GUEST EDITORIAL

Insulin: Concierge Medication or Human Right?

Joyce Lee, MD, MPH

There is a growing recognition that we are reaching a crisis in the US diabetes community with regard to the price of insulin. If you search for "insulins" on GoodRx.com you will see a huge range of prices for different types of insulin. The insulins that I have traditionally used for my patients with type 1 diabetes include short acting analog insulins like Humalog ($549) or Novolog ($551), and long acting insulins like Lantus ($274), Levemir ($436), and the new generic/"follow-on" long acting insulins like Basaglar ($234).

Because some of my patients with diabetes use more than 100 units a day, this means that they need at least three vials of insulin a month, which costs nearly $1400– tragically higher than the cost of their rent or a mortgage. The high cost of insulin doesn't include all of the additional supplies they need for self-monitoring, including blood glucose testing strips (as high as $1 per strip), sensors for continuous glucose monitoring ($350 a month), glucagon ($280), visits to a healthcare provider and more.

HAS INSULIN ALWAYS BEEN THIS EXPENSIVE?

The answer is no. There are clinicians and patients who can remember when a vial of insulin used to cost $20, and studies have shown that the costs of insulin have increased dramatically over the last few decades. For example, studies using Medicaid data have shown that annual payments for a patient requiring 40 units of insulin a day increased from $771 in 2001 to $2852 in 2014 (a 370% increase) for rapid acting insulin, and from $891 in 2001 to $2848 in 2014 (a 320% increase) for long acting insulin. These costs are increasingly being passed onto patients and their families as the number of individuals on high deductible health plans or who are uninsured grows.

This crisis in insulin pricing is taking a human toll. Families are now using crowdfunding sites like GoFundMe to fundraise to pay for their insulin. And there are too many stories in the news about patients, who when faced with a $1300 insulin bill at the pharmacy, must ration their insulin and suffer catastrophic consequences, including an increased risk of complications and even death.

WHY IS INSULIN SO EXPENSIVE?

Here are just a few of the contributing factors:

- The US government lacks negotiating power with regard to drug pricing, and therefore pays more for insulin than any other country, leading to a prescription

drug market that prices "primarily on the basis of what the market will bear."

- Companies that want to make generic insulin, may lack the manufacturing capabilities and a supply chain for producing insulin.

- The use of "evergreening" by pharmaceutical companies, in which they make very minor tweaks in a drug to extend the life of a drug patent, through minor modifications in the drug itself but even more commonly now though updates to drug delivery devices rather than the drug itself.

- The use of patent infringement lawsuits by pharmaceutical companies, who file them to prevent or delay entry of generic/follow-on competitors for up to years. For example, a lawsuit against the follow-on to Lantus called Basaglar resulted in a 30-month delay in approval, during which the company could charge more for Lantus before it went off patent.

- The rise of the pharmacy benefit manager, which is an entity that negotiates rebates with pharmaceutical companies, taking a proportion of the drug cost as profit without any sort of price transparency.

- And let's not forget, that very important factor called greed.

Not surprisingly, the major players with the ability to change the pricing (pharmaceutical companies, pharmacy benefit managers, and insurers) put the blame on anyone except themselves.

1. They blame the "complicated" healthcare system:

   "There are no quick and easy answers, because the system is complex and complicated," Lilly spokesman, Gregory Kueterman said. "Even just simply lowering prices, while that seems like an easy answer, it wouldn't necessarily lower the prices of the high-deductible plan. They'd have to keep paying till they hit that deductible."

2. The pharmaceutical companies blame the pharmaceutical benefit managers and insurers. When the 3 manufacturers of insulin in the US were asked about pricing of insulin:

   "Sanofi, Lilly and Novo Nordisk all highlighted discounts they provide, and also pointed the finger at health insurers."

   "Ashleigh Koss, a spokeswoman for Sanofi, told Business Insider that Lantus had not had a price increase since November 2014 in the US. «In fact, because of aggressive discounting and rebates to insurance plans, PBMs, and government programs, the net prices of Lantus over the cumulative period of the last five years actually went down,» she said."

3. The pharmacy benefit managers and insurers blame the pharmaceutical companies.

   "Rebates don't raise drug prices, drug makers raise drug prices."

The public has been outraged by a number of different prescription drug pricing scandals in the news, including the mark-up of Epipen prices by CEO Heather Bresch of Mylan Pharmaceuticals, or the 5000% price increase for Daraprim orchestrated by now convicted ex CEO of Turing Pharmaceuticals Martin Shrkeli. The increases in insulin price may not have been as dramatic and have occurred more gradually over a longer period of time, but do the companies involved in the pricing of insulin deserve any less negative attention? Scientists Frederick Banting, Charles Best, and James Collip who discovered and established the first patent for insulin, sold it for $1 to

ensure the discovery could be accessed by all individuals with diabetes. They would be outraged if they could see how difficult it is for people to afford insulin today.

Insulin has tragically become a concierge medicine, available only to those who are well off and have good insurance, when it should be a right. As James Elliott, advocate and individual with type 1 diabetes said, "We're locked into paying whatever insulin companies decide. It's like paying for oxygen and having three companies decide what the price should be."

In response to the crisis there have been a number of developments:

- The patient community has begun the important advocacy on this topic, organizing protests at Eli Lilly, and planning protests at the other insulin companies.
- Type 1 International is a global diabetes advocacy organization working to improve sustainable access to insulin, supplies, care and treatment for everyone with type 1 diabetes.
- The Diabetes Patient Advocacy Coalition has started the Affordable Insulin Project, offering tools, resources, and data for patients, caregivers, employers, and healthcare professionals to support increasing affordable access to insulin.
- The Juvenile Diabetes Research Foundation has developed a Type 1 diabetes Health Insurance Guide to help patients navigate health insurance issues.
- The American Diabetes Association has asked politicians to examine the supply chain for insulin and have asked for transparency of pricing.
- Finally, politicians themselves have begun to advocate. US Senator Bernie Sanders and Congressman Elijah Cummings have asked the Justice Department and Federal Trade Commission to investigate anticompetitive conduct and made accusations of price collusion among the companies, as there have been suspicious increases in insulin prices among brands in lock step (i.e. a 16.1% increase in Lantus followed by a 16.1% increase in Levemir the next day; or an 11.9% increase in Lantus, followed by an 11.9% increase in Levemir). It's possible that governmental intervention may be the only way to address this crisis.

Everyone in the diabetes community needs to speak up and advocate for our patients on this critically important issue. As the advocate and endocrinologist Dr Irl Hirsch said in his publication, Insulin in America: A Right or a Privilege?

"But to those who detest the thought of having our government involved in the distribution of insulin, I would say that I detest more the pain, suffering, cost, and potential death from diabetic ketoacidosis resulting from patients' inability to afford insulin."

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