

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. Paul Hudson
Chief Executive Officer
Sanofi
55 Corporate Drive
Bridgewater, NJ 08807

Dear Mr. Hudson:

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 other countries. One study showed that the average list price for insulin in the United States is

¹ Letter from Rep. Frank Pallone, Jr., Chairman, Rep. Diana DeGette, Chair, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, to Olivier Brandicourt, Chief Executive Officer, Sanofi (Jan. 30, 2019).

² House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *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 Olivier Brandicourt, Chief Executive Officer, Sanofi (Jan. 30, 2019).

more than 10 times that of 33 other countries.⁴ As your own 2021 pricing report states, the average out-of-pocket costs for a patient using one of your insulin products have increased 82 percent since 2012.⁵

Over 34 million Americans—10.5 percent of the United States population—have diabetes.⁶ 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,⁷ 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.⁸

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.⁹

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.¹⁰ Your company's February 13, 2019, response to that letter stated that "Sanofi fully understands the importance to patients of both access to, and affordability of, our medicines" and that Sanofi is "committed to helping patients get the treatment that they are prescribed."¹¹

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

⁵ Sanofi, *2021 Pricing Principles Report* (www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/Sanofi-US/Home/corporateresponsibility/Sanofi_2021_Pricing_Principles_Report.pdf) (accessed Aug. 9, 2021).

⁶ Centers for Disease Control and Prevention, *National Diabetes Statistics Report, 2020* (Feb. 11, 2020) (CS 314227-A).

⁷ U.S. Food & Drug Administration, *FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes* (July 28, 2021) (press release).

⁸ American Diabetes Association, *The History of a Wonderful Thing We Call Insulin* (www.diabetes.org/blog/history-wonderful-thing-we-call-insulin).

⁹ American Diabetes Association, *New Data Alert: COVID-19 Brings Crisis of Access for Millions Living with Diabetes* (Dec. 23, 2020) (press release).

¹⁰ Letter from Rep. Frank Pallone, Jr., Chairman, Rep. Diana DeGette, Chair, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, to Olivier Brandicourt, Chief Executive Officer, Sanofi (Jan. 30, 2019).

¹¹ Letter from Michelle Carnahan, U.S. Country Chair and Head, North American Primary Care Business Unit, Sanofi, to Rep. Frank Pallone, Jr., Chairman, Rep. Diana DeGette,

Your company's Executive Vice President of External Affairs, Kathleen Tregoning, also testified at a hearing on April 10, 2019, on the rising cost of insulin. At that hearing, Ms. Tregoning said that "[p]atients are rightfully angry about rising out-of-pocket costs for many medicines and we all have a responsibility to address a system that is clearly failing too many people."¹² Ms. Tregoning also said that "[e]very actor in the system has a role to play and Sanofi takes our responsibility very seriously."¹³

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 more 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,

Chair, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce (Feb. 13, 2019).

¹² House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, Testimony of Kathleen Tregoning, Executive Vice President for External Affairs, Sanofi, *Hearing on Priced Out of a Lifesaving Drug: The Human Impact of Rising Insulin Costs*, 116th Cong. (Apr. 2, 2019).

¹³ *Id.*

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;
 - 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