Duty Ethics Within Insulin Manufacturing

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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:

Unexpected medical diagnoses can completely shatter the world view of the diagnosed, and can greatly impact their quality of life. Whether it is losing control over a part of your body, or becoming reliant on a medicine that you need to live, there are an entirely new set of struggles that the afflicted now have to work through. Medical technologies and treatments can help maintain or restore quality of life to patients, however in the US they can be extremely expensive, which has been the case for insulin. Type 1 diabetics rely on insulin so they do not die. Diabetes is a condition that results from a lack of insulin production within the pancreas. Insulin is a hormone that regulates sugar within the bloodstream. Having not enough insulin in your body leads to high blood sugar levels, which can be extremely damaging to the body (CDC 2017). That is why it seems absurd that a drug that people rely on to continue living has a significant price attached to it with the prices getting more expensive each year. This leads us to the question - How have insulin manufacturers distributed insulin and made it accessible to those that need it?

With that question in mind, I look at the conditions that have allowed insulin manufacturers to structure their business in its current model, and what external factors are causing pressure for them to change or adjust their model. Currently, there are three main insulin manufacturers that produce almost all of the insulin in the insulin manufacturing space. Those companies are Eli Lilly, Novo Nordisk, and Sanofi. These massive pharmaceutical companies currently produce approximately 95% of the US's insulin supply (Quinn, 2018). In addition to this, they hold the patents for insulin treatments, which prevents other pharmaceutical companies from entering the insulin manufacturing space, eliminating any sort of competition that could arise from competing businesses.

Insulin manufacturers have been locked into raising prices on insulin due to the rebate system commonly found in their distribution process, which has interfered with their sense of duty as perceived in Kantian ethics. My literature review will cover the history of insulin therapy, both its discovery, how it was handled in its early stages, and how that changed over time to reach the point we are at now. In terms of data, I collect legislative bills that have been passed in regards to insulin accessibility and see how the insulin conditions both before and after that piece of legislation are altered, if at all. For insulin conditions, mainly I am talking about the pricing of doses as well as demographics of who can access it. Main takeaways from this information will be whether or not insulin manufacturers need to be pushed by outside sources to make insulin more accessible, and what allows these manufacturers to set up their business to reach the point they are at now. I find that manufacturers need external forces to push them in a more accessible direction. In recent history however, manufacturers themselves have made decisions that steer them in a more accessible direction.

Literature Review:

Originally, the isolation of insulin, which led to the discovery of insulin treatments, occurred in a lab at the University of Toronto in 1921 (Lewis & Brubaker, 2021). This was a breakthrough discovery due to the fact that now individuals with type 1 diabetes, a condition that impacts the production of insulin in the body, were able to take treatments to keep them healthy. Prior to this, being diagnosed with type 1 diabetes was a death sentence. Once discovered, the University of Toronto's health entity Connaught Antitoxin Laboratories went about producing and providing insulin for little to no cost, but realized that they were not able to keep up with the output (Beran et al., 2021). In order to satisfy the increasing demand, in May of 1922 the University of Toronto ended up making an agreement with Eli Lilly that gave Eli Lilly exclusive

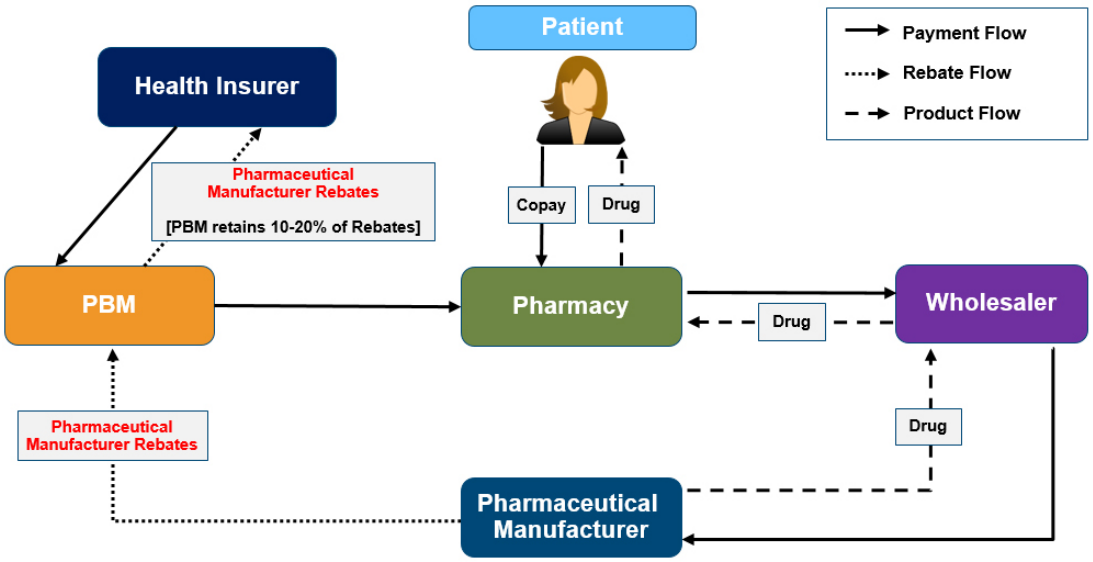
rights to manufacture and distribute insulin completely free to selected doctors and hospitals. However, after one year, Eli Lilly would be able to start charging for insulin (Lewis & Brubaker, 2021). Eli Lilly is one of the big three production manufacturers still seen today.

Diabetes has been an increasing problem within the US. In the year 2000, the percentage of the US population that had been diagnosed with diabetes was 4.4% while in 2015, that number rose to 7.4% or ~23.35 million people (CDC, 2017). Of those numbers, 1.9 million were diagnosed with type 1 diabetes (American Diabetes Association, 2022). Although type 1 diabetics are the ones that rely on insulin every day, many individuals with type 2 diabetes also take some form of insulin as treatment as well. While the diabetic population has increased over time, so has the price of insulin. According to the American Action Forum, the average list price of insulin went up 11% annually from 2001 to 2018, with the average annual per capita price rising towards $6,000 (American Diabetes Association, 2022).

One of the incentives that pharmaceutical companies have for having a higher list price is the rebate system that is in place for prescription drugs. The supply chain of prescription drugs includes many actors including the pharmaceutical manufacturer, the pharmacy branch manager (PBM), the health insurer, the pharmacy, the wholesaler, and finally the patient. A pharmaceutical manufacturer will set an initial list price which is the price they are expecting people to buy their product at, which is bought by a wholesaler and distributed to paying pharmacies, where finally the patient is able to buy it for the set list price (Alston et al., 2018). The PBM develops a formulary which is a list of drugs that is covered by the health insurer and carried by the pharmacy. They are also the ones that negotiate rebates with manufacturers. These rebates are generally based upon the list price of the drug in question. A flowchart of these connections can be seen below in Figure 1:

Figure 1

Flowchart of Pharmaceutical Drugs & Rebates



Note: (Alston et al., 2018), Details the actors involved within the prescription drug supply chain. Since PBMs are the ones that set what drugs a pharmacy will provide for their patients, manufacturers will provide a rebate to the PBMs when purchasing their product in order to incentivize the PBMs to prioritize their product over competitors (KFF, 2019). So essentially, PBMs are paying a discounted price in order to give preferred treatment to those manufacturers. A larger issue arises when the competitors start making deals with the same PBMs and end up providing a larger rebate. This creates a back and forth between manufacturers to see who is willing to give PBMs the largest rebate so that the manufacturer's product is the one being sold to customers. The only way for a larger rebate to be provided is by raising the list price. In some scenarios, PBMs have been recorded as getting as high as 70% of the list price as a rebate (Jackson, 2021). Since it is the overall list price that is increasing, this is all at the expense of the patient, who has to start paying more and more for the same exact product they have been buying.

There has been intervention from external forces both domestically in the US as well as globally. Within the US price of insulin is a massive barrier for people, but globally, one in two people that need insulin lack the proper access to the need for treatment (Ewen et. al, 2019). Recently, the World Health Organization (WHO) placed insulin on their Prequalification Program (Beran et. al, 2021), as well as the Essential Medicine List (Beran & Yudkin, 2010). This has allowed a plethora of accessibility options to open up to countries around the world that might not have had access beforehand. The prequalification program is a list of medications that WHO maintains filled with medicines that people might depend on to survive, such as insulin. WHO works with national health agencies to help those that might not be able to acquire those medications access what they need, particularly in low-income countries. The essential medicine list is another list that WHO updates every two years that selects medications that are the most safe, effective, and cost effective depending on public health relevance as well as disease prevalence.

I have chosen duty ethics as my STS framework, specifically Kantian ethics. Kantian ethics focuses on acting favorably due to good will instilled with a sense of duty, and to treat humans in an equitable manner (Johnson, 2020). Due to the fact that the insulin manufacturers are responsible for providing treatments for others that desperately need it, I would assume that they would have a strong sense of duty to help everyone within their power. Utilizing the lens of Kantian ethics, we can establish how these manufacturers should be acting in order to fulfill their ethical duty. With that established, we can see what actions they would need to take in order to fix their current processes from an ethical standpoint. There are some critiques to this framework however. It can be said that it fails to take into account any exceptions to the rules that might have to be made in order to take the morally correct path, such as lying to protect someone, as

wells as the fact that it does not take into account the consequences of the actions taken (Schinzinger & Martin, 2000). Philosopher William David Ross came up with an alternative way to process these moral conundrums through separating duties into prima facie duties and self-evident duties. A prima facie duty is a duty that can be exempted if certain criteria is met within a situation, while the self-evident duties are the duties that can be seen as taken priority over the prima facie (Skelton, 2010).

Methods:

My methods for data collection included collecting information from an array of sources. Firstly, looking through legislation that has been passed within the US government that pertains to healthcare and accessibility to insulin. Additionally, medical journals discuss current demographics for insulin users and current accessibility as well as accessibility in the past. Lastly, I have collected historical facts from journal articles about how insulin treatment was discovered and how the manufacturing process started and changed over time. Since I am doing a historical analysis with some policy analysis, these methods made the most sense to gather the information that would be most beneficial. This made it so I could analyze insulin trends over time and what external factors have played a part in influencing those trends.

Analysis:

Kant's discussion on his deontological viewpoint often comes from the viewpoint of an individual, so it is important to see how the framework's ethical duties apply to an institution, such as an insulin manufacturer. In Byron Kaldis' *Could the ethics of institutionalized health care be anything but Kantian? Collecting building blocks for a unifying metaethics* he posits that institutions can absolutely be judged through the Kantian framework. "Considered as such sets of causal series comprising the actions of appropriate individuals falling under them in accordance

with their legislated blueprint, institutions, too, can indeed be objects of judgment by means of Kantian criteria" (p. 47). Essentially, Kaldis is explaining that you can use the overall layout/mission of a company or institution as well as the actions of the more prominent figures involved with those places to judge them through a Kantian lens. Kalis goes on to say that institutions are able to manifest patterns of action in which you can recognize ethical obligations present. Since it is established that these larger bodies can be evaluated, it is important to understand what type of duties that an insulin manufacturer would be beholden to.

Pharmacists have been tied with operating with a sense of duty ever since the profession began. This is brought up in the book *The Law and Ethics of the Pharmaceutical Industry* written by Graham Dukes (2006): "The principle was established that the people must be able to depend on the pharmacist or apothecary to perform his tasks in a manner on which they could rely utterly, having insufficient knowledge of their own to judge medicines which he supplied" (p.87). People have no choice but to trust that these pharmacists are making and supplying them with the medicine and treatments they need because they have no other option. This dependence is a perfect example of the sense of the duty that pharmacists have, establishing a solid foundation for duty ethics itself.

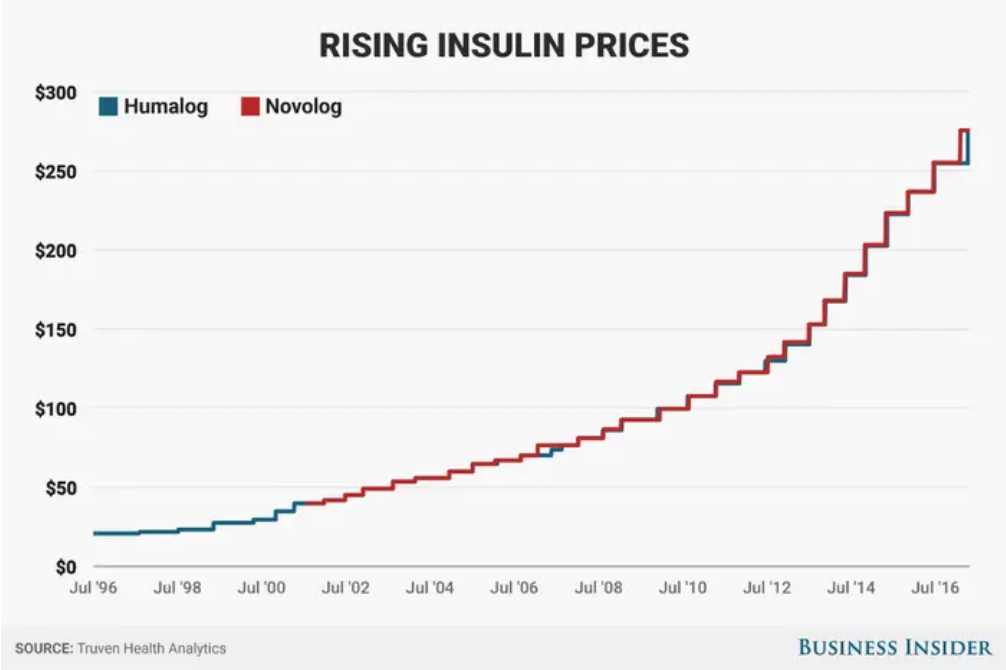
As the pharmacist profession took on responsibility for that duty when it was established, that can extend into the modern times while looking at Kant's idea of innate and acquired duties. Williams and Chadwick discuss Kant's *Metaphysics of Morals* in their paper *Responsibilities for Healthcare: Kantian Reflections* and describe acquired duties as following: "Most of the duties that concern us when we think of a given person's responsibilities are acquired. This does not necessarily mean that they are chosen or voluntarily incurred. … Somehow or other, though, the duty has devolved onto [them]" (p.158). Here Williams and Chadwick clarify the fact that an

acquired duty can come as a result of one's role, when someone else ends up requiring or relying on someone to complete a duty. As stated before, someone entering the insulin manufacturing space has acquired this duty to produce insulin for the sake of those in need. It can be argued that raising the insulin price to inaccessible levels is resulting in insulin manufacturers failing this duty. This failure indicates that there is now an "unowned duty" present according to Williams and Chadwick. They emphasize this need for an action but no one is there to provide the necessary function. This is where you would imagine that there is a company not providing adequate care, that a new competitor that could offer the same services at a cheaper price. Williams and Chadwick agree with this from an ethical standpoint saying "We often feel duty-bound to take account of others' wrongdoing" (p.159). This failing at their duty would be considered an insulin manufacturer's wrongdoing, however there is no one stepping up to fill that role due to the tight control on the insulin patent that is held by the big three manufacturers. The insulin patent has been exclusively held by them in the US for around 100 years.

After the insulin patents had been acquired by larger manufacturers, they did start pricing them at a higher point. In fact, insulin prices have had a continuous upward trend ever since insulin treatment was made available over 100 years ago. While this could be justified in Kantian ethics for having to sustain the workers with a solid livable wage, the increases specifically in the last 20 years or so have increased at a historically high rate, going far beyond that possibility. In 2021, the insulin market in the US was valued to be $8.44 billion dollars (Fortune Business Insights, Nov 2022). Considering this information along with the fact that there is no healthy competition coming from other insulin manufacturers, it's hard to justify the increase in cost, particularly when it is lowering the accessibility to insulin itself. Figure 2 shows the price of a vial of insulin between 1996 and 2016:

Figure 2

Graph of Rising Insulin Prices



Note. Pflanzer, 2017. Rising vial prices of Humalog and Novolog insulins

As seen in the image above, even in just the past ten years, the list price of these insulins rose over 200%. If the current insulin situation were to remain the same, and the price increase trend continued, it would be harder and harder for lower income individuals that rely on these vials to have steady access to them.

Although there are some avenues of relief in regards to insulin access, some people are excluded from these access points. Some of these access points include federal Medicaid and insurance companies. These rising insulin prices are so exorbitantly high however, that if you miss the mark for these avenues, it can be crippling. Many people find themselves just above the Medicaid income threshold, leaving them ineligible to take advantage of it even though they are almost in the exact same position as other Medicaid users. Additionally, there are people that leave their family insurance plan at 25 and are left exposed to paying for the full price for insulin

out of pocket due to the fact that some insurance options they have are not much better. This has led to individuals needing to restructure how they live simply to afford insulin when they can. From the viewpoint of duty ethics, having the ability to provide an essential medicine to someone whose quality of life is slipping, and keeping that behind a barrier they cannot access completely violates the morals of helping those through a sense of duty. An *NPR* report details how a mother lost her son, Alec Smith, to diabetic ketoacidosis; the condition that a lack of insulin results in. Smith was informed by his pharmacist that his diabetes supplies would be about $1300 per month, with a majority of that being attributed to insulin. The month after going off of his mother's insurance, he was found dead due to diabetic ketoacidosis. It was believed that he was rationing his insulin to last him until he got paid, however he did not make it. (Sable-Smith, 2019). Stories like this make it clear that these insulin manufacturers do not try to make insulin accessible to those that truly need it. If the companies themselves are not willing to make their product more widely available, then there has to be some external force pressuring them into the right direction

Within Kantian ethics, a person's actions are not needed to be put in check by an external party or force, based on the fact that the action comes from a sense of duty to the fellow person. In recent years, the US government has intervened in an attempt to make insulin more accessible to US citizens, however there is only so much that they can intervene on. Just in recent years, there was an executive order from former President Trump that discussed the lowering of insulin prices, which did end up going into effect on January 22, 2021 (Chesak, 2022). This was rescinded by President Biden when he entered office citing that this had created high administrative costs for impacted health centers, as well as these new rules leading to a decrease in staff available to help with emergency services (Chesak, 2022). Just from this one scenario, it

is clear that having the government interfere on a surface level like this can be much more complicated than it would appear. The most productive change would arise from a restructuring of the system that is causing the insulin prices to rise. While these legislations being passed can help provide relief, it acts more like a band aid, and not a solution to the root of the problem. President Biden has also mentioned in his 2022 state of the union address the possibility of capping insulin prices at $35 a month (Chesak, 2022). Implementing something like this would be massive for diabetic individuals, and something very similar to this is being done in Canada already (Inskeep & Aubrey, 2022) with successful results.

Conclusion:

It is important to remember that just because a treatment for a condition has been discovered, that does not mean that everyone that needs it can access it. A great leap scientifically can only truly benefit the public if there is an equitable way to distribute it to where it is needed. Ideally, with this information being brought to light more, further legislation can be passed making insulin accessible to any and all people that need it. Lobby groups can help advocate for this legislation or aid in petitioning against manufacturers to alter how they are approaching their distribution methods.

I would hope that people that are developing their own medical technology/treatment would be able to reflect upon the information seen in this paper and reevaluate just how they want to go about distributing it. Whether that is deciding against selling their patent to a large corporation and losing control of their product, or finding that right manufacturer that aligns with their values, whatever allows them to have a fairly priced and accessible product. In the case of the latter, if the distribution model is similar to how the pharmaceutical space works, then manufacturers would have to risk skipping that middleman and sell straight to

pharmacies/customers if they want to focus on an ethical supply chain. In most cases this would most likely be a last resort due to the fact it would be a more costly method of distribution. Researching how other similarly life-impacting medical technology/treatment is distributed and how accessible it is to the patients that need it could be interesting future research. Cross examining the results from that with what was found here would help to observe if there is an established pattern for products like these, in which case a restructuring of the norm would be best. Alternatively, if the other situations are jarringly different, then we could look at where the difference stems from, and if it is replicable or not. Although historically medical treatments have lacked accessibility and have had a financial barrier, it appears as if both government legislation and the manufacturers themselves are taking steps to make insulin access more equitable.

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