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REDEFINING REALITY: HOW THE SPECIAL DIABETES PROGRAM IS CHANGING THE LIVES OF AMERICANS WITH TYPE 1 DIABETES

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C O N T E N T S

REDEFINING REALITY: HOW THE SPECIAL DIABETES PROGRAM IS CHANGING THE LIVES OF AMERICANS WITH TYPE 1 DIABETES

WEDNESDAY, JULY 10, 2019

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 9:33 a.m., in Room 106, Dirksen Senate Office Building, Hon. Susan M. Collins (Chairman of the Committee) presiding.

Present: Senators Collins, Tim Scott, McSally, Hawley, Braun, Rick Scott, Casey, Blumenthal, Jones, Sinema, and Rosen.

Also present: Senator Shaheen.

OPENING STATEMENT OF SENATOR SUSAN M. COLLINS, CHAIRMAN

The CHAIRMAN. The hearing will come to order.

Good morning, everybody. It is wonderful to welcome all of you here to Washington, DC. This is our 11th Children's Congress, and it is always a privilege to work with JDRF families, whose commitment to promoting life-changing research to prevent, treat, and ultimately cure Type 1 diabetes inspires me.

I want to welcome not only our Ranking Member, Senator Casey, and Senator Scott from Florida, but also we have a special guest, and that is the Co-Chair with me of the Senate Diabetes Caucus, Senator Jeanne Shaheen of New Hampshire, so thank you for joining us here today as well.

Let me shorten my opening comments this morning because we do have votes beginning at 11 o'clock, and I want to make sure that we have time to hear from all of our witnesses.

As I said, I want to begin by welcoming the more than 160 children who have traveled to Washington from all across the country to share your personal stories. You will tell us what it is like to live with Type 1 diabetes, just how serious it is, and why it is critical for Congress to fund the research necessary to discover better treatments, more effective technology, and, ultimately, a cure.

Your personal stories really matter. They motivate Senators and Members of the House to get involved in the cause. In my case, one of my very first meetings as a brand-new Senator was with Maine families with children with diabetes, and I will never forget this 10-year-old little boy looking up at me, and he told me that he wished he could take just 1 day off from having diabetes—his

birthday or Christmas, but of course, he could not, and that really touched me, and it led me to start the bipartisan Senate Diabetes Caucus.

I want to give a special welcome to two delegates from Maine: Ruby Anderson from Yarmouth, who is going to be testifying, and Lydia Bryant from Ellsworth. I am very proud that you are here representing our great State.

Since the last convening of the Children's Congress 2 years ago, we have made remarkable strides with new technological discoveries that are already changing the lives of people with Type 1 diabetes. We celebrated the FDA approval of an artificial pancreas system for children ages 14 and older. Now the artificial pancreas is also available for kids who are ages 7 to 13, opening the door for better day-to-day management of diabetes.

Today's research represents tomorrow's cure. Just last month, a new study, the first of its kind, illustrated the potential of an immunotherapy drug to delay the onset of Type 1 diabetes by an average of 2 years. What a significant breakthrough.

These advances have only been possible due to our bipartisan commitment to funding diabetes research. Since I founded the bipartisan Senate Diabetes Caucus in 1997, Federal funding for diabetes research has tripled, and these research dollars are yielding results. We now spend more than $1 billion on diabetes research.

The Special Diabetes Program, in particular, has contributed to phenomenal discoveries, especially advancements in technology. This program provides an additional $150 million each year for T1D research, and another aim of this program is equally important: The Special Diabetes Program also studies diabetes in American Indians and Alaskan Natives, who experience Type 2 diabetes at nearly three times the rate of the national average, so the Special Diabetes Program is important both for people who have Type 1 and also for Native Americans and Alaskan Natives.

Over the past 22 years, the Special Diabetes Program has contributed $2.8 billion to improve the lives of people living with diabetes.

By the end of September, we must pass legislation to reauthorize the Special Diabetes Program, and that is what you need to tell all the Members of Congress. It has strong bipartisan support; 68 Senators signed a letter to Senate leadership that Senator Jeanne Shaheen and I authored advocating for this program, and I am pleased to report to you that just last week the Senate HELP Committee, on which I serve, approved a 5-year authorization of the Special Diabetes Program. That is the longest authorization ever, so that is really good news.

Finally, let me just say that I am very concerned about the spiraling cost of insulin. The cost of managing diabetes is growing at an alarming rate. Between 2012 and 2016, average insulin spending for patients with Type 1 diabetes nearly doubled, and last year, a father from Maine testified that he turned to drug importation from Canada after the price of a 90-day supply of insulin for his son with Type 1 tripled to $900.

I am going to put the rest of my statement in the record so that we can expedite the hearing, but let me just end by telling you two things.

First, until last fall I had no personal connection at all with Type 1 diabetes. Then my nephew married a young woman who has Type 1 diabetes and has her own blog, so I feel like I am now officially a part of the JDRF family, and, second, it is truly inspiring to look out and see this wave of Carolina blue. I did the best I could to come close to matching it, but your passion and hope for a cure are contagious, and together I am confident that we will continue the progress and achieve that goal.

Thank you.

Senator Casey.

OPENING STATEMENT OF SENATOR ROBERT P. CASEY, JR., RANKING MEMBER

Senator CASEY. Thank you, Chairman Collins, for holding this hearing. We are grateful to be back again with so many delegates of the JDRF Children's Congress. I want to welcome you back to the Senate. I know many of you have been here over many years now.

I am pleased to welcome four delegates from Pennsylvania: Adriana, whom I will introduce a little bit later, as well as Joey, Libby, and Mairead and their families.

It is so important that you have joined us because finding a cure for Type 1 diabetes requires a combined effort from people of all ages and backgrounds. Advances in treatment and our understanding of Type 1 diabetes has come a long way.

As Chairman Collins mentioned, in just the past decade, more and more people have gained access to continuous glucose monitors and, more recently, the use of the artificial pancreas. In large part, this progress is due to those of you in this room—young and a little bit older than young.

We are grateful that you are here again to bring a sense of urgency to this issue. Many of the advocates who have traveled to Washington before to press for funding for this program are doing so again today, and we are grateful.

We are pleased to report, as Senator Collins said, the extension of the funding is already in the works, and I was proud as a member of the Health, Education, Labor, and Pensions Committee—so-called HELP Committee—to support the 5-year extension of the reauthorization of the Special Diabetes Program.

This sets up the possibility for the longest extension ever. We need to make sure that the full Senate passes it, as Senator Collins said, by the end of September and also that the House does the same.

By securing stable funding for medical research, that is just one part of the agenda. We must also be sure that each individual and family can afford lifesaving treatment.

During a hearing last year, this Committee took a magnifying glass to the rising cost of insulin, and just recently, the Committee concluded a three-part hearing series on the cost of prescription drugs.

It will not surprise anybody in this room that the cost of insulin featured prominently during those hearings as well. Let me summarize why there is such an urgency to address the price of prescription drugs as it applies to today's hearing.

Number one, the rising cost of prescription drugs is not occurring in isolation. It is part of a larger challenge that many Americans face every day trying to make ends meet.

"Flat wages and high costs" might be the fastest way to say it. For so many families, the cost of prescription drugs is like a bag of rocks thrown on their shoulders every day, in addition to the other bags of rocks they are carrying around: high health care costs, college tuition, child care costs, and the like.

We have lots of work to do to make sure that we are focused on and get results on lowering the cost of prescription drugs. We know that less costly insulin is about, oh, maybe only 100 years overdue.

As we will hear today, the price an individual or family must pay for a vial of insulin is also impacted by health insurance coverage. That is why the Affordable Care Act and Medicaid are critically important to shield families from very high and onerous out-of-pocket costs for insulin.

In Pennsylvania, because of Medicaid, insulin for most children is fully covered. That should be the case in every single State, and so today I am introducing the Affordable Health Care for Children with Disabilities Act, which will encourage States to adopt policies that Pennsylvania put in place over 20 years ago.

We have got a sacred responsibility to children and to young adults—and to their parents who are here today—as well as those across the country, to do everything in our power to make sure that we are doing everything we can to make life better.

Thank you to Chairman Collins and all of our delegates and parents and friends and advocates. We are so grateful you are with us today.

Thank you.

The CHAIRMAN. Thank you very much.

Our first witness today is a familiar face to our Committee, Dr. Griffin Rodgers, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, at the National Institutes of Health. Dr. Rodgers assumed his position in 2007, and he has testified before us I believe six times at six different Children's Congress hearings. It is always a great pleasure to hear from him and to get an update on the research that is being done.

Next we are pleased to welcome Dr. Aaron Kowalski. Dr. Kowalski is the new president and CEO of JDRF, and he is the first person with Type 1 diabetes to lead this organization. He has a strong research background, having served as the organization's chief mission officer.

Our next witness you may recognize from Broadway or his numerous roles on television and in major motion pictures such as "Titanic" or "Argo." He is the award-winning actor Victor Garber, and we are so pleased to have him with us today. He has received—I hope I have these statistics right—five Emmy nominations, four Tony Award nominations, and one Screen Actors Guild Award, and there is another that—maybe I got those statistics wrong, but he has received a lot, let us put it that way, because he is such an extraordinary actor, and he also has, which is most pertinent to this hearing, Type 1 diabetes, which he has managed for almost 60 years.

Then we will hear from my constituent, Ruby Anderson, who is joining us today from Yarmouth, Maine. Now, I have met Ruby several times, and it was really fun looking at the pictures of her when she was even much younger than the 9 years old that she is now, and she is a great advocate for better treatments and working toward a cure or means of prevention, so I am delighted to welcome you, Ruby, here today. It is great to have you.

I will now turn it over to the Ranking Member to introduce our final witness from his State.

Senator CASEY. I am pleased to introduce Adriana Richard. Adriana is 16 years old, a resident of Milton, Pennsylvania. She is joined here by her mom, Kristy. She traveled pretty far to get here. Northumberland County is not an easy ride, a couple hours at least, and we are grateful you are here.

Adriana has lived with Type 1 diabetes since she was 5 years old, and like delegates here today, she has not let the disease slow her down. Along with excelling at her school work, she educates her peers about Type 1 diabetes and also through Instagram created an online support group. She serves as a member of the JDRF Teen Task Force where she mentors newly diagnosed children. She has even published a book about living with Type 1 diabetes entitled, "The Real T1D."

Adriana, thanks for being here, and thanks for being a dedicated advocate with JDRF and for bringing your testimony here today and your example and helping us create a sense of urgency to get the job done here in the Senate. Thank you.

The CHAIRMAN. Thank you.

Dr. Rodgers, it is a pleasure to have you back.

STATEMENT OF GRIFFIN P. RODGERS, M.D., M.A.C.P., DIRECTOR, NATIONAL INSTITUTE OF DIABETES, DIGESTIVE AND KIDNEY DISEASES, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, BETHESDA, MARYLAND

Dr. RODGERS. Thank you. Chairman Collins, Senator Casey, members of the Committee, thanks for this invitation to testify and for your strong support of Type 1 diabetes research at the NIH, including the Special Diabetes Program, or SDP.

The SDP has enabled us to take on challenges and to conduct critical trials that were unlikely to have been done with our regular appropriation or by the private sector, and I am pleased to be testifying along with Dr. Kowalski, and I would especially like to recognize my other fellow witnesses—Ruby Anderson, Adriana Richard, and Victor Garber.

All of you here today and the people you represent across the country are the true heroes in advancing diabetes research. NIH research studies would not be possible without your participation, your passion, and your commitment.

In 2 years since I last testified, major scientific advances have come from the long-term, sustained investment in the SDP. Just last month, NIDDK Type 1 Diabetes TrialNet reported truly exciting results. For the first time ever, early preventive treatment was shown to delay clinical Type 1 diabetes.

Now, in this study, people at high risk for the disease were treated with a drug targeting the immune system and had a striking

2-year delay in the progression to clinical Type 1 diabetes. That is 2 years they did not have to take insulin. That is 2 years they did not have to check their blood glucose, 2 more years of good health toward preventing or delaying Type 1 diabetes complications.

It is important to note that this trial, which relied on screening thousands of people to identify those eligible to enroll, would not—I really should say could not have been conducted outside of TrialNet. Looking ahead, there is a queue of other promising agents to prevent Type 1 diabetes progression, and we plan to test those with TrialNet.

There is also good news for people who are working every day to manage their Type 1 diabetes. Since I last testified, several continuous glucose monitors, or CGMs, have been approved by the FDA, including the first CGM that does not require a fingerstick calibration, the first fully interoperable CGM, and the first fully implantable CGM. Each of these received NIDDK or SDP support during their development.

These approvals come on the heels of the 2016 FDA approval of the first hybrid artificial pancreas. The early development of this device and, in fact, much of the research toward the development of artificial pancreas technologies have been significantly spurred by SDP support, and going forward, our goal is to develop multiple artificial pancreas technologies so that all people with Type 1 diabetes can choose what is best for them.

Importantly, SDP fills a critical gap by studying populations under study by industry, such as young children and older adults. In addition, SDP supports—NIDDK recently funded research to develop an artificial pancreas system customized to the need of pregnant women. We want to make sure that people use and benefit from new technologies, so our research is also focusing on incorporating these devices in clinical care and looking for new ways to enhance their usability.

As everyone here knows, managing technology is not a cure. We are also supporting research toward a cure, including understanding the autoimmune attack in Type 1 diabetes, and since I last testified, there has been progress in our ability to study single cells in the pancreas. This is giving us never before seen insight into Type 1 diabetes and how it progresses, and we can now visualize at the same time and study the interactions of individual insulin-producing beta cells and other pancreatic cells and immune cells involved in this autoimmune attack.

Complementing this effort is exciting research to develop islets on a chip like the one you see before me here. This is empty, but this chip can contain beta cells, blood vessels, and other components of the islets needed to function in the body, and this tiny but mighty chip, developed with SDP support, can allow us to test new therapies very quickly and efficiently and determine which are likely to be beneficial in clinical trials, and we are excited about applying other cutting-edge technologies in Type 1 diabetes. For example, artificial intelligence and machine learning approaches hold great promise for clinical applications such as diagnosing diabetic eye disease. Research to combat these and other complications is critical to improving people's health and their quality of life.

As I hope my testimony has highlighted, our efforts were significantly strengthened by the last SDP renewal, which allowed scientists to pursue their long-term research projects without interruption.

With the incredible progress already achieved through the SDP and the promise for future research, we are really extremely hopeful that we can reach our goal of preventing and curing this disease.

I would be pleased to answer any questions you may have. Thank you.

The CHAIRMAN. Thank you very much for such encouraging testimony. The trials that are underway are so exciting.

Our next witness is Dr. Kowalski. Dr. Kowalski.

STATEMENT OF AARON J. KOWALSKI, PH.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, JDRF, NEW YORK, NEW YORK

Dr. KOWALSKI. Thank you. Chairman Collins, Ranking Member Casey, and members of the Committee, thank you all for welcoming us here today.

The JDRF Children's Congress delegates sitting here before you, these amazing kids, all have Type 1 diabetes, or T1D, an autoimmune disease that destroys the cells that make insulin in their pancreases. I too live with Type 1 diabetes, as does one of my brothers, Stephen.

These amazing children and their parents work very, very hard to manage T1D. It is very difficult, but today we can live healthier lives than ever before because of research funded by the Special Diabetes Program. As a scientist by training and now as president and CEO of JDRF, I can tell you that your leadership and the strong bipartisan support for SDP has led to numerous research breakthroughs, transforming lives and bringing us closer to our ultimate goal: cures for Type 1 diabetes.

Just last month, as Dr. Rodgers pointed out, a clinical trial showed that a new artificial pancreas system supported by the SDP has helped people maintain more consistent and healthier blood glucose levels. Also, the FDA approved the first continuous glucose monitor and insulin pump that can work interoperably. This will allow for people with diabetes to select component devices of their systems without having to put together a do-it-yourself system. This choice is critical as people with diabetes achieve better outcomes when they can choose the tools that are right for them.

This progress builds on the success of the first artificial pancreas system which came to the market in 2017, thanks to your leadership, Senator Collins, which has had a major positive impact for our community, and of course, to stay healthy we need access to these advances, and we need access to affordable insulin. It is unacceptable for anyone to ration insulin due to cost. We need the Government and the private sector to act now.

I want to thank Senator Collins, Senator Casey, Senator Shaheen, and so many others for your commitment to this issue. It is so incredibly important.

As Dr. Rodgers noted, last month we had exciting news in immunotherapies. A clinical trial funded by the SDP and by JDRF published results in the New England Journal of Medicine that

found a drug can delay the onset of Type 1 diabetes for 2 years in children and adults. This is so important. The delay in onset is likely to have long-term benefits that will have a tremendous impact on our community and the overall health care system. This progress is thanks to leadership and foresight to invest in multi-year funding in SDP research.

While there is great progress, we are here because there is still important work to be done. The SDP must continue to invest in innovative immunotherapy and beta cell therapy research. We need to understand why the immune system goes awry and how we can eliminate these attacks.

We need to understand better what triggers Type 1 diabetes. An environmental determinant study has screened more than 425,000 children to understand what factors trigger the onset of Type 1 diabetes. This SDP-funded study is more than halfway through, and it is crucial that it be finished. I cannot overstate how important this trial is.

At the same time, we need to reduce the burden from kidney and heart disease. Senators, let me tell you that this research is too important to have an expiration date. In 2017, when the SDP renewal was delayed, there were real implications. Within TrialNet, enrollment was postponed in a promising prevention trial. By the time the funding was in place, some of the people who would have been eligible had since developed full-onset Type 1 diabetes and were no longer eligible to participate in the trial. We cannot allow this to happen again.

We are so grateful for the outstanding leadership of the Senate Diabetes Caucus Co-Chairs Senator Collins and Senator Shaheen, who championed a letter in support of the SDP and has been signed by 68 Senators. The Special Diabetes Program is making a real difference in every life here impacted by Type 1 diabetes. We need Congress to re-enact a 5-year renewal of the program and keep researchers working without interruption so that when these children are my age, they can say they used to have Type 1 diabetes.

Thank you.

The CHAIRMAN. Thank you very much for your testimony.

Mr. Garber, welcome, and thank you so much for being here today.

STATEMENT OF VICTOR GARBER,
ACTOR, NEW YORK, NEW YORK

Mr. GARBER. Thank you. Chairman Collins, Ranking Member Casey, and members of the Committee, thank you for inviting me to testify today. It is an honor to be here with the JDRF 2019 Children's Congress.

I was diagnosed with Type 1 diabetes when I was 11 years old, nearly 60 years ago, but I remember vividly that my diagnosis was a traumatic event for my family, and especially for my mother. I have a distinct memory of her standing on the porch as my father drove me to the doctor. The fear and desperation in her eyes remains an indelible image in my mind.

Whenever I meet the mother of someone with Type 1, I am brought back to that moment and to that confusion, panic, and un-

certainty, which is why I am so determined to do everything I can to help find a cure for this disease. I am here today, with these amazing delegates, to implore you to keep supporting advances in Type 1 research, by supporting a long-term renewal of the Special Diabetes Program. It has been said before, and it will be said again.

After my diagnosis, I was kept in the hospital, where I learned to inject oranges with insulin syringes, until I was brave enough to try it on myself. My new and confusing diet consisted of weighing food on a small scale and deciphering carbohydrate ratios. I have no idea what that is, which is why I am still guessing today. In those days, we had to boil syringes to ensure sterility and test blood sugar levels with urine in a test tube. We have come a long way, but not far enough.

As I adjusted to my new reality, I was determined that I would not be deterred from living the life I envisioned. When I was 16, I left home to pursue my show business dream. I was a folk singer, dishwasher, played tiny parts on TV shows and movies. Hard enough for any teenager, but balancing blood sugars, with inexplicable highs and lows, making healthy food choices, getting proper rest was daunting. I can only say that my determination and will kept me from just giving up.

Thanks in large part to the Special Diabetes Program, living with Type 1 diabetes today is vastly different from when I was a teenager. My access to amazing diabetes technology, like a continuous glucose monitor that can be used with different types of insulin pumps, gives me constant information to help avoid blood sugar highs and lows, and I am so fortunate to be able to afford insurance that allows me to choose the best insulin pump and glucose monitor for my specific lifestyle. This should be everyone's right.

My anxiety level has—I have not got much time. My anxiety level has decreased somewhat since those days. Living an erratic life in movies, television, and theater has become more manageable thanks to funding for the Special Diabetes Program which made all these things possible. However, it is imperative that Congress provides a long-term renewal of the program, which will ensure that critical research can continue unimpeded and enable more life-changing breakthroughs for the children you see here today.

Finally, I would be remiss if I did not tell you how concerned I am about the skyrocketing cost of insulin. The idea that someone has to ration insulin in 2019 due to greed and avarice is unconscionable. No mother in the U.S. should lose her son due to insulin rationing, and no father should have to rely on buying insulin from Canada to keep his child alive. I am lucky, extremely lucky, to have good health insurance, but I am paying more than I should be for the life-saving drug that I would die without. Senators, this is simply unacceptable. Dealing with Type 1 diabetes is already hard enough. Chairman Collins, Ranking Member Casey, Senator Shaheen, and others of this Committee, I want to thank you for addressing the insulin pricing issue head on and beg you to keep up the fight to bring down these costs.

As you do, please keep your commitment to the research our community desperately needs to find a cure for Type 1 diabetes. A cure. We need you to keep the momentum going by renewing the

Special Diabetes Program before it expires at the end of September and put it on stable funding for years to come. If you do that, you will make it easier for all these delegates to live their dreams and enable them to thrive without the fear of Type 1 diabetes holding them back.

Thank you, Chairman Collins, Ranking Member Casey, and members of the Committee, for your support and your time today.

The CHAIRMAN. Thank you so much for your testimony.

Ruby, you are up.

STATEMENT OF RUBY ANDERSON, CHILDREN'S CONGRESS DELEGATE, YARMOUTH, MAINE

Miss ANDERSON. Chairman Collins, Ranking Member Casey, Senators, thank you for inviting me to talk to you today.

My name is Ruby Anderson. I am 9 years old and just finished third grade at Yarmouth Elementary School in Yarmouth, Maine.

I was diagnosed with Type 1 diabetes just before my second birthday. I do not remember not having Type 1 diabetes, but I am lucky because I have devices that can help me manage my Type 1 diabetes.

I have been using an Omnipod insulin pump since I was about 3 years old. It has no tubes, which I like, and I do not have to take shots, but sometimes it hurts when I have to change my pod every 3 days.

I also have been using the Dexcom G6 continuous glucose monitor for over a year. I love it. Things have gotten a lot easier. Now I can just check my numbers on my phone. My mom even lets me ride my bike to school because now she can see my numbers on her phone wherever she is.

Before the G6, I was checking my blood sugar up to 10 times a day. Now, I still have to prick my finger, but sometimes not for weeks, but as great as my pump and G6 are, T1D is still really hard to manage. I have to count carbohydrates in everything I eat, make sure I am giving myself enough insulin to keep my blood sugar from going too high. If I give myself too much, I go low. Even if I do my very best, my numbers can still be way off and I do not feel good.

My G6 and pod sometimes alarm when I am in class, at home doing homework, playing lacrosse with my friends, and swimming at the beach. It even went off one time on an airplane. That was awkward.

When it goes off, I have to stop and check my numbers. I will have to eat or drink when I am low or take more insulin if I am high. My parents, my brother and sister, and friends and teachers all help me if my numbers are too high or too low.

I wish my diabetes would just disappear, and Senators, I do not want my brothers and sisters to get Type 1 diabetes.

We need more research to find a cure. We need even better devices. We need to figure out what causes Type 1 diabetes so we can stop it.

All of the kids here at JDRF Children's Congress need you to continue to support us.

When I grow up, I want to be a scientist—partly because Type 1 diabetes research is so important, and if they have not found a cure for diabetes by then, I will.

When we have a cure, I am going to have a party and invite everybody in the whole entire world. Senator Collins, you will be first on my list.

The CHAIRMAN. Thank you.

Miss ANDERSON. Thank you for listening and for all you do for kids like me.

The CHAIRMAN. Thank you so much.

Dr. Rodgers, sign her up right now, and I am coming to that party.

Adriana, welcome. We are delighted to have you here.

STATEMENT OF ADRIANA RICHARD, CHILDREN'S CONGRESS DELEGATE, MILTON, PENNSYLVANIA

Ms. RICHARD. Chairman Collins, Ranking Member Casey, Senators, thank you for asking me to speak here today.

My name is Adriana Richard. I am 16 years old and from a small town in central Pennsylvania called Milton.

I am a proud member of the JDRF Central Pennsylvania Teen Task Force. Last year, we raised over $10,000 with our JDRF One Walk team.

I wrote a book, "The Real T1D," and started an Instagram account to share my T1D story because I am one of many living with diabetes every day. I am not the only one going through this.

I go to diabetes camp most summers. It is my favorite time of year because I am not judged and I can be myself.

I am here today to share my voice as an advocate for people with T1D because I have been motivated by the struggles I have experienced.

See, I was diagnosed with Type 1 diabetes when I was 5 years old. All I remember from my diagnosis was that my parents were scared for me. I am the oldest of four kids and the only one in my family with diabetes. In elementary school, I was sometimes teased for being different or for always being with the nurse. School is already a stressful environment and having diabetes only makes it more difficult. I have gone through some hard times.

A few years ago, I was having really bad lows, which means my blood sugar was getting dangerously low, but the thing is I did not know it. I felt fine. I also had really bad highs. In fact, one especially bad time I had DKA, or diabetic ketoacidosis, and was hospitalized. I felt really sick and was in a lot of pain. DKA is very serious as it can lead to a coma or worse.

I was constantly battling diabetes and managing my everyday life with no breaks. I was physically and emotionally exhausted, and basically suffering from burnout.

Thankfully, I have been able to manage T1D better over the last year, primarily since I got my Dexcom CGM. It catches my highs and lows before they get bad, and I can check my levels on my phone. It also alerts my parents, which is a huge relief because sometimes I miss the alarms on my phone when I am asleep.

Before, I had to check my levels right before going to bed and hope that I would not get too low during the night. Now, I feel much better when I wake up in the morning.

My life with Type 1 diabetes is easier with this technology, which is thanks in part to funding from the Special Diabetes Program.

That is why I am here to ask you to support the SDP. It needs to be renewed.

We are so close to finding cures for diabetes, and if we stop research now, there is no way we will ever find it. Until then, we need the SDP for research to help our everyday lives with Type 1 diabetes to help scientists and engineers invent things like CGMs that have changed my life.

In fact, after Children's Congress, I will be taking the driver's test to get my license. I am excited and my parents are, too, knowing that my CGM will help me more easily manage my blood sugar levels while I focus on navigating the roads in Milton.

Senators, people with Type 1 diabetes can do anything we set our minds too. We just have extra responsibilities.

The research funded by the SDP helps people like me—all of us here today—handle those responsibilities and will ultimately give us a cure.

I am grateful that as a resident of Pennsylvania the cost of my insulin is zero dollars because it is fully covered as a life-sustaining medicine under Medicaid. Thank you, Senator Casey, for your interest in expanding this program broadly so that kids with diabetes in other States may also benefit.

Thank you all for listening to my story, and thank you for your support of people with Type 1 diabetes.

The CHAIRMAN. Thank you. Thank you very much, Adriana.

Ruby, you have such a joyful, positive attitude, and you participate in everything. You do not let your diabetes stop you at all. Could you tell us what advice you would give to another child who has just learned that they have Type 1?

Miss ANDERSON. I would say to be brave and not let diabetes get in your way.

The CHAIRMAN. I think that is great advice. It really is.

Dr. Rodgers, I was struck as you went through how the technology has changed and the many advances that have been made possible by the Special Diabetes Program, and in the more than 20 years that I have headed the caucus and worked as an advocate for Type 1 diabetes, I have noticed a tremendous change in the technology. I think about how bulky and big the initial pumps were and here we are now with the artificial pancreas and the closed loop with the continuous glucose monitor, and it truly is amazing.

I would like you to focus a little bit more on the prevention side. I am really excited about the TrialNet results that you described. Could you tell us what most excites you when you look at prevention and cures?

Dr. RODGERS. Absolutely. The long-term support of the Special Diabetes Program has really allowed us to invest in the critical infrastructure necessary for TrialNet to do its—set up these prevention trials. Conducting prevention trials requires identifying and enrolling people at risk for Type 1 diabetes who have not yet developed clinical disease, so finding these people is crucial, and it requires screening a lot of people, so far we have screened over 200,000 people at risk, including 15,000 annually now, and as Dr. Kowalski said, if you can find them, there is a window of opportunity before they actually develop the clinical disease that you can

use for testing them in crucial trials. If you miss that window, then they would have to go into a different trial.

As a result of that exciting work that was just reported last month, the next trial is obvious. You want to see whether these particular drugs might have a benefit if you give it a second time, but we have really a whole host of drugs that are in a queue that are just as promising as this one that with the infrastructure that has been created by the Special Diabetes Program and TrialNet, they are ready to go, but of course, we would not want to start a trial unless we have the funding to know that we can complete it, but thanks for your strong support.

The CHAIRMAN. Thank you. That is very encouraging.

Mr. Garber, you have emerged as a voice in the diabetes community for those who have really been affected by the skyrocketing cost of insulin, and we talked a little bit about this this morning, but it is ironic that you are from the very birthplace of insulin, in London, Ontario, and insulin was first discovered in 1921 and has been used in various forms to treat diabetes for nearly a century, and that is why I am personally so outraged by the tripling of price. It just does not make sense to me.

As a Canadian now living in New York State, what is your reaction to the extraordinary lengths that some families are having to go to get the insulin their children need?

Mr. GARBER. You know, I was not really as conscious of it until like a year ago when I started hearing—I knew it was a difficult situation, but when I realized what the—I was on insurance, so I was always—I was paying, you know, what seemed an okay amount of money, and then when I—actually, the woman whose son was rationing insulin, that is what really sent me over the edge. I could not believe it, and part of it is because I was not really paying attention, and I thought this is unimaginable, this is unconscionable, and so I just got—I have just been—and everywhere I go now, people are just saying, "What is happening?" I do not really understand how pharmaceuticals—I do not understand the—I think there are too many middlemen that are benefiting. Meanwhile, these children are dying. I do not get it. I just do not get it, and yet, you know, in other States, there is no cost for insulin, so what does that tell you?

The CHAIRMAN. Well, it is unconscionable, and I want you to know that our Committee devoted an entire hearing to the cost of insulin, and we passed a bill—Senator Casey and I are both on the Senate HELP Committee, and we passed a bill that has several measures in it to deal with the rising cost of prescription drugs, but the insulin example is the worst because it is not as if a whole lot of R&D went into the initial investment.

Mr. GARBER. Right. Yes, you know, I think I mentioned to you it was sold for a penny, the patent, in London, Ontario.

The CHAIRMAN. Right.

Mr. GARBER. So that no one would ever be denied insulin, and that just has to come back.

The CHAIRMAN. Thank you.

Senator CASEY. Thank you, Chairman Collins.

I want to start by commending the work of the delegates and, in particular, commend and salute the testimony by Ruby and

Adriana. I am trying to think if at the age of 9 or the age of 16 I could do what you have done today, and I am certain the answer is no, and I just am grateful that you are willing to do this, but also I want you to know not only in the work you are doing as advocates on this issue, but more broadly, you both have a very bright future, and we may put you in charge of some other projects before you leave Washington.

I want to note for the record as well, as you know, when we have a hearing like this, Senators will be back and forth and in and out, so I hope when someone is here and then leaves you do not attribute that to a lack of interest. Senator Jones, for example, just indicated to me as he left he has got to go to a classified hearing in the Armed Services Committee. He is hoping to be back, and I think that is true of a number of Senators, so we are grateful that people can see that back and forth when they are balancing hearings and different issues.

I wanted to start, though, with Adriana, not only because she is from Pennsylvania but that sure helps to have the first question, but it is pretty clear to all of us, as is true, I think, of every one of your fellow delegates, that you have not allowed diabetes to control your life, and you have indicated over and over again by way of your example and by your testimony and otherwise that that is the case.

You mentioned in your testimony that you published a book on what it is like to live with T1D, and you have actually given it that title. You have also used Instagram and other platforms and methods to make sure that you are helping to reduce the stigma. In fact, I just left the hallway that you and I were in, you were doing a television interview, and you sounded really good on television.

You have used every possible resource, every possible opportunity to get the message out. You have also taken on the role as a mentor as part of the JDRF Teen Task Force, as I mentioned, so I guess one of the questions I have is: What questions do you get, Adriana, when you are interacting with young people or interacting with adults? Are there common questions? Are there common concerns? Or is there a message that you want to reiterate today that comes from those questions?

Miss RICHARD. Yes, so the question I probably get asked mostly all the time is what is on my arm because of my CGM, or what is on my hip because of my pump. I could be in a store just walking around, and a little girl or a little boy will point at it. I just make it a point to go up and just talk to them and explain to them what it is.

The other one would probably be that diabetes is from eating too much sugar. I get that all the time, which is not true at all. Diabetes is an autoimmune disease. It is not caused by eating too much sugar or being overweight.

Senator CASEY. Well, it is important to repeat those messages, especially in Washington, and we are grateful you are willing to do it.

I wanted to turn to Dr. Rodgers. I am sure that I share—and I think I speak for a lot of people—the gratitude of everyone in this room when I say thank you for your leadership at NIDDK. The work being done by researchers across the country to find a cure

for T1D is very promising. In your testimony, you discuss that these researchers keep moving closer to that elusive cure. Some of the work that is happening at research institutions in Pennsylvania and I know other places is inspiring and promising.

Could you highlight some of that new and promising research? I will ask you to start with Pennsylvania and go beyond there if we have some time.

Dr. RODGERS. Sure. I will try to be brief. Absolutely. Researchers at the University of Pennsylvania, for example, are part of the SDP-supported Human Islet Research Network, or HIRN for short, including something called the "Human Pancreas Analysis Program." They are developing some very novel techniques to understand the single cells inside of the pancreas and how they change with respect to the progression of the disease.

As you understand this at a single cell level, you can begin to think about new targets for either delaying the progression or potentially curing the disease if you can halt that progression, and the people at the University of Pennsylvania are really doing an outstanding job.

Another example is in Pittsburgh. The University of Pittsburgh actually serves as one of these TrialNet sites that I talk about in my testimony. They are lining up the patients, getting them in this cure for new preventive strategies, and we are really excited about the TrialNet and the participation of people in Pittsburgh.

Senator CASEY. Thank you very much, Doctor.

The CHAIRMAN. Senator Braun, welcome.

Senator BRAUN. Thank you, Madam Chair.

This is important to me. I have learned a lot about autoimmune diseases over the years, Crohn's and colitis, digestive disorders, asthma, neurological. Why this is so important is because if we find the secret to what causes Type 1 diabetes, I think we are going to unravel a host of other diseases in finding a cure. That is why I think it is so important you keep doing what you are doing and that we stay on point here.

In my own business, I tried to address health care and the cost of it, referred to where we should not be rationing medicines that are so important. We should not be grappling with the cost of insurance that is overwhelming. I took on the insurance companies nearly 11 years ago myself, and it was a wrestling match that you would not believe, but there are ways to address it, and what we want to do is keep the best of our health care system that gives us technology and breakthroughs, but somehow drive the costs down, and it would take a whole other time period, but you can do that through being engaged in your own well-being, emphasizing wellness over remediation, finding transparency and getting competition among the providers so that we can keep the best of what we have got and not contend with some of the things that are the worst about our current system.

The other thing would be current budget woes here. This should be something we should never have to consider whether we would have enough money to fund, along with many other things that, you know, center around disease, disasters, some of the things that we should never be worried about how do we pay for that, because to me it is an important part of what the Federal Government

should do. We are in the context of running trillion dollar deficits here, and one thing as a mainstream entrepreneur, I hope to weigh in on how we get this place in better health so that we can always be there for good causes like this.

The question I want to drill in on, when it comes to the particular disease of Type 1 diabetes, what I have learned is there is generally a genetic predisposition to almost all of these autoimmune diseases and an environmental trigger that might be part of it. Can you explain to us—and I like the fact that you are getting down to single cell analysis. That seems like that might get us on the right trail. When it comes to Type 1 diabetes, is it more of a genetic predisposition or an environmental trigger or that mysterious combination of both?

Dr. RODGERS. That is an excellent question, Senator Braun. Type 1 diabetes is a disease that is largely genetic. In fact, Type 1 diabetes, we know more about the genetics of Type 1 diabetes. Ninety percent of the attributable genetic risk is already known for Type 1 diabetes. First-degree relatives of people with Type 1 diabetes, there is about a 15–fold increased risk of developing the disease, and that is why we screen their relatives of people with Type 1 diabetes in order to put them in these prevention trials once they develop it.

Now, you are right. Just because you have the genes and that genetic risk does not mean that you are going to absolutely develop the disease. There is something in the environment that triggers that risk and makes that risk a reality, and that is the reason that we have an ongoing study called "TEDDY." In Government, everything is an acronym. TEDDY stands for The Environmental Determinants of Diabetes of the Youth." In this study, we had to screen about 425,000 individuals in order to get 6,000 individuals who we are going to be following from birth through the age of 15. That is going to end in 2025, and in them we are collecting all types of samples—blood samples, urine samples, saliva, stool samples. We are getting medical records on them. We are understanding about outbreaks, you know, within their schools and other environments, and from that and all these samples that we are collecting, we are doing these studies called "omic technology" and using big data to analyze what it is in the environment that is actually triggering that. If we knew and it turns out that it is a virus, for example, it is likely that we can make vaccines to prevent people from developing the immune—or if it is something in the diet, for example, one can suggest dietary restrictions.

I would say that Type 1 diabetes is the best example of this combination of genetic risk with environmental factors, and we will understand that by 2025, what those—and it is probably not just one factor. It is probably multiple factors.

Senator BRAUN. Thank you. I have got to go to an Environment and Public Works Committee meeting where we are talking about roads and bridges, but thank you for the attendance. Since I have been here 6 months, this is the best showing of any Committee. It is important to keep up the passion so that we get the message, and again, I think you lead in the autoimmune category, and if we find the cure, it is going to benefit a lot of other ailments as well.

Thank you so much.

The CHAIRMAN. Thank you.

Senator Sinema.

Senator SINEMA. Well, thank you, Chairman Collins and Ranking Member Casey, for hosting today's important hearing on the Special Diabetes Program. I also want to give a shout-out to our Children's Congress delegates, especially to Grant from Gilbert, Arizona, and Rachel from Flagstaff. Are they here? Hi. I saw Rachel. Is Grant here? Oh, my gosh. You can do that all day. Hi, Grant.

Grant, age 5, was diagnosed with Type 1 diabetes just a few days before his second birthday. He was recently recognized for raising almost $50,000 for JDRF, and he would like to be a firefighter when he grows up, but he is already a hero to so many of us in Arizona.

Rachel, age 16, is managing multiple chronic conditions, but that has not slowed her down. She likes to hike, lift weights, and has excelled in both varsity volleyball and swimming. I could take some swimming tips from you. You are really an inspiration to me.

Grant and Rachel are two young Arizonans who are in D.C. today representing more than 750,000 Arizonans living with diabetes. I am grateful for their advocacy and look forward to working with them to ensure Arizonans get the health care they need.

I also would like to thank our witnesses for their testimony and now jump into a few questions. My first question is for Dr. Kowalski, but I would encourage any of our witnesses to weigh in.

In 2019, the Arizona Department of Health Services published its first-ever Diabetes Action Plan. The report noted that not all health plans in Arizona cover diabetes self-management education, which are programs that help patients learn about managing their diabetes. I am proud to co-sponsor legislation introduced by Senator Shaheen and Chairman Collins which would expand access to diabetes self-management education programs for Medicare beneficiaries.

As innovative technologies and new smart insulins become available, education will be crucial to helping patients make informed choices about their care and learn about financial assistance programs if needed.

Dr. Kowalski, what barriers prevent patients from accessing diabetes management resources? And what more can be done to ensure this education is available to all newly diagnosed patients with diabetes?

Dr. KOWALSKI. Thank you, Senator. That is an excellent question because diabetes is a unique disease in that you are dosing a very dangerous drug every day on your own and only see the doctor every 3 to 6 months, so you are doing this, and it does require significant education.

There are barriers. Cost can be a barrier. We have heard about the cost of insulin, but it is really insurance coverage for diabetes treatments across the board, whether it is pumps or sensors or education and doctor's visits. It is a barrier for many families.

Then there is simply not enough diabetes educators and diabetes endocrinologists who specialize in Type 1 diabetes out there. In a State like Arizona where folks may have to drive long distances, take off from work, that is a significant burden on families.

Every family in this room knows that education plays an incredibly important role when you are making a decision with a drug that, if given too much, can cause hypoglycemia and be very dangerous, so these programs play a significant role in the health of our community.

Senator SINEMA. Thanks.

My next question is for Dr. Rodgers. Your testimony placed a high priority on research on the impact of new technologies in special populations, such as children, older adults, and pregnant women. I agree, and I also believe that that means increasing our investment in the Special Diabetes Program for Indians.

Since the program was created in 1997, diabetes rates among Native populations have dropped by 54 percent, and tribes have the resources to more effectively manage diabetes-related complications such as kidney and heart disease. For example, the Navajo Nation's Special Diabetes Project runs the Window Rock Sports Center as a community resource to educate members on diabetes management and offer free health assessments.

Can you share with the Committee any specific insights from recent research that would be of interest to our tribal partners? And are there barriers to including more tribal members and other populations in research and clinical studies?

Dr. RODGERS. Thank you. Well, as you mentioned, the Special Diabetes Program, and as Chairman Collins mentioned, has the additional Special Diabetes Program for Indians, or SDPI, and, of course, working in consultation with the Indian Health Service and the Tribal Leadership Council, they have coordinated the provision of care in many sites, which actually explains the drop in some of the complications that we have seen, but nonetheless, Native Americans have the highest risk for Type 2 diabetes of any populations actually in the country.

We have been working closely with the SDP program that we have in conjunction with our sister organization, the CDC, to do a study called "SEARCH" in which we are looking at the onset of diabetes in individuals up until the age of 19, diabetes in youth, and we are seeing a growth in Type 2 diabetes in Native American populations. Having this early information provides us to get them involved more in preventive trials and in treatment trials, because I can tell you that Type 2 diabetes in children is an extremely severe disease as well. SEARCH also has indicated one other thing, which is actually a followup to Senator Braun's comment, that we are seeing an increase in the incidence of Type 1 diabetes across all groups over the last 10 years, but particularly in certain underrepresented groups previously, particularly non-Hispanic whites—or, I am sorry, the Hispanic population, and in them, the genes are different, which means that there is not the standard—the genes that I talked about in terms of this genetic risk, which means that there is something in the environment that is even triggering the autoimmune disease at a greater frequency, and that is something that we have to understand, how these subpopulations are reacting to the environmental changes, and hopefully with the continuing support of the SDP we can understand the heterogeneity of the disease as it affects different groups.

Senator SINEMA. Thank you.

Thank you, Madam Chairman.

The CHAIRMAN. Thank you.

Senator Scott, we are delighted to have you here today.

Senator TIM SCOTT. Thank you, Madam Chair.

To the panel, thank you all for being here this morning. To the kids, God bless you. It is certainly encouraging and exciting to see so many advocates participating in this country. I will say that your advocacy is powerful. I am an advocate for you all because of a friend of mine who was diagnosed around 9 years old, a guy name Billy Siegler, who today is 53 years old, married. His son is now looking at going to the Medical University of South Carolina, perhaps in part because of his father's challenge of Type 1 diabetes, so your future is incredibly bright.

One of the things I love about the hearing today is that we are witnessing around the country, hopefully folks are watching, powerful advocacy come to life, and there are three advocates from South Carolina who are here today that I would like to highlight, and one of the things I have learned by reading through so many of the bios is that you all are not just advocates for Type 1 diabetes. Many of you are advocates for Type 2 diabetes. You are also advocates in many different ways, and the three individuals that I will talk about are classic examples of what is possible. Hannah from Lake Wylie, South Carolina, is 17 years old. Is she here with us? There she is.

Hannah was diagnosed at 8 years old. She now enjoys participating in cross country and track and field not only from an athletics perspective but also a Type 1 diabetes advocate perspective. Through participating in sports, she has been able to spread awareness about T1D to her peers as well as the prevention of Type 2. Thank you for your advocacy.

We also have with us Katie, who is 14 years old. She was diagnosed at 5. She lives in Charleston, South Carolina, my home town. Is she here? Thank you. God bless you. She is a talented musician. This is pretty impressive. Is this accurate, Katie? Let me know if I am embellishing at all, okay?

Politicians do that sometimes. Not me, of course, but you are good at many instruments, including the piano, organ, cello, guitar, and percussion. I will have you know that when I was in the third grade, I played the cello, and they came and took it back.

I am not sure what that says about me, but it is nothing positive.

She and her entire family advocate for Type 1 diabetes funding with other JDRF advocates.

William, who is age 14, from Summerville, South Carolina. William, what is up?

Master WIMBERLY. Hey.

Senator TIM SCOTT. How you doing, man?

Master WIMBERLY. Good.

Senator TIM SCOTT. Go Green Waves.

Master WIMBERLY. Oh, yes.

Senator TIM SCOTT. All right. All right.

For those of you not from South Carolina, Green Waves is a wonderful high school to attend in South Carolina.

William was diagnosed at 3 years old. William is an honor student. Honor student, you make really good grades? William is an

honor student. He is also a very good tennis player. Accurate? Awesome, awesome. These kids are so humble. We could use some of that in Congress. Thank you very much.

When William is not on the tennis court or in the classroom, you can find him enjoying the outdoors, particularly the water, or on the golf course. William is also an active advocate for diabetes. He is involved in a number of events. One of the things I am so excited about when I listen to the stories and I hear and read about the involvement is if we can have more folks like you all helping us understand and appreciate the significant impact that funding can have on combating the disease, I think we can make not steps forward but leaps forward.

Let me use the balance of my time, Dr. Rodgers, to ask you a question about the advancements that have happened over the last 4 or 5 years, and then in a perfect world with proper funding, what could their lives be like in 20 years?

Dr. RODGERS. Well, the advances that have happened in the last 4 years have really been extraordinary. Following the first FDA approval for an artificial pancreas, there are at least four that we are currently studying, four important international studies using various combinations of these technologies, including one technology that not only develops or delivers insulin but also glucagon in a manner very analogous to what the pancreas does, for example, the ability to have interchangeable parts, interoperability that Dr. Kowalski mentioned, and using these technologies now, we really want to push the limit to put these in real life situations over extended periods of time, over broader age groups is what we are currently testing, and so hopefully the results of those research efforts will be useful for kids here so that they will be able along with their health care provider to pick the best instrument and AP technology that will be useful for them.

Again, that is just technology. We really are sort of looking at cures, and so other things that have happened in the last few years is actually thinking about a way to get the cells that make the insulin from an individual and get them back in terms of transplantation by using the person's own cells, encapsulating them in a device that would be impermeable to the immune attack that occurs as a way to correct them.

Of course, in the prevention arena, you have heard about what we mentioned, this one treatment. There are several others just lined up that we think, you know, within the next several years might be more readily available.

Ultimately, we want to find a cure, and that cure can be directed at whatever that trigger is that turns on the immune system in each individual. That we would like to learn in order to prevent that from happening. I think that that is a real possibility for the kids who are assembled before you today, and I am very excited about that possibility.

Senator TIM SCOTT. Thank you very much.

Mr. Garber, thank you for your willingness to be an advocate, and we do miss you on "Legends of Tomorrow."

The CHAIRMAN. Thank you very much.

Senator ROSEN. Well, thank you, Madam Chair. Thank you all for being here. I have to tell you, this is, I want to say, the best-

looking, the most enthusiastic, the most passionate, infectious in a good kind of a way, group that we have had before us, and I know that whatever you all do, from what you have learned here through your advocacy, your passion, your commitment, your willingness to stand up, you are going to be great, whatever your future is, and I have got to give a shout-out to a couple Nevadans. Where are you, Charlie Bell, Ashley Bellows? Let us see. Oh, there you are down here. Go, Nevada, and they are great advocates for what they are doing here for JDRF and for all the other things in their life, and every parent here, any parent watching out there, be very, very proud of these young kids.

What I want to say is that the Special Diabetes Program, of course, combined with the hard work of JDRF has really paved the way for innovative research on Type 1 diabetes, leading to new therapies, innovative technology, and progress toward a cure. This progress is particularly meaningful to Nevada because diabetes is an increasingly common condition that affects Nevadans at higher rates than the national average.

Excuse me. I have allergies today.

Roughly 12 percent of adults living in Nevada have one of the two types of diabetes. Last week, I visited the Reno Sparks Indian Colony. They have a tribal health clinic there. We discussed the higher rates of diabetes among tribal members. Diabetes has a heavy impact on patients at this clinic. It is a stark reminder of why we must continue to invest in critical programs to ensure the patients have access to the best care possible.

To the doctors here today, I want to talk a little bit about the artificial pancreas, where that is at, how it is going to help kids in the future.

Dr. RODGERS. Well, thank you for your question. The artificial pancreas, just to the extend the previous comments, really I think it is going to have a great benefit. As it constantly monitors glucose from minute to minute and changes that occur with exercise and diet, it can appropriately adjust the insulin infusions, and there are multiple artificial pancreas technologies that are becoming available. We are supporting some of the pivotal trials in some of those, but we are also, with SDP support, supporting advances for even the next generation of artificial pancreas, and I think that that will make the people who sit in front of you, make their lives much simpler.

We have to understand that there could be technology that is available, but if people do not use it or are unable to use it, then that can create barriers, and so at least from the standpoint of usability, we are putting a tremendous amount of investment into studies to understand how to make these more usable ultimately for patients.

Senator ROSEN. Well, I want to tell you, I just came from a wonderful event called "Girls Who Code," and it is about the future of not just girls who code but innovation technology and the next gen taking on careers in STEM, so artificial pancreas, research, studies, analytics, everything you do, how can we be sure to help you continue to invest, have the people pipeline to do the kinds of research that you need? How is a STEM education for these kids here going to help them and all of us?

Dr. RODGERS. It absolutely will help. I have to say that I personally spend a fair amount of time going to high schools and to colleges talking about the importance of STEM education. For example, just take the artificial pancreas. You would think that you—obviously, you need a bioengineer to try to devise the micro circuitries and other things, but it also takes computer engineers. It takes people with strong mathematic information and education. It also takes chemists and people skilled in biochemistry to devise the next generation of smart insulins and smart glucagons and other drugs that would man those pumps, and people who are sort of thinking about something that I mentioned, artificial intelligence and deep machine learning, because it is with these advances that people who participate in just their usual care, we can learn from the groups almost instantaneously, and this information can actually be fed back to improve the lives of people using the current technologies.

Senator ROSEN. We can take your passion, your imagination, your intelligence, and if we put you into these careers where you can use them, you can create a future of possibly no more diabetes.

Dr. RODGERS. Exactly.

Senator ROSEN. Thank you. I appreciate it.

Dr. RODGERS. Thank you.

The CHAIRMAN. Thank you very much, Senator Rosen.

Dr. Kowalski, in your testimony you discuss not only the impact on families, but also the great cost-saving potential of the research that has resulted from the Special Diabetes Program. That is why I think this investment is one that really pays dividends, both in improving the health care and health of all of these young people, but also the impact on the Federal Government. For example, the adoption of the artificial pancreas technology in adults could save Medicare $1 billion over 25 years. You mentioned that another SDP-funded trial related to the slowing of the progression of early kidney disease in people with Type 1 could save literally billions of dollars in the Medicare program.

What additional research and development has similar cost savings potential?

Dr. KOWALSKI. Thank you, Senator Collins, because such an important benefit of this funding is the economic benefit. Of course, to the families it is huge, but to our economy, reducing the high blood sugar of diabetes reduces the risk of diabetes complications, and we fear these complications such as eye and kidney disease—as you point out, we can reduce significant burden to Medicare due to end-stage renal failure.

I must say to Senator Rosen's question about artificial pancreas systems, my brother and I have been on a hybrid closed loop for 3 years each. Thank you again for your leadership. It is really transforming lives here. My brother used to have severe hypoglycemia challenges. Each hospital visit due to a severe hypoglycemic episode on average is about $20,000, so these technologies, you have the long-term complications of diabetes, but the short-term complications like severe hypoglycemia or, as Adriana pointed out, diabetic ketoacidosis, also is very costly to the Government, to employers, to insurance companies, so this is tangible, real benefit on a personal level, but also on an economic level.

The CHAIRMAN. That is a great example. It is also why I am always puzzled if an insurance company denies coverage for a device that is going to help keep people healthy. That just does not make sense to me not only from a compassion standpoint or a health care standpoint, but economically it does not make sense for the very statistics that you mentioned.

Ruby, I want to go back to you. In a recent article that was in the Portland Press Herald, your mom said, "We make diabetes-related decisions probably every 15 to 30 minutes all day, every day, and through the night. It is relentless." You do not let that get you down. You are a very active fourth grader. I am told you play a variety of sports. You enjoy art, you love playing with friends and exploring, and that is so encouraging to everyone.

How have you been able to remain so active while also making sure that you take care of your health?

Miss ANDERSON. I make sure that I bring like stuff for when I go low, and I always pack an extra pump, and I just—sometimes I just ignore diabetes.

The CHAIRMAN. I think that is true of a lot of the children here. You just live a normal life, and you get some help from your teachers and school nurse, too, don't you?

Miss ANDERSON. Yes.

The CHAIRMAN. That must help out also.

Adriana, I was struck that you mentioned in your testimony that when you go home, you are taking your driver's test. First of all, I want to wish you the best of luck. I failed the first time, so if at first you do not succeed, try again. How has diabetes technology allowed you and your parents to feel comfortable with this upcoming change and responsibility?

Miss RICHARD. Definitely, so I have the Dexcom so my parents can watch my blood sugars wherever I am at, and I know that it is going to help me feel more safe and help them make me feel—have them be like more okay with it, so if I was low, they can just give me a call, and it can also hook up to like anything Bluetooth, so as long as I like—when I am in my car, my alerts will go through the car, so they are really loud, which will definitely help.

The CHAIRMAN. That is great. I think that is a great example of the difference that technology can make, and as I said, for someone who has worked on this issue for decades, the advances in technology are so exciting, and I have seen that with other Maine families that I have worked with.

Senator CASEY. Thanks very much. I wanted to start by highlighting the legislation I mentioned earlier. For those of you who do not know about the Pennsylvania example I cited, this bill that I have introduced—will be introducing today, I should say, will be an expansion of Medicaid where the Federal Government would initially pay 90 percent of the Federal match. Some will say, oh, well, we should not do that. Some will say we cannot do that. We will have the usual arguments, but we have expanded Medicaid once, and a lot of people got health care, and we should do it again for children who have disabilities, and in this case, it would help children with Type 1 diabetes.

The way it works in Pennsylvania is children are benefited by a special pathway. In this case, these are children who meet the Sup-

plemental Security Income, so-called SSI, disability criteria, so they meet the criteria in that program for a disability. However, their household income, the household they live in, exceeds the SSI limits that would make them eligible for Medicaid, so we would change that. We would treat the child with the disability as a household. Simple as that. Right now 70,000 children in Pennsylvania benefit. I think this should be a national program, not just in Pennsylvania or a few States.

We are going to be continuing to work on that, and we will talk more about it, in addition to, of course, pushing the No. 1 priority for today, which is the reauthorization of the Senate program.

I wanted to end my questions with Adriana, where I started. Adriana, you have become a role model, and Ruby has as well, and I know there are other role models in this room today for so many people in your community and for young people especially, but I want to ask you, who is the most important role model for you after your diagnosis?

Miss RICHARD. Right after I was diagnosed? It was probably my Nana, because she has Type 2, so she was always just like there, and she knew exactly what was happening, how to calm me down, tell me everything was going to be okay. She was probably my closest person after I was diagnosed.

Senator CASEY. We are happy to hear that, and I am sure you serve in that role for a lot of people today, so thank you.

I know in the interest of time I will cut my questions short and move forward.

The CHAIRMAN. Thank you very much for all of the work that you have done, Senator Casey.

I also want to salute Senator Jeanne Shaheen for all of her work. She is unable to come back. She has a granddaughter with Type 1, and she and I have worked as a bipartisan team because diabetes does not discriminate. It does not care if you are a Republican or a Democrat or an Independent or Green or whatever, and that is why this should continue to be a bipartisan cause, and it always has been. I have always had a Democrat as my Co-Chair of the Diabetes Caucus since I founded it back in 1997, and I am pleased to have Senator Casey as a strong member of it as well.

I want to thank each of our witnesses for being here today. It is thrilling to have Victor Garber here to tell us what it is like to grow older with Type 1 diabetes, and his example is really encouraging to all of us.

The work that is being done at NIH and Dr. Rodgers' longstanding commitment and working so closely with us on the Special Diabetes Program has been wonderful.

Dr. Kowalski, I think it is wonderful that JDRF now has a president and CEO who understands firsthand the challenges of Type 1 diabetes. You have had excellent leaders in the past as well, but we are delighted to work with you.

Of course, most of all, I want to thank all of the delegates who are here today, but especially Ruby and Adriana, who are so articulate and, you are right, Senator Casey, I cannot imagine at their ages being able to come before a Senate Committee and testify and help us better understand.

I also want to do a shout-out to some families in Maine who have really educated me on this issue. I believe that I first met Ruby and her mom through the Sweeney family, and I have watched their son, Aidan, grow up from age 4 to now he is 17. He testified at age 4 before one of the Children's Congress, and they are great advocates.

The Seer family, who have a summer cottage very close to mine, have three members of their family with Type 1 diabetes.

Now, as I mentioned, my new niece, Nicole Wiesendunger, also is a tremendous advocate for people who Type 1.

I mention these families—and there are so many more—because I want all the delegates who are here from across the Nation to know what a difference your advocacy makes. You are the reason that we could get more than 60 Members of the Senate to sign the letter on the Special Diabetes Program. You are the reason that we were successful in getting an extension in Committee for 5 years. You are the reason that we have been able to invest billions of dollars in research that has made such a difference in your lives and will continue to make a difference in the lives of others, but we could not do it without you, and I am inspired by that sea of blue that is out there, so when you go forth today and you visit your Members of Congress, tell them what it is like to have diabetes, but also give them a little nudge to help us on the research and on renewing the Special Diabetes Program, because, believe me, it is really hard for them to say no to you, and I am sure that you will all make a huge difference. You touch me every time that you are here, and you help me redouble my own commitment to finding more effective treatments, a cause of diabetes so that we can prevent it, and the many causes most likely, and ultimately a cure, and that day we will have the big party that Ruby has mentioned, but again, be encouraged because the difference between 1997 and 2019 is absolutely enormous, so we are making good progress.

I want to thank all of you for being here today, and I want to also thank my staff, which worked extremely hard on this hearing, and also the people at JDRF who were wonderful in cooperating with us and bringing all these children from all over America to Washington, so I know that this sea of blue is going to take over the halls of Congress today, and that will bring us closer to the dream that we all share, and that is an end to diabetes.

Committee members will have until Friday, July 19th, to submit additional questions for the record. There may be a few, and we will pass them on your way, but again, I thank you and I now yield to Senator Casey.

Senator CASEY. Thank you, Chairman Collins, for both convening this hearing and for your great advocacy on this issue for so many years. We want to thank our witnesses, both doctors. Mr. Garber, we want to thank you in particular for bringing your personal story and in particular the story about your mom and to refer back to the two words you used, the fear and desperation that you saw that day is something that we all need to be reminded of, and I think because of the advancements, because of the work that you and others have done, a lot of moms may not have that same fear and desperation. We are grateful for that inspiration.

To Ruby and Adriana, you have got a bright future, and as I said before, we are going to put you in charge of some other projects while you are here. We have got to get things moving in the Senate, so we will give you that assignment later.

I want to thank the delegates from JDRF. In particular—and I did not do this earlier. This is my failing because my colleagues were doing it about when they introduced members from their States, so I want to ask Joey, Libby, and Mairead to put your hands up, if I can see them.

The CHAIRMAN. Over there.

Senator CASEY. Oh, great. Thank you. Thanks for doing that. I should have done that earlier.

We know that for our witnesses, especially the younger witnesses, it is challenging to testify before Congress, and we are grateful that you did this, and you are certainly equal to any of the witnesses we have invited to testify on any hearing.

I also know that you will have a successful day ahead of you. As Senator Collins said, it is much more compelling and persuasive when you appear at the doorway of a Member of Congress than when one of us is appearing as a colleague, and you will be able to make the case about the importance, the urgent importance of reauthorizing the Special Diabetes Program and also making sure that we make the case to get it through both chambers and to get it signed into law.

We look forward to working with you on that reauthorization, continuing the support that we will provide on investing in research and addressing the rising cost of insulin, and we are grateful for your presence today.

Thank you very much.

The CHAIRMAN. Thank you.

Senator Blumenthal has just arrived. Obviously, we are about to adjourn the hearing, and we are halfway through the vote, so if you could ask one question quickly, that would be great.

Senator BLUMENTHAL. You know, I will skip my questions. I will submit them for the record.

I just want to thank you, Madam Chairwoman and Ranking Member Casey, for having this hearing. Again, most important, I thank everyone who is attending this absolutely packed room, which is very inspiring—believe me, very inspiring. I was here earlier, and I have had various other Committee meetings, including Armed Services, but I just want to State my unequivocal support for this measure and also for efforts to reduce the costs of insulin. This astronomically rising cost of a life or death medicine is reprehensible. It is a disgrace for this country that we cannot act more quickly and effectively, and in the presence of so many young people who are so inspiring to us, I think you have given us the impetus to try to do more and do it better, so I thank you all for being here today, and I particularly want to thank members of the Connecticut delegation, Logan Merwin and Emma DelVecchio, and all of the advocates and activists who are here today. When people say to me or ask me what can we do to improve the State of our democracy, they should come and see this kind of showing this morning.

Thank you very much.

The CHAIRMAN. Thank you very much, Senator. Thank you.

I note the delegates are getting tired and the vote is on. The photographer has asked that we come down and get a couple of photos with the sea of blue, and so we are going to do that, but this hearing is now adjourned. Thank you so much.

[Whereupon, at 11:13 a.m., the Committee was adjourned.]

APPENDIX

Prepared Witness Statements

Testimony
Before the
Special Committee on Aging
United States Senate

"Redefining Reality: How the Special Diabetes Program is Changing the Lives of Americans with Type 1 Diabetes"

Statement of
Griffin P. Rodgers, M.D., M.A.C.P.
Director
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
U.S. Department of Health and Human Services

National Institutes of Health

For Release on Delivery
Expected at 9:30 a.m.
Wednesday, July 10, 2019

Chairman Collins, Ranking Member Casey, and distinguished Members of the Committee, thank you for your invitation to testify at this hearing on type 1 diabetes. I am Griffin P. Rodgers, M.D., M.A.C.P., Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which is one of the 27 Institutes and Centers of the National Institutes of Health (NIH) within the U.S. Department of Health and Human Services (HHS). It is my great honor to be here today to tell you about some of the significant recent scientific progress and future research opportunities in type 1 diabetes and its complications, including research supported by the *Special Statutory Funding Program for Type 1 Diabetes Research* (*Special Diabetes Program*).

Diabetes takes an enormous personal and economic toll on our country, but we are making great strides in efforts to reduce that burden through the support of biomedical research. As such, NIH invests more than $1 billion a year in diabetes research, including studies on type 1 diabetes, type 2 diabetes, gestational diabetes, and diabetes complications; NIDDK supports the majority of diabetes research at NIH. The NIH investment includes funding from the *Special Diabetes Program*, which has enabled the agency to undertake challenges in type 1 diabetes beyond what we could support with our regular appropriations, and to conduct certain types of trials, like comparative effectiveness trials and trials of generic drugs, that were unlikely to have been conducted by the private sector. The NIH investment in combating type 1 diabetes has been complemented by the support and efforts of our research partners—academic institutions, the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and charitable and patient advocacy groups such as the JDRF, the American Diabetes Association (ADA), and the Leona M. and Harry B. Helmsley Charitable Trust.

Through the invaluable support of Congress, through collaborative and coordinated research efforts, through the hard work of our scientists, and through the dedication of our clinical research volunteers, we have made important progress toward our goals of understanding, preventing, treating, and ultimately curing type 1 diabetes.

ALLEVIATING THE BURDEN OF MANAGING TYPE 1 DIABETES

It is imperative that the research we support ultimately reach and benefit the public, so I am excited to share with you how our investments are paying off. As you know, management of type 1 diabetes is extremely burdensome. Because their pancreatic insulin-producing beta cells have been destroyed by the immune system, people with type 1 diabetes—or the parents of young children with the disease—must do the work of the lost beta cells by monitoring blood glucose levels and administering insulin. Since I last testified before this Committee 2 years ago, several new continuous glucose monitors (CGMs)—devices that automatically track blood glucose levels throughout the day and night—have been approved by the FDA. These include: the first CGM that does not require fingerstick calibration;[1] the first fully interoperable CGM designed to be used as part of an integrated system with other compatible medical devices and electronic interfaces, which also does not require fingerstick calibration;[2] and the first fully implantable CGM.[3] These devices not only make management easier today, but they are also key steps in the development of tomorrow's technologies. I am pleased to report that NIDDK-

[1] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577890.htm
[2] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm602870.htm
[3] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611454.htm

or *Special Diabetes Program*-supported research contributed to the development or testing of each of these devices.

We are also supporting other promising research that could help alleviate the burden of managing type 1 diabetes. For example, an NIDDK-supported small business is developing an improved formulation of glucagon, which is a hormone that raises blood glucose levels (as opposed to insulin, which lowers them). People with type 1 diabetes may need to administer glucagon in an emergency when their blood glucose levels fall dangerously low. Currently, glucagon is available in powder form and must be mixed with liquid right before use. But a new, soluble, stable glucagon formulation under development would be ready-to-use in a rescue pen. Such a device could make it less burdensome for patients and caregivers, such as school personnel, to administer glucagon in an emergency.

DEVELOPING BETTER TECHNOLOGIES TO IMPROVE GLUCOSE CONTROL

While we are extremely excited about this progress, we recognize that there is still work to do to reduce the burden of the disease. Despite these advances in technology, the children here today and people of all ages with type 1 diabetes remain susceptible to dangerous and frightening episodes of hypoglycemia (low blood glucose) and to developing long-term complications that affect their eyes, kidneys, nerves, heart, and other organs. The NIDDK's landmark Diabetes Control and Complications Trial (DCCT) and its follow-up study, the Epidemiology of Diabetes Interventions and Complications (EDIC), demonstrated that intensive blood glucose control, beginning as soon as possible after diagnosis, prevented or delayed the development of these long-term complications. Decades of research through DCCT/EDIC has shown that people with type 1 diabetes can dramatically increase their likelihood of living longer, healthier lives by practicing early, intensive blood glucose management.

The challenge is that intensive blood glucose control is difficult to achieve and maintain. Data from the SEARCH [4]for Diabetes in Youth study, co-led by CDC and NIDDK, reported that over 70 percent of adolescents with type 1 diabetes had hemoglobin A1c (HbA1c) levels—a measurement of blood glucose levels over time—over the recommended 7.5 percent level for that age group.[5] SEARCH data also showed that 17 percent of adolescents had HbA1c levels above 9.5 percent, putting them at dangerous risk for long-term complications.[6] These data emphasize the urgent need to continue to develop new approaches to improve glucose control, and NIDDK has invested significant resources provided by the *Special Diabetes Program* to develop glucose management technologies, including artificial pancreas systems. An artificial pancreas has three components: a glucose-sensing component that measures blood glucose levels and sends data to a computer; an insulin delivery device; and a computer that calculates the amount of insulin needed and instructs insulin delivery based on that calculation, thereby "closing the loop" between glucose sensing and insulin delivery. While research is continuing to show how artificial pancreas devices benefit patients, it is imperative that these devices allow people to live full lives and do activities that they enjoy, including exercise. *Special Diabetes Program*-supported scientists demonstrated that artificial pancreas use in adolescents with type 1

[4] https://www.searchfordiabetes.org/dspHome.cfm
[5] https://www.ncbi.nlm.nih.gov/pubmed/19394043
[6] https://www.ncbi.nlm.nih.gov/pubmed/19643434

diabetes improved blood glucose control and reduced hypoglycemia compared to usual care during extended vigorous outdoor exercise at a ski camp.[7]

NIDDK continues to build on recent successes and to support research at all stages to advance artificial pancreas technology. First, NIDDK is supporting clinical trials that are testing artificial pancreas technologies in larger groups, in wider age ranges, over longer periods of time, and in largely unrestricted conditions. Some of the trials are testing the cutting-edge CGMs that I mentioned earlier in my testimony. For example, some of these trials could advance the goal of having interoperable artificial pancreas components so that newly developed insulin pumps and glucose sensors could be paired with existing algorithms, making it easier and faster to develop next-generation artificial pancreas systems. Additionally, one of the trials is testing artificial pancreas technologies in children potentially as young as 4 years old, which could expand the user population for this technology; the commercially available hybrid artificial pancreas is approved in children ages 7 and older.

Second, NIDDK continues to support research conducted by small businesses to develop innovative technologies to improve the components of artificial pancreas devices. With *Special Diabetes Program* support, small businesses are developing improved glucose sensors, insulin pumps, and formulations of insulin and glucagon, including the glucagon formulation I described earlier. Improved components could help speed the development of more fully automated artificial pancreas technology and make the devices simpler and more user friendly.

Third, NIDDK recognizes that new tools and technologies for type 1 diabetes management will only benefit people if they can use them. Therefore, we also support research to identify the most effective ways to incorporate artificial pancreas technologies into clinical care and how to enhance the usability of these new tools to help patients in their decision making. This includes *Special Diabetes Program*-supported research that is studying glucose management technologies in adults ages 65 years or older, to improve glucose control, quality of life, and the health of older people with type 1 diabetes, as well as research developing an artificial pancreas system that is customized to the individual needs of pregnant women. Such research illustrates an important and unique aspect of artificial pancreas research supported by the *Special Diabetes Program*: we are encouraging research in populations that are understudied by industry, such as children and adolescents, older adults, pregnant women, people with poorly controlled blood glucose levels, and people who suffer from frequent, severe episodes of hypoglycemia or who are unaware when their blood glucose levels fall dangerously low. These populations could benefit from artificial pancreas technologies, so we are placing a high priority on supporting research studying the devices in these special populations.

Through these research efforts largely supported by the *Special Diabetes Program*, we are striving to reach our goal of developing multiple different artificial pancreas technologies for people of all ages, so that all people with type 1 diabetes, their caregivers, and their healthcare providers can choose the technology best suited to their needs.

RESTORING BETA CELL FUNCTION

[7] https://www.ncbi.nlm.nih.gov/pubmed/28855239

Artificial pancreas technology represents an important and near-term approach to managing type 1 diabetes, but it is not a cure. Thus, a major, longer-term aim of our research is to identify ways to replace lost beta cells and thereby restore insulin production—a biological cure for the disease. A critical research effort making progress toward this goal is NIDDK's Human Islet Research Network (HIRN), which receives support from the *Special Diabetes Program*. HIRN is conducting multiple avenues of research to better understand how beta cells are lost in type 1 diabetes and to identify strategies to protect or replace them in people. This includes research to replicate any remaining beta cells or to coax other cell types, such as glucagon-producing alpha cells, into becoming beta cells.

HIRN has been on the leading edge of capitalizing on novel technologies that are allowing us to gain unprecedented insights into the pancreas at a single-cell level. Historically, many biological experiments have been performed on groups of cells, assuming that all cells of a particular "type" are identical. However, we are learning that individual cells within a population may differ dramatically, and these differences can have important consequences in health and disease. In recent studies, HIRN scientists utilized a novel technology, called imaging mass cytometry, to visualize individual beta cells and other pancreatic cell types, as well as immune cells involved in the autoimmune attack, simultaneously in a pancreas.[8] A surprising finding was that some people newly diagnosed with type 1 diabetes had a similar proportion of beta cells in their pancreas as those without disease, suggesting that even at disease onset when people need to take insulin, their pancreas may still have high numbers of beta cells. This finding indicates that there may be a window of opportunity to protect or replicate these cells. Using this novel technology to characterize individual cells and their interactions in the pancreas could lead to a new understanding of how type 1 diabetes progresses and help to inform the development of new therapies to prevent or treat the disease.

HIRN researchers are also developing an exciting new tool to advance the study of type 1 diabetes: islet chips. (Islets are clusters of beta cells and other cell types found in the pancreas.) These chips are tiny, bioengineered three-dimensional models that support survival and function of human islets in the laboratory setting. These microenvironments incorporate or mimic diverse elements that support islets in the body, such as blood vessels, and are therefore a better representation of human islet physiology than conventional two-dimensional islets grown on plastic dishes. These islet chips are also incorporating immune components and will enable HIRN researchers to study interactions between human beta cells and immune cells to mimic aspects of the autoimmune process involved in type 1 diabetes. They will also serve as a platform for testing novel type 1 diabetes therapies—potentially saving time and money in terms of identifying the most promising therapies to test in people.

Our efforts to develop new and improved approaches for cell replacement therapy have been informed by progress in islet transplantation. Researchers recently reported results from a follow-up study to a Phase 3 trial conducted by the Clinical Islet Transplantation Consortium, which is co-led by NIDDK and the National Institute of Allergy and Infectious Diseases (NIAID), and which tested islet transplantation in people with type 1 diabetes who had persistent impaired awareness of hypoglycemia and frequent severe hypoglycemia events despite expert care. Islet transplant recipients not only reported a decrease in diabetes-related concerns and

[8] https://www.ncbi.nlm.nih.gov/pubmed/30713109; https://www.ncbi.nlm.nih.gov/pubmed/30713110

fears, but also felt better overall, despite the need to take daily immunosuppressive drugs to prevent transplant rejection.[9] These patient-reported outcomes are consistent with the clinical benefits that the trial participants achieved after undergoing islet transplantation.[10] The NIDDK plans to build on progress and continue its strong support of research to find ways to protect or replace beta cells toward curing type 1 diabetes.

UNDERSTANDING THE CAUSES OF TYPE 1 DIABETES TOWARD DISEASE PREVENTION

We are also pursuing research to understand the causes of type 1 diabetes so that we can identify prevention strategies and alleviate the burden of this disease in future generations. For example, we have made significant progress in understanding the genetic contributors to type 1 diabetes: because of NIDDK's Type 1 Diabetes Genetics Consortium and other groups, we know over 50 genes or genetic regions that affect disease risk, representing about 90 percent of the genetic contributors in the White population who have the highest prevalence of the disease. Building on this success, NIDDK is supporting research to understand the function of identified genetic regions to determine how they may influence disease development, which could lead to prevention or treatment targets.

Environmental factors also play a role in type 1 diabetes, though the specific factors responsible have not yet been identified conclusively. The role of environmental factors is underscored by data from the SEARCH study, which has found that the rate of new diagnosed cases of type 1 diabetes is increasing among youth in the United States. SEARCH has also shown that, although type 1 diabetes has historically affected primarily non-Hispanic White youth, the disease is an increasing burden for minorities, such as Hispanic and African American youth considered to be at lower genetic risk. These rising rates of type 1 diabetes suggest that there is an unknown factor—or factors—in the environment that may interact with genetic risk to trigger type 1 diabetes onset. Identifying causative or protective factors—such as an infectious agent, dietary components, or some other factor—is critical to understanding the disease process and to developing prevention strategies.

Toward these goals, NIDDK, through the *Special Diabetes Program*, supports an ambitious, long-term clinical research study called The Environmental Determinants of Diabetes in the Young, or TEDDY. After screening over 425,000 newborns, TEDDY is currently following over 6,000 of them at high genetic risk of type 1 diabetes until they are 15 years old. The biological study samples that have been generously contributed by the dedicated TEDDY families are now being analyzed with genomic, metabolomic, proteomic, and other cutting-edge technologies. Important new insights are already beginning to emerge. TEDDY researchers found that vitamin D levels were lower in infancy and childhood in children who developed autoimmunity, a precursor to type 1 diabetes, and this was particularly true in children who had a specific genetic variant in the vitamin D receptor gene.[11] These results highlight how an environmental factor (vitamin D) interacts with an individual's genetic background (vitamin D receptor gene) to affect health and disease—highlighting the importance of both genetic and environmental factors.

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[9] https://www.ncbi.nlm.nih.gov/pubmed/29563196
[10] https://www.ncbi.nlm.nih.gov/pubmed/27208344
[11] https://www.ncbi.nlm.nih.gov/pubmed/29061729

Results from TEDDY are also providing insights into childhood health and development in general, specifically new details about how environmental factors affect the microbes in the gut (*i.e.*, the gut "microbiome") as children age.[12] In one of the largest-ever clinical microbiome studies in infants and children, the researchers discovered that children's gut microbiome developed in three distinct phases: a developmental phase (3-14 months of age), a transitional phase (15-30 months of age) where the microbiome diversifies, and a stable phase (31-46 months of age) where the microbiome's composition is largely established. Breastfeeding—even partially—was found to play a crucial role in infants' gut microbiome development; probiotics, antibiotic use, and other factors also had an effect. Researchers also found a possible beneficial effect on risk for type 1 diabetes from bacteria that produce short-chain fatty acid molecules. These molecules are often made during fermentation of indigestible carbohydrates like fiber, and future research will be needed to determine whether these molecules or the bacteria that produce them protect against type 1 diabetes. These results from TEDDY are just the tip of the iceberg with respect to the findings that are expected to stem from this effort that has the potential to revolutionize our ability to prevent type 1 diabetes.

TESTING STRATEGIES TO PREVENT OR SLOW THE PROGRESSION OF TYPE 1 DIABETES

As we improve our understanding of the underlying causes of type 1 diabetes through efforts such as TEDDY and research on the function of risk genes, NIDDK's Type 1 Diabetes TrialNet is uniquely positioned to test new and emerging prevention strategies. TrialNet is a large, collaborative international consortium for clinical trials of therapies to delay or prevent type 1 diabetes progression. TrialNet also supports research to understand the progression of type 1 diabetes and to identify people at risk for the disease.

Data from TrialNet, TEDDY, and other studies led to a paradigm shift in how the type 1 diabetes disease course is defined. We now know that the disease progresses through distinct stages, allowing identification of type 1 diabetes before symptoms appear. This knowledge makes it possible to conduct trials in early stage disease to try to prevent or slow disease progression before clinical onset. These prevention trials require screening thousands of people each year to identify those who are eligible to enroll, and we are extremely grateful for the dedication and enthusiasm of participating TrialNet families.

TrialNet collaborates closely with NIAID's Immune Tolerance Network (ITN) on trials in people with newly diagnosed type 1 diabetes; both TrialNet and ITN receive support from the *Special Diabetes Program*. These trials have had recent success in identifying agents that not only slow progression of the disease in those newly diagnosed, but also hold great promise as prevention strategies. For example, a recent TrialNet study showed that treatment with a medicine that suppresses the immune system, called anti-thymocyte globulin (ATG), preserved insulin production and improved blood glucose control for at least 2 years in people with newly diagnosed type 1 diabetes, as compared to placebo.[13] This finding opens up the possibility of testing ATG alone or in combination with other agents to see if it could prevent progression of type 1 diabetes earlier in the course of the disease.

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[12] https://www.ncbi.nlm.nih.gov/pubmed/30356187; https://www.ncbi.nlm.nih.gov/pubmed/30356183
[13] https://www.ncbi.nlm.nih.gov/pubmed/30967424

This concept of first testing agents in new-onset type 1 diabetes through TrialNet or ITN, and then testing them earlier in the disease course, has been a successful model for TrialNet operations. Two of TrialNet's ongoing three prevention trials are testing agents that were previously studied in people with newly diagnosed type 1 diabetes: abatacept and anti-CD3 monoclonal antibody. Results of the anti-CD3 trial were published last month in the *New England Journal of Medicine,* and we are excited about the promise of this therapy for preventing progression to clinical type 1 diabetes in high-risk individuals. In a third trial, TrialNet is testing a medicine, called hydroxychloroquine, that is already used to reduce symptoms and progression of other autoimmune diseases, such as lupus. We are enthusiastic about building on the results of recent TrialNet trials to advance our goal of identifying novel type 1 diabetes prevention strategies.

PREVENTING, TREATING, AND REVERSING DIABETIC COMPLICATIONS

Because of improvements in treatment and new technologies, people with type 1 diabetes are living longer than ever before, so it is more important than ever to pursue research on diabetes complications to improve their health as they age. NIDDK works closely with other NIH components to support research on devastating and often life-threatening diabetes complications.

Blindness is a debilitating and feared complication of diabetes. Research supported by the National Eye Institute's DRCR Retina Network, with *Special Diabetes Program* support, has changed the course of clinical practice over the last decade. Network studies were the first to demonstrate superior efficacy of anti-vascular endothelial growth factor (VEGF) drug therapy compared to laser for treating diabetic macular edema (DME), the most common cause of vision loss among people with diabetic eye disease in the United States. Results from these and other studies have led to changes in clinical practice guidelines for diabetic eye care, demonstrating the far-reaching impact of this Network. Importantly, many of these studies would not have been supported by industry, such as those that compared different drugs. Most recently, the Network demonstrated that people with good vision, despite having DME involving the center of the macula, can safely forego immediate treatment of their eye condition as long as they are closely monitored and treatment begins promptly if vision worsens.[14] This finding could save patients from unnecessary costs and risks associated with treatment, and adds to the Network's successful track record of conducting studies that are informing clinical practice and reaching the people who can benefit from them.

Recent research supported by NIDDK and the National Heart, Lung, and Blood Institute is shedding light on why people with type 1 diabetes have a higher risk for cardiovascular disease (CVD) compared to people with type 2 diabetes.[15] By analyzing biological samples from people who participated in the NIDDK's DCCT, as well as samples from people with type 2 diabetes, scientists found that poor blood glucose control was associated with cardiac autoimmunity—*i.e.*, the presence of at least two cardiac autoantibody types (signs of an autoimmune reaction)—in people with type 1 diabetes but not those with type 2 diabetes. People with type 1 diabetes who had cardiac autoimmunity also had a higher risk of both accelerated

[14] https://www.ncbi.nlm.nih.gov/pubmed/31037289
[15] https://www.ncbi.nlm.nih.gov/pubmed/30586738

atherosclerosis and CVD events. The cardiac autoantibodies developed decades before the CVD complications, suggesting that those autoantibodies may represent early biomarkers of CVD risk specifically in people with type 1 diabetes. It also suggests a role for autoimmune mechanisms, possibly through inflammatory pathways, in the development of CVD in people with type 1 diabetes. This result, along with DCCT/EDIC's demonstration that good blood glucose control reduces the risk of CVD, also underscores the importance of helping people with type 1 diabetes find ways to achieve and maintain good blood glucose levels.

The NIDDK is also bolstering research toward identifying new therapies for diabetic foot ulcers, a serious complication of diabetes that could lead to amputation. The Institute is supporting a new Diabetic Foot Consortium to validate biological markers for diabetic foot ulcers that could be used to predict healing outcomes, guide treatment decisions, and monitor healing and response to treatment. The long-term aim is to lay the foundation for a clinical trial network to test therapies that can improve healing and prevent amputations. Recent research supported by NIDDK and several other NIH components has also shed light on the underlying mechanisms associated with wound healing. Scientists discovered that a type of immune cell called a macrophage converts into another cell type to become part of healed skin—a process that is crucial for wound closure and that may be impaired in diabetic wound healing.[16]

The NIDDK, with funding from the *Special Diabetes Program*, is also supporting new research to understand the effects of type 1 diabetes on bone mass/quality and fracture risk. Results of this research could help identify strategies to mitigate excessive fracture risk observed in people with type 1 diabetes.

EMERGING OPPORTUNITIES IN TYPE 1 DIABETES RESEARCH

The scientific achievements that I have described today are just a few examples of the exciting progress in research on type 1 diabetes and its complications. With new and emerging technologies being applied to the study of type 1 diabetes, the knowledge being gained is unprecedented. Our efforts were significantly strengthened by the most recent renewal of the *Special Diabetes Program*, which enabled the NIH to continue many programs that I described in my testimony, allowing scientists to pursue their long-term research projects without interruption. The extension also enabled the NIH to launch new clinical trials and issue numerous new Funding Opportunity Announcements to support novel research areas, permitting us to capitalize on emerging opportunities in type 1 diabetes beyond what we could support with the regular appropriation. Responsibly administering the funds of the *Special Diabetes Program* and maximizing their value are among NIDDK's highest priorities.

We are committed to fostering scientific collaboration and resource sharing to maximize return on scientific research investments. The NIDDK places a high priority on providing access to research resources that could help elucidate the molecular underpinnings of type 1 diabetes and its complications. For example, biosamples and data from completed studies are available to the broad research community through the NIDDK Central Repositories; this valuable resource made possible the finding about CVD and type 1 diabetes that I described earlier.

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[16] https://www.ncbi.nlm.nih.gov/pubmed/29507336

We are also committed to extracting as much knowledge as possible from the large amounts of data that are being generated from *Special Diabetes Program*-supported research. For example, HIRN researchers are exploring machine learning and artificial intelligence approaches to data analysis. The software that HIRN is developing will be open-source and available for free, and will enable researchers to incorporate machine learning into their data analyses. Machine learning also holds promise for clinical applications, such as diagnosing diabetic eye disease. We are excited about the potential for using these state-of-the-art technologies to advance both research and clinical applications related to type 1 diabetes.

It is also critical to ensure that we foster and grow a diverse biomedical research workforce that can conduct future research in type 1 diabetes and its complications. Thus, we also support efforts such as career development programs for endocrinologists pursuing research careers and early stage investigator awards to attract exceptional new talent to HIRN. The purpose of such programs is to recruit and retain scientists with different areas of expertise whose talents will enhance the type 1 diabetes field.

Looking forward, the NIDDK, under the auspices of the statutorily required Diabetes Mellitus Interagency Coordinating Committee, solicited input from scientific and lay experts about future research directions in type 1 diabetes and its complications at a workshop held this past May.[17] Numerous opportunities emerged at that meeting that would capitalize on the significant progress to date and move us closer to our goals of understanding, preventing, treating, and ultimately curing type 1 diabetes. Additionally, NIDDK support of type 1 diabetes research will continue to be guided by strategic planning efforts and input at scientific conferences and workshops. We are also mindful that our research must benefit people with or at risk for type 1 diabetes across the lifespan. As people with type 1 diabetes are living longer, NIDDK research will continue to respond to the changing needs of those affected.

In these multifaceted endeavors, we value our partners—other NIH Institutes, our sister HHS agencies, academic institutions, and charitable and patient advocacy groups like JDRF, the Helmsley Charitable Trust, and ADA. Together, our collaborative achievements are improving the lives of people with type 1 diabetes. Partnerships between NIDDK, FDA, and JDRF accelerated the development of artificial pancreas technologies; continued partnership will be critical to advance the field further.

It is worth noting that much of the research supported by the *Special Diabetes Program* goes beyond type 1 diabetes and benefits people with other diseases, such as type 2 diabetes and other autoimmune disease. For example, a *Special Diabetes Program*-supported finding in which scientists used the CRISPR-Cas9 gene editing approach to reprogram a type of human immune cell has the potential to be applied toward the development of new therapies for type 1 diabetes, other autoimmune diseases, and cancer.[18] In addition, CGM technologies are being used by people with type 2 diabetes, including in hospital settings. Many of the other advances I described in my testimony, such as the insights about childhood microbiome development in TEDDY and research on diabetes complications, could shed light on other diseases.

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[17] https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/diabetes-mellitus-interagency-coordinating-committee-dmicc/meeting-agendas-summaries-presentations

[18] https://www.ncbi.nlm.nih.gov/pubmed/29995861

CONCLUDING REMARKS

I appreciate this opportunity to share with you these exciting scientific advances, ongoing efforts, and emerging opportunities in type 1 diabetes research. We are extremely grateful for the continued support of Congress that has allowed NIH to vigorously support research to combat type 1 diabetes and its complications. We look forward to continuing our strong partnerships with patient advocacy groups, research institutions, and our sister federal agencies. We also thank our dedicated clinical study participants, without whom the clinical research I described today would not be possible. With the remarkable progress already achieved through support from the *Special Diabetes Program*—and the promise of future research—NIH remains steadfast in our goals of preventing, treating, and ultimately curing type 1 diabetes. With continued research, it is possible to imagine that people could lead a life free of the burden of type 1 diabetes and its complications.

Thank you Chairman Collins, Ranking Member Casey, and Members of the Committee. I will be pleased to answer any questions you may have.

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases

Dr. Griffin P. Rodgers was named Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)—one of the National Institutes of Health (NIH)—on April 1, 2007. He had served as NIDDK's Acting Director since March 2006 and had been the Institute's Deputy Director since January 2001. As the Director of NIDDK, Dr. Rodgers provides scientific leadership and manages a staff of more than 630 employees and a budget of nearly $2.03 billion.

Dr. Rodgers received his undergraduate, graduate, and medical degrees from Brown University in Providence, R.I. He performed his residency and chief residency in internal medicine at Barnes Hospital and the Washington University School of Medicine in St. Louis. His fellowship training in hematology was in a joint program of the NIH with George Washington University and the Washington Veterans Administration Medical Center. In addition to his medical and research training, he earned an MBA, with a focus on the business of medicine/science, from Johns Hopkins University in 2005.

As a research investigator, Dr. Rodgers is widely recognized for his contributions to the development of the first effective—and now FDA approved—therapy for sickle cell anemia. He was a principal investigator in clinical trials to develop therapy for patients with sickle cell disease and also performed basic research that focused on understanding the molecular basis of how certain drugs induce gamma-globin gene expression. More recently, he and his collaborators have reported on a modified blood stem-cell transplant regimen that is highly effective in reversing sickle cell disease in adults and is associated with relatively low toxicity. He has been honored for his research with numerous awards including the 1998 Richard and Hinda Rosenthal Foundation Award, the 2000 Arthur S. Flemming Award, the Legacy of Leadership Award in 2002, and a Mastership from the American College of Physicians in 2005. In 2018 Dr. Rodgers was elected as a fellow to the American Association for the Advancement of Science and the Royal College of Physicians (London).

Dr. Rodgers has been an invited professor at medical schools and hospitals both nationally and internationally. He has been honored with many named lectureships at American medical centers and has published over 250 original research articles, reviews, and book chapters, has edited four books and monographs, and holds three patents.

Dr. Rodgers is a member of the American Society of Hematology, the American Society of Clinical Investigation, the Association of American Physicians, the American Academy of Arts and Sciences, and the National Academy of Medicine, among others. He served as Governor to the American College of Physicians, as Chair of the Hematology Subspecialty Board, and as a member of the American Board of Internal Medicine Board of Directors.

Dr. Rodgers serves as a chair, co-chair, and member of numerous high-level trans-NIH and HHS scientific and administrative committees. He is chair of the NIH Nutrition Research Task Force, co-chair of the NIH Obesity Research Task Force, and serves on the Executive Committee leading the Accelerating Medicines Partnership. He also co-leads the Illuminating the Druggable Genome program of the NIH Common Fund, and is a member of the NIH Steering Committee, NIH-Food and Drug Administration (FDA) Joint Leadership Council, and NIH-Centers for Medicare & Medicaid Services (CMS) Leadership Council, among others.

Testimony by

Aaron J. Kowalski, Ph.D.

President & CEO, JDRF

At the Hearing entitled:

"Redefining Reality: How the Special Diabetes Program is Changing the Lives of Americans with Type 1 Diabetes"

Wednesday, July 10, 2019, at 9:30 a.m.

Before the

United States Senate Special Committee on Aging

Dirksen Senate Office Building, Room 106

Washington, D.C.

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Introduction

Chairman Collins, Ranking Member Casey, and Members of the Committee, thank you for welcoming all of these delegates who are in the nation's capital for the JDRF Children's Congress, and for giving me the opportunity to testify before you today.

All of the delegates sitting before you live with type 1 diabetes, or T1D, a disease caused by an autoimmune response that damages the cells that make insulin. I too live with type 1 diabetes, and have since the age of 13. So does my brother Stephen, who was diagnosed back in 1977 at the age of 3.

Before the discovery of insulin in the early 1920s, type 1 diabetes was universally fatal. Its discovery saved millions of lives; however, insulin is not a cure. Type 1 diabetes requires constant management, 24 hours a day, 7 days a week, 365 days a year, to avoid dangerous high and low blood sugars and devastating complications.

Diabetes impacts every aspect of life. These children do so much hard work to manage their diabetes – they are truly amazing and their parents are too. Each of these families can share countless stories about how difficult T1D can be, as can mine.

Special Diabetes Program Making a Tremendous Difference

But we can also tell you that today, we can better manage this disease and live healthier lives than ever before, because of research funded by the Special Diabetes Program – due to your leadership.

On behalf of all of us, I want to thank you. The Special Diabetes Program (SDP) is making a tremendous difference in our lives and in our hopes for the future. Your strong bipartisan support for the SDP has led to numerous research breakthroughs, transforming lives and bringing us closer to our ultimate goal of curing this disease.

I am a scientist by training and have spent the last 15 years at JDRF, the world's largest charitable funder of T1D research, becoming its President and CEO in April.

In my time at JDRF, I've seen firsthand how the combination of federal diabetes research funding and JDRF's private investment constitutes one of the most effective public-private partnerships focused on curing a chronic disease.

Allow me to share some of the highlights.

Progress in Artificial Pancreas Systems

Just last month, exciting clinical results were released showing that a new artificial pancreas system which both doses and withholds insulin at appropriate times helped people with T1D maintain more consistent, and healthier, blood glucose levels. The clinical study, supported by the SDP, found that the advanced hybrid closed-loop technology resulted in more time in range – fewer highs and fewer lows – with no severe hypoglycemic events, normalized overnight glucose levels, and importantly, less burden for people with T1D.[1]

Also in recent months, the U.S. Food and Drug Administration has approved the first continuous glucose monitor (CGM)[2] and insulin pump[3] that can work interoperably, and needed software is not far behind. This will create the opportunity for people with diabetes to select the component devices of their system, tapping into tremendous innovation without having to put together a 'do it yourself' system.

This progress all builds on the success of the first artificial pancreas system which came on the market in 2017,[4] several years earlier than expected thanks to your leadership, Senator Collins, and innovative research supported by the SDP. This system was discussed extensively at a hearing in this Committee two years ago and has had a major positive impact for our community.[5]

Thus, thanks to the SDP, we will soon have access to multiple FDA approved artificial pancreas systems, enabling people with T1D and their doctors to *choose* the system that works best for them. This choice is critically important, because we know that people with diabetes achieve better outcomes when they can choose the tools that are right for them in managing their disease.[6] That's why at JDRF, while our goal is to cure T1D, we also are fighting for ways for people with T1D to stay healthy until that day. That entails supporting research to develop next-generation technology, strongly

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[1] Kwon, J, Brown A. "Tandem's Control-IQ System Increases Time in Range and Lowers A1C in People with Type 1 Diabetes", *diaTribe*, June 28, 2019. Accessed at https://diatribe.org/tandems-control-iq-system-increases-time-range-and-lowers-a1c-people-type-1-diabetes.

[2] U.S. Food and Drug Administration, "FDA authorizes first fully interoperable continuous glucose monitoring system, streamlines review pathway for similar devices," March 27, 2018. Accessed at https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-fully-interoperable-continuous-glucose-monitoring-system-streamlines-review.

[3] U.S. Food and Drug Administration, "FDA authorizes first interoperable insulin pump intended to allow patients to customize treatment through their individual diabetes management devices," February 14, 2019. Accessed at https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-interoperable-insulin-pump-intended-allow-patients-customize-treatment-through.

[4] U.S. Food and Drug Administration, "MiniMed 670G System", July 26, 2018. Accessed at https://www.fda.gov/medical-devices/recently-approved-devices/minimed-670g-system-p160017s031.

[5] U.S Senate Special Committee on Aging, "Progress Toward a Cure for Type I Diabetes: Research and the Artificial Pancreas" July 26, 2017 hearing. Accessed at https://www.aging.senate.gov/hearings/progress-toward-a-cure-for-type-i-diabetes-research-and-the-artificial-pancreas.

[6] American Association of Clinical Endocrinologists and American Association of Diabetes Educators to UnitedHealthcare, May 23, 2019. Accessed at https://www.diabeteseducator.org/docs/default-source/advocacy/provider-letter-to-uhc-ceo--aace-aade.pdf?sfvrsn=2.

advocating for affordable insulin and other diabetes management tools, and adamantly opposing health plan policies that limit choice.

Progress in Immunotherapies

Another promising area of research that has been advanced by funding from the SDP and JDRF involves the use of immunotherapies to delay or prevent the onset of T1D. Last month, the clinical trial network, TrialNet, published results in the *New England Journal of Medicine* that found the immunotherapy drug teplizumab can delay the onset of T1D for an average of two years in children and adults.[7]

I cannot emphasize enough how important this finding is.

Every day without T1D matters. A delay in onset is likely to have long-term benefits for glycemic control, and the reduction in acute and long-term complications would have a tremendous impact on the daily lives of our community and to our overall health system.

Moreover, this study raises the possibility that in the future targeted immunotherapies could mitigate or even cure T1D. While this study was a phase 2, not a phase 3 trial, it shines the light on a promising potential pathway.

This progress is thanks to your leadership and Congress' foresight to invest in multi-year funding for SDP research.

Progress in Eye Therapies

When I was first diagnosed with T1D 35 years ago, vision loss was almost a given in T1D.

Today, thanks to the SDP, and investments by JDRF and the private sector, there are multiple therapies available to help preserve and even improve sight. These advances make the difference between being able to see well enough to drive – or not.

The SDP also filled a critical research gap by funding a comparison of three drugs for the treatment of diabetes-related eye disease.[8] The results help patients, clinicians, insurers and policymakers make better informed decisions about targeted treatment. This comparison likely would not have happened in the private sector.

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[7] Herold, K, Bundy, B, Long, S, Bluestone, J, "An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes", *NEJM*, June 9, 2019. Accessed at https://www.nejm.org/doi/10.1056/NEJMoa1902226.

[8] **The Diabetic Retinopathy** Clinical Research Network, "Aflibercept, Bevacizumab, or Ranibizumab for Diabetic Macular Edema" N Engl J Med 2015; 372:1193-1203. Accessed at https://www.nejm.org/doi/10.1056/NEJMoa1414264.

More Work to Be Done

Yet, while these developments have altered the science of T1D, and reduced the burden of the disease so that people have better outcomes, we are here today because there is still important work to be done.

The Special Diabetes Program must continue to invest in innovative immunotherapy and beta cell research, our most promising cures pathways. To make progress towards curing T1D, we need to understand why the immune system goes awry, and how we can eliminate these immune attacks. Unlocking these answers would have implications across numerous diseases, from multiple sclerosis and rheumatoid arthritis to cancer. At the same time, we need to test additional novel approaches to prevent or slow the onset of T1D in those most at-risk to develop it.

We need to capitalize on the amazing scientific promise in beta cell therapies. Thanks to the SDP, the Human Islet Research Network was established to organize collaborative research about beta cell regeneration and replacement. It is helping us better understand how beta cells, the cells in the body that produce insulin, are damaged in people with T1D so we can find strategies to protect or replace them and ultimately cure the disease.

We need to better understand the triggers for T1D. The Environmental Determinants of Diabetes in the Young study (TEDDY) 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 the onset of the disease.

This SDP-funded study is more than halfway to completion. Information on diet, infections, and other exposures is being analyzed from children who are progressing or now have full disease onset to help us understand what causes T1D so strategies can be developed to prevent it altogether. The extensive data gathered from this study will benefit research into other autoimmune diseases as well. It's crucial that we see this study to completion.

At the same time, we need to reduce the burden from kidney and heart disease.

Kidney disease is a life-threatening complication of T1D that creates a significant personal and economic burden. In 2015, end-stage renal disease cost Medicare $34 billion. If new therapies could lower ESRD rates by 50 percent, Medicare would save more than $51.6 billion in 10 years.[9]

A promising SDP-funded trial is testing whether a generic medication may halt or slow the progression of early kidney disease in people with T1D. This trial is yet another

[9] Winn, A, Skandari, R, O'Grady, M, and Huang, E. "Potential Medicare Savings of Reduced End Stage Renal Disease in Patients with Diabetes," February 2019. Unpublished white paper.

example of how the SDP is filling critical gaps as pharmaceutical companies have no incentive to test for new uses of a generic drug.

Heart disease is also a significant burden for people with diabetes. In 2014, 1.5 million people with diabetes were hospitalized for major cardiovascular disease.[10] Overall, people with diabetes face a twofold increase in heart disease compared to those without diabetes.[11] However, people with T1D face an even greater risk.[12]

Additional research is needed to evaluate implications for treatment, such as conducting studies to determine if certain drugs have protective effects against heart disease in people with T1D.

The Importance of Your Leadership

Together, this is just a snapshot of all the Special Diabetes Program is – and could be – doing to help Americans living with T1D. Senators, let me say that this research is too important to have an expiration date.

We know what happens when this funding is put on hold. In 2017, when the SDP renewal was delayed, there were real implications. Within the TrialNet clinical trial network, enrollment was postponed in a promising prevention trial. By the time funding was in place and enrollment began, some people who would have been eligible had since developed full onset T1D and could therefore no longer enroll.

With continuous funding, their diagnosis potentially could have been delayed. We cannot risk slowing the momentum we've gained, and allow this to happen again.

We are so grateful to all the Senators here today for their support of the SDP.

We are particularly grateful for the outstanding leadership of the Senate Diabetes Caucus Co-Chairs, Senators Collins and Shaheen, who championed a bipartisan letter in support of the SDP which 68 Senators sent to the Senate leadership in May.

We are very pleased that in June, S. 1895, the Lower Health Care Costs Act, was approved by the Senate Committee on Health, Education, Labor, and Pensions with a five year renewal of the SDP.

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[10] Centers for Disease Control and Prevention, "National Diabetes Statistics Report, 2017". Accessed at https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

[11] Sarwar N, Gao P, Seshasai SR, Gobin R, Kaptoge S, Di Angelantonio E, Ingelsson E, Lawlor DA, Selvin E, Stampfer M, Stehouwer CD, Lewington S, Pennells L, Thompson A, Sattar N, White IR, Ray KK, Danesh J. "Diabetes mellitus, fasting blood glucose concentration, and risk of vascular disease: a collaborative meta-analysis of 102 prospective studies." *Lancet*, 2010. Accessed at https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)60484-9/fulltext.

[12] de Ferranti, Sarah D et al. "Type 1 diabetes mellitus and cardiovascular disease: a scientific statement from the American Heart Association and American Diabetes Association." *Diabetes Care* vol. 37,10 (2014): 2843-63. Accessed at https://care.diabetesjournals.org/content/37/10/2843.article-info.

Conclusion

As you can see, the Special Diabetes Program is making a real difference in the lives of people with T1D.

We need Congress to enact a five year renewal of the program to keep researchers working, without interruption.

And, we need your continued leadership, so that when these children are my age, they can say they "used to have T1D".

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

Testimony of

Victor Garber

From

New York, New York

At the Hearing entitled:

"Redefining Reality: How the Special Diabetes Program is Changing the Lives of Americans with Type 1 Diabetes"

Wednesday, July 10, 2019, at 9:30 a.m.

Before the

United States Senate Special Committee on Aging

Dirksen Senate Office Building, Room 106

Washington, D.C.

Chairman Collins, Ranking Member Casey, and members of the Committee, thank you for inviting me to testify today. It's an honor to be here with delegates from the JDRF 2019 Children's Congress.

I was diagnosed with Type 1 Diabetes when I was 11 years old. It's been nearly 60 years, but I remember vividly that my diagnosis was a traumatic event for my family, and especially for my mother. I have a distinct memory of her standing on the porch as my father drove me to the doctor. The fear and desperation in her eyes remains an indelible image in my mind.

Whenever I meet the mother of someone with Type 1, I am brought back to that moment, to that confusion, panic, and uncertainty, which is why I am so determined to do everything I can to help find a cure for this disease. I am here today, with these amazing delegates, to implore you to keep supporting advances in Type 1 research, by supporting a long term renewal of the Special Diabetes Program.

After my diagnosis, I was kept in the hospital, where I learned to inject oranges with insulin syringes, until I was brave enough to try it on myself. My new, and confusing diet consisted of weighing food, on a small scale, and deciphering carbohydrate ratios, which I'm still guessing at today. In those days, we had to boil syringes to ensure sterility, and test blood sugar levels, with urine in a test tube. We've come a long way.

And as I adjusted to my new reality, I was determined that I would not be deterred from living the life I envisioned. When I was 16, I left home to pursue my show business dream. I was a folksinger, dishwasher, and played tiny parts on TV shows and movies. Hard enough for any teenager, but balancing blood sugars, with inexplicable highs and lows, making healthy food choices, getting proper rest, could take its toll. I can only say, that determination, and will, kept me from giving up.

Thanks in large part to the Special Diabetes Program, living with Type 1 Diabetes today is very different than back when I was a teenager. My access to amazing diabetes technology, like a continuous glucose monitor, that can be used with different types of insulin pumps, gives me constant information to help avoid blood sugar highs and lows, and I'm so fortunate to be able to afford insurance that allows me to choose the best insulin pump and glucose monitor for my specific lifestyle.

My anxiety level has decreased somewhat since those days. Living an erratic life in movies, television and theatre has become more manageable thanks to funding for the Special Diabetes Program which made all these things possible. However, it is imperative that Congress provides a long term renewal of the program, which will ensure that critical research can continue unimpeded and enable more life-changing breakthroughs for the children you see here today.

Finally, I would be remiss if I did not tell you how concerned I am about the skyrocketing cost of insulin. The idea that someone has to ration insulin in 2019, due to greed and avarice, is unconscionable. No mother in the U.S. should lose her son due to insulin

rationing, and no father should have to rely on buying insulin from Canada to keep his child alive. I am lucky to have good health insurance, but I am still paying far more than I should be, for the life-saving drug that I would die without. Senators, this is simply unacceptable. Dealing with Type 1 Diabetes is already hard enough. Chairman Collins, Ranking Member Casey, Senator Shaheen, and others of this committee, I want to thank you for addressing the insulin pricing issue head on, and beg you to keep up the fight to bring down these costs.

As you do, please keep up your commitment to the research, our community desperately needs to find a cure for Type 1 Diabetes. We need you to keep the momentum going by renewing the Special Diabetes Program before it expires at the end of September, and put it on stable funding for years to come. If you do that, you will make it easier for all these delegates to live their dreams and enable them to thrive without the fear of Type 1 Diabetes holding them back.

Thank you Chairman Collins, Ranking Member Casey and Members of the Committee for your support and your time today.

Testimony of

Ruby Anderson, age 9

From

Yarmouth, Maine

At the Hearing entitled:

"Redefining Reality: How the Special Diabetes Program is Changing the Lives of Americans with Type 1 Diabetes"

Wednesday, July 10, 2019, at 9:30 a.m.

Before the

United States Senate Special Committee on Aging

Dirksen Senate Office Building, Room 106

Washington, D.C.

Chairman Collins, Ranking Member Casey, Senators – thank you for inviting me to talk to you today.

My name is Ruby Anderson. I am 9 years old and just finished 3rd grade at Yarmouth Elementary School in Yarmouth, Maine.

I was diagnosed with type 1 diabetes (T1D) when I was almost two years old. I don't remember not having T1D.

But I am lucky because I have devices that help me manage my T1D.

I have been using an Omnipod insulin pump since I was about three years old. It has no tubes, which I like, and I don't have to take shots. But sometimes it hurts when I have to change my pod every three days.

I also have been using the Dexcom G6 continuous glucose monitor for over a year. I love it. Things have gotten a lot easier because now I can just check my numbers on my phone. My mom even lets me ride my bike to school because now she can see my numbers on her phone wherever she is.

Before the G6, I was checking my blood sugar up to 10 times a day. Now, I still have to prick my finger, but sometimes not for weeks.

But as great as my pump and G6 are, T1D is still really hard to manage.

I have to count carbohydrates in everything I eat and make sure I'm giving myself enough insulin to keep my blood sugar from going too high. If I give myself too much, I go low. Even if I do my very best, my numbers can still be way off and I won't feel good.

My G6 and pod sometimes alarm when I'm in class, at home doing homework, playing lacrosse with my friends, and swimming at the beach. It even went off one time on an airplane. That was awkward.

When it goes off, I have to stop and check my numbers. I'll have to eat or drink if I'm low or take more insulin if I'm high. My parents, my brother and sister, and my friends and teachers all help me if my numbers are too high or low.

I wish my diabetes would just disappear. And Senators, I don't want my brother or sister to get T1D.

We need more research to find a cure. We need even better devices. And we need to figure out what causes T1D so we can stop it.

All of the kids here at JDRF's Children's Congress need you to continue to support us.

When I grow up, I want to be a scientist – partly because T1D research is so important.

And if they haven't found a cure for diabetes by then, I will.

And when we have a cure, I'm going to have a party and invite everyone in the whole entire world. Senator Collins, you will be first on my list.

Thank you for listening and for all you do for kids like me.

Testimony of

Adriana Richard, age 16

From

Milton, Pennsylvania

At the Hearing entitled:

"Redefining Reality: How the Special Diabetes Program is Changing the Lives of Americans with Type 1 Diabetes"

Wednesday, July 10, 2019, at 9:30 a.m.

Before the

United States Senate Special Committee on Aging

Dirksen Senate Office Building, Room 106

Washington, D.C.

Chairman Collins, Ranking Member Casey, Senators – thank you for asking me to speak here today.

My name is Adriana Richard. I am 16 years old and from a small town in central Pennsylvania called Milton.

I'm a proud member of the JDRF Central Pennsylvania Teen Task Force. Last year, we raised over $10,000 with our JDRF One Walk team.

I wrote a book – "The Real T1D" – and started an Instagram account to share my T1D story because I'm one of many living with diabetes every day. I'm not the only one going through this.

I go to diabetes camp most summers – it's my favorite time of year because I'm not judged and I can be myself.

I am here today to share my voice as an advocate for people with T1D because I have been motivated by the struggles I have experienced.

See, I was diagnosed with type 1 diabetes when I was five years old. All I remember from my diagnosis was that my parents were scared for me. I am the oldest of four kids, and the only one in my family with diabetes.

In elementary school, I was sometimes teased for being different or for always being with the nurse. School is already a stressful environment and having diabetes only makes it more difficult.

I've gone through some hard times.

A few years ago, I was having really "bad lows" – which means my blood sugar was getting dangerously low. But the thing is: I didn't know it. I felt fine. I also had really bad highs. In fact, one especially bad time I had DKA or diabetic ketoacidosis – and was hospitalized. I felt really sick and was in a lot of pain. DKA is very serious as it can lead to a coma or worse.

I was constantly battling diabetes and managing my everyday life with no breaks. I was physically and emotionally exhausted - and basically suffering from burnout.

Thankfully, I've been able to manage T1D better over the last year, primarily since I got my Dexcom CGM. It catches my highs and lows before they get bad, and I can check my levels on my phone. It also alerts my parents, which is a huge relief because sometimes I miss the alarms on my phone when I'm asleep.

Before, I had to check my levels right before going to bed and hope that I wouldn't get too low during the night. Now, I feel much better when I wake up in the morning.

My life with T1D is easier with this technology, which is thanks in part to funding from the Special Diabetes Program.

That is why I am here to ask you to support the SDP. It needs to be renewed.

We're so close to finding cures for diabetes and if we stop research now, there's no way we will ever find it. Until then, we need the SDP for research to help our everyday lives with T1D – to help scientists and engineers invent things like CGMs that have changed my life.

In fact, after Children's Congress, I will be taking the driver's test to get my license. I am excited and my parents are, too, knowing that my CGM will help me more easily manage my blood sugar levels while I focus on navigating the roads in Milton.

Senators, people with T1D can do anything we set our minds too -- we just have extra responsibilities.

The research funded by SDP helps people like me – all of us here today – handle those responsibilities, and will ultimately give us a cure.

And I'm grateful that as a resident of Pennsylvania the cost of my insulin is zero dollars because it's fully covered as a life-sustaining medicine under Medicaid. Thank you, Senator Casey, for your interest in expanding this program broadly so that kids with diabetes in other states may also benefit.

Thank you all for listening to my story, and for your support of people with T1D.

Statements for the Record

Opening Statement
Senator Susan M. Collins, Chairman
"Redefining Reality: How the Special Diabetes Program is Changing the Lives of Americans with Type 1 Diabetes"
July 10, 2019

Good morning everybody. It's wonderful to welcome all of you here to Washington D.C. This is our eleventh Children's Congress and it is always a privilege to work with JDRF families, whose commitment to promoting life-changing research to prevent, treat, and ultimately cure Type 1 diabetes inspires me.

I want to welcome not only our Ranking Member Senator Casey and Senator Scott from Florida, but also we have a special guest, and that is the co-chair of the Senate Diabetes Caucus, Senator Jeanne Shaheen of New Hampshire, so thank you for joining us here today as well. Let me shorten my opening comments this morning because we do have votes beginning at 11:00 and I want to make sure that we have time to hear from all of our witnesses.

As I said, I want to begin by welcoming the more than 160 children who have traveled to Washington from across the country to share your personal stories. You will tell us what it's like to live with Type 1 diabetes, just how serious it is, and why it is critical for Congress to fund the research necessary to discover better treatments, more effective technology, and, ultimately, a cure.

Your personal stories really matter. They motivate Senators and members of the House to get involved in the cause. In my case, one of my very first meetings as a brand new Senator was with Maine families with children with diabetes, and I'll never forget this 10-year-old little boy looking up at me, and he told me that he wished he could take just one day off from having diabetes-his birthday or Christmas-but of course he could not, and that really touched me and it led me to start the bipartisan Senate Diabetes Caucus.

I want to give a special welcome to the two delegates from Maine - Ruby Anderson from Yarmouth, who's going to be testifying, and Lydia Bryant from Ellsworth. I'm very proud that you are here representing our great state.

Since the last convening of the Children's Congress two years ago, we have made remarkable strides with new technological discoveries that are already changing lives for people with Type 1 diabetes. We celebrated the FDA approval of an artificial pancreas system for children ages 14 and older. Now the artificial pancreas is also available for kids who are ages 7 to 13, opening the door for better day-to-day management of diabetes.

Today's research represents tomorrow's cure. Just last month, a new study, the first of its kind, illustrated the potential of an immunotherapy drug to delay the onset of Type 1 diabetes by an average of two years. What a significant breakthrough.

These advances have only been possible due to our bipartisan commitment to funding diabetes research. Since I founded the bipartisan Senate Diabetes Caucus in 1997, federal funding 2 for diabetes research has tripled and these research dollars are yielding results. We now spend more than $1 billion on diabetes research.

The Special Diabetes Program, in particular, has contributed to phenomenal discoveries, especially advancements in technology. This program provides an additional $150 million each year for

T1D research, and another aim of this program is equally important: the Special Diabetes Program also studies diabetes in American Indians and Alaskan Natives, who experience Type 2 diabetes at nearly three times the rate of the national average, so the SDP is important both for people who have Type 1 and also for Native Americans and Alaskan Natives.

In total, over the past 22 years, the Special Diabetes Program has contributed $2.8 billion to improve the lives of people with diabetes.

By the end of September, we must pass legislation to reauthorize the Special Diabetes Program and that's what you need to tell all the members of Congress. It has strong bipartisan support, 68 Senators signed a letter to Senate leadership that Senator Shaheen and I authored advocating for this program. I am pleased to report to you that just last week the Senate Health Committee, on which I serve, approved a five year authorization of the SDP. That's the longest authorization ever, so that's really good news.

Finally, let me just say that I am very concerned about the spiraling cost of insulin. The cost of managing diabetes is growing at an alarming rate. Between 2012 and 2016, average insulin spending for patients with Type 1 diabetes nearly doubled. Last year, a father in Maine testified that he turned to drug importation from Canada after the price of a 90-day supply of insulin for his son with Type 1 tripled to $900.

I am going to put the rest of my statement in the record so that we can expedite the hearing, but let me just end by telling you two things. First, until last fall I had no personal connection at all with Type 1 diabetes. Then, my nephew married a young woman who has Type 1 diabetes and has her own blog, so I feel like I'm now officially a part of the JDRF family, and second, it is truly inspiring to look out and see this wave of Carolina blue. I did the best I could to come close to matching it, but your passion and hope for a cure are contagious, and together I am confident that we'll continue the progress and achieve that goal.

National Indian Health Board

TESTIMONY OF THE NATIONAL INDIAN HEALTH BOARD
Regarding the Hearing Entitled
"Redefining Reality: How the Special Diabetes Program is Changing the Lives of Americans with Type 1 Diabetes"
Senate Special Committee on Aging
July 10, 2019

Chairwoman Collins, Ranking Member Casey, and Members of the Senate Special Committee on Aging, thank you for the opportunity to offer testimony related to the hearing held on July 10, 2019, entitled "Redefining Reality: How the Special Diabetes Program is Changing the Lives of Americans with Type 1 Diabetes," and specifically, the Special Diabetes Program for Indians (SDPI). On behalf of the National Indian Health Board (NIHB) and the 573 federally recognized Tribes we serve, I submit this testimony for the record.

As part of the Balanced Budget Act of 1997, Congress established the Special Diabetes Program for Type 1 Diabetes (SDP) to address the serious limitations in Type 1 diabetes research resources and the Special Diabetes Program for Indians to address the growing epidemic of Type 2 diabetes in American Indian and Alaska Native (AI/AN) communities. Together, these programs have become the nation's most strategic, successful, and comprehensive effort to combat diabetes. SDP and SDPI are transforming lives and changing the diabetes landscape in America.

Today, SDPI is funded at a level of $150 million per year and supports 301 diabetes treatment and prevention programs in 36 states. With funding for this critical program set to expire on September 30, 2019, ***NIHB urges the Committee members to support long term renewal of SDP and SDPI, with a funding increase to $200 million for each program.***. SDPI has not had a funding increase since 2004, and in that time it has lost an astounding *37%* of its impact solely to medical inflation. The rising cost of insulin further reduces the program's impact if it remains flat funded. Long term renewal at $200 million per year will allow SDPI to generate continued measurable improvements in the prevention and treatment of diabetes and enhancement of the successful economic opportunities in Tribal communities.

The federal promise to provide Indian health services was made long ago.[1] Since the earliest days of the Republic, all branches of the federal government have acknowledged the nation's obligations to the Tribes and the unique trust relationship between the United States and Tribes. While the Indian Health Service (IHS) is the primary agency by which the federal government meets the trust responsibility for direct health services, the trust responsibility is shared by the entire federal government. Programs like SDPI play a vital role in fulfilling the promise this country made to the Tribes. This trust responsibility is as valid today as it was at the beginning of our Republic. By providing Tribes with the resources they need

[1] Based on treaties between Tribes and the United States for the exchange of peace and Tribal lands as well as United States Supreme Court cases and statutory acts, the Federal Trust responsibility is an absolute legal obligation under which the United States has the highest responsibility and trust to Indian Tribes. The Snyder Act of 1921 (25 USC 13) legislatively affirmed this trust responsibility. To facilitate upholding its responsibility, the federal government created the Indian Health Service (IHS) and tasked the agency with providing health services to AI/ANs.

to tackle one of the greatest health challenges, SDPI remains a critical piece of the federal government's efforts to fulfill that trust responsibility. Congress must renew the program before the end of Fiscal Year 2019.

NIHB appreciates the longstanding support from members of the Aging Committee, and from the entire Senate, for SDPI. The Senate Diabetes Caucus, chaired by Chairwoman Collins, sent a bipartisan letter in support of SDP and SDPI to Senate leadership. 68 Senators signed onto the letter, including ten members of the Aging Committee. A similar letter from the House Diabetes Caucus saw 379 Representatives sign on, 85% of that chamber! We are deeply appreciative of this bipartisan showing of support for a program that is saving lives and money.

If the Senate's legislation as it is currently written passes into law, SDP and SDPI will be renewed for five years, the longest renewal period in the programs' history. Grantees throughout Indian Country would have a sense of certainty and stability from Congress. Knowing what funding is available will allow for long term planning, improve decision making, and increase employee retention. We are thankful to see bipartisan support for the Senate's five-year renewal. However, the Senate legislation would flat fund the program at $150 million in annual spending. While this funding level has allowed for significant success in the past, an increase to $200 million would double down on that success by allowing more Tribes to access the program and ensuring that Tribal grantees are able to increase the impact of prevention and treatment efforts in their communities. NIHB therefore remains hopeful that legislation to that effect becomes law in 2019. In the House of Representatives, H.R. 2680, the Special Diabetes Programs for Indians Reauthorization Act of 2019, has bipartisan support for a five-year renewal at $200 million per year.

In many health indicators, AI/ANs rank at or near the bottom when compared to other demographic groups. The AI/AN life expectancy is 5.5 years less than the rate for the U.S. all races population. AI/ANs suffer disproportionally from a variety of diseases. According to IHS data from 2009-2011 (the latest year for which data is available), AI/AN people die at higher rates than other Americans from alcoholism (560% higher), kidney disease (50% higher), and diabetes (220% higher). Indian Country also suffers disproportionately from diagnosed diabetes at a rate 61% higher than the general U.S. population. In short, AI/ANs are more likely to have diabetes and more likely to die as a result. To make matters worse, the IHS, which is responsible for providing health care to 2.6 million AI/ANs, is severely underfunded. In 2017, IHS per capita spending was $4,078, as compared to $8,109 for Medicaid, $10,692 for the Veterans Health Administration, and $13,185 for Medicare.[2]

Chronic poverty, historical trauma, remote locations, and a devastatingly under-funded Indian health delivery system all contribute to these statistics. The United States is too great a nation to stand idly by while AI/ANs live with these realities.

The Special Diabetes Program for Indians – Data Shows Extraordinary Progress

According to the 2017 National Diabetes Statistics Report from the Centers for Disease Control and Prevention (CDC), AI/AN adults have the highest age-adjusted prevalence rate of diagnosed diabetes compared to other major racial and ethnic groups at **15.1 percent**. Some regions of Indian Country have

[2] Government Accountability Office Report. GAO-19-74R, Indian Health Service: Spending Levels and Characteristics of IHS and Three Other Federal Health Care Programs. December 10, 2018.

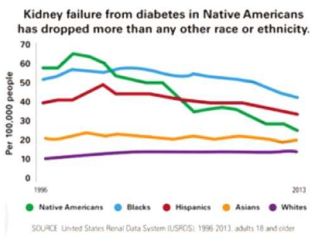
diabetes rates as high as 33.5 percent, with specific communities having Type 2 diabetes reach a level as high as 60 percent. It is also important to note that this disease is increasingly affecting young people, which is posing a significant threat to future generations of AI/ANs. Sadly, many young people in our communities believe that Type 2 diabetes is inevitably their future.

Fortunately, due to the important work funded by SDPI, this trend is starting to reverse. In communities receiving SDPI funds, the program has increased diabetes prevention and treatment services. These increased services have translated into remarkable improved health outcomes related to diabetes including:

- Between 1999 and 2013, the incident rate of end-stage renal disease (ESRD) due to diabetes in AI/AN people ***fell by 54%*** — a greater decline than for any other racial or ethnic group.[3]

- Average low-density lipoprotein (LDL) cholesterol, which is associated with multiple health problems, declined from 118mg/dL in 1998 to 92 mg/dL in 2014. Improved control of LDL cholesterol can reduce cardiovascular complications by 20-50 percent

- 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.[4] Every percentage drop in A1C results can reduce risk of eye, kidney, and nerve complications by 40 percent.



In addition to this data, SDPI has resulted in many positive, macro-level, changes for Tribal communities receiving SDPI funds. More than 80 percent of SDPI grant programs now use recommended public health strategies to provide diabetes prevention activities for AI/AN children and youth. This represents a 73% increase in primary prevention and a 56% increase in weight management activities targeting children and youth. Additionally, communities with SDPI-funded programs have seen a 57% increase in nutrition services, a 72% increase in community walking and running programs, and a 65% increase in adult weight management programs.

SDPI is a success story in Indian Country for several reasons. First, and most importantly, the program is locally managed and focuses on approaches that are culturally relevant to each Tribal community. One grantee in Maine was able to purchase equipment to measure patients' weight, total body water, percent body fat, and other indicators of diabetes. Staff developed culturally and age-appropriate activities to encourage youth in the community to be measured. Because of SDPI's funding and flexibility, those clinic staff in Presque Isle, Maine, are now able determine which youth have a BMI equal or greater than the 85th percentile without having to refer them to a different provider. The community clinic can focus on youth that need additional screening for pre-diabetes/diabetes and culturally-tailored healthy eating and fitness education. This one improvement can help save the lives of youth in the Aroostook Band of Micmac Indians Tribe at risk for diabetes and leaves them feeling better equipped to make real, serious, and lasting lifestyle changes in keeping with their Tribe's cultural values.

[3] CDC Vital Signs October 2016
[4] IHS SDPI 2014 Report to Congress

Additionally, SDPI programs emphasize a holistic approach. For example, the Alaska Native Health Tribal Consortium's SDPI program focuses on several key areas, which include: providing direct patient care at the Alaska Native Medical Center and in field clinics around the state; maintaining a registry of all Alaska Native people with diabetes and those at high-risk for developing diabetes; and providing diabetes prevention and evidence-based treatment through community outreach events, programs, trainings, writings and continuing education.

A Strong Return on Federal Investment

In addition to the remarkable health outcomes of the SDPI program, it is also providing a strong return on federal investment by creating significant savings to the Indian Health Service, Medicare, Medicaid and other third party payers. As noted above, ESRD has decreased significantly in the AI/AN population resulting in additional savings for the treatment of patients through hemodialysis services. For every year a patient is kept off of dialysis, Medicare saves $88,000 per patient. A May 2019 report from the Health and Human Services Assistant Secretary of Planning and Evaluation concluded that the prevention and treatment activities at the Tribal level funded by ***SDPI saves Medicare up to $52 million every year!*** In short, SDPI saves lives and money.

These investments in Tribal communities mean that community health programs will be provided with long-term nutrition care and desperately needed health investments. In many areas, health jobs are limited, so SDPI is enabling these communities to increase employment and contributes to overall economic growth. SDPI is truly an exemplary public health program, and could serve as a model for other diabetes treatment and prevention programs throughout the country.

Type 2 diabetes – a preventable disease – remains an epidemic throughout Indian Country. But with SDPI, Tribes have made remarkable differences for thousands of individual patients that participate in the program. They have also transformed their communities thanks to SDPI. The program places emphasis on the health of the whole people, not only the individual. This has led to more community gardens, exercise activities and awareness of health issues. If Congress fails to renew SDP and SDPI, the loss of these funds would have devastating impacts for the health of AI/AN people. Further, the loss of this program would also mean increased costs for Medicare, IHS, and other government programs that treat individuals with complications due to diabetes.

NIHB urges the Senate to pass long term renewal for SDPI. With the tools provided by SDPI, young people across Indian Country will stop believing Type 2 diabetes is inevitable and will soon declare, "Diabetes is **not** my future."

Please do not hesitate to reach out to the National Indian Health Board if you have any questions. Thank you for your consideration of these matters.

Yours in Health,

Victoria Kitcheyan

Victoria Kitcheyan
Chairperson
National Indian Health Board

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