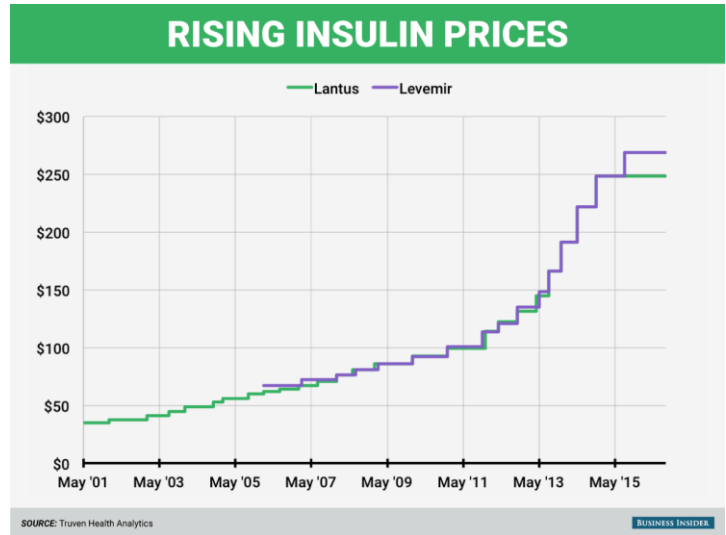
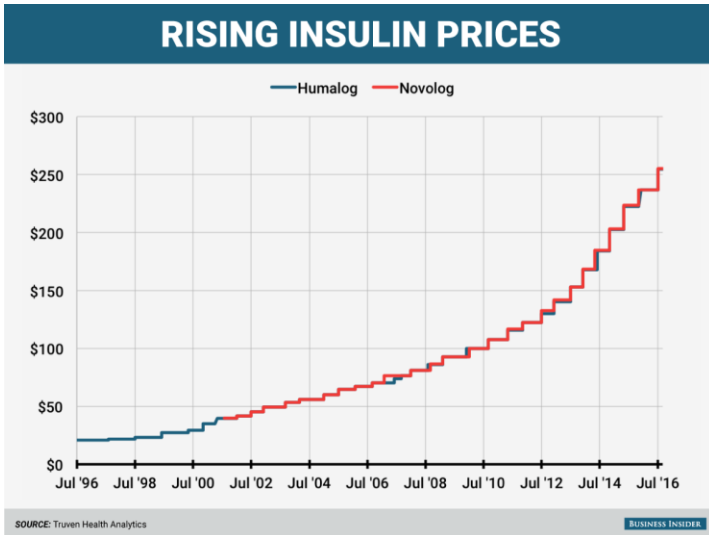


## Reed-DeGette Insulin Price Inquiry: Background & Key Findings

The American public has long been clamoring for policymakers to take steps to make prescription drugs more affordable. In recent years, these calls have grown much more frequent over insulin. Average insulin prices have nearly tripled between 2002 and 2013. Many patients are also becoming more exposed to high prices due to high deductibles, coinsurance, and various formulary exclusions. Rising insulin costs, however, are driven by a complex array of factors. We believe the Congressional Diabetes Caucus has a responsibility to explore in depth the causes of high insulin costs and work toward meaningful solutions for the diabetes community.



Humalog (Eli Lilly) and Novolog (Novo Nordisk) are two short-acting insulins while Lantus (Sanofi) and Levemir (Novo Nordisk) are two long-acting insulins.

In order to better understand how we got here, it is helpful to briefly review the nearly 100-year journey from insulin's discovery to modern-day insulin products. Before 1921, being diagnosed with diabetes was a death sentence. Children with diabetes rarely survived longer than a year after diagnosis. In 1921, Frederick Banting, J. J. R. Macleod, Charles Best, and James Collip conducted a number of experiments at the University of Toronto. These experiments led to the first pure formula of insulin. For their discovery, Banting and Macleod were awarded the Nobel Prize in Physiology or Medicine in 1923. In January 1922, they treated Leonard Thompson, a 14-year-old diabetic. This discovery was hailed as a miracle, and considered a monumental step forward in medicine.

Despite the opportunity to become very wealthy, the research team sold their patent to the University of Toronto for just one dollar each. In other words, these scientists refused extraordinary financial gain in order to benefit humankind with the hope to conquer and end suffering and death from diabetes. The University of Toronto then gave pharmaceutical companies the right to manufacture insulin royalty-free. In the years since, insulin has gone through many various stages of innovation and improvement. In 1950, Novo Nordisk created NPH, an intermediate acting insulin. Thirty years later, synthetic "human" insulin became widely available, manufactured by Eli Lilly. Finally, in the mid-1990s, Eli Lilly began selling insulin analogues designed to either have a shorter or longer duration of action.

Despite incredible innovation over the past century, insulin still remains out of reach and, at times, unaffordable for many Americans. As a result, some patients are forced to make extremely difficult financial choices, cut back on their doses or stop taking insulin altogether. This is unacceptable. That's

why Congressman Tom Reed (R-NY) and Congresswoman Diana DeGette (D-CO), the Co-Chairs of the Congressional Diabetes Caucus, have met with stakeholders and experts over the past few months to learn more about the rising price of insulin and growing cost burden on patients. On June 22, 2017, Reed and DeGette sent letters to America's Health Insurance Plans (AHIP), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the Pharmaceutical Care Management Association (PCMA) requesting meetings on this topic. Those meetings are now complete. Reed and DeGette also met with the American Diabetes Association during this period.

Below is a summary of key findings from these meetings. In the coming weeks and months, we plan to gather more detailed information from stakeholders in the insulin supply chain and the diabetes community in our effort to craft meaningful policy solutions that address this issue. We hope to include other stakeholders in these conversations, such as pharmacies, physicians, employers, wholesalers and distributors. We also plan to continue the dialogue with stakeholders we already met with, particularly patient advocates. Lastly, we plan to reach out and encourage relevant government agencies to take steps to improve insulin affordability through the regulatory process where possible.

### **Key Findings from Stakeholder Meetings**

***Rising list prices.*** The Wholesale Acquisition Cost (WAC), or list price, for insulin has been rising rapidly since the 1990s. Pharmaceutical companies are responsible for setting the WAC price. WAC pricing decisions are complex and opaque, but different pressure points across the supply chain appear to factor into these decisions. Insulin list price increases have also been “shadowing” each other (*i.e.* rising in tandem) for reasons that are not fully understood. Payment for many stakeholders across the supply chain appears to be predicated on the WAC price, which could create perverse incentives.

***Flat net prices.*** In some cases, the net price pharmaceutical companies collect after various rebates and discounts are factored in has remained relatively flat despite WAC increases. In other words, even though WAC prices are increasing, the amount the pharmaceutical company takes home has not always increased. The spread between the WAC and the net price is being consumed by stakeholders elsewhere in the supply chain. Where and how these rebates are used likely varies. There is little data available on this topic. There seems to be agreement, however, that rebates are often used to help lower premiums.

***Product innovation.*** Insulin has existed for nearly 100 years. During that time, major breakthroughs have occurred, such as moving from animal-derived extracts to synthetic analogs. In recent years, innovation has been more incremental. For example, insulins have been developed to be shorter or longer acting, have safer and more convenient delivery devices, *etc.* Each innovation is associated with additional FDA review and new patent protection. There is disagreement about the extent to which new innovation justifies price increases.

***Rebates.*** Rebates on insulin could be as much as 30 to 40 percent off the WAC price, and in some cases may be even higher. It seems that rebates are most often being used to lower premiums for everyone enrolled in a health plan, versus passing lower prices on to the specific patients who use insulin. PBMs may be passing on a growing portion of the rebates to insurers and employers, especially for larger clients. In some cases, PBMs are passing on 100 percent rebates. Stakeholders did not agree about the extent to which the insulin market is competitive and which players in the supply chain have the most leverage in these negotiations. A growing portion of rebates are also paid retrospectively based on certain performance metrics, such as meeting dispensing thresholds.

***Formularies.*** Formulary placement is central to rebate negotiations between pharmaceutical companies and PBMs. Insurers work closely with PBMs in designing their formulary structure. Health plans almost always have at least one form of insulin on a low cost-sharing tier of their formularies. Patients, however,

may prefer an insulin that is on a higher cost-sharing tier or is completely excluded from their health plan's formulary. Payers appear to be moving more insulins to higher tiers due to rising prices.

***Deductibles, coinsurance, and exclusions.*** Higher cost-sharing tiers may require patients to pay a percentage of the price negotiated with the pharmacy (*i.e.* coinsurance). The price negotiated with the pharmacy is often similar to WAC and higher than the negotiated price with the payer. When an insulin is excluded from a formulary, patients may have to pay the full cost out-of-pocket. Medicare beneficiaries are experiencing similar problems when they reach the so-called “donut hole.”

***Patient switching between insulins.*** Formulary design might be encouraging patients to switch from one insulin to another. Some patients, however, may resist financial pressure to switch away from an insulin that works for them. Evidence about potential risks to patients caused by switching between different insulins appears to be very limited. Thus, it is not clear how easily patients can switch to an insulin on a lower cost-sharing tier when these situations occur. Lower-cost insulins therefore might not always be viable options. It is also unclear the extent to which physicians are familiar with cost implications for patients when making insulin prescribing decisions.

***Barriers to generic and biosimilar entry.*** To date, there is only one “biosimilar” in the insulin space. In order to see a greater impact on price, more biosimilars would need to enter the market. Even then, downward pressure on pricing may not be as significant as it is in other therapeutic categories since biosimilars are more expensive to manufacture than small molecule generics. A number of factors are also creating barriers to biosimilar entry, including complications caused by FDA guidance on biosimilars, patent protection, and life cycle management and marketing practices by the pharmaceutical industry.

***Reimbursement by government programs.*** Formulaic pricing in government programs may be influencing decision-making across the supply chain. For example, discounts and rebates required under Medicaid or the 340B Drug Discount Program may limit pharmaceutical companies' willingness to offer deeper discounts to other payers. These programs, however, are important to ensuring the government and patients served by government programs get the best price possible.

***Patient assistance and discount cards.*** All the pharmaceutical companies that make insulin offer some type of financial assistance to certain patients who cannot afford their insulin. For uninsured or low-income populations not enrolled in Medicaid, patient assistance programs (PAPs) are sometimes available. For insured patients whose preferred insulin is not covered or only available with high cost-sharing, co-pay and discount cards are sometimes available. The extent to which these programs are accessible and utilized by patients is not fully known. These programs may also have a market-skewing effect. PBMs also sometimes offer point-of-sale discounts to patients.

***Value-based contracting.*** Stakeholders generally agreed that working toward value-based contracting and reimbursement could deliver better results for patients and payers.