

The Special Diabetes Program

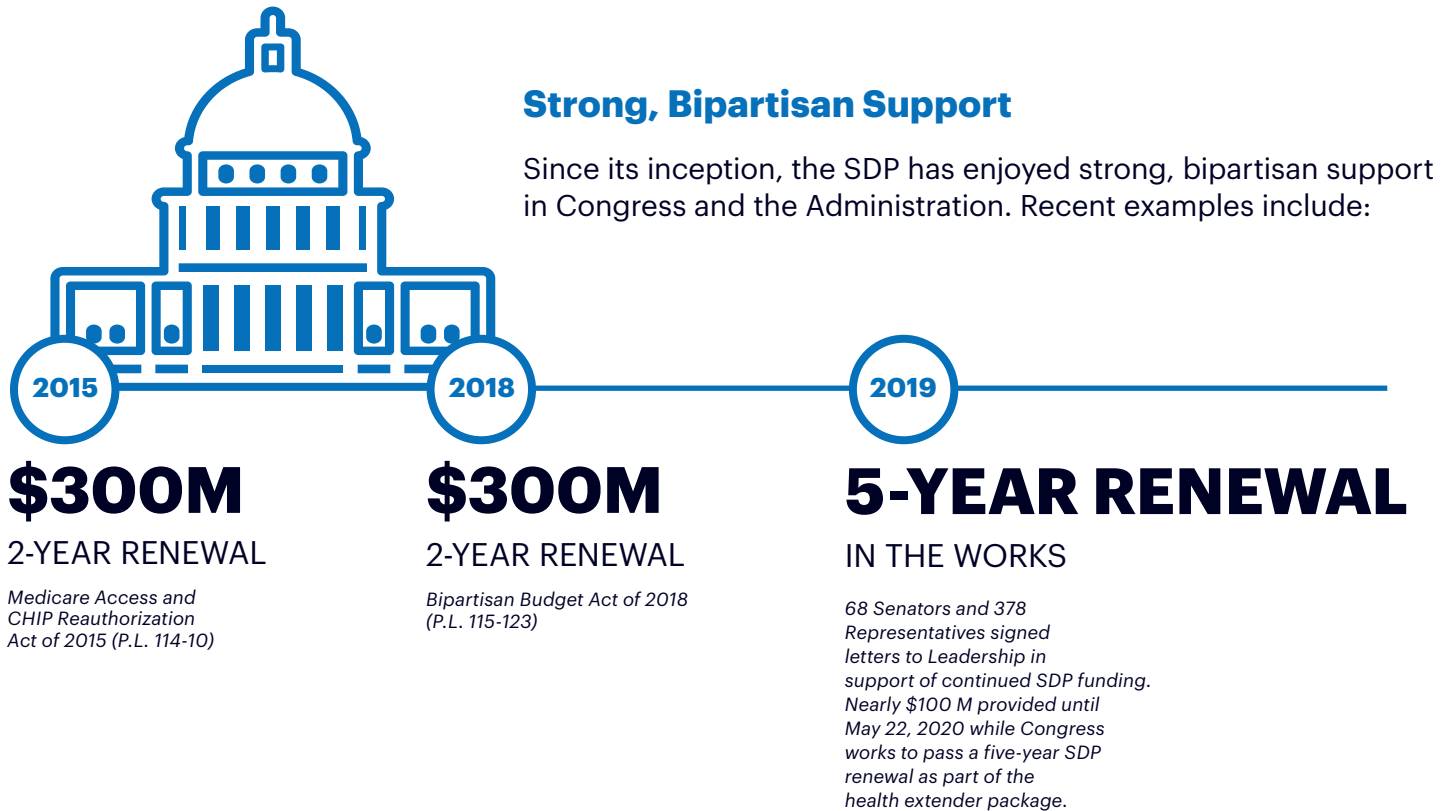
Accelerating Life-Changing Breakthroughs Together



Joshua

Joshua was diagnosed with Type 1 Diabetes (T1D) when he was just 11 months old. He loves to play all positions in lacrosse, but has a heart for goalie. He is very active in Boy Scouts and is an honor roll student. He has participated in several clinical trials over the years. When he grows up he wants work on creating the coding for new diabetes technology.

Thanks to the Special Diabetes Program (SDP), groundbreaking research has improved lives for Americans living with diabetes and brought us many steps closer to a world without type 1 diabetes.



The Special Diabetes Program

Congress created the SDP to address the growing burden of diabetes on people living with the disease and our nation's economy. The program comprises two initiatives—one to advance T1D research at the National Institutes of Health (NIH) and one to fund treatment, education and prevention programs for American Indian and Alaska Native populations, which are disproportionately affected by type 2 diabetes (T2D). Congress renews these programs together, currently at \$150 million each per year.

The JDRF community is grateful for the tradition of broad, bipartisan support in Congress for the SDP. We ask Congress to provide a five-year renewal of the SDP by May 22, 2020 so researchers can build upon past successes, allocate funding most effectively, and continue promising trials that could lead to better treatments, prevention strategies and ultimately cures for T1D.



Nilia is 14 and in 9th grade. She enjoys hanging out with friends and being on her phone. As a newborn, she participated in a screening as part of an SDP-funded trial which revealed she is at risk for developing T1D. She is still participating in this trial—which is investigating whether diet, illnesses, or other exposures during childhood are environmental triggers of T1D onset. This critically important research has the potential to prevent T1D onset altogether.

SDP-Supported Breakthroughs and Opportunities

Artificial Pancreas

The SDP accelerated the development of lifesaving artificial pancreas (AP) systems, which help people with T1D to achieve tighter blood-glucose control while needing to think less about their diabetes. Tighter control lessens the risk of long-term complications like diabetic eye disease, kidney failure, heart disease and amputations, as well as the constant threat of low blood-glucose emergencies.

Two systems are on the market today and the SDP is supporting research that will lead to other next-generation systems being available in the future.

Why is government support of AP systems important? A recent study estimates that glucose-lowering strategies, such as the use of AP systems, in working-age adults who have T1D will result in \$1.1-\$2.2 billion in savings to Medicare over 10 years.

Heart Disease

While people with diabetes are living much longer, they face a two- to threefold increase in heart disease compared to people without diabetes. A recent meta-analysis of studies unrelated to the SDP has shown that drugs known as sodium-glucose cotransporter 2 (SGLT2) inhibitors have high cardiovascular protective effects in people with T2D and significantly reduced the risks of major adverse cardiac events. Since T1D and T2D are different diseases and people with T1D tend to be diagnosed at an earlier age, there is a critical need to conduct large-scale studies with SDP funding to determine if SGLT2 inhibitors have a similar effect for those with T1D.

Diabetic Kidney Disease

Kidney disease is a potentially life-threatening complication of T1D and type 2 diabetes, and end-stage renal disease (ESRD) creates a tremendous economic burden, costing Medicare \$34 billion in 2015. If new therapies could lower ESRD rates by 50 percent, Medicare would save more than \$51.6 billion in 10 years and nearly \$136 billion in 25 years, per a recent study.

A recent study using a generic drug thought to slow or halt the progression of early kidney disease in people with T1D did not meet its endpoint. However, the samples collected and continued following of the group will enable researchers to assess the possibility of delayed effects of the drug and gather more data on the risk factors and development of diabetic kidney disease over time.

Diabetic Retinopathy

As a result of SDP research, the FDA approved a drug that preserves and even improves vision in people who have diabetic eye disease. This advance makes the difference between being able to see well enough to drive or work—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 help patients, clinicians, and insurers 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.



Vinnie has lived with T1D for more than 35 years. Despite the constant ups and downs that come with the disease, he remains optimistic. Vinnie enrolled in the Preventing Early Renal Loss in Diabetes (PERL) clinical trial, which tested a new way to reduce the loss of kidney function in people with T1D using a generic drug. This SDP-funded study may provide insights on the risk factors and development of diabetic kidney disease over time and bring scientists one step closer to preventing one of the leading complications of diabetes.

If new therapies could lower ESRD rates by 50%, Medicare would save more than \$51.6 billion in 10 years and nearly \$136 billion in 25 years.

Environmental Triggers

Researchers are more than midway through a 15-year study, with more than 8,000 at-risk children enrolled at birth, to determine what environmental factors influence T1D onset. Information on diet, infections and other exposures is being analyzed to increase our understanding of the cause of T1D, as well as other autoimmune diseases.

Results to date indicate that there are multiple pathways leading to T1D onset and that breastfeeding is the most important factor in determining how the gut microbiome, which may affect the immune system, develops in the first years of life. Ongoing measurements of further exposures, gene variants and other studies are needed so that strategies can be developed to prevent T1D onset, ranging from a vaccine to specific dietary changes.

Immune Therapies

For the first time every, an immune therapy treatment was able to delay for more than two years the onset of T1D in those with a high risk of developing the disease. The therapy is now in a phase III clinical trial, being tested in people recently diagnosed with T1D.

Because current immune therapy drugs can have side effects, further research will help find and develop drugs with more selective action, as well as drug combinations, to prolong a newly diagnosed person's ability to produce insulin and ultimately halt the autoimmune attack permanently.

Beta Cell Replacement

Transplanting insulin-producing beta cells from cadaveric donors into a person with T1D has proven to be successful, and can normalize blood glucose for years. This therapy would provide a functional cure but it relies on the limited amount of donor islets and recipients must take powerful immunosuppressant drugs.

There have been remarkable advances in generating an unlimited source of insulin producing cells, and strategies to protect them after transplantation without the need for broad immune suppression; but there is a critical need for further research and clinical trials that will one day deliver life-changing therapies that place healthy insulin producing cells back into the bodies of people with T1D.

Type 1 diabetes (T1D) is an autoimmune disease in which a person's pancreas stops producing insulin, a hormone people need to get energy from food.

The Burden of Diabetes

Type 1 diabetes (T1D) strikes suddenly both children and adults at any age. Its onset has nothing to do with diet or lifestyle. Though T1D's causes are not yet entirely understood, scientists believe that both genetic factors and environmental triggers play a role. There is currently nothing you can do to prevent it and there are no cures.

Type 2 diabetes (T2D) is not an autoimmune disease. With T2D, the body still produces insulin but cannot use it effectively. While T1D and T2D are different, the resulting costly and burdensome complications are the same.

\$327B



Annual cost of diabetes to the U.S. economy in 2017

34.3M



Number of Americans with diabetes

32%



Percent of Medicare budget spent on people with diabetes

30%



Staggering increase in the prevalence of T1D diagnoses in the U.S. in just two years (2017-2019), with youth cases growing most sharply among minority groups

3x



Health costs of diabetes predicted to nearly triple in the next 25 years

#1



Diabetes is the leading cause of kidney disease, blindness in working-age adults and amputations unrelated to accidents

Together, we can and must do better.

People with diabetes are living longer, healthier lives with fewer complications because of scientific advances, including innovative research supported by the SDP. Continued funding of the SDP will keep this research going, improve these sobering statistics, relieve the daily burden for people with T1D and reduce the economic toll of diabetes to the healthcare system and the U.S. government.



JDRF—A Partner with the Federal Government

JDR is the leading global organization funding T1D research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications. To accomplish this, JDRF has invested more than \$2.5 billion in research funding since our founding in 1970. Our work complements Federal diabetes research and together, our collaboration constitutes one of the world's most effective public-private partnerships focused on curing a disease.

We've accomplished so much but significant further research is required to cure, prevent and treat T1D and its complications.

A five-year renewal of the SDP will make a world of difference. Thank you for your support.



Alecia has been living with T1D for 40 years. Because of the Special Diabetes Program, living with T1D just became a whole lot easier.

Alecia participated in a 9-month clinical trial for an automated closed-loop artificial pancreas at Mt. Sinai Hospital in New York City. This trial, funded by the SDP, is giving her better control of her diabetes than she has had at any point in her life. It minimizes low blood sugars and corrects high blood sugars, giving her peace of mind that is allowing her to sleep through the night—something she hasn't done regularly in decades.

Alecia is looking forward to the day when others can have access to this incredible technology.

Please join us in supporting the renewal of the SDP.