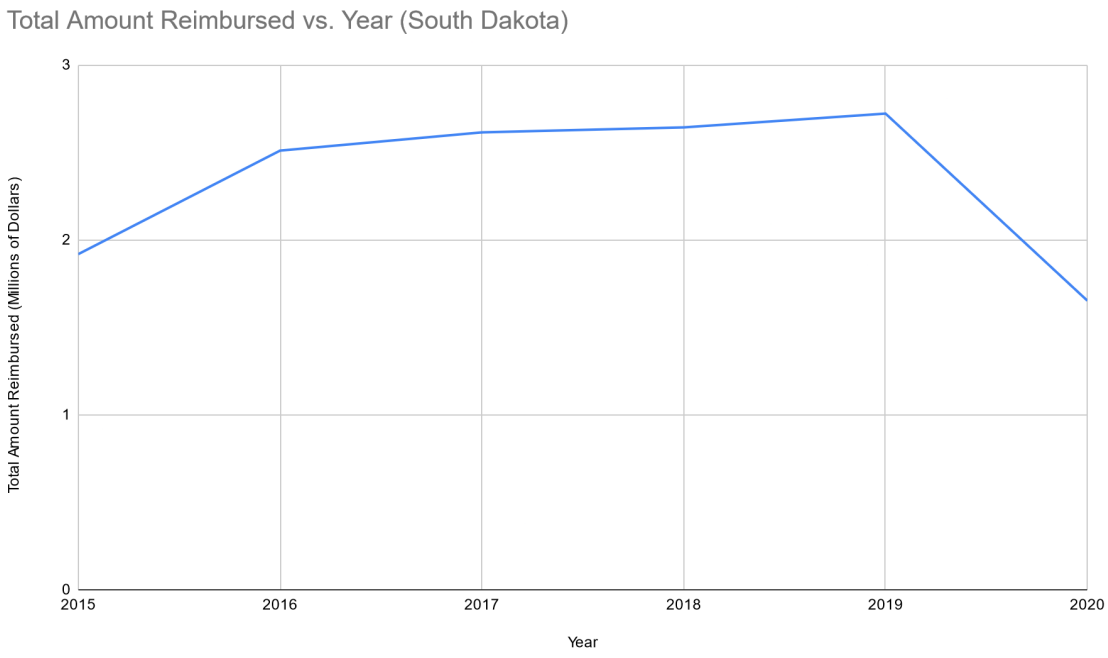
That being said, the lack of legislative action is only one piece of the puzzle with regards to pharmaceutical pricing. The legislative action of a state may not be representative of the overall tone of discussion of pharmaceutical pricing in that state, as various factors including demographic breakdown and economic status can lead to discordance between the desires of a state's population and desires of its legislators. In addition, some states may desire non-legislative solutions to these problems, in which case action could be focused on something such as a non-governmental organization's attempts to reduce prices for patients. In a situation such as South Dakota's, where government intervention ranges from slim to none, this is

especially pertinent, as in those circumstances it becomes increasingly likely that other parties will attempt to reduce costs either for themselves or for others.

Collection of news sources and blog posts from South Dakota revealed a non-legislative environment similarly focused on other issues. Performing searches for “South Dakota” paired with “insulin” and “Epipen” on Nexis Uni and ProQuest revealed far more references to tangentially related issues, chief among them news regarding a lawmaker on trial whose crime included a reference to insulin. Finding sources actually located within the state was difficult, with many references coming from outside sources which simply referenced events in South Dakota. After filtering through a large number of inapplicable articles, a clearer picture began to form. The majority of relevant sources came from local news and blog posts in rural communities, with multiple coming from advocates for underserved and economically disenfranchised communities such as Native Americans. These posts focused on price caps as a proposed solution to rising prices, citing the difficulty in attaining care for people who would have to drive hours to receive medical attention. Among these more focused posts, the situation was described as a crisis requiring urgent attention, with price caps being preferred due to their immediate impact on peoples’ financial wellbeing. This paints a picture of a small community of patients in South Dakota being drowned out of public view by other issues - an assessment which logically falls in line with the lack of legislative attention paid to the problem due to the weak force of interest the group would command.

Finally, moving on to the Medicaid utilization data, South Dakota displays behavior that is consistent both with the rest of its actions and with itself. That is to say, the amount reimbursed for rapid-acting insulin in South Dakota is relatively low and constant across the period in question. Figures 7a and 7b below detail the amount spent by South Dakota’s Medicaid program

over the time period, and show that the amount hovers somewhere around two million dollars per year consistently. When normalized against diabetic population, this amount translates to roughly fifty dollars per patient (of note: this amount does not represent the actual amount spent per patient on insulin, as not all diabetic patients in each state are enrolled in that state's Medicaid program. This value is simply meant to be a rudimentary method of reducing the bias that would be introduced by studying only the raw expenditure amounts shown in the utilization data). The insights from this information are twofold: first, the overall amount spent and amount spent per person are relatively low, albeit not enormously so when compared to the other states which will be examined, and second, the amount has not been subject to much change as the national debate has raged on.



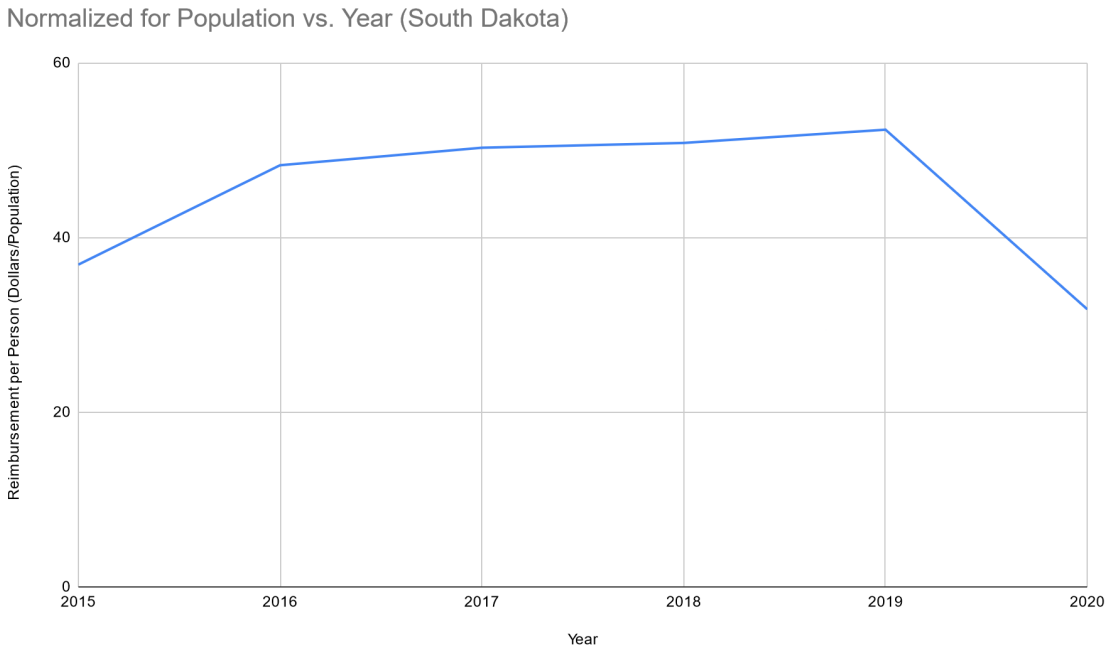



*Figure 7: a.) A chart of the total Medicaid reimbursement amount for rapid-acting insulins in South Dakota between the years of 2015 and 2020. b.) The same chart, with an additional normalizing factor which takes the state's diabetic population into account.*

Overall, South Dakota's data implies a confirmation of the lack of attention paid to the price of pharmaceuticals in the state. From the legislative, social, and economic perspectives displayed in this data, the focus is elsewhere by all accounts. The amount paid by the state for rapid-acting insulin has decreased over the past year, but in doing so has only fallen to the same levels as the state has encountered in the near past. Therefore, the results seem to state that South Dakota's success in reducing insulin costs has been low, with the trend indicating that the state's lack of focus on the issue has led costs to remain relatively stagnant.

**Rhode Island**

Rhode Island represents a state with a "middle-of-the-road" approach to legislating pharmaceutical prices. With forty-eight pieces of legislation that fit the criteria of this thesis, Rhode Island is ranked seventh in the nation for amount of legislation, and yet has only roughly half the legislative efforts of New Jersey by comparison, a fact caused by the large jumps in quantity of legislation between the states in the top five. As such, Rhode Island represents the upper end of states which devote a reasonable amount of attention to pharmaceutical pricing as a policy problem, and so was selected to represent the moderate approach. This approach is supported by many moderates on both sides of the United States' political spectrum, and seeks to find a middle ground between free market reign and governmental protection of patients. Many proponents of this style of legislation are attempting to curb price gouging and other abusive practices while remaining as uninvested as possible in the business world.

In terms of targets, Rhode Island is representative of the average state across the country in two primary ways. First, a diversity of targets are at least touched upon, demonstrating the wide variety of approaches that state lawmakers have taken to attempt to curb drug prices. Second, the majority of these efforts are aimed at either transparency or pharmacy benefit managers. These two targets represented by far the most frequently targeted entities in state legislations, as out of the 986 efforts included in this thesis, 377 targeted pharmacy benefit managers and 155 targeted transparency. As Rhode Island is meant to depict the "average" case for the purposes of this research, the fact that its distribution of targets is roughly average lends support to it filling this role. Another way in which Rhode Island is representative of the norm is in its ratio of successful legislation; of the 35 bills included in this research, fully 30 of them were pending further action, a trend that is reflected in many other states and which could be

interpreted as indicative of the moderacy of many states' approaches. This moderacy is thus reflected in most aspects of Rhode Island's quantitative analysis, as the combination of these factors implies a legislature that is interested in acting but hesitant to proceed and is interested in pursuing multiple options to determine which will be the most viable. The full breakdown of the targets of Rhode Island's legislative efforts can be seen in figure 8 below, and illustrates this diversity of approaches via the relatively even split between the various approaches.

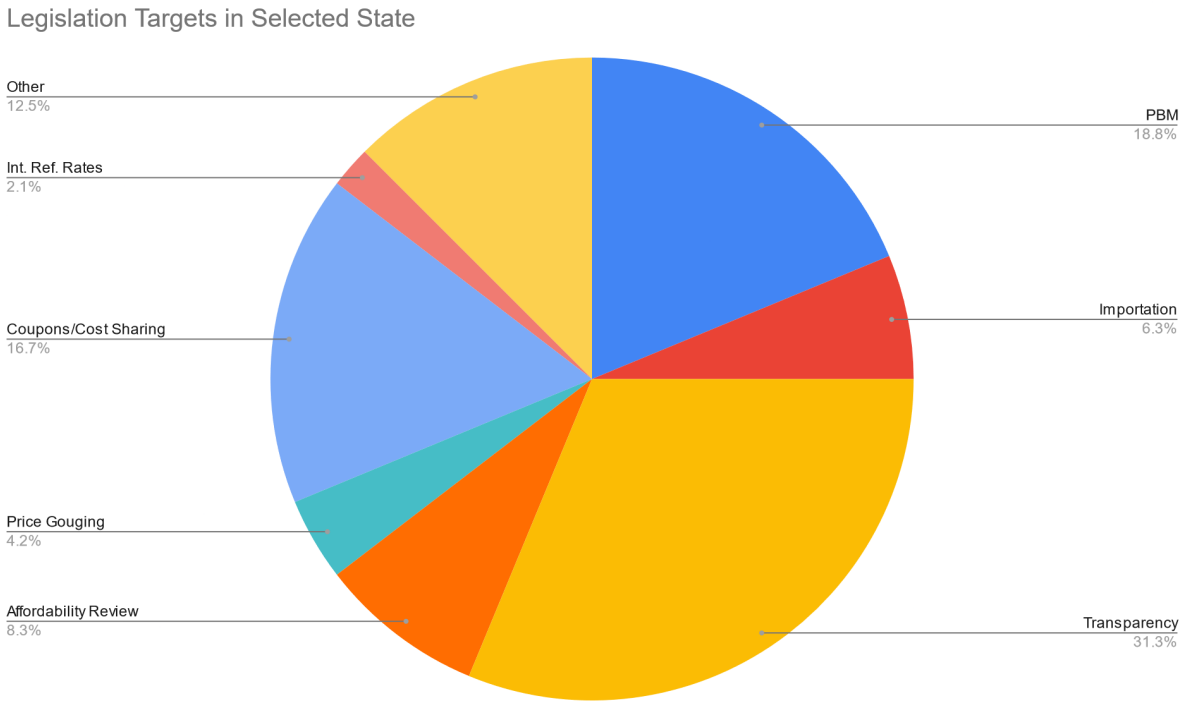



*Figure 8: a pie chart showing the split in targets of legislation meant to reduce pharmaceutical prices in Rhode Island.*

As the amount of legislative efforts present in the states in question increases, it is expected that the amount of non-legislative focus will increase as well. Whereas a state like

South Dakota exhibits qualities that are indicative of the patient population being small or disenfranchised, a state like Rhode Island likely has a more vocal population, as such advocacy is what would lead to greater legislative focus in the first place. While there are other variables of note such as the political leaning of the state's legislature, it is important to state that greater legislative efforts likely come alongside greater public outcry. It is possible as well that the inverse would be true, and that the increased legislative attention paid to the issue would satiate the public and reduce outcry. However, this reaction would be contingent on those efforts being successful and noticeably reducing the price of care for patients.

The news and blog posts pulled from NexisUni and Proquest yielded results largely in line with the expected trend. Whereas the South Dakota results required significant combing to find relevant results, and the relevant results were largely from constituents, Rhode Island's search yielded multiple references to insulin and Epipen pricing in particular, and specifically to the legislature's desire to address the crisis. Included among these results were multiple indicating a desire from Senator Sheldon Whitehouse to not only reduce prices, but specifically to find the root of the problem and direct efforts accordingly. These results were, however, dispersed somewhat among results pertaining to the opioid epidemic, which implies a similar shift of focus as in South Dakota. The fact that the results found in this search were more targeted but similarly dispersed as in a state with significantly lower legislative attention paid to pharmaceutical pricing further supports the developing trend, as well as the moderacy of Rhode Island's approach. That is to say, the news and blog posts from Rhode Island indicate that both the public and the legislature are aware of the problem of pharmaceutical pricing and do consider it a major issue, but are also occupied with other priorities.

With regards to Medicaid reimbursement costs, the information for Rhode Island is rather interesting. Beginning in 2015, Rhode Island spent a very small amount on reimbursement for rapid-acting insulin (less than a million dollars), but this amount quickly rose to above six million dollars shortly afterwards. This spike in costs was maintained until 2018, at which point a strong downturn in expenditure occurred. When normalized for the population of diabetics in Rhode Island, the amount spent per person thus ranged from almost 0 to almost 100, peaking at the highest value witnessed among all three states. These drastic changes in expenditure are reflective of the additional attention paid in the state to the issue, and are illustrated in figure 9 below. Indeed, the "story" told by this data matches what has been implied by the rest of Rhode Island's data, namely that the rising impact of the crisis has forced an otherwise moderate legislature to action in attempts to contain rising prices. Based on the sharp decline, it seems that the efforts pursued in Rhode Island were somewhat successful, although the meteoric rise in prices in the first place presents its own questions. In addition, as many of Rhode Island's efforts are still works-in-progress, it is necessary to consider whether those legislative efforts are actually what has caused the changes in spending as opposed to non-governmental efforts or simple changes in the state government's spending patterns.

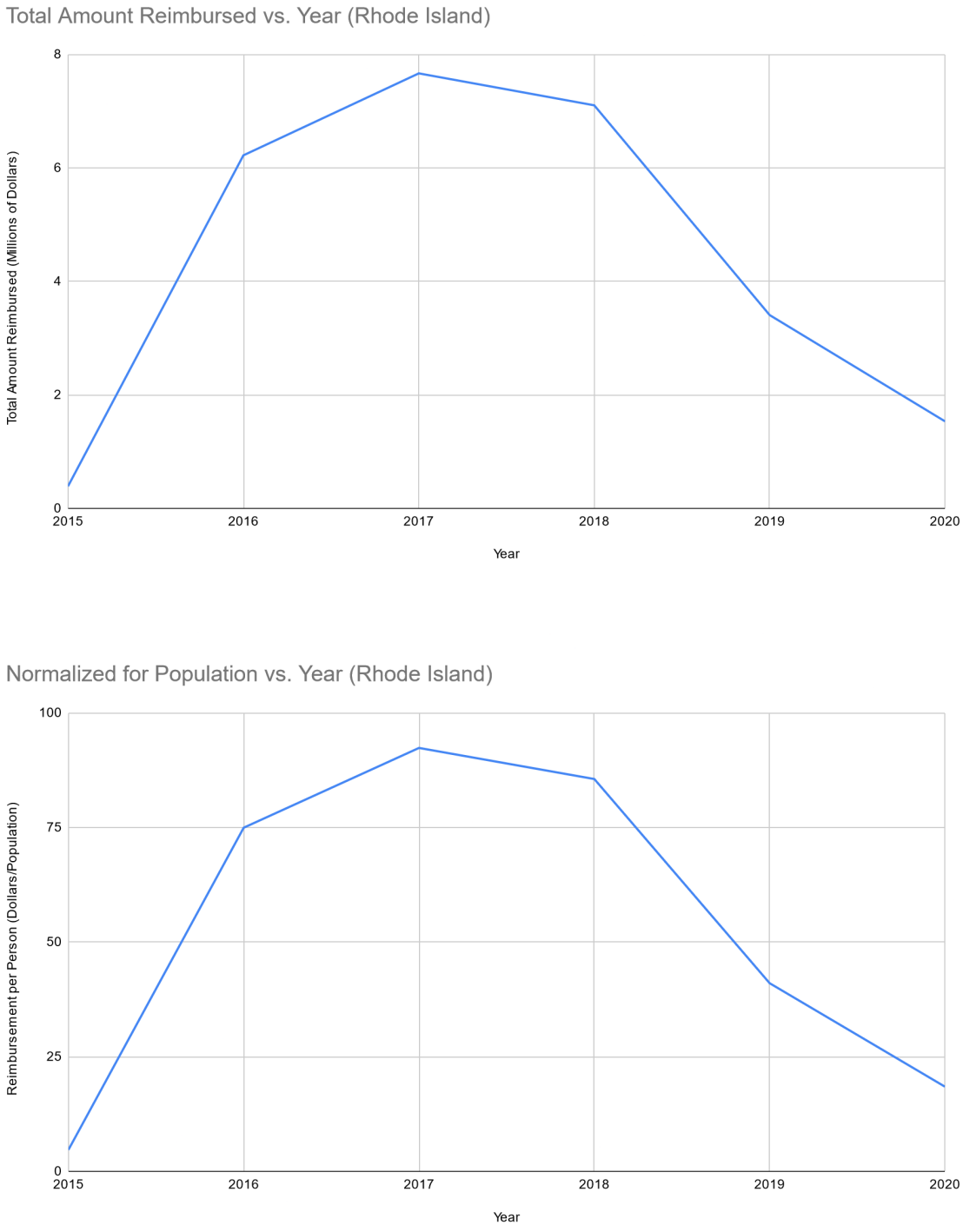



*Figure 9: a.) A chart of the total Medicaid reimbursement amount for rapid-acting insulins in Rhode Island between the years of 2015 and 2020. b.) The same chart, with an additional normalizing factor which takes the state's diabetic population into account.*

Rhode Island's data continues the pattern that was expected from South Dakota, with additional legislative attention coinciding with both additional public attention and an increase in the level of change in Medicaid reimbursement amounts. The fact that these results are consistent with the hypotheses expected by common sense is encouraging, as it implies a possibility of state legislative efforts at least being somewhat successful in curbing costs. However, before such a conclusion can be drawn, it is important to examine the zenith of legislative efforts and whether they have been more effective than those shown in both South Dakota and Rhode Island, and in addition, to compare the three states against each other in order to determine the adequacy of such efforts on a national scale.

**New Jersey**

Finally, moving to the highest end of the legislative spectrum, New Jersey was selected to represent states with a proactive approach to legislating high drug prices. With a whopping 99 pieces of legislation in the 2015-2020 period, New Jersey has the most efforts of any state, and is only closely rivaled by New York. New Jersey is well documented as a state with a deep investment in the pharmaceutical industry, and this large quantity of legislation makes it the best current example of a heavily legislated approach. This style of legislation is supported by many on the progressive side of the United States political spectrum, and is characterized by a desire to actively rein in pharmaceutical prices to standards that are set outside of industry influence. However, as will soon be seen, this strategy can also be co-opted by certain industry actors to influence overall efforts and potentially reduce efficacy. New Jersey demonstrates not only a

large amount of legislation, but similar patterns to those witnessed in other heavily regulated states - a pattern that is, in many ways, concerning.

The breakdown of targets for New Jersey's legislative efforts, displayed in figure 10 below, is immediately striking for the overwhelming majority of legislation that is targeted at pharmacy benefit managers. Almost half of New Jersey's 99 pieces of legislation are targeted in some way at pharmacy benefit managers, representing a share more than three times larger than the next most numerous (the catch-all "other" category). This is a trend that was observed in many of the more heavily regulated states based on the quantitative data used in this thesis, and so while it clearly differs from a more diversified approach, it was determined to be representative of the average with regards to the category that New Jersey represents. This can be seen in the aforementioned split of targets across the country, in which pharmacy benefit managers are targeted by roughly a third of all legislative efforts. In addition, much like Rhode Island, the vast majority of New Jersey's legislative efforts are works-in-progress, as of the 77 efforts included in this research, 71 were pending. There are multiple interpretations of these results that are possible, but there are two important caveats to note. First, New Jersey has an order of magnitude more citizens than either Rhode Island or South Dakota, and so also has an order of magnitude more diabetic patients who represent a significantly stronger political force. Second, many pharmaceutical companies have bases of operations in New Jersey and are known to be a powerful lobbying force in the state (Landers and Sehgal, 2004). With this in mind, the target breakdown coupled with the lack of success of legislative efforts in passing the legislative process implies that, while there is a powerful push in New Jersey to lower drug prices, it is being countered by certain interest groups which seek to profit from high prices while shifting blame elsewhere.

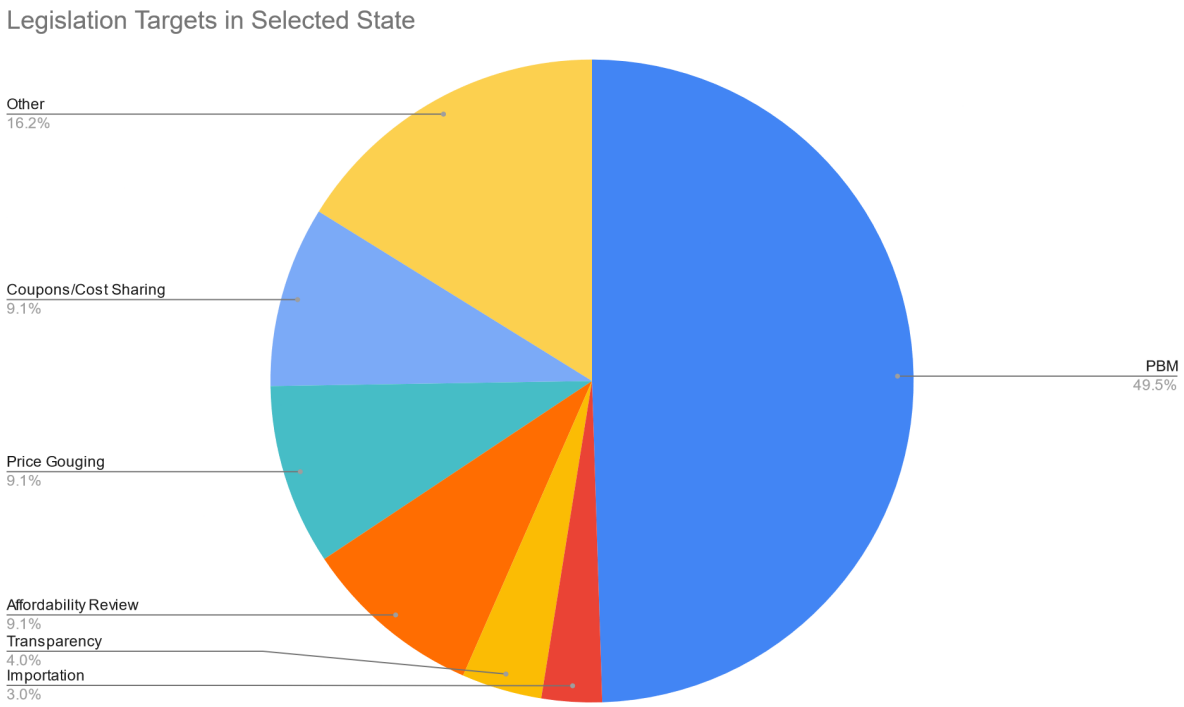



*Figure 10: a pie chart showing the split in targets of legislation meant to reduce pharmaceutical prices in New Jersey.*

With a population approaching the tens of millions and a significantly more urban environment than Rhode Island and South Dakota, New Jersey is a state which in theory has much more to lose to high drug prices. The pressure which New Jersey is under to lower drug prices is thus likely significantly higher than in other states simply by economies of scale, and this greater attention is clearly displayed in the higher amount of legislation. The question remains, however, whether this legislative attention has yielded dividends in the reduction of expenditures on notable products. Herein lies the issue in these heavily focused efforts: if, for example, pharmacy benefit managers turned out to not have a major impact on pharmaceutical

pricing, then the majority of New Jersey's legislative efforts would be wasted, and the higher effort would not be effectively directed. While this is not necessarily a problem inherent with state interventions, it is one that must be taken into consideration, as these policies are not crafted in a vacuum. If state interventions prove to be more susceptible to lobbying from powerful interest groups, that could be a justification for federal legislation to be carried out.

The qualitative analysis of New Jersey's social focus on the issue of excessive drug pricing again yielded results consistent with those expected. Whereas both South Dakota and Rhode Island required some amount of filtering through results to find relevant outcry, for New Jersey the process involved filtering out results that were *not* pertinent to the topic, as they were the minority. Almost every piece of news or blog post found in the search pertained directly to the issues at hand, with multiple references to hearings being held to investigate high drug prices, community members voicing anger at the state of the market, and in general an almost laser-focused public which seemed deeply attentive to the issue. Indeed, many of the results of this analysis included updates on major events in the pursuit of lower drug prices, such as the status of state lawsuits targeting price gouging and excessive hikes or the status of potential alternatives to expensive name brand products such as the Epipen. These results correlate with the amount of legislation seen in the state, as they are indicative of the greater sway that patient interest groups hold in inciting responses from legislators, likely due in part to the fact that it is difficult to ignore such a large patient population. Therefore this section of analysis implies that the public of New Jersey is similarly concerned with high drug prices as the legislature seems to be, and in many cases is demanding more direct action in reducing prices for citizens.

With regards to Medicaid reimbursement amounts, New Jersey's pattern can be interpreted to roughly follow a similar trend as the other two states, albeit once again an order of

magnitude more dramatically. New Jersey's reimbursement amounts start in the range of 35 million and quickly spike close to 50 million, but around 2018 these amounts dip rapidly to the 10 million mark similarly to Rhode Island's. This pattern can be seen in figure 11 below, which also displays that the adjusted amount which accounts for New Jersey's diabetic population falls between 20 and 80 dollars per person in general. This trend therefore follows a similar progression as that of Rhode Island, but with more drastic changes in price due to the economies of scale at play. As such, while per person New Jersey has begun spending a similar amount less as the other states, overall it has spent tens of millions of dollars less on rapid-acting insulin in the past two years. However, the consistency of these results raises questions due to the similarity in patterns between states with vastly differing legislative approaches, a topic which will be discussed in the following subsection when the three states are full compared to one another. New Jersey's reimbursement data nonetheless implies a massive downshift in costs of acquiring rapid-acting insulin, an overall encouraging trend to be observed in varying locales.

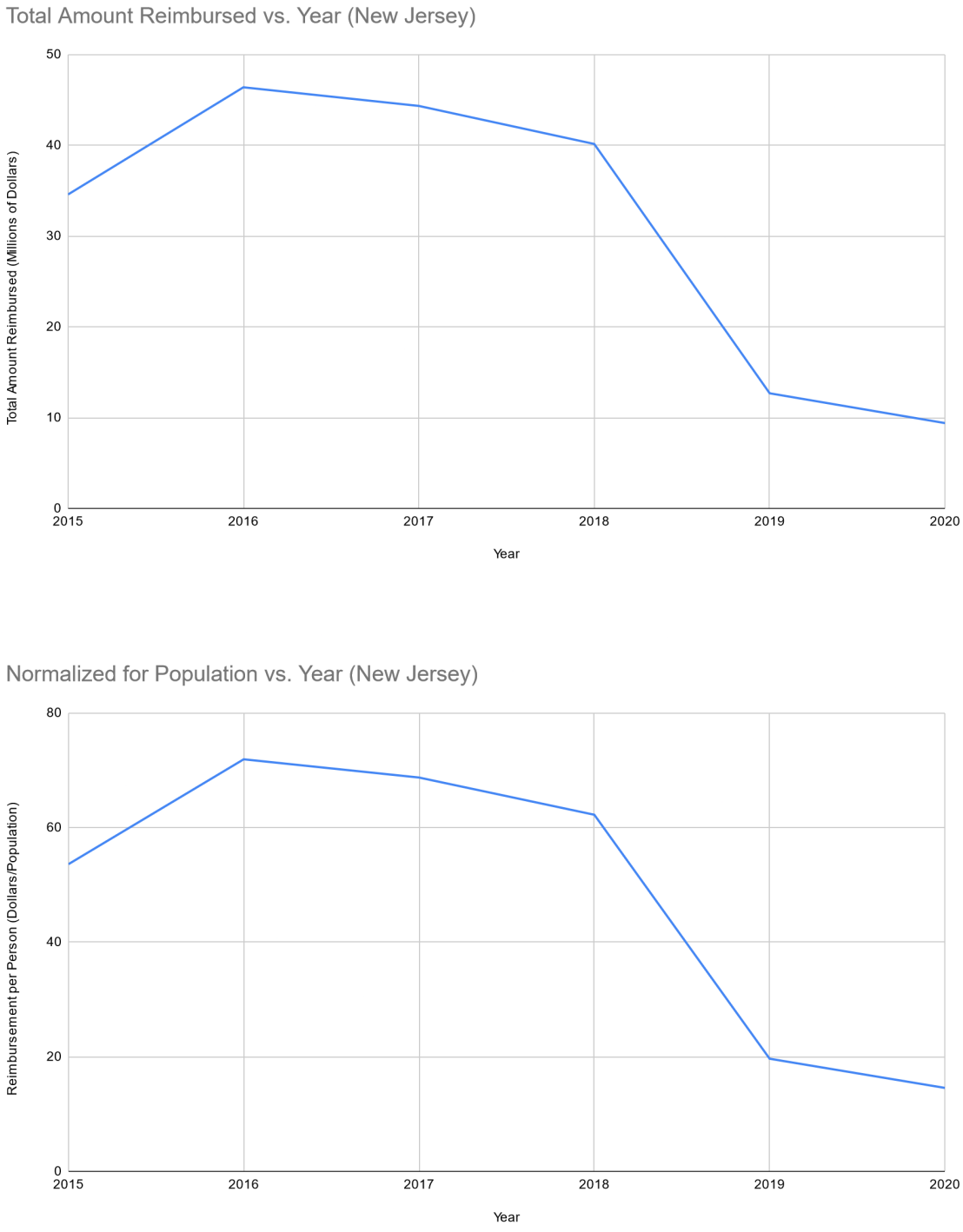



*Figure 11: a.) A chart of the total Medicaid reimbursement amount for rapid-acting insulins in New Jersey between the years of 2015 and 2020. b.) The same chart, with an additional normalizing factor which takes the state's diabetic population into account.*

New Jersey represents the prototypical case for requiring legislation in the first place. The population of patients is large, and they are vocal in their demands for fair and equitable care, which has yielded significant legislative attention which the public is particularly attentive to. In New Jersey, high drug prices are a big-ticket political item which has enjoyed its share of the limelight in the modern era, and this is reflected in its legislative response. However, the intense focus this response has taken on pharmacy benefit managers raises some concerns about its suitability - concerns which may be elucidated upon comparison of the three states' approaches.

## Comparisons

With the three states' individual results laid out, it is now necessary to make comparisons of their results to determine whether any is visibly more effective than the others. The three states have vastly different approaches to legislating high drug prices, not just in terms of quantity but in terms of targets as well. With this in mind, and making sure to be cognizant of the different public responses in each state as well, the utilization metrics that have been displayed thus far can be displayed side by side to observe comparative trends that are more difficult to quantify or see when each is viewed in isolation.

Figure 12 below displays the previously shown data side-by-side, both in terms of total reimbursement amounts and normalized reimbursement amounts. Beginning with the total reimbursement amounts depicted in figure 12a, it can be seen that New Jersey's reimbursement amounts were an order of magnitude higher than either Rhode Island or South Dakota's, and that all three states saw peaks in expenditure between the years of 2016 and 2017. In addition, all the

states have been on a recent downward trend, with New Jersey and Rhode Island both experiencing noticeable downturns in expenditure between 2018 and 2019. New Jersey's decrease in spending is particularly dramatic, dropping to almost the levels of the other two states despite the massive contextual differences in patient population. While overall reimbursement amounts are difficult to extract valuable comparisons from due to these contextual differences, the fact that New Jersey's expenditures are approaching the same levels as the other two states in spite of a patient population almost ten times as large is interesting.

Moving on to the normalized reimbursement amounts in figure 12b, a very interesting trend develops. First, the pattern noticed in the total reimbursement amounts is repeated more dramatically here, with all three states starting at relatively low expenditures, seeing peaks in the years of 2016-2018, then witnessing dramatic drops as the data approaches the current year. Particularly different in this comparison is Rhode Island, which starts with the lowest expenditure, rapidly rises to the highest expenditure, and subsequently falls back to almost tied for lowest expenditure over the noted time period. This chart emphasizes as well the stability of South Dakota's expenditure, and makes it clear that while New Jersey spends an order of magnitude more overall in rapid-acting insulin reimbursements, it does not spend more per patient than either of the other states. The most striking result here is the similarity in pattern between all three states, as well as being able to compare the intensity of each state's changes in reimbursement amounts. From this it can be shown that Rhode Island's reimbursement per person changed the most dramatically, while South Dakota's was practically constant but still subjected to similar patterns as the other two.

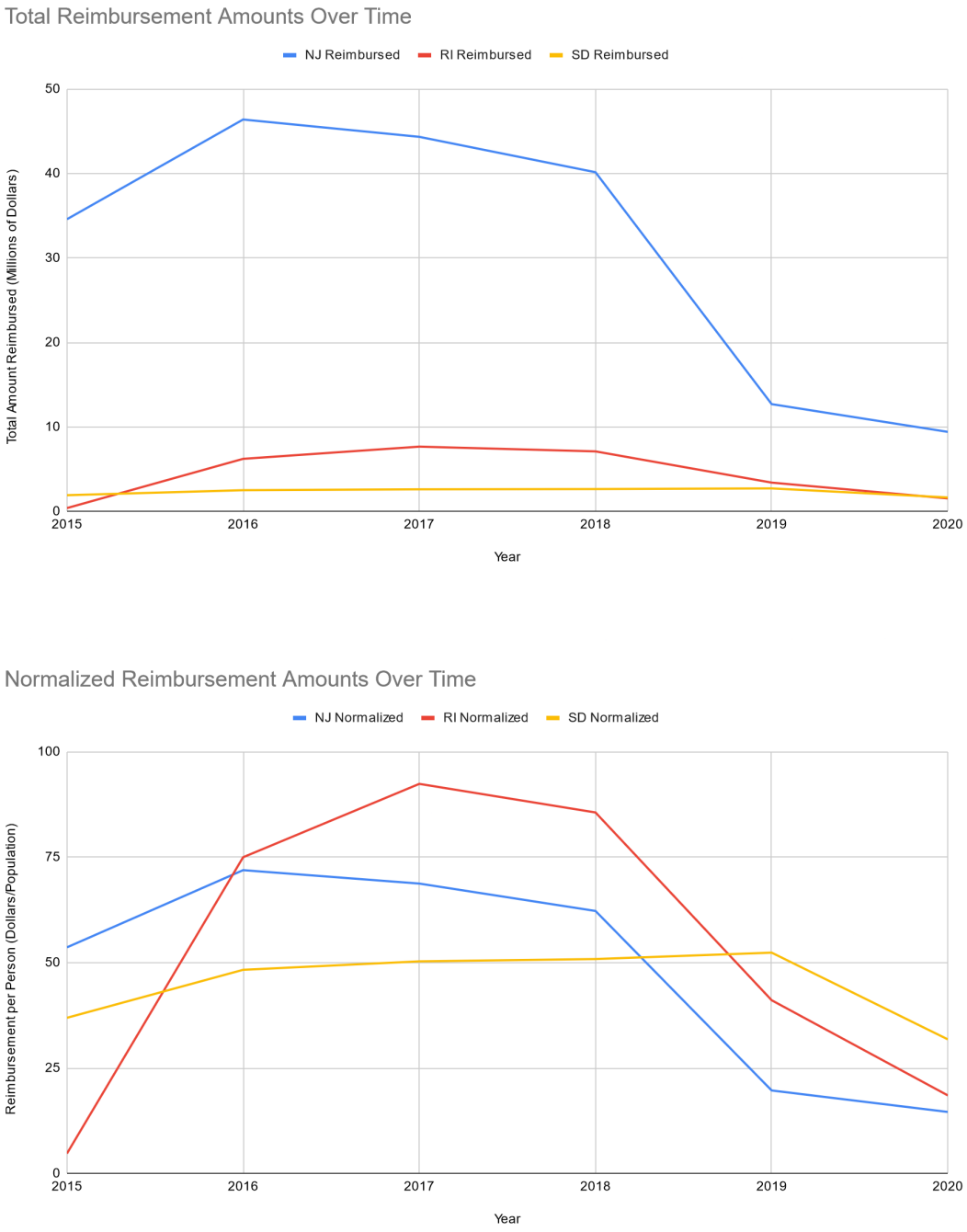



*Figure 12: a.) the charts from figures 7a, 9a, and 11a compiled to compare total Medicaid reimbursement amounts for rapid-acting insulin in South Dakota, Rhode Island, and New Jersey. b.) the charts from figures 7b, 9b, and 11b compiled to compare the same charts when modified to account for diabetic patient population in each state.*

Making qualitative comparisons between the news and blog posts found in each state can also help to inform as to a national baseline and each state's unique context. In terms of prevalence of relevant results, New Jersey had a significantly higher portion than Rhode Island, which itself had a significantly higher portion than South Dakota. While Rhode Island and South Dakota have similar population statistics, it was significantly easier to find pertinent posts when searching in Rhode Island. New Jersey's selected articles were also more explicitly focused on and knowledgeable about the state of the subject matter, referencing active legislation and hearings, while the other two states seemed to have a less experienced focus on the issue. Many articles from South Dakota and Rhode Island suggested potential solutions, but seemed to be more focused on other issues, whereas New Jersey seemed completely focused on tackling the problem of high drug costs. Especially in the context of the other two states, New Jersey's public focus is unique. Even Rhode Island, which has a significant amount of legislative focus on the issue, was nowhere near as focused on the issue from a public perspective as New Jersey was.

One important factor to consider when comparing these states is the relative size of each state's pharmaceutical industry. As has already been mentioned, New Jersey is widely considered to be a hub for pharmaceutical companies, but is it markedly more so than Rhode Island and South Dakota? Using each state's Quarterly Census of Employment and Wages, it is possible to compare average employment amounts in specific industries as a benchmark of that state's investment in that industry. Intuitively, one might expect metrics of gross domestic product in each state to represent a more accurate view of the size of an industry in it, but due to the circumstances of how GDP is broken up, pharmaceutical production falls into a variety of disparate categories which coincide with other industries, making it difficult to directly compare. According to these QCEWs, in the 4th quarter of 2020, the average employment in the

pharmaceutical industry in each state was as follows: 1,086 in South Dakota, 2,814 in Rhode Island, and 43,831 in New Jersey. Even accounting for the differences in population between the states, New Jersey employs significantly more people in the pharmaceutical industry than either of the other two states being compared. This implies that the state is truly a hub for the industry as has been asserted in the media.

These results raise interesting insights both in isolation and when compared to one another. There are multiple possible interpretations of these results, however, and it is important to analyze what the most likely cause is for each and, in addition, to discuss the difficulties and limitations encountered in the acquisition of these results. Indeed, if there is one insight that can be confidently derived from this research, it is that the compilation of this information was surprisingly difficult given its apparent ubiquity.

## ***Discussion***

Before launching into the discussion of these results, it is important to note that one of the key insights that will be discussed further in this section is the ambiguity of the results that have been collected here. The following analysis represents my interpretation of the results that I have compiled, but due to a combination of the uncertainties in each dataset and the less-than-rigorous circumstances of their compilation, there are other entirely valid and mutually exclusive interpretations that bear merit. While I will be asserting my interpretation for the purposes of having a dedicated set of findings for this thesis, it should be noted that the ultimate result of this research is its inconclusive results. For the sake of transparency and thoroughness, another possible interpretation of these results will be briefly analyzed at the end of the discussion, and will be compared to my interpretation to highlight the difficulties encountered in creating the case studies.

The process of collecting, processing, and analyzing this information has yielded numerous insights into the state of pharmaceutical prices in the United States. Not only does this information have major implications in and of itself, but the difficulties encountered in the process of its generation have helped to inform about major gaps in current knowledge. These insights taken together have a myriad of potential policy implications, which suggest a variety of approaches which may be better suited to addressing the problem. All this being said, any and all insights gleaned from this analysis must be cognizant of the major limitations that the aforementioned difficulties created in the execution of this research. These limitations themselves inform as to where additional research and efforts must be directed in order to create more rigorous analyses in the future.

**General Discussion**

The selection of South Dakota, Rhode Island, and New Jersey was satisfactory for the parameters of this thesis. Based on the analysis of state pharmaceutical legislation, they seemed to be representative of their respective classes, with South Dakota having practically no legislation, Rhode Island having a medium amount of widely varied legislation, and New Jersey having a significant amount of heavily targeted legislation. New Jersey in particular demonstrated the trend witnessed in the upper levels of quantity, in that it had an intense focus on legislation targeting pharmacy benefit managers. This focus is important to note, as it could have many implications. Perhaps the two most obvious are that pharmacy benefit managers are major stakeholders in pharmaceutical pricing practices and that something is directing more invested actors to focus their efforts there as opposed to on manufacturers. This reason could be a legitimate understanding of where exorbitant prices come from, but given how opaque that sphere of information is, it is equally likely that the powerful lobbying force of manufacturers is attempting to influence the direction of legislation so as to not be targeted themselves. This intense focus on pharmacy benefit managers would be entirely wasted if they are not the cause of higher prices, but would prove to be an invaluable delay for the responsible actors.

Similarly concerning for the efficacy of state legislation is the massive portion of legislative efforts which remain locked in transit, either stuck in legislative purgatory or struggling through layers of bureaucracy. Despite having an order of magnitude more legislative efforts than South Dakota, New Jersey had similar numbers of *successful* legislation. While New Jersey clearly pays better attention to the issue of pharmaceutical pricing, it is unclear whether that additional attention yields tangible results, or if it is just “lip service” which does not herald true change. The low rates of efforts passing is certainly reflective of the politically divisive

environment of the twenty-first century, especially on the issue of healthcare, but while this is now par for the course it is nonetheless indicative of another weakness in the state approach. Namely, state approaches tend to be more incremental as compared to sweeping federal interventions - therefore, state legislation often relies on an interlocking web of successful legislation, a web that can be disrupted if any part of it fails. Alongside the potential that these efforts are being led astray by lobbying groups, the quantitative analysis does not imply particular success from state legislatures.

Moving on to the qualitative portion of the research, the news and blog articles yielded results in line with what common sense dictates. In South Dakota, economies of scale prevail - while there are concerned populations within the larger population, they are too small and isolated to be a major sociopolitical force, and are therefore disenfranchised and unable to affect the direction of the state's legislature. In Rhode Island, the diffuse focus on the issue implies it being one of many at the forefront of the populace's mind. This matches up well with the diversity of targets witnessed in the legislative efforts, as the passive focus would lead to a more widespread set of approaches as opposed to approaches favored by any individual group. New Jersey, meanwhile, clearly demonstrates a strong focus on pharmaceutical pricing, as well as an interesting trend of the heightened focus yielding a tightened focus in turn. This may be due to a phenomenon in which political actors pursue pharmaceutical pricing as a platform, and as part of doing so craft specifically focused plans which target one entity in particular, as compared to a more diverse approach where multiple targets may seem attractive to a less invested actor.

Another point of interest within the analysis of news sources was the seeming unification of concerned parties on the *degree* of the problem. That is to say, there were practically zero articles which addressed the problem as a minor or easily addressed one. Instead, every post

decried the issue as a crisis needing immediate attention. While there were some more moderate viewpoints, most were concerned with continuing to encourage innovation from the pharmaceutical sector as opposed to any belief that the problem was less intense than others claimed. It seems that, in general, if a source was aware of the problem, they considered it to be one of the foremost problems in the United States, whereas anyone who wasn't firmly convinced was more likely to think of it as not a problem at all. This division may be based in lived experience - anyone familiar with debilitating medical costs can feel the personal impact of the current state of things, while more insulated communities may have positive experiences with the United States healthcare system and so may not be fully considering the ramifications of high pharmaceutical prices on the day-to-day lives of other people.

Finally, regarding the comparative results, a very interesting trend emerges. With *both* the overall and normalized reimbursement amounts, by 2020 all three states had equalized to very similar levels. In addition, they followed almost identical trends, with reimbursement amounts increasing leading up to 2018 and 2019, followed by dramatic decreases. While initially this trend may seem encouraging for the suitability of state efforts, in many ways it actually implies the opposite. Despite having vastly different legislative approaches, all three states exhibited similar trends following almost identical patterns and ending up with very similar levels of reimbursement. This implies that the differences in their results are not due to the differences in their legislative approach, but rather due to some other variable. For example, the trend could be reflective of a change in federal governance of state spending which forced reductions in reimbursement amounts, or in a redefinition of the Medicaid reimbursement policy which changed how states reimbursed for rapid-acting insulin. It could also be indicative of a shift in spending from one type of insulin to another, in which case the metric would be deceptive of the

true state of expenditures. While it is uncertain exactly what this unified trend implies, it is clear at least that it does *not* confirm that one state's approach is more effective than any other's. As a matter of fact, it is arguable that this confirms the opposite - despite a significantly greater attention (and, no doubt, taxpayer dollars) paid towards addressing pharmaceutical prices, New Jersey failed to affect their expenditure in a way that differentiates them from states with less heavy-handed methods. If the trend is the same regardless of how hard the state pushes to legislate the issue, then it is likely that affecting the issue from the state level is impossible from a practical standpoint. In addition, the unified trends may imply something like a shift towards privatized insurance, a shift which would deepen the already staggering complexity of the field and leave it out of regulated hands.

Also of interest is the sensitivity in each state, that is to say, how much variation each state experienced in reimbursement amounts. Lower amounts of variation imply that the state's expenditure is less sensitive to wider changes, whether due to a success in suppressing prices or another factor. In terms of normalized amounts, Rhode Island displayed the most sensitivity, experiencing a wide range of costs per patient. Overall, New Jersey's sensitivity was highest by a wide margin, likely reflecting the much higher patient population in the state. Given that these sensitivities seem to reflect population statistics, it is likely that they are indicative of the larger patient populations in Rhode Island and New Jersey.

While New Jersey's expenses are certainly an outlier compared to the other two states, comparisons between Rhode Island and South Dakota are particularly valuable due to the similarities in their population statistics. While New Jersey's population numbers close to the tens of millions, Rhode Island and South Dakota both are around the one million mark, albeit with a significant difference between their diabetic populations. With that in mind, the significant

difference in sensitivity between Rhode Island and South Dakota stands out - with similar patient populations, it is strange that Rhode Island would experience so much more drastic changes in expenditure per patient. This small insight may be key - the similar contexts between the states allow a more direct comparison, and in this case it appears that Rhode Island was successful in reducing prices in a more dramatic way than South Dakota. This may be explained by the diverse approach of legislation taken by Rhode Island, as with so many targets touched upon by the legislature it is likely that some amount of efficacy was attained. That being said, South Dakota's significantly lower sensitivity implies some amount of insulation from drastic price shifts. Even this potentially has layers however - perhaps that insulation comes from prices already being inflated to their maximal amounts, with overall costs only being low due to the low patient population. Overall, the only thing that is truly clear from this data is that more information is needed. It is, within the bounds of this research, impossible to determine what the cause of any of the aforementioned trends are, and additional context is required from a variety of sources.

Before moving forward, it is important to consider the cost to patients of these seeming shortcomings. First and foremost, a failure of state legislatures to lower prices implies the same to be true for patients. After all, if a government can't figure out how to save money, how can an individual?. This leads to list price becoming actual price for some number of patients, forcing them to pay prices meant to be reduced by rebates and insurance. In the arms race of prices and discounts, prices can be raised with the stroke of a pen, but reductions come after months or years of organizing. Mollifying efforts will always lag behind and leave patients to pay more. Thus with the primary avenues of cost reduction failing, patients are left doubly harmed by the failure of state legislation - they both pay higher prices and are left with no sign of progress towards them lowering, to speak nothing of the time and resources invested in failed efforts.

**Benefits of a Federal Approach**

While the definitively directive insights from this research are limited, it is nonetheless clear that the issue of exorbitant pharmaceutical pricing persists. Despite a variety of states taking a variety of approaches, trends seem similar across the United States and prices remain high, with patients continuing to struggle under the financial burden. Indeed, the qualitative analysis of news and blog posts imply that many areas of the country still consider the issue to be a pressing one. Therefore, this research serves to support the theory that the current approach is inadequate. Approaching the issue from the state level appears to be moderately effective at best, and countervailing forces of economic inflation and perverse incentives conspire to counteract any and all incremental progress. All this to say, this is not an issue that has been sensationalized by the United States media - it is persistent, has a profound impact on people's lives and wellbeing, and has not been adequately addressed even by a variety of efforts pursued over the better part of a decade. With this in mind, alternatives must be considered. Federal intervention is, at this point, seeming more and more attractive both from this research and in the eyes of the public. Therefore, analyzing the potential benefits of a federal approach is pertinent to determine whether it might be the logical next step.

One of the primary weaknesses of the state approach highlighted by this research is the low rate of success of state legislative efforts. While federal politics are often more divisive than state politics, there is a corresponding benefit - namely that each piece of legislation holds significantly more weight than any individual state approach. Therefore, while a federal approach may experience many failures before a success, the success will likely be more impactful than if the same success rate were experienced on the state level. The weight and legitimacy of federal legislation also makes it unlikely that an implemented system would be

removed before its effects could be felt, in a similar way to how the Affordable Care Act has persisted despite significant political opposition throughout its institution. Therefore, while federal intervention would likely experience similar difficulties as state interventions (if not more), any successful legislation's effectiveness could be significantly greater.

Another benefit to a federal approach highlighted by this research is the ability to cut through many of the layers of legal opposition that have been levied against state efforts. Many defendants of pharmaceutical prices have argued that state level legislation violates federal legislations that govern interstate commerce, international intellectual property rights, and more. States, in their position as always being more or less subservient to the federal government, are unable to adequately counter these arguments, which puts a powerful arrow in the quiver of bad-faith actors who are invested in high prices. A federally mandated approach, however, would have more ground on which to argue against such concerns, or even to modify the legislation in question in order to not contradict proposed systems. Therefore, a federal approach would likely remove a major roadblock that has been successfully levied to block state legislation, allowing for a wider range of approaches that may enable action that will be significantly more effective.

In addition, the blunt instrument of federal intervention may be better suited to cutting through the complex web of interactions that is the situation in the pharmaceutical industry. One issue that states face is that, in the absence of the ability to interfere with federal systems, they must instead devote time and resources to pinpointing specific targets where optimizations can be made to reduce prices. This more granular approach works well for other problems, but as has been mentioned prior, is dependent on incremental change and continuous efforts. In the pharmaceutical industry, it seems that any gains made in one part of the system are counteracted by actors in a different part. Untangling the proverbial Gordian Knot of where exorbitant prices

come from may not be as effective as simply slicing the knot in twain. As has been demonstrated by our European neighbors, there are multiple systems that can be implemented in order to, regardless of the myriad of variables at play in determining pricing, insulate patients from those costs. For example, a government-run insurance system that ensures everyone is insured to the same baseline level would guarantee that nobody ever pays too much for a drug they need, as would hard price caps on individual products. The bluntness of these approaches is not to say they would be clumsy - they can still be implemented targeting specific pain points of the system, or could be designed to be overarching. The point is that the simplicity of intention and execution that can accompany federal legislation becomes more valuable the more complex a field is.

An important aspect to also consider when weighing the benefits of federal intervention is the moral imperative mentioned prior in this text. The problem of high pharmaceutical prices has plagued the modern American patient for the better part of a decade and has already claimed many lives. The qualitative analysis, as mentioned, showed a unified community decrying it as a crisis of the modern era. With so many people impacted, and with so many different attempts on a more localized scale proving to have been ineffective, the time has come for the federal government to step in. The market has proven that it will not self-regulate, and state legislatures have proven to be unable to impact the problem in a major way. The problem persists, and if nothing else the federal government has a responsibility to serve its constituents and investigate what the best solution might be.

**Policy Implications**

To summarize the policy implications of this information, let us return to the research questions first posed in this thesis. We will answer these questions in turn and create a final analysis of what implications the collected data has.

1. **Is there a noticeable correlation between the number of legislative efforts a state undertakes to control drug prices and the accessibility of drugs in that state?**

The information compiled here is insufficient to draw a definite conclusion to this question. Depending on the reader's interpretation of the results, they may determine that such a correlation does or does not exist. This ambiguity comes in large part due to the fact that the metrics utilized in this research are, at best, shakily representative of the true state of things in each state - a fact caused by the difficulty in acquiring standardized data of relevance.

2. **If such a correlation exists, do greater numbers of efforts yield sufficient increases in accessibility, or if not, do they seem like they will in the near future?**

Given the answer to the first question, it is again impossible to answer whether current efforts are sufficient. Not only is the answer to this question subjective based on what one considers "sufficient," it is also intrinsically tied to whether one sees a significant relationship between legislative quantity and utilization metrics as a measure of accessibility. Given the information used in this thesis, and as an extension the information generally available within the scope of research such as this, it appears to be impossible to gauge such correlations as adequate or not.

3. **What major roadblocks do state legislators face in attempting to implement drug pricing policy, and are those roadblocks best addressed with a state, federal, or other approach?**

The ambiguity highlighted by the first two questions is in and of itself indicative of the most important roadblock faced by state legislators: lack of information. Without access to sufficient information regarding where high drug prices come from and the size of the problem in the state, legislators are forced to guess as to the best way to approach legislation, leading to both resources and, more importantly, *time* being wasted. In addition, this ambiguity helps support legal challenges to state efforts in that parties interested in maintaining high prices are able to convincingly argue that they should not be the target of such legislation. Thus the clearest and most actionable insight of this research is that more information is needed to guide legislation. While the answer to whether this is best approached from a state or federal level is open to interpretation, given the fact that challenges to state transparency initiatives are often levied on the federal level, there may be significant utility to approaching this specific problem from the same level.

With the answers to the research questions laid out, it is possible to craft a general plan for what policy measures might be taken. The following insights are most clearly elucidated by the data presented in this thesis:

- Information regarding the inner machinations of pharmaceutical pricing is deeply complex and obfuscated. This obfuscation makes it difficult to craft policy solutions. Current measures to enforce transparency have been unsuccessful due to being mistargeted or blocked by federal legislation. Therefore, a large amount of additional research and information is required to determine what further steps could be taken.
- Until such time as the above information becomes available, a less accommodating attitude towards the various stakeholders in the pharmaceutical industry may be useful. Manufacturers and pharmacy benefit managers often point fingers to one another

regarding who is to blame, but the state of the overall system is such that none of the actors can be proven to be innocent without additional transparency.

- Federal legislation displays many benefits that may be well suited to addressing exorbitant pharmaceutical prices. As such, including federal options in considerations of how best to approach this problem may be worthwhile.
- The major health impact of high prices places significant strain on patient populations and time pressure on legislative efforts, which significantly raises the bar on what policy can sufficiently address the problem.
- Non-governmental organizations currently spearhead a major portion of efforts to reduce prices for patients. These organizations may have valuable insights for states attempting to formulate legislation.
- Additional scrutiny must be paid to the lobbying force of both pharmaceutical manufacturers and pharmacy benefit managers. These lobbying forces both benefit from high pharmaceutical prices, and so must be carefully critiqued to account for this perverse incentive.

## Policy Recommendations

Let it be stated outright that the information gathered here is not sufficient to determine a concrete policy path forwards. A number of questions remain unanswered: should it be the state or the federal government's responsibility primarily? What should the approach be? What should the target of legislation be? Should legislation even be the avenue by which this problem is addressed? This thesis serves only to provide a very rudimentary grasp of the problem as it currently exists in the United States at large. It is notably missing an analysis of specific pieces

of enacted legislation for efficacy, which would most certainly be a part of any attempt to craft a definitive legislative approach to high drug prices. As such, this thesis will not include any definitive policy recommendations, save one: as has been demonstrated by the focus on transparency in current efforts, both the state and federal governments must first focus on gathering enough information to firmly understand the problem.

With that disclaimer made, I would like to provide my personal interpretation of the results gathered here to provide an example of the sorts of conclusions that could be drawn from this information:

- I believe that the federal government is best suited to intervene in the situation as it currently stands, due to the following reasons:
    - The federal government has the ability to institute nationwide informational transparency standards which could provide a standardized database of information for policy actors to draw from.
    - States suffer from federal level legal challenges to attempts to enforce transparency - the federal government is better able to dispute these.
    - To “stem the bleeding” on high prices and allow for more time to craft policy, temporary price control measures may be useful. These are best enforced from the federal level.
- Federal intervention is not the end-all be-all to fix this problem. The granularity and localized approach of states seems to better suit the vastly differing patient populations within each state. Therefore, a hybrid federal/state approach, in which federal actors seek to provide resources (especially information) to state actors, may be valuable.

These recommendations explicitly do not include any recommendations for *specific* policy initiatives. As has been mentioned, the scope of this thesis is too limited to recommend a specific policy action. In addition, while our European and Asian neighbors may provide examples of policy, it is incredibly important to note that the United States has a myriad of unique circumstances which require accounting for in any policy solution. All this to say, any recommendations that come from this thesis, mine or otherwise, must be limited to general directives. These directives can inform future research in order to eventually yield actual policy.

## Limitations and Further Research

While the previously outlined insights are surely pertinent for the field of healthcare governance, it is nonetheless imperative that the limitations of this research be addressed in a thorough manner. As a matter of fact, the methods employed in this thesis were significantly limited, and the limitations have deeply affected the relevancy of the final results. These limitations are not without value, and imply many areas where additional research can be conducted to allow for more rigorous continued study in the future.

First, it is pertinent to mention the limitations of the methodology employed in this research. Due to the very limited scope of the research being conducted, many variables could not be considered for their impact on pharmaceutical prices. These variables include the political inclination of the states in study, the average financial status of citizens of those states, the relative urban percentage of each state's population, and many, many more. These factors could have massive impacts on pharmaceutical pricing and, in addition, could have interactive effects with each other and with legislative attention. Further research would ideally include a more holistic approach to each state's case study and would consider many more relevant variables in

a more rigorous statistical analysis. This information was not included here for feasibility reasons - just as it was difficult to acquire metrics of drug utilization, it was found to be practically impossible to acquire a full picture of a state's pharmaceutical industry landscape in the time allotted. In addition, while the assumptions made in this research are theoretically sound, there is no guarantee that they are proper. It is possible, for example, that Rhode Island is not representative of the moderate approach to state legislature of drug pricing, in which case a major premise of this thesis is called into question. Finally, there is a very real possibility of bias in the execution of this research. The framing of pharmaceutical pricing as a crisis in the United States, or a problem to be solved, implies that there must be something fundamentally wrong with the currently implemented system, whereas it is possible that the problematic symptoms are actually indicative of a different problem or a flaw in implementation.

On the topic of variables, utilizing the quantity of legislative *efforts* (as opposed to quantity of efforts passed into law, efficacy analysis of individual efforts, or another variable entirely) presupposes that such a metric is an adequate measure of a state's level of focus. Indeed, attempting to measure the level of focus itself presupposes that level of focus could be correlated to reduced prices. While the reasoning for this decision, namely the desire for a standardized source of data, is a valid one, it speaks heavily to the ambiguity of this research. These variables cannot be definitively linked to the problem at hand without major assumptions being made.

The difficulties in the gathering of the data presented in this thesis cannot be overstated. The complexity of the pharmaceutical industry and the systems by which patients acquire drugs creates so many intersecting layers that acquiring a full picture view is practically impossible. This yields a host of problems and limitations: first, the utilization data employed in this thesis

may simply be an inadequate representation of pharmaceutical pricing, as it fails to take into account a significant number of outside variables and other actors. However, it was specifically selected due to its consistent source and other factors which enabled it to act as an easy comparative metric between states. This complexity is therefore a major limiting factor, as the myriad layers make for an environment which is almost impossible to adequately summarize without intensive, long-running research. Further research could be performed which employs a methodology intended to circumvent this complexity - one such study could instead use survey data from each state which finds an average "drug expense" from patients in those states, or in other words, the amount they spend over a period of time on out-of-pocket pharmaceutical costs. The circumstances of this initial foray into analyzing the suitability of state approaches did not allow for such a method, and therefore this thesis was instead directed to form a general qualitative understanding of the situation as it stands in order to direct future efforts.

Another inherent limitation in judging the suitability of state legislation is the assumption that said legislation is crafted with the proper intention of reducing pharmaceutical prices. As has been touched upon earlier in this paper, the pharmaceutical industry represents an incredibly wealthy and powerful lobbying force, a strength that is felt especially dramatically on the state level. Examples like New Jersey, where half of all legislative efforts are targeted at pharmacy benefit managers, show the manifestation of that power. As such, it is impossible to tell whether actors with perverse incentives had any say in the creation of state legislation. Taken together with the fact that the *vast* majority of legislative efforts tabulated in the data were works-in-progress, it is possible that the metric of quantity of legislation is not an adequate measure of a state's true investment in the problem of pharmaceutical prices. More in depth research could be conducted which could focus instead on successful legislative efforts or which

could involve an analysis of lobbying expenditures from invested actors in the states in question, which could provide an additional dimension of nuance to the discussion of a state's intention and success.

Judging state legislation also presupposes that federal legislation could be a more effective tool at addressing rising pharmaceutical prices. While, conceptually, the metaphorical sledgehammer of federal intervention promises relatively easy and sweeping changes, it is entirely possible that such efforts would be hamstrung in the legislative process by bad faith actors, or that after implementation new problems would arise to negate their efficacy. This thesis is thereby limited by the lack of understanding of how and in what form such legislation would be implemented. Without at least a theory of what form a federally mandated system might take, it is difficult to judge whether it would be more effective than current efforts. Therefore the implications of this thesis are limited entirely to an analysis of the efficacy of current solutions, and are not meant to provide a definitive answer of what federal legislation might take the place of current state efforts. Analysis of the United States (both in aggregate and on a state-by-state basis) is required to understand what sort of system, perhaps modeled on success stories in our European counterparts, would be most applicable and effective in our unique context. This touches as well on another limitation of this research, which is an inadequate understanding of the unique context of each state as mentioned previously. Ideally, this basic framework of methodology would be repeated with more personally invested and thorough understandings of each chosen state's unique circumstances.

Finally, one major limitation that must be acknowledged in any research pertaining to the pharmaceutical industry is the bias imposed by the pressure of time. Pharmaceutical prices have been a hotly debated topic for the greater part of the 2010s, and it is a well documented fact that

many people suffer and die under current circumstances on a daily basis. This, and the fact that it is so prevalent in United States media, puts a premium on short-term fixes as opposed to long-term systemic solutions. As such, alternative solutions like quick and blunt federal legislation sound more appealing than, for example, state efforts which may seek to take effect over the course of years or decades. While obviously the haste imposed upon the issue of pharmaceutical prices is warranted, and faster solutions are therefore more valuable, it is nonetheless important to acknowledge that this thesis presupposes that state efforts that are currently ineffective will continue to be ineffective in the future. Analysis of this presupposition would require a thesis in and of itself, as it would require a much more in-depth analysis of all currently implemented and soon-to-be implemented pharmaceutical price legislation, as well as the creation of another metric to estimate long-term efficacy. This thesis instead takes a more-or-less snapshot view of the issue - a view which, while valuable, is limited in a pertinent way that bears emphasizing. A more in-depth analysis, perhaps on a single state as opposed to comparatively between states, could provide key insights into the nuance of state legislation and whether any individual examples are meant for long-term benefits.

While these limitations no doubt put the insights of this thesis into perspective, they are themselves incredibly valuable. One of the most pertinent insights that this research has derived is that of helping to understand the breadth of what information is *not* currently available for research. Completing this thesis involved many struggles to develop and attain reasonable metrics for any number of things, but these difficulties can help to inform where other researchers could continue with their own work. The limitations of this thesis have thus helped to elucidate the missing pieces of the puzzle of pharmaceutical pricing, allowing us to determine

new paths forward so as to develop the holistic view which will provide a more complete and comprehensive answer to the question of not just what *is* being done, but what *should* be done.

**Alternative Interpretations**

To highlight the degree to which these limitations hamper deterministic analysis of these trends, let us take a moment to consider an alternative interpretation of these exact same results which yields practically diametrically opposed conclusions. Take the results pictured in Figure 12a and 12b under consideration once again. While my interpretation was that the trends followed similar patterns, and thus each approach seemed similarly successful, it could instead be said that Rhode Island and New Jersey were able to significantly curtail spending in a relatively short period of time, despite experiencing large increases in spending immediately prior. Rhode Island was even able to go from almost no spending to the highest peaks in the normalized graph and back down to almost nothing in this very brief period. South Dakota, meanwhile, experienced almost no fluctuations in overall spending, implying that the issue was less pronounced in the state as the normalized amounts fell in line with overall averages.

With this general interpretation of the results, a very different picture emerges than the one painted by my own interpretation of the results. The two more legislated states appear to have been successful in reducing prices to a major degree, implying that state level legislation has been effective at its intended goal. Meanwhile, from the perspective of the less legislated state, the problem may as well not exist - the state's news analysis implies the public cares little about pharmaceutical prices, and spending remains constant despite rising prices nationwide. If this interpretation is the true one, then it carries a variety of implications:

- Rhode Island's balanced legislative approach was the most effective at curtailing spending in a dramatic way.
- Based on the difference between Rhode Island and New Jersey's success, there still may be a plateau of efficacy where additional legislation is no longer necessary.
- That being said, New Jersey's approach was successful in reducing bulk spending in its larger population, and so may be more tailored to serving such populations.
- The general focus on pharmacy benefit managers as a target of legislation is warranted, as the states that have focused on them have been successful in reducing spending.
    - As a follow up, if pharmacy benefit managers are indeed to blame, then pharmaceutical companies have been forthright with their theories and are likely trustworthy in informing decisions.
- Legislation does not necessarily need to be enacted in order to curb spending, implying that the mere threat of legislative action is enough.

So what makes this interpretation less valid than the one I have presented thus far? While my personal opinion is that the key failing of this theory is in the lack of enacted legislation, which to me implies another factor influencing spending as opposed to legislative differences, the true answer is: absolutely nothing. An interpretation of these results that is grounded in these concepts would be entirely valid, as there is nothing that inherently disproves them. The same can be said about various other interpretations. Herein we find the roadblock that most limits this research's efficacy: with so little concrete data to analyze, it is difficult at best to narrow down variables and carve out a true picture of what is going on.While I believe my interpretation to be the most likely, it in no way precludes the possibility of other interpretations being closer to the truth. As mentioned previously, there is a veritable laundry list of additional research and

information that would have to be done to confidently find the sources of high pharmaceutical prices. As such, the degree to which state legislation is effective may largely depend on your metric of success. To me, the ongoing outcry regarding the lack of affordability in necessary drugs is indication that these states, while effective at reducing expenditure with more legislation based on these metrics, have been unsuccessful on a grander scale.

## ***Conclusion***

In the end, this research has yielded more confusion than anything, but at least elucidates a path forward. If anything has truly been displayed by this thesis, it is how incomplete the picture is with regards to what affects pharmaceutical pricing and, in turn, what are effective targets for the goal of reducing prices. This was demonstrated not only in the difficulty encountered in gathering relevant data, but in the stringent limitations that the data that was acquired was subject to. If a true answer to the question of how to reduce pharmaceutical prices is to be reached, this information needs to be made publicly accessible, or at least accessible to those formulating solutions. This first step is well established and understood throughout the debate on this issue. Transparency is, and is well known to be, the first step.

While this is, in many ways, discouraging, it also provides the first steps we must take. The resistance to transparency efforts has been powerful, but powerful resistance is often the sign of progress being made. After all, with so much money to be made in pharmaceuticals, if the path to cost reduction is easy, then it is likely false as well. This counteracting force must not be underestimated. The United States places a premium on cordial interactions, especially in business - but if the past decade is any example, it seems clear that at least some actors in the pharmaceutical industry are willing to allow people to suffer in pursuit of profit. A keen and skeptical eye must be kept on the motivations of those who seek to influence the provision of government, both state and federal, on the pharmaceutical industry. It is an unfortunate truth that we cannot assume that everyone involved holds proper motivation at heart.

While the data presented in this thesis has proven its own inadequacies, it has also provided at least some insight into the current state of things. That state is dire. Despite almost a decade of consistent and growing attention on the state level to the issue of pharmaceutical

prices, with results that could be interpreted as successful, they continue to pose an issue to the health and wellbeing of American patients, with no signs of slowing down. Even *if* the efforts discussed here have been successful in stemming the bleeding, they may not be enough to address the overarching problem. In these circumstances, a federal response is not only warranted, but in my opinion, practically obligated. It would be morally and legally improper to allow especially the most egregious examples outlined here to continue unabated. It seems unlikely that the market will self-regulate. If the state legislatures lack the force of law and unified purpose necessary to implement systemic change and private actors have either no incentive or no ability to impact change, then someone else must step up. Even if the federal response is focused on identifying the heart of the problem, it is necessary at this point. A line must be drawn in the sand: one way or another, we cannot allow people to suffer and die under the burden of treatable illnesses, holding them at needlepoint, telling them to choose between disease and bankruptcy.

# ***Appendices***

## Appendix 1: Total Legislative Efforts by State with Overall Target Breakdown

| State | Totals | | Target | Totals |
|---|---|---|---|---|
| NJ | 99 | | PBM | 377 |
| NY | 96 | | Transparency | 155 |
| MN | 82 | | Other | 137 |
| MA | 66 | | Coupons/Cost Sharing | 133 |
| PA | 51 | | Importation | 100 |
| IL | 49 | | Affordability Review | 47 |
| RI | 48 | | Price Gouging | 28 |
| WV | 44 | | Unsupported Price Hikes | 5 |
| VA | 41 | | Int. Ref. Rates | 4 |
| MI | 38 | | Total | 986 |
| HI | 36 | | | |
| OR | 36 | | | |
| MD | 34 | | | |
| NH | 34 | | | |
| OK | 34 | | | |
| WA | 33 | | | |
| TN | 32 | | | |
| IN | 31 | | | |
| LA | 29 | | | |
| CT | 26 | | | |
| ME | 26 | | | |
| TX | 25 | | | |
| CA | 23 | | | |
| KY | 23 | | | |
| MO | 21 | | | |
| CO | 20 | | | |
| OH | 18 | | | |
| MS | 17 | | | |
| UT | 17 | | | |
| VT | 17 | | | |

| | | | | |
|---|---|---|---|---|
| FL | 16 | | | |
| DE | 15 | | | |
| MT | 15 | | | |
| NM | 15 | | | |
| NV | 15 | | | |
| GA | 12 | | | |
| IA | 12 | | | |
| NC | 12 | | | |
| AZ | 11 | | | |
| KS | 11 | | | |
| NE | 11 | | | |
| WI | 10 | | | |
| WY | 10 | | | |
| ND | 9 | | | |
| SC | 9 | | | |
| AR | 8 | | | |
| AL | 7 | | | |
| ID | 7 | | | |
| SD | 5 | | | |
| AK | 2 | | | |

## Appendix 2: Summarized Rapid Acting Insulin Utilization Data

| Year | NJ Reimbursed | RI Reimbursed | SD Reimbursed |
|---|---|---|---|
| 2015 | 34583498.16 | 392729.11 | 1919385.12 |
| 2016 | 46388969.35 | 6223603.28 | 2511273.73 |
| 2017 | 44337468.14 | 7667370.06 | 2615562.6 |
| 2018 | 40149044.57 | 7104748.94 | 2644042.6 |
| 2019 | 12697590.06 | 3409410.03 | 2722883.89 |
| 2020 | 9413148.38 | 1536401.5 | 1653480.78 |
| Year | NJ Normalized | RI Normalized | SD Normalized |
| 2015 | 53.6178266 | 4.731676024 | 36.91125231 |
| 2016 | 71.92088271 | 74.98317205 | 48.29372558 |
| 2017 | 68.74026068 | 92.37795253 | 50.29928077 |
| 2018 | 62.24658073 | 85.59938482 | 50.84697308 |
| 2019 | 19.68618614 | 41.07722928 | 52.36315173 |
| 2020 | 14.5940285 | 18.51086145 | 31.79770731 |

## Appendix 3: Population Statistics

| State | Population (Census 2019) | Diabetic Population (estimated 2020) | Diabetic Percentage |
|---|---|---|---|
| South Dakota | 884659 | 52000 | 5.87797106 |
| Rhode Island | 1059361 | 83000 | 7.834911801 |
| New Jersey | 8882190 | 645000 | 7.261722616 |

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