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U.S. HOUSE OF REPRESENTATIVES
ENERGY & COMMERCE COMMITTEE
OVERSIGHT & INVESTIGATIONS SUBCOMMITTEE HEARING ENTITLED
'PRICED OUT OF A LIFESAVING DRUG: THE HUMAN IMPACT OF RISING INSULIN COSTS'
APRIL 2, 2019

Chairwoman DeGette, Ranking Member Guthrie, Chairman Pallone, Ranking Member Walden and Members of the Subcommittee — thank you for the spotlight you are placing on the issue of insulin affordability.

In 1977, my younger brother Stephen was diagnosed with type 1 diabetes. It was a bolt out of the blue. I was diagnosed with type 1 diabetes in 1984. My career has been focused on the fight to cure this terrible disease and to help people stay healthy until that day. As the Chief Mission Officer of JDRF, the leading organization funding type 1 diabetes research, I am grateful for the opportunity to share our perspective and the experiences of those who are grappling, day-to-day, with skyrocketing insulin costs.

Type 1 diabetes is a fatal disease without insulin treatment. Millions of Americans must take insulin many times a day, every day, just to survive. Yet the cost of insulin has soared.

- A study in the *Journal of the American Medical Association* showed that the average price of insulin tripled from 2002 to 2013.[1]

- A study from the Health Care Cost Institute found that among people with type 1 diabetes, the per person annual spending on insulin as well as the point-of-sale price doubled between 2012 and 2016.[2]

- Data from the Centers for Medicare & Medicaid Services show the price of insulin delivered through an insulin pump more than quadrupled from 2010 to 2019.[3]

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[1] Hua X., Carvalho, N., Tew, M., Huang, E., Herman, W., Clarke, P. "Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013," *JAMA*, April 5, 2016; 315(13):1400-1402. This study shows the average price of insulin tripled from $4.34 to $12.99 per milliliter from 2002 to 2013. Since a vial of insulin is 1000 units or 10mL, these data indicate the price per vial increased from $43.40 in 2002 to $129.90 in 2013.

[2] "Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices." Health Care Cost Institute, January 21, 2019. Accessed at https://www.healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices. The study shows the average spending on insulin for people with type 1 diabetes increased from $2,864 in 2012 to $5,705 in 2016.

[3] Average sales price data accessed at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html for reimbursement code J1817. Data show that in the first quarter of 2010, the price of insulin delivered through an insulin pump was $2.349 per 50 units; in second quarter of 2019,

Beyond the data are the lives of real people – your constituents. As I travel the country, the number one question that families with type 1 diabetes ask me is: how can we make insulin more affordable?

My own family has been affected: My brother has benefited tremendously from advances in today's modern insulins – they have significantly reduced life-threating and incredibly costly, severe low-blood sugar episodes. But even as a small business owner in New Jersey, Steve was spending $8,000 per year out-of-pocket. His wife switched jobs to obtain better insurance that would cover the cost of his insulin.

Many individuals and families are facing similar challenges.

As prices have increased, insurance is often covering less. Like my brother, more and more Americans have been enrolled in high deductible health plans, in which they pay the full cost of health care until they reach their deductible. From 2007 to 2017, at the same time as the rapid rise in insulin prices, the percent of people with employer-sponsored insurance covered by high-deductible plans rose from 14.8 percent to 43.4 percent, with less than half having a health savings account to help pay for costs of care during the deductible phase.[4]

Imagine someone who uses four vials of insulin a month and pays the full list price of $275 per vial – they would pay a total cost of $1,100 per month just for insulin, not counting other diabetes supplies or health care costs.

When people with diabetes cannot afford insulin, they can resort to drastic and life-threatening measures to stay alive.

A recent study from Yale found up to 25 percent of people with diabetes are actually taking less insulin than what they need, just to save on costs. The 2018 study surveyed a cross-section of patients with insulin-dependent diabetes, finding that one in four reported cost-related insulin underuse, which was associated with poor glycemic control. The patients surveyed who reported cost-related insulin underuse had lower income levels, variable drug coverage and

price had risen 472 percent to $11.080. Since a vial of insulin is 1000 units or 10mL, these data indicate the price per vial increased from $46.98 in 2010 to $221.60 in 2019.

[4] Data on trends in high deductible plan use are here: https://www.cdc.gov/nchs/products/databriefs/db317.htm. Other studies have shown effects on costs and outcomes of people with diabetes switching from low deductible to high deductible health plans. See Wharam, J.F., Zhang, F., Eggleston, E., et al., "Diabetes Outpatient Care and Acute Complications Before and After High-Deductible Insurance Enrollment: A Natural Experiment for Translation in Diabetes (NEXT-D) Study," *JAMA Internal Med*. 2017; 177(3):358-368 and Wharam, J.F. Zhang, F. Eggleston, E. et al., "Effect of High-Deductible Insurance on High Acuity Outcomes in Diabetes: A Natural Experiment for Translation in Diabetes (NEXT-D) Study," *Diabetes Care*. 2018; 41(5);940-948

employment, and three-fold higher odds of having an HbA1c value greater than 9 percent, compared to patients who did not report underuse.[5]

Taking less insulin to save on costs often leads to greater economic and personal tolls. A 2018 report by the Centers for Disease Control and Prevention found that the rates of hospitalizations for diabetic ketoacidosis (DKA) in the U.S. increased by 54.9 percent from 2009 to 2014, after a slight decline from 2000 to 2009.[6] Another study found 188,965 total hospitalizations for DKA in 2014, up from 118,808 in 2003, with an average cost of $26,566 in 2014 and a total national bill of $5 billion.[7]

At a time when new innovations can enable people with type 1 diabetes to live longer, healthier lives than ever before, the dramatic rise in the cost of insulin is undercutting this progress. To get the best outcomes, people with diabetes need access to affordable insulin and diabetes management tools year around.

The conclusions are clear: when people with diabetes cannot afford insulin and other diabetes management tools, they are not able to manage their blood sugar, threatening their health and driving up costs for complications, doctor visits, and hospitalizations.

At times, tragically, the results can be fatal.

No one should suffer or die because they cannot access insulin.

The time for real action is now.

Through our Coverage2Control campaign, JDRF has been rallying our community to call on companies to lower the price of insulin, and for health plans, employers, and the government to take steps to lower out-of-pocket costs.

Coverage2Control focuses on three things to help people with type 1 diabetes control the disease: predictable and reasonable out-of-pocket costs for insulin and diabetes management tools; the freedom to choose the type of insulin and insulin pump that's right for them; and for all life-saving technology to be covered, including artificial pancreas systems.

On behalf of JDRF, I want to thank Congress for your commitment to solving this problem.

We need systemic change, change that you can help make happen.

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[5] Herkert, D. M., Vijayakumar, P., Luo, J., Schwartz, J., Rabin, T. L., Defilippo, E. M., & Lipska, K. J. (2018). "Cost-Related Insulin Underuse Is Common and Associated with Poor Glycemic Control," *Diabetes,67*(Supplement 1). doi:10.2337/db18-2-or.

[6] Benoit SR, Zhang Y, Geiss LS, Gregg EW, Albright A. Trends in Diabetic Ketoacidosis Hospitalizations and In-Hospital Mortality — United States, 2000–2014. MMWR Morb Mortal Wkly Rep 2018;67:362–365.

[7] Desai, D., Mehta, D., Mathias, P., Menon, G., Schubart, U.K., "Health Care Utilization and Burden of Diabetic Ketoacidosis in the U.S. Over the Past Decade: A Nationwide Analysis,"*Diabetes Care*. 2018; 41(8): 1631-1638.

Actions to Lower Prices

First, manufacturers need to lower the list price of insulin. To do this, rebates, which make up an astonishing 70 plus percent of the list price of insulin, must be eliminated from the drug reimbursement system. In the current system, companies give discounts to pharmacy benefit managers and health plans, while increasing prices at the pharmacy counter. JDRF supports the Administration's proposed anti-rebate rule change which would end rebates in federally-funded health insurance plans. We believe that the proposed regulation is a significant positive step toward ridding us of a system that has driven significant price increases for insulin over many years and ask Congress to take action to end rebates in the commercial sector as well.

Subsequently, manufacturers must lower list prices and restrict increases to no more than the Consumer Price Index. If this occurs, we believe that strong competition among insulin manufacturers will quickly push them to lower prices to net levels, which will greatly benefit patients who need this drug to survive.

At the same time, the Food and Drug Administration should continue its support of authorized generic insulin products and pathways for biosimilars, which will provide more options for people with diabetes at the pharmacy counter.

Actions to Lower Out-of-Pocket Costs

Second, insurers and employers must provide affordable coverage that reflects insulin's role as a life-saving drug. Specifically, we support removing insulin and diabetes management tools from the deductible so costs are consistent throughout the year, as health plans do for "preventive" drugs. We also support the use of flat dollar co-payments for insulin, rather than coinsurance which changes as list prices change, so that people with diabetes are not hit with unexpected increases in out-of-pocket costs.

At the same time, the public and private sector need to do more to help those who are uninsured, and those who are in high-deductible plans, obtain the insulin they need to stay alive. Companies should do more to provide free or low cost insulin to those who need it, and Congress should extend funding for Community Health Centers which provide insulin on a sliding fee scale. Information about these resources for low cost insulin are available at www.jdrf.org/insurance.

Human insulin can be used to manage diabetes and prevent DKA and death. It can be purchased at many pharmacies without a prescription for less than $30 per vial. While we should preserve this option, it is a band-aid, not a solution to insulin access. Human insulin is not as effective as newer products that have been engineered to have significant improved properties – such as faster action and more reliable absorption and activity, which allows people with diabetes to maintain tighter blood sugar control.

Actions to Promote Innovation

Third, we need to continue to invest in research. At JDRF, we believe affordability, accessibility, and innovation go hand-in-hand to improve outcomes. Thanks to Congress' strong, bipartisan commitment to the Special Diabetes Program joined with private investment from organizations like JDRF, we are making progress on glucose-responsive and faster-acting insulins, artificial pancreas systems, beta cell replacement, and immunotherapies. Our goal is to cure T1D, and in the meantime make advancements that enable people to stay healthy until we have a cure.

While we work towards a brighter tomorrow, we need to ensure that today, all those who need it can obtain the insulin they need to stay alive. We appreciate the outstanding leadership of the members of Congress here today. I ask you to continue to fight alongside us. Thank you.