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Written Testimony for the Hearing: "What is Fueling the Diabetes Epidemic?"

Chairman Sanders and Ranking Member Cassidy, I am Dr. Kasia Lipska, a physician scientist at the Yale School of Medicine in the Section of Endocrinology and Metabolism. Thank you for the opportunity to present my testimony. I am here in my personal capacity as an expert in endocrinology and practicing clinician, and I am not representing the Yale School of Medicine.

My research has focused on the safety and effectiveness of medications to treat type 2 diabetes. I have evaluated trends in utilization of these medications over time and examined associated health outcomes. My overarching goal has been to generate evidence that patients and doctors can use to make decisions about what treatment is best for each individual. However, I realized that in my own practice, I was often forced to make decisions with my patients about medications – not based on scientific evidence about their safety and effectiveness – but rather on what options were affordable, even if those options were far from ideal. As a result, I expanded my research to consider cost-related barriers to treatment. In 2017, we conducted a survey in our Yale Diabetes Center and showed that 1 in 4 patients with diabetes, who were prescribed insulin, rationed this medication due to cost.[1] I became involved in advocacy efforts for affordable insulin. In addition to writing editorial pieces in national media outlets such as the New York Times,[2] and testifying before the House Energy & Commerce Committee on the human impact of rising insulin costs,[3] I have worked closely with T1International, an advocacy organization that does not accept any money from the pharmaceutical industry or any other entity that might influence their ability to speak out freely.

As a clinician, I take care of patients who have already developed diabetes. There are now over 38 million people with diabetes in our country.[4] Nearly 1 in every 3rd older adults has diabetes.[4]

My focus with patients is to reduce the risk of complications of diabetes, such as heart attacks, strokes, amputations, kidney failure, and blindness. My clinic is in the Yale Diabetes Center in New Haven, CT where we serve over 3,000 patients with both type 1 and type 2 diabetes. About a third of our patients are insured by Medicaid, a third by Medicare, and a third have commercial insurance. New Haven's age, education, and race/ethnicity demographics reflect those of our nation.[5] One of the biggest challenges in my clinical practice – including this past year – is still figuring out how to get my patients access to affordable treatment. This is what it's like in my clinic. I saw a 71-year-old man who is a retired auto body mechanic for follow up the other day. He has type 2 diabetes, obesity, fatty liver disease, and coronary heart disease. He was taking metformin for his diabetes, but his blood sugars were uncontrolled. I prescribed Ozempic (semaglutide) but he was not able to fill this due to cost. We tried the other medications in the same class, but those were also expensive. I switched to Jardiance (empagliflozin), a pill for type 2 diabetes that reduces the risk of cardiovascular complications, but he had to stop this as well because our 340B program no longer offers it at a discount. He ended up on glipizide, probably the worst possible choice for his type 2 diabetes. Glipizide is associated with a risk of low blood sugar reactions and tends to result in weight gain.

Even the best medications cannot help patients if they cannot afford them. According to a national survey, in 2021, 16.5% of people with diabetes rationed their insulin because of cost.[6] This is not just due to lack of insurance coverage. Among Medicare beneficiaries with diabetes, 1 in 10 reported skipping, delaying, or taking less medication to save money.[7] What's more, when patients fill their

perscriptions and purchase the insulin that they need, this is often extremely costly for them. Using nationally representative data from 2017 and 2018, we found that 14.1% percent of Americans reached catastrophic levels of out-of-pocket spending on insulin, defined as spending more than 40% of their disposable family income on insulin alone.[8]

There has been progress in making insulin affordable – in large part due to tireless advocacy efforts by many people living with the disease, including organizations like T1International, fighting for access to insulin for all. And progress has been made thanks to the many policies that you have proposed or passed into law to improve insulin affordability. But on the whole, insulin is still way too expensive. My patients continue to struggle to pay for this drug. Over a century ago, inventors of insulin gave their patent to the University of Toronto, for $1, so that humankind would have affordable access to the drug forever.[9] Instead, drug companies have been very resourceful at controlling the market, gaming the patent system to block more affordable competitors, inflating their product prices ever since.[2]
And now that there are many new medications for diabetes, we must apply the lessons we learned from insulin to not make the same mistakes again.

There has been so much excitement about the new medications in type 2 diabetes and obesity. That's because some of the medications, including semaglutide (marketed by Novo Nordisk as Ozempic for type 2 diabetes and as Wegovy for obesity), really seem to work. They not only help people lose weight but also reduce the risk of complications related to diabetes and obesity.[10,11] In recent trials, these medications reduced the risk of cardiovascular complications by 20-25%.[10,11]

But the price tags for these new medications are outrageous. Ozempic, the brand name for semaglutide approved for type 2 diabetes, has a U.S. list price of over $900 per month. Wegovy, the brand name for the same drug approved for obesity, is $1,300 per month.[12] If Medicare were to fully cover Wegovy for all of its beneficiaries with obesity, we as American taxpayers would end up with a $268 billion invoice.[12] To give you some perspective, that's 70% of all the money that was spent on prescription drugs in the U.S. in 2021.[13] And could we stop at one year? Probably not. What we know about semaglutide, and the related medications, is that they work while people take them. However, as soon as they stop, their weight comes back.[14] So patients are looking at a potentially lifelong treatment and we could be facing the most expensive subscription service in the history of medicine.

How do we find a way to make these drugs affordable? We can't assume that this will simply get better with time, as patents expire after several years. There is just too much money on the table and the pharmaceutical industry is not about to walk away.

What can Congress do to help patients like mine? Ozempic is priced at roughly $100 per month in Sweden and just $80 in Australia and France.[15] That's 10% of what we are being asked to pay. One explanation is that those governments are negotiating prices directly with the pharmaceutical companies.[16] That's not socialized medicine. That's smart negotiating. That's a group of people leveraging their buying power to get a good deal.

The Inflation Reduction Act already authorizes the Secretary of the Department of Health and Human Services (HHS) to negotiate prices with pharmaceutical companies under specific provisions, and for a limited set of drugs. Notably, 4 out of the 10 initial medications selected for negotiation are medications for type 2 diabetes. But neither semaglutide nor the related medications in the same class are currently on the list of these drugs. As a result, millions of Americans are being asked to pay an impossible price – almost $900 a month – to get treatment that has the potential to change their lives. Many simply can't.

That money is needed to pay rent, buy groceries, or make a car payment. So they go without. I see these patients every week in my clinic.

Price negotiation is critical, but I believe we must do more. Pharmaceutical companies have absolutely no restrictions on the "launch prices" of their products, nor is there any evidence that these prices are reflective of research and development costs.[17] No amount of expert negotiation can bring down drug prices years later when the launch price is anchored to be sky-high. We have to align the launch price with the drug's value, the costs to develop and manufacture the drug, and what patients can afford. This is a rational approach that is in place in many other developed countries.

But I want to be clear here: medications ***alone*** cannot be the solution to the diabetes and obesity epidemics. We need to be more far sighted and strategic than that. Neither diabetes nor obesity is a moral failure or a personal choice. Just telling people to eat less and exercise more is *not* going to solve the problem – that strategy has failed thus far. Instead, we must address the upstream causes of obesity on the systemic level, such as reducing food deserts and improving built environments.[18] (As my fellow experts have already made clear.)

The reality is that the drug industry is really good at pushing its solutions and its products. Drug companies are powerful, sometimes more powerful than governments. Novo Nordisk, which is based in Denmark, now has a market value that is bigger than its host nation's GDP.[19] And so, perhaps inevitably, the path of least resistance will be for us to prescribe our way out of this problem. So I leave with you two thoughts: [1] drugs ***alone*** can't save us, they're only ***part*** of the solution; and [2] before we sign up for that never-ending "subscription service," and spend trillions of dollars, let's be smart consumers and have the government at the negotiating table, right from the start. Every extra dollar spent on these exorbitantly priced drugs is another dollar not available to address the systemic issues contributing to diabetes and obesity in the first place.

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