

# **The Failure of The Affordable Insulin Now Act for the Uninsured**

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**Bethany Iudica**

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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**

Recently, addressing the problem associated with the cost of insulin has been at the forefront of many policy discussions. The Affordable Insulin Now Act, which, beginning in 2023, will cap cost-sharing for enrollees in the Medicare Part D plan for a month's supply of covered insulin products at \$35, was signed into law in September of 2022 (H.R.6833, 2022). This bill extends the model introduced by the Centers for Medicare & Medicaid Services in 2020, under which Medicare Part D enrollees have a capped copayment for a month's supply of insulin at \$35 (Cubanski et al. 2020). The passing of the Affordable Insulin Now Act in the United States of America lays the foundation towards lower insulin prices worldwide, but it fails to address gouging insulin prices for the broader population that relies on insulin.

The failure in the creation of this policy yields many consequences: enrollees of Medicare Part D will have a \$2,000 out-of-pocket cost for prescription drugs beginning in 2025, uninsured diabetics see no change in insulin prices, and there is no limit to the price that insulin manufacturers can charge ("The Inflation Reduction Act Lowers Health Care Costs for Millions of Americans", 2022). Insulin manufacturers will continue to earn enormous profit margins in insulin vials that take \$5 to produce while Americans will pay upwards of \$300 per vial of insulin (Marston, 2022). 31 million Americans remain uninsured, and the 2 million uninsured Americans with diabetes must continue to ration other priorities to afford this life-saving drug (Hirsch, 2022). While the lack of inclusivity of The Affordable Insulin Now Act has been attributed to the gross negligence of Congress incumbents, this fails to address the power of insulin manufacturers. If we continue to blame incumbent politicians solely, we will fail to understand how other actors can influence the course of action in policy creation. I will explore

the pressures that insulin manufacturers put on those in the insulin network as well as the power that they hold over the market.

I argue that pressure from large manufacturers as well as negligence concerning rising insulin prices and out-of-pocket costs for many Americans led to the failure of The Affordable Insulin Now Act to be inclusive, which I will analyze using actor-network theory. Actor-network theory explains how the shifting relationships of human and non-human actors can shape the social and technological world, which I will use to analyze the uninsured-insulin network. I will review quotes from federal policy-makers, written policy, historical attitudes of insulin manufacturers, and evidence that cheaper insulin is possible to strengthen my argument. I claim that The Affordable Insulin Now Act fails to be inclusive due to pressure from large manufacturers to retain their monopoly and the United States government's negligence concerning rising insulin prices and high out-of-pocket costs for many diabetic Americans.

## **Literature Review**

Scholars have attempted to explain high insulin costs and suggest ways to remedy the situation, but have failed to address the entire network that is involved in the problem. Schneider et al. (2022) attribute high insulin prices in the United States to a lack of national regulation, and Cefalu et al. (2018) attribute high insulin prices to the complexity of the insulin supply chain. I will outline how these scholars have previously attempted to address the problem of high insulin prices.

### *Comparative Insulin Prices*

Schneider et al. compare insulin prices in the United States to those in Canada to explain the discrepancy between United States' insulin prices and other nations. They use this data to explain that policy reform in the United States is the solution to the problem; however, this fails

to address the other actors that make up the uninsured-insulin network. As laid out below according to Schneider et al., Americans are paying much more for insulin than Canadians (2022).

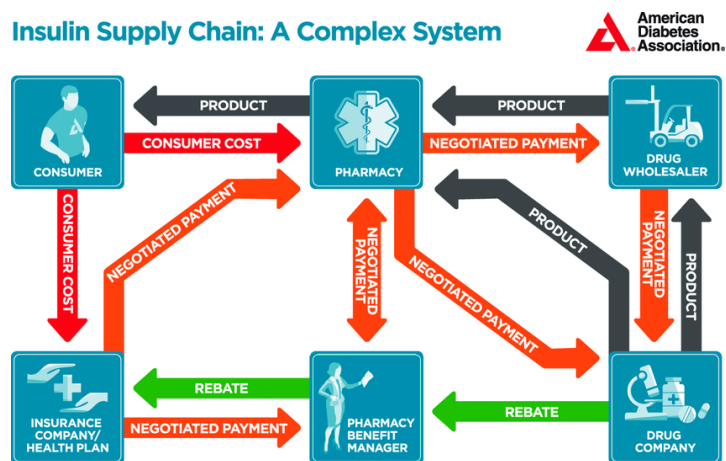
In 2018, the United States spent 28 billion USD on insulin compared to \$484 million in Canada. In the same years, the average American insulin user spent \$3490 on insulin compared to \$725 among Canadians. Over the study’s period from 2016 to 2019, the United States' average cost per unit of insulin increased by 10.3% compared to Canada’s 0.01%. According to Schneider et al., while policies exist in Canada to control drug pricing, the lack of price regulation in the United States is a large contributor to the high insulin prices in the United States. Schneider et al. believe that implementing national legislation using reference pricing could decrease insulin prices in the United States (Schneider et al., 2022).

*Insulin Supply Chain*

Cefalu et al. lay out the insulin supply chain, as depicted in Figure 1, in an attempt to explain the reasoning behind high insulin prices; however, this fails to address the other actors that make up the uninsured-insulin network. As laid out below according to

Cefalu et al., many stakeholders along the supply chain contribute to the high insulin prices before the product reaches diabetics’ hands (2018).

Manufacturers are the creators and the source of insulin and distribute insulin to wholesalers or directly to pharmacies. Three main manufacturers, Eli Lilly, Novo Nordisk, and



**Figure 1: Insulin Supply Chain**

Sanofi - the “Big Three” - dominate 90% of the United States insulin manufacturing. Wholesale distributors purchase insulin from the manufacturers and distribute it to pharmacies, hospitals, and other medical facilities. The top three drug wholesalers in the United States - AmerisourceBergen Co., Cardinal Health, and McKesson Corp. - pocket 90% of revenue from distribution. Pharmacies purchase insulin from wholesale distributors and collect cost-sharing amounts through copayments, coinsurances, or the full price of insulin per the patient’s health plan. Pharmacy Benefits Managers contract with health plans to manage outpatient pharmaceutical benefits for their clients (Cefalu et al., 2018).

The complexity of the insulin supply chain (as seen in Figure 1) drives up insulin prices for the consumer. With few companies dominating each of their respective industry, there is little to no room for new companies to enter the space in an attempt to drive prices down. Cefalu et al. argue that the supply chain complexity is wholeheartedly to blame for high insulin prices. They conclude that the current pricing and rebate system encourages high list prices and many intermediaries in the supply chain reap profits from this flaw. Additionally, the lack of transparency throughout the supply chain allows stakeholders to charge higher prices because it isn’t clear how money is flowing. PBMs have substantial market power, primarily making deals with the manufacturers that offer the most attractive rebate (Cefalu et al., 2018).

With this, Cefalu et al. offer recommendations to remedy the problems throughout the insulin supply chain. The primary solution is to increase overall transparency throughout the supply chain; stakeholders should help diabetics pick the insulin prices that are more affordable and beneficial for them, rather than convince diabetics to choose the more expensive insulin. They also argue that uninsured diabetics should have access to the best insulin at an affordable

price. Finally, they recommend that the Food and Drug Administration should facilitate the process of bringing a biosimilar to market (Cefalu et al., 2018)

While both of these scholars offer different reasons for high insulin costs, they fail to realize that the problem is systematic; it is crucial to understand and address the entire network to see the most effective change. A combination of the scholar's solutions will be the most effective way to lower insulin prices in the United States.

### **Conceptual Framework**

Actor-network theory provides an efficacious framework for characterizing the network of uninsured insulin users because it allows the parts of this network to be isolated and analyzed. In this paper, actor-network theory will be used to deconstruct and analyze the function of the defined sociotechnical system. Actor-network theory functions as a strategy to describe social activity and how the shifting relationships of human and non-human actors can shape the social and technological world. An actor is defined as any entity that does things, and whose role is networking with heterogeneous elements within the network. All actors are on the same level, so all relevant actors are seen as just as important as the next in creating social situations. The strength of the relationships between human and non-human actors can create power within the network. A network is defined as the transient collection of human and non-human actors; material-semiotic networks can come together to act as a whole. Actor-network theory attempts to identify a network builder who recruits both non-human and human actors into their network to accomplish a specific goal. The process of recruiting said actors to form and maintain an actor-network is known as translation (Bærenholdt & Jóhannesson, 2009).

Translation is the concept in which the primary actor attempts to create a network of actors that all agree that the network is worth building and defending. In Michel Callon's efforts

to apply actor-network theory to study economic life, he defined four moments of translation: problematization, interessement, enrollment, and mobilization of allies. Problematization is defined as the network builder's attempt to make themselves important to other actors in the network by defining the nature of the actors, the network, and the problem. Interessement involves recruiting and solidifying actors into their roles designated by the network builder to solve the problem. In enrollment, the definition and relationships of the roles as assigned to each actor are addressed by the network builder. Finally, mobilization is the process of ensuring that spokespeople for the collective are representative of members of the network. The processes of translation encompass all negotiations, calculations, and acts of persuasion. Translation is a process, never completely accomplished, which may result in a power struggle in which few actors take the lead and other actors are silenced (Bærenholdt & Jóhannesson, 2009).

I will use actor-network theory to analyze The Affordable Insulin Now Act, which caps cost-sharing for Medicare Part D enrollees and private insurance holders for a month's supply of insulin at \$35, to determine how human and non-human actors prevent the success of affordable insulin technologies. Specifically, I will use the concept of translation to determine the point in which The Affordable Insulin Now Act failed to be inclusive. Actor-network theory will allow me to thoroughly analyze the pressure from large insulin manufacturers as well as negligence concerning rising insulin prices and out-of-pocket costs for many Americans. The Affordable Insulin Now Act fails to be inclusive due to pressure from large manufacturers to retain their monopoly and the United States government's negligence concerning rising insulin prices and high out-of-pocket costs for many diabetic Americans. Policy, historical attitudes of manufacturers, and quotes from policy-makers will be analyzed through actor-network theory to understand the uninsured-insulin network.

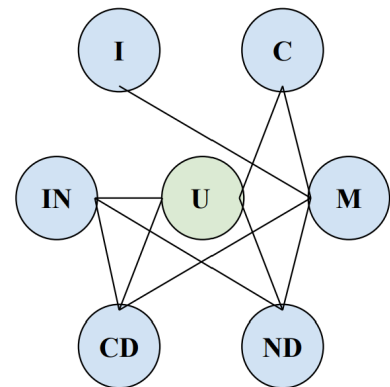
## Analysis

### *Network formation*

To properly analyze and construct the uninsured-insulin actor-network, the actors within the network must first be defined. The human and organizational actors are as follows: (i) the *United States government* that created and passed the Affordable Insulin Now Act, (ii) the *manufacturers* that make insulin and completely dominate the insulin market, (iii) *covered diabetics* which include people that require insulin who are covered by the Affordable Insulin Now Act, (iv) and *not covered diabetics* which includes people that require insulin but are not covered by the Affordable Insulin Now Act. Additionally, the non-human and technological actors are identified as (v) *insulin* which is required by 2.2% of the U.S. population to survive, and (vi) *capitalism* which allows the manufacturers to create monopolies (Yunusa, 2021).

To better understand the working and transient relationships between these actors, I will draw the associations by tracking the network's formation through the phases of translation.

While many actors influence the price of insulin, the government's failure to limit the amount that insulin manufacturers can charge proves to be the most impactful (Marston, 2022). Based on the government's ability to influence the uninsured-insulin network, I assume that the United States government is the primary actor formed through translation. The uninsured-insulin network is outlined in Figure 2. In the first phase of translation, problematization, the United States government determines that a solution to the problem of overpriced insulin is required. The government identifies that an



**Figure 2: The uninsured-insulin actor-network in practice.** U is the United States government, I is insulin, CD is covered diabetics, M is manufacturers, ND is non covered diabetics, C is capitalism, and IN is insurance companies



important actor in the form of insurance companies is needed to reduce the amount that enrollees have to pay for their insulin

During interssement, the U.S. government recruits other human actors into the network by aligning their interests to the problem definition. The government recruits the consumers, covered and not covered diabetics, which are the actors in need of affordable insulin. Their interest aligns with the interest of the U.S. government, and they are categorized by the government to determine which consumers will most benefit from the solution to their problem; diabetics with Medicare Part D are characterized as covered diabetics and all other diabetics are characterized as not covered diabetics. The government recruits insurance companies to cap the amount that enrollees have to pay for insulin.

During enrollment, the manufacturers, covered diabetics, and not covered diabetics accept their roles and form associations as outlined in Figure 2. The not covered diabetics see no change in their everyday life, as their insulin prices are not lowered under the Affordable Insulin Now Act (H.R.6833, 2022). The covered diabetics see a cap cost-sharing for a month's supply of covered insulin products at \$35, which substantially changes their lives and saves them a significant amount of money (H.R.6833, 2022). The insurance companies that represent the covered diabetics accept that they can not charge enrollees more than \$35 out-of-pocket for their insulin per month (Amin et al., 2022). Under these conditions, the uninsured and not covered diabetics in the United States, a majority of diabetics, are left in the cold.

The uninsured-insulin actor network fails in the enrollment and mobilization of the network. As discussed, the uninsured and not covered diabetics are ignored through enrollment. The not covered diabetics are neglected through mobilization, as they are not represented through the Affordable Insulin Now Act, which completely fails to address the problem that the

United States government initially set out to solve. The failure in the creation of this policy results in the continued high insulin prices for not covered diabetics, as manufacturers are still able to charge as high of prices as they see fit. Insulin manufacturers will continue to earn enormous profit margins while the uninsured are continuing to pay the sale price for insulin. The construction of this actor-network induces insulin prices to be extreme for not covered diabetics. To further analyze the cause of high insulin prices, I will explore the pressures that insulin manufacturers put on those in the insulin network as well as the power that they hold over the market.

### *Manufacturers*

The nature of the insulin market in the United States provides a substantial obstacle to lowering insulin prices; thus, it is crucial to analyze how the manufacturers as actors continue to control costs within the network. An estimated 2.2% of the U.S. population relies on insulin to survive, but the number of people that take insulin is strikingly less (Yunusa, 2021). This issue can be attributed to the rising insulin prices in the United States and across the world. Currently, three manufacturers control 90% of the insulin market in the United States: Eli Lilly, Novo Nordisk, and Sanofi (Cefalu et al., 2018). The ability for the manufacturers to charge high prices for insulin and the capability for monopolies to form is protected under capitalism, another non-human actor in the network. Under capitalism, businesses are privatized, allowing them to patent their products to prevent biosimilars to enter the market and charge less. The monopoly on insulin by the Big Three elevates consumer costs; the companies are aware that their consumers are vulnerable and not in a place to negotiate the cost of this life-saving drug (Cefalu et al., 2018). The prevalence of the insulin crisis in the United States suggests that the Big Three understands the harm they are causing diabetics, but, evidently, their only concern is to do what

is in the best interest of their company. The Affordable Insulin Now Act was an attempt to combat this socio-technical challenge, but insulin manufacturers have a hand in impeding the act's success.

The insulin supply change is lengthy and complicated, but it starts with the manufacturers. The price that the manufacturers sell insulin to wholesale distributors has a direct effect on the price that the consumer pays at the tail-end of the supply chain. Due to these three distributors almost wholly controlling the market, they can charge whatever they want and the vulnerable population that makes up their consumers will still pay for the lifesaving medication. As of 2020, no generic or biosimilar insulins have been approved in the United States due to the patent protection on the devices that deliver the dose of insulin. The device patents prove to be a notable obstacle for biosimilars to come to market due to the popularity of pens and pumps and the inability of other types of devices. This insinuates that biosimilars have attempted to come to market, but the market control that the Big Three have has prevented other drugs from penetrating the market. The Big Three have been accused of anticompetitive conduct, and any introduction of a new competitor may elicit anticompetitive tactics, deterring any new products from entering the market. The Big Three have priced out competitors in other countries, and they would most likely do the same to any new competitors in the United States, making it financially impossible for competitors to enter the market. This further suggests that the Big Three are comfortable with their position, and have no intention of alleviating diabetics of the burden of high insulin prices. Without intervention from the primary actor in the actor-network, the United States government, this ensures that the Big Three will continue to dominate the insulin market and set prices to maximize their earnings (Knox, 2020).

I have argued that insulin manufacturers have historically acted selfishly and deprived people of a life-saving medication; however, as of March 1, 2023, Eli Lilly has announced that they will cut insulin prices by 70% and cap patient out-of-pocket costs at \$35 per month (“Investors”, 2023). This price cut will “cap out-of-pocket costs for patients who use Lilly insulin and are not covered by the recent Medicare Part D cap” (“Investors”, 2023). While this is a step in the right direction, unfortunately, there are still a few issues that prevent everyone from having access to affordable insulin. Firstly, while the announcement claims that the cap will apply to all patients, the particulars state that the cap automatically applies to patients with private insurance, but the uninsured must sign up for Eli Lilly’s copay assistance program to benefit. This assistance program only provides Eli Lilly medications for free for up to 12 months; after that, the uninsured will be stuck with paying full price (“What is Lilly Cares: Lilly cares”, n.d.). Additionally, other insulin manufacturers must follow suit to guarantee that everyone has access to affordable insulin. For these reasons, Eli Lilly’s announcement to lower insulin prices does not guarantee affordable insulin for everyone for the duration of their treatment.

### *United States Congress*

The lack of federal regulation in the United States surrounding insulin prices enables high insulin prices; thus, it is crucial to analyze the United States government as the primary actor in the uninsured-insulin actor-network. Policy surrounding lowering the price of insulin has not been a bipartisan issue. For years, the democratic party has had a longstanding goal of capping insulin prices for the millions of Americans that rely on the life-saving drug to treat diabetes. While many bills have been proposed to cap the price of insulin over the last few years, the bills continually failed to pass in the Senate. For instance, one GOP aide stated that the reason some GOP senators are opposed to such a bill is that “if we do fix [the problem of high insulin costs],

and that shows government action can solve a problem, then maybe that shows that government can solve problems and should apply to more situations” (White & Corwin, 2022). Additionally, the difficulty of passing an insulin-relief bill can be attributed to policy complexity and using insulin as an argument for broader legislation, which can result in less support for the bill. This suggests a broader systematic issue within the United States Congress; regardless, this mentality ultimately has prevented the implementation of an insulin price relief bill. The majority of Republicans are opposed to price regulation or negotiation, and drug companies have been able to swing enough Democratic votes to stifle action in a narrowly divided Congress. For these reasons, Democrats in March of 2022 moved the Affordable Insulin Now Act forward. The passage of the Affordable Insulin Now Act is a drop in the bucket of gouging drug prices; after revisions to attempt to win the vote necessary for passage, the bill has been reduced to a form that is extremely limiting and only reduces insulin prices for a small amount of the population that relies on insulin to survive. The realization of the limiting nature of this bill suggests that affordable insulin prices may not be seen until the far future. This should not be a bipartisan issue; if democrats and republicans could agree on a policy that benefits the most amount of people, then diabetics would not be rationing their insulin supply to survive. The United States government has direct control over insulin prices; they can circumvent the other obstacles that cause high insulin prices to relieve American diabetics but have failed to do so.

## **Conclusion**

This paper used actor-network theory to analyze and understand the contributors to the failures of The Affordable Insulin Now Act. The failure in the creation of this policy yields many consequences: enrollees of Medicare Part D will have a \$2,000 out-of-pocket cost for prescription drugs beginning in 2025, uninsured diabetics see no change in insulin prices, and

there is no limit to the price that insulin manufacturers can charge (“The Inflation Reduction Act Lowers Health Care Costs for Millions of Americans”, 2022). While the lack of inclusivity of The Affordable Insulin Now Act has been attributed to the gross negligence of Congress incumbents, this fails to address the power of insulin manufacturers. If we continue to blame incumbent politicians solely, we will fail to understand how other actors can influence the course of action in policy creation. I explored the pressures that insulin manufacturers put on those in the insulin network as well as the power that they hold over the market. I claim that The Affordable Insulin Now Act failed to be inclusive due to pressure from large manufacturers to retain their monopoly and the United States government’s negligence concerning rising insulin prices and high out-of-pocket costs for many diabetic Americans.

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