



Testimony by

Aaron J. Kowalski, Ph.D.

President & CEO, JDRF

Before the

U.S. House of Representatives

Committee on Energy & Commerce, Subcommittee on Health

Hearing on “Investing in America’s Health”

June 4, 2019

For media inquiries contact:

C.J. Volpe, JDRF

cvolpe@jdrf.org

212-401-2136

Chairman Pallone, Ranking Member Walden, Chairwoman Eshoo, Ranking Member Burgess, and Members of the Subcommittee, thank you for giving me the opportunity to testify before you today.

In 1977, my younger brother Stephen was diagnosed with type 1 diabetes (T1D). It was a bolt out of the blue. I was diagnosed with type 1 diabetes in 1984, when I was 13 years old. Because of that, I went on to get my doctorate in microbiology and molecular genetics, and then I focused my career on the fight to cure this terrible disease and to help people with diabetes stay healthy until that day.

I have worked at JDRF – the world’s largest charitable funder of type 1 diabetes research – for 15 years, and just 8 weeks ago, I became its President & CEO.

I have traveled the country talking with many thousands of people affected by diabetes. And I am here today with a simple message from our community: the Special Diabetes Program is making a tremendous difference in our lives and in our hopes for the future. We need you to continue to give it robust support.

We are grateful for the leadership of this committee on both sides of the aisle over the years and the strong bipartisan support in Congress for the Special Diabetes Program or SDP. By supporting the SDP, you have been the catalyst that has fundamentally changed diabetes management, diabetes care, and have brought us ever closer to cures.

What you are funding are not simply science experiments. What you are funding is research that has led – and is leading – to significant advances. I can’t even begin to describe this transformation in how we manage diabetes in just the past 10 years. After pricking my fingers to draw blood an estimated 51,000 times over the last 35 years, continuous glucose monitoring (CGM) technology – the initial development of which was supported by the SDP – has allowed me to go without a single poke for over five months now. Vision loss used to be a given in T1D; today multiple therapies are available to help preserve sight. These advances would have been unthinkable to me in 1984, 1994, or even 2004.

Continued funding of the SDP, also known as the Special Statutory Funding Program for Type 1 Diabetes Research, will keep this research and this transformation going. It will relieve the daily burden for people with T1D, reduce serious complications of the disease, and bring us steps closer to a world without this disease.

In addition, lives are being transformed by the Special Diabetes Program for Indians or SDPI program which funds prevention and treatment programs for those in American Indian and Alaska Native communities that are disproportionately impacted by type 2 diabetes. The clinical results have been impressive, with the significant reductions in the incidence of kidney disease and other complications.

Today, I will discuss the progress that is a result of both programs, and then look forward to answering any questions you may have.

Type 1 diabetes or 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. T1D lasts a lifetime and people with T1D must take insulin to live. Type 2 diabetes, also known as T2D, is a metabolic disease. With T2D, the body still produces insulin but cannot use it effectively. While T1D and T2D are different, the resulting complications are the same. Overall, diabetes imposes a tremendous burden on individuals who have it as well as society at large.

Approximately 30 million Americans have T1D or T2D, and that number is expected to rise in years to come. According to a study in *Diabetes Care*, diabetes cost the US economy \$327 billion in 2017 alone. Since there are so many complications that come with diabetes, about a third of the Medicare budget is spent on people with diabetes.

To address the burden of diabetes, the Special Diabetes Program was created as part of a bipartisan budget deal, and has been supported by both chambers of Congress and both parties ever since. And thanks to the funding successive Congresses have provided, we have seen major progress in T1D research that has directly led to improvements in the health and quality of life of people with diabetes. Allow me to share some of the highlights.

Kidney disease is a potentially life-threatening complication of T1D, and end-stage renal disease creates a tremendous economic burden, costing Medicare \$34 billion in 2015. If new therapies could lower end-stage renal disease rates by 50 percent, Medicare would save more than \$51.6 billion in 10 years. A promising SDP-funded trial is testing whether allopurinol, a generic medication used to treat gout, may halt or slow the progression of early kidney disease in people with T1D. In this case, SDP is filling a critical gap as commercial pharmaceutical companies have no incentive to invest in testing new uses for this generic drug.

Diabetic retinopathy, which can lead to blindness, is one of the most devastating complications of diabetes. As a result of SDP research, the FDA has approved multiple drugs that preserve and even improve vision in people who have diabetic eye disease. These advances make the difference between being able to see well enough to drive or hold a job – or not. The SDP also filled a critical research gap by funding a comparison of three drugs for the treatment of diabetic eye disease. The results, released in 2015, help patients, clinicians, insurers and policymakers make better informed decisions about targeted treatment. This comparison likely would not have happened in the private sector. With continued funding researchers could conduct trials using a generic drug to see if it also prevents or halts the progression of retinopathy.

We know that one of the best ways to prevent these complications from diabetes is to make it easier to better manage diabetes. Over the years, the SDP has funded some of the most consequential leaps forward in diabetes management, giving people with T1D access to multiple new tools to enable better glucose control. These multiple options, which are essential as what may work for one person may not be the best for another, include the first FDA-approved CGM not needing finger-stick calibration, the first FDA-approved fully implantable CGM, and the first FDA-approved iCGM system that can be used as part of a system with other compatible medical devices and electronic interfaces. And perhaps the largest leap forward – the first FDA-approved

artificial pancreas (AP) system – also came on the market several years earlier than expected thanks to innovative research supported by the SDP. This not only will transform lives: according to one study, Medicare could save \$1 billion over 25 years with the use of AP systems in adults.

And this is just the start.

The SDP is supporting research that will lead to other next-generation systems being available in the future. This includes advanced clinical trials to test AP technology with greater automation, larger groups, wider age ranges, longer time periods and with understudied populations.

To make progress towards curing T1D, we need to understand why the immune system goes awry, and how we can eliminate these immune attacks. This has implications across numerous diseases, from multiple sclerosis and rheumatoid arthritis to cancer. We also need to understand how to protect and regenerate insulin-producing beta cells that have been damaged.

The SDP is funding innovative, multi-disciplinary scientific consortia and path-breaking research utilizing big data analytics and other new research methods.

For instance, The Environmental Determinants of Diabetes in the Young – or TEDDY program – has screened more than 425,000 children and enrolled 8,600 children determined to be at-risk of developing T1D to understand what environmental factor or factors trigger T1D onset. The study is more than halfway to completion and information on diet, infections, and other exposures is being analyzed from children who are progressing or now have full T1D onset. By identifying triggers, strategies could be developed to prevent onset altogether. The data collected from this study could also benefit other autoimmune diseases, such as celiac disease.

Another example is TrialNet – the International Consortium for Clinical Trials to Delay or Prevent T1D Progression – in which SDP-funded researchers have screened more than 200,000 relatives of people with T1D and continue to screen more than 15,000 people annually to identify the early stages of T1D before any symptoms appear. This, in turn, is allowing us to test novel approaches to prevent or slow the onset of T1D in those most at-risk to develop it.

Finally, the Human Islet Research Network is working to help us better understand how beta cells, the cells in the body that produce insulin, are lost in T1D and find strategies to protect or replace them in people, which is an important step toward curing the disease.

While SDP research funding moves us closer to cures and improves the quality of care for those with T1D, the SDPI program that is funded by the Indian Health Service has played a critical role in tackling T2D among American Indians and Alaska Natives, a population that is disproportionately suffering from the disease.

In fact, between 1994 and 2002, the prevalence of T2D grew from 11.5 percent to 15.3 percent of the adult American Indian and Alaska Native population, and these communities have a

diabetes prevalence rate approximately two times the national average. Moreover, American Indians and Alaska Natives are 1.8 times more likely to die from diabetes than the general US population.

Thanks to the SDPI, which funds evidence-based diabetes treatment and prevention programs that help over 700,000 people in 35 states, there have been marked improvements in average blood sugar levels and reductions in the incidence of cardiovascular, eye, and kidney disease.

In fact, there have been no further increases in the prevalence of type 2 diabetes in these populations since 2011. The average A1c level, the standard means of measuring glucose control, decreased from 9.0 percent in 1996 to 8.1 percent in 2014, resulting in reduced risk of eye, kidney, and other complications. From 1996 to 2013, there was a 54 percent decrease in the incidence of diabetes related end-stage renal disease in American Indian and Alaska Native adults, which saved thousands of people from a very debilitating complication and HHS estimates generated approximately \$500 million of Medicare savings over a 10-year period.

As you can see, the SDP and SDPI programs are making a real difference in the lives of people with type 1 and type 2 diabetes.

That is why JDRF strongly supports House bills 2668 and 2680 introduced by Representatives DeGette, Reed, O'Halleran, and Mullin that will raise the amount of funding to \$200 million a year for SDP and SDPI, and fund them for five years.

All of us at JDRF are grateful that 378 Representatives, including nearly all of the Members on this subcommittee and the full Committee, signed a letter to leadership led by Representatives DeGette and Reed that recognizes the important contributions of the programs and calls for the programs' renewal. We look forward to working with this broad group to get these bills passed, and to continue to advance T1D research.

Thank you, and I'd be happy to take any questions.