

United States Senate

WASHINGTON, DC
20510

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Douglas J. Langa
President
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Mr. Jørgensen and Mr. Langa,

We write to you today to request more information on your decision to discontinue production of Levemir (insulin detemir), one of only three basal (long-acting) insulins on the market.¹

As you know, more than 7 million patients in the United States – including all patients living with Type 1 and many with Type 2 diabetes, as well as gestational diabetes – rely on a steady supply of insulin to survive.² Long-acting insulins are the most prescribed and commonly used insulin, accounting for nearly two-thirds of all insulin treatment visits.³ Long-acting insulins are the fastest growing market segment and remain popular with patients for their ability to lengthen the time between injections while maintaining baseline blood glucose levels. Of the long-acting insulins, Levemir has the shortest duration and is the only insulin FDA-approved for pregnancy.

On March 14, 2023, Novo Nordisk announced that the U.S. list prices of several insulin products, including Levemir, would be lowered starting on January 1, 2024.⁴ Levemir is the only branded, long-acting insulin product for which Novo Nordisk announced a list price reduction. On November 8, 2023, before its 65 percent price cut had taken effect, Novo Nordisk announced that Levemir would be discontinued, with supply disruptions beginning in mid-January 2024 and formal discontinuation of the Levemir FlexPen vial on December 31, 2024. The discontinuation

¹ USA Today, “Diabetes patients lament drugmaker's decision to discontinue Levemir insulin.” Ken Alltucker, March 21, 2024, <https://www.usatoday.com/story/news/health/2024/01/28/levemir-insulin-will-be-discontinued/72261823007/#:~:text=Levemir%20is%20one%20of%20three,lasts%20up%20to%2042%20hours>.

² Cefalu, William T., et al. “Insulin Access and Affordability Working Group: Conclusions and Recommendations.” American Diabetes Association, American Diabetes Association, 11 May 2018, diabetesjournals.org/care/article/41/6/1299/36487/Insulin-Access-and-Affordability-Working-Group.

³ Sudipa Sarkar, MD. “Insulin Types and Devices Used by Adults with Type 2 Diabetes in the US.” JAMA Network Open, JAMA Network, 12 Oct. 2021, jamanetwork.com/journals/jamanetworkopen/fullarticle/2784811.

⁴ “Lowering US List Prices of Several Products.” Novo Nordisk, 14 Mar. 2023, www.novonordisk.com/news-and-media/latest-news/lowering-us-list-prices-of-several-products-.html.

notice cited supply chain constraints, formulary placement issues and confidence in the availability of alternative treatments as reasons for the decision.⁵

We have vigorously advocated for universal access to affordable insulin products. Unfortunately, that goal remains out of reach for too many Americans, in particular for in-demand, long-acting insulins with proven outcomes. Spending on insulin has tripled in the last ten years, and 17 percent of patients report rationing their insulin due to cost.^{6,7} Furthermore, access to affordable, in-demand biosimilar insulins will be further restricted by Novo Nordisk's decision to discontinue Levemir, as discontinuation creates significant barriers to demonstrating biosimilarity without a sample to reference.⁸

With this in mind, we are alarmed by Novo Nordisk's decision to discontinue Levemir before allowing the price reduction to go into effect, and are concerned that Novo Nordisk failed to take into consideration patient access to affordable, long-acting insulin substitutes prior to the discontinuation. Given the importance of Levemir's availability to patients across the U.S. and to better understand the impact of this decision on patients, we ask that you respond to the following questions before May 1, 2024:

1. Please detail issues related to formulary placement for Levemir, as well as any steps Congress can take to alleviate such issues in the future.
2. Please detail ongoing supply chain constraints that led to the discontinuation of Levemir, as well as any steps Congress can take to alleviate such issues in the future.
3. Please detail steps Novo Nordisk has taken to ensure that patients currently prescribed Levemir, including those with preferred formulary placement of Levemir, have access to similar long-acting insulin products without gaps in coverage and at similar cost-sharing.
4. Does Novo Nordisk intend to decrease the price on any other long-acting insulin product, such as Tresiba, similar to the price decrease of Levemir in March 2023?
5. Will Novo Nordisk commit to produce Levemir until a biosimilar product becomes available?
6. Has Novo Nordisk been contacted by any manufacturers expressing interest in producing a biosimilar for Levemir?
 - a. If yes, will Novo Nordisk help facilitate the introduction of a Levemir biosimilar into the market?

⁵ "About Levemir®: Levemir® (Insulin Detemir) Injection 100 Units/ML." About Levemir® | Levemir® (Insulin Detemir) Injection 100 Units/mL, www.mynovoinsulin.com/insulin-products/levemir/home.html. Accessed 22 Mar. 2024.

⁶ Parker, Emily D., et al. "Economic Costs of Diabetes in the U.S. in 2022." American Diabetes Association, American Diabetes Association, 1 Nov. 2023, diabetesjournals.org/care/article/47/1/26/153797/Economic-Costs-of-Diabetes-in-the-U-S-in-2022.

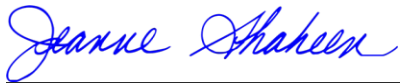
⁷ Gaffney, Adam, et al. "Prevalence and Correlates of Patient Rationing of Insulin in the United States: A National Survey." *Annals of Internal Medicine*, 18 Oct. 2022, www.acpjournals.org/doi/abs/10.7326/M22-2477?journalCode=aim.

⁸ Feldman R. Leading with the trailing edge: facilitating patient choice for insulin products. *J Law Biosci*. 2023 Dec 12;10(2):lsad033. doi: 10.1093/jlb/lsad033. PMID: 38094183; PMCID: PMC10718803.

- b. If no, will Novo Nordisk commit to making the relevant patents, technologies, and manufacturing capabilities available to expedite the introduction of a Levemir biosimilar?

Thank you for your attention to this matter. We look forward to your timely response.

Sincerely,



Jeanne Shaheen
United States Senator



Raphael Warnock
United States Senator



Elizabeth Warren
United States Senator