

# **The Causes and Effects of the Steadily Increasing Price of Insulin in the US**

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science  
University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree  
Bachelor of Science, School of Engineering

Benjamin Hamer  
Spring, 2021

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

Signature \_\_\_\_\_ Date \_\_\_\_\_  
Benjamin Hamer

Approved \_\_\_\_\_ Date \_\_\_\_\_  
Tsai-Hsuan Ku, Department of Engineering and Society

## **The Causes and Effects of the Steadily Increasing Price of Insulin in the US**

### **Introduction**

In 2015, Martin Shkreli, then CEO of Turing Pharmaceuticals, increased the price of the Daraprim, a life-saving drug for AIDS and cancer patients, from \$13.50 a pill to \$750 overnight (Shefali, 2018). Daraprim is an extreme example of an ever-rising healthcare concern in the United States: cost. The burden of the increasing cost of healthcare is particularly important for life-saving pharmaceutical drugs. The most widespread example of this is insulin, a life-saving drug for people with Type 1 or 2 diabetes. In 1921, Frederick Banting discovered the ability to extract insulin from a cow pancreas. He refused to profit off the patent, and his co-inventors sold it to the University of Toronto for \$1. Today, more than 34 million people (~10%) in the United States have diabetes and the average person using insulin in the United States has experienced a daily cost increase from \$7.80 in 2012 to \$15 in 2016.

The US has a free market approach when it comes to healthcare pricing. In theory, this means the price of pharmaceutical drugs are set freely, based on supply and demand principles. A common argument in favor of the free market approach to insulin is that allowing the market to regulate itself promotes innovation. One measure of innovation is patents, and in the US four companies have filed over 200 patents on insulin technology since 1995 (Kaplan and Beall, 2016). However, I want to quantify the benefit of insulin innovations, and if new insulin technology is leading to better health outcomes for patients. More importantly, to establish if this innovation is what the patients need and if it improves patients' quality of life.

This research primarily provides the patients' take on the progression of insulin by surveying them and seeing how their experience using insulin is affected by price increases. These patients can be divided into two groups, with each group having common needs. It is

important to investigate if the needs of the users are filled by the product that pharmaceutical companies provide. Secondly, the benefit of new insulin technology will be investigated as a case study between an old insulin delivery device: syringe and vial, compared to the insulin pen.

### **Literature Review**

There has been copious amounts of research involving the increasing price of insulin over recent years. Although different sources come up with different causes and solutions to the price of insulin, they tend to have thematic similarities. The themes were narrowed down to four: patient choice, technological exclusivity, price negotiation, and government policy. This literature review connects several sources by organizing the research around these themes.

The first theme is patient choice. Patients lack choice in insulin pricing, as their options are limited (Hayes, 2020). The patient's choice is in the physician, who prescribes the medication and patient involvement in the physician's choice is variable. The physician's choice can also be affected by gifts and targeted ads from pharmaceutical companies (Schwartz and Woloshin, 2019). The most well-meaning physicians can be influenced by misleading research financed by pharmaceutical companies such as "Insulin Analogs- Are They Worth It? Yes!" (Gunberger 2014). Grunberger asserts analog insulin is superior to human insulin, but has a clear conflict of interest due to his funding coming from a major insulin provider, Novo Nordisk. He overstates the benefits of analog insulin and other researchers such as the World Health Organization disagree in the generalization that analog insulin is better (Kaplan and Beall, 2016). Studies funded by large pharmaceutical companies can affect the decision making of the physicians who prescribe the medications. The patient also has a lack of choice in insurance due to many Americans' insurance being provided through their employer. This limits their options and

incentivizes insurance companies to lower the cost of insurance for the business, instead of lowering the cost for the patient.

The second theme is technological exclusivity. Pharmaceutical companies are constantly making new patents to push the technology forward, but more importantly, to keep insulin technology under intellectual copyright. Many new patents on insulin technology have been filed in the last few years, and market exclusivity for these products lasts 12 years (Hayes and Barnhorst, 2020). This prevents generic brands from competing with alternatives. The second part of technological exclusivity is pharmaceutical companies sending gifts to and lobbying physicians in order to convince them to primarily prescribe only new products. The World Health Organization has asserted that this new technology has negligible benefit to the patient, especially when compared to increased cost (Kaplan and Beall, 2016). The relationship between the price of insulin and innovation is of particular interest to the engineer. In order to explore this interaction, the main sector of modern insulin innovation was investigated: delivery devices. There are four main insulin delivery devices. Syringes are the traditional delivery device which injects the insulin liquid from a vial using a very fine needle. Insulin pens are single use or reusable devices where you can select the amount of insulin and it loads itself once inserted into the vial. Another option is insulin pumps, which can be operated or run automatically injecting insulin as needed. These are easy to use but can be extremely expensive and somewhat cumbersome. Finally, there is inhaled insulin which is fast acting, but has to be used with long-acting insulin for type 1 diabetics.

The third theme is price negotiation. Most drugs in the United States are priced with a free market approach, but the principle of supply and demand does not work for a life-saving drug like insulin. The consumer for insulin has no choice in the demand, they must buy the drug

to survive, and this need can be abused. Three pharmaceutical companies, Eli Lilly, Novo Nordisk, and Sanofi provide a vast majority of prescribed insulin and insulin delivery systems and they seek to maintain an oligarchy-monopoly system over the prices of insulin (Kaplan and Beall, 2016). The companies can have a “handshake” deal where they take advantage of a market on which they have all the leverage. There is also a lack of transparency in cost for manufacturing and creation of new technology which affects drug prices (Schwartz and Woloshin, 2019). This makes negotiating difficult for the party lacking information. In addition, the consumer has no direct access to negotiation.

The fourth theme is government policy. The government could do more to control drug prices, but actively makes policy which leads to further increases in price (Engelberg, 2015). An example is the FDA being prohibited by law from negotiating prices through Medicare. Pharmaceutical companies also receive millions of dollars a year in funding for research and development from the government (through taxpayers). However, patients do not see any reduction in their cost from this funded money. These companies also spent \$171 million in 2017 lobbying politicians to have favorable policy (Lucas and Hancock, 2018).

### **STS Framework/Research Method**

Primarily, this thesis will enhance previously done research into patient choice. Patient choice will be analyzed using the Social Construction of Technology (SCOT) framework. The first step of this framework is to divide patients into relevant social groups which have similar needs. Insulin patients were divided into two relevant social groups according to their insurance type: private or employer insurance, and Medicare or Medicaid. The Medicare/Medicaid group consists of people over 65, or people under a low yearly income threshold. These people have lower yearly wages and are more likely to have other health problems besides diabetes. The

private/employer group consists mainly of the active workforce. This group tends to have more disposable income and is less likely to have other medical conditions. This type of grouping is convenient because it separates vulnerable patients (Medicare/Medicaid) from the less-vulnerable (employer/private insurance). The next step in SCOT is to determine the needs or problems of the identified social groups. Obviously, both groups want the best health outcomes, but one group may prefer a lower cost over the best possible insulin. The initial plan was to survey diabetics using online forums, however this endeavor was not successful, as it was difficult to reach enough people for significant results. Instead, a survey commissioned by the American Diabetes Association was used. This survey asks patients in the relevant social groups about their experiences with insulin use, with particular emphasis on price. These established needs of the social groups can be applied to the insulin technology which is provided by pharmaceutical companies. The hypothesis that pharmaceutical companies are not communicating with social groups, because they provide a product which does not address their needs, can then be evaluated.

The theme of technological exclusivity will also be investigated using document analysis. This theme is particularly interesting to engineering and engineering ethics due to its close relationship to innovation, which is central to an engineer's responsibilities. Insulin technology is an incredibly complex topic. The cost and health outcomes of insulin technologies are difficult to measure due to the long-term nature of diabetes, as well as efforts by pharmaceutical companies to hide their costs. First, the insulin drug itself will be investigated by looking at current insulin drugs, and their alternatives or prospective alternatives. Secondly, insulin delivery devices will be investigated. There are many insulin delivery devices, and it is difficult to determine the relative costs and benefits of different devices. Technological exclusivity in delivery devices can

be simplified and investigated in the form of a case study between two insulin deployment methods: insulin pens versus vial and syringe. The insulin pen is particularly useful as a case study between old and new technology due to its simplicity. In contrast to an insulin pump/artificial pancreas, the insulin pen is a simple mechanical device, which allows it to be easily compared to the syringe in terms of cost and effectiveness.

### **Data Analysis**

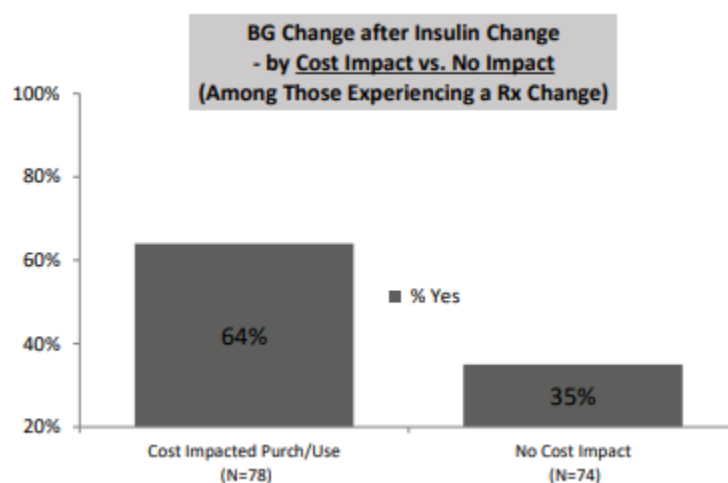
Vault Consulting conducted a survey of 535 individuals who use insulin in 2018. The participants are caregivers of child insulin users, adult insulin users, or caregivers of adult insulin users. The users were also surveyed based on demographics, as well as geography, in order to be representative of the insulin user population. Using SCOT, insulin users are divided into relevant social groups by insurance type: private insurance, employer insurance, Medicare, and Medicaid. (There are also people who have veteran-status insurance and no insurance, but they were excluded from analysis due to low representation.) These groups tend to have consistent needs from their insulin, which can be determined based on decision making around insulin use. Insurance-based groups also reflect the key aspect of this thesis: the price of insulin. Insurance is the most important indicator of how much as well as what type of insulin/insulin deployment the patient can afford.

**Table 1: Survey respondents divided by insurance type (Vault, 2018)**

<b>Insurance Type</b>	<b>Respondents</b>	<b>2016 National *</b>
Insurance bought through employer or spouse's employer	37%	49%
Insurance bought individually	13%	7%
Medicare	28%	19%
Medicaid	13%	14%
TRICARE or Veterans Affairs	4%	2%
Other Government health insurance plan	3%	
No current health insurance coverage	3%	9%

From 2017 to 2018, 39% of all insulin users experienced an increase in the amount they personally pay for insulin. Of these, 72% indicated it increased slightly and 17% indicated it increased greatly. The social groups experienced this price increase relatively equally. However, this price increase can have different effects on each social group depending on their ability to absorb increased financial burden.

**Figure 1: Blood Glucose change as affected by cost (Vault, 2018)**



By looking at the ways cost affects insulin use/purchase, the divide between those who have employer/individual insurance and those with Medicare/Medicaid becomes evident. From 2017 to 2018, 30% of all insulin users changed their insulin prescription. When this change in prescription was due to cost, 64% of patients experienced a blood glucose change versus just 35% of patients who changed for a different reason. This change in blood glucose due to cost shows the real impact of increasing prices. Medicare/Medicaid patients are more likely to change insulin due to cost. Those who changed insulin due to cost were more likely to experience instability in the form of blood glucose change. Additionally, as seen in Table 2, those with Medicare are less likely to take their prescribed dose, and a majority of patients with Medicaid underdose. The Medicare/Medicaid group was more likely to miss 1-2 doses per week and more



than twice as likely to change to a cheaper insulin in order to afford it. Increasing insulin prices disproportionately affect the Medicare/Medicaid group because that group has less wealth in order to afford increasing costs. This reflects a need for the Medicare/Medicaid group for decreased prices over a need for better insulin.

**Table 2: Ways cost impacts insulin purchase/use (Vault, 2018)**

	Total	Employer	Individual	Medicare	Medicaid
	(A)				
Base: Amount personally paid affected how purchased insulin in past year in Q17	(133)	(49)	(23)*	(35)	(16)*
<b>Regularly take less than the prescribed dose</b>	<b>26%</b>	<b>18%</b>	<b>17%</b>	<b>26%</b>	<b>63%</b>
<b>Missed 1-2 doses per week</b>	<b>23%</b>	<b>10%</b>	<b>22%</b>	<b>31%</b>	<b>25%</b>
<b>Dr/I chose a cheaper insulin</b>	<b>23%</b>	<b>18%</b>	<b>13%</b>	<b>31%</b>	<b>31%</b>
<b>Missed 1-2 doses per month</b>	<b>20%</b>	<b>22%</b>	<b>9%</b>	<b>20%</b>	<b>19%</b>
<b>Used a patient assistance program</b>	<b>20%</b>	<b>18%</b>	<b>30%</b>	<b>20%</b>	<b>29%</b>
<b>Used a discount drug website/program</b>	<b>20%</b>	<b>27%</b>	<b>26%</b>	<b>11%</b>	<b>6%</b>
<b>Did not fill at least one prescription</b>	<b>18%</b>	<b>20%</b>	<b>17%</b>	<b>14%</b>	<b>13%</b>
<b>Used a rebate or coupon</b>	<b>17%</b>	<b>16%</b>	<b>35%</b>	<b>6%</b>	<b>25%</b>
<b>My health/Rx plan chose a cheaper insulin</b>	<b>14%</b>	<b>12%</b>	<b>9%</b>	<b>23%</b>	<b>19%</b>

Both underdosing or changing insulin, in order to reduce the financial burden of insulin, results in negative effects. When cost affects insulin use, measurable negative outcomes such as severely low blood sugar and ER visits increase (Table 3). Many patients who adjusted insulin use due to cost had other negative physical health effects. In addition to these physical health

**Table 3: Negative health outcomes as affected by cost (Vault, 2018)**

	All	Cost Affected Purchase/Use	Cost Did NOT Affect Purchase/Use
Experience severely low blood sugar episodes past 3 months	54%	72%	42%
Have had at least 1 ER visit in past 3 months	32%	53%	22%
Last A1C 7.5 and above	65%	80%	59%
<16 hours/day spent in recommended blood glucose range	62%	80%	56%

effects, patients had to sacrifice their lifestyle. Nearly, 40% of respondents chose between insulin and entertainment and 35% chose between insulin and vacation. Of those who experienced a price increase, 70% reported stress/anxiety as a result of the price increase. These negative

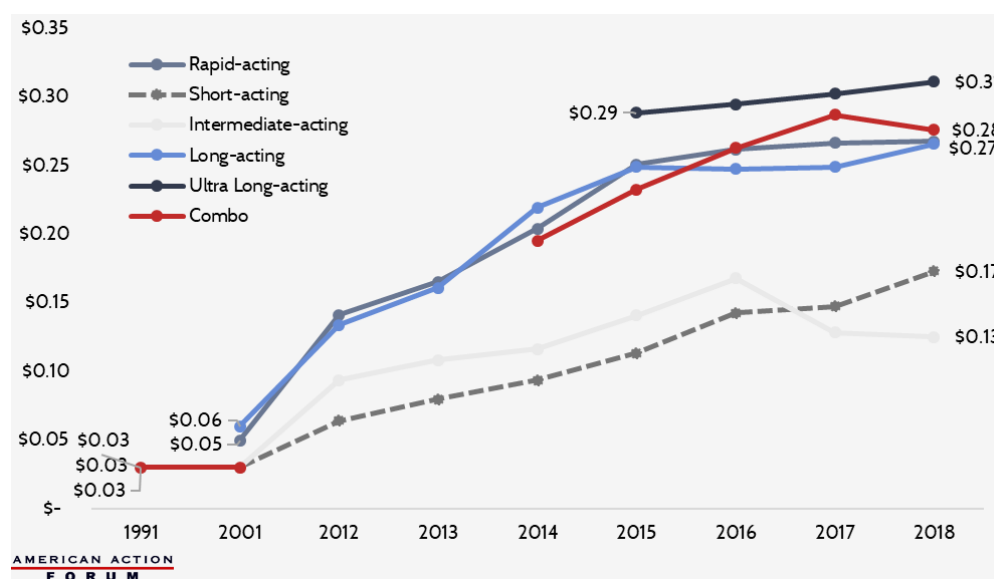
effects disproportionately hurt those in the Medicare/Medicaid group because they are more likely to ration insulin or pick based on cost rather than what is best for their health. This again points to the need for decreased price. The Medicare/Medicaid group is suffering in particular because they are being forced to under-utilize their insulin in order to be able to afford it. Many of the problems they are experiencing would go away if they could simply afford to take their prescribed dosage.

The main assertion in the prospectus was that the communication channel between pharmaceutical companies and insulin users was broken down. This is backed up by the testimony of those who experienced a price increase. There is a profound, negative physical and psychological impact on patients who struggle to afford insulin. There are also measured negative effects such as ER visits and variable blood glucose levels as a result of insulin price increase. These negative effects are felt disproportionately by patients on Medicare and Medicaid, as they do not have excess wealth to absorb the increased financial impact. These negative effects are a reflection of the Medicare/Medicaid social groups need for insulin technology to be cheaper. The Medicare/Medicaid group consists of nearly 35% of insulin users, and their needs from the insulin product are being completely ignored. The exclusion of this need directly causes worse health outcomes on those who struggle to pay for insulin. This is in direct contradiction to the assertion that the increased price of insulin is a result of a better product which positively affects patients. Increasing the price directly causes more negative outcomes. Increased prices hurt the employer/private insurance group financially, but the Medicare/Medicaid group's overall quality of life is negatively impacted.

Another angle on the price of insulin is the cost of the drug itself. Currently, analog insulin dominates the market, and is primarily produced by Novo Nordisk, Eli Lilly, and Sanofi.

These three companies are involved in anything having to do with insulin. The ADA found that Lilly, Novo Nordisk, and Sanofi represent 99% of the total insulin by value, 96% by total market volume, and 88% of global product registrations. Novo manufactures insulin products in 111 countries, Sanofi has products registered in 101 countries, and Eli Lilly has products registered in 94 countries (Priyanka, 2018). From 2001 to 2014, the price of insulin has increased an average of 9% per year (Figure 2). There is clearly collusive price-fixing between these three companies, but there are ways to combat this.

**Figure 2: Average Price of Insulin from 1991 to 2018 (Hayes and Barnhorst, 2020)**



One typical result of high prices is the development of generic alternatives, biosimilars. One study estimated that the cost of insulin could be reduced to \$78-130 a year by having a competitive biosimilar market, rather than just a few companies (Howe, 2021). In 2013, Merck began developing a biosimilar to Sanofi's Lantus insulin. They eventually received FDA approval in 2017, but had production held up due to litigation from Sanofi (which can last up to 30 months). Merck eventually terminated the biosimilar program based on Sanofi's Lantus due to cost of development. Similarly, Mylan, along with Biocon, also attempted to make a biosimilar,

but have been met with a similar lawsuit (Digrande, 2021). These two examples show the power that technological exclusivity through patents and other intellectual property protects can grant. Sanofi, Novo Nordisk, and Eli Lilly make it extraordinarily difficult and expensive, even for large companies like Merck and Mylan, to enter into the insulin market. This allows insulin prices to continue to increase with no available alternatives for patients.

The main avenue of insulin innovation is in delivery devices, specifically to compare the price and efficacy between insulin pens versus syringe and needle. Many researchers note the lack of direct comparisons and clinical and economic outcomes between the vast array of insulin products. There are some studies comparing the insulin syringe to pens, but their results vary. Prescription costs are higher for pens than syringes per year (\$535 vs \$670) (Thethi, 2013). However, overall costs tell a different story. Insulin pens tend to lead to higher compliance than vials/syringes (53% to 69% for pen devices versus 50% to 62% for vials/syringes) (Rasca, 2017). This higher level of compliance of the pen leads to better health outcomes and less emergency and inpatient visits, which saves money. In comparison to the traditional insulin syringe, Baser found no difference in annual cost for the pen, while Cobden found annual costs decrease by \$1748 per patient and Lee found a decrease of \$1590 per patient (Thethi, 2013). The health and economic benefits of an insulin pen over the syringe are a positive sign for innovation in a field where innovation has been pointed to as a problem. Insulin pens are marginally more expensive initially, but increased compliance makes them cheaper in the long run. The insulin pen is an innovation which is beneficial in a classical way, as it results in better health outcomes. Additionally, the insulin pen can be connected to SCOT, by addressing the Medicare/Medicaid patients' need for reduced cost. This case study shows that the problem with insulin pricing is not innovation itself, but how innovation is used as one of many tactics to increase the price of

insulin. The insulin pen is truly an object without ethics. It acts as an indicator of the power of the insulin network, which uncontrollably increases prices.

### **Conclusion**

Healthcare innovation is conducted in the name of better, more effective products. However, the negative impact of the increasing price of insulin shows that this innovation is not worth the current price increases. From 2017 to 2018, a majority of insulin users experienced a price increase, and many of those changed their insulin prescription due to this price increase. Additionally, a considerable portion of insulin users reduced insulin purchase or use just to be able to afford it, which results in worse health outcomes. Patients who change their insulin use due to price were more likely to have unsteady blood glucose levels and experience physical and emotional side effects (Vault, 2018). These negative outcomes affect the Medicare/Medicaid social group more, due to their inability to absorb increasing prices. Their needs from insulin technology are ignored, as they are a minority of the patient group (35%). Rather than being designed around patient needs, insulin technology is priced to extract more wealth from the patients by pricing around the more wealthy private/employer insurance group.

Novo Nordisk, Sanofi, and Eli Lilly control the insulin technological system and are able to use technological exclusivity as a tool to control the market. These companies use the insulin drug itself as well as delivery devices as ways of maintaining control of the system. These companies can collude to raise the prices of analog insulin, and litigate to prevent cheaper alternatives from being developed and sold. The insulin pen shows that innovation can still do good in this industry, by simultaneously reducing price and improving health outcomes. Patents and intellectual property are tools of the pharmaceutical industry which are used to maintain control over the insulin market. These tools allow Novo Nordisk, Sanofi, and Eli Lilly to

increase their market share, expand their global reach, and generate more wealth. They control the market by promoting new, exclusive insulin products and litigating potential competitors.

## References

- Cefalu, T. (2018). Insulin Access and Affordability Working Group: Conclusions and Recommendations. American Diabetes Association.
- Digrande, S. (2021). Merck Terminates Follow-on Insulin Agreement with Samsung Bioepis. AJMC.
- Engelberg, Alfred B. (2015). How Government Policy Promotes High Drug Prices. Health Affairs.
- Grunberger, George. (2014). Insulin Analogs- Are They Worth It? Yes! American Diabetes Association.
- Hayes, S. and Barnhorst, M. (2020). Understanding the Insulin Market. American Action Forum.
- Hoskins, Mike. (2020). Moving the Needle on Insulin Pricing: the Bernie Sanders Bus and Beyond. Healthline.
- Howe, D. (2021). How Much Does It Cost To Produce Insulin? Beyond Type 1.
- Insulin. (2020). Advameg, Inc.
- Kaplan, W. and Beall, R. (2016). The global intellectual property ecosystem for insulin and its public health implications: an observational study. PubMed Central.
- Lucas, E. and Hancock, J. (2018). How High Drug Prices and Big Lobbying Budgets Go Together for Big Pharma. Fortune.
- Luo, J., Khan, N., Manetti, T. et al. (2019) Implementation of a Health Plan Program for Switching From Analogue to Human Insulin and Glycemic Control Among Medicare Beneficiaries With Type 2 Diabetes. Jama Network.
- Luthra, Shefali. (2018). ‘Pharma Bro’ Shkreli Is In Prison, But Daraprim’s Price Is Still High. KHN.
- Pinch, T. and Bijker, W. (1984). The Social Construction of Facts and Artefacts. Social Studies of Science.

- Priyanka. (2018). Globally, Top 10 Insulin Manufacturers Are Dominated by Europe and North America. Envision Intelligence.
- Rasca, P., Meah, Y., Ellis, J., et al. (2017). Comparative Effectiveness of Rapid-Acting Insulins in Adults with Diabetes. JMCP.
- Schwartz, L. and Woloshin, S. (2019). Medical Marketing in the United States, 1997-2016. Jama Network.
- Sismondo, Sergio. (2010). An Introduction to Science and Technology Studies: Actor-Network Theory. Wiley-Blackwell.
- Thethi, T. (2013). Comparing insulin vials to pens – comparison of charges, not healthcare benefits. Taylor and Francis Online.
- Vault Consulting, LLC. (2018) Insulin Affordability Survey. American Diabetes Association.