Hearing before the Senate Health, Education, Labor and Pensions Committee

Testimony of David A. Ricks Chair and Chief Executive Officer at Eli Lilly and Company

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Chairman Sanders, Ranking Member Cassidy, and distinguished members of the Committee, thank you for the opportunity to participate in today's hearing. My name is David Ricks. I'm the Chair and CEO of Eli Lilly and Company.

I joined Lilly—an American company headquartered in Indiana—26 years ago because I believed in Lilly's life-saving and life-sustaining mission. Innovation is at the heart of what we do, particularly for people with diabetes. In the early 1920s, people with type 1 diabetes had a life expectancy of only a handful of years after diagnosis. With the first animal-derived insulin, Lilly extended life expectancy into a person's thirties. Now, following a century of innovation, life expectancy for people with type 1 diabetes is in their sixties.

But we're not done. Diabetes still significantly reduces a person's life expectancy. Even with modern insulin and devices, two thirds of people struggle to keep their disease under control. So there's more work to do, not only on diabetes, but also many other diseases like Alzheimer's and cancer.

That's why Lilly consistently invests 25% of our total revenue into research and development—\$7.1 billion last year and \$8.5 billion budgeted this year. That enables us to introduce new medicines—19 in the last decade, including the first Covid antibody therapy, and more medicines in the pipeline. Just last week, we shared exciting results from a study on a promising new Alzheimer's medicine, which followed approximately \$8.5 billion in research and development for Alzheimer's and other neurodegenerative afflictions and literally decades of work, including previous late-stage failures of three other potential Alzheimer's medicines.

Of course, new medicines do no good if people can't access them. That's why I'm proud that we've led the industry in making insulin affordable. Because of our efforts, people pay an average of \$20.48 for a month's supply of Lilly insulin—less than 75 cents per day—and that was before we recently announced a new series of actions that will drive that average even lower.

We began this effort years ago. Lilly hasn't raised the list price for any of our insulins since 2017, the year I became CEO. In fact, we've only cut them. In 2016, we launched the first follow-on biologic basal insulin in the U.S., Basaglar, at a discount to the original brand. In 2019, we launched Lispro, a nonbranded copy of our leading insulin Humalog, at a 50% discount, then later a 70% discount, and now only \$25 per vial. And when we saw the insurance system was not always working for people who need insulin, we were the first and still only company to cap what people pay at \$35 per month for all of our insulins—which is now automatic wherever possible—even when patients have no insurance or when their insurance would have forced them to pay much more. Our efforts are making a real impact—saving people with diabetes over \$185 million last year and, so far this year, we're helping over 100,000 people save \$20 million *each month*.

Lilly has led the way on affordability against the headwinds of a healthcare system that now incentivizes others to prefer higher list-price medicines. Higher list prices allow for higher fees and rebates, which can increase patients' out-of-pocket costs while benefiting insurance companies, employers, and people who don't need medicines.

Lilly's Lispro is just one of many examples. Unfortunately, many other actors still prefer the higher-priced Humalog (with its higher fees and rebates) to the lower-priced Lispro (with its lower fees and rebates). Today, only one in three people has access to Lispro through their insurance despite the fact that it cost 70% less and is identical to Humalog. A lot of attention has been focused on increases in the list price for insulins over time. But even before our recently announced price reductions, our net price for Humalog—what Lilly receives after paying fees and rebates—was about the same as when we launched it in 1996, adjusting for inflation. List-price increases in the past went almost entirely to paying everincreasing fees and rebates. Last year, about 80% of our insulin list prices went to paying fees and rebates to companies who didn't invent, develop, manufacture, nor study the medicine. Lilly got the remaining 20%. And with that 20%, Lilly not only covered the cost of making and distributing insulins—including supporting 4,000 high-paying manufacturing jobs with full benefits and pensions here in America—but we also paid for our out-of-pocket cap commitments and poured 25% of all of our revenues back into research and development for new medicines.

Reforms are needed. We need a system that incentivizes both world-leading innovation and lower out-of-pocket costs for Americans. Those reforms must help patients at the pharmacy counter, while also maintaining the incentive for U.S. companies to continue to invest worldleading amounts into research and development—an incentive that results in Americans having access to more and newer medicines than any other country. We're ready to continue to do our part, and we're confident that policy solutions that will address the real underlying problems are possible and relatively simple. We look forward to continuing this important dialogue.

A. Embracing the Next Century of Innovation

Innovation is woven into Lilly's fabric. In 1923, we introduced the world's first commercially available insulin, which was animal based and crude by modern standards. In the decades that followed, we helped pioneer significant advancements to enhance the purity, concentration, and delivery of insulin. In 1982, we launched Humulin, the first genetically engineered human insulin (and the world's first medicine created using recombinant DNA technology), ending concerns about whether there would be enough animal-based insulin to serve

the growing number of people with diabetes. In 1996, we launched a new genetically engineered insulin, Humalog, which provides tighter blood sugar control with a lower risk of hypoglycemia. And we've continued to innovate throughout the last decade, including launching the rapid-acting mealtime insulin Lyumjev in 2020, which begins working faster than other mealtime insulins.

But our work is not done. Only one in three people living with diabetes has control over the disease. That's why we are not satisfied with treating people in the future with only the medicines available today. We are actively investing and working on new solutions for people with diabetes, that if successfully developed and approved, could make a significant impact. This includes a glucose-responsive insulin that can sense sugar levels in the blood and automatically activate as needed, and Basal Insulin Fc, a once-weekly basal insulin injection.

We outpace our competitors by consistently investing 25% of our total revenue in research and development. We invested \$7.1 billion in 2022, and we plan to invest \$8.5 billion this year. We employ more than 5,000 people in the U.S. in pharmaceutical research and development activities, including a substantial number of physicians, scientists holding graduate or postgraduate degrees, and highly skilled technical personnel. These are good-paying American jobs for people doing really good things. Over the last decade, we introduced 19 new medicines, and we hope to launch several more by the end of this year.

Lilly's investments cut across many major diseases like Alzheimer's, cancer, diabetes, and autoimmune diseases. Our neurodegeneration pipeline, for example, reflects thirty years and billions of dollars spent developing potential medicines for Alzheimer's and related afflictions— \$8.5 billion in the last 15 years alone. We were proud to report, just last week, the exciting results of our Phase III clinical study for donanemab, our potential new Alzheimer's medicine, which will hopefully be approved by the FDA and covered by CMS soon. At 18 months compared to placebo, study participants on donanemab had a 40% less decline in their ability to perform activities of daily living, and participants on donanemab experienced a 39% lower risk of progressing to the next stage of disease. There's finally real hope on the horizon for patients and families ravaged by Alzheimer's.

Lilly's new Alzheimer's medicine is a testament to American ingenuity and American capitalism. Without our market-based system, Lilly's efforts to find a solution for Alzheimer's would never have been possible. Along this multi-decade project, Lilly proceeded to extraordinarily expensive late-stage clinical trials with three other drugs that, unfortunately, ended in failure. But we persevered and continued to pour resources into the effort motivated by the promise of filling this vast unmet medical need, which finally led to the success for the field and for people living with Alzheimer's that we reported last week. And we hope that all Americans who need it—including those in Medicare—will benefit from it, if approved. Under a system of socialized medicine that some advocate—where the government imposes artificial price controls, and it guides, directly or indirectly, the direction of medical research—Lilly's Alzheimer's efforts would have not been possible.

This experience is not unusual in the pharmaceutical industry. As with donanemab, all our groundbreaking medicines inevitably occur alongside exploration, trials, and billions of dollars in investment that do not result in FDA-approved medicines. The average cost to discover and develop a new medication is \$2.6 billion, and the average length of time from discovery to the introduction of a new medicine is 10 years.¹ 90% of drug candidates fail. But we believe those costs and struggles are worth it: they yield newer and better medicines that once were

¹ Eli Lilly and Company, *Key Facts* (2023), https://bit.ly/3Fy2lNl.

inconceivable for diseases that were once untreatable. They save and improve the lives of the patients we exist to serve.

Compared to those living in other countries, Americans benefit in unique ways from our market-based economy. Studies have shown that nearly 90% of new medicines launched are available to people in the United States,² and Americans get access to those new medications within four months of a medicine's launch³—rates that far exceed any other country. For example, Canadians typically wait 17 months to get access to new medicines and then only have access to about half of the newer branded medicines.

We should aspire to have a system that incentivizes *both* world-leading innovation *and* lower costs for patients. The U.S. market-based system produces the best results for patients because it efficiently allocates resources to accomplish breakthroughs that people need to survive and lead better lives. Alternative systems like socialized medicine starve innovation because price controls drain the incentive to make big and necessary investments, not to mention more intrusive tendencies to dictate research priorities.

Simply put, new medicines and scientific breakthroughs like donanemab would not be possible under any other system. And experience elsewhere tells us these other systems don't work. As trends in Europe towards socialized medicine increased, research and development spending there migrated to the United States. For example, Lilly alone will likely spend about the same on research and development this year as the entire country of Germany, which had a gross domestic product of over \$4.2 trillion. We should protect the current system that continues to

² "New analysis shows that more medicines worldwide are available to U.S. patients," PhRMA, June 5, 2018, https://catalyst.phrma.org/new-analysis-shows-that-more-medicines-worldwide-are-available-to-u.s.-patients.

³ *Research and Development in the Pharmaceutical Industry*, Congressional Budget Office, April 2021, https://www.cbo.gov/publication/57126.

support that level of investment into the next generation of medicines that many so desperately need—and we can do it while enacting reforms that protect patients at the pharmacy counter.

Lilly prioritizes keeping as much of our research and development and manufacturing work in the United States as possible. We are proud to be a U.S.-based company—headquartered in Indianapolis for nearly 150 years—with nine production, distribution, and corporate administrative sites in the United States, and research and development facilities in five different states. Over the past three years, Lilly has invested \$6.4 billion in U.S.-based manufacturing sites to deliver medicines to people worldwide. In 2022, we committed to invest more than \$2 billion in new facilities in Indiana to manufacture existing and future medicines and more than \$1 billion in a new facility in North Carolina to manufacture medicines and devices. Just last month, we committed to investing an additional \$1.6 billion in our new Indiana facilities to support the manufacturing of several medicines. Lilly is also the only major insulin manufacturer that has end-to-end supply chain capability for insulin within the United States.

We are also proud of our research, development, and manufacturing to help Americans during the COVID-19 pandemic. We tested an existing medicine and developed new antibodies in record time, receiving Emergency Use Authorization for three COVID-19 therapies. Our manufacturing teams boosted Lilly's production of our COVID-19 antibodies from zero doses to nearly one million by the end of 2020—all while maintaining high quality standards. And we experienced no supply disruptions across our portfolio of medicines, despite unprecedented challenges.

B. Insulin Affordability – \$35 Insulin and Lilly's Industry-Leading Solutions

We are tremendously proud of the work we have done to make Lilly's insulins affordable for everyone. Lilly led the way earlier this year in announcing we were reducing insulin prices, launching a new lower-priced biosimilar, and enhancing our efforts to ensure that all people have affordable access, regardless of their insurance status. We announced we are cutting the list price of Humalog and Humulin, our two most-popular insulins, by at least 70%. We embraced competition by launching Rezvoglar, a biosimilar to, and interchangeable with, a competitor's basal insulin (Lantus), at a 78% lower price. We also lowered Lispro's list price again, now to \$25 per vial, making it the lowest list-priced mealtime insulin available and less than the price of Humalog in 1999. And we enhanced our efforts to cap out-of-pocket costs for all our insulins at \$35 per month—a program we first introduced in 2020—by making it automatic for most people. That's \$35 for all our insulins, regardless of the number of pens or vials someone needs in a month.

Our commitment to ensuring people have affordable access to insulin is not new. Over 25 years ago, in 1997, Lilly began supporting a separate charitable organization called Lilly Cares, which provides free Lilly medicines to people who qualify. Eligible people with a household annual adjusted gross income of up to 400% of the federal poverty level, which for a family of four means an annual income of about \$120,000, can receive insulin for free.⁴

Lilly has also introduced competition and lower list price insulins. In 2016, we launched the first follow-on biologic basal insulin, Basaglar, at a significant discount to Sanofi's Lantus, which created competition in the long-acting insulins market. In 2019, we introduced more competition, this time competing with ourselves, when we introduced Lispro. We launched Lispro at half of Humalog's list price, and then cut Lispro's list price again to 70% less than Humalog. Effective May 1 of this year, we further reduced Lispro's list price to \$25-per-vial, which is *less* than the list price of Humalog in 1999.

⁴ For more information about Lilly Cares, including available products and eligibility requirements, see LillyCares.com.

Unfortunately, lower list prices don't necessarily translate to lower costs for people because the lower-priced medicines are not always available to insured patients due to their insurance plan design. Lilly has taken the lead in helping those left with high out-of-pocket costs. In early 2020, we introduced the Lilly Insulin Value Program. Under this program, people who have commercial insurance or no insurance at all can visit InsulinAffordability.com, click two checkboxes, and within seconds receive a savings card to fill their entire monthly prescription of any Lilly insulin for \$35. And those without internet access can get the \$35 card by calling the Lilly Diabetes Solution Center at 1-833-808-1234. Our \$35 program does not require any application, waiting period, identifying information, or income thresholds. We made this solution even easier earlier this year by automating the \$35 cap wherever possible for people with commercial insurance, so they no longer need to present the savings card to their pharmacist or even know the program exists. Whatever their insurance company would have charged them for their monthly supply of Lilly insulin, we buy it down to \$35 automatically, with no action needed by the person filling the prescription.

We also partnered with the Centers for Medicare and Medicaid Services several years ago to pioneer the Medicare Part D Senior Savings Model, expanding our \$35 solutions to Medicare. Under this program, seniors in participating plans can fill their insulin prescriptions for no more than \$35 per month. This program is now the law of the land, as Congress has made Lilly's \$35 monthly cap permanent for seniors in Medicare Part D. Congress can go further. We encourage Congress to make the same \$35 monthly cap—which Lilly already provides—permanent for people with commercial insurance or no insurance at all, too.

Our programs work. Last year, our commitment to cap insulin costs saved people with diabetes over \$185 million (which Lilly covers). And so far this year, each month, it saves 100,000

patients about \$20 million. Lilly regularly supports these people at a loss—paying rebates *and* paying down someone's prescription at the pharmacy—sometimes losing hundreds of dollars on a prescription to ensure someone doesn't have to pay over \$35 at the pharmacy counter. Because of our efforts over the past few years, in 2022, people paid an average of \$20.48—less than 75 cents per day—for their entire monthly supply of Lilly insulin, and we expect that number to decrease further this year.

C. Insulin Highlights the Broader Structural Change that Is Needed

Unfortunately, one company alone cannot ensure everyone has affordable access to the medicines they need. Our healthcare system creates an incentive for other actors to prefer higher list prices. This incentive then shifts healthcare costs onto people with chronic illnesses to support lower overall premiums for those fortunate to be healthier—the opposite of how insurance is supposed to work. This isn't right. Until we address those underlying structural issues, we will not fix the problems at the root of high out-of-pocket costs.

Let me explain why. The vast majority of people have insurance coverage. They pay premiums, and their insurance is supposed to cover the cost of their medicines. But often it doesn't. People increasingly need to pay for more of their medicines out of pocket, especially when they have a high deductible health plan, until they hit their deductible.

At the same time, Lilly wants to ensure that people have access to our medicines by including our medicines on formularies—the list that determines whether a person's medicines are covered by insurance at all. Getting on formulary is the best way to ensure most people can access our medicines affordably—once again, that's how insurance is supposed to work. But that requires manufacturers to pay ever-increasing rebates and fees, which can place upward pressure on medicines' list prices. If we cannot offer competitive rebates, our medicines may be excluded

from formularies, and people cannot access them. Last year alone, to ensure our medicines were covered, Lilly paid more than \$12 billion in rebates for all our medicines, and \$1 billion in fees.

Last year, about eighty cents of every dollar spent on our insulins went to pay rebates and fees. Only twenty cents of each dollar went to Lilly, even though we create insulin and employ thousands of employees in the United States, who receive good salaries and benefits (including pensions) and work 24 hours a day to manufacture it. Our net price for insulin—again, what Lilly receives after paying increasing rebates and fees—is about the same today as when we launched Humalog in 1996 after adjusting for inflation. List price increases, which have not occurred after 2017, went to increases in rebates and fees to make sure as many people as possible had access to our insulin through their insurance.

This system does not help people who rely on our medicines. Some say that most of the rebates are passed on to health plans. We don't have the visibility to verify that, but either way it's one step short. Not enough of those savings are passed along to people at the pharmacy counter who are prescribed the rebated medicine. Instead, others in our healthcare system say they often use those dollars to lower overall premiums. In the case of chronic medicines like insulin, where people's prescriptions are generating rebates that don't help them at the pharmacy counter, this dynamic effectively "transfer[s] financial resources from sick patients to healthy premium-paying beneficiaries—the opposite of what insurance is supposed to do."⁵ The chronically ill need our system's support; they cannot be responsible for subsidizing the healthy.

Some say manufacturers like Lilly should simply lower their list prices on insulin. We tried. But our experience proves that won't solve the problem. Again, in 2019, we launched Lispro, a nonbranded version of our most popular insulin, Humalog, for half the list price, and

⁵ *Testimony of Erin Trish, Ph.D.*, Senate Committee on Commerce, Science, and Transportation (Feb. 16, 2023).

later further dropped its list price to 70% below Humalog and now only \$25 per vial. We hoped others would be eager to make this lower-priced option available to people because it would reduce their out-of-pocket costs in the deductible phase of a high deductible health plan. Unfortunately, they did not. Today, only one in three insured Americans has a policy that covers Lispro, leaving patients with only higher-priced options. That's because Lispro's lower list price means other actors receive lower rebates and fees—fees tied to a percentage basis to the list price—even though the net cost to the health plan should be the same (or lower) regardless of whether they choose the high- or low-list price version *of the same medicine*.

Our experience refutes the argument some have made that our recent decision to reduce insulin prices shows we could always have done so without risking access for people with diabetes. In fact, it proves we were right to be worried. While many factors went into our recent decision, we saw an opportunity to accomplish our longstanding goal of delivering lower list-price insulins due to changes in market dynamics that we hoped might reduce the risk that our inability to offer high rebates would result in exclusion of our medicines from formularies. Still, in leading the way, we took a risk that lower prices would result in exclusion. We hope that doesn't happen.

The preference for high list prices is not unique to insulin or to Lilly. The link between rebates and higher list prices has played out with many other medicines, and this dynamic has been documented by recent government reports discussing medicines that treat asthma⁶ and hepatitis C.⁷ Earlier this year, for example, Amgen launched a Humira biosimilar at two different prices: 5% and 55% discount off of Humira's list price—the exact same medicine at two prices.

⁶ Medicare Payment Advisory Committee (MedPAC). Analysis of Part D Data on Drug Discounts and Rebates (Sept. 30, 2022), https://pink.pharmaintelligence.informa.com/-/media/supporting-documents/pinksheet/2022/10/medpac-slides-29-sept-2022.pdf?rev=293b80c5a8634f4985d4b69437b33593&hash=5BE40A6DF109D4432E1E09852C46DC7F.

⁷ Office of the Inspector General, HHS. Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending (Aug. 2022), https://oig.hhs.gov/oei/reports/OEI-BL-21-00200.pdf.

It was widely reported that other actors would likely favor the higher-priced option—just like they favored Humalog over Lispro.⁸ These examples show that, while some say they want lower list prices, their actions show they often deny or limit coverage of lower-cost medicines, including generics and biosimilars.

D. We Can Achieve Meaningful Solutions through Simple Fixes

As these dynamics show, the affordability solutions that Lilly has implemented are a bandaid on a much larger problem. But fixes are not complicated, and we can have a system that incentivizes both world-leading innovation and lower costs for Americans. Reforms that target and eliminate—the incentive for high list prices are necessary and can help provide long-term solutions for patients' out-of-pocket costs. That is why we advocate for policies that untether fees from list prices, ensure rebates for a medicine go directly to the people who use it, and increase transparency in the healthcare system.

Delink Fees and Price. We support removing the incentive for high prices by delinking other actors' revenue streams from a medicine's list price. Fees, rebates, and other payments in the healthcare system are often calculated as a percentage of list price. Higher prices mean they make more money, but the same services are performed whether a medicine is \$10 or \$100. We can fix that problem by ensuring that payments are based on the services actually provided, not a medicine's list price.

Ensure People Benefit from Rebates. No one should have to pay more for their medicine than their insurer pays. Payer negotiated discounts are typically passed fully to patients for all healthcare services, but not for medicines. Lilly believes any rebate it pays should be passed

⁸ Silverman, Ed. Amgen pricing for its Humira biosimilar may benefit PBMs and insurers more than patients (Jan. 31, 2023), https://www.statnews.com/pharmalot/2023/01/31/amgen-humira-biosimilar-pbm-rebates-insurers/; see also Brennan, Zachary. Amgen launches the first US Humira biosimilar at two different list prices (Jan. 31, 2023), https://endpts.com/amgen-launches-the-first-us-humira-biosimilar-at-two-different-list-prices/.

through to people at the pharmacy counter to offset the cost of their medicines, not to support someone's bottom line or to subsidize the healthy. Some states have already implemented this rule by requiring that rebates for any specific medication directly reduce out-of-pocket costs for the people using that medication. This approach would enable manufacturers' price concessions to flow directly to people and lower their costs at the pharmacy counter. Lilly has long supported this approach to reducing out-of-pocket costs, including in the context of the proposed rebate rule that was proposed four years ago and then legislatively delayed.⁹

Cost-Sharing Reform. Lilly supports reforming the cost-sharing structures in insurance plans. This could take the form of expanding the preventive medication lists on insurance formularies to include insulin, which would reduce the amount that people spend on insulin in the deductible phases of their plans and eliminate any risk that they may be exposed to the full list price for their medications. Today, many plans exempt insulin from the deductible requirement by including it on a preventative medicines list, which is an important step toward a more sustainable model that mitigates potentially high out-of-pocket costs that people with chronic illnesses may face. Finally, Lilly also supports legislation like the Affordable Insulin Now Act, which would cap the monthly out-of-pocket costs of all insulins at \$35—a federal solution that would make permanent part of what Lilly has already done on its own. Access to \$35 insulin should not depend on whether the person has Medicare, commercial insurance, or is uninsured.

Increase Transparency. We support additional transparency in the system. We commend legislation like the Pharmacy Benefit Manager Transparency Act of 2023, which encourages fair and transparent practices that benefit local pharmacies and consumers.

⁹ See HHS, Proposed Rule, Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2340 (Feb. 6, 2019).

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We at Lilly appreciate that the Committee shares our commitment to insulin affordability, and we will continue to do our part. We stand ready to work with this Committee—and all other actors and policymakers who share this goal—to find lasting and meaningful solutions.

Thank you for the opportunity to be here today. I look forward to your questions.