

Case Studies of Insulin Price Regulation

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

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Introduction

Diabetes is the eighth leading cause of death in the United States and is a condition endured by roughly 11% of the population. This condition is not only becoming more prevalent, the costs associated with diabetes have exponentially increased over the past decade. The cost of diabetes has become so high, that in 2022, the associated costs equated to approximately \$413 billion USD, which is roughly \$12,022 per person (*National Diabetes Statistics Report | Diabetes | CDC, 2023*). The price increases seen in the insulin market are unique to the United States with our prices increasing at a rate 1000 times that of Canada over the same three year period (Schneider, 2022). To begin combatting the ever-increasing cost of insulin the State and federal governments have begun drafting policy aimed at reducing the monthly out of pocket costs to a more affordable one. These policies vary from state to state in which the state of policy origin's political party either permits or denies new price-capping measures. State and federal policies are beginning to make living with Type I diabetes affordable, reducing the number of avoidable deaths due to insulin rationing. This paper will analyze policy of insulin and diabetic technology price regulations revealing how different states are shaped by their political leaning.

Background

In the United States alone, approximately 38.4 million individuals are classified as diabetic with 1.2 million new cases diagnosed each year (*Statistics About Diabetes | ADA, n.d.*). The total number of individuals diagnosed with diabetes is expected to increase by 54% to more than 54.9 million incidences between 2015 and 2030 (Rowley et al., 2017). Diabetes is a chronic, long-lasting, condition that affects the mechanisms for blood sugar regulation which often is treated using manufactured insulin. Insulin is a naturally occurring pancreatic hormone that is essential for your body to turn glucose into energy (*What Is Insulin?, n.d.*). All Type 1 and some

Type 2 diabetics require manufactured insulin to regulate their blood sugar due to insufficient production by their pancreas. Access to insulin in the United States had never presented an issue, even with the introduction of higher quality versions and analogs of insulin. Unfortunately, within the past 20 years, the lack of price regulations on insulin in the United States has been the largest contributor towards the dramatic price increases (Hirsch, 2016). The rates at which insulin prices have increased have made it near impossible for millions to be able to afford their prescribed insulin. Federal and state governments have begun implementing price-capping policies on insulin and diabetic technologies, restricting further price increases, and increasing financial access to insulin. Effective as of January 2022, the US federal government was successful in passing a bill price capping insulin at \$35 per monthly subscription, however this was limited to Medicare Part D enrollees (Sayed et al., 2023). An attempt to expand the price caps to those with private insurance was rejected by Senate Republicans, who argued that the price caps were not the solution (Casey, 2023). The increases in the price of insulin as of late show that the issue is not solely an issue of increased quality but the result of government interactions with the pharmaceutical companies responsible for the development of and pricing of insulin. Each political party has a unique view towards the regulation of pharmaceutical prices and this has led to policies that vary by state.

The average American living with diabetes is spending significantly higher amounts for nearly identical insulin when compared with various other countries, even within the United States residents of different states pay differing amounts for the same product. Through an analysis of state policy as well as an evaluation of the various groups involved in the creation, distribution, and pricing of insulin products in the US this paper will aim to explain the differences in pricing created by the US and how the political affiliation influences it.

Methods

An exploration into the development and production of insulin was conducted to provide sufficient background to understand the source of the significant price increases that have been seen throughout the past decade. With the solid foundation of the insulin pricing environment, policies were analyzed for differences in access to and price management of insulin and diabetic devices on both federal and state levels. In order to reduce the scope of which states to choose, an understanding of which states had insulin price capping policies and their tendency of political lean was developed. After this, two states that currently have insulin price capping policy from each of the political leaning categories, liberal, conservative, and swing, were selected. These categories were selected based on the common classification of states during a presidential election because that is when a state's preferred political party is often expressed. Of the 25 states with insulin price capping policy, Texas and Alabama were selected to represent the conservative states, New York and Minnesota the liberal states, and Montana and Colorado the swing states. These states were selected by having almost always voted for a particular party, conservative states, and liberal states, or having an almost 50% chance of voting for either party.

Once states were selected, state policy involving the price regulation of insulin that had been enacted was used, with supporting documents from organizations such as the American Diabetes Association. States were compared and evaluated focusing on the maximum price for insulin and to whom the price caps were offered to. These comparisons were done between states of the same category and with those of across categories to provide an evaluation of spread across a political leaning and between them. This was able to display how politics is influencing the insulin pricing crisis and showed the varying amounts of people that were granted access to the price capped insulin products.

Results and Discussion

Insulin prices have been on the rise over the past decade and the increase can be attributed to the nature of the disease and market. Since insulin is a life-sustaining drug for those with diabetes, individuals must be willing to pay whatever it takes for insulin in order to survive. The insulin market has been under a near monopoly control in which three major insulin producing companies (Novo Nordisk, Sanofi-Aventis, and Eli Lilly) have successfully controlled the market for a majority of the past century. Their domination in the insulin market is due in part to patent evergreening, a term used to refer to an extension of a patent life, therefore extending the monopoly protection (Rajkumar, MD, 2020). The near monopoly domination of the insulin market accounts for only part of the reason for rising insulin prices in the United States and the federal government has begun to taking steps to address these prices with the passing of Insulin Affordability and the Inflation Reduction Act which became effective in January of 2023 (Sayed et al., 2023). Although limited in its reach it was able to provide more affordable insulin for millions of Americans as states began to create policies of their own. However, the current two-party system in the United States has been a source of contention when developing and implementing policy addressing healthcare. The differences in policies are shown through the case studies of conservative, liberal, and swing states in the United States.

Conservative States

The GOP's stance on healthcare has been to reduce the federal control over private insurance and Medicaid and instead are in favor of states claiming their previous role of regulating local insurance markets. The Lone Star State, Texas, is the second largest in the United States by population with approximately 12% of the state's population being diagnosed with diabetes. From a political perspective, Texas has voted for the Republican candidate in 11 of

the past twelve presidential elections. The Texas government enacted Senate Bill 827 in September of 2021, this bill capped the copay for a 30-day supply of insulin at \$25 for all Texans that are enrolled in the government-funded insurance plans (*Texas SB827 | 2021-2022 | 87th Legislature*, n.d.). This bill does exclude individuals with private insurance and the uninsured, restricting access to affordable insulin for many Texans. The Texas government has begun to place pressure onto the previously mentioned main three insulin producing companies in the United States, in hopes of discovering the reason for the significantly increasing cost of insulin (Pearson, 2021). The outcome of this will be to demand these evergreening companies to change their pricing methodology. The GOP has been the dominant political party in Alabama since the state's return to the union post-civil war. Similar to Texas, Alabama too has voted for the GOP candidate in a presidential election 11 consecutive elections since the 1980 election. The insulin price capping policy in Alabama expands access to a broader group of individuals than that of the Texas policy. Under the Alabama House Bill 249 enacted in April of 2021, granted individuals with health insurance policies issued or delivered in the State of Alabama access to \$100 per 30-day supply of insulin regardless of the type or quantity of insulin necessary to fill the prescription (*Alabama HB249 | 2021 | Regular Session*, n.d.).

Liberal States

The liberal perspective is that healthcare is both an equal right and a human necessity for all individuals, and the government is responsible for the creation of affordable universal healthcare (Bodenheimer, 2005). Liberal states' policy tends to promote a more progressive approach to provide affordable healthcare to those who need it. Therefore, liberal states tend to implement policies that all for greater access to healthcare benefits and programs. The state of New York passed a new state policy in 2020 that set a restriction on the price of insulin to be no

greater than \$100 per monthly supply of insulin for New Yorkers with state-regulated health insurance (*NY State Senate Bill 2019-S7506B*, n.d.). In 2023, the New York State Attorney General Letitia James made a breakthrough towards insulin affordability for the uninsured in their state. The New York Attorney General was able to secure an agreement with Novo Nordisk, one of the previously mentioned big three insulin producers in the United States, to cap the price of insulin at \$35 per monthly prescription for the uninsured New Yorkers for the next five years (New York, 2023). The Minnesotan state government has created the Minnesota Insulin Safety Net Program. This program is designed to help increase access to affordable insulin for Minnesotans. This program can be divided into two parts, urgent need, and continuing need, each with its own set of qualifications for eligibility. The urgent need program allows individuals in dire need of insulin to receive a one-time, 30-day supply for \$35 depending on eligibility. Similarly the continuing need program grants eligible individuals the access to 90-day supplies of insulin for a co-pay no greater than \$50 (*Minnesota Insulin Safety Net Program*, n.d.). The death of Alec Smith due to insulin rationing after aging off of his parents' health insurance sparked the Alec Smith Insulin Affordability Act in Minnesota leading to the previously mentioned program (*Rep. Michael Howard - Minnesota House Passes Alec Smith Insulin Affordability Act*, n.d.).

Swing States

The term swing state, also known as a battleground state, is any state in which the Democratic or Republican parties have similar chances of winning the state in a Presidential election. These states therefore see a lot of attention during an election year due to this ability to swing the election in one's favor introducing their citizens to many differing perspectives during a campaign season. In the past 40 years, Colorado has been won by either political party 50% of

the time, with a current trend favoring the Democratic party in the past four elections (*Presidential Voting Trends in Colorado*, n.d.). Colorado was the first state to enact policy back in 2019, House Bill 19-1216 capped the price on insulin at \$100 per 30-day supply regardless of amount or type of insulin. This bill also mandated an investigation into the insulin drugs pricing, business practices, reports, or any other data deemed necessary by the department of law (*Prescription Drug Insulin Pricing Report*, n.d.). Similarly, New Mexico is nearly 50% for either political party in the past 12 elections. Being the third state to enact an insulin price-cap policy in 2020, New Mexico also has one of the lowest co-pay caps for insulin at just \$25 for a 30-day supply. The New Mexican policy applies to each individual and group health insurance policy, health care plan, certificate of health insurance and managed health care plan delivered or issued for delivery in the state of New Mexico (Cadena & Ivey-Soto, n.d.).

Policy Comparison

Liberal states are at the forefront in efforts to reduce the cost of prescription insulin by providing access to broader groups of citizens. Both researched states are able to provide price-capped insulin to their citizens regardless of having insurance. Minnesota's Insulin Safety Net Program is able to provide continuous insulin supplies for eligible individuals at \$50 per 90-day supply, which is the lowest price per day of insulin of any of the states researched. Similarly, New York Attorney General James was successful this past year in securing an agreement with one of the largest insulin producers (Novo Nordisk) to give the uninsured access to prescription insulin at \$35 per 30-day supply. This agreement made by the NY Attorney General is the first increase in access to affordable insulin, since a state has passed its original insulin price regulating policy. Though the swing states may have been the first few to enact insulin price capping policy, Colorado and New Mexico passing their respective policies four

and five years ago, not much has been done since their introduction to expand access or further reduce the price of insulin. Colorado first set a precedent for states to follow in the act of reducing the ever-rising insulin costs, with the launching of an investigation into the environment that allowed for the price increases. Lastly, the conservative states, Texas and Alabama, being two of the only eight conservative states with policies related to insulin pricing, have limited reach or have the caps set at much higher prices. Similar to Colorado, Texas too decided to demand an investigation into the pricing methodologies when enacting the price capping bill. Alabama's policy does extend to individuals delivered insurance within the state; however, this excludes the uninsured population which are at the greatest risk of insulin rationing due to extreme costs.

Insulin Market

The insulin market has been dominated for decades by three large corporations, Novo Nordick, Sanofi-Aventis, and Eli Lilly, which have run an oligopoly on the market. These companies have restricted access to the market through an evergreening of their patent allowing for a lack of competition, letting the companies control the price of insulin. As states began enacting policies to regulate the price of insulin and other diabetic technologies, they have also launched investigations into the oligopoly. The investigations are aimed at uncovering possible violations in the pricing methods of insulin through the entire development and distribution pathways that have caused the price of insulin in the US to be exponentially higher than other developed countries. States such as Texas and Colorado were some of the first to launch this type of investigation on insulin pricing. Colorado's Attorney General published a report stating that the lack of competition is a reason to blame for the rise of insulin prices. As more information

becomes available through these investigations it becomes the government's responsibility to act and better address the prescription pricing problem.

Conclusions

As the insulin prices continue to increase at rates 1000 times that of neighboring countries, the number of states that draft policies capping the price of prescription insulin is only expected to increase. Though federal regulations are applicable to a greater number of citizens than any state policy could, states are able to pass policy more efficiently and help people sooner. Further policy creation by states can help curb the rising costs of prescription insulin for millions of Americans making it affordable once again. As shown through the case studies of samples from liberal, conservative, and swing states, political leaning is influential on insulin price regulating policies. Liberal states are proving to be the most inclusive with their policies reaching the most individuals with a special attention on the uninsured population. The swing states were some of the first states to implement policies that regulated the price of insulin and were major motivating forces for other states and a sign of hope for millions living with diabetes. Colorado, specifically, being the first state to regulate the price of insulin also was first to launch an investigation into the production and distribution methods of insulin to determine why the price has been allowed to reach the levels it has. The conservative states granted access to those with state-funded policy or to those with insurance delivered within their state, however, both in this study exclude the uninsured population which is in the most need of the price caps. Across states and political preferences there was a motivation to take action against the ever-rising prices of insulin through investigative research to determine the why behind the uniquely American price of insulin. With the understanding of the influence of political parties on insulin price capping policy, the impact that these policies have been having on the states should be

evaluated. On the individual, local community, and statewide levels the impact that the insulin price capping policies have had should be understood to help guide future health policy in the future. Additionally, an understanding explaining the significant price increases that insulin has experienced to better regulate the mechanisms in place that have allowed for this to happen.

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