

Congress of the United States

Washington D.C. 20515

Month XX, 2023

The Honorable Kevin McCarthy
Speaker of the House
U.S House of Representatives
Washington, D.C. 20515

The Honorable Hakeem Jeffries
Democratic Leader
U.S. House of Representatives
Washington, D.C. 20515

Dear Speaker McCarthy and Democratic Leader Jeffries:

Thank you for your long-standing support of the Special Diabetes Program (SDP), an essential resource in our nation's investment in diabetes research, treatment, education, and prevention programs. We write today to ask for your continued commitment to this program by ensuring its reauthorization prior to its expiration this September.

Diabetes is our country's most expensive chronic disease in both human and economic terms, affecting people of all ages, races, and in every region of our country.¹ It is a leading cause of heart disease and stroke.² Additionally, it is the number one cause of kidney disease, blindness in working-age adults, and lower-limb amputations.^{1,3,4} Approximately one in four healthcare dollars and one in three Medicare dollars are spent treating people with diabetes.^{1,5} The total cost of diagnosed diabetes in the United States in 2017 was \$327 billion, with \$237 billion spent on direct medical costs and another \$90 billion on reduced productivity.¹ Medical expenditures for individuals diagnosed with diabetes are roughly 2.3 times higher than expenditures for those without the disease.²

Overall, the economic costs of diabetes, adjusted for inflation, increased by 26 percent from 2012 to 2017, and these costs are expected to increase as the number of people with diabetes continues to grow.² According to the Centers for Disease Control and Prevention's National Diabetes Statistics Report, an estimated 1.4 million new cases of diabetes (5.9 per 1,000 persons) were diagnosed among U.S. adults in 2019.⁶

While the increase in these statistics is very concerning, the Special Diabetes Program is making meaningful progress. The Special Diabetes Program is comprised of two partner components: the Special Statutory Funding Program for Type 1 Diabetes Research (SDP) and the Special Diabetes Program for Indians (SDPI). Since the program's inception, it has delivered meaningful and impactful resources and research breakthroughs for the 37 million Americans with diabetes and 96 million with prediabetes, as well as their loved ones who are impacted by the

¹ American Diabetes Association. "Economic Costs of Diabetes in the U.S. in 2017." *Diabetes Care* 41, no. 5 (May 2018): 917-28. doi: <https://doi.org/10.2337/dci18-0007>.

² "Putting the Brakes on Diabetes Complications." Centers for Disease Control and Prevention. November 3, 2022. <https://www.cdc.gov/diabetes/library/features/prevent-complications.html>.

³ Li, Y., N. R. Burrows, E. W. Gregg, A. Albright, and L. S. Geiss. "Declining Rates of Hospitalization for Nontraumatic Lower-Extremity Amputation in the Diabetic Population Aged 40 Years or Older: U.S., 1988-2008." *Diabetes Care* 35, no. 2 (February 2012): 273-77. doi:10.2337/dc11-1360.

⁴ "Common Eye Disorders and Diseases." Centers for Disease Control and Prevention. June 3, 2020. <https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/diabetic-retinopathy>.

⁵ Gold, Marsha, Sc.D., Ronette Briefel, Dr.P.H., R.D., and The MPR Study Team. *Study of Federal Spending on Diabetes: An Opportunity for Change*. Report. Mathematica Policy Research, 2007.

disease.⁶ It is essential that we continue to invest in the research necessary to develop a cure for diabetes, as well as support the programs that help prevent and treat the disease and its complications.

The SDP funds research that leads directly to the development of new insights and therapies that improve the lives of those with diabetes, and accelerating progress towards curing and preventing the disease. Likewise, the SDPI has a significant and positive impact on the health of American Indians and Alaska Natives (AI/AN), who are disproportionately affected by type 2 diabetes (T2D).⁶ The SDPI is making it possible to develop and sustain quality diabetes treatment and prevention programs in AI/AN communities where they are most needed, and for the first time, diabetes prevalence in AI/AN adults decreased, dropping from 15.4% in 2013 to 14.6% in 2017.⁷

Some notable developments from the SDP and SDPI include:

- **Type 1 Diabetes (T1D) Prevention:** Landmark research conducted by SDP-funded TrialNet demonstrated for the first time ever that early preventative treatment with a drug targeting the immune system delayed onset of clinical T1D for two years.^{8,9} This drug was recently approved by the FDA and is the first ever disease modifying therapy for T1D. Further, a truly groundbreaking 15-year study of 8,600 children is currently ongoing to determine what environmental factors influence the onset of T1D. Researchers believe that, by identifying specific triggering factors, new strategies can be developed to prevent the initial onset of the disease.
- **Diabetes Prevention in the AI/AN Community:** Communities with SDPI-funded programs have seen substantial growth in diabetes prevention resources, including more than doubling the number of on-site nutrition services, physical activity and weight management specialists for adults, and an exponential increase of sites with physical activity services for youth. For the first time, from 2013 to 2017 diabetes incidence in AI/ANs decreased each year.⁷ In short, SDPI has been one of the most successful programs ever created to reduce the incidence of and complications from T2D.
- **Artificial Pancreas (AP) Systems:** SDP-funded research laid early groundwork for developing AP systems, which are proven to reduce costly and burdensome T1D complications and improve the quality of life for those with the disease.¹⁰ SDP funds led to the first fully automated insulin-dosing system being made available to patients in

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

⁷ "Special Diabetes Program for Indians 2020 Report to Congress. Changing the Course of Diabetes: Charting Remarkable Progress." IHS Division of Diabetes Treatment and Prevention. 2020.

⁸ Sims EK, Bundy BN, Stier K, Serti E, Lim N, Long SA, Geyer SM, Moran A, Greenbaum CJ, Evans-Molina C, Herold KC; Type 1 Diabetes TrialNet Study Group. Teplizumab improves and stabilizes beta cell function in antibody-positive high-risk individuals. *Sci Transl Med.* 2021 Mar 3;13(583): eabc8980. doi: 10.1126/scitranslmed.abc8980. PMID: 33658358; PMCID: PMC8610022.

⁹ Herold KC, Bundy BN, Long SA, Bluestone JA, DiMeglio LA, Dufort MJ, Gitelman SE, Gottlieb PA, Krischer JP, Linsley PS, Marks JB, Moore W, Moran A, Rodriguez H, Russell WE, Schatz D, Skyler JS, Tsalikian E, Wherrett DK, Ziegler AG, Greenbaum CJ; Type 1 Diabetes TrialNet Study Group. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes. *N Engl J Med.* 2019 Aug 15;381(7):603-613. doi: 10.1056/NEJMoa1902226. Epub 2019 Jun 9. Erratum in: *N Engl J Med.* 2020 Feb 6;382(6):586. PMID: 31180194; PMCID: PMC6776880.

¹⁰ U.S. Department of Health and Human Services. National Institutes of Health. *Special Statutory Funding Program for Type 1 Diabetes Research: Progress Report.* Bethesda, MD: National Institute of Diabetes and Digestive and Kidney Diseases, 2016.

2017, some 5-7 years earlier than expected. Positive results from clinical trials since then have led to another FDA-approved AP system and next-generation AP devices that have outperformed first-generation devices in adolescents and young adults.¹¹ According to one study, the use of AP systems in adults could save Medicare roughly \$1 billion over 25 years.¹²

- **Kidney Disease**: Researchers have discovered that 6.5 years of intensive blood glucose control can cut in half the onset of impaired kidney function in people with T1D.¹³ This reduction in end-stage renal disease could save Medicare roughly \$126 billion over 25 years. Also remarkable, between 1996 and 2013, incidence rates of end-stage renal disease (ESRD) in AI/AN individuals with diabetes declined by 54 percent.¹⁴ This reduction alone already saved an estimated \$520 million between 2006-2015.¹⁵
- **Eye Therapies**: SDP-funded research discovered that combining a drug with laser therapy can reverse vision loss in people living with diabetes.¹⁰ The SDP also filled a critical research gap by funding a head-to-head comparison of three drugs for the treatment of diabetic eye disease. The results are helping patients, clinicians, and insurers identify the right therapy and course of treatment for each individual person.¹⁰ Since the creation of this program, diabetic eye disease rates have decreased by more than 50% for AI/ANs, resulting in a reduction of vision loss and blindness among AI/AN patients.⁷ Furthermore, if all patients with T2D receive the recommended screenings and treatment for eye disease, it would lead to an estimated annual savings of \$472.1 million for the federal budget, and 94,304 person-years of sight. Each additional person enrolled in screenings generates an estimated cost savings of \$975, even when the federal government is responsible for all associated costs.¹⁶
- **Glucose Control**: The average blood sugar level, as measured by the hemoglobin A1C test, decreased from 9.0 percent in 1996 to 8.1 percent in 2014 in the AI/AN population. Every percentage point drop in A1C results can reduce the risk of eye, kidney, and nerve complications by up to 40 percent.¹⁷

¹¹ Bergenstal RM, Nimri R, Beck RW, et al. A comparison of two hybrid closed-loop systems in adolescents and young adults with type 1 diabetes (FLAIR): a multicentre, randomised, crossover trial. *Lancet*. 2021;397(10270):208-219. doi:10.1016/S0140-6736(20)32514-9.

¹² O'Grady, Michael J., Priya John, and Aaron Winn. "Substantial Medicare Savings May Result If Insurers Cover 'Artificial Pancreas' Sooner for Diabetes Patients." *Health Affairs* 31, no. 8 (2012): 1822-829. doi:10.1377/hlthaff.2011.1052.

¹³ The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin dependent diabetes mellitus. *The New England Journal of Medicine*. 1993;329(14):977-986. doi:10.1056/NEJM199309303291401.

¹⁴ Bullock A, Burrows NR, Narva AS, et al. Vital Signs: Decrease in Incidence of Diabetes-Related End-Stage Renal Disease among American Indians/Alaska Natives — United States, 1996–2013. *MMWR Morb Mortal Wkly Rep* 2017; 66:26-32. DOI: <http://dx.doi.org/10.15585/mmwr.mm6601e1>.

¹⁵ Department of Health and Human Services, Assistant Secretary for Planning and Evaluation. "The Special Diabetes Program for Indians: Estimates of Medicare Savings." May 2019.

¹⁶ Indian Health Service. Cost Basis- IHS Joslin Vision Network Teleophthalmology Program. <https://www.ihs.gov/teleophthalmology/costbasis/>.

¹⁷ Diabetes Control and Complications Trial Research Group. The absence of a glycemic threshold for the development of long-term complications. *Diabetes*. 1996; 45:1289-1298.

- Reductions in Hospitalizations: Hospitalizations for AI/AN due to uncontrolled diabetes dropped by 84 percent in 2015 – from 57.9 hospitalizations per 100,000 to 9.4 per 100,000 adults.⁷ It is expected that this contributed to significant savings in healthcare costs.

The Special Diabetes Program improves the lives of the over 133 million Americans living with or at-risk of developing diabetes, while also greatly reducing the long-term healthcare expenditures related to its complications. For these reasons, further investment in these vital programs is essential to continue outreach and education, plan next steps for research programs, and effectively allocate research resources – all of which play an important role in helping to better treat, prevent, and ultimately cure diabetes.

Thanks to your leadership, both components of the Special Diabetes Program continue to receive strong bipartisan support. We look forward to working together to ensure that the SDP and SDPI continue to function as critical components of the national strategy to address T1D research and diabetes in the AI/AN communities.

Sincerely,

Diana DeGette
Member of Congress

Gus Bilirakis
Member of Congress