

**Testimony of Michael B. Mason  
Senior Vice President, Connected Care and Insulins at Eli Lilly and Company**

**Before the**

**United States House of Representatives  
Committee on Energy and Commerce  
Subcommittee on Oversight & Investigations**

Chair DeGette, Ranking Member Guthrie, and Members of the Subcommittee; Chairman Pallone, Ranking Member Walden, and other Distinguished Members: My name is Mike Mason, and I am the Senior Vice President for Connected Care and Insulins at Eli Lilly and Company (“Lilly”). Thank you for the opportunity to participate in today’s hearing. I would also like to thank the members of your staff who took the time to meet with us to discuss the important issue of affordable access to diabetes medications. I am pleased to be here today to continue our conversation.

Like many people who work at Lilly, I have a personal connection to the issues we will discuss today. Four of my immediate family members live with diabetes. I have seen them cope with the daily burdens of the disease, including finger pricks and insulin injections before each meal. I have seen the devastating complications of diabetes in their lives, and I know first-hand how they benefit from new, innovative treatments. Often our phone calls and visits turn to their diabetes. Over the years, these conversations centered on how they were managing their diabetes. But within the last 2-3 years, these conversations have changed. We now spend more time talking about how much they pay for insulin.

As a leader at Lilly, it’s difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don’t have affordable access for chronic medications.

Achieving affordable access to medications for everyone will require multiple groups to work together, including manufacturers, pharmacy benefit managers, health insurers, distributors, pharmacies, employers, and policymakers. But while long-term solutions are being discussed, Lilly knew we had to act to provide solutions today. Lilly has long provided support for individuals having trouble affording their insulin, including through savings cards and our support of the Lilly Cares Foundation. Over the past several years, however, we have recognized that there is an increased need to address affordability challenges and have been implementing a wide range of initiatives to make our insulins as affordable as possible for as many people as possible.

In 2017, Lilly began participating in savings programs that provide a 40% discount to those with private insurance. We also began the process of commercializing a lower-priced version of our most commonly prescribed insulin, Humalog U100, that will have a wholesale acquisition cost (WAC) or “list price” that is 50% lower than branded Humalog. Our goal is to make a lower-priced insulin alternative available within the limits of the current health care system. Earlier this year we received a response from federal regulators that allowed us to move forward, and we are now bringing this product, called Insulin Lispro, to the market.

We have also implemented other solutions. For example, we provide automatic discounts at the pharmacy counter that cap the cost of a prescription for Lilly insulins at \$95 for those in the deductible phase of high-deductible plans. This is a significant benefit for those in the deductible phase of high-deductible plans, who might otherwise be paying thousands of dollars for their insulin before their deductible is met. In addition to these automatic discounts at the pharmacy, we launched the Lilly Diabetes Solution Center, which connects individuals to a suite of affordability solutions. With these programs and others, we’ve built a safety net to try to

prevent anyone from falling through the cracks and having to pay retail price for their Lilly insulins.

Our solutions are working to reduce out-of-pocket costs. Today 95% of prescriptions for Humalog in the U.S. cost consumers less than \$95 at the pharmacy, 90% cost less than \$50, and 43% cost \$0.<sup>1</sup> As Insulin Lispro launches and is added to formularies and we continue to educate the diabetes and medical community about our Lilly Diabetes Solution Center, even more people will pay less for Humalog.

Although Lilly has taken steps to make insulin more affordable, we recognize that broader systemic change in our current healthcare system is needed. This will require action by all relevant stakeholders, but we are ready to play our role and we are confident that a solution is possible. We look forward to continuing our dialogue with the Subcommittee and other stakeholders about these important issues.

## **I. Lilly's Investments in Treatments for People Living with Diabetes**

Eli Lilly was founded in Indiana in 1876 and remains a U.S. company. We employ over 16,000 people in the U.S. Our headquarters are in Indianapolis—as they have been for over a hundred years—and we also have a significant manufacturing and research and development presence in New Jersey, California, New York, and Massachusetts.

Lilly has been committed to helping people with diabetes for nearly a century. In 1923, Lilly introduced the world's first commercially-available insulin product, at a time when a diagnosis of diabetes was virtually a death sentence. While this was an incredible breakthrough that saved lives, the insulin was sourced from animals using what would by today's standards

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<sup>1</sup> Based on IQVIA data, FIA data (August 2018 – December 2018).

seem a crude process and one that raised supply and quality concerns. Over many years, advances were made to enhance the purity, concentration, and dosing regimen of that first insulin. As technology continued to evolve, in 1982, Lilly introduced human insulin, the world's first human health care product created using recombinant DNA technology.<sup>2</sup>

Since then, Lilly has spent billions of dollars in research and development to improve the lives of people with diabetes. In 1996, Lilly launched a new biotech insulin, Humalog, which mimics the body's own rapid insulin response. Humalog has made it easier for people with diabetes to manage their blood glucose and facilitated advancements in modern insulin pumps. In 2015, Lilly obtained approval for the first follow-on insulin biologic, Basaglar, which introduced significant competition in the long-acting insulin market as the lowest-priced basal analog available. This product currently has a list price that is 23% lower than the list price of the most commonly prescribed basal insulin, Lantus<sup>®</sup>. In 2018, Lilly announced its investment in a drug discovery partnership that we hope could move people with diabetes away from insulin altogether by developing cell therapies that would allow insulin-producing pancreatic beta cells to be delivered through implanted devices.<sup>3</sup> Lilly is also active in the space of digital health solutions and is developing a connected diabetes system consisting of devices that we hope will improve adherence, outcomes, and convenience. Before the discovery of insulin, a child diagnosed with Type 1 diabetes at age 10 typically died within 2.3 years of diagnosis. Insulin was literally life-saving: It expanded the life expectancy of the average person with Type 1

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<sup>2</sup> <https://www.lilly.com/milestones-of-lilly-caring-and-discovery>.

<sup>3</sup> *Lilly and Sigilon Therapeutics Announce Strategic Collaboration to Develop Encapsulated Cell Therapies for the Treatment of Type 1 Diabetes* (Apr. 4, 2018), <https://www.prnewswire.com/news-releases/lilly-and-sigilon-therapeutics-announce-strategic-collaboration-to-develop-encapsulated-cell-therapies-for-the-treatment-of-type-1-diabetes-300624199.html>; Alex Keown, *Eli Lilly Plunks Down \$63M Upfront in Deal With Startup Sigilon* (Apr. 4, 2018), <https://www.biospace.com/article/eli-lilly-plunks-down-63m-upfront-in-deal-with-startup-sigilon/>.

diabetes into the early 40s, and eventually to where it is today in the late 60s. But our work is not done. Our hope is that one day the life expectancy for a person diagnosed with diabetes will be no different than any other American.

Lilly is proud of our history of innovation in the treatment of diabetes, but improved medications and technologies will result in better outcomes only if people with diabetes have affordable access to them. Affordability is of critical importance to Lilly, and it's an area where we have invested time and resources to develop solutions.

## **II. The Current U.S. Healthcare System: Prices, Rebates, and Insurance Design**

The recognition that people increasingly face high out-of-pocket costs for their insulin caused all of us at Lilly to reflect on how we got here and what actions we could take to try to solve this problem in the short-term and in the long-term. The U.S. healthcare system has evolved over the last six to seven years. Historically, people with diabetes paid only a flat co-pay at the pharmacy, and insurance plans covered most medications. More recently, however, the market began moving to restrictive formularies,<sup>4</sup> which limit the number of medications covered on someone's health plan. In some classes like meal-time insulin, insurers started covering only a *single* brand of medication. To ensure that people's insurance plans would continue to cover their treatments, pharmaceutical companies, including Lilly, have had to pay larger discounts in the form of rebates. At the same time, mandatory discounts for federal programs were also increasing. With the cost to secure access increasing, pharmaceutical companies raised list prices<sup>5</sup> to remain viable, maintain access for patients using their

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<sup>4</sup> Drug formularies are ranked lists of drugs that insurers and PBMs use to determine whether certain medicines will be covered by insurance.

<sup>5</sup> Any discussion of drug pricing within the current system requires a clarification of terms because the "price" or "cost" of a medication may represent different concepts to different participants in the healthcare system. Manufacturers like Lilly typically set a medication's "list price," which is the amount that the manufacturer charges

medications, and ensure that they are able to continue to fund lifesaving research and development.

Because of the increasing rebates and fees that Lilly provides to purchasers and insurers (or their PBMs), and other fees and costs Lilly incurs, increases in list prices for Lilly insulins have not necessarily resulted in net price increases. For example, between 2014 and 2018, for our most broadly used Lilly insulin product, Humalog U100, the list price increased by 51.9%.<sup>6</sup> During that same time period, the amount of rebates Lilly paid increased at a greater rate, causing the average net amount that Lilly received—often referred to as the “net price”—to decline by 8.1%.<sup>7</sup> That translates into insurance plans on balance paying a lower net effective price for Humalog.

The chart below shows the average list price and net price for Humalog U100 from 2014 through 2018.<sup>8</sup>

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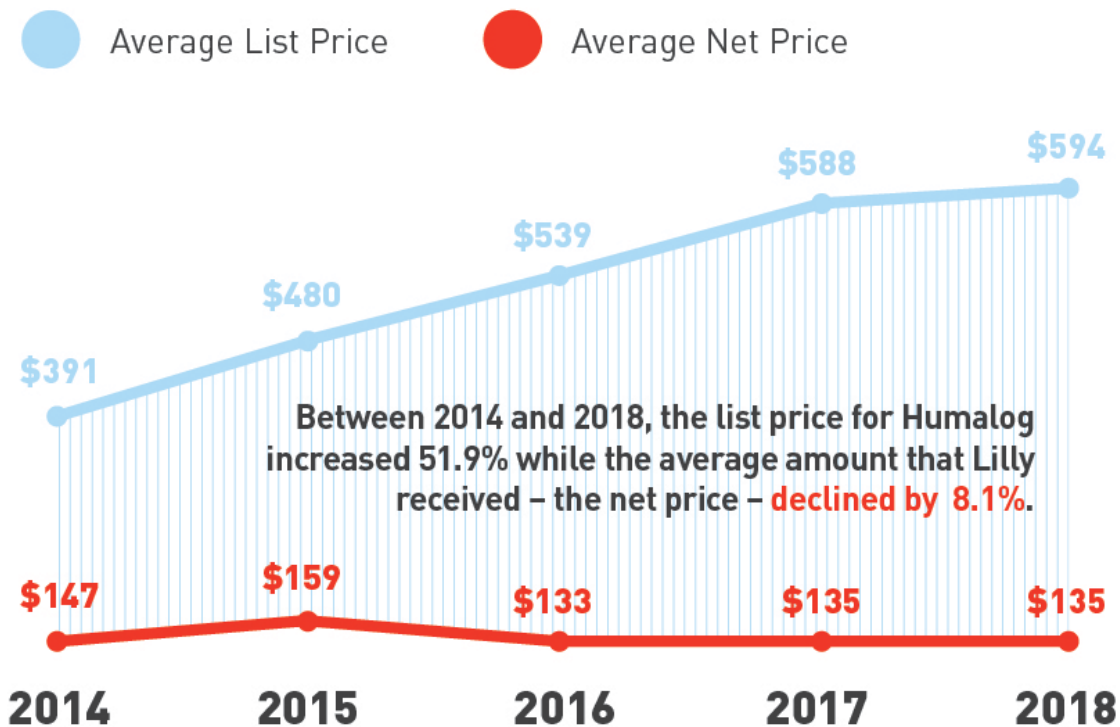
to its wholesale distributor customers. The wholesalers then re-sell the medication to pharmacies at a price that those parties separately negotiate. The pharmacies, in turn, dispense the medication to patients and in most cases are paid a price that is individually negotiated by the patient’s insurer or by a PBM retained by the insurer. Importantly, manufacturers typically provide rebates and/or fees to insurers or their PBMs, and to federal and state health programs, that reduce the cost of the medication to those entities. Manufacturers also pay other discounts and fees and incur costs related to co-pay assistance to patients and affordability programs. All of these payments reduce the amount that is ultimately realized by the manufacturer (which is sometimes referred to as a “net price”).

<sup>6</sup> Eli Lilly and Company 2018 Integrated Summary Report at 16, <https://investor.lilly.com/static-files/ae580ba4-5d84-4862-a5d2-99a1d784d7a8>. Humalog U100 is the most broadly used Lilly insulin product. The last list price increase for Humalog U100 was May 2017. The net price in the chart represents the average revenue Lilly realized per patient per month for Humalog U100 if taken as prescribed. Because of rebates and fees Lilly provides insurers and/or PBMs, increases in list prices do not always reflect increases in net prices.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

## HUMALOG® (U100) AVERAGE LIST AND NET PRICE (USD) PER PATIENT PER MONTH, IF TAKEN AS PRESCRIBED\*



\*Average List and Net price per patient per month is calculated based on average prescribed utilization of Humalog U100, the most broadly used presentation of Humalog (Source: IQVIA LAAD Data 2014-2018). In 2018, per IQVIA reported data, if taken as prescribed, the average Diabetes patient using Humalog U100 would have consumed approximately 19 MLs of insulin per month; this equates to approximately 2 vials or 6.4 Kwikpens. The actual utilization per patient per month may differ significantly depending on multiple factors, including prescription amounts and adherence behaviors.

Overall, the system continues to work well for the majority of people who are prescribed a Lilly insulin. As noted above, the out-of-pocket cost for Humalog, Lilly’s most commonly prescribed insulin, is less than \$50 a month for 90% of retail prescriptions, and less than \$100 for 95% of retail prescriptions.<sup>9</sup> Moreover, as discussed further below, individuals without

<sup>9</sup> Based on IQVIA data, FIA data (August 2018 – December 2018).

insurance or on Medicare Part D whose income is less than 400% of the federal poverty line can obtain Lilly insulins for free.

Additionally, under Medicaid, Lilly insulins are available at little or no cost to individuals or to the government.<sup>10</sup> Indeed, Humalog is essentially free to Medicaid programs, as Lilly pays a rebate of approximately 100%.<sup>11</sup> Public programs designed to assist the medically needy and financially vulnerable, including Medicaid, have expanded greatly in recent years. With enactment of the Affordable Care Act (“ACA”), the Medicaid population increased from 54.5 million in 2010 to 73.4 million in 2017.<sup>12</sup> Providing insulin to this population at little or no cost is a significant step towards ensuring affordable access for those in need.

But despite the fact that the current system works well for the majority of people prescribed Lilly insulin, we recognize that it does not work for everyone. Individuals’ specific out-of-pocket costs vary significantly depending on numerous factors, most notably the type and terms of their insurance coverage, which Lilly does not control. Depending on the terms of someone’s insurance, list price changes often have no effect on their out-of-pocket costs for insulin. But some people, including those enrolled in high-deductible health plans and Medicare Part D, may incur higher out-of-pocket costs for certain prescriptions because of their insurance design. Although Lilly pays a rebate for access on insurance plans, patients don’t always benefit from the rebates at the pharmacy.

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<sup>10</sup> Letter from Joe Kelley to Hon. Greg Walden *et al.* at 21 (Feb. 27, 2019).

<sup>11</sup> Letter from Joseph Kelley to Hon. Frank Pallone, Jr. and Hon. Diana DeGette at 3 (Feb. 13, 2019).

<sup>12</sup> Statista, Total Medicaid Enrollment from 1966 to 2017 (in millions), <https://www.statista.com/statistics/245347/total-medicaid-enrollment-since-1966>.



### **III. Gaps in Affordable Access**

Lilly has long provided support for people living with chronic conditions who face high out-of-pocket costs for their medications, but in recent years we have recognized an increasing need to address affordability challenges, as more people bear a greater share of their medications' costs. To that end, Lilly has focused on identifying the primary coverage gaps for people taking our insulins and has identified three groups of people most likely to be paying higher out-of-pocket amounts: (1) individuals in the deductible phase of private high deductible health plans; (2) individuals in the coverage gap phase (or “donut hole”) of Medicare Part D; and (3) individuals without insurance. Each of these gaps is detailed below.

#### High Deductible Private Insurance

In recent years, employers focused on providing employees health insurance plans with low premiums and increasingly selected high deductible health plans to achieve that. These plans require members to pay thousands of dollars before insurance coverage starts. In about half of these plans, employers give special treatment to medication for chronic diseases, such as exempting those medicines from deductible requirements through the use of preventive drug lists. In the other half, employers choose a plan design that utilizes rebates paid by pharmaceutical companies on drugs like insulin to buy down premiums for the general population. The result is that people who take insulin or other medications for chronic conditions pay full retail prices at the pharmacy during the deductible phase of coverage and do not directly benefit from rebates paid in connection with those medicines. This places a great burden on people with diabetes and others who rely on medications to treat chronic conditions.

### Medicare Part D Coverage Gap

Once a person covered by Medicare Part D has spent a certain amount on covered prescription drugs, a coverage gap known as the “donut hole” begins. While in that phase, the person will pay up to 25% of the plan’s cost for brand-name drugs. Our review of data indicates that since enacting our current safety net of solutions, almost 90% of the people exposed to a prescription cost above \$100 for Humalog at a retail pharmacy were enrolled in Medicare Part D. In most cases, federal regulations prohibit Lilly from subsidizing the cost of insulin for people on Medicare during the coverage gap.

### No Insurance

The third primary group of people that Lilly has identified as lacking access to affordable insulin are those without any insurance coverage, who pay retail price at the pharmacy throughout the year. Lilly estimates that each month there are approximately 1,600 prescriptions for Humalog filled at a retail pharmacy by likely uninsured individuals or individuals in a period of transition between insurance coverage who pay near list price for their prescription.

## **IV. Lilly’s Solutions**

Recognizing that individuals exposed to high prescription drug costs have a real and pressing need for immediate solutions, particularly those who rely on medications to treat life-threatening, chronic conditions like diabetes, Lilly has instituted multiple programs designed to reach each of the segments of people who need assistance affording their insulin.

These solutions are currently helping more than 20,000 additional people each month more easily afford their insulin. We want people to use our solutions, and our intent is to make these solutions as easy to access as possible. For example, if you are uninsured or have private

insurance you can gain immediate access to savings offers with no paperwork or applications to complete. If you or a loved one is having trouble paying for our insulin, please call our Lilly Diabetes Solution Center at 833-808-1234. Lilly's solutions are discussed further below.

### Automatic Discounts

Lilly currently offers savings directly to people in the high-deductible phase of their insurance plans by capping their prescription cost at \$95 at the pharmacy. When a person in a high-deductible insurance plan fills a prescription for a Lilly insulin, the individual generally will pay no more than \$95 out of pocket at the pharmacy, and Lilly will pay the remainder of the cost.<sup>13</sup> The discount is automatically applied at the point of sale, and therefore has an immediate impact on the cost paid by the insured person. This takes place behind the scenes when the insurance claim is processed and does not require the individual to enroll in any programs or request that the savings offer be applied. In fact, individuals may not even be aware of these “buy-downs” or may be surprised by them.

These buy-downs are in addition to the rebates that Lilly is already paying. Indeed, when Lilly pays the cost of a person's prescription during the deductible phase and also continues to pay the full contractual rebate, it loses money on each prescription. This is not a sustainable long-term solution, but it is one that Lilly felt was necessary to ensure that individuals had access to affordable insulin while we work towards broader systemic changes.

These automatic discounts are not available to all people, however. Federal regulations prohibit us from subsidizing prescriptions for people insured through government programs such

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<sup>13</sup> Significantly, the portion that Lilly pays is counted towards the patient's deductible.

as Medicare Part D. This program also cannot be used by individuals without insurance because there is no insurance claim to process, triggering the savings offer.

### Lilly's Insulin Lispro

As discussed above, we recently announced the introduction of a lower-priced version of Humalog. We sought to bring a lower-priced version of our product to the market because we recognized that other solutions, though important, still left some people vulnerable to high out-of-pocket amounts for insulin. We expect the introduction of Lilly's Insulin Lispro to particularly benefit individuals enrolled in Medicare Part D who are on the coverage gap. Because of legal restrictions outside of our control, these individuals do not have access to as many of our other solutions as people covered by private insurance plans. By introducing this second version, Lilly can provide a lower-priced insulin quickly without disrupting access to branded Humalog, on which hundreds of thousands of people currently depend.

It is important to note that our introduction of Insulin Lispro will not prevent any other companies from manufacturing a generic version of Humalog. None of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product.

### Other Discount Programs

Since 2017, Lilly has participated in Blink Health ([www.blinkhealth.com](http://www.blinkhealth.com)) and Inside Rx ([www.INSIDERx.com](http://www.INSIDERx.com)), savings programs that offer savings of up to 40% off the list price of Lilly's most commonly prescribed insulins. These programs are available to people through smart phone applications and offer savings at the point of sale. Our participation in these

programs was an initial step to provide discounts to people on Lilly insulins who had private insurance or were uninsured.

### Donations of Free Insulin

For many years, Lilly has provided free insulin products to a variety of organizations and programs. We broadened the scope of that support from emergency relief organizations to include donations to relief networks that supply insulin to nearly 150 free clinics. These clinics provide not only free insulin, but also access to medical care and other free medications and supplies.

Since January 1, 2014, Lilly has provided over 5 million free pens/vials of Humalog, Humulin, and Basaglar to these organizations and programs in the U.S. Program qualification requirements vary depending on the nature of the program and as determined by the organization, but in all instances, the insulin provided is free to qualifying individuals.

### Lilly Cares

Lilly also supports and donates insulin to Lilly Cares, a separate charitable organization.<sup>14</sup> Lilly Cares provides free insulin to patients who do not have insurance or have Medicare Part D and have a household annual adjusted gross income of up to 400% of the federal poverty level.

### Lilly Diabetes Solution Center

Recognizing that some solutions described above will not help people unless they know about them, Lilly launched the Lilly Diabetes Solution Center (“LDSC”) in August 2018. The Solution Center is a patient-focused helpline staffed by medical professionals, which connects

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<sup>14</sup> <https://www.lillycares.com/resources.aspx>.

people living with diabetes to any of Lilly’s various resources and solutions based on their individual needs. These solutions include savings cards (requiring no paperwork and no application), an immediate supply of insulin, or information about one of the clinics that can offer free insulin that Lilly has donated. The LDSC also can connect patients to Lilly Cares. Lilly has publicized the LDSC through press releases, social media channels, and advertising campaigns—including direct-to-consumer print ads—that directly target people with diabetes, the general public, and specific communities of color with a higher risk of diabetes.

These solutions help ensure that insulin is affordable for people who fall within the coverage gaps described above. But some people might ask—why doesn’t Lilly just drop the list price of its insulin products? This is an important and fair question. The answer is that lowering list prices is too disruptive under the current health care model. Distributors, PBMs, insurance companies, long-term care facilities, and pharmacies have all entered into contracts that are based on a rebate model tied to current WAC or list prices. No pharmaceutical manufacturer has lowered list price for a significant medication because it is too disruptive to the system and thus to people who rely on that medication. Introducing a new, lower list price second version of a medication is the only practical approach under the current health care model. In the face of these complex dynamics, systemic change is needed. In the meantime, we have taken action within the constraints of the current system to lower insulin prices, for example by introducing a half-price version of Humalog.

#### **IV. Towards a New Approach**

While Lilly has worked hard to introduce the many solutions it has in place to make insulin affordable for people with diabetes today, we recognize that we need more than a series of patchwork fixes, and that long-term change will require the participation of all industry

stakeholders. We appreciate the Subcommittee’s attention to these important issues, and we look forward to continued dialogue about potential solutions.

One proposal that Lilly believes is worthy of consideration is adding insulin to preventive medications lists, which would lower out-of-pocket costs such as by exempting insulin from deductibles (sometimes called “first dollar coverage”). Because of how the private health care system works today and the complexity of high deductible health plans, some people have full coverage for treatments to manage their chronic conditions while others must meet out of pocket and deductible requirements for the same treatments. Making people with chronic diseases like diabetes pay high prices for their medications does not make sense as a matter of public policy. While billions of dollars are spent in the United States each year on medical expenses directly related to diabetes, only 6% of that is spent on insulin.<sup>15</sup> The vast majority is spent to treat the serious and costly complications of diabetes. When people with diabetes take their medications, they live healthier lives, reducing overall health care costs. As a result, insurance design that makes insulin and other medications for chronic conditions available at low out-of-pocket costs is a matter of sound public policy.

A nationwide systemic preventive drug list that assesses the holistic nature of treatment and takes into account the overall savings afforded by access to preventive treatment would address this disparity in affordability, while also reducing overall costs to the system. We also look forward to the re-introduction of the Chronic Disease Management Act in this Congress which will provide legal certainty to health plans that want to exempt chronic medications from deductible requirements.

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<sup>15</sup> American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017* at 8 (Mar. 22, 2018), <http://care.diabetesjournals.org/content/diacare/early/2018/03/20/dci18-0007.full.pdf>.

Lilly also supports the policy objective of reducing the out-of-pocket burden as advanced by HHS' recently proposed rule.<sup>16</sup> We believe the proposal has the potential to lower peoples' out-of-pocket costs at the pharmacy counter by enabling manufacturers' discounts to flow directly to individuals. But in order to effectively address this issue, the proposal must be extended to private insurance, not just Medicare Part D.

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As I explained above, for me, ensuring affordable access to diabetes medication is personal. Like all of us at Lilly, I recognize the impact of higher out-of-pocket costs on individuals struggling to afford their insulin. We are committed to doing our part to address this issue in a meaningful way.

Thank you for the opportunity to be here. I look forward to your questions.

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<sup>16</sup> See HHS, Proposed Rule, *Fraud and Abuse; 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).