

ONE HUNDRED SEVENTEENTH 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
Minority (202) 225-3641

August 19, 2021

Mr. Doug Langa
Executive Vice President, North America Operations
President of Novo Nordisk Inc.
Novo Nordisk
800 Scudders Mill Road
Plainsboro, NJ 08536

Dear Mr. Langa:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee continues to explore issues surrounding patient access to affordable drug products, including insulin. The Committee is writing to follow up on our January 2019 letter¹ and April 2019 hearing² regarding these issues. We request your company's continued assistance in understanding the ongoing increase in insulin prices and the continued obstacles people living with diabetes face in accessing lifesaving medication.

When we last wrote to you in January 2019, we noted that the price of insulin had continually and unjustifiably skyrocketed over the past few decades.³ The Committee is troubled that despite your company's expressions of shared concern, insulin prices in the United States remain unacceptably high. This is particularly frustrating considering Americans continue to bear a disproportionately high financial burden for their insulin compared to diabetes patients in

¹ Letter from Rep. Frank Pallone, Jr., Chairman, Rep. Diana DeGette, Chair, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, to Doug Langa, President of Novo Nordisk Inc. (Jan. 30, 2019).

² House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Hearing on Priced Out of a Lifesaving Drug: The Human Impact of Rising Insulin Costs*, 116th Cong. (Apr. 2, 2019).

³ Letter from Rep. Frank Pallone, Jr., Chairman, Rep. Diana DeGette, Chair, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, to Doug Langa, President of Novo Nordisk Inc. (Jan. 30, 2019).

other countries. One study showed that the average list price for insulin in the United States is more than 10 times that of 33 other countries.⁴

Over 34 million Americans—10.5 percent of the United States population—have diabetes.⁵ Many of these individuals rely on insulin to stay alive and lead healthy lives. And while there have recently been some positive developments, including the approval of the first interchangeable biosimilar insulin product,⁶ the Committee remains concerned that many individuals suffering from diabetes are left without meaningful access to insulin due to its cost, despite the drug being available for approximately 100 years.⁷

Furthermore, the coronavirus disease of 2019 (COVID-19) pandemic has exacerbated the struggles many diabetes patients experience to access health care and food in addition to the insulin that they need to maintain their health.⁸

This Committee sent your company a letter on January 30, 2019, seeking information about the prices of your insulin products, the basis for the price of your products, and any efforts that your company had undertaken to ensure access to those requiring insulin.⁹ Your company's February 13, 2019, response to that letter stated that Novo-Nordisk "share[d] [the Committee's] concerns about affordability" and that Novo-Nordisk recognized that, despite its efforts to make insulin more affordable, "more needs to be done."¹⁰

⁴ Rand Corporation, *The Astronomical Price of Insulin Hurts American Families* (Jan. 6, 2021).

⁵ Centers for Disease Control and Prevention, *National Diabetes Statistics Report, 2020* (Feb. 11, 2020) (CS 314227-A).

⁶ U.S. Food & Drug Administration, *FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes* (July 28, 2021) (press release).

⁷ American Diabetes Association, *The History of a Wonderful Thing We Call Insulin* (www.diabetes.org/blog/history-wonderful-thing-we-call-insulin).

⁸ American Diabetes Association, *New Data Alert: COVID-19 Brings Crisis of Access for Millions Living with Diabetes* (Dec. 23, 2020) (press release).

⁹ Letter from Rep. Frank Pallone, Jr., Chairman, Rep. Diana DeGette, Chair, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, to Doug Langa, President of Novo Nordisk Inc. (Jan. 30, 2019).

¹⁰ Letter from Raphael A. Prober, Counsel, Steven R. Ross, Counsel, Akin Gump Strauss Hauer & Feld LLP, to Rep. Greg Walden, Ranking member, Rep. Brett Guthrie, Ranking Member, Subcommittee on Oversight and Investigations, Rep. Michael C. Burgess, M.D., Ranking Member, Subcommittee on Health, House Committee on Energy and Commerce (Feb. 13, 2019).

Additionally, you testified at a hearing on April 10, 2019, on the rising cost of insulin. At that hearing, you said that “[e]ven one patient rationing insulin is too many. We need to do more.”¹¹ You also stated, “Patients are telling us that we need to do more, and we hear them.”¹²

We are committed to increasing access to affordable medicines and fighting the rising cost of insulin. Given your company’s representations in 2019 that this is a shared concern, we are interested in learning what has been done to alleviate this issue since that time. We therefore request that you provide the following information by September 17, 2021:

1. Please provide the annual prices, including list price and net price, of your marketed insulin products since January 2019. Please provide this information by product and by year.
2. To the extent any of your marketed insulin products have increased in price (either list price or net price) since January 2019, please provide an explanation for, and description of each price increase.
3. Please provide your gross revenue and net profit from each of your marketed insulin products since January 2019. Please provide this information by product and by year.
4. Please describe any research and development into your current or new insulin products since January 2019.
5. Please describe what steps your company has taken since January 2019 to increase patient access to insulin, including specifically any steps your company has taken to lower the cost of insulin since January 2019.
6. Please provide the following information regarding your patient assistance program, as it relates to your insulin products:
 - a. A description of the process for a patient to enroll in your patient assistance program, including the documentation necessary for an applicant to be enrolled, average time from application to enrollment, and average time from enrollment until a patient sees a reduction in the out-of-pocket cost of their insulin;
 - b. the number of individuals that have applied to your patient assistance program since January 2019;


¹¹ House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, Testimony of Doug Langa, Executive Vice President, North America Operations, President, Novo Nordisk Inc., *Hearing on Priced Out of a Lifesaving Drug: The Human Impact of Rising Insulin Costs*, 116th Cong. (Apr. 2, 2019).

¹² *Id.*

- c. the number of individuals that have been enrolled in your patient assistance program since January 2019;
 - d. the average reduction of out-of-pocket spending and the average remaining out-of-pocket spending by patients in your patient assistance program since January 2019; and
 - e. the amount, if any, your company has claimed in tax deductions since January 2019 due to your patient assistance program.
7. Please describe whether the COVID-19 pandemic has affected your insulin products in any way, including manufacturing or supply challenges, alteration of planned pricing changes, or revisions to your patient access program.

Thank you for your prompt attention to this matter. If you have any questions, please contact Will McAuliffe with the Committee staff at (202) 594-6378.

Sincerely,


Frank Pallone, Jr.
Chairman


Diana DeGette
Chair
Subcommittee on Oversight
and Investigations