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Senator Elizabeth Warren United States Senate Washington, DC 20510

Dear Senator Warren,

On March 1, <u>Eli Lilly announced</u> it would reduce the list prices of some of its insulins, including Lispro, the unbranded version of the name-brand Humalog. At a <u>recent congressional hearing</u> with the CEOs of insulin manufacturers and pharmacy benefit managers, David Ricks, Eli Lilly's CEO, again celebrated that \$25 insulin Lispro was available to patients as of May 1.

However, patient advocates with T1International have tried to get insulin Lispro in pharmacies in states across the country and the vast majority have been unable to get the promised \$25 insulin.

A lowered priced insulin doesn't save lives if it's unavailable. Over seven million people who rely on insulin to survive every day do not have time to wait for Eli Lilly and other insulin manufacturers to follow through on their promises. Now is the time to cap the list price of all insulins for all Americans.

Introduction:

Adjusted for inflation, Eli Lilly's list price — the price at which the manufacturers sell the drug to wholesalers — for Humalog, a short-acting brand-name insulin, has increased by 680% since it first began to be sold in the United States in 1996. Over <u>7 million Americans</u> rely on injected insulin to stay alive and healthy. Many use more than one insulin dosage form or type. <u>One in four patients</u> has rationed insulin due to cost. Those without insurance, Black patients, Indigenous patients, patients of color, and others who are marginalized in the United States have <u>significantly higher rates</u> of insulin rationing. <u>Eight in ten</u> adults say the cost of prescription drugs is unreasonable.

Since a person dependent on a drug to live will pay whatever they must to survive, absent strong regulations limiting drug prices, pharmaceutical companies can and will continue to charge as much as they can for such lifesaving medicines, irrespective of the damage and suffering they cause.

The impact of this is consequential. One dollar out of every \$4 spent on US health care costs is spent on caring for people with diabetes, including \$237 billion each year on direct costs. The majority of these costs are for complications related to diabetes, conditions which are exacerbated by rationing insulin (for those who survive it).

Many patients without insurance pay the full list price of insulin. The approximate average list price of a vial of short-or fast-acting insulin on the market today is \$208. Most patients with type 1 diabetes need 2-4 vials per month. Insulin costs just \$3.61-\$6 per vial to manufacture. While Eli Lilly and other manufacturers have been touting their patient assistance programs, many patients are not eligible, and these programs have coverage limits. Capping the list price of insulin to \$25 would save patients with and without insurance thousands of dollars a year.

Almost everyone living with type 1 diabetes has had to contend with outrageous insulin list prices, even patients with good insurance. Perhaps their preferred insulin is not covered by their insurance, such as the case for Deirdre Waxman, who is unable to access the \$35 monthly copay cap for Medicare beneficiaries for one of her insulin prescriptions because it wasn't on her insurance's formulary. Nearly every patient with diabetes has experienced an insulin crisis. Matthew Criag of Oregon ran out of insulin while waiting for a prescriber to authorize a prescription after he got sick and needed more to survive. Jasmine Foutes of Kentucky found herself out of insulin when the glass vial broke. These types of incidents where a patient's needs change or equipment malfunctions are common, yet the high cost of insulin means they precipitate financial disaster for thousands of Americans every year.

Making medicines affordable requires addressing the monopoly pricing power of pharmaceutical companies. To ensure that medicines are affordable to everyone, regardless of insurance status, means addressing the list price and not just the cost for those with insurance. Addressing price impacts everyone, but more so those who are most at risk of rationing. T1International <u>celebrated</u> the announcement of Eli Lilly's \$25 vials of insulin Lispro for exactly these reasons. Theoretically, any patient who is reliant on insulin can access insulin Lispro at this price point, regardless of insurance status or prescription refill cycle.¹ However, we are concerned that this promise will not be realized.

T1International's program priorities include working toward a higher standard of research, data, and statistics about the issues faced by those with diabetes. Additionally, we believe in centering the lived experience of patients with diabetes. As such, we invited our volunteer patient advocates who attempted to obtain a vial of insulin Lispro for \$25 from May 1 to June 7 of 2023 to share their experience. Out of twenty-two attempts at pharmacies in thirteen states and the District of Columbia, almost no one was able to obtain Lispro at the promised \$25 a vial.

¹A note on Walmart insulins: Walmart has sold \$25 vials of human (non-analog) insulin for years. In July 2021, Walmart introduced its own brand of analog insulin, ReliOn, sold for \$73 per vial. While ReliOn carries Walmart's private label, it is manufactured for Walmart by Novo Nordisk, one of The Big Three. Therefore, Walmart's ReliOn is a captive generic, which means it continues the pharmaceutical industry practice of portioning off a segment of the market for a somewhat lower price. In the case of ReliOn, the lower price is achieved through a cheaper version marketed to this demographic. Captive generics are not a solution to the insulin price crisis.

Patients have been unable to access insulin Lispro for \$25 a vial for three main reasons. First, pharmacies are not adjusting the list price of insulin at the counter. Second, insulin Lispro is not available in many pharmacies. Third, pharmacists are reluctant to fill patients' prescriptions for name-brand Humalog with the authorized generic, unbranded insulin Lispro.

Inaccessible insulin Lispro: Price

Eli Lilly's promise of \$25 insulin lispro vials has not been kept: as of writing this letter, vials of insulin Lispro are not universally available for \$25 a vial. The average list price quoted to volunteer patient advocates was \$107.31. The variety of prices often ranged from \$165 to \$19. Most volunteer patient advocates also reported that the pharmacist tech that they spoke with did not know about Eli Lilly's pricing announcement and many were confused by how their computer system was ringing up the much higher price after advocates shared the press release.

For example, Jared Sibbitt of Montana called four pharmacies in town and was eventually able to get insulin Lispro for as cheap as \$29 a vial. "No one had heard of the Eli Lilly press release" he said, and the pharmacy that sold him the \$29 vial was "surprised they sold it so cheap." Yet in the same town, another pharmacy quoted him \$139 for one vial of Lispro.

Inaccessible insulin Lispro: Availability

In 2019, your office and Senator Blumenthal's office surveyed pharmacies in 204 counties across the country and found that 83% of pharmacies did not have Lispro in stock and available to patients. In May and early June 2023, we found similar results: over half of T1International volunteer patient advocates who attempted to access insulin Lispro faced availability issues.

Many patient advocates were not able to receive a quote of Lispro due to it being out of stock. Five attempts to receive Lispro led to no price quote of what Lispro would cost them if they ordered it, leading to further future uncertainty.

For example, Tammy Craft said that her local CVS in Florida did not have any Lispro in stock and that they were not able to order it as it was not showing up in their system. For Staci Golar in Idaho, pens but no vials were available at her pharmacy on the first attempt, and no Lispro was in stock, at all, on her second. None of the pharmacy staff had heard about the \$25 price cap. One patient was told "We don't have that in stock... they send Lispro when they have it." Another patient, Aashna Shah, called her local CVS in Durham, North Carolina to ask if they stocked Lispro. The pharmacy transferred her to three different people within the CVS, and after many minutes of hold music and talking to confused pharmacy employees, she was told that they did not have Lispro in stock.

"If Eli Lilly is going to promise \$25 vials of insulin Lispro, it needs to be easily available and accessible instead of being yet another hoop to jump through and stress about. A lower-priced insulin doesn't save lives if it's unavailable, it is simply a strategic PR move," said Kate Pidwerbecki in Oregon. "And patients

like me don't have time to wait for Eli Lilly and other insulin manufacturers to follow through on their promises."

Inaccessible insulin Lispro: Prescription access

Insulin Lispro is an authorized generic, unbranded version of insulin Humalog, a short-acting insulin. This means that they are the same biologic product, both manufactured by Eli Lilly, but sold under a different name. By making their own authorized generic (Lispro), manufacturers can keep all the profits from the generic, while also retaining the high list price for the name-brand drug (Humalog). Any patient with a prescription for insulin Humalog, the brand-name, should be able to get a prescription for the unbranded, so long as the prescription doesn't say some version of "no substitutions" or "dispense as written." As such, T1International recommended that for patients with a prescription for any short-acting insulin other than Humalog or Lispro (for example, Novolog, the name-brand of aspart insulin), they ask their prescriber for an additional prescription to be able to access the \$25 insulin Lispro. This step in itself can be prohibitive for patient access.

For example, Emmabella Rudd of Florida had a Humalog prescription and was told by her local Walgreens pharmacy that she needed to contact her doctor for an updated Lispro prescription and that they couldn't fill her Humalog prescription with Lispro. Jeff Richmond in Washington was unable to get his Humalog prescription filled with Lispro at his local Walgreens because "the pharmacist didn't like the prescription since it didn't have a max dosage on it." After confirming that the list price for Lispro would have been \$164 for a single vial, he decided to not follow through with asking his prescriber.

Not having appropriate insulin prescriptions can be a matter of life and death. Kevin Houdeshell of Ohio passed away in 2014 over the New Year's holiday when he was left with no refills of his insulin. His death was preventable. Kevin's Laws allow for expanded pharmacist scope of practice and for pharmacists to dispense emergency insulin without a prescription under specific circumstances. As of 2023, 41 states have passed some expanded pharmacist scope of practice that would impact patients with insulin access.

Structural Access

Overall, the only volunteer patient advocates who were able to obtain insulin Lispro for any affordable price (less than \$70) were those who also worked in healthcare. No patients who identified as people of color were able to access insulin Lispro at all.

Conclusion and Recommendations

All patients must have access to the insulin they need, whether they are patients with private insurance, patients without insurance, or those who are most vulnerable to rationing insulin. Insulin manufacturers should be stopped from charging excessive prices. Additionally, policies should prevent drug corporations and middlemen from using anti-competitive tactics to interfere with patient access to lower-priced biosimilar and unbranded generic insulin products.

As such, we recommend the following:

- 1. All insulin manufacturers should lower the list price of all insulins. No price reductions have been announced for at least <u>eight</u> commonly-prescribed insulins. Creating more competition is critical for overall insulin affordability and access.
- 2. Insulin list prices must be regulated for all insulins. Insulin manufacturers have not committed to lowering the list price of all insulins, and they can raise prices at any time. There is no regulation on the price of insulins in the United States, including new insulin launch prices. Notably, insulin Lispro's price reduction was only for the vial, not the Kwikpens used by many patients (still priced at \$160 per 5 pens). Congress holds a crucial role to regulate insulin list prices for all insulins in holding corporate players to account.
- 3. All insulin cost policies, including copay caps, should cover people with and without insurance.
- 4. Pharmacies should adjust their retail prices to reflect the updated manufacturer list prices.
- 5. All manufacturers' discounts, coupons, and savings cards should be applied for all patients (regardless of insurance status) automatically.
- 6. Insulin manufacturers should work with pharmacies (chain and independent pharmacies) to ensure wide availability of affordable insulins and support pharmacist education for unbranded generic and biosimilar switching. This will be especially important as Eli Lilly, Novo Nordisk, and Sanofi lower the list prices of a combined nine other insulins by January 1 2024. Pharmacists are largely unaware and are not adequately informing patients about the availability of unbranded insulins and biosimilars or supporting patients in accessing affordable insulins.
- 7. Drug manufacturers' anti-competitive tactics must be reformed to halt them from unduly extending patent monopolies and delaying biosimilar competition, including pay for delay agreements, product hopping, and citizen petition abuses.
- 8. Emergency access of insulin must be increased by expanding pharmacists' scope of practice, including passing Kevin's Laws in states and federally, and allowing for switching from brand-name to unbranded insulins without additional prescriptions and for insurance coverage.

Please let us know if you have any questions.

Sincerely,

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About T1International

T1International is a global type 1 diabetes advocacy organization led by people with type 1 diabetes for people with type 1 diabetes. T1International believes in a world where everyone with type 1 diabetes – no matter where they live – has access to everything they need to survive and achieve their dreams. We accept no funding from pharmaceutical companies and provide advocacy training and support to advocates.

In 2014, T1International launched the #insulin4all campaign, which has grown into a global movement. T1International supports 42 #insulin4all Chapters across the United States and advocates and partners in more than 20 countries around the world. T1International supports local communities by giving them the tools they need to stand up for their rights so that access to insulin and diabetes supplies becomes a reality for all. To learn more and to get involved, see www.t1international.com.