

**TESTIMONY OF DOUGLAS J. LANGA**  
**NOVO NORDISK INC.**  
**BEFORE THE U.S. HOUSE OF REPRESENTATIVES**  
**COMMITTEE ON ENERGY AND COMMERCE**  
**SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS**  
**APRIL 10, 2019**

*Introduction*

Chairwoman DeGette, Ranking Member Guthrie, and Members of the Committee, on behalf of the over 42,000 employees of Novo Nordisk, including nearly 6,000 in the United States, I appreciate the opportunity to be here for today’s hearing. My name is Doug Langa, and I am the Executive Vice President, North America Operations, and President of Novo Nordisk Inc. I joined the company in 2011, after working in the pharmaceutical and device industries in a number of roles for more than 25 years, including in marketing, market access, sales, and accounts management.

At Novo Nordisk, we are dedicated to improving the lives of patients living with diabetes and supporting efforts to prevent its life-threatening complications. As an industry leader in developing innovative treatments for diabetes, we are deeply concerned about the factors that limit access to our medicines—including affordability. It is our ambition that everyone who could benefit from our medicines can access them, at costs that they can afford.

My testimony today will offer our company’s perspective on the pressures that exist in the U.S. healthcare system around the pricing of insulin medications, including how changes in benefit designs and the increasing commonality of high-deductible health plans have contributed to rising out-of-pocket costs for prescription medicines. My testimony will also address the innovation that has occurred in insulin and diabetes care and management. This is an important issue, as some have inaccurately suggested that insulin therapy has not changed since it came into use approximately 100 years ago. The truth is that the insulin medicines we sell today, including human insulin, are not the same therapies that were used nearly a century ago. Innovations in insulin and diabetes care over the years have dramatically improved the way patients manage their disease. And we are not slowing down; we have new treatments in the pipeline that will continue to meaningfully improve patients’ lives.

Further, I will discuss Novo Nordisk’s commitment to addressing affordability. Novo Nordisk provides a number of programs to help patients who cannot afford their medications—some of these programs have been in place for nearly two decades. As I will describe in further detail, Novo Nordisk offers a diabetes Patient Assistance Program (“PAP”) and co-pay assistance programs; and partners with Walmart, CVS Health, and ESI to offer high quality Novo Nordisk human insulin for approximately \$25 a vial. While these programs are important options when

patients do not have adequate insurance coverage, they are not a substitute for the much needed reform to the drug supply chain.

We can—and must—do our part to bring relief for patients who cannot afford the out-of-pocket costs of their medications. But we cannot solve the affordability problem alone. The U.S. healthcare system is complex, and many entities play a part in determining what patients pay for their prescriptions. A solution that will bring meaningful relief for patients must address the roles of all participants in the drug supply chain.

Pharmaceutical companies set the Wholesale Acquisition Cost (known as “WAC,” and also commonly referred to as the “list” price) which is the price we charge to wholesalers and distributors who purchase medicines from our company. How pharmaceutical companies like Novo Nordisk set WAC, or list, prices and the relationship these prices bear on the ultimate price patients pay at the pharmacy counter should be examined. But WAC price is only part of the story, and any effort to understand and solve the problems inherent in the supply chain for prescription medicines must explore the rebates, discounts, and fees paid to pharmacy benefit managers (“PBMs”), insurance plans, distributors, and other entities in the supply chain. After our medicines leave our facilities and enter the supply chain, we have limited visibility into how the actions of downstream entities ultimately impact the price that patients pay for medicines at the pharmacy counter. We look forward to working with this Committee, and other stakeholders in the complex U.S. healthcare system, to develop solutions that will help patients affordably access the medications they rely on.

As described at the close of this testimony, I will address some of the proposed solutions that Novo Nordisk believes could bring meaningful change for patients. Novo Nordisk is committed to doing its part and to helping find solutions to the very real affordability challenges that patients are experiencing.

### ***About Novo Nordisk***

For more than 90 years, Novo Nordisk has been uniquely focused on the development of pharmaceutical products and devices to help people with diabetes. The company began when a husband and wife from Copenhagen, August and Marie Krogh, a professor and physician respectively, visited the United States in 1922 and learned that people with diabetes were being treated with insulin. Mrs. Krogh was a physician who herself had type 2 diabetes, but she also treated patients with type 1 diabetes in her practice. After meeting with the two Canadian researchers who discovered insulin, Mr. and Mrs. Krogh brought that innovative therapy back to Denmark.

While our company has grown rapidly since its founding, and we have broadened our work to include medications to treat obesity, hemophilia, and hormone imbalances, our principal mission since day one has been improving the lives of people with diabetes. Today, over 29 million patients use our diabetes products, and our medications are available in more than 170 countries. In the United States, we offer a variety of diabetes medicines, including short- and long-acting insulins and Glucagon-like peptide-1 receptor agonist (“GLP-1”) products for diabetes and obesity. We also offer innovative delivery methods, including injection pens that make dosing and administration of medicines more convenient and less painful for patients.

Although we are proud of the innovative therapies we have been able to bring to patients, we recognize that prevention is more effective than even the best treatment. For that reason, Novo Nordisk has created initiatives dedicated to the prevention and early detection of type 2 diabetes.

The innovative medicines and delivery systems we produce are the result of significant and ongoing investment in research and development. But we know that these investments will not help patients if they cannot afford the out-of-pocket costs for our medicines. Like you, I am deeply troubled by reports of patients rationing insulin because they cannot afford it. As a company whose legacy is rooted in the treatment of this serious disease, the people of Novo Nordisk believe that this is unacceptable. Even one patient rationing insulin is one too many.

### ***The U.S. Healthcare System and Insulin Pricing***

As an innovator and manufacturer of prescription medicines, Novo Nordisk sets the WAC price for the medicines it sells. Although many other participants in the healthcare supply chain impact what patients ultimately pay at the pharmacy counter, there is no doubt that the WAC price is a significant component, particularly for those patients with high-deductible health plans, those who have co-insurance, and those who are uninsured and not covered by any government drug benefit programs.

It is important to recognize, however, that WAC price is not set in a vacuum. Rather, WAC price is set against the backdrop of the competitive environment in which we operate. After Novo Nordisk sets the WAC price, we negotiate discounts, rebates, and other price concessions with supply-side entities, like PBMs, who act on behalf of employers and health insurers and determine whether our medications will be covered on their formularies. Because of consolidations that have occurred over the past several years, the PBMs testifying here today now control access to medications for over 80 percent of the covered U.S. population, or roughly 220 million people. With such a substantial market share, these companies are able to exert considerable leverage in negotiations. If they do not extract the rebate concessions they demand (and we recognize that PBMs are under pressure from employers and health plans to deliver certain dollar amounts in savings), they can and do exclude products from formularies, essentially making them unavailable to patients who rely on them every day. The pressure to provide higher rebates is constant and escalating, and rebate percentages have increased year-over-year for the last several years.

Recently, pharmaceutical companies have come under pressure to explain the increasing out-of-pocket costs for certain medicines, including insulin. While increased competition in a marketplace would usually lead to lower prices, our current healthcare system is built on misaligned incentives that have led to rising costs in medicines. Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor's higher-priced product on their formulary to the exclusion of others.

Exclusion from a major formulary would have significant consequences for patients and for our company. If our medicines were not covered on formulary, patients whose diabetes is well-controlled by a Novo Nordisk product would be forced to either switch to another product, which might not work as well for them, or pay much more to stay on their physician-prescribed Novo Nordisk medicine. This is not a hypothetical risk: just last week, the Committee heard from Gail deVore, who testified that she cannot afford Fiasp<sup>®</sup> because it is not on her formulary, and she therefore mixes it with NovoLog<sup>®</sup> against her doctor's orders. For the company, exclusion from a major formulary typically results in a significant financial loss (as well as loss of market share), which would compromise Novo Nordisk's ability to continue to innovate with the goal of defeating diabetes.

For these reasons, we are acutely focused on the rebates our payers, including PBMs, will demand when we set WAC prices. Last year, across all products and channels, we paid an average of 68 cents for every dollar of sales to PBMs and other payers and supply-side entities in the form of rebates and other discounts and fees—nearly \$17.8 billion. These rebates, discounts, and other price concessions are the single largest investment Novo Nordisk makes in ensuring its products are broadly available to patients. And the percentage we pay has been increasing each year—it is up from 64 percent in 2017, 59 percent in 2016, 56 percent in 2015, and 48 percent in 2014. Further, because of the portion of our gross sales consumed by rebates and other discounts, net prices for our medicines, including our insulins, have declined year-over-year for every year from 2015 through 2018, and experienced double-digit declines in 2017 and 2018. By way of example, the following graph shows WAC and net prices for NovoLog<sup>®</sup> Flexpen<sup>®</sup> dating back to 2003.

## NovoLog<sup>®</sup> FlexPen



\*Adjusted for inflation  
 \*\*2018 reflects December YTD  
 \*\*\* Y axis represents Annual List & Net Price Indices adjusted for CPI-U  
 CAGR = compound annual growth rate



As this graph shows, WAC price increases (factoring in the negotiations and concessions described above) have translated year-over-year to a 1.6% overall decline in NovoLog®FlexPen® net price when adjusted for inflation.

In spite of its complexities, this system of WAC prices and rebates works for many patients who have health insurance and who are charged reasonable co-pays for their prescriptions. But it does not work for everyone: many patients do not see the full benefit of the discounts we provide to PBMs to secure formulary access, and some see little to no benefit at all. In particular, uninsured patients and patients covered by high-deductible health plans pay close to the full WAC price for our medicines. Others, such as those with co-insurance or Medicare Part D patients in the coverage gap, may also pay a substantial portion of the WAC price. This is true even where Novo Nordisk has already paid a substantial rebate to the PBM to secure formulary access for the particular medication.

Unfortunately, as a pharmaceutical company, we do not have the ability to control what an individual insured patient pays for his or her prescriptions; that is a function of the individual's health plan benefit design. Similarly, we do not have control over whether the rebates we pay to ensure formulary access actually result in lower out-of-pocket costs for patients; that is the decision of the PBM, which determines how to apply the rebate. But we do know that more patients are facing an affordability challenge. Although there have always been some patients without insurance or who pay an above-average portion of WAC price for other reasons (and Novo Nordisk has attempted to relieve the burden on those patients through various affordability programs, described below), the number of patients struggling to afford their medicines has grown in recent years. This is due, in part, to the increasing prevalence of benefit designs that require patients to shoulder large out-of-pocket costs, such as high-deductible health plans. The number of individuals covered by this type of plan has increased over the last ten years and, according to the Centers for Disease Control and Prevention, high-deductible health plans now represent approximately 43 percent of private insurance plans in the United States. For these patients, the price they pay at the pharmacy counter simply does not reflect the significant rebates Novo Nordisk provides to the PBMs managing their pharmacy benefits.

My intent in highlighting the problems inherent in the complex U.S. healthcare system is to underscore that fixing the rising out-of-pocket costs of prescription drugs will require the commitment of all stakeholders in the supply chain. We at Novo Nordisk are committed to doing our part. We recognize the impact that changes in the healthcare market, especially the growth of high-deductible health plans, have had on patients. As we became aware that more patients were struggling to afford their medicines, we took steps to try to address the problem, including our commitment in 2016 to limit WAC price increases to single digit percentages annually. We have honored that pledge since we made it. We have also expanded our affordability programs, which I describe in greater detail below. But we know that we can do more, and we will do more. Novo Nordisk looks forward to being part of the solution that helps patients obtain access to affordable medicines.

### ***Innovation in Diabetes Treatment and Care***

Over the last five years, Novo Nordisk has invested over \$10 billion in research and development, much of which is aimed at finding new therapies that improve diabetes patients'

ability to manage and live with this chronic disease. In fact, Novo Nordisk is the largest private funder of diabetes research and development in the world. Novo Nordisk has also formed research collaborations to further innovation in diabetes, including one with the Massachusetts Institute of Technology to develop a capsule device that contains compressed insulin, which is injected into the patient after the capsule reaches the stomach. This capsule would potentially replace insulin injections through pens or syringes, making it easier for patients to receive their medication. We are also conducting research into stem cell therapies to treat diabetes in collaboration with the University of California, San Francisco, as well as other chronic diseases. In 2016, we began a \$2 billion investment in a new production facility in Clayton, North Carolina, which, once operational in 2020, will be the only facility outside Denmark where we manufacture active pharmaceutical ingredients for diabetes medications. To our knowledge, this project is the largest active pharmaceutical manufacturing construction project in the United States. These are just some of the innovative and cutting-edge research and development and manufacturing projects underway at Novo Nordisk.

These efforts build on the work we have already done throughout Novo Nordisk's history to continuously improve our insulins and other medicines in a way that offers meaningful change to patients who live with this disease each day. Recently, some have suggested that the insulin now on the market is essentially the same product as the insulin first produced almost 100 years ago. That is simply not the case. Early diabetes treatments used bovine and porcine insulins. Novo Nordisk was the first to convert porcine insulin into human insulin in the 1980s using recombinant DNA technology. Human insulin revolutionized the treatment of diabetes because it could be produced in a purer form and reduced the occurrence of allergic reactions. Human insulin is an FDA-approved, high-quality treatment and remains safe and effective for managing both type 1 and type 2 diabetes. In fact, human insulin was used in the Diabetes Complications and Control Trial in the 1990s that set new standards of care in diabetes. Human insulin is part of the standard of medical care in the United States and throughout the world. Today, approximately 775,000 people in the United States use our human insulins. In 2018, those medicines constituted 21 percent of our insulins sold in this country and 44 percent sold worldwide.

The development of analog insulins in 2000 represented another significant change in diabetes therapies. Our analog insulin, which we sell under the name NovoLog<sup>®</sup>, is a modified form of human insulin in which the amino acid structure of the insulin molecule has been altered at specific sites to change the onset and duration. For patients, this provides better control of mealtime blood glucose levels by more closely matching the body's natural insulin action. In doing so, the medication allows for a more flexible lifestyle, as injections can be taken immediately before, or even just after, meals. This flexibility offers a meaningful improvement in quality of life for patients because it means that they do not have to take insulin at the same time every day.

Five years later, we launched Levemir<sup>®</sup>, a long-acting insulin that has shown improved glucose control benefits by providing blood sugar control for up to 24 hours and a reduction of hypoglycemia risk. In addition, Levemir<sup>®</sup> is considered to be weight neutral, meaning it is not typically associated with the weight gain patients often experience with insulin treatment.

In 2015, we introduced Tresiba<sup>®</sup>, a long-acting basal insulin, offering once daily dosing at any time of day for both type 1 and type 2 diabetes patients. This medication's unique mechanism of action allows for improved blood sugar control with a lower risk for nighttime hypoglycemia as compared to other basal insulins. In addition to its standard concentration, Tresiba<sup>®</sup> is available in a more concentrated formula for those patients who require higher doses of insulin, allowing them to take a single dose per day with a pen device. Most recently, in 2017, we introduced Fiasp<sup>®</sup>, a new short-acting insulin that offers quicker onset. These two recent advances, Tresiba<sup>®</sup> and Fiasp<sup>®</sup>, have allowed people who are insulin-dependent to safely and effectively control their diabetes around mealtime, when blood sugar rises quickly after eating, as well as overnight. For patients, better nighttime control may mean the difference between getting a good night's sleep and sleep interruptions caused by diabetes.

We have also created new, more accurate and convenient delivery systems that allow patients to take their insulin through pen injection devices rather than with a traditional vial and syringe.

These developments in diabetes care and treatment demonstrate Novo Nordisk's commitment to improving the lives of its patients through new medications and delivery systems. We will continue to innovate to address the needs of patients and to meet our goal of defeating diabetes.

### ***Novo Nordisk's Commitment to Patients and Affordability***

For many years, Novo Nordisk has invested in programs to help patients afford their medicines. Like our investments in research and innovation, we view these investments as part of our overall commitment to improving the lives of patients living with diabetes. Although these programs are not intended to take the place of adequate insurance coverage, they are important options that are aimed at ensuring all patients can successfully and affordably manage their diabetes.

Novo Nordisk has offered a Patient Assistance Program since 2003. The PAP provides free medicines, including all Novo Nordisk insulin medications, to eligible patients who do not have insurance; Medicare patients who incur high costs while in the Part D coverage gap or who do not have Part D coverage and have been denied the Extra-Help/Low-Income subsidy; and patients who are Medicaid eligible but have been denied Medicaid.<sup>1</sup> With a maximum income requirement of 400 percent of the federal poverty limit, 59 percent of American households could qualify for free Novo Nordisk medicines under our PAP.<sup>2</sup> Thus, a family of four with income up to \$103,000 may receive free medications through our PAP. For individuals, the income limit for participation is \$49,960. Typically, we are able to ship medicines to patients who qualify for our diabetes PAP within seven to ten days of the patient submitting a complete

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<sup>1</sup> Information about the PAP and its eligibility criteria can be found on the Novo Nordisk website. In addition, at [www.novocare.com](http://www.novocare.com), patients can get help on how to access our company's assistance programs and receive guidance about applying for these programs.

<sup>2</sup> See Kaiser Family Foundation, "Distribution of the Total Population by Federal Poverty Level (above and below 400% FPL)," at <https://www.kff.org/other/state-indicator/population-up-to-400-fpl/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

and accurate application. In 2018, nearly 50,000 Americans received free insulin from Novo Nordisk through this program.

In addition to the PAP, Novo Nordisk offers coupons or co-pay assistance to help patients by decreasing what they pay at the pharmacy counter. We offer this assistance on a variety of our medicines, including NovoLog<sup>®</sup>, Tresiba<sup>®</sup>, Levemir<sup>®</sup>, and Fiasp<sup>®</sup>. In 2018, Novo Nordisk provided more than \$200 million in assistance to patients through coupons and co-pay cards.

Through partnerships with Walmart, CVS Health, and ESI, Novo Nordisk human insulin is available at approximately \$25 a vial to any cash-paying patient, regardless of income and insurance coverage status. Through a longstanding partnership with Walmart (which began in 2000), safe and effective Novo Nordisk-manufactured human insulin is available at Walmart stores for \$25 per vial. In 2017, we partnered with CVS Health and ESI to expand the \$25 human insulin offering to tens of thousands of pharmacies nationwide. Last year, we also started to provide human insulin in a convenient pen injection device through Walmart. Through the CVS Health and ESI programs, commercially eligible patients can purchase this same Novo Nordisk insulin for around \$25 at 68,000 pharmacies in the CVS Health retail network and 40,000 ESI participating pharmacies. In total, through these partnerships, Novo Nordisk estimates that it is currently providing high quality, affordable Novo Nordisk-manufactured human insulin to over 500,000 people. While newer analog insulins offer significant improvements in terms of *how* they are absorbed into the body, human and analog insulins work exactly the same way in lowering blood glucose once in the bloodstream. In fact, the standards of care set by the American Diabetes Association guidelines do not recommend one type of insulin over another. It is my sincere hope that patients who are struggling to afford their insulin and who might be rationing will consider this affordable and safe option. Again, one patient rationing insulin is one too many.

Novo Nordisk has adjusted these programs over the years to address our patients' needs for affordable medications and to address the gaps inherent in the healthcare system. We will continue to monitor the effectiveness of these assistance programs, including enhancing outreach to patients and physicians to raise awareness of the programs we offer, so that all who need assistance may find a program that fits their needs. In addition, we will continue to explore additional steps to provide relief to patients who need it. However, as I have described, these are not comprehensive solutions, and more is needed to address a complex system in need of reform.

### ***Policy Proposals***

In addition to the many ways Novo Nordisk demonstrates its commitment to people with diabetes, Novo Nordisk supports policy changes and legislation that, when implemented properly, benefit patients and address high out-of-pocket pharmacy costs.

One policy change that could help address affordability, particularly for patients with chronic diseases like diabetes, is the Chronic Disease Management Act ("CDMA"). Although this bill has not been introduced in the House of Representatives in this Congress, Novo Nordisk has consistently supported this bill in previous Congresses. The CDMA would require that the IRS preventive drug list include medicines that prevent chronic disease progression or



complications, like insulin.<sup>3</sup> Under current law, patients in a high-deductible health plan with a health savings account (“HSA”) must pay 100 percent of their treatment costs for chronic diseases unless deemed “preventive;” the definition of “preventive,” however, is narrow and only includes treatments that would prevent a disease in the first place. The CDMA would modify current law to give these plans the flexibility to cover services and medicines used to treat chronic diseases such as diabetes before meeting the plan deductible. As noted previously in this testimony, high-deductible health plans represent a growing percentage of plans offered today, with 20.2 million Americans enrolled in these plans in 2016.<sup>4</sup> Diabetes patients in high-deductible health plans with an HSA are particularly vulnerable to high out-of-pocket costs because their health plans are not responsible for providing any coverage for insulin until these patients spend through their respective deductibles. This can create significant financial hardships. As we have all seen, insulin rationing due to affordability can cause tragic and senseless deaths, as well as medical emergencies, which drive avoidable and expensive hospitalization costs. Novo Nordisk urges Congress to pass legislation to change the IRS definition of “preventive” to include insulin so that diabetes patients in high-deductible health plans with HSAs can gain first dollar coverage for insulin.

Novo Nordisk also fully supports the policies underlying the OIG’s proposed rebate rule.<sup>5</sup> The proposed rule, if appropriately implemented, will address some of the very challenges described earlier in this statement by moving Medicare Part D away from a system that provides rebates to entities such as PBMs and toward providing upfront pharmacy discounts to patients at the point of sale. Importantly, the proposed rule could lower patients’ out-of-pocket pharmacy costs for millions of Part D beneficiaries by realigning market incentives so that discounts are directed to those patients who need prescription drugs. While Novo Nordisk supports the proposed rule and its implementation in both Medicare Part D and the commercial market, we urge a cautious approach before making a full transition into the commercial market. Novo Nordisk believes that the wholesale conversion of both markets simultaneously could be challenging in the marketplace and disrupt patient access to medications.

Additionally, Novo Nordisk encourages adoption of policies that support diabetes prevention measures. Novo Nordisk has worked to improve access to diabetes prevention interventions by supporting increased funding for the National Diabetes Prevention Program (“DPP”). The DPP is a public-private partnership that offers evidence-based, cost-effective interventions to help prevent type 2 diabetes in communities across the United States. By working to increase the DPP’s appropriations, both directly and through our leadership in the Diabetes Advocacy Alliance, we are helping to ensure individuals in every state have access to this important program. We urge Congress to work with the Centers for Medicare and Medicaid

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<sup>3</sup> Chronic Disease Management Act of 2018 (H.R.4978/S. 2410).

<sup>4</sup> America’s Health Insurance Plans (AHIP). “2016 Survey of Health Savings Account – High Deductible Health Plans.” February 2017. [https://www.ahip.org/wp-content/uploads/2017/02/2016\\_HSASurvey\\_Draft\\_2.14.17.pdf](https://www.ahip.org/wp-content/uploads/2017/02/2016_HSASurvey_Draft_2.14.17.pdf).

<sup>5</sup> Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. 84 Fed. Reg. 2340 (Feb. 6, 2019).

Services to explore ways to encourage and increase provider participation in the DPP to ensure Medicare patients have access to these important interventions to help prevent type 2 diabetes.

At the state level, Novo Nordisk is an active advocate for legislation requiring states to develop data-driven diabetes action plans, which include policy recommendations from state Medicaid agencies and public health and state employee health benefits departments on how individuals at risk for diabetes can be better identified and how diagnosed patients can achieve better outcomes. Through Novo Nordisk's advocacy in collaboration with the American Diabetes Association, this legislation has been adopted in 23 states and has included funding recommendations for expanded access to evidence-based DPPs and reimbursement for diabetes self-management education.

### ***Conclusion***

It is time for all of us to do our part to ensure affordable access to insulin in the United States—not just to those for whom the system is working, but critically to those for whom the system is not working. Novo Nordisk pledges to be a part of that solution and to work with the Committee and others in our complex healthcare system to address the complicated landscape of laws, regulations, market forces, and supply-chain stakeholders that affect the price people pay for insulin. It is time for real change, and we look forward to being an effective partner with this Committee and others in Congress, the Administration, and the healthcare industry in that critical effort.