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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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December 6, 2019

Scott P. Serota
President and Chief Executive Officer
Blue Cross Blue Shield Association
225 North Michigan Avenue
Chicago, Illinois 60601

Dear Mr. Serota:

We are continuing to investigate the rising costs of health care across numerous services and products, including, but not limited to, spending on hospitals, physicians, and prescription drugs. As part of this work, we have focused on the increasing price of insulin for patients with diabetes. We therefore request information from your company to better understand the role of health insurers in reducing the cost of insulin for patients.

Earlier this year, we sent letters to biopharmaceutical manufacturers (manufacturers) and pharmacy benefit managers (PBMs) to obtain information about insulin pricing and the impact that the current prescription drug supply chain has on patient costs. The Subcommittee on Oversight and Investigations also held two hearings on the topic, hearing testimony from manufacturers, PBMs, patient advocacy groups, physicians, and patients. We asked these stakeholders numerous questions, including questions about the complexity of the prescription drug supply chain, patient access and affordability issues relating to insulin, the manufacturer's role in setting the list price of insulin, the impact that rebates and other discounts negotiated by PBMs have on out-of-pocket costs for patients, and the financial relationships between the two entities.

Although the list price of many insulin products significantly increased over the past decade, the net price received by manufacturers for many of these insulin products stayed the same or decreased over the same period. Indeed, all three insulin manufacturers—Eli Lily, Novo Nordisk, and Sanofi—explained that one of the factors driving higher list prices for insulin was the increased importance of providing rebates to PBMs and health plans to maintain formulary access. For instance, Novo Nordisk testified that the net prices of the company's insulin

products have declined from 2015 through 2018 even though list prices have been increasing.[1] As an example, Novo Nordisk said the list price of the NovoLog FlexPen increased 310 percent since 2003 while the net price decreased by 21 percent during this period.[2] Similarly, Eli Lilly testified that the list price of Lilly's most broadly used insulin product, Humalog U100, increased by 51.9 percent between 2014 and 2018 while the average net amount Lilly received for the product decreased by 8.1 percent during the same period because of the rebates Lilly paid for the product.[3] Likewise, Sanofi testified that there has been a decline in the average aggregate net price of the company's products over the last several years, including insulin products, because of the rebates that the company pays to payers and other supply chain intermediaries.[4]

The three PBMs that testified before the Subcommittee—Express Scripts, OptumRx, and CVS Health—told the Committee most of the rebates that they negotiate with manufacturers are passed through to health plan clients and, as a result, these PBMs have been able to help control, and in some instances reduce, insulin spending for their clients. For example, Express Scripts testified that plans enrolled in the company's clinical solutions experienced a 1.5 percent decline in unit cost for insulin in 2018.[5] CVS Health testified that the company's 2018 data shows that they have been able to decrease the total cost of diabetes drugs, including insulin, by 1.7 percent despite brand price inflation of 5.6 percent.[6] OptumRx testified that, for insulin, the company has "been able to negotiate with competing brand manufacturers to obtain significant discounts off of list prices, allowing plans to place the drug with the lowest overall cost to the customer in a preferred position on the formulary."[7]

Unfortunately, even though the average net price that manufacturers are receiving for many insulin products is decreasing and PBMs are working with health plans to help reduce the cost of insulin for health plans, many Americans are facing increased out-of-pocket costs for their insulin at the pharmacy counter. Indeed, Sanofi shared information highlighting that "the average net price of Lantus, [the company's] most prescribed insulin, has declined by over 30 percent since 2012, while the average out-of-pocket burden for patients with commercial

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[1] *Priced out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong., Testimony of Douglas J. Langa, Novo Nordisk, Inc. (Apr. 10, 2019).
[2] *Id.*
[3] *Priced out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong., Testimony of Michael B. Mason, Senior Vice President, Connected Care and Insulins at Eli Lilly and Company (Apr. 10, 2019).
[4] *Priced out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong., Testimony of Kathleen W. Tregoning, Executive Vice President, External Affairs, Sanofi (Apr. 10, 2019).
[5] *Priced out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong., Testimony of Amy Bricker, R.Ph., Senior Vice President, Supply Chain, Express Scripts (Apr. 10, 2019).
[6] *Priced out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong., Testimony of Thomas M. Moriarty, Executive Vice President, Chief Policy and External Affairs Officer, and General Counsel for CVS Health (Apr. 10, 2019).
[7] *Priced out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong., Testimony of Sumit Dutta, M.D., Chief Medical Officer, OptumRx (Apr. 10, 2019).

insurance and Medicare has increased by approximately 60 percent over that same period."[8] Along the same lines, during the Subcommittee's recent hearings, we heard that many insured and uninsured individuals pay the list price—or close to it—for insulin at the pharmacy counter if they do not have access to a patient assistance program. Even worse, we heard that patients who cannot afford their insulin will sometimes ration, dilute, or not take their insulin, which can have severe short- and long-term negative health consequences.

As you know, the price that a patient ultimately pays for insulin depends on multiple factors, and insurers have significant influence on the out-of-pocket costs of insulin. Some of the characteristics of the current health care market that directly impact out-of-pocket costs for patients include the increasing number of high deductible health plans (HDHPs), a transition from flat-copays for prescription medicines to requiring patients to pay a percentage of the list price of the medicine (*i.e.*, coinsurance) by some plans, the use of preventive drug lists, changes in formulary design and the increasing use of restrictive formularies, the increasing demand for rebates, and whether rebates are directly passed through to patients. Not only do these factors have a direct impact on the out-of-pocket costs for insured individuals, but some of them—such as the increasing demand for rebates—also indirectly impact the cost of insulin for uninsured individuals since they may have an influence on the product's list price.

We are therefore examining the role of insurers in the prescription drug supply chain, including questions about how insurers make decisions about plan design, the use of rebates in the insulin market, and the level of transparency between insurers and their supply chain partners. During our recent work, we heard that insurers approach these issues in many ways. For example, some health plans pass rebates directly through to plan beneficiaries while other health plans use rebates to lower premiums for all their beneficiaries. Express Scripts testified:

> In the Medicare Part D program, rebate savings are passed to Part D plan sponsors and are responsible for saving enrollees and taxpayers billions of dollars each year since the Part D program began.... In the commercial market, rebates are an effective tool that employers and health plans use to generate more savings for prescription drugs. Employers and other plan sponsors that work with Cigna and Express Scripts choose how rebates are used. Some use them to lower premiums and cost sharing, others choose to expand access, fund wellness programs, or provide discounts to consumers at the point-of-sale. Nearly half of Express Scripts' clients have opted for 100 percent pass-through of rebates.[9]

In the same hearing, CVS Health testified that the company had "over ten million lives covered in a point-of-sale rebate program today" and that CVS Health "really advocate[s] a zero co-pay for insulin and other preventive medications" as the "cost savings associated with

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[8] *Priced out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong., Testimony of Kathleen W. Tregoning, Executive Vice President, External Affairs, Sanofi (Apr. 10, 2019).

[9] *Priced out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong., Testimony of Amy Bricker, R.Ph., Senior Vice President, Supply Chain, Express Scripts (Apr. 10, 2019).

adherence is significant."[10] On the other hand, Sanofi testified that rebates "are not necessarily going all the way through to patients" and instead are "being used for other parts of the system and we don't have visibility to (*sic*) how those rebates get used."[11]

We therefore request your assistance to better understand the relationship between insulin's list price and its negotiated price and the impact that this negotiation process has on patients and medication adherence. Accordingly, we request that you provide answers to the below questions by January 6, 2020. When applicable, answer each question as it relates to each insurance market (*e.g.*, commercial plans, Medicare Part D, Medicaid, the Children's Health Insurance Program, and Exchange plans under the Patient Protection and Affordable Care Act).

1. **Cost of insulin to health plans and use of rebates negotiated on your company's behalf.**

    a. Has the cost of on-formulary insulin for each plan offered by your company increased or decreased over the past 10 years? Please describe how much the price has increased or decreased for each plan during this period.

    b. What percentage of plans offered by your company pass rebates through to insured customers at the point-of-sale for insulin? For the plans that pass-through rebates, what percentage of rebates are passed through to insured customers at the point-of-sale? For the plans offered by your company that do not pass through rebates, please explain: (1) how those plans use the rebates that they receive for insulin from manufacturers and other supply chain entities, including the percentage of rebate dollars that go to each purpose; and (2) how your company tracks the use of rebate dollars and ensures that they are used for the stated purposes.

2. **Formulary development.**

    a. Please describe how the formulary is structured for each plan offered by your company and list each of the insulin products included on each formulary for the past 10 years. If the insulin products included on the formularies have changed, please describe why these changes have occurred, whether the changes were made during a plan year, and the number of beneficiaries using an insulin product when it was removed from a formulary. If a change was made in the middle of a plan year, please describe why the insulin product was removed from the formulary and how it impacted current enrollees.

    b. Do any plans offered by your company use restrictive or exclusive formularies for any category of insulin products? If so, please describe when your company started using restrictive and/or exclusive formularies and why your company

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[10] *Priced out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong., Preliminary Transcript, 66 (Apr. 10, 2019).
[11] *Id.* at 52.

started using these types of formularies. Please also describe how much a beneficiary would pay for an insulin product that is not covered by their plan and whether the amount paid by that individual would be applied toward their deductible. Please also describe whether there is any process an individual can follow to obtain coverage of an insulin product that is not covered by their plan, how long that process takes, and the percentage of requests that are granted for coverage of off-formulary insulin products.

c. If any plans offered by your company exclude certain insulin products from the plan's formulary because those insulin products are not the lowest net cost for the plan, please explain why the plan excludes these products from the formulary rather than negotiating some rebates for these products and including them on the formulary with higher cost-sharing obligations for the beneficiary.

3. **Health benefit design.**

a. How does your company decide how to structure the cost sharing obligations for a beneficiary for each insulin product covered by your company? Are different insulin products typically placed on different tiers? Why?

b. Do any plans offered by your company use preventive drug lists, and if so, what percentage of plans offered by your company that use preventive drug lists include insulin on the preventive drug list? If plans offered by your company use preventive drug lists, do these plans provide first dollar coverage for medicines on the preventive drug list? Will your company change any of its policies relating to insulin based on the new guidance that the Internal Revenue Service (IRS) issued in July 2019 expanding the list of preventive care benefits permitted to be provided by a high deductible health plan (HDHP) under section 223(c)(2) of the Internal Revenue Code without a deductible, or with a deductible below the minimum deductible for an HDHP? Why or why not?

c. Other than the beneficiary's deductible, are most of the cost-sharing obligations for beneficiaries of plans offered by your company structured as a flat co-pay or as coinsurance? Has this structure changed at all over the past 10 years? If so, please describe how the structure has changed and why.

d. Have the out-of-pocket costs for each on-formulary insulin product for beneficiaries enrolled in your company's plans increased or decreased over the past 10 years? Please describe how much the out-of-pocket costs for each insulin product have increased or decreased during this period.

e. Does your company consider how different benefit designs potentially impact adherence to certain medicines such as insulin and the long-term health and financial consequences of reduced adherence? If so, please explain.

4. **Supply chain relationships.**

    a. Please list all the supply chain partners that your company negotiates with and describe how these negotiations impact the price of insulin for your beneficiaries.

    b. What services does your company's PBM provide to your company for each market? How does your company compensate your PBM (*e.g.* flat fee or percentage fee)?

5. **Transparency.**

    a. Does your company know the specific details of all the fees charged by PBMs relating to the services that they provide to your company? If not, please describe why this information is not shared with your company.

    b. Does your company know the exact dollar amount of rebates your PBM negotiates for each insulin product offered by your company and the dollar amount of rebates retained by the PBM?

    c. Does your company know the rebates offered to your company by each insulin manufacturer for each insulin product before formulary decisions are made for the plans offered by your company? If not, please explain why your company is not provided with this information.

    d. Does your company know the amount of money that your PBM reimburses pharmacies if a beneficiary of one of your company's plans fills an on-formulary insulin prescription at that pharmacy counter? If not, please describe why this information is not shared with your company.

    e. Is there any information and/or data that your company does not have access to relating to insulin that would help your company improve outcomes for patients or reduce the cost of insulin for patients with diabetes? If so, please describe.

    f. Has your company increased the transparency for its enrollees and physicians regarding the price of insulin to the company and the specific out-of-pocket costs for that enrollee? If so, please describe.

6. **High Deductible Health Plans (HDHPs).**

    a. Some of the individuals that have the highest out-of-pocket costs for insulin are individuals enrolled in a HDHP. Please provide the number of beneficiaries enrolled in a HDHP for each year for the past 10 years and the average out-of-pocket costs for each insulin product offered on the formulary of these plans.

7. **Patient assistance programs**.

    a. Many stakeholders have developed programs to help reduce out-of-pocket costs for insulin users. While not a long-term solution to the current drug pricing issues, these programs are helping to provide more diabetics with insulin at a reasonable cost in the short-term. Does your company offer any patient assistance programs to help reduce the out-of-pocket costs of insulin for your beneficiaries? If so, please describe.

8. In addition to providing written answers to the questions above, please provide a copy of any standard contracts used with your supply chain partners that impact the price of insulin products for your company or your company's beneficiaries.

Please also make arrangements to provide a briefing to staff to review your response. Please contact Natalie Sohn or Brittany Havens with the minority staff at (202) 225-3641 if you have any questions about this request. Thank you for your prompt attention to this request.

Sincerely,

Greg Walden
Republican Leader

Brett Guthrie
Republican Leader
Subcommittee on Oversight
and Investigations

Michael C. Burgess, M.D.
Republican Leader
Subcommittee on Health

cc. The Honorable Frank Pallone, Jr., Chairman, Committee on Energy and Commerce
cc. The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
cc. The Honorable Anna G. Eshoo, Chair, Subcommittee on Health