



**Written Testimony of William T. Cefalu, MD
Chief Scientific, Medical and Mission Officer
American Diabetes Association
“Priced Out of a Lifesaving Drug:
The Human Impact of Rising Insulin Costs”
United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
April 2, 2019
Washington, DC**

**Media Contact:
Michelle Kirkwood
Vice President, Scientific, Medical
and Mission Communications
American Diabetes Association
(703) 299-2053
mkirkwood@diabetes.org**

**For Further Information, Contact:
Meghan Riley
Vice President, Federal Government Affairs

American Diabetes Association
(703) 253-4818
mriley@diabetes.org**

**Statement to the U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
William T. Cefalu, MD, Chief Scientific, Medical and Mission Officer
American Diabetes Association
April 2, 2019**

Thank you, Chair DeGette, Ranking Member Guthrie, and distinguished members of the Subcommittee on Oversight and Investigations for the opportunity to discuss the issue of insulin affordability. As you know, more than 30 million Americans have diabetes. Approximately 7.4 million of them rely on insulin. For millions of people with diabetes—including all individuals with type 1 diabetes—access to insulin is literally a matter of life and death. There is no medication that can be substituted for insulin. As the leading organization whose mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes, the American Diabetes Association believes that no individual in need of insulin should ever go without it due to prohibitive costs.

In 1921, Canadian scientists Frederick Banting and Charles Best discovered insulin, revolutionizing diabetes care and making it possible for patients to **live** with the disease. Along with their partner, James Collip, who purified the insulin, Banting and Best sold the patent for insulin to the University of Toronto for \$1 each to ensure affordable insulin for all who needed it. Further discoveries have resulted in new formulations of insulin over the years, advancing from animal insulin, to human insulin, and more recently in the 1990s to analog insulins. The advancements achieved with the analog insulins allow for a more physiologic

replacement of insulin in the body. In recent years there have been fewer advancements in insulin formulations, yet prices continue to rise, even for off-patent insulins.

The “Economic Costs of Diabetes in the U.S in 2017” report, released by the ADA last year, shows the direct and indirect costs of diagnosed diabetes increased 26 percent in five years to a total of \$327 billion in 2017, making diabetes the most expensive chronic illness in America. Approximately \$31 billion was spent on medications directly used to treat diabetes, including nearly \$15 billion in insulin costs.

In recent years, the cost of insulin has become a growing problem for people with diabetes. Between 2002 and 2013, the average price of insulin nearly tripled, causing patients’ out-of-pocket costs to rise and creating a tremendous financial burden for many who need insulin to survive. In early 2018, the ADA conducted a nationally representative survey asking individuals with diabetes if the cost of their insulin has risen and if the rise in cost has affected their use of insulin. Dangerously, more than a quarter of respondents indicated they made changes to their purchases of insulin over the preceding year due to the cost.

When people cannot afford the insulin they need, they may skip doses or take less than they need—known as rationing. This puts them at risk for devastating and sometimes deadly complications. Long-term complications include cardiovascular disease, blindness, lower-limb amputations, and kidney disease. Depending on each individual’s condition, if a person with type 1 diabetes goes without insulin for as little as one day, they can begin to develop a condition of

metabolic decompensation called diabetic ketoacidosis, which if not immediately and effectively treated, can lead to death.

Increasingly, the ADA has heard stories of individuals forced to ration their insulin or forced to go without other important necessities, so they can purchase the amount of insulin they need. We had to act on behalf of the people we represent.

In November of 2016, the ADA's Board of Directors unanimously passed a resolution calling on all entities in the insulin supply chain, including manufacturers, wholesalers, Pharmacy Benefit Managers (PBMs), insurers, and pharmacies to substantially increase transparency in pricing associated with the delivery of insulin, and to ensure that no person with diabetes is denied affordable access to insulin. While transparency alone won't reduce the cost of insulin, it will help us understand the underlying causes and could lead to important reforms.

The ADA's resolution also called upon Congress to hold hearings with all entities in the insulin supply chain to identify the reasons for the dramatic increases in insulin prices and to take action to ensure that all people who use insulin have affordable access to the insulin they need.

In concert with the Board resolution, the ADA initiated a grassroots petition calling for the same actions. As of March 2019, more than 480,000 people have signed the petition, making it the largest collection of signatures for any single ADA petition. In the time since the resolution and petition were launched, the ADA has also collected more than 800 stories from people with diabetes, caregivers, and health care providers who are directly burdened by the increasing costs of insulin.

For example, we heard from Ann in Colorado. Ann is a nurse and her husband is a police officer. They have two young children with type 1 diabetes who must use insulin every day. At the beginning of the year, their monthly insulin costs total nearly one thousand dollars. When the pharmacist first asked Ann for this sum of money she was shocked and asked him to run the prescription through their insurance. He already had. Despite having insurance, the King family had to pay 875 dollars out of pocket for just a month's supply of insulin. Ann had to leave the medication at the pharmacy and go home to comb through her family's monthly budget to make sure they had enough money to pay for the medicine that keeps their two children alive.

As a physician and clinician scientist, I have witnessed first-hand how the incredible research advances and innovative therapies resulting from investment in biomedical research have dramatically improved the lives of those with diabetes. However, I have also observed that the incredible innovation may not benefit those who are not able to access and afford such treatments. This became even more apparent to me when I joined the ADA as the Chief Scientific, Medical and Mission Officer in February 2017, where I have had the vantage point to appreciate more fully the daily struggles of individuals with diabetes through their stories.

In the spring of 2017, and in discussions with the ADA's Board of Directors, an Insulin Access and Affordability Working Group (Working Group) was established to ascertain the full scope of the insulin affordability problem and to advise the ADA on the development of strategies that will result in viable, long-term solutions to bring down the cost of insulin for all who need it. I serve as Chair of

the Working Group, which is composed of outside experts, past members of the ADA's Board, and the ADA's staff. Throughout 2017 and into 2018, the Working Group convened a series of meetings with stakeholders throughout the insulin supply chain to learn how each part of the complex system impacts the out-of-pocket costs for individuals with diabetes. The Working Group held discussions with more than 20 stakeholders representing entities throughout the insulin supply chain, including pharmaceutical manufacturers, distributors, PBMs, pharmacies, pharmacists, health plans, employers, and people with diabetes and caregivers. The final product of the Working Group was a white paper, published in the journal *Diabetes Care* last May, outlining what we learned from discussions as part of our stakeholder interview process and existing public information.

Through a rigorous process that examined all levels of the insulin supply chain, the Working Group learned a lot about a very complicated and complex system. Most importantly, we noted there are numerous stakeholders involved in multiple opaque transactions, and there is much more we need to know. The Working Group concluded the following:

- List prices of insulin have risen precipitously in recent years. Between 2002 and 2013 the average price of insulin nearly tripled.
- The current pricing and rebate system encourages high list prices:
 - As list prices increase, the profits of the intermediaries in the insulin supply chain (wholesalers, PBMs, pharmacies) increase since each may receive a rebate, discount, or fee calculated as a percentage of the list price.

- There is a lack of transparency throughout the insulin supply chain. It is unclear precisely how the dollars flow and how much each intermediary profits.
 - Manufacturers are rarely paid the list price for insulin. The so-called net price—which reflects what the manufacturers receive—is much lower, however, in most cases, the data are not publicly available.
 - In the vast majority of cases, discounts and rebates negotiated between PBMs and manufacturers, and between PBMs and pharmacies that affect the cost of insulin for the person with diabetes, are confidential.
 - PBM clients (often large employers in most cases) are not privy to these negotiations, nor do they know the net price obtained by the PBM for insulins.
 - Formulary considerations and decisions are not transparent.
- PBMs have substantial market power.
 - PBMs' primary customers are health plans and employers, not patients.
 - PBMs negotiate rebates from manufacturers using formulary placement as leverage.
 - PBMs often exclude from the formulary insulins made by the manufacturer that offers the lowest rebate.
 - As a result of negotiation, rules for coverage differ from plan to plan and year to year, or even within the same plan year.
 - When insulins are excluded from the formulary, moved to a different cost-sharing tier or removed during the plan year, it

places a burden on people with diabetes and providers and may have a negative health impact.

- PBMs receive administrative fees from their clients (health insurance plans) for utilization management services (prior authorization, etc.). Often, it is the PBM that determines which and how many drugs on the formulary are subject to utilization management.
- People with diabetes are financially harmed by high list prices and high out-of-pocket costs:
 - Regardless of the negotiated net price, the cost of insulin for people with diabetes is greatly influenced by the list price for insulins.
 - Out-of-pocket costs vary depending on the type of insurance each individual has and the type of insulin prescribed. The costs can be significantly higher for people who are uninsured, who have an insurance plan with a high deductible, and who are in the Medicare Part D donut hole.
 - Manufacturer rebates often are not directly passed on to people with diabetes.
- Patients' medical care can be adversely affected by formulary decisions;
 - People with high cost-sharing are less adherent to recommended dosing, which results in harm to their health.
 - Formulary exclusions and frequent formulary changes cause uncertainty, increase financial costs for people with diabetes, and could have serious negative consequence on the health of people with diabetes.

- The regulatory framework for development and approval of biosimilar insulins is burdensome for manufacturers.
 - There are not enough biosimilar insulins on the market.
 - Prices for biosimilar insulins are not likely to be reduced unless there are several biosimilars that can be substituted for the brand name analog insulin, rather than only one.
- Prescribing patterns have favored newer, more expensive insulins:
 - Newer insulins, including analogs, are more expensive than older insulins, including human insulins.
 - Human insulin may be an appropriate alternative to more expensive analog insulins for some people with diabetes.

Given the above conclusions, the Working Group also makes the following recommendations, as outlined in the white paper:

- Providers, pharmacies, and health plans should discuss the cost of insulin preparations with people with diabetes to help them understand the advantages, disadvantages, and financial implications of potential insulin preparations.
- Providers should prescribe the lowest price insulin required to effectively and safely achieve treatment goals.
 - This may include using human insulin in appropriately selected patients.
 - Providers should be aware of the rising cost of insulin preparations and how this negatively impacts adherence to the clinical treatment by people with diabetes.

- Providers should be trained to appropriately prescribe all forms of insulin preparations based on evidence-based medicine.
- Cost-sharing for insured people should be based on the lowest price available.
- Uninsured people with diabetes should have access to high quality, low-cost insulins.
- Researchers should study the comparative effectiveness and cost-effectiveness of the various insulins.
- List price for insulins should more closely reflect net price, and rebates based on list price should be minimized. The current payment system should rely less on rebates, discounts, and fees based on list price.
- Health plans should ensure that people with diabetes can access their insulin without undue administrative burden or excessive cost.
 - Payers, insurers, manufacturers, and PBMs should design pharmacy formularies that include a full range of insulin preparations, including human insulin and insulin analogs, in the lowest cost-sharing tier.
- PBMs and payers should use rebates to lower people with diabetes' costs for insulin at the point of sale.
- There needs to be more transparency throughout the insulin supply chain.
- Payers, insurers, manufacturers, PBMs, and people with diabetes should encourage innovation in the development of more effective insulin preparations.
- The U.S. Food and Drug Administration should continue to streamline the process to bring biosimilar insulins to market.
- Organizations like the American Diabetes Association should:

- Advocate for access to affordable and evidence-based insulin preparations for people with diabetes.
- Ensure that health providers receive on-going medical education on how to prescribe all insulin preparations, including human insulins, based on scientific and medical evidence.
- Develop and regularly update clinical guidelines or standards of care based on scientific evidence for prescribing all forms of insulin and make these guidelines easily available to health care providers.
- Make information about the advantages, disadvantages, and financial implications of all insulin preparations easily available to people with diabetes.

The conclusions and recommendations of the Working Group are only a starting point. Beginning with increased transparency within the insulin supply chain, every stakeholder must work together toward a common goal—ensure affordable insulin is within reach for all who need it.

Following the publication of the white paper, the ADA also released a set of public policy recommendations that we believe will help bring down the cost of insulin, including:

- Increasing pricing transparency throughout the insulin supply chain;
- Lowering or removing patient cost-sharing for insulin;
- Increasing access to health care coverage for all people with diabetes;
- Streamlining the biosimilar approval process.

The ADA looks forward to continuing to work with you and others in Congress to develop strategies to lower the rising costs of insulin. Again, thank you Chair

DeGette, Ranking Member Guthrie, and all members of the Subcommittee on Oversight and Investigations for convening a hearing on this critical issue.