A Silent Pandemic: A Proposal to End the Insulin Crisis

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Introduction

The climate surrounding type 1 diabetics in the United States is bleak and in desperate need of reform. High prices and limited access grip the nation. Nearly 37.3 million Americans are diabetic. Approximately 1.6 million people are living with T1D (Type 1 Diabetes), including approximately 200,000 between 0-20 years old and 1.4 million 20 years old and older (CDC National Diabetes Statistics Report, 2020). A recent digital demonstration put on by T1International revealed that one in two diabetics do not have access to insulin. This startling statistic beckons our attention and requires a unified approach. The United States is a unique outlier in an analysis of insulin prices worldwide. As an international superpower and leader in the medical industry, the U.S. maintains insulin prices well above those of other developed countries, such as the United Kingdom, Australia, and Canada, as well as developing countries like Chile, Peru, and Turkey. Exorbitant list prices effectively gatekeep a vital medication from a vulnerable demographic.

Numerous grassroots movements have sought to change the grim reality of living with diabetes in the United States to no avail. Suffocating supply prices reign. Recently, Congress has seen two bills specifically aimed at lowering insulin prices. President Donald Trump attempted to lower insulin prices in 2019 by passing a rule that ensured federally funded health centers "were passing along discounted rates of insulin" (Cai). His insulin price cap was simply a "modest tweak" (KHN) that only affected a small subset of seniors enrolled in a voluntary Medicare program (Florko). This exclusive discount ignored several crucial diabetic populations and was simply a political ploy to gain voter support of older demographics (KHN).

The House of Representatives voted on Thursday, March 31, 2022, to approve new legislation that would limit "cost-sharing for insulin under private health insurance and

Medicare." (Sprunt). The Affordable Insulin Now Act, let by the Democratic party, passed with a vote of 232-193 (Sprunt). The bill is set to cap insulin prices at either $35 a month or 25% of an insurance plan's negotiated price (Affordable Insulin Now Act). Critics argue that the bill does not lower drug prices but rather caps a patient's copay. Although the Affordable Insulin Now Act would only implement a copay, the bill reaches a greater number of people than the price cap President Trump proposed.

The aforementioned bills fail to garner universal support to effectively lower insulin list prices. While the Affordable Insulin Now Act remains stalled in the Senate, alternating resistance from both parties to the respective bills reveals that the fight for cheaper insulin is staunchly partisan. President Trump's insulin pricing rule faced heavy opposition from the Democratic party in 2019. Similarly, the Affordable Insulin Now Act only gained 12 Republican House members in the vote to pass the measure (Sprunt). Lowering the cost of insulin ought not be a partisan issue. Bipartisan support is necessary to achieve sustainable prices.

What is Type 1 Diabetes?

Type 1 diabetes is a chronic disease that follows a person from diagnosis to death. This autoimmune disease renders a person incapable of producing insulin—a necessary hormone that converts carbohydrates into energy and nutrients. Without insulin, the body will break down fat and muscle, resulting in weight loss. If left untreated, the body enters diabetic ketoacidosis (DKA)—a condition where one's blood becomes oversaturated with ketones, causing the blood to become acidic. Ketones are chemicals the body creates when it breaks down fat instead of glucose for energy. If a person remains in DKA for an extended period, they will enter diabetic coma. The body, lacking energy and nutrients, begins to shut down organs until death. A useless

pancreas instills reliance on artificial forms of insulin. Currently, no universally identifiable cause or cure for type 1 diabetes exists. Type 1 diabetics, then, must adhere to a rigorous medical routine that involves monitoring blood glucose levels, food intake, administering artificial insulin, and many more tedious yet critical medical tasks (source).

What is Insulin?

Medicinal advancement is driven "by clinical need, hand in hand with opportunities generated by novel chemical and mechanical engineering technologies" (Home 1). This paradigm characterizes the evolution of insulin therapy since 1922 when the first "artificial" insulin was derived from cow insulin (Diabetes UK). Since this discovery, science has moved away from animal insulin to a fully artificial formula. The "purification" of insulin has been a continual process marked with engineering developments and heated debates in the switch "to manufacture in microorganisms" (Home 1). While advancement in formula improves the overall treatment of type 1 diabetes, restrictive patents inflate insulin prices thus hindering access to a vital medication.

The Silent Pandemic: The U.S. T1D Climate

Currently, the United States has three primary insulin manufacturers: Eli Lilly, Novo Nordisk, and Sanofi. The lack of competition among insulin manufacturers grants exclusive control to the three main companies. Such control, then, creates a closed market void of competition. The insulin industry has experienced unparalleled price increases over the last twenty years. List prices of branded insulin increased by 262% between 2007 – 2018 (Hernandez et al.). These increases have contributed to the rapid decline in diabetic health. Millions of people rely on insulin to live, yet over a quarter of type 1 diabetics are forced to ration their insulin supply due to high cost (Schaffer). This phenomenon is commonplace and diabetic testimonies

are well documented (Sable-Smith; Jones; Lipska; and Ahne et al.). Patients who ration or abstain from taking insulin risk blindness, amputations, hospital stays, and death (Lipsak). Due to the biologic classification of insulin, patent evergreening is the common trend that grants Big Pharma market exclusivity, thereby generating price gouging (Fralick and Kesselheim). Patent evergreening occurs when brand-name companies patent slightly modified old drugs as new inventions (Collier). Claims to innovation and quality control have long protected insulin patents and justified astronomical price increases. Additional data indicate that direct R&D expenditure ratios have decreased since 2009 while distributions to shareholders have increased (Lazonick et al.). This evidence confirms that high insulin prices are not linked to R&D and manufacturing costs. The financialization of insulin-manufacturing companies has prioritized maximizing shareholder value at the expense of patient access and treatment innovation. Therefore, the need for legislative action is vital.

The Insulin Supply Chain

A contributing factor to skyrocketing insulin prices is the route which insulin travels before it reaches its final destination: the patient with diabetes. Several major stakeholders which have differential degrees of negotiating power help determine the price of insulin. The stakeholders are outlined below:

- **Pharmaceutical Manufacturers**: the source in the insulin supply chain. Manufacturers facilitate the distribution of insulin to insulin wholesalers. Although insulin manufacturers can distribute directly to purchasers, few drugs are directly distributed to patients and consumers. Three primary pharmaceutical manufacturing companies operate in the United States—Eli Lily, Sanofi, and Novo Nordisk—which control 90% of the insulin market (Wirtz et al.).

- **Wholesale Distributors**: purchase insulin from manufacturers and distribute to pharmacies, hospitals, and other medical facilities. Wholesalers purchase insulin according to the Wholesale Acquisition Cost (WAC)—commonly referred to as insulin's *list price*. Manufacturers pay a fee for distribution services, which is also negotiated through the WAC. The top three drug wholesalers in the U.S.—AmerisourceBergen Co., Cardinal Health, and McKesson Corp.—pocket 90% of revenue generated from distribution (*2018-19 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors*).
- **Pharmacies**: purchase insulin from wholesale distributors following the WAC but receive a negotiated discount. Pharmacies also collect various cost-sharing amounts such as coinsurance, copayment, or full price on insulin designated through a patient's health plan. The pharmacies are then reimbursed by Pharmacy Benefit Managers (PBMs). Reimbursement is calculated by the Average Wholesale Price "plus a dispensing fee minus a negotiated discount and any cost-sharing collected from the patient" (Kyalwazi and Hurtado).
- **Pharmacy Benefit Managers** (PBMs): contract with health plans to manage outpatient pharmaceutical benefits for their clients. PBMs determine what drugs are covered, how much dispensing fees and reimbursement pharmacies receive, and the amount patients owe per cost-
- **Sharing**. Additionally, PBMs negotiate discounts and rebates with Pharmaceutical Manufacturers, thereby negotiating what percentage of rebates go to health plans. Caremark, Express Scripts, and OptumRx control over 75% of the PBM market share (Fein).

The complexity of the insulin supply chain creates an exclusive market where profit reigns over patient access.

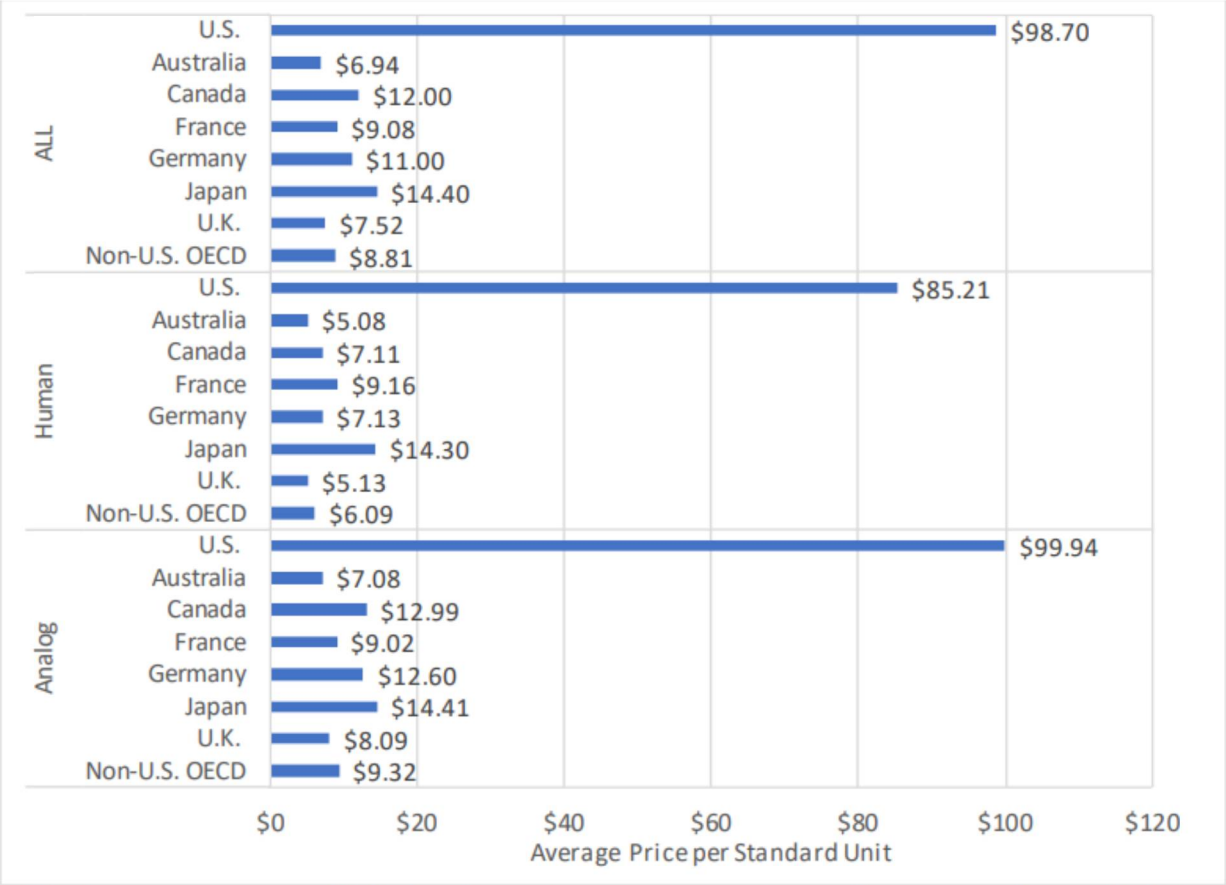
Insulin Prices Worldwide

The United States has the highest insulin price in the world (ASPE). The standard unit of insulin cost "more than ten time the price in a sample of 32 foreign countries" in 2018 (ASPE). The U.S. unit price was $98.70 while the average unit price in the 32 non-U.S. OECD [1](the Organisation for Economic Co-operation and Development) countries was $8.81 (10). According the Office of the Assistant Secretary for Planning and Evaluation's (ASPE) 2020 report, "the U.S. prices for the mix of insulin used in the U.S. were 8.1 times prices paid in all non-U.S. OECD countries combined" (11). These statistics compare U.S. insulin brands with the insulin "market basket" (ASPE) used in OECD countries. The report also adjusted the mix of insulin so that the brands used were the same in the United States and in the OECD countries. Even with this adjustment, a large price differential remained. Interestingly, the U.S. average gross manufacturer prices were 3.8 times higher than prices in Chile, 27.7 times higher than Turkey, and 8.1 times prices paid in all non-U.S. OECD countries (10). The ASPE report addresses further counterarguments to the collected sample data and strongly concludes that U.S. net prices are at least 4 times higher than other countries. The analysis confirms that insulin prices in the U.S. cost drastically more than that of both developing and developed countries.

Figure 1 displays the cost per unit of insulin types around the world—the United States ranks the highest in all categories by a wide margin.

[1] The Organisation for Economic Co-operation and Development (OECD) is a group of 37 member countries that discuss and develop economic and social policy. Members of the Organisation for Economic Co-operation and Development (OECD) are typically democratic countries that support free-market economies.

Fig. 1. The Cost Per Unit of Insulin in the Developed World

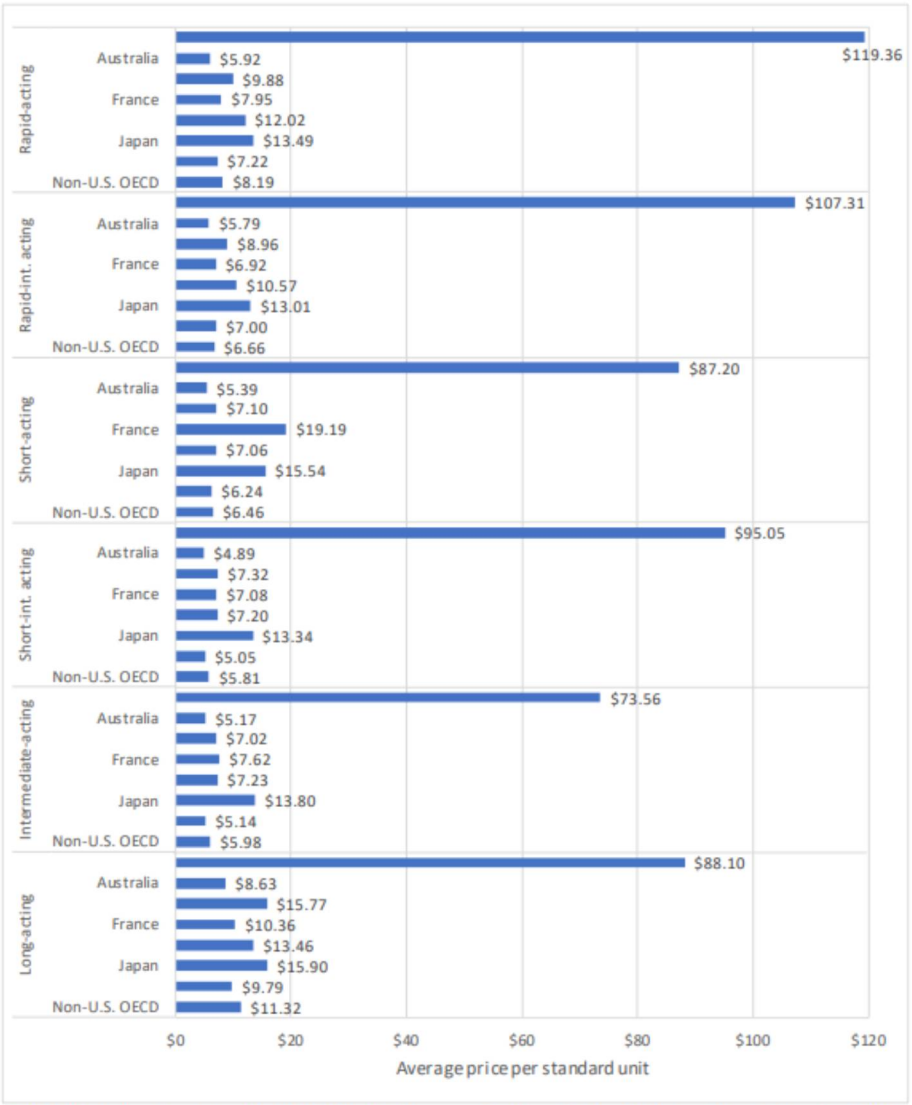


SOURCE: Authors' analysis of IQVIA MIDAS data from an extract provided by ASPE (run date: October 29, 2019).

ASPE's report also breaks down unit price by insulin timing category. Figure 2 illustrates the price gap per timing category. This breakdown is crucial to their findings as many diabetics (primarily those with type 1) take multiple times of insulin depending on the release time. The listed timing categories are long acting, intermediate acting, short acting, short-initial acting rapid acting, and rapid-initial acting. Long-acting insulins acts as a basal that works in the background to maintain level blood sugar levels over a long period of time. Short acting, or regular, insulins are used to cover blood sugar spikes and carbohydrate intake—it is classified as a mealtime insulin. Rapid acting insulins function the same as short acting however, it begins

working 15 minutes after injection and only lasts 2-4 hours. Short acting starts work approximately 30 minutes after initial injection and lasts 3-6 hours (Doskicz). Intermediate insulins are less common as they work for about 12 hours. It could function as a basal but is not an optimal choice. Novolin N is the only intermediate type of insulin (Dosckiz).

Fig. 2. Cost of Insulin Type in the U.S., Australia, France, Japan, and Non-U.S. OECD



SOURCE: Authors' analysis of IQVIA MIDAS data from an extract provided by ASPE (run date: October 29, 2019).

Both figure 1 and 2 confirm that insulin prices in the United States, regardless of timing type, are exorbitantly higher than any other country.

A Plan of Action

It is time that the United States addresses one of the most pressing healthcare crises to date—the insulin price crisis. The path forward is difficult and requires the utmost participation and support not only from the American people but from Senators and Representatives themselves. Further, a resolution to the insulin price epidemic must have full bipartisan buy-in. We can no longer accept a polarized bill to lower out-of-pocket costs. Merrill Goozner claims we must bypass "our fragmented insurance system with a common purchasing program that unites all consumers." Goozner suggests that the federal government could "jointly purchase all forms of insulin" from manufacturers and then "turn them over to pharmacies and other distributors free of charge" (n. pag.). Goozner's proposal eliminates burdensome markups in the distribution chain thereby lowing the price of insulin which the federal government would purchase. I propose to expand upon Goozner's plan of a purchasing pool by mimicking the COVID-19 distribution plan.

The governmental response to the current COVID-19 pandemic provides an exceptional model to restructure insulin distribution in the U.S. In September 2020, the United States Department of Health and Human Services and the Department of Defense published a document detailing the distribution of the COVID-19 vaccines in the United States. "From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine" conveys the strategy of Operation Warp Speed (OWS) through four major categories: distribution, administration, monitoring, and engagement. Throughout the document, the HHS utilizes strong rhetoric reinforcing the urgency of vaccines and demonstrates determination of dispersion. Within the first few paragraphs, the HHS asserts that this vaccine program "requires precise coordination across federal, state, local, tribal and territorial governments" (1). The

health officials then outline the three E's of success: "to ensure efficient, effective, and equitable access" (1). They sprinkle in additional phrases such as "must be able to deliver vaccines immediately," "maximize coverage," and "mass vaccination" to undergird the criticality of the contemporary moment. Not only does this pressing language establish exigence, but it also exposes the pandemic-induced desperation. COVID-19 resulted in a worldwide public health crisis that has brought immense tragedy to every country and every people group. As death rates increase, so too does fear, chaos, and pain. The rhetoric displayed within the first page of "From Factory to the Frontlines" reifies the importance of equitable vaccine access. Urgency drives the effort to vaccinate every person in the U.S. Moreover, the document provides a breakdown of the core distribution strategy. The three key components are as follows:

- Partnerships with state, local, and tribal health departments, territories, tribes, and federal entities to allocate and distribute vaccines, augmented by direct distribution to commercial partners.
- A centralized distributor contract with potential for back-up distributors for additional storage and handling requirements.
- A flexible, scalable, secure, web-based IT vaccine tracking system for ongoing vaccine allocation, ordering, uptake, and management.

There exists a strong emphasis on cooperation among the 64 jurisdictions the CDC works with. The continued inclusion of tribal and territory partnerships further illustrates the importance of extending the reach of the vaccine. The HHS even comments on reaching underserved populations vowing to ensure rural populations can receive the vaccine and claim they have "decades of experience working" (3) to fulfill the needs of hard-to-reach populations. They affirm "the objective is to ensure no one desiring vaccination will face an economic barrier to

receiving one" (7). Lastly, the HHS simultaneously predicts and addresses future public health changes: "If the risk of COVID-19 persists such that there remains a public health need for an ongoing vaccination program, COVID-19 vaccines will ultimately be universally available and integrated into routine vaccination programs, run by both public and private partners" (5). This statement is the third phase of a potential phased structure under distribution. All the aforementioned quotations illustrate the force the OWS intends to use to provide unbiased, universal access to the vaccine if one chooses it. Throughout this document, the HHS demonstrates that they not only have the resources to advance the vaccine plan, but they also have the will for implementation and commitment to adjusting to the way COVID-19 will change public health.

My question, then, is why does the American public and our representatives not feel the same call to urgency with diabetes—a chronic disease that claims hundreds of thousands of lives every year? Unfortunately, the key word in that sentence is "chronic." The term denotes a disease that lasts the entirety of one's life. This lifetime contract means continuous consumption of insulin—a guaranteed consumer group for pharmaceutical companies. However, this predatory practice of price-gouging insulin has created an epidemic of its own. Large demographics either ration insulin or abstain from taking any due to absurdly high prices. My proposal, then, is to restructure insulin distribution to mimic that of the COVID-19 strategy explained in "From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine."

Four major reasons explain why we should mirror the OWS distribution approach:

1.) Working partnerships/cooperation goal;

2.) Centralized distributor;

3.) Immediacy; and

4.) A flexible tracking system for allocation, ordering, uptake, and management.

While the OWS lists only three key components of distribution, immediacy is a driving force behind the entire plan. Such urgency ought to prompt universal insulin allocation.

First, "From the Factory to the Frontlines" prizes partnerships with state, local, and tribal health departments. In fact, the CDC is working with each level to "hone existing plans for vaccine distribution and administration" (3). The HHS adapted successful routine immunization infrastructure to support this vaccine program. Moreover, through the Coronavirus Aid, Relief, and Economic Security (CARES) the CDC awarded grants to prepare immunization programs for vaccine distribution and administration. The funding "will be used to enhance capacity to support staffing, communication and stakeholder engagement, pandemic preparedness, and mass vaccination" (3). To carry out their plan, a multi-agency federal team chose five pilot jurisdictions to create a basic administration plan to serve as models for other jurisdictions. The pilot jurisdictions were also tasked with developing "microplans" to identify vaccination sites and logistical considerations for onboarding IT systems. Each jurisdiction covers a wide range of demographics and locations. The design includes highly populated, urban areas and rural regions with low population density. Moreover, the plan's focus on helping "hard-to-reach" demographics echoes the insulin industries' neglect of specific people groups like Blacks, Hispanics, and people of lower socioeconomic status who suffer disproportionately from diabetes (7). Therefore, the inclusivity of this plan makes it a desirable model for insulin distribution.

Further, a centralized distributor for insulin will eliminate manufacturers' grip on high prices. The HHS asserts that centralized distribution "allows the government full visibility,

control, and ability to shift assets and use data to optimize vaccine uptake" (4). Although government control represents a contested topic in the political arena, the insulin market is actually missing government oversight, as there are no regulations to control the pharmaceutical monopolies. Unlike the COVID-19 vaccines, there is no need to create "injection sites" for insulin. Instead, pharmacies will continue to act as distributors. The HHS admitted that the COVID-19 pandemic has accelerated "a trend towards different ways of engaging with the healthcare system" (4). Successful delivery of the COVID-19 vaccine required pharmacies to play a more critical role. Since pharmacies are already responsible for supplying insulin to diabetics, they can continue to play that crucial role and aid in the distribution of free universal insulin. Lastly, a tracking system like VTrckS (the HHS's Vaccine Tracking System) can centralize and organize allocation, ordering, uptake, and management.

A few objections may arise regarding a universal insulin distribution plan. First, capitalists will argue that free insulin is not feasible for the U.S. economy. The United States budget simply does not have the room to support millions of type-1 diabetics. While the task to supply insulin to 1.84 million type-1 diabetics is daunting, it is actually quite attainable by following the model outlined in "From the Factory to the Frontlines." Several of the plan's components would allow the U.S. to provide free insulin to those who would benefit most. The charge for a centralized distributor specifically establishes compatibility between strategy and budget. More control is designated to the federal government to track usage rates and plan accordingly for monetary allocation.

Another counterargument against free insulin contends that it would cut profits of the three main insulin manufacturers. While this argument clearly disregards human life for profit, it may be refuted from a practicality standpoint. Elli Lilly, Novo Nordisk and Sanofi maintain a

closed market in the pharmaceutical industry. The absence of true competition translates into high prices and outrageous profits for the respective monopolies. However, issuing free insulin would hardly hinder these companies. Instead of garnering profits from insulin consumers directly, the government would bear the brunt of the bill. Again, the COVID-19 pandemic provides a perfect illustration of the payout insulin companies could gain. Pfizer, BioNTech, and Moderna received approximately $34 billion in pre-taxed profits for 2021 (Oxfam). This statistic stands as evidence of the profit Elli Lilly, Novo Nordisk, and Sanofi will reap in the switch to "free" insulin. It is regrettable that these insulin monopolies will continue to gain, yet it is far more imperative that diabetics in the United States have unrestricted access to insulin.

The last significant counterargument arises in the difference between a chronic medicine and a one-time vaccine. Admittingly, insulin is not a one-time injection like the COVID-19 vaccine. Rather, insulin is administered according to complex blood glucose sliding scales and carbohydrate-based unit ratios. Moreover, regular injections of both short- and long-acting insulins are necessary to sustain life. However, discussions about an annual COVID-19 vaccine are in current circulation and the addition of boosters are prime examples that COVID-19 is not a one-time shot.

COVID-19 and Diabetes

The effects of the pandemic prove to be more invasive and diverse than first predicted. A prime example is an in-depth study by Yan Xie and Ziyad Al-Aly that reveals a close relationship between COVID-19 patients and diabetes. Their study analyzed data from a cohort of 181,280 participants. The study divided the participants into three groups: one contained people who had a positive COVID-19 test between March 1, 2020, and September 30, 2021, and survived the first 30 days after contracting the virus; a contemporary control group that enrolled

participants between March 1, 2010, and September 30, 2021; and a historical control group that enrolled participants between March 1, 2018, and September 30, 2019. Both control groups "had no evidence of SARS-CoV-s infection" (Xie and Al-Aly 1). Participants in all three groups were diabetes free before cohort entry. After a follow-up of 352 days, the researchers found that people who had COVID-19 were about 40% more likely to develop diabetes "within a year after recovering" compared to the control group participants (Xie and Al-Aly 1). Al-Aly, the lead author of the study, said, "What's surprising is that it is happening in people with no prior risk factors for diabetes" (1). The report predicts that around 1% to 2% of people who were infected with COVID-19 will develop diabetes as a result. This prediction means that of the 80 million people in the U.S. who had COVID, 800,000 to 1.6 million people are at risk for developing diabetes (Xie and Al-Aly 1).

This unfortunate link between COVID-19 and diabetes warrants the proposal for free insulin. If the government continues to fund COVID infrastructure, then they should also allocate funding to supplement diabetes related costs—the most prominent and crucial one being insulin. Medical professionals predict a high increase in diabetes diagnoses following the pandemic. During normal times, doctors expect "roughly 1.5 million" new diabetes diagnoses on top of the 34 million people already living with diabetes (Diaz). The frequency of insulin rationing and medical conditioned based poverty expedites the urgency to amend the insulin price crisis.

Conclusion

Diabetes is the pandemic that has quietly persisted through decades. Although millions suffer from this chronic disease, little aid exists to mitigate the costly impacts of living with diabetes. Within the last twenty years, the list price of insulin increased by nearly 1200% (Roberts). Moreover, insulin is produced and sold in a closed market that values year-end sales reports. The iron triangle of insulin manufacturers continues to find loopholes that extend patent life, price-gouge insulin, and eliminate market competition thereby hegemonizing a life-saving and sustaining medication. I maintain that prioritization should focus on preserving life not garnering profits. The same urgency that rapidly produced COVID-19 vaccines ought to drive the fight for free insulin. Moreover, the increased percentage of diabetes diagnosis in COVID-19 survivors amplifies the need for governmental support. Now more than ever we need free insulin, and the COVID-19 distribution plan provides an opportune pathway to achieve that goal.

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