## What is the cost of a life?

For some people, smuggling drugs across the border is a life or death situation. American citizens plan elaborate trips to Mexico and Canada to return with thousands of dollars worth of life saving drugs. These people aren't trying to get high. They're just trying to stay alive. Crossing the Canadian and Mexican borders for insulin has become a common practice for millions of Americans living with diabetes. In 2016, Americans with type one diabetes spent an average of \$5,705 on insulin for just one year. (Biniek, Johnson) Which simplifies to about \$475 per month just to stay alive. For Americans without insurance or high deductibles, this number reaches as much as \$1,300 per month. (Stanley) In Mexico, a box of Lantus Basal insulin costs \$70, compared to \$693.40 in the states. (Crossman) Even when you include travel cost and time taken off of work, traveling across the border is still cheaper than buying insulin in the United States. In her article for T1international, Robin Crossman said she was "Literally shaking" after hearing the price difference on a trip to Tijuana after running out of her insulin due to the inability to finance her high deductible. (Crossman) These high prices have left Americans desperate to try anything to get insulin, from border jumping, to creating gofundmes, and even rationing their insulin dosages. While smuggling pharmaceuticals across the border is illegal, insulin rationing is still the most dangerous of these practices. Insulin rationing is when patients with type one diabetes take a smaller dose than directed by their doctor in an attempt to make their insulin supply last longer. This practice is used in response to the huge financial burden of diabetes. In 1921, resilient surgeon Frederick Banting injected his first human patient with

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insulin. Insulin is a hormone discovered in the pancreas that helps convert glucose to energy.

Before this was known, patients who suffered from diabetes were treated with starvation diets and died within a few years after diagnosis. (Bliss) His discovery gave patients diagnosed with diabetes another chance at life. Banting and his team sold the patent for insulin for \$1, hoping to keep it accessible to everyone. (Bliss) In an interview for the Washington Post, Micheal Bliss says "these were discoverers who were trying to do a great humanitarian thing, and they hoped their discovery was a kind of gift to humanity" (Stanley) Banting is quoted saying "Insulin does not belong to me, it belongs to the world." (Bliss) Not long after the patent was sold drug companies began manufacturing insulin, and the prices skyrocketed. In 2019, a month's supply of Humalog fast acting insulin is \$320. In addition to a fast acting Insulin, Patients with diabetes will spend about \$1,000 per month on medical supplies just to stay alive. (Rowley) These supplies include fast acting insulin, slow acting insulin, test strips, alcohol swabs, syringes, blood glucose meters, glucose tablets, and glucagon kits. While Banting did not believe Insulin belonged to him, drug manufacturers do not share the same mindset. Insulin prices have been steadily rising, leaving 50% of 100 million patients without reliable access to life sustaining medication. (Barber). It is possible to make insulin more accessible in the United States with more generics, stricter patent laws, and price regulation by the government.

For most drugs, the generic versions are about 80% cheaper. For insulin the generics are only 20% cheaper.(T International) Insulin is a biologic, a substance made from living things, which makes it much harder to make a generic compared to chemically synthesized drugs. In the past insulin for humans was extracted from animals, but today it is made using bacteria. The nature of insulin makes it extremely hard to produce generics that act the same as the original.

John Rowley compares it to baking a cake without recipe in his article for T1international, "The situation is a bit like trying to recreate a friend's sponge cake without having their recipe. After a lot of work and time you will probably be able to make a very similar cake, but the method you use will almost inevitably be different from that of your friend."(Rowley) Even after a biosimilar is made, it must go through rigorous testing to determine if it works as well as the novel drugs. This is another factor that offsets production of generic insulins. Only 3 companies, Eli Lilly, Novo Nordisk, and Sanofi, produce 90% of all insulin. (T1international) While production of biosimilars of insulin is possible, they are mostly made by these same three companies. Since these companies control the generics as well, the prices remain high.

The patent system was originally set into place to encourage competition and reward the hard work of indivuals. Today, this system is abused by drug companies to create monopolies. President Trump is quoted on his speech on drug pricing in 2018 saying "Our patent system will reward innovation, but it will not be used as a shield to protect unfair monopolies." (I-MAK) A

patent for a drug normally lasts 20 years. Through a process called evergreening insulin companies have made patents last much longer. Evergreening is when drug companies take out multiple patents on the same drug in an attempt to create a competitive free market. This process makes it nearly impossible for biosimilars to enter the market. Sanofi, the company that produces

Lantus, has created a competition free market for the next 37 years through evergreening. (T1international) Sanofi did this by filing 74 patent applications after the drug was already on the market. (I-MAK) This abuse of the patent system has allowed Lantus to have a price increase of

114% since 2012. (I-MAK) This evergreening has lead to diabetics being forced to pay full price for a life saving medication, without the option of a generic.

Lack of intervention by the government has also let insulin prices creep up over the years. In 2019, Colorado passed a law capping the cost of insulin at \$100 a month. As mentioned previously, the average cost of insulin per month is \$475, so this kind of price cap would make a massive difference for people living with diabetes. 26% of Americans ration insulin because of the cost. (Bailey) If this type of regulation was implemented nationwide, it could help lower this number and make insulin more accessible. One limitation of this law is that it does not help patients who don't have insurance. The Alec Smith Emergency Act was attempted to be set into place in 2019. It was named after a Minnesota man who died after insulin rationing in 2017. (Lagarde) This law would make it possible for patients with type one diabetes to fill emergency insulin prescriptions at no cost. This act was first set into motion by his mother after his death. The act did not pass, but got a lot of attention. This kind of procedure could prevent deaths due to insulin rationing.

One in four families have a hard time paying for their prescriptions. (I-MAK) It has been suggested that using older, less stable versions of insulin could help patients who cannot afford access to newer insulins. "Walmart Insulin" has been a cheap solution offered to patients. This insulin is sold for \$25 a vial. This seems like a great way to cut costs, but it will also cut quality. This insulin was approved by the FDA in 1950. At this time, diabetics would have to inject insulin 3 to 4 hours before meals opposed to 15 minutes for modern humalog. This would cause

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unstable and unpredictable blood sugars, as well as a rigid eating schedule. This would result in higher A1C levels, which can cause problems such as eye and kidney disease(Nichols) While this cheaper insulin would keep patients alive, it would not help their quality of life. NPH insulin can be used as a temporary, emergency solution for diabetics who can't afford insulin. It cannot be used as a long term solution to treat diabetes because of it's unpredictable nature.

On a summer Tuesday in 2018, Laine Lu found her boyfriend, Alec Smith, dead in his apartment. He had complained of abdominal pain and fatigue for weeks. His death was ruled as a result of Diabetic Ketoacidosis. (Stanley) Diabetic Ketoacidosis is described by endocrinologist Marina Basina as "the most serious and life-threatening diabetes emergency. It's characterized by severe insulin deficiency, severe hyperglycemia (high blood sugars) and increased production of counter-regulatory hormones such as glucagon, adrenaline, cortisol and growth hormone." (Boise) If left untreated, a patient suffering from Diabetic Ketoacidosis will die quickly. Alec made too much to qualify for medicaid, but still could not afford the out of pocket costs for his insulin. His monthly pharmacy bills totaled over \$1,300 which was more than his biweekly paycheck. Alec had been skimping on his insulin doses in an attempt to save money and ultimately paid the price. He was only 26 years old, and had been kicked off of his parent's insurance only a month prior to his death. (Stanley) After his death, Alec's mom became an advocate for affordable insulin. In an interview with T1international she says "My son was in the prime of his life, he had so much to look forward to. I will never get to see him fall in love, marry the woman of his dreams or raise a family. I will never get to see him tackle the dreams he had. I will never get to spend another Christmas or birthday with him, he will never get to see his daughter grow up and he will not be there on her wedding day to walk her down the aisle."

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(Wofford) Sadly, this story is not uncommon. Several people die each year due to insulin rationing related to the raising prices of insulin. Even with insurance or well paying jobs, one emergency can make it impossible for a patient with diabetes to be able to afford their medication. Insulin prices are not just robbing wallets, they're robbing families of their loved ones. With more generics, stricter patent laws, and more regulation from the government, insulin can become more accessible. Affordable insulin will prevent stories like Alec's from repeating. A push towards a reform in insulin prices can help make deaths from insulin rationing a thing of the past.

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