

The Growing War between the Pharmaceutical Industry and Diabetic Patients

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Scientific and Financial History of Insulin

With the initial discovery of insulin in 1923, the original scientists decided to sell their patent to the University of Toronto rather than keep a profit for themselves – this ensured that no company could monopolize the treatment of diabetes with insulin. The scientists sold their patent for \$1.00 to the university, which was then licensed for other companies to use and improve the initial formulation of insulin. One of the original scientists, John J. Macleod cited this as “... a great service to humanity,” as many diabetics now had access to a crucial medication they needed (Johnson, 2021). However, soon after insulin treatment became popular prices of insulin began to rise. From 1991 to 2001, the average list price of insulin per milliliter rose 2.9% annually. This rate of annual increase then rose to 9.5% from 2002-2012, and then again to 20.7% from 2012-2016 (Hayes, 2020). This continued increase in insulin prices has become a burden on many diabetic patients, with the annual expenses becoming close to \$6,000 now and potentially doubling to \$12,000 by 2024 (Hayes & Farmer, 2020).

Increasing insulin prices has left many diabetics in dire conditions where they must ration or used expired insulin to control their diabetes. Improperly using insulin can lead to potentially-fatal diabetic ketoacidosis, which led to several deaths occurring during 2017-2019 (RCA, 2021). Advocates have cited these deaths in their fight against the pharmaceutical giants that produce and price synthetic insulin in hopes to reduce the price gouging which is done against insulin. Their voices and protests have manifested in the form of legislations being introduced at both the federal and state levels.

Federal Legislation and Policy to Combat Increasing Insulin Prices

Several pieces of legislation have been introduced into congress over the past several years in an attempt to control insulin prices. During the Obama administration, an executive order was signed which aimed to increase transparency from drug companies to state when they are undergoing drug shortages (Exec. Order No. 13588, 2011). The Preserving Access to Life-Saving Medications Act was also introduced by the House of Representatives and the Senate, but neither body voted on the legislation. Under the Trump Administration, an agreement was made between the United States government and insulin manufacturers to reduce the insulin price for individuals with Medicare (Alonso-Zaldivar, 2020; Exec. Order No. 13937, 2020). This was, however, later rescinded under the Biden administration under the claim that this would only benefit a small proportion of all insulin users. Arguably the most important piece of legislation to be introduced in the past several years is the Affordable Insulin Now Act, which was passed by the House of Representatives in March 2022 (H.R.6833, 2022). This act was originally part of the larger Build Back Better plan initiated by the Biden administration, but was introduced into congress as an independent act once the Build Back Better plan failed to gain a majority vote in the senate (Smith, 2022). The Affordable Insulin Now Act aims to lower insulin prices for insured individuals to either \$35 per month or to 25% of the insurance companies negotiated price. However, one of the largest complaints behind this bill is that it only affects individuals who are insured and leaves uninsured individuals paying with the same high prices for insulin. Furthermore, the bill does not try to regulate the price-gouging techniques utilized by pharmaceutical companies and rather only tries to control current insulin prices. Many other bills were also introduced within this time period, such as the Lower Costs, More Cures Act of 2019

and the Preserving Access to Life-Saving Medications Act of 2011, but these bills never gained enough support to be voted on and were consequently killed (Hayes *et al.*, 2020; S. 296, 2011).

State Legislation and Policy to Combat Increasing Insulin Prices

Passing of state legislation is significantly easier than federal legislation as the disparities in political ideology between lawmakers tends to be smaller, and therefore there have been more successes seen in controlling insulin prices at the statewide level (Quorum, 2021). As of July 2021, 15 different states (Colorado, Connecticut, Delaware, Illinois, Maine, Minnesota, New Hampshire, New Mexico, New York, Texas, Utah, Vermont, Virginia, Washington, and West Virginia) have enacted policies to limit insulin copay prices (Kenney, 2021). In addition to this, New Mexico and Virginia have also passed laws which limit out-of-pocket insulin expenses for individuals who do not have insurance (Hayes *et al.*, 2020). Currently, the most drastic legislation has been passed in Minnesota, where in 2020 the Alec Smith Insulin Affordability act was passed. This act allowed for individuals to receive an emergency supply of insulin at minimum cost regardless of insurance status (MBP, 2022). This law was a major success for diabetic patients, as more than 1,100 residents in Minnesota were able to gain access to insulin which they otherwise would not have had access to (Associated Press, 2022). Similar to the complaints with federal legislation, many argue that these laws do not support those who are uninsured and are primarily targeting the insurance companies instead of the manufacturers who are determining the list price of the drug. As a result, they argue that legislations such as these will only increase the premiums that insurance companies will charge to their patients.

While both legislations and policies passed at the statewide and federal level have been beneficial steps towards making diabetic treatment more accessible, they are far from solving the problem of rising insulin prices. Statewide legislations are only available in certain states, and

nationwide legislations have either failed to pass or will take several years before they take effect (H.R.5376, 2021). In ideal conditions, legislation and deaths should not be needed to control the accessibility to insulin. But that is not the case in the United States, and with studies suggesting that the situation may only get worse for diabetic patients, it is important to take a deeper look into this conflict between pharmaceutical companies and diabetic patients to understand the current prices of insulin treatment.

Monopolization and Innovation in Insulin Design

The insulin market is primarily controlled by 3 different companies - Novo Nordisk, Sanofi, and Eli Lilly (Rajkumar, 2020). Current United States patent law states that a patent will protect intellectual property for 20 years, allowing manufacturers to have some degree of monopolization on their product during this time period but not afterwards. However, companies such as Novo Nordisk and Eli Lilly have been able to keep their control over the market through patent evergreening, which is the process where several patents are claimed for the same product. (Kaplan & Beall, 2016). Since the initial discovery of insulin in 1921, there have been several modifications made to the formulation and synthesis of insulin which have increased the efficacy and shelf-life of insulin treatments. Each modification made by these companies had allowed for them to file for more patents and consequently extending their control over the insulin market. For example, Lantus, a long-acting insulin used by type I and type II diabetics made by Sanofi, has had 70 secondary patents filed while their initial patent expired in 2015 (Amin, 2018). The combination of number of patents along with broad intellectual property definitions has significantly extended their claim to intellectual property, and has consequently given them the power to defend their intellectual property by filing lawsuits against anything that may infringe on their intellectual property.

A method to try and break the monopoly held by these three companies is through the production of biosimilars. For many other name brand medications such as Tylenol® and Advil®, their primary ingredient (acetaminophen and ibuprofen, respectively) can be identically reproduced with different inactive ingredients to produce cheaper generic variants. This is possible due to the nature of the key ingredient being a small-molecule which can be identically reproduced through a defined chemical process. However, the production of generic insulin is not possible because insulin is a much larger compound which is produced through the help of biological organisms. The usage of biological organisms in manufacturing insulin introduces heterogeneity which does not affect the efficacy of the drug, but does affect the primary structure of the drug. To account for this, the term “biosimilars” was assigned to medications (as opposed to the term “generics”) influenced by biological manufacturing methods that prevent the creation of exact duplicates of a particular drug (Kim & Bindler, 2016). The FDA approval process for biosimilars is stringent, and to date there are only 35 approved biosimilar drugs in the United States (of which many have yet to come to market due to patent litigations) (FDA, 2022). Of these 35, only two (Semglee produced by Mylan and Biocon and Rezvoglar produced by Eli Lilly) are insulin biosimilars that have been approved by the FDA. Both Semglee and Rezvoglar compete with Sanofi’s Lantus and are cheaper alternatives which were approved in 2021 and 2022, respectively (Briskin & Hopcroft, 2022; Yan, 2021). There are also other alternative insulin options which are either considered “follow-on” insulin or “authorized generic” (Lispro produced by Eli Lilly, Insulin Aspart by Novo Nordisk, Admelog by Sanofi, and Basaglar by Eli Lilly), but these are all produced by the same three pharmaceutical giants which control the insulin market in the United States (DiabetesMine, 2021).

One reason why it has been difficult for other companies to enter the insulin production space is because it is often much more expensive attempting to produce a biosimilar than making a novel drug (White & Goldman, 2019). Furthermore, patent evergreening done by Eli Lilly, Sanofi, and Novo Nordisk has made it even more difficult to produce a biosimilar product without infringing on the broad intellectual claims made by their patents. However, with the approval of Semglee, it brings hope of new manufacturers being able to enter this space and bring diversity to the insulin products available.

Insulin Production Pipeline

In the war between the pharmaceutical companies and diabetic patients, it is important to consider how the price of insulin treatments are determined. Most pharmaceutical companies will cite the ever-increasing price of insulin treatment as being justified by the research and development needed to continuously improve on current treatments (JP, 2018). However, a deeper analysis into insulin production and supply chain reveals that the insulin pipeline is complex and contains several different parts (Cefalu *et al.*, 2018).

The movement of the physical drug follows a relatively linear path from the manufacturer to wholesaler to pharmacy to patient, but the movement of the associated money is much less clear. Manufacturers have a list price for their medication which is paid by wholesale distributors or directly by pharmacies. The wholesale distributor will then sell the medication to a pharmacy, but for a potential higher list price than the price paid to the manufacturer. The pharmacy will consequently charge a different price to the patient which will depend on a multitude of factors, the most important being the insurance coverage that the patient has.

The complexity in the insulin supply chain shows that varying fees and price changes can lead to a growing gap between the price that is listed by the manufacturer and the price paid by

the customer. Furthermore, while the manufacturer determines the list price based on their research and development costs, the blame for higher insulin prices cannot fall directly on the manufacturer due to each stakeholder in the supply chain playing a role in the final price paid by the patient.

Role of Insurance Companies and Pharmacy Benefit Managers in Insulin Pricing

Outside of the supply chain, the insurance companies and pharmacy benefit managers (PBM) play a central role in connecting the manufacturer, pharmacy, and patient. Patients pay a certain premium to an insurance company to gain the benefits from the plans that they offer. The PBM interconnects the pharmacy, insurance company, and manufacturer by taking and giving payments between all three parties – the PBM takes payment from the insurance company and will negotiate a price for the product with the pharmacy, while also receiving payment in the form of rebates from the manufacturer. Rebates paid by the manufacturer are a double-edged sword in that they help to lower the overall price paid by the patient, but it is in the PBM's interest to get the largest rebate possible from the manufacturer to maximize their own profits, which is only done by increasing the list price determined by the manufacturer (Rajkumar, 2020). The market is monopolized by 3 PBM's: Express Scripts, CVS Caremark, and OptumRX. However, these three PBM's are not independent as they all have some degree of influence from insurance companies – Express Scripts is part of Cigna, CVS Caremark is part of Aetna, and OptumRX is a subsidiary of United Healthcare (Beyond Type 1, 2022). Manufacturer's must compete with other manufacturer's by offering attractive rebate options to PBM's, otherwise they risk losing an outlet to sell their product. This has been a large culprit into why insulin price spikes have been universal and in unison over the past several years (Tribble, 2017).

Advocates for Diabetic Patients and Pharmaceutical Companies

For the diabetic patients, the two largest advocacy groups are the Diabetes Patient Advocacy Coalition (DPAC) and the Right Care Alliance (RCA). The DPAC was formed by other diabetic patients who believed their voice was not being heard when important legislation was being passed, and they aim to ensure quality and access of care to diabetic patients (DPAC-about, n.d). A few of their important advocacy points include better insurance coverage for all types of insulin treatments and stricter regulation of the rebate system which often will increase the final price of insulin paid by a patient (DPAC-advocacy, n.d). The RCA is a more generalized grass-roots coalition consisting of physicians, patients, and community members who aim to hold health care organizations accountable for putting patients over their own profits. One of their largest campaigns was their insulin campaign, where they have organized multiple protests to raise awareness for the deaths caused by insulin rationing (RCA, 2021). Some of the largest successes from advocacy groups such as DPAC and RCA have been lobbying for statewide and nationwide legislations, such as state-wise legislation for insulin price-caps in several different states and increased Medicare coverage through the Expanding Access to Diabetes Self-Management Training (DSMT) Act (Healthline Media, 2020).

For pharmaceutical companies, their primary voice is given through the Pharmaceutical Research and Manufacturers of America (PhRMA), a lobbying organization that claims to advocate for “public policies that encourage the discovery of important, new medications for patients by biopharmaceutical research companies” (PhRMA - about, n.d). There are several pharmaceutical companies which are members apart of PhRMA including the three insulin pharmaceutical giants Novo Nordisk Inc, Eli Lilly, and Sanofi. One of the primary ways that PhRMA does their lobbying is through campaign donations to legislatures in Congress. In 2021,

reports cited PhRMA spending over \$117 million on lobbying and campaign donations (Aboulenein & O'donnell, 2021). The consequence of this is having many legislatures oppose legislation which may have a negative impact on PhRMA's members. This was seen when looking at legislatures who opposed the Lower Drug Costs Now Act, where many of those who opposed had received close to \$1 million in funding from PhRMA. PhRMA also attempted to prevent the Alec Smith Insulin Affordability Act from being passed in Minnesota, claiming that it was unconstitutional for the state to take private property from the manufacturer without pay. This lawsuit was eventually thrown out by a US District Court judge (MMA, 2021). While many of PhRMA's actions have shown their organization as being less patient-centric and more focused on the profits of their members, PhRMA does offer resources to introduce further transparency into the insulin supply chain and why insulin prices are continuously increasing (PhRMA – Diabetes and Insulin, n.d).

Outside of the advocacy groups mentioned here, there is another group of individuals who term themselves as "biohackers." Biohacking is a broad term given to freelance researchers who are finding novel ways to optimize and improve human body performance. Specifically, to diabetes, the Open Insulin Foundation was founded by a series of biohackers who aim to formulate an open-source protocol on creating insulin treatments that could be used by anyone (OIP, n.d). Their research offers a more direct solution to the war between pharmaceutical companies and diabetic patients by making insulin more easily accessible to all without having to pass significant legislation. While there is no guarantee of this protocol working, researchers are hopeful since insulin production and synthesis are very well documented. If positive results are achieved, there is hope that the protocol could be adapted to treat other metabolic diseases and disorders.

Looking Outside of the United States

Much of the conflict between diabetic patients and pharmaceutical companies has been isolated to within the United States. While other nations have also seen an increase in insulin prices, nowhere has it been as significant as in the United States. Studies have shown that compared to other high-income nations, insulin prices within the United States are eight times higher (Mulcahy *et al.*, 2020). Compared to the United States, many nations that have cheaper insulin prices also have governments which directly negotiate with manufacturers to determine their value. This combined with higher taxation rates allows for those nations to provide greater coverage for their citizens. Specifically in Germany, drugs are evaluated by an independent board to determine their value within the market. Once valued, they determine the maximum value that an individual will pay out-of-pocket for that drug. The maximum value is determined by the household income for that individual (either 1% or 2% of their income depending on the drug and condition) and is tightly regulated since many individuals in Germany are on public health insurance plans (Luthra, 2019). While the situation in Germany is not directly comparable to what is occurring in the United States, it gives insight into potential legislation and reform which could increase insulin accessibility without hindering manufacturer profits.

Conclusion

At the surface level, it appears that the conflict between pharmaceutical companies and diabetic patients can be simplified to high prices set by pharmaceutical companies which diabetic patients are the victim of. However, a deeper analysis reveals that the is not straight forward and is impacted by a variety of stakeholders in the insulin production pipeline. This machine has been allowed to become so large and complex due to the lack of federal regulation, which is

what starkly distinguishes the conflict in the United States compared to other places around the world. To counter this, pressure has been placed on legislatures from advocacy groups providing a voice to diabetic patients, and this has resulted in changes to both federal and state legislation. While the conflict is far from being resolved, the introduction of biosimilar insulin products and price-controlling regulations have already increased the accessibility to insulin for diabetic patients, and opens the door for further changes to be made that may potentially help resolve the conflict.

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