



Testimony by

Aaron J. Kowalski, Ph.D.

Chief Executive Officer, JDRF

At the Hearing entitled:

“What’s Fueling the Diabetes Epidemic?”

Thursday, December 14, 2023, at 10:00 a.m.

Before the

United States Senate

Committee on Health, Education, Labor, and Pensions

Dirksen Senate Office Building, Room 430

Washington, D.C.

For media inquiries contact:

Casey Fielder, JDRF

media@jdrf.org

509-939-7767

Chairman Sanders, Ranking Member Dr. Cassidy, and Members of the Committee, I am Dr. Aaron J. Kowalski, Chief Executive Officer for JDRF, the leading global organization harnessing the power of research, advocacy, and community engagement to advance life-changing breakthroughs for type 1 diabetes - T1D. As a scientist by training, a person living with T1D, and someone with a brother with T1D, I have been honored to work for JDRF and to represent individuals and families impacted by T1D for the past 19 years, four of which have been in my current role.

I am also honored to testify and appreciate the committee's focus on diabetes. I would like to start with a thank you. Because of your bipartisan leadership and support, and the steadfast leadership of Senate Diabetes Caucus Co-Chairs, Senators Susan Collins and Jeanne Shaheen, the Special Diabetes Program and the Special Diabetes Program for Indians (SDPI) are making a tremendous difference in the lives of people with diabetes and their hope for the future. These programs have helped to fundamentally change what it means to live with diabetes, have put new life-changing therapies in our hands, and have brought us closer to cures.

JDRF and our countless volunteers are grateful the committee recognizes the importance of maintaining this momentum and building upon this progress with the approval of S. 1855, the Special Diabetes Program Reauthorization Act of 2023. We thank you and continue to work with your colleagues to ensure the two-year, \$170 million per year for each program, is enacted.

Diabetes – A Costly and Burdensome Disease

Far too many people are aware of “diabetes” but do not know the difference between type 1 diabetes (T1D) and type 2 diabetes (T2D). T1D is an autoimmune disease in which a person's pancreas stops producing insulin, a hormone that enables a person to utilize energy from food. The condition lasts a lifetime, and people with T1D must take insulin to live. T2D is a metabolic disease. With T2D, the body still produces insulin but cannot use it effectively.

Today, more than 37 million Americans have diabetes and 96 million have prediabetes.¹ Of those with diabetes, JDRF estimates that 1.4 million people have T1D. Diabetes affects people of all ages and races across the country. The complications that result from the condition are significant -- ranging from heart disease and strokes to lower-limb amputations -- and reduce life expectancy by at least 10 years in people with diabetes compared to people without diabetes. As a result of the breadth and impact, the total annual cost for diabetes in 2022 was \$412.9B, including \$306.6B in direct medical costs and \$106.3B in indirect costs.²

¹ Centers for Disease Control and Prevention. National Diabetes Statistics Report website. <https://www.cdc.gov/diabetes/data/statistics-report/index.html>. Accessed July 6, 2023.

² American Diabetes Association. New American Diabetes Association Report Finds Annual Costs of Diabetes to be \$412.9 Billion. <https://diabetes.org/newsroom/press-releases/new-american-diabetes-association-report-finds-annual-costs-diabetes-be> (2023)

Research for both T1D and T2D is critical to gain further understanding, advance therapies, and find cures for both conditions. JDRF and others are investing significantly in research, but absent additional investments the advances will slow significantly, while the costs of diabetes continue to rise exponentially.

JDRF - Partnering with the Federal Government

Before I share some of the exciting breakthroughs resulting from the SDP, I want Congress to know that JDRF's private funding works hand in hand with SDP funding to ensure that the most important and promising research projects have the support they need. JDRF accelerates the path to cures by raising funds and allocating them to T1D research and therapy development, as well as by leveraging our expertise and leadership to bring in additional funding and supporters.

I am proud to say that JDRF has invested more than \$2.5 billion in research funding since our founding in 1970. And through direct research investments and partnerships within the public and private sectors, including through the SDP, we helped raise \$473 million for T1D research and therapy development in JDRF's 2022 fiscal year. Investments from the JDRF T1D Fund, which is a separate mission-driven venture philanthropy fund focused on equity investments in companies developing life-changing T1D products, is a part of this total. This partnership between the public and private sectors is what it takes to deliver major advances for T1D research.

The Special Diabetes Program - Accelerating Breakthroughs

There has been tremendous progress that gives us hope for a brighter future. Here are some examples of the advancements that are exciting to the T1D community where the SDP played a role.

- **First Disease-Modifying Therapy Brought to Market**

The SDP enabled the creation of TrialNet, the largest clinical network for T1D. TrialNet conducted the clinical trials that led to the November 2022 U.S. Food and Drug Administration (FDA) approval of Tzield, the first disease-modifying therapy for individuals at-risk for developing T1D. This therapy can delay T1D onset for almost three years; other therapies to delay and prevent onset are advancing in the research pipeline.

A delay in the onset of T1D has a tremendous impact on the daily lives of people at risk for T1D, their families, and the overall healthcare system. It frees them from the constant burden and stress of blood glucose monitoring and insulin administration. It frees them from the worry and fear of short-and long-term complications, while giving them the opportunity to learn more about disease management. And it enables one to avoid the medical emergency that often accompanies a T1D diagnosis. This is both clinically and emotionally meaningful.

With a therapy to delay T1D onset and others on the horizon, screening for the risk factors that trigger T1D is even more important. TrialNet has a screening program for those with a direct relative who has T1D; however, anyone who tests positive for risk factors may be eligible to enroll in a clinical trial. JDRF launched T1Detect, a community-based education and awareness program to expand screening to the general population. JDRF is also studying the age or ages when screening should be done. We know the need to focus on screening is great and look forward to talking with you further about it.

- **Advances in Cell Therapies**

Another recent exciting development in diabetes research is the June 2023 FDA approval of the first cell therapy for adults with T1D. The approval is specifically for adults unable to maintain average blood glucose levels due to repeated severe episodes of low blood glucose levels or hypoglycemia. This therapy, with the use of immunosuppression, takes deceased donor islets and places them into people with T1D. This is an important first for the diabetes community, as it is a therapy that allows some patients to go without any injected or infused insulin for several years. This therapy could also have promise for the estimated eight million Americans with T2D who rely on insulin administration every day. Clinical trial data resulting from the SDP-supported Clinical Islet Transplantation Consortium contributed to this pivotal step toward identifying cures.

- **Artificial Pancreas Systems**

Yet another area of progress that is a real game changer for people with T1D is technology to better manage blood glucose levels. An artificial pancreas (AP) system consists of an insulin pump, a continuous glucose monitor (CGM), and a computer program called an algorithm that allows the pump and CGM to communicate with each other to give the right amount of insulin at the right time – much like the pancreas does in people without T1D. AP systems are not perfect, but they allow people to think about their diabetes a little less and have better blood glucose control, which improves the quality of life of those impacted by T1D and helps to mitigate costly and burdensome long-term diabetes-related complications. I was very involved in the development of AP systems and the approval process, and I'm thrilled to see the benefits that have resulted for myself, my brother who also lives with T1D, and the entire diabetes community.

SDP-funded research laid the early groundwork for developing AP systems. In fact, SDP funds contributed to the first fully automated insulin-dosing system being made available to patients in 2017, five to seven years earlier than expected. Positive results from SDP-supported clinical trials since then have led

to other FDA-approved systems and next-generation AP devices that have outperformed first-generation devices in children, adolescents, and young adults.

Individuals with T2D and athletes are also benefitting from some of this research. Many are now using CGMs to better monitor their blood glucose levels; gain valuable information about how food, exercise, stress, and other factors impact their levels; and better manage their levels for improved health or peak performance.

The Special Diabetes Program for Indians (SDPI) – Making a Difference

The SDP's sister program, the SDPI, is also demonstrating significant progress towards the prevention and treatment of T2D in American Indian and Alaska Native communities, which are impacted disproportionately by the disease. The SDPI serves 780,000 American Indians and Alaska Natives across 302 programs in 35 states. The program focuses on community-directed approaches that are culturally based.

Since the beginning of the SDPI, blood glucose levels have decreased by 11 percent, average LDL cholesterol risk factors have reduced by 25%, diabetes-related kidney disease has been cut by more than half, fewer people are developing diabetes, and primary prevention and weight management programs for Native youth have increased. That's amazing. These successes will continue, and even greater progress will be made with the continued federal investment contained in S. 1855.

Future Opportunities – Building on the Momentum

While the opportunities before us are abundant, here are a few examples in need of funding with the next SDP renewal.

- **Fund Long-Term Research Programs and Clinical Trials**

Continued support of the SDP would keep several long-term T1D-oriented research programs and clinical trial networks running strong, enabling them to continue their work which has yielded so many exciting and promising discoveries. For example, The Environmental Determinants of Diabetes in the Young (TEDDY) study of 8,600 children, enrolled at birth and being followed until they are 15 years old, seeks to understand which environmental factors trigger or protect against T1D onset. Information on diet, infections, and other exposures is being analyzed from children who are progressing toward - or now have - full T1D onset. Results to date indicate that there are multiple pathways leading to T1D. Further investigation is needed to develop strategies to prevent the onset of the disease, ranging from a vaccine to specific dietary changes. The data

collected from this study could also benefit other autoimmune diseases, such as celiac disease.

- **Protect Heart and Kidney Health for Those with T1D**

SGLT inhibitors, such as Invokana, Farxiga and Jardiance, protect heart and kidney health for people with type 2 diabetes but are not yet FDA approved for people with T1D. There is an immediate need to develop evidence-based strategies to ensure these drugs can be used safely by people with T1D, which could significantly reduce costly and devastating impacts of heart and kidney disease.

A recent study shows that for the current population living with T1D, lowering End Stage Renal Disease rates by 50% is expected to generate Medicare savings that build over time. At the ten-year mark, the cumulative savings to Medicare are \$5.1 billion. By the 25-year mark, Medicare savings reach \$13.6 billion³. These savings estimates do not incorporate individuals who will be diagnosed in the future and therefore are conservative.

- **Investigate Cardiovascular Disease in People with T1D**

Cardiovascular disease (CVD) in people with T1D is not as well studied as in people with T2D, even though it is a major cause of death in people with T1D. There is a major unmet need to identify the mechanisms that promote earlier development of CVD in people with T1D, to learn and develop new interventions to prevent and treat it.

Long-term, Uninterrupted SDP Support – A Critical Need

The critical research supported by the SDP requires lengthy periods to achieve optimal results. A long-term reauthorization would allow the National Institute of Diabetes and Digestive and Kidney Diseases to carefully plan the use of funds, which are directed toward new and ongoing clinical trials that take multiple years to complete.

Technology development also takes time. The noteworthy progress in developing artificial pancreas and other glucose management technologies has been spurred by long-term SDP support, as I noted earlier. For the scientists who conduct the research, long-term, sustained funding is incredibly important. With the uncertainty of sustained funding, they may pursue other research opportunities elsewhere. The assurance of long-term funding is also important to attract new talent to this field and to maintain a pipeline of future generations of scientists to conduct T1D research.

³ Winn, A, Skandari, R, O’Grady, M, and Huang, E. “Potential Medicare Savings of Reduced End Stage Renal Disease in Patients with Diabetes,” May 2023. Unpublished white paper.

Again, I thank you Chairman Sanders, Ranking Member Dr. Cassidy, and Members of this committee for advancing S. 1855 – bipartisan legislation led by Senators Susan Collins and Jeanne Shaheen to renew the SDP and SDPI. I urge Congress to move swiftly and enact the 2-year, \$170 million per year reauthorization for both programs so we can keep this exciting and life-changing momentum going.

Insulin Affordability – Also a Critical Need

While the focus of my remarks is on the SDP and SDPI, it is important to note that people with diabetes need access to affordable insulin until we have cures. I appreciate the committee's interest in addressing this issue, as we all know the current drug pricing system does not work for countless people who need insulin to survive. Progress has been made but we need to take the next step. JDRF urges Congress to pass the bipartisan INSULIN Act of 2023, led by Senators Susan Collins and Jeanne Shaheen, which establishes a \$35 per month insulin copay cap for people with commercial insurance and includes other provisions that would make insulin more affordable for everyone, regardless of insurance status.

Thank you again for the opportunity to testify. I look forward to answering your questions.