The Special Diabetes Program

ACCELERATING LIFE-CHANGING BREAKTHROUGHS TOGETHER

Brynn

Brynn was diagnosed with type 1 diabetes (T1D) when she was two years old. She loves cheerleading and eagerly looks forward to starting kindergarten soon. Most of all, she is looking forward to a world without 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

T1D strikes both children and adults at any age and suddenly. 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 is no cure.

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.

- **$322B**: Annual cost of diabetes to the U.S. economy in 2012
- **32%**: Percent of Medicare budget spent on people with diabetes
- **21%**: Increase in the prevalence of T1D in people under age 20 between 2001 and 2009
- **3x**: Health costs of diabetes predicted to nearly triple in the next 25 years
- **29M**: Number of Americans with diabetes; predicted to nearly double in the next 25 years
- **#1**: Diabetes is the leading cause of kidney disease, blindness in working-age adults and amputations unrelated to accidents

These numbers are unacceptable. 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 and relieve both the daily burden for people with T1D as well as the economic toll of diabetes-related costs to the healthcare system and the U.S. government.
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.

**Strong, Bipartisan Support**

Since its inception, the SDP has enjoyed strong, bipartisan support in Congress and the Administration. Recent examples include:

- **2010**
  - $150M (2-YEAR RENEWAL)
  - (S. 3058 & H.R. 3668) Medicare and Medicaid Extenders Act of 2010 (Public Law 111-309)

- **2012**
  - $150M (1-YEAR RENEWAL)
  - 72 Senators and 272 Representatives signed SDP letters.
  - American Taxpayer Relief Act of 2012 (P.L.112-240)

- **2013**
  - $150M (1-YEAR RENEWAL)
  - 76 Senators and 339 Representatives signed SDP support letters.
  - Protecting Access to Medicare Act of 2014 (P.L. 113-93)

- **2015**
  - $300M (2-YEAR RENEWAL)
  - Medicare Access and CHIP Reauthorization Act of 2015 (P.L. 114-10)

**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. Congress renews these programs together, currently at $150 million per year each.

The SDP has led to significant scientific breakthroughs like new treatments that have improved vision among people with diabetic eye disease (the leading cause of blindness in the United States) and artificial pancreas (AP) technology that will automate blood glucose management.

Renewing the SDP will allow researchers to build on past successes and continue to conduct promising trials that will lead to better treatments, prevention and a cure for T1D. The SDP is set to expire September 2017; however, Congress has a history of renewing the program well in advance of the expiration date to ensure that large-scale clinical trials can continue without interruption and research dollars are allocated most effectively.
ARTIFICIAL PANCREAS
In clinical trials, patients with T1D achieved tighter blood glucose control by using AP systems that limit time spent outside healthy blood glucose range, while needing to think less about their diabetes. This lessens 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.

The FDA has approved a system that shuts off insulin when glucose is low, and outpatient studies are testing more automated systems that deliver insulin when glucose is high. The next generation of an AP system is expected on the U.S. market in 2017.

Why is government support of AP systems so crucial? A recent study estimates use of AP technologies in working-age adults who have T1D will result in nearly $1 billion in savings to Medicare over 25 years.

GLUCOSE CONTROL
NIH-supported researchers developed an experimental form of insulin designed to work only when blood glucose levels start to rise, providing the right amount of insulin at the right time with minimal involvement by the person with diabetes. The product is in commercial development.

Further research is needed in alternate approaches to help increase the likelihood of success.

SDP-Supported Breakthroughs and Opportunities

ARTIFICIAL PANCREAS

DIABETIC KIDNEY DISEASE
Kidney disease is a potentially life-threatening complication of T1D, and end-stage renal disease (ESRD) creates a large economic burden, costing Medicare $29 billion in 2009. If new therapies could lower ESRD rates by 50 percent, Medicare would save more than $14 billion in 10 years and nearly $126 billion in 25 years.

No new drugs have been developed for diabetic kidney disease in two decades, but a current trial is testing whether a generic medication used to treat gout may halt or slow the progression of early kidney disease in people with T1D. With this study, the SDP fills a critical gap since commercial companies have no incentive to invest in testing new uses for a generic drug.

DIABETIC RETINOPATHY
The FDA approved a drug in 2012 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 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 early 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.

Nilia is an active 10 year old who loves karate, dancing, and singing at the top of her lungs. As a newborn, she participated in a screening as part of an SDP-funded trial which revealed she is at risk for developing T1D. Ten years later, 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.
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. The NIH has begun to analyze the information on diet, infections and other exposures which will make a major contribution to understanding the cause of T1D, as well as other autoimmune diseases.

Strategies could be developed to prevent T1D onset, ranging from a vaccine to specific dietary changes. For example, data has indicated that use of probiotics in early childhood may reduce the risk of T1D, while cow’s milk-based formula, thought to potentially increase risk, seems to have no effect.

Immune therapy drugs have been shown to slow the immune attack for approximately one year or more in patients newly diagnosed with T1D. Patients required less insulin and had improved blood glucose control for a period of time.

Because current immune therapy drugs can have side effects, further research will help find and develop drugs with more selective action to prolong a newly diagnosed person’s ability to produce insulin and ultimately halt the autoimmune attack permanently to prevent T1D.

If new therapies could lower ESRD rates by 50%, Medicare would save more than $14 billion in 10 years and nearly $126 billion in 25 years.

Insulin-producing islet cells transplanted from cadaveric donor pancreases into patients with difficult to control T1D significantly reduced both loss of consciousness from hypoglycemia and dependence on injected insulin for over five years.

Further research on developing other sources of islets, encapsulating islet cells to protect against the immune attack and need for immunosuppressant drugs, and transforming a patient’s own cells into insulin-producing beta cells could lead to better glucose control without the need for injected insulin for longer periods of time.
**JDRF Can’t Do It Alone**

JDRF research and advocacy efforts seek to do the greatest good for the largest number of people in the shortest period of time. We know we can only do so with continued partnership with the Federal government. The combination of Federal diabetes research funding and JDRF’s private investment 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. Thank you for your support.

Please join us in supporting the renewal of the SDP.

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**Melissa**

Melissa Kampmann can’t remember what life was like before her type 1 diabetes diagnosis at 11 years old. However, during a weeklong clinical trial of an automated closed-loop artificial pancreas (AP) system at the University of Virginia in January 2014, she got a glimpse of what it might be to not have life revolve around managing T1D.

In her trial, Melissa relied on the AP system to get her safely through the night. An algorithm processed data from a CGM and automatically instructed a pump to deliver precisely calibrated insulin doses—resulting in a safe blood glucose level throughout the trial. Melissa hopes one day this AP system will be available for her and her young daughter who also has T1D.