Should Insulin be Inaccessible Due to the Current Market?

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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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Diabetes is a disease that occurs when a person is no longer able to produce a sufficient amount of insulin from their pancreas, which leads to an increased level of sugar in the bloodstream. In order to combat this disease, insulin must be taken daily to maintain sugar levels to prevent the body from suffering long term damage such as blindness, loss of limbs, or death. Taking insulin to combat this disease is simple. However, procuring this life-saving drug can be difficult due to high prices. As stated by MD Rajkumar, "One vial of Humalog (insulin lispro), which used to cause $21 in 1999, costs $332 in 2019, reflecting a price increase of more than 1000% " (Rajkumar, 2020, p. 1). Pharmaceutical companies were able to raise and maintain these high prices because the government has implemented minimal restraints to protect the livelihood of insulin users. Companies' tactics to bypass current restrictions include buying patents from generic brands, making small adjustments to current patents to keep information proprietary longer, and increasing prices to counteract policies the government implemented for Medicare insulin users. The use of these tactics has led to an inaccessibility gap for insulin users which could potentially be solved by investing more funds into insulin research. Responsible research and innovation is the framework for this paper and in the case of insulin it encompasses finding more affordable alternatives and redesigning the current systems in place which are inhibiting both. With the knowledge that pharmaceutical companies are able to charge exorbitant prices for the life changing drug insulin, is this situation acceptable and how should we as a society take steps to stop this and promote responsible research and innovation within the insulin sector?

This situation is unacceptable because major pharmaceutical companies should not be able to abuse the patent system to delay generic brands from accessing their intellectual property. The patent system was designed with two goals: to encourage and reward advancements and

promote further innovation via competition. According to Herman and Kuo, a company or individual is rewarded by having their intellectual property patented which gives them sole rights over a concept or commodity for twenty years (Herman & Kuo, 2021). In this time period companies usually try to make as much money as possible to get a return on investment from funds spent on research and product development. After this period, innovation is prioritized by releasing this information so other parties can make different versions of a product or incorporate ideas into their processes for further development. In relation to drug development, the patent system is essential for consumers because after patents expire, generic brand companies are able to produce alternative drugs which usually lead to "... a 20-30 per cent reduction of a drug price, with further price decreases with each additional generic entrant, leading, in some instances, to a fall in price of up to 90 per cent" (Gurgula, 2020, p. 1066). Overall, the decrease in pricing is important for consumers who will pay less for life saving drugs due to the availability of more options. Despite the design of this give and take system, pharmaceutical companies have prioritized the reward portion of this system over innovation. This is possible by a few patent based strategies such as creating secondary patents and using reverse payment settlements to buy out generic brands (Kesselheim et al., 2017).

In regards to patents for drugs, an array of problems can arise from the use of secondary patents. A secondary patent differs from a basic patent because it protects the manufacturing process of the drug, while a basic patent offers protection for the active ingredient in a product (Gurgula, 2020). Companies will procure a series of secondary patents which extend well beyond the time span of the basic patent in order to own a product for longer. Although the secondary patents extend the life of the basic patent, more often than not, the changes they prevent generic brands from making during formulation are "...modifications [that] may provide little or no

therapeutic benefits to the patient compared to the original drug" (Gurgula, 2020, p. 1059). In essence, some of these patents are solely to preserve ownership and it allows companies to create a monopoly over the production of a drug.

Using secondary patents in this manner inherently goes against the second goal of the patent system which is to promote competition. Abuse of the patent system upon further inspection into the insulin part of the drug sector is evident, because three major pharmaceutical companies have applied this strategy and created a monopoly over the process for producing insulin. The ". . .three major insulin manufacturers serving the United States market [are]: Eli Lilly, Novo Nordisk, and Sanofi" (Herman & Kuo, 2021, p. 5). The fact that a limited number of biogenerics are available for insulin can be attributed to these major suppliers. Due to this monopoly, as already discussed, "One vial of Humalog (insulin lispro), which used to cause $21 in 1999, costs $332 in 2019, reflecting a price increase of more than 1000% " (Rajkumar, 2020, p. 1). Charging such exorbitant prices for a life saving drug should not be allowed, and more restrictions ought to have been put in place so statements like this would not have become a gut wrenching truth.

The second method major pharmaceutical companies have used to keep generic brands off the market is paying them reverse payment settlements. Generic brands have challenged "the validity" of patents presented by companies and often, instead of bringing to light that intellectual property is integral to the process, these companies decide to pay off the generic brands to drop the case (Kesselheim et al., 2017, p. 2). According to Kesselheim and coauthors, "[t]he Federal Trade Commission (FTC) estimates that these settlements cost consumers $3.5 billion annually by preventing or delaying generic drugs from entering the market" (Kesselheim et al., 2017, p. 2). This proves that major pharma companies' objectives are to gain as much

money as possible within the life of their patent. Disregarding generic brands and not allowing them to enter the market supports this belief and makes it apparent what their true agendas are. That is why stopping generic brands from significantly dropping the value of their product even if this implies limiting accessibility for consumers is necessary. To reiterate, paying off generic manufacturers is another way to evade the patent system, which in the long run believes competition breeds innovation. This supports the argument that major pharmaceutical companies should not be allowed to monopolize the insulin industry and that further regulation is needed.

Possible suggestions to combat current problems in this system include implementing more stringent decision making for secondary patents and creating legislation for antitrust laws (Kesselheim et al., 2017). For example, many secondary patents that make small changes to a product which have little to no effect on its efficacy would not be able to pass if the decision making process was stringent. To some extent, the number of secondary patents would decrease and the overall time companies could keep intellectual property would subsequently decline. Second, the implementation of antitrust laws would limit the current power dynamic major pharma companies have. As stated by the financial reporter and senior journalist Alexandra Twin , "Antitrust laws are regulations that encourage competition by limiting the market power of any particular firm" (Twin, n.d.). Putting such legislation into practice would give generic brands more protection from larger competitors and would level the playing field. Although this option seems quite straightforward, there would most likely be push back from the current major companies, and they would try to retain as much power as possible under the new system. To deter this, the transition would need to be swift so as to not give the current monopolies the chance to corrupt the new system by paying off personnel involved in the process.

Major pharmaceutical companies should not be able to charge exorbitant prices by going against legislation implemented to help Medicare Part D participants afford insulin. Medicare Part D is a health coverage plan that insures users for medications such as daily prescriptions which aren't covered by Medicare Part A or Part B; Medicare Part B only covers medicines you might get at a doctor's office such as a shot. Through Medicare Part D, users are able to purchase generic drugs as well as brand name prescription drugs by paying a premium as well as a copayment depending on the tier of the drug (*Your Guide to Medicare Drug Coverage*, n.d.). In theory, this program seems like it would help insulin users afford their medications. However, the network for insulin distribution is complicated and often leaves Medicare Part D users paying more out-of-pocket fees while manufacturers, distributors, and insurance companies turn a profit.

Pricing for insulin can change at several points as insulin transitions from the hands of producers to consumers. According to the chief scientific and medical officer of the American Diabetes Association William T. Cefalu and others, the insulin distribution chain consists of: manufacturers who make insulin, drug wholesalers who sell to pharmacies, pharmacies who sell directly to patients, pharmacy benefit managers who negotiate prices for pharmacies and insurance companies. To begin, manufacturers set a list price for insulin, which wholesalers and pharmacies are able to purchase directly (Cefalu et al., 2018). In regards to trends in pricing over the years, "... the list price of Eli Lilly's human insulin analog, Humalog, [has] increased by 138% between 2009 and 2015, while the net price to the manufacturer increased by 6%" (Cefalu et al., 2018, p. 4). This statement depicts the fact that insulin producers have been increasing prices drastically despite the fact that the actual costs for developing insulin have seen minimal increases. Some of this profit can be attributed to the trend that when one manufacturer increases their list price, other ones follow shortly after, causing the overall price in the market for insulin

to increase. Next, wholesalers purchase insulin from manufacturers, then sell it to pharmacies; however, they usually sell using the highest list price. Following this, pharmacies sell to consumers, but on the backend they are getting prices negotiated with pharmacy benefit managers (PBMs) whose clients are employers and insurance companies (Cefalu et al., 2018). At all of these checkpoints prices for insulin can be negotiated to be a higher price while the consumers of insulin have little to no say in the matter.

Specifically on the manufacturer end, prices for rebates have been increased leading to Part D users paying higher out-of-pocket costs. As stated by physician Chien-Wen Tseng and others, between 2014 and 2019 the out of pocket costs of Part D users "... increased 11% from $1,199 to $1,329" (Tseng et al., 2020, p. 1). According to deputy director of the Program on Medicare Policy at KFF, which focuses on health policy research, Juliette Cubanski, and others, this was possible because manufacturers offer large rebates to PBMs and insurance companies to put their insulin in higher tiers which directly increases the amount plan users pay. Rebates act as a discount for the medication coming from the manufacturer and often PBMs will take the rebate. Despite Medicare Part D being in place, these transactions occur outside its scope, but its users are still affected (Cubanski et al., 2020). The effects can be felt in the tier system which works as follows: a lower tier (Tier 1) under Medicare Part D means the copayment for a user is less, while a higher tier (Tier 3) translates to the individual paying more for their copayment (*Your Guide to Medicare Drug Coverage*, n.d.). In turn, manufacturers negotiating to get their product into a higher tier has led to "...percentage increases in prices for insulin products…[which] translate to higher out-of-pocket spending over time" (Cubanski et al., 2020, p. 11). Tier 3 users are paying the highest out-of-pocket prices possible to obtain the medications they need for everyday life at the expense of PBMs getting a discount and manufacturers

profiting. As a society we should not accept these conditions for insulin users, and we should hold manufacturers accountable to keep affordable prices for those in desperate need of this medication.

In order to combat this gap in Medicare Part D that allows manufacturers to charge more money, suggestions include eliminating rebates and capping the overall out-of-pocket costs insulin users must pay. Eliminating the possibility of getting a rebate from manufacturers would stop PBMs from adjusting the tier they put a medication in. This would be possible if legislation were to be implemented possibly limiting the distribution chain from having so many intermediaries such as the PBMs and wholesalers. For example, in China the "Two-Invoice System" was invoked in 2017; this system allows two invoices to be made before the medicine reaches a patient, one of them being the manufacturer and the other a distributor (e.g. a pharmacy) (Ran et al., 2022, p. 2). If this type of system were implemented in the United States it could help decrease how much insulin prices fluctuate after leaving the manufacturer, and overall restructure the distribution supply chain of insulin. In addition to eliminating rebates, capping out-of-pocket costs for insulin is another option. Recently legislation was passed capping insulin costs for patients at $35 (Cubanski et al., 2020). This solution as well as allowing patients to negotiate the price for insulin, could help insulin users regain some of their power from the current distribution system. These two suggestions in conjunction will help insulin users to afford the medicines they need and help recalibrate the current system. Using any of these recommendations will allow for insulin users to have greater access to the medicine they need while holding pharmaceutical companies and those within the supply chain accountable.

Lastly, the current state of the insulin market should not be acceptable because it limits the amount of research possible to produce a better product. As aforementioned, the abuse of the

patent system has limited competition in the insulin market, and this in turn reduces innovation. To combat the current lack of innovation, more money should be directed into research and development of insulin. Investing in research will incentivize individuals to create biosimilars and can lead to the production of more efficient treatment for diabetics. According to the American Diabetes Association (ADA), sources of funding for diabetes research include the government, the private sector, and the "plural sector" (*Why Are We Failing to Address the Issue of Access to Insulin? A National and Global Perspective | Diabetes Care | American Diabetes Association*, n.d.).

Beran et al., faculty at the University of Geneva and University of Yaounde, suggest a plausible solution to bridge the insulin inaccessibility gap using the government as a regulator; the first step is to invest heavily in research and development. The WHO (World Health Organization) model in this article states that many patents for insulin expired by 2015, and this is the perfect time to develop new technology to replace the current means of using insulin. Examples of new technological innovations include "smart insulin" which reduces a person's risk of hypoglycaemia, which is low sugar levels in the blood (Beran et al., 2021, p. 2). Ways to support these types of research endeavors include getting funds from the government which have the power to regulate the price of medications. This is possible by adding insulin to the current list of priority medications. Doing so will decrease the overall price of insulin since it would be considered essential medicine and this would lead to it being more accessible to patients (*Why Are We Failing to Address the Issue of Access to Insulin? A National and Global Perspective | Diabetes Care | American Diabetes Association*, n.d.).

Using the plural and private sector as funds for research would also shake up the current system which lacks innovation. The plural sector is defined as an entity that acts as a neutral

party. Currently there aren't many organizations that are neutral since many groups seek to profit from insulin production. However, funding research for universities and organizations such as the ADA (American Diabetes Association) would allow the insulin market to flourish (Beran et al., 2021). With universities seeking out ways to improve insulin manufacturing, experiments could be conducted and results would be obtained more easily without the worry of turning a profit like what is seen in pharmaceutical companies. Compared to some companies' research and development departments, universities could serve as good research areas to get unbiased information which then could be scaled up to manufacturing levels. In contrast, the private sector which is profit driven should be used to fund research because if the results are promising they could benefit their company and provide a return on investment. Currently the private sector doesn't try to link diabetes to sustainability goals or enact incentives for helping low income individuals obtain insulin, like how phone providers will build services in lower income regions despite the costs (Beran et al., 2021). If these types of initiatives were taken in the insulin sector, it would help a lot of patients obtain insulin more easily while improving the image of some companies. Companies could also benefit from not losing money in sales to insulin users who are willing to get insulin from out of the country. As stated by Knox, "With the high costs of insulin and the significantly lower prices abroad, some people are already travelling from the United States to Mexico to purchase insulin at a cheaper price" (Knox, 2020, p. 21). By investing in solutions to cheaper insulin production companies, the private sector could profit from these sales which are currently being lost to competitors.

In conclusion, pharmaceutical companies should not be able to charge such high prices for insulin because they are blatantly abusing the patent system, placing Medicare Part D users at a disadvantage for profit, and because the current insulin market limits the amount of research

capable of creating better products for diabetics. All of these instances show how insulin users are being charged at higher prices than what is necessary for the life saving drug. This type of insulin market should not continue because it disproportionately places the burden on insulin users to find a way to get the medication they need rather than protecting their rights to be entitled to this medication despite economic factors. To counteract the current system it is necessary to start with the basics and provide more opportunities for insulin research and development, while concurrently improving legislation to protect insulin users. With these recommendations it will be possible to create an environment where research and innovation are able to thrive, and in turn lead to a better insulin market on both the consumer and producer sides.

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