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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
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February 6, 2019

Mr. Tim Wentworth
Chief Executive Officer and President
Express Scripts Holding Company
One Express Way
St. Louis, MO 63121

Dear Mr. Wentworth,

We have been examining the rising costs of health care across numerous services and products, including, but not limited to, spending on hospitals, physicians, and prescription medicines. During our review of the prescription drug supply chain, we heard concerns about the rising cost of prescription drugs in many categories of medicines, and one medicine that has received attention due to list price increases is insulin. We therefore request information to better understand the role of Pharmacy Benefit Managers (PBMs) in reducing the cost of insulin for patients.

Numerous reports have discussed how the list price of insulin has skyrocketed over the past decade—according to a 2016 study, the average list price of insulin nearly tripled between 2002 and 2013.[1] The list price of a medicine, however, oftentimes is not the amount of money that the manufacturer receives for the product nor is it the actual price paid for the medicine. Instead, as Matt Eyles, Senior Executive Vice President and Chief Operating Officer for Policy and Regulatory Affairs at America's Health Insurance Plans testified before the Committee on Energy and Commerce in December 2017, the list price is the "starting point for plans and PBMs to negotiate lower prices for consumers."[2] The Committee wrote to various PBMs on August 30,

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[1] William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, Diabetes Care, at 2-3 & 11 (May 2018), *available at* http://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019; Xinyang Hua, MSc, Natalie Carvalho, PhD, Michelle Tew, MPH, et al., *Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013*, THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (2016), *available at* https://jamanetwork.com/journals/jama/fullarticle/2510902.

[2] *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115th Cong., Preliminary Transcript, 15 (Dec. 13, 2017).

2018, to better understand how PBMs negotiate lower prices for consumers.[3] We appreciated your prompt response to that letter. Through the responses we received to the letter, we learned that PBMs typically obtain rebates and discounts that reduce the manufacturers' list prices for nearly all products in competitive therapeutic drug categories.[4] These rebates and discounts help to limit price growth of medicines. For example, one PBM stated that "[f]or our PBM clients, including the employers, unions, health plans and government programs we serve, we have kept drug price growth at a minimal of 0.2 percent in 2017, the lowest in five years, despite manufacturer brand list price increases on drugs near 10 percent."[5]

While these savings are important to help reduce health care costs and improve patient access to life-saving medicines such as insulin, we remain concerned that many Americans struggle to afford their medicines and that there is a lack of transparency surrounding how much medicines are costing patients. Press articles have highlighted instances where individuals with diabetes have stopped taking insulin, switched to less effective formulations, or started rationing the medicine due to its high price and suffered adverse health consequences as a result.[6] One survey found that 45 percent of diabetics have gone without insulin due to its price.[7]

Although it is clear that the list price of insulin is increasing, there is not as much transparency about the changes in the net price for insulin over the past decade since information about manufacturer rebates or coupons is considered proprietary information and therefore typically not publicly available.[8] Some reporting has revealed that the net price of insulin has not increased as rapidly as the list price. For example, in 2016, the *Wall Street Journal* reported that, while the list price of insulin had more than doubled since 2011, the net price had remained

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[3] See H. Energy and Commerce Committee, *Letters to Pharmacy Benefit Managers Regarding their Role in the Drug Supply Chain* (Aug. 30, 2018), *available at* https://republicans-energycommerce.house.gov/wp-content/uploads/2018/08/20180830CVS.pdf.

[4] *See, e.g.*, Letter from Douglas Stoss, Vice President, Federal Affairs, Humana, Inc. to The Honorable Greg Walden, Chairman, H. Energy and Commerce Committee, the Honorable Michael C. Burgess, Chairman, Subcommittee on Health, H. Energy and Commerce Committee, and the Honorable Gregg Harper, Chairman, Subcommittee on Oversight and Investigations, H. Energy and Commerce Committee (Oct. 2, 2018) (on file with the Committee).

[5] Letter from Melissa Schulman, Senior Vice President, CVS Health Government and Public Affairs to The Honorable Greg Walden, Chairman, H. Energy and Commerce Committee, the Honorable Michael C. Burgess, Chairman, Subcommittee on Health, H. Energy and Commerce Committee, and the Honorable Gregg Harper, Chairman, Subcommittee on Oversight and Investigations, H. Energy and Commerce Committee (Oct. 5, 2018) (on file with the Committee).

[6] *See, e.g.*, William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, Diabetes Care, at 8 (May 2018), *available at* http://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019; Aimee Picchi, *The rising cost of insulin: "Horror stories every day,"* CBS NEWS (May 9, 2018), *available at* https://www.cbsnews.com/news/the-rising-cost-of-insulin-horror-stories-every-day/.

[7] R. Scott Rappold, *Spiking Insulin Costs Put Patients in Brutal Bind* (Jul. 25, 2018), *available at* https://www.webmd.com/diabetes/news/20180725/spiking-insulin-costs-put-patients-in-brutal-bind.

[8] *See, e.g.*, Jean Fuglesten Biniek, William Johnson, *Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices*, HEALTH CARE COST INSTITUTE (Jan. 21, 2019), *available at* https://healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices.

almost flat during that same period.[9] Similarly, a 2018 report by an Insulin Access and Affordability Working Group found that there have been greater increases in the list prices than the net prices for insulin. More specifically, the report stated:

> The Working Group found a number of examples from public sources showing that the net price to the insulin manufacturers has grown at a slower rate, or has gone down, compared to list prices. For example, the net price of the insulin formulation Lantus (glargine) increased more or less in parallel with the list price from 2007 to 2013. However, the net price has decreased in recent years. As a result, the net price increased by 57% between 2007 and 2016, increasing 23% as fast as the list price reported as a 252% increase of the same period.
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> Reports on other insulin products also illustrate the difference between the rapid increase in list price as compared with the slower increase in net price to manufacturer, a trend that may have started earlier for some insulin formulations. Bloomberg News reported an estimate by independent market research firm that the list price of Eli Lilly's human insulin analog, Humalog, increased by 138% between 2009 and 2015, while the net price to the manufacturer increased by 6%.
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> Novo Nordisk also published data for two of their insulin products, NovoLog and NovoLog FlexPen. Since the early 2000s, the [compound annual growth rates (CAGRS)] for the list prices for NovoLog and NovoLog FlexPen have been in the range of 9.8-9.9%. This translated into large total increases in the list prices: 353% (2001-2016) for a NovoLog vial and 270% (2003-2016) for a FlexPen. In contrast, net prices received by the manufacturer increased at a more modest rate with CAGRs of 3-36%--more in line with the rate of inflation for the overall economy.[10]

The difference in the rate of growth in the list price of insulin compared to the net price of insulin raises important questions regarding what entities in the supply chain, if any, are benefitting from the substantial increase in insulin list prices. Moreover, our work has revealed that increases in the list price of a medicine can have a direct impact on the out-of-pocket costs for patients. For example, during the Committee's December 2017 hearing entitled "Examining the Drug Supply Chain," the Executive Vice President of the Pharmaceutical Research and Manufacturers of America (PhRMA), Ms. Lori M. Reilly, explained how a patient's insurance plan may require them to pay the full undiscounted price in some instances.[11] Ms. Reilly, testified:

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[9] Denise Roland and Peter Loftus, *Insulin Prices Soar While Drugmakers' Share Stays Flat*, THE WALL STREET JOURNAL (Oct. 7, 2016), *available at* https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764.

[10] William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, Diabetes Care, at 2-3 & 11 (May 2018), *available at* http://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019 (Citations omitted).

[11] *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115th Cong., Preliminary Transcript, 15 (Dec. 13, 2017).

> Due to the growing gap between list and net prices, patients' cost sharing for medicines is increasingly based on prices that do not reflect plan sponsors' actual costs. For example, market analysts report that negotiated discounts and rebates can lower the net price of insulin by up to 50% to 70%, yet health plans require patients with deductibles to pay the full undiscounted price. As a result, a patient in a high-deductible health plan who pays the list price each month for insulin maybe paying hundreds—or even thousands—more annually than their insurer.[12]

Furthermore, in response to the August 30, 2018 letter that the Committee sent to PBMs, we heard that lower list prices would likely result in immediate savings for patients. For example, when asked how a lower list price for a medicine would impact beneficiaries, one PBM said:

> If the patient has a high deductible health plan, the lower price would pass directly to the patient. If a patient pays a coinsurance, (percentage of the drug cost) amount the savings would also be included proportionately in the patient pay amount. If the patient has a flat copay, the savings would only be realized if the price of the drug were below the set copay.[13]

Given the potential negative impact that list price increases have on out-of-pocket costs for patients, we are interested in deepening our understanding of the rationale for list price increases and which entities in the supply chain, if any, benefit from increased list prices. Recently, CVS Health issued a slide deck categorizing the fact that "[b]rand inflation levels [are] lower than historical levels" as a headwind.[14] In describing this slide, the CEO of the company said "[w]e also expect brand inflation to continue to moderate this year which would impact client commitments in the PBM business as we have guarantees related to the level of rebates we provide."[15] This comment raises questions about how, if at all, PBMs depend on list price increases for products such as insulin.

We therefore request your assistance in better understanding 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 following questions by February 20, 2019:

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[12] *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115th Cong., Testimony of Lori M. Reilly, Executive Vice President, Policy, Research, and Membership, Pharmaceutical Research and Manufacturers of America (Dec. 13, 2017).

[13] Letter from Roger Burgess, Founder and CEO, ProCare Pharmacy Benefit Manager, Inc. to The Honorable Greg Walden, Chairman, H. Energy and Commerce Committee, the Honorable Frank Pallone, Jr., Ranking Member, H. Energy and Commerce Committee, the Honorable Michael C. Burgess, Chairman, Subcommittee on Health, H. Energy and Commerce Committee, and the Honorable Gregg Harper, Chairman, Subcommittee on Oversight and Investigations, H. Energy and Commerce Committee (Sept. 27, 2018) (on file with the Committee).

[14] Larry Merlo, President and Chief Executive Officer, CVS Health, *Transforming the Consumer Health Care Experience*, 37th Annual J.P. Morgan Healthcare Conference (Jan. 8, 2019), *available at* http://investors.cvshealth.com/~/media/Files/C/CVS-IR-v3/documents/2019-jp-morgan-slides.pdf.

[15] Larry Merlo, President and Chief Executive Officer, CVS Health, *CVS Health Corporation CEO Larry Merlo presents at J.P. Morgan Healthcare Conference Transcript* (Jan. 8, 2019), *available at* https://seekingalpha.com/article/4232174-cvs-health-corporation-cvs-ceo-larry-merlo-presents-j-p-morgan-healthcare-conference?part=single.

1. **Negotiations based on the list price for insulin**. Manufacturers set the list price for insulin products. The list price of insulin is the starting point for negotiation that other stakeholders in the prescription drug supply chain undertake with drug manufacturers. Employers, health plans, unions, and government programs hire PBMs to negotiate discounts and reduce prescription drug costs.

    a. Please describe the rate of growth for the net price of each major insulin product in the market over the past year, the past five years, and the past ten years. For each major insulin product, if the net price of the insulin product has increased for your clients, please explain why it has increased during this period.

    b. Please describe the rate of growth for the list price of each major insulin product in the market over the past year, the past five years, and the past ten years. For each major insulin product, if the net price of the insulin product has grown at a slower rate than the list price of that product—or has gone down compared to the list price—please explain whether this has had an impact on your company's profitability during this period.

    c. Please describe the amount of rebates, discounts, and other price concessions that your company has negotiated for your clients for each of the major insulin products in the market.

    d. Are there any insulin products that the manufacturer does not provide any price concessions for? If so, please identify these products.

    e. What specific tools has your company used to reduce the cost of insulin for patients (*e.g.*, exclusion from formularies, encouraging the use of lower-cost alternatives, prior authorization)?

    f. Please explain whether you have any contractual obligations to your clients regarding the level of rebates that you will provide to them and any penalties that you suffer if these rebate levels are not achieved. How would an increase in list prices affect these guarantees?

    g. Please list all of the contractual terms in your existing contracts that are impacted by the list price of a medicine (*e.g.*, any service and/or administrative fees that are based on the list price of a medicine) and whether these terms are considered rebates under the contract.

    h. Please describe whether your company's contracts include any provisions that result in your company receiving an additional payment if the list price increases by a certain percentage (*e.g.*, inflation payments/rebates). Please describe whether you retain all, or a portion of, these payments.

2. **Out-of-pocket costs for insulin and patient choice.** As previously stated, out-of-pocket costs can be significant for insulin due to its high list price and many individuals with diabetes have stopped taking insulin because of increasing costs. As you know, there are programs available to help make medicines such as insulin more affordable.

    a. What is the range of out-of-pocket costs for your clients' enrollees for each type of insulin product in the market?

    b. What is the average out-of-pocket cost for your clients' enrollees for each type of insulin product in the market?

    c. Please describe any programs that your company has offered to help diabetics access insulin over the past ten years and the impact of that program. If the program was terminated, please describe why the program was terminated.

    d. Please describe any restrictions that you impose on the pharmacies in your network that can dispense insulin.

3. **Value-based contracts.** Please describe whether value-based/outcomes-based contracting could be applied to insulin products.

4. **Medication Adherence.** As you know, higher medication adherence rates improve health outcomes and help reduce health care costs.

    a. Please describe whether your company tracks medication adherence for insulin. If so, please describe what has happened to medication adherence for insulin as list prices have increased.

    b. Please describe any services that your company provides to promote medication adherence for insulin.

5. **Competition in the marketplace.** According to Dr. Gottlieb, March 2020 will be a "watershed moment for insulin products" because products that are biosimilar to, or interchangeable with, existing insulin will be able to come to market.[16]

    a. Does your company believe there is sufficient competition in the insulin marketplace?

    b. How does your company expect the list price and net price of insulin to change in the next five years, and why?

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[16] U.S. Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new actions advancing the agency's biosimilars policy framework* (Dec. 11, 2018), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628121.htm.

Please also make arrangements to provide a briefing to Committee staff to review your response by February 20, 2019. Please contact Natalie Turner or Caleb Graff with the Committee 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
Committee on Energy and Commerce

Brett Guthrie
Republican Leader
Subcommittee on Oversight
and Investigations

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

cc. The Honorable Frank Pallone
cc. The Honorable Diana DeGette
cc. The Honorable Anna Eshoo