



Advocating for people with type 1 diabetes around the world

To: The Honorable Xavier Becerra, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

CC:

Senator Charles Schumer, Senate Majority Leader
Senator Mitch McConnell, Senate Minority Leader
Representative Mike Johnson, Speaker of the House
Representative Hakeem Jeffries, House Minority Leader
Mr. Reed Showalter, Senior Policy Advisory, National Economic Council, the White House

December 4, 2024

Subject: Urgent Appeal for Continued Access to Levemir Insulin in Light of Discontinuation

Dear Secretary Becerra,

We are writing to express serious concerns about the impending discontinuation of Levemir insulin (generic name, insulin detemir) by Novo Nordisk and to urge the U.S. Department of Health and Human Services (HHS) to take immediate action to ensure continued access to this critical medication. We are a coalition of people with diabetes, people caring for loved-ones with diabetes, and allies working to instill better access and affordability for insulin and diabetes care supplies. Although Novo Nordisk has stated privately that they would not enforce any patents, allowing for biosimilar production, the manufacturer's decision to halt production and not enable an alternative version of the same treatment to be made available presents a significant risk to diabetes patients who rely on it for disease management.

Public Health Impact

Diabetes continues to be a significant public health challenge in the United States, affecting over 37 million Americans, as reported by the Centers for Disease Control and Prevention (CDC) (source). Three years ago, over 1 million prescriptions for Levemir were issued for people on Medicaid; while data on usage among privately insured people is not available, millions more are likely to have used Levemir.(1) Levemir is a long-acting insulin and is unique in that it has a shorter time of action ideal to match changing basal insulin needs due to menstruation, teen growth hormones, and athletic activity.(2) Long-acting analog insulins like Levemir are a cornerstone of diabetes management, particularly for individuals who have not been able to switch successfully to other formulations. Additionally, there is



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significant clinical evidence around the benefit of Levemir as a long-acting insulin option for pregnant patients with diabetes. The abrupt discontinuation of Levemir could leave patients with limited and more expensive options, forcing them to make difficult choices about their health.

Patient Choice

People living with diabetes should have the opportunity to choose between different types of insulin to use what works best for them. Different types of insulin (such as rapid-acting, long-acting, and pre-mixed) offer flexibility in timing and administration, which can be essential for managing blood glucose levels effectively. Flexibility to choose between available insulins can help mitigate negative factors affecting insulin therapy such as complicated dosing regimens, fear of hypoglycemic events, and injection site reactions.(3)

Levemir and Tresiba are the only long-acting analogue insulin that is a different chemical composition than glargine. Glargine is a long-acting analogue insulin that lasts up to 24 hours (name-brands Lantus, Basaglar, Rezoglar, Semglee, Toujeo, etc). Tresiba's ultra-long time of action of 42 hours is too difficult to manage for many with insulin needs that change more quickly (such as menstruating people, athletes, and pregnant persons).(4–6) Moreover, weight gain and night-time hypoglycemia (low blood sugar levels) appear to be less with Levemir.(4–8)

Need for Immediate Biosimilar Availability

Novo Nordisk's statement commitment to not enforce patents for Levemir should, in theory, facilitate the production of affordable biosimilar versions. However, the lack of market incentives and manufacturing delays often stall the introduction of biosimilars (sources). Novo Nordisk's statement to not enforce patents on Levemir comes without legal guarantee, posing significant risk for entrants concerned that Novo Nordisk might change their mind and litigate. HHS can play a pivotal role by prioritizing the approval and distribution of affordable generic insulin alternatives. Furthermore, the department could work with generic manufacturers to expedite production and address any potential supply gaps left by Novo Nordisk's discontinuation. Given the lack of commercial interest to date, HHS should also explore the feasibility of publicly manufactured insulin, for example through initiatives like CalRx, which is already manufacturing similar products.

The Importance of Sustained Affordability

The financial burden of insulin remains a pervasive issue for millions of Americans; insulin prices in the United States are often ten times higher than the global average.(9) Even with Levemir off-patent, it is crucial that the transition to biosimilars does not come at the cost of accessibility or affordability. A



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strategic, coordinated response from HHS would prevent market disruptions and ensure that patients have continuous access to life-saving insulin.

Call to Action

We respectfully request that HHS consider the following actions:

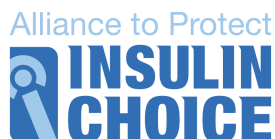
- Ask Novo Nordisk to constructively identify potential suppliers and engage in technology transfer to expedite production
- Secure legally binding commitments to Novo Nordisk's informal assurance that they will not prosecute patent infringement for Levemir-related patents, including patents relating to the molecule, processes for manufacture, method of use, and devices.
- Partner with generic manufacturers to ensure that production meets national demand.
- Explore options for federal procurement, manufacturing, and/or subsidies to keep generic insulin prices affordable for uninsured and underinsured populations.

Conclusion

The discontinuation of Levemir insulin by Novo Nordisk poses a significant risk to people with diabetes who depend on this essential medication. Swift action by HHS to promote the availability and affordability of generic alternatives is vital to prevent disruptions in diabetes care. Thank you for your attention to this urgent issue, and we are hopeful that HHS will take decisive steps to safeguard public health.

Sincerely,

Alison Smart
Alliance to Protect Insulin Choice



Ken Berry
American Diabetes Society



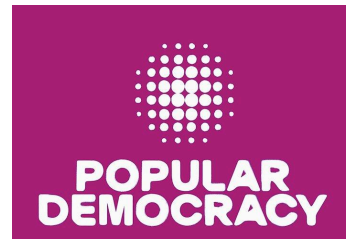


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