Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin"

April 10, 2019

Mr. Mike Mason, Senior Vice President, Lilly Connected Care and Insulins Global Business Unit, Eli Lilly and Company

The Honorable Joseph P. Kennedy III (D-MA)

1. **At the Oversight Subcommittee hearing on April 2, 2019, the witnesses spoke about the ineffectiveness of patient assistance programs and testified the programs are untimely, unworkable, and a barrier to accessing insulin. Whether the programs' criteria are too difficult to find or the application processes require already sick people to jump through hoops, there is wide consensus the programs are a cruel substitute for lower list prices.**

   Regarding patient assistance programs specifically for insulin at your company, please provide a clearer picture of how they operate by answering the following questions.

   a. **Where can patients find information on eligibility and criteria for the programs?**
   b. **What are the eligibility criteria for the programs?**
   c. **What information and documents must patients submit in order to qualify for the programs?**
   d. **What number of patients apply for the programs each year, what number are approved, and what number are denied?**
   e. **What are the ten most common reasons your company denies a patient's application?**
   f. **Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?**
   g. **How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018? How much did your company spend on advertising for insulin in 2018?**

Eli Lilly and Company ("Lilly") understands the importance of ensuring that our various insulin products are both accessible and affordable to individuals with diabetes. We have a number of programs in place to increase affordable access to our insulins. Information about these programs, their eligibility criteria, their utilization, and Lilly's efforts to make them widely available is set forth below.

Promoting affordable access begins with ensuring that our insulins are available to patients with insurance, which includes both private insureds and those covered by Medicare

Part D. Like other manufacturers, Lilly competes for placement on insurance formularies on the basis of product attributes like efficacy and safety, and by providing rebates to reduce the cost of insulin to pharmacy benefit managers ("PBMs"), payers, and patients. In 2018, for Basaglar, Humalog, and Humulin, Lilly paid approximately $4.4 billion[1] in rebates, discounts, and other price concessions, or over 50% of the $8 billion in gross sales of those products. By paying these rebates, Lilly ensures that its insulins are available to patients with insurance, who typically have low out-of-pocket costs.

We recognize that despite the rebates Lilly pays to ensure formulary access, some individuals remain exposed to high prescription drug costs. These patients have a real and pressing need for immediate solutions—particularly those who rely on medications to treat life-threatening, chronic conditions like diabetes. For this reason, Lilly has instituted multiple programs designed to reach each of the segments of people who need assistance affording their insulin. These programs work in a variety of ways. The Centers for Medicare and Medicaid Services ("CMS") narrowly define pharmaceutical manufacturer-sponsored "patient assistance programs" as those that "provide financial assistance or drug free [sic] product (through in-kind product donations) to low-income individuals to augment any existing prescription drug coverage."[2] Lilly provides in-kind product donations to charitable organizations, including Americares, Direct Relief, Dispensary of Hope, and Lilly Cares, separate non-profit organizations that conduct "patient assistance programs" for low-income individuals.

To fill additional gaps in coverage, Lilly has implemented other programs to promote access and affordability that may be relevant to your inquiry but do not fall within the CMS definition of a "patient assistance program." Below, we provide information on the range of initiatives undertaken by Lilly in addition to product donations.

- Insulin Lispro Injection: We recently launched the authorized generic ("AG") version of Humalog, Insulin Lispro Injection ("Insulin Lispro"). Insulin Lispro has a 50% lower list price than its identical medicine, Humalog U-100 and is available in both vial and KwikPen form. We sought to bring a lower-priced version of our product to the market because we recognized that Lilly's other solutions, though important, still left some people vulnerable to high out-of-pocket costs for insulin. We expect the introduction of Insulin Lispro to particularly benefit individuals in the deductible phase of their coverage period, as well as those enrolled in Medicare Part D who are in the coverage gap. The patients who benefit from Insulin Lispro in these periods should see their out-of-pocket costs cut in half. Because of government restrictions, the over 500,000 individuals taking Humalog who are enrolled in Part D do not have access to as many of our other solutions as people covered by commercial insurance plans. By introducing this AG version, Lilly can provide a lower-

[1] This figure includes: rebates for formulary access, value-based agreements, price protection penalties, patient adherence support programs, and incremental rebates associated with product bundling. This figure also includes administrative fees, which PBMs require and which are categorized as price concessions for purposes of government price reporting. These figures do not include discounts associated with mail order or cash card programs facilitated by a PBM, since they neither contribute nor are tied to conditions affecting coverage of a product.

[2] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html.

priced insulin quickly while maintaining access to branded Humalog, on which well over one million people currently depend.

- Automatic Discounts[3]: Lilly also offers savings directly to people in the high-deductible phase of their insurance plans by capping their prescription cost at $95 at a retail 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.[4] 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 occurs 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.

- Co-Pay Cards and Cash Savings Cards (collectively, "Savings Card Programs"): Lilly provides various Co-Pay Cards and Cash Savings Cards that allow patients to obtain Lilly insulins at lower prices during the high-deductible phase of a commercial insurance plan or when they are paying cash because they do not have insurance coverage. These cards typically are used when the Automatic Discounts discussed above are not available at a particular pharmacy or for patients paying cash. A Co-Pay Card is a physical or virtual card presented at the time a prescription is filled where the patient discount is adjudicated as a secondary payer in addition to the patient's insurance. Cash Savings Cards are physical or virtual saving cards for patients without commercial insurance where Lilly provides a discount to the patient that is adjudicated at the point of sale with Lilly serving as the primary payer.

- Point-of-Sale Savings Programs: Since 2017, Lilly has participated in Blink Health (www.blinkhealth.com) and Inside Rx (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 have commercial insurance or are uninsured.

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

[3] Consistent with HHS OIG guidance on copayment coupons (OIG Special Advisory Bulletin—Manufacturer Copayment Coupons September 2014), the automatic discount and Co-Pay Assistance Programs are not intended to be utilized where payment may be made, in whole or in part, under a federal health care program.

[4] Significantly, the portion that Lilly pays is counted towards the patient's deductible.

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.

To access information on Lilly's affordability programs, including eligibility requirements, patients can visit www.insulinaffordability.com, a Lilly website that provides information on the LDSC, Point-of-Sale Savings Programs (referred to on the website as "Discount Programs"), and Savings Card Programs. They can also call the LDSC, which provides information on many programs. The number for the LDSC is (833) 808-1234. In addition to helping patients enroll in these programs, the LDSC will also connect eligible patients with the separate non-profit Lilly Cares. Information regarding Lilly Cares and its requirements can be obtained from its website: https://www.lillycares.com/resources.aspx.

Lilly's affordability programs, including the Automatic Discounts, Savings Card Programs, and the Point-of-Sale Savings Programs, are readily available to patients. They require no applications and have only limited eligibility requirements. As noted above, the Automatic Discounts take place when the insurance claim is processed and do 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. Our Savings Card Programs are broadly available to patients with commercial insurance or paying cash. To qualify for these programs, the patient must be a U.S. resident, be 18 or older, have a prescription for a Lilly insulin, and not have government insurance. There is no income cap. Similarly, a patient with commercial insurance may gain access to the Point-of-Sale Savings Programs simply by signing up. Lilly makes these programs as broadly accessible as possible. While patients with government insurance are excluded from the Automatic Discounts, Savings Card Programs, and the Point-of-Sale Savings Programs, this exclusion is imposed by the government, not by Lilly.[5]

Access to the LDSC is also broadly available to patients without an application and without satisfying any additional eligibility requirements. When a patient calls the LDSC, she is connected with a healthcare professional who assesses which assistance program may be the best fit. If the patient expresses an urgent concern about accessing medication, the Lilly representative's first step is to identify ways of addressing that need. For instance, the representative may be able to offer a free month's supply of insulin. Once the immediate need has been addressed, the healthcare representative moves to a conversation about longer-term solutions. Patients who meet the minimal eligibility requirements noted above are provided with assistance through Lilly's Savings Card Programs or Point-of-Sale Savings Programs. A patient who has Medicare Part D insurance is connected to Lilly Cares, since (as noted) Lilly may not, consistent with applicable government guidance, help these patients through its Automatic Discount, Savings Card, or Point-of-Sale Savings Programs. Additionally, if a patient volunteers income information indicating that the patient may be eligible for free insulin from Lilly Cares,

[5] Federal guidance has prevented Lilly and other manufacturers from subsidizing prescription costs for people insured through government programs such as Medicare Part D. OIG Special Advisory Bulletin—Manufacturer Copayment Coupons September 2014.

the LDSC representative refers the patient there. The LDSC can also provide patients with a list of clinics that provide free medication in or near her zip code. Finally, LDSC representatives are also able to provide information about Insulin Lispro. There are no separate income requirements that a patient must meet to obtain assistance from the LDSC, and no paperwork is required.

Only Lilly Cares requires patients to submit an application form.[6] (As previously noted, Lilly Cares is a non-profit organization separate from Lilly, but for convenience, we provide publicly available information from Lilly Cares herein.) The Lilly Cares application is available at: https://www.lillycares.com/_Assets/pdf/LillyCares_Group_ABApplication_EmgalityProgram_Eligibility_Update.pdf. The form explains the separate Lilly Cares eligibility requirements, one of which relates to income. To access insulin drugs through Lilly Cares, a patient's household income may be no more than 400% of the federal poverty limit ($100,400 for a family of four).[7]

We want people to use our solutions, and our intent is to make these solutions as easy to access as possible. In 2018, Lilly spent more than $108 million on Automatic Discounts and Savings Card Programs, plus an additional $3 million on Point-of-Sale Savings Programs. The amount spent on Automatic Discounts and Savings Card Programs in 2019 is expected to rise to at least $200 million. Information from our vendors indicates that in 2018, the Automatic Discounts and Savings Card Programs served 525,403 unique patients, for a total of 1,636,797 redemptions. The Point-of-Sale Savings Programs are independently administered, and Lilly does not maintain enrollment data on those. Because Lilly's Automatic Discounts, Savings Card Program, and Point-of-Sale Savings programs do not require applications, Lilly does not have "denial" information for these programs. Utilization or denial data related to Lilly's donations of free insulin is not readily available because product donations are distributed by separate charitable organizations. The chart below, however, shows Lilly's donations of insulin from the Humalog, Humulin, and Basaglar product families from 2014 – 2018:

[6] Other free clinics to which Lilly donates medicines may also require application forms.

[7] https://www.lillycares.com/_Assets/pdf/LillyCares_Group_ABApplication_EmgalityProgram_Eligibility_Update.pdf.

Organization	Quantity of Pens[8] and Vials
2014	
AmeriCares	380
Catholic Medical Missions Board	7,200
Diabetes Camps	34,504
Direct Relief	12,344
Lilly Cares Foundation	980,352
Lilly Medicare Answers	3,488
MAP International	200
Partners in Health	6,512
Project HOPE	43,000
2015	
Catholic Medical Missions Board	12,700
Diabetes Camps	39,807
Direct Relief	17,696
Lilly Cares Foundation	748,540
Lilly Medicare Answers	189,449
2016	
Catholic Medical Missions Board	19,050
Diabetes Camps	40,284
Direct Relief	23,693
Lilly Cares Foundation	1,038,710
2017	
AmeriCares	23,910
Catholic Medical Missions Board	4,700
Diabetes Camps	50,587
Direct Relief	164,325
Project HOPE	1,500
Lilly Cares Foundation	928,664
2018	
AmeriCares	24,600
Catholic Medical Missions Board	14,900
Diabetes Camps	46,812
Direct Relief	153,900
Dispensary of Hope	23,200
Lilly Cares Foundation	1,233,096
Total (2014-2018)	**5,888,103**

Approval or denial data for the separate non-profit entity Lilly Cares is available through that organization's 2018 Annual Report, which states that 88% of people who applied were approved for up to a year of coverage.[9] According to that Report, more than 52,000 patients were provided with $320.3 million in diabetes medication in 2018.[10]

[8] This table refers to the number of pens donated—not the number of boxes of pens donated.

[9] http://www.lillycares.com/_Assets/pdf/Lilly_Cares_2018_Annual_Report.pdf.

[10] *Id.*

Lilly's various programs to promote access and affordability have different requirements for requalification. Because there are no eligibility requirements for Insulin Lispro, there are no requalification requirements. Similarly, the Automatic Discounts take place automatically and require no patient action at any time. The Savings Card Programs typically last for a year and must be reauthorized on a yearly basis. The criteria for reauthorization are the same as for initial eligibility: the patient must be a U.S. resident, be 18 or older, have a prescription for a Lilly insulin, and not have government insurance.

The last subsection of this question asks how much Lilly spent on public awareness campaigns to promote its patient assistance programs in 2018 and how much Lilly spent on advertising for insulin in 2018. Lilly has implemented a comprehensive public awareness campaign for the LDSC that uses its sales force, social media, direct healthcare provider and pharmacy communications, and outreach to elected officials and patients. Our primary efforts are focused on healthcare providers and pharmacists providing care for people living with diabetes. Our national sales force proactively promotes awareness about our LDSC offerings. They are trained to provide information about how patients can connect with the LDSC and the various affordability solutions that are available. They also encourage healthcare providers to distribute LDSC flyers, patient cards, and office magnets, which list the call center's phone number and hours.

For 2018, Lilly also spent approximately $5.3 million on advertising the LDSC, which launched in August of that year, directly to patients. This is more than one-fifth of the amount Lilly spent on consumer awareness programs (including advertising) for its insulin products that year (approximately $23.4 million).[11] And about 50% of that $23.4 million was spent on a patient education campaign for patients who may have questions about how to start using Lilly insulin or how best to adhere to the treatment going forward.

In addition to paid advertising, Lilly promotes the LDSC through social media. Since August 2018, Lilly has published eight blog posts about the LDSC on LillyPad,[12] Lilly's official blog, and more than 145 social media posts on our corporate Twitter, Facebook, and LinkedIn accounts.[13] For example, during the federal government shutdown in 2018 – 2019, we published a blog post[14] and ran a paid LinkedIn advertising campaign to inform federal employees that they were eligible for discounts. We have directed more than 1,000 questions about insulin

[11] Consumer expenses reflect promotional activities designed to support patients initiating insulin treatment whom already received an insulin prescription from their Health Care Provider. Examples include branded paid search advertising and printed materials for patients. Also, included are unbranded disease state education digital content sponsored by Lilly USA, LLC. This may also include branded advertising presented alongside unbranded content. These expenses, including the unbranded content, are classified as promotional advertising by Eli Lilly and Company.

[12] https://lillypad.lilly.com; *see, e.g.*, Mike Mason, *Helping People with Insulin Affordability*, LILLYPAD (Aug. 1, 2019), https://lillypad.lilly.com/entry.php?e=11030.

[13] Lilly's corporate divisions each maintain their own social media accounts; these numbers include posts by Eli Lilly & Company and by Lilly Diabetes.

[14] *Help for People, Including Federal Employees*, LILLYPAD (Jan. 16, 2019), https://lillypad.lilly.com/entry.php?e=11221.

affordability to the LDSC via these social media channels in response to private direct messages and public posts. We also have issued three press releases about the LDSC since its launch.

In addition, we have reached out individually to hundreds of elected state officials to alert them of the LDSC, including governors and representatives in states such as California, Delaware, Idaho, Kentucky, Maryland, Massachusetts, New Jersey, New York, Pennsylvania, and Tennessee. Moreover, during the federal employee shutdown earlier this year, we sent similar notices to reach employees who may have needed assistance during the furlough.

The costs of advertising the LDSC are only a portion of the overall costs of operating the Solution Center. In 2018, Lilly spent approximately $3 million to staff the LDSC with healthcare professionals who answer individuals' questions. We opened the LDSC with four dedicated agents, but due to marketing efforts and increased awareness, we have had to increase our headcount by nearly 400% since our launch in August 2018, and that growth continues. Additionally, the $3 million spent in 2018 does not account for unallocated Lilly expenses, such as training and support from Lilly employees. These expenses are in addition to the $108 million noted above spent in 2018 on Automatic Discounts and Savings Card Programs and the $3 million spent on Point-of-Sale Savings Programs.

Overall, our solutions are working to reduce out-of-pocket costs. Today 95% of prescriptions for Humalog in the United States cost consumers less than $95 at the retail pharmacy, 90% cost less than $50, and 43% cost $0.[15] These figures reflect the cost for Humalog at the retail pharmacy regardless of the phase or term of the patient's health plan. Now that Insulin Lispro has launched, we hope it will be added to more formularies. At the same time, we continue to educate the diabetes and medical community about our Lilly Diabetes Solution Center so that even more people will pay less for their insulin.

2. Regarding patient assistance programs at your company for all types of medication, please provide a clearer picture of how they operate by answering the following questions.

a. Where can patients find information on eligibility and criteria for the programs?
b. What are the eligibility criteria for the programs?
c. What information and documents must patients submit in order to qualify for the programs?
d. What number of patients apply for the programs each year, what number are approved, and what number are denied?
e. What are the ten most common reasons your company denies a patient's application?
f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?

[15] Based on IQVIA data, FIA data (August 2018 – December 2018).

g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018? How much did your company spend on advertising for medication in 2018?

Lilly manufactures a variety of medications in the oncology, cardiology, immunology, endocrinology, and other spaces. As defined by CMS, Lilly's patient assistance programs center on donations to Lilly Cares and other charitable organizations. The following medications are available for free from Lilly Cares: Alimta, Cialis, Cymbalta, Cyramza, Emgality, Erbitux, Evista, Forteo, Glucagon, Humatrope, Lartruvo, Olumiant, Portrazza, Prozac, Strattera, Symbyax, Taltz, Trulicity, Verzenio, Zyprexa, Zyprexa Relprevv, and Zyprexa Zydis.[16] Approval or denial data for Lilly Cares is available through that organization's 2018 Annual Report, which states that 88% of people who applied were approved.[17] According to that Report, more than 52,000 patients were provided with $320.3 million in diabetes medication in 2018.[18]

The Lilly Cares application is available at: https://www.lillycares.com/_Assets/pdf/LillyCares_Group_ABApplication_EmgalityProgram_Eligibility_Update.pdf. The Lilly Cares oncology patient assistance program application is available at: https://www.lillycares.com/_Assets/pdf/LillyCares_oncology_application_Program_-Eligibility_Update.pdf. These applications set forth the eligibility and documentation requirements for the Lilly Care programs. Other third-party charitable organizations to which Lilly donates medication each distribute product to their network of clinics subject to their own patient eligibility requirements.

3. Are there any medications not on your company's patient assistance program? Please provide a list of the drugs that are available for patient assistance and those that are not a part of patient assistance programs.

All of Lilly's insulins are covered by the programs discussed in response to Question 1. Please see Lilly's response to Question 2 for information about the non-insulin drugs available through Lilly Cares, a separate non-profit organization. Lilly Cares does not provide Adcirca, Gemzar, Glyxambi, Jardiance, Jentadueto, Synjardy, and Tradjenta. These drugs are either: (1) off patent and have competition from approved generics; or (2) are products we co-promote but do not manufacture or set associated prices.

4. Does your company make medication available to patients for free or reduced prices, or does it use a private foundation or other third parties to operate patient assistance programs? When your company makes contributions of medication to private foundations, such as Sanofi's Patient Connection, Sanofi's Foundation for North America, Novo Nordisk's NovoCare, Eli Lilly's Lilly Cares, or other third parties, does

[16] http://www.lillycares.com/content/lillycaresgroupa_druglist.html; https://www.rxassist.org/pap-info/company-detail?CmpId=16.

[17] http://www.lillycares.com/_Assets/pdf/Lilly_Cares_2018_Annual_Report.pdf.

[18] *Id.*

your company correspondingly reduce its tax liability? Please provide the amount by which your company reduced its tax liability for 2018 as a result of making contributions to patient assistance programs.

As discussed above, Lilly donates medicines to Lilly Cares, a separate charitable entity, and other charitable organizations that provide free insulin to patients. Lilly is eligible for a charitable tax deduction related to those donations computed in accordance with the relevant Internal Revenue Code and Treasury Regulations. The costs of Lilly's other patient access and affordability programs are recorded as sales reductions or operating expenses and are not eligible for a charitable tax deduction.

The Honorable Brett Guthrie (R-KY)

1. **In March 2019, Eli Lilly announced that it was launching an authorized generic version of Humalog. In a staff briefing, Eli Lilly said that it anticipated providing supplemental rebates for the authorized generic version of Humalog.**

    a. **Will Eli Lilly request that Pharmacy Benefit Managers (PBMs) include both the authorized generic and the brand version on their formularies? If so, why? Does Eli Lilly anticipate that one version of the product will be preferred on the formularies over the other version of the product?**

Lilly will offer and has offered all PBMs access to Insulin Lispro, the AG version of Humalog, at the same or better net price as Humalog. We believe having both options available to patients at the same formulary status (or, potentially, to have a better status for the AG) is appropriate so that individuals in a deductible phase or individuals with co-insurance would have a lower-cost option available. Our experience to date, however, is that most PBMs continue to prefer branded Humalog even when the net cost is comparable because that option offers more total rebate dollars, and many of their health plan and employer clients value the total rebate dollars that they receive when their members purchase prescription medications. As described further below, those health plans and employers use the rebate dollars they receive to marginally reduce premiums for all of their insureds, rather than using them to reduce patients' out-of-pocket costs for insulin at the pharmacy counter. As a result, most PBMs have indicated that they are considering several approaches for Insulin Lispro, such as excluding Insulin Lispro entirely from formularies, offering the AG only on "niche" formularies, or placing the product on formulary but at a higher cost-sharing tier.

    b. **Will the introduction of the authorized generic have any impact on the list or net pricing for the branded version of Humalog (*e.g.*, will the rebates Eli Lilly offers to PBMs for Humalog change)?**

We have not increased the list price of Humalog with the launch of Insulin Lispro. Launching a lower-priced product does have other costs to Lilly, especially to branded Humalog. Since we announced Insulin Lispro, some PBMs have demanded more generous rebates on

Humalog in exchange for formulary access. For example, where the net price of Humalog after the rebate is higher than the net price of the AG, PBMs have requested that we increase their Humalog rebates so that the net price of Humalog is at least equal to the lower AG net price. As detailed further below, PBMs' clients include health insurance plans and employer groups who value the total rebate dollars that they receive. Thus, even with the net prices the same, most PBMs appear to prefer Humalog, the product that generates more rebate dollars.

2. **There have been press reports about a letter that one Pharmacy Benefit Manager (PBM), OptumRx, sent to pharmaceutical manufacturers requesting that pharmaceutical manufacturers provide the PBM with notice if the manufacturer decides to lower the list price of the medicine. Has Eli Lilly received a letter from any PBMs or insurers requesting that it provide the PBM or insurer with notice before Eli Lilly lowers the list price of insulin or any other medicine? If so, please list the entities that have sent such a letter to Eli Lilly and describe the requirements set forth in the letter.**

    a. **Does Eli Lilly have any contractual obligations to provide a supply chain partner with notice before lowering the list price of insulin or any other medicine? If so, please list the entities and describe the contractual provisions.**

No. Lilly received the communication referenced above but did not agree to the request.

    b. **Has Eli Lilly provided any of its supply chain partners with notice of a list price decrease? If so, please describe these interactions.**

No.

    c. **What happens to Eli Lilly's rebate obligations with PBMs if Eli Lilly lowers the list price of insulin or any other medicine?**

Theoretically, the dollar amount Lilly must pay in rebates should decrease if Lilly lowers the list price of a medicine, because rebates are calculated as a percentage of, and thus fixed to, a product's list price. It is possible, however, that channel partners will seek to renegotiate agreements to increase rebate and discount percentages because their financial forecasts would have been based on a product with a higher list price.

    d. **Has the letter sent by OptumRx or any other similar requests by supply chain partners impacted Eli Lilly's decisions regarding whether to lower the list price of insulin or any other medicine? If so, please describe.**

The above-referenced letter, coupled with the commercial responses to our authorized generic Insulin Lispro, illustrates the challenges and barriers to lowering list prices. As noted above, many health plans and employers value the greater total rebate dollars that they receive

from those medications. Consequently, some PBMs have indicated that manufacturers must maintain the total dollar amount of rebates paid to them even if the list price of a prescription medication is reduced. Indeed, the above-referenced letter proposed an alternative rebate calculation whereby Lilly would be required to pay the same amount of rebate dollars on a prescription drug with a lower list price. Such demands make it difficult for Lilly to reduce list prices and retain comparable levels of patient access on PBM formularies.

These market dynamics underscore the need for systematic reform. One proposal, which is sometimes called "first dollar coverage," is described in more detail below.

3. **We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. For example, in Eli Lilly's testimony, Eli Lilly described how the net price of its most broadly used insulin product decreased by 8.1 percent while the list price increased by 51.9 percent. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many PBMs that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why manufacturers continue to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price. Please explain.**

Lilly has always sought to make its insulin medications affordable for patients who depend on them. For years, Lilly was able to accomplish this by providing significant discounts off of the list price in the form of rebates to PBMs and other payers. These rebate payments ensured that Lilly's insulin products were covered on PBM formularies under terms that provided affordable access for patients. In recent years, PBMs have begun to offer only one manufacturer's insulin products on their formularies, while blocking patients' access to competing products. PBMs have used this leverage to negotiate with manufacturers for larger rebates, placing downward pressure on Lilly's "net prices," *i.e.*, the amount that Lilly receives on each prescription. At the same time, increasing numbers of patients have been moved to insurance plans with larger deductibles and cost-sharing obligations, such that they do not directly benefit from the larger rebates paid by Lilly and other manufacturers. These developments have created affordability challenges for a growing number of patients, even as net prices for Lilly's insulins have stayed flat or declined.

Unfortunately, this affordability challenge cannot be addressed simply by lowering list prices. While the PBMs' clients, which include health insurance plans and employer groups, may prefer products that have a low net cost, they also value the total rebate dollars that they receive when their members purchase prescription medications. Many plans and employers use these rebates to subsidize lower premiums for all members. This has had the effect of increasing out-of-pocket costs for patients with significant cost-sharing obligations, especially those with chronic illnesses like diabetes. For example, Lilly pays substantial rebates even for patients who are responsible for the full cost of their insulin prescription during the deductible phase of their

health plan. Rather than using the rebate dollars to reduce those patients' out-of-pocket costs, many health plans use the rebate dollars to marginally reduce premiums for all of their insureds.

Lilly's recent launch of Insulin Lispro, a lower-priced authorized generic version of its most popular insulin product Humalog, illustrates this dynamic. Insulin Lispro is available at a list price that is 50% less than Humalog, and the rebates Lilly has offered on Insulin Lispro would provide PBMs a net cost that is comparable to branded Humalog. However, because the list price of Insulin Lispro is substantially lower than the list price of Humalog, the total rebate dollars offered on Insulin Lispro are lower. Unfortunately, after months of contract negotiations, Lilly has only been able to gain limited formulary access for Insulin Lispro. We expect that it will be covered for less than 15% of patients with commercial health insurance and less than 25% of Medicare Part D patients.

One proposal that Lilly believes is worthy of consideration is adding insulin to preventive medications lists, which would lower out-of-pocket costs by, for instance, 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.[19] 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. Independent actuarial analyses have shown that adding first dollar coverage for insulin patients would increase policyholders' premiums by just 43 cents per month while enabling insulin patients to affordably maintain their insulin therapy.[20] This would be a significant step toward a more sustainable model that addresses the unacceptably high out-of-pocket costs faced by some patients.

4. During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are sometimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.

a. What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?

[19] Am. Diabetes Ass'n, *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.

[20] E. Anne Jackson, Matthew Berman & David M. Liner, *Mitigating Out-of-Pocket Costs for Prescription Drugs*, MILLIMAN (Dec. 2016).

b. Does your company support moving to a system where administrative fees are based on a flat fee instead?

As this question notes, manufacturers are often required to pay a specified administrative fee percentage, rather than permitted to freely negotiate the amount. Often, agreeing to these fee percentages is characterized as a "bid condition" by the PBMs—failure to acquiesce to this condition will result in an offer being rejected as "non-compliant." Since these are non-negotiable terms, manufacturers have no choice but to accept them.

We do not believe there are any advantages to setting PBM administrative fees as a percent of product's list price (WAC). Indeed, calculating administrative fees as a percentage of the list price can create uncertainty among manufacturers, PBM clients, and policymakers regarding the economic substance of such transactions. To the extent that such administrative fees are passed on to customers, as some PBMs have stated, it may be more appropriate to classify them as rebates.

The Honorable Jeff Duncan (R-SC)

1. One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba and Fiasp and have also created new, more accurate and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.

Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and "manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents."

So, which is it? Is there innovation in the insulin market or not?

Yes, there is innovation in the insulin market as well as in the treatment of diabetes generally. Today's modern insulins have improved substantially since 1923. That year, Lilly pioneered the manufacturing and distribution of Iletin, the first animal-based insulin. Iletin was the first real hope for treating diabetes, a fatal disease then with no effective treatment options. But Iletin was created through processes most would view as crude today—extracting insulin from animal pancreases—leading to purity and quality concerns. Decades later, modern innovation led Lilly to introduce the first recombinant DNA insulin and, eventually, the first

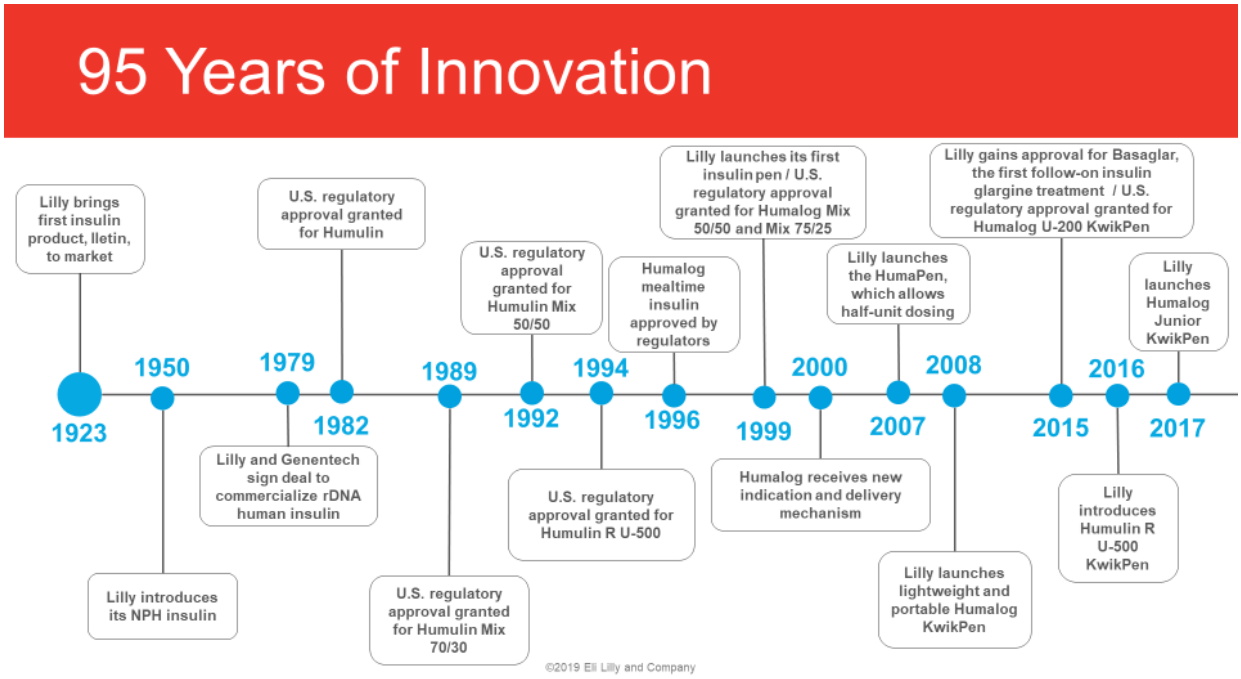
human analog insulin. These improvements have been part of a dramatic change in the way diabetes is treated.

Lilly brought the first genetically engineered medicine, Humulin, to market in 1982, ending concerns about whether there would be enough animal-based insulin to serve the growing number of people with diabetes. This product saved lives by allowing the use of a biosynthetic form of human insulin. In 1996, Lilly launched another biotech insulin, Humalog, which mimics the body's own rapid insulin response and has made it easier for people with diabetes to manage their blood glucose. For evidence of the importance of this innovation, one need look no further than how much more often physicians prescribe modern insulins, like Humalog, compared to older human insulins, like Humulin. While human insulin is cheaper and widely available,[21] the vast majority of prescriptions for Lilly insulins are for Humalog. Moreover, not every new insulin product is widely adopted. The continued preference for Humalog demonstrates that this product was truly innovative and is still effective at helping people control their diabetes.

In 2015, Lilly obtained approval for the first follow-on insulin biologic, Basaglar. This product currently has a list price that is 23% lower than the list price of the most commonly prescribed basal insulin, Lantus. We also have developed a wide range of other diabetes treatments in oral and easy-to-use injectable forms that help people control their glucose levels. The wide range of therapies we offer is essential for physicians and patients to create individualized treatment plans for diabetes.

[21] For example, although not a Lilly product, the availability of ReliOn—human insulin sold by Walmart at a price to the patient of approximately $25—provides another option for patients unable to otherwise obtain access to affordable insulin. See https://corporate.walmart.com/_news_/news-archive/2012/07/24/walmart-launches-effort-to-save-diabetes-patients-up-to-60-million-annually.

A timeline showing some of Lilly's significant insulin advancements is set forth below:



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 diabetes into the early 40s, and eventually to where it is today in the late 60s. But our work is not done. The life expectancy of a patient diagnosed with Type I diabetes is still 11-12 years lower than that of the average American. Our hope is that one day the life expectancy for a person diagnosed with diabetes will be no different than that for any other American.

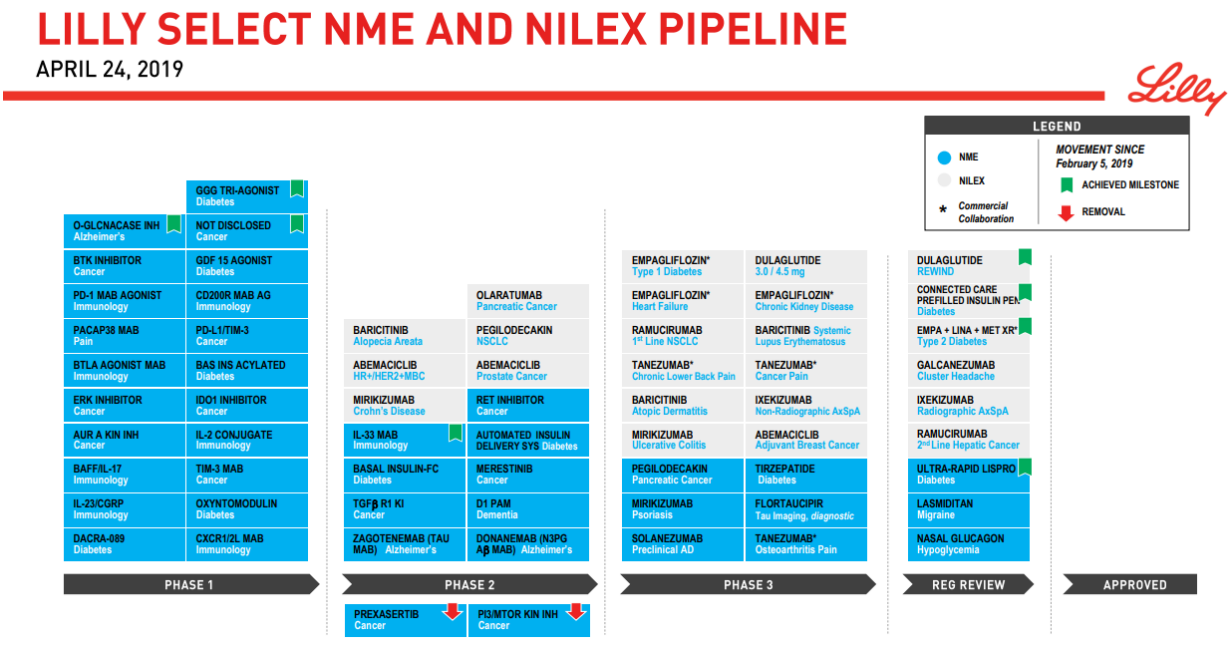
As an innovation-based pharmaceutical company, Lilly continues to push the boundaries of science today to bring better treatments to people with diabetes and other conditions tomorrow. Only about half the people living with diabetes and using insulin are able to fully control their condition. Increased innovation is needed to make diabetes easier to manage, and Lilly is committed to driving new innovative treatments to ease the burden of living with diabetes. For example, later this year, we expect to introduce an easier-to-use nasal glucagon treatment for life-threatening hypoglycemia. 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.[22] And in 2020, if approved, we expect to introduce an even faster-acting version of insulin. Lilly is also active in the space of digital health

[22] *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.

solutions and is developing a connected diabetes system consisting of devices that we hope will improve adherence, outcomes, and convenience.

Lilly is not merely an insulin manufacturer, nor is our focus limited to insulin or diabetes. In 2018 alone, Lilly spent more than $5.3 billion on research and development, accounting for more than 20 percent of total revenues, in multiple therapeutic areas other than diabetes, including oncology, immunology, Alzheimer's disease, and chronic pain. The revenues we earn on our portfolio of products, including insulins, directly support research and development for tomorrow's life-saving medicines. Any one, or all, of our potential treatments still in development could fail during clinical trials. Indeed, risk and uncertainty are inherent to drug discovery. A recent and heartbreaking example of the risk that our company undertakes can be seen in solanezumab, a potential treatment for Alzheimer's disease that did not succeed in its last stage of clinical testing. Had it succeeded, solanezumab would have been the first disease-modifying drug to treat Alzheimer's. Nevertheless, Lilly remains committed to Alzheimer's research, and our portfolio includes other potential approaches, including a BACE inhibitor in clinical trials.

Below is a visual representation of Lilly's pipeline for new molecular entity ("NME") and indication or line extension ("NILEX") drugs.



2. **One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one 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."**

Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."

So, which is it? Are there patents preventing innovation and competition or not?

We do not believe OptumRx was talking about Lilly.[23] No patents prohibit competitors from launching products similar to Lilly insulins. In fact, none of our insulin active ingredients are currently protected by patents. Additionally, although Lilly has filed or holds patents on certain delivery systems used with some of our insulins (e.g., U.S. Patent Number 7291132 covering "medication dispensing apparatus with triple screw threads for mechanical advantage"), this is not a barrier to insulins delivered in a variety of other ways. In fact, Sanofi launched a follow-on insulin lispro product to compete with Humalog in April 2018, and no patent litigation or other regulatory impediment inhibited Sanofi's launch of its product. The general absence of patents covering Lilly insulins is verifiable in the FDA Orange Book, which is available and searchable on the FDA's website at https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

[23] OptumRx's written testimony from the April 10, 2019 hearing before the House Energy & Commerce Committee cites a study on Lantus, an insulin manufactured by Sanofi. https://docs.house.gov/meetings/IF/IF02/20190410/109299/HHRG-116-IF02-Wstate-DuttaS-20190410.pdf.