Chair DeGette, Ranking Member Guthrie, and distinguished members of the Energy & Commerce subcommittee on Oversight and Investigations: Good morning. My name is Dr. Kasia Lipska. I am an endocrinologist and a research scientist on faculty at the Yale School of Medicine. I am grateful for the opportunity to share my experiences as a clinician and scientist. I’d like to state for the record: I don’t have any financial ties whatsoever to drug manufacturers. My views are my own.

**Insulin Rationing: The Scope of the Problem**

First, I want to tell you about 3 people with diabetes because their stories illustrate the crux of the problem.

One is a 78-year-old woman who has had type 2 diabetes for over 30 years. She takes several injections of insulin each day. Her blood sugars were running too high, and she knew that this put her at risk for complications of diabetes – including blindness, kidney failure, and amputations. But she didn’t want to increase the dose of her insulin. She told me she simply couldn’t afford to.

The second is a 70-year old man who still works full time as an engineer to support not only his wife but also his daughter and her children. He also requires insulin for treatment. He came to me because insulin was costing him several hundred dollars a month, which he could not afford.

Finally, there’s a young woman in her mid-twenties who has type 1 diabetes. She deliberately let her sugars run high, so she could be admitted to the hospital and get free samples of insulin, upon discharge. It was a risky plan – she could have died – but that’s how desperate she was.

Seeing patients like these, led me to wonder just how common this was. In the summer of 2017, we conducted a survey of 199 patients at our Yale Diabetes Center
to get a better picture.\textsuperscript{1} About 26% of the patients were 64 years or older, half were women, 61% were White, 42% had type 1 diabetes, and 58% had type 2 diabetes. Twelve percent reported annual household incomes of $100,000 or greater.

Prescription coverage varied: 34% were insured by an employer-sponsored plan, 20% by Medicare Part D, and 43% by Medicaid (with or without Medicare).

We found that \textbf{1 in 4 (25.5\%)} reported using less insulin than prescribed over the past year, specifically because of cost. Insulin rationing was common across all of the different prescription coverage plans and across most demographic factors.

However, patients with annual income levels below $100,000 per year were more likely to ration insulin compared with patients with incomes above this level.

Not surprisingly, we found that patients who rationed insulin were more likely to have poor control of their blood sugars. Specifically, patients who reported cost-related underuse (vs those who did not) had 3 times the odds of having poor blood sugar control, even after adjusting for other factors associated with blood sugar control.

These findings based on data from a single center likely apply to the U.S. as a whole. First, our center’s diabetes patients are similar to the population of U.S. patients with diabetes (except – like many diabetes centers – we care for a larger proportion of patients with type 1 diabetes and for patients with type 2 diabetes who require insulin). Based on data from the National Health Interview Survey, about 38% of U.S. adults with diabetes are 65 years or older, 49% are women, 65% are White, and 13% report family income levels of $100,000 or greater.\textsuperscript{2} These characteristics are quite similar to those of the respondents of our survey. In addition, New Haven’s demographics are almost a perfect mirror of our nation.\textsuperscript{3}

The implications of this study are profound. Insulin is a life saving drug. It keeps patients with diabetes alive and out of the hospital. Over the short term, use of insulin

\begin{thebibliography}{9}
\bibitem{3} 'Normal America' Is Not A Small Town of White People. April 28, 2016 available at: https://fivethirtyeight.com/features/normal-america-is-not-a-small-town-of-white-people/.
"The metropolitan area that looks most like the U.S. is New Haven, Connecticut" based on age, educational attainment, race, and ethnicity metrics. .
prevents diabetic ketoacidosis and death in patients with type 1 diabetes. Over the long term, it reduces chances of complications, including blindness, dialysis, and amputations in patients with either type 1 or type 2 diabetes. When patients use less insulin than is necessary, their blood sugars run high, and they incur risks of these devastating complications.

**Insulin rationing results in poor health outcomes, but also higher spending on diabetes care.** Direct medical costs associated with diabetes were estimated at $237 billion in 2017, with 30% spent on hospital inpatient care.\(^4\) In one study done in an inner-city hospital, insulin discontinuation was the leading cause of recurrent hospital admissions for diabetic ketoacidosis, an acute complication of diabetes associated with high morbidity and mortality.\(^5\) Among patients who stopped insulin, 27% reported they lacked money to buy insulin and 5% were stretching their supply. These hospital admissions might have been avoided with adequate access to affordable insulin. Another study estimated that greater adherence to diabetes drugs could lower hospital use by 13% and could save nearly $5 billion annually.\(^6\) The study projected that improved adherence could avert 699,000 emergency department visits and 341,000 hospitalizations annually. On the other hand, worsening adherence would only increase spending on diabetes care in the long run.

**The Skyrocketing Insulin Prices**

Let me give you a sense of why so many patients ration insulin. One vial of Lantus insulin – which can last for a week or a month, depending on the dose needed – costs $200 at a Connecticut pharmacy.\(^7\) That’s the best price available. If a patient wants to take this insulin as a prefilled pen – which is more convenient – that will run them almost $300. And this price has skyrocketed in recent years.\(^8\) **Insulin costs about 7**

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6. Jha AK, Aubert RE, Yao J, Teagarden JR and Epstein RS. Greater adherence to diabetes drugs is linked to less hospital use and could save nearly $5 billion annually. *Health Affairs (Project Hope)*. 2012;31:1836-46.
times more than it did 2 decades ago. Just to be clear: That’s 7 times more for the same exact product.

Why Have Prices Gone Up?

Insulin has been around for nearly a hundred years. In 1923, Banting, Best, and Collip, discoverers of insulin, famously sold their patent to the University of Toronto for $1 each. In doing so, they sought not profit but rather publication of their process, with the hope that others would be able to benefit from it and that “no one could secure a profitable monopoly.” For the sake of quality control, insulin was initially produced on the University of Toronto campus, but given the size of the market, the University partnered with Eli Lilly to allow for more large-scale production of insulin in the U.S. However, it didn’t take long for trouble to come. In April of 1941, Eli Lilly along with two other drug makers, were indicted by the Federal grand jury on charges of illegal price fixing.

Currently, Eli Lilly, along with Novo Nordisk and Sanofi Aventis, are the only three drug makers that produce all of the insulin products used in the U.S.

Drug makers – and the many experts and organizations who are beholden to them – make excuses for why prices have gone up. They say it’s the fault of PBMs or wholesalers, or the high-deductible insurance plans that expose patients to the high list prices for drugs. But the bottom line is that drug prices are set by drug makers. The list price for insulin has gone up dramatically – and that’s the price that many patients pay. This is what needs to come down. It’s as simple as that.

Indeed, recent research suggests that high prices primarily benefit the drug makers. In 2016, the estimated US expenditures on pharmaceutical drugs totaled $480 billion. Two-thirds of this total ($323 billion) went to drug manufacturers in the form of net revenues. The remaining third ($157 billion) was retained as gross profits in the

supply chain. PBMs and wholesalers together captured approximately 8.5% ($23 billion and $18 billion, respectively).\(^\text{13}\) Clearly, drug makers pocketed the largest share of drug expenditures and were the biggest beneficiaries of high drug prices.

**What Can Be Done?**

I’m here today because as a clinician I have very little to offer my patients in the clinic. The patient assistance programs offered by drug makers do little more than provide a public relations benefit. It’s hard to find a patient who meets their criteria. I can help them shop for the best price of insulin, connect them with a discount pharmacy, sometimes switch to a less expensive insulin product. But these are Band-Aid solutions. What we need to do is exert pressure on drug makers to reduce those prices.

Any attempt to lower prices is often criticized as undermining innovation. Yes, insulin sold today is better than the pork or beef insulin extracts available nearly a century ago. But that’s not the issue in question here. The price of Humalog insulin has increased more than ten-fold since 1996, when it cost just $21 per vial. Since then, there’s been no innovation to improve Humalog. It is the same exact insulin hormone. The only thing that’s changed is the price: it now costs over $250 a vial.

In closing, I want to thank the Subcommittee for taking up this critical issue of insulin pricing. We have a moral obligation to address this problem. My patients are counting on you.

\(^\text{13}\) ibid.