THE TRUTH ABOUT INSULIN PRICES

PATIENTS FOR AFFORDABLE DRUGS

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Almost 30 million Americans live with diabetes — a disease that can cause organ damage and death if not treated with insulin or other appropriate therapies. Today, three drug manufacturers control the global insulin market and have raised prices on American patients by nearly 300% in the last ten years.[1]

This report tells the story of how the insulin crisis came to be, and what we can do to fix it.

A MEDICAL BREAKTHROUGH

Before the invention of insulin in 1921, people with type 1 diabetes had few treatment options and rarely lived more than a few years after diagnosis. When Frederick Banting, Charles Best, Bertram Collip, and John Macleod first extracted animal insulin for use in humans, they knew it would revolutionize diabetes treatment forever.[2]

The inventors of insulin refused to put their names on the patent because they believed it was unethical to profit from a public health breakthrough that would save millions of lives. The scientists famously wanted insulin to be accessible to everyone and realized they needed help scaling their operations to meet demand.[3] So Banting, Best, and Bertram sold the rights to insulin for $1 each and partnered with drug manufacturer Eli Lilly. Although the company deserves credit for the initial production and distribution of insulin, its involvement marked the beginning of a narrow corporate stronghold on insulin that would place profits ahead of patients for years to come. By 1941, Eli Lilly and two other insulin makers had already been accused of price fixing — a troubling indication of future behavior. Today, the insulin market is run by a global cartel that is still fraught with unethical behavior almost eighty years later.[4]

$12 Billion

federal spending on Lantus, Humalog, and Novolog products in 2017

1 in 4

number of patients with diabetes who ration their insulin

300%

the amount drug corporations increased U.S. insulin prices in the last ten years

THE INSULIN MARKET IN 2019

The year 2021 will mark the 100th anniversary of insulin's discovery, but modern versions of the drug remain out of reach for countless diabetic patients across the United States. One in four Americans ration their insulin due to the high price of the medication.[5]

The principal reason for this is that three companies — Eli Lilly, Novo Nordisk, and Sanofi — control 99% of the global insulin market.[6] These companies employ a range of questionable business tactics to effectively neutralize all threats to their profits.

Price Gouging and Price Fixing

Evidence shows that it costs between $2.28 and $3.42 to produce a vial of human insulin and between $3.69 and $6.16 to produce a vial of analog insulin.[7] Despite low production costs, the price of insulin has nearly tripled in the past ten years.[8] For example*:

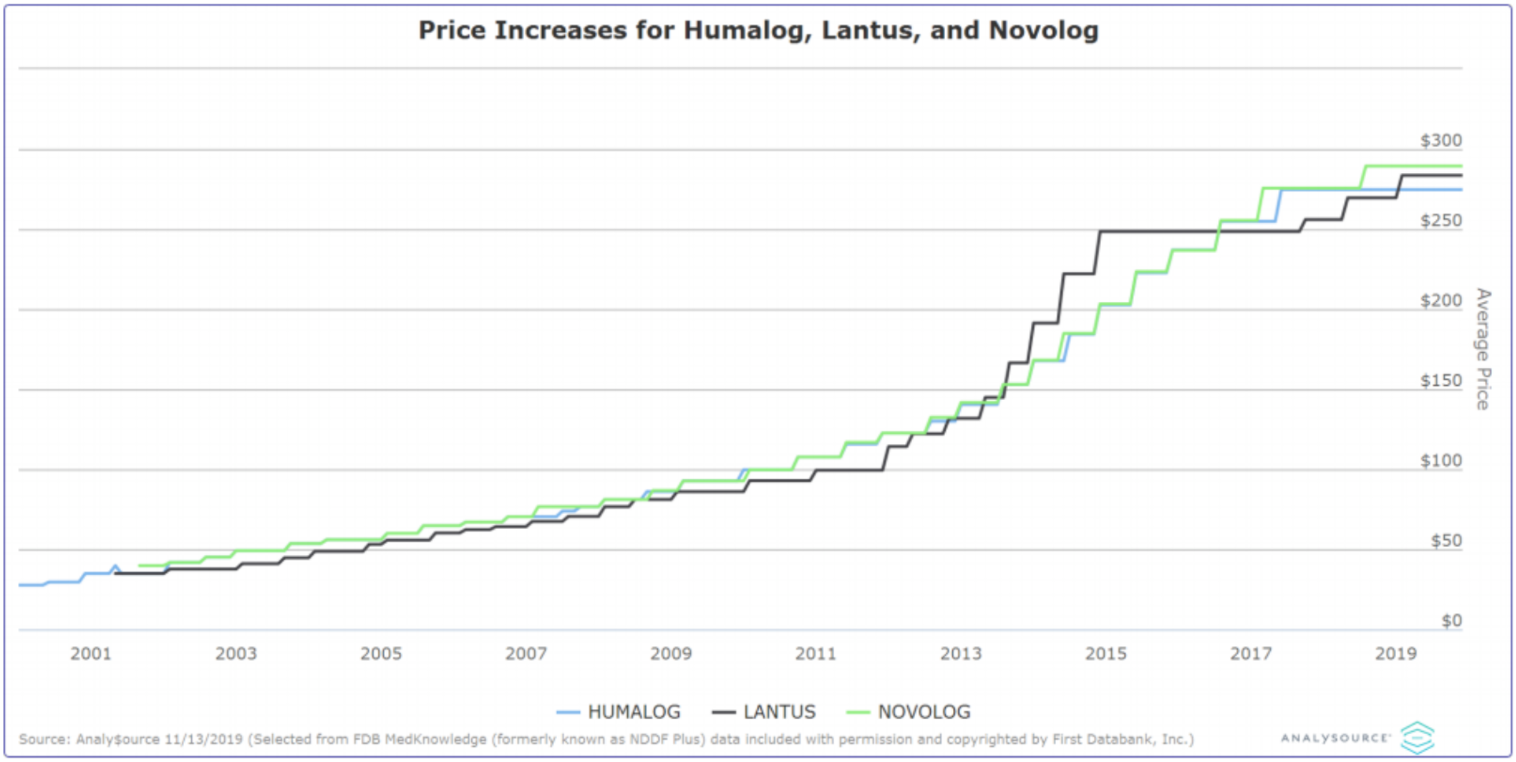
- **Eli Lilly's** Humalog insulin came onto the market in 1996 at a price of $20 and now carries a list price of $275 — more than a 1200% increase.[9] This series of 34 price hikes has provided Eli Lilly with $35 billion in sales since the drug launched.[10]
- Despite entering the market in 2001 with a price of $34, **Sanofi** has hiked the price of Lantus insulin 27 times. It is now $284 and Sanofi makes $15 million a day selling it.[11, 12]
- The price of **Novo Nordisk's** Novolog insulin has risen from $39 to $289 in the 18 years it has been on the market.[13] This 628% price increase has brought the company more than $150 billion in sales on the product.[14]

The presence of three companies in the insulin market should mean competition to drive down prices. However, the insulin cartel recognizes that price competition is a threat to revenue and profit, so the companies signal to each other that they do not intend to lower prices in an effort to capture the market share. They even take this form of collusion one step further and increase their prices in lockstep — a practice called shadow pricing.[15]

"In the 40 years that I've had type 1 diabetes, the biggest hurdle has always been affording my insulin. The formula that I currently use has been on the market since 1996 - and what used to be $25 a vial is now $350 a vial. These prices do not allow for any disposable income in my household, we always must budget for my medication first. If my insulin is unexpectedly expensive for the month, my mortgage is in question. We can not just go out to eat or put gas in the car without planning. Everything I do I have to plan."

- Gail DeVore, Colorado

*Price for a package of 10 vials at 100 unit/mL



This chart depicts shadow pricing between Eli Lilly, Novo Nordisk, and Sanofi. As you can see, the prices for Novo Nordisk's Novolog and Eli Lilly's Humalog almost completely overlap, demonstrating the companies' tacit agreement to increase prices in sync. With no generic competitors on the market to undermine the price hikes, these brand companies are allowed to take advantage of their stranglehold on the insulin market.

GAMING THE PATENT SYSTEM

How can a drug invented in 1921 still have patent protection? The U.S. patent system is designed to reward innovation by conferring 20 years of patent protection and a temporary market monopoly; after exclusivity expires, generic entry is intended to propel competition and lower prices. To avoid competitive threats, Eli Lilly, Novo Nordisk, and Sanofi surrounded their drugs with patent protection by engaging in practices such as evergreening and patent thicketing.

Insulin manufacturers make incremental changes to products in order to gain new patents that prolong their monopolies. Up to the late 1990s, many of the changes brought by drug manufacturers were meaningful improvements in the safety of insulin products.[16]However, in recent years, these truly innovative improvements have slowed. And the changes from the 90s should be nearing or already reached patent expiration.

Instead, insulin manufacturers have manipulated the patent system to achieve protection until 2030 or later.[17] They do this by applying for multiple, overlapping patents. This tactic effectively creates a thicket of protection around their most valuable property — insulin. For example, Lantus — a long-acting insulin made by Sanofi — is protected by a portfolio of 49 patents that will block competition for 37 years.[18] Ninety-five percent of these patents were filed after Lantus entered the market in 2001. Sanofi's original patent on Lantus insulin expired in 2015, but due to the company's gaming of the system, generic entry is barred until 2028 or later.[19] Sanofi is not the only manufacturer engaging in manipulative tactics to prolong its monopoly. Novo Nordisk's Novolog, which entered the market in 2001, has obtained patent protection through 2032.[20] Eli Lilly has made spin off versions of its blockbuster insulin, Humalog, which entered the market in 1996, providing it with patent exclusivity until 2024.[21] These practices are abuses of the patent system that enable the insulin cartel to extend and exploit its monopoly pricing power and hike prices for as long as possible. And as a result of this gaming of the patent system, no sophisticated generic insulin exists.

BUYING INFLUENCE

Amid public backlash and rising political pressure, pharmaceutical companies are spending record amounts on campaign donations and lobbying. Insulin manufacturers leverage their Washington influence to protect their control of the insulin market and their ability to inflict high prices on patients who rely on insulin. In 2017, Novo Nordisk spent $3.2 million on federal lobbying.[22] To date in 2019, Eli Lilly has channeled $5.1 million into federal lobbying efforts.[23]

PRICE FOR TAXPAYERS

It's not just patients who are price gouged by these three companies. American taxpayers carry a large burden of the cost as funders of Medicare and Medicaid — the nation's largest health insurance programs. Take Medicare, the health insurance program for older Americans and people with disabilities; in 2017, insulin spending in Medicare's Part D program exceeded $13 billion — an 840% increase from 2007. The program's spending per beneficiary on insulin increased from $862 to $3,949 over a recent nine year period.[24] Lantus insulin consistently ranks among Medicare Part D's top five most costly medications while raking in blockbuster revenue for its maker, Sanofi.[25] Similarly, Eli Lilly's Humalog generated over $2.8 billion in revenue in 2017 — more than $1 billion of that was from the federal government.[26, 27]

In 2017, insulin products were the second most costly group of drugs for the Medicaid program, which serves our nation's low-income populations and millions of children. For Novolog, Humalog, and Lantus products, Medicaid spent over $3 billion in 2017.[28] Spending per insulin prescription in Medicaid nearly doubled in just three years.[29] The increase in spending for these insulins is largely due to Sanofi, Eli Lilly, and Novo Nordisk's annual price hikes on the medications. Due to the price gouging from these three companies, our nation's most vulnerable citizens are being exploited and taxpayers pay the bill.

Prices of Non-Insulin Diabetes Medications[30]

	Januvia	Avandia	Tradjenta	Bydureon Pen	Byetta	Farxiga	Invokana	Jardiance
Current Price	$1,354	$228	$1,308	$699	$729	$492	$1,482	$1,478
% Increase Since Market Entry	209%	45%	115%	59%	71%	58%	88%	64%

There are two types of diabetes: type 1 diabetes, which requires the use of insulin, and type 2, which is either managed with non-insulin medications or insulin, depending on severity.[31] For type 2 diabetics who rely on oral diabetes medications, treatment often comes at a steep price.

THE IMPACT ON PATIENTS

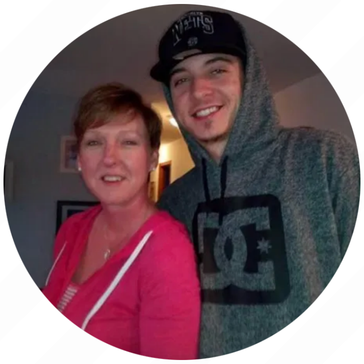
Millions of Americans living with diabetes are forced to make hard decisions such as purchasing their medications or paying for other necessities like food and rent. Since type 1 patients require insulin to survive, many have resorted to rationing insulin or traveling to other countries to purchase the drug.

Rationing

Diabetic patients forced to make the difficult and dangerous decision to ration their insulin are not rare. Research shows that 25% of diabetic patients report changing their insulin use due to cost, including using less than what is prescribed or stretching out vials as long as possible. These decisions lead to persistent high blood sugar which can result in infections, organ damage, and death.[32, 33]

In fact, deaths due to insulin rationing have become tragically more frequent in recent years. Nicole Smith-Holt lost her 26-year-old son Alec to diabetic ketoacidosis — a deadly condition that results from rationing — three days shy of his payday because he couldn't afford his $1,300-a-month insulin and supplies.[34] **In 2019 alone, reported deaths from insulin rationing have included: Jesimya David Scherer-Radcliff, 21;[35] Kayla Davis, 29;[36] Josh Wilkerson, 27;[37] Meaghan Carter, 47;[38] and Jada Louis, 24.[39]**

PATIENT STORIES: RATIONING



“My son died because he could not afford his insulin. There was nobody to be there with him, to hold his hand or to call for help. I think about if he had never moved out, if he had lived at home, somebody would've seen the signs. I'll probably feel guilty every day for the rest of my life. I felt like Alec’s death was such an isolated incident, and it’s not. This is happening far too frequently. He would be here if his life-saving medication was priced at a reasonable rate.”

Nicole Holt-Smith, Minnesota

“With two young diabetic daughters, it was always a struggle for our family to afford insulin. That led to my sister and I sharing what we had. My little sister almost lost her life sharing her insulin with me. Last May, she rationed a dose and went into diabetic ketoacidosis. It was the worst day of my life, and felt like it was all my fault. If lives depend on this medicine, why is the price so high? My parents live with the constant fear of losing a child. There shouldn't be a price tag on me or my sister’s life.”

Sa’ra Skipper, Indiana

"I was diagnosed with diabetes 22 years ago. My family was fortunate enough to be able to afford my insulin growing up, but when I graduated college and got my first job, I started to worry about how I would afford it. At one point, when my supply was low, I even considered rationing. Now, I now work as Community Organizing Director at Patients for Affordable Drugs because no one should be forced to choose between insulin and their rent."

Lauren Stanford, Washington D.C.

Traveling to other countries

An increasing number of diabetic patients are left with no choice but to purchase lower priced insulin in Canada or Mexico. The price for insulin in Mexico and Canada is one-tenth the price of insulin in the U.S. In Canada, the price for an insulin vial is around $30 while it costs around $300 for a vial in America.[40]

> "I was deep into credit card debt, and had no other choice but to keep putting my insulin and other supplies on credit cards. Naturally, I hate to say it, but my first instinct was that this was my fault. That I'm the problem. This is what it costs to be sick. This is what led me to start traveling to Mexico to purchase my insulin. I was just getting the supplies that I needed without any barriers whatsoever. Why isn't it this easy in the US?"
>
> \- **Robin Cressman, California**

SOLUTIONS

There is an unprecedented energy in Congress and in state legislatures to lower drug prices — especially insulin prices. Here are three comprehensive drug pricing policy solutions under consideration by the 116th Congress that could positively impact insulin prices. These policy solutions would bring drastic reform to the pharmaceutical industry.

- **Lower Insulin Prices**
  - H.R. 3 would grant the Secretary of Health and Human Services authority to negotiate the price of insulin to no more than 120% of the cost in other wealthy nations.
- **Penalties on Unjustified Price Increases**
  - H.R. 3 in the House of Representatives and S. 2543 in the Senate both require drug manufacturers to pay a penalty to the federal government if they increase their prices faster than the rate of inflation, a practice common among insulin manufacturers.
- **Patent Abuses**
  - S. 1416 would allow the Federal Trade Commission to bring a lawsuit against a drug company if they create a patent thicket around their product.

ENDNOTES

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