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PROGRESS TOWARD A CURE FOR TYPE I DIABETES: RESEARCH AND THE ARTIFICIAL PANCREAS

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JULY 26, 2017

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

The Committee met, pursuant to notice, at 9:30 a.m., in room SD–106, Dirksen Senate Office Building, Hon. Susan M. Collins (Chairman of the Committee) presiding.

Present: Senators Collins, Scott, Fischer, Casey, Gillibrand, Donnelly, Warren, and Cortez Masto.

Also present: Senator Shaheen.

OPENING STATEMENT OF SENATOR SUSAN M. COLLINS, CHAIRMAN

The CHAIRMAN. Good morning. What a wonderful sea of blue I see out there. Welcome.

I am delighted to convene this biennial hearing in conjunction with the JDRF 2017 Children's Congress to examine how Type 1 diabetes affects Americans of all ages. This is the tenth Children's Congress that the JDRF has held in Washington, DC, and it is the ninth that I have chaired. It is such a privilege to work with JDRF, whose commitment to finding a cure is unwavering.

Let me welcome our distinguished witnesses and the more than 160 delegates who have traveled here from every state in the Nation and from around the world to this year's Children's Congress. We are really glad to have you here.

[Applause.]

The CHAIRMAN. Thank you for coming to share your personal stories and to tell Members of Congress what it is like to live with diabetes, just how serious it is, and why it is so important that Congress fund the research necessary to discover better treatments and, ultimately, a cure.

I want to give a special shout-out to the two delegates from the great State of Maine: Charlie Albair of Gray, who we will hear from later, and Brady Chappell of Naples. I am so proud that you are here representing our state.

We also will be joined shortly by our colleague Senator Jeanne Shaheen, who joins me as the Co-Chair of the Senate Diabetes Caucus. She has been a strong advocate for those living with the disease, including her own granddaughter.

Since founding the Senate Diabetes Caucus 20 years ago, I have learned a lot about the difficulties and, at times, heartbreak that this disease causes for so many American families as we await a cure.

Diabetes is a lifelong condition. It does not discriminate. It affects people of every age, race, and nationality. It also takes a major financial toll. The devastating disease costs our country an estimated $240 billion a year—a cost that is skyrocketing and is projected to reach more than $490 billion by the year 2020. Treatment of diabetes accounts for one out of three Medicare dollars. In fact, medical costs for Americans with diabetes are more than double those incurred by individuals without diabetes.

The statistics are pretty overwhelming. But the burden is particularly heavy for individuals with Type 1 diabetes. Usually diagnosed in childhood or adolescence, Type 1 diabetes is a lifelong disease that, to date, one can never outgrow.

Thankfully, there is good news for people with diabetes. Since I first started the Diabetes Caucus, funding for diabetes research has more than tripled. It is now about $1 billion a year. As a result, we have seen encouraging developments in the management, treatment, and potential cures for Type 1 diabetes.

One program in particular at the National Institutes of Health has led to phenomenal discoveries, and that is the Special Diabetes Program. This critical program provides an extra $150 million a year for Type 1 diabetes research, and that is in addition to the regular NIH appropriation for diabetes research.

Last year, the Special Diabetes Program led to the development of the first-ever, FDA-approved artificial pancreas, which can control blood glucose levels automatically and will revolutionize diabetes care. So the Special Diabetes Program is changing the future of diabetes.

You know, when I first held these hearings, there was not even a very usable pump. Now we have a really small pump. How many of you wear a pump? Look at that. Wow.

Now, are any of you involved in the clinical trials for the artificial pancreas? All right. That is wonderful. Well, I think that that holds such great promise.

And today you will hear from some of our witnesses about how truly life-changing these innovative technologies can be. Other advances in technology, like continuous glucose monitors, are helping patients better control their blood glucose levels, and you know that that is key to preventing diabetes complications.

So what is our task? This year, we must pass legislation to extend the Special Diabetes Program because, otherwise, it will expire in September. Are you all on board with that?

[Applause.]

The CHAIRMAN. So the great news is due to the efforts that all of you have been making. Seventy-five senators signed a letter that I led in September urging that this federal investment continue. Seventy-five senators out of 100. You hardly get 75 senators to agree on anything nowadays.

[Applause.]

The CHAIRMAN. So with the continuation of this investment, we can see a future in which all the children who are here today can look forward to a better and brighter tomorrow.

It is so inspiring for both Senator Casey and me and for all those who will be joining us to look out and see that wave of Carolina Blue—each of you personally affected by diabetes. But let me just end by taking a moment to remember a personal hero—and we have put up her picture on the screen—who worked so passionately on behalf of all of you and testified year after year at the Children's Congresses in the past.

Mary Tyler Moore endured the ups and down of Type 1 diabetes for many years, but she did not complain. She focused her energy on finding better treatments and a cure to improve the lives of all of you. So we will honor Mary's legacy by continuing the work to which she committed so much of her life.

Again, thank you all for joining us from all over the country, and I am now very pleased to turn to our Ranking Member, Senator Casey, for his statement. Thank you.

[Applause.]

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

Senator CASEY. Let us hear it for Senator Collins, our Chairman.

[Applause.]

Senator CASEY. We do not get a chance to do that very often. I am grateful you participated in that. We do not do it enough, but we do want to thank Chairman Collins for having the hearing and also for her years and years of work on these issues. And we are grateful that you all are here to help us this year.

We are also pleased that we will have the Co-Chair of the Diabetes Caucus, Senator Shaheen, to participate in our hearing today. That is unusual, when you are not a member of a committee to be part of another committee hearing. So we are grateful that she is willing to spend that time and to do that work.

We are also pleased to have so many delegates here of the JDRF Children's Congress to help us in the Senate to get this message out and to work with us. It is so important that you have joined us today because finding a cure for Type 1 diabetes requires a combined effort from people of all ages and all backgrounds. Thanks to the delegates for advocating for the Special Diabetes Program.

Each of you, each delegate here will be more persuasive than I will be in making the case. That is why it is so important that you are here today. Please continue to tell elected officials, not only here in Washington but around the country in your own communities and your own states, why research funding matters.

Investing in research has led to the development of the artificial pancreas. Investing in research means a lot of you do not have to use needles to track your blood sugar levels. Investing in research also means that your diabetes has not stopped you from going to camp or playing outside at recess or riding a bike or doing so many other things. These are just a couple of examples of the success of the Special Diabetes Program and what can be accomplished when Congress fully funds our promise to fight Type 1 diabetes.

You are also here during an important debate about health care. So, in addition to telling those of us on the Committee and in Congress about the importance of this program, it is important to explain why health insurance matters, why Medicaid and CHIP are so important to you and your families.

We must ensure that people who have Type 1 diabetes are not denied care or asked to pay more for their care. That used to happen once in a while around here when people would make those arguments, but too often lately those arguments have not been made. We want to ensure that when you get older you can access care that is affordable as well.

The Senate health care bill, in my judgment, could lead to higher costs for individuals and families in this room.

I am pleased that our witnesses are here today with us.

In my case, because I represent the State of Pennsylvania, I am grateful to welcome Lorynn to the witness table and grateful for her testimony and also grateful that she is willing to share not only why research is so important, but why affordable care is as well. Max and Ryan—if you can put your hands up—are also Pennsylvania delegates. Thank you to Max and Ryan for being here as well.

So we look forward to hearing from Lorynn and the other witnesses. We are grateful that each of you is here to provide testimony. And I look forward to working with Chairman Collins and others to ensure that the Special Diabetes Program continues in 2018 and beyond. And I am convinced that together we can turn Type 1 into type none.

Thank you.

[Applause.]

The CHAIRMAN. Thank you very much, Senator Casey.

I also want to acknowledge the presence of Senator Fischer from Nebraska. Senator Warren and Senator Gillibrand from Massachusetts and New York will be back shortly.

And we now get to hear from the stars of the show, and that is our panel of witnesses. And it is appropriate that I use the word "star" because our first witness is actor Paul Sparks. Paul is known for his roles in the HBO series "Boardwalk Empire" as well as the Netflix series "House of Cards." And no—Washington really is not like that.

[Laughter.]

Mr. SPARKS. I did not think so.

The CHAIRMAN. I want to go on record.

[Laughter.]

The CHAIRMAN. Paul was diagnosed with Type 1 diabetes at the age of 28, and he has since been a powerful advocate for JDRF and for those with Type 1. And I think that is the starring role that he is probably most proud of.

Second, we will hear from Dr. Griffin Rodgers, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health. Dr. Rodgers has testified before us so many times, and I always look forward to hearing his update. I know how talented and committed that he is.

And, of course, I take special pleasure in welcoming our witness from the great State of Maine, Charlie Albair. Charlie is 10 years

old and was diagnosed with Type 1 at age 6. Nevertheless, be careful because he has a red belt in the martial arts. He also plays football, baseball, and basketball. He has been active in his community, raising awareness about what it is like to live with Type 1 diabetes.

I am now going to turn to our Ranking Member to introduce our witness from Pennsylvania.

Senator CASEY. Thanks very much, Chairman Collins. I was mentioning before that one of our witnesses is from Pennsylvania: Lorynn Watt. Lorynn is 17. She is a rising senior from Stroudsburg, Pennsylvania, up in northeastern Pennsylvania near where I live. And despite living with Type 1 diabetes since the time she was 9, Lorynn, like all of the delegates before us, has not let the disease slow her down or stop her from pursuing her goals.

Along with her regular academic work as a high school student, she is very involved in extracurricular activities. For example, in the upcoming school year, she will be directing the school play, participating in the Community Service Club, and serving on the Prom Committee. So that is a pretty busy schedule coming up.

Lorynn, thank you for making the time in your schedule to become active in JDRF and advocating here in Washington on behalf of your peers. We look forward to your testimony. Thank you.

The CHAIRMAN. Finally, we will hear today from Angie Platt. Angie serves on the board of the Los Angeles Chapter of JDRF as well as JDRF's International Board of Directors. But her impressive work does not end there. She is also the mother of Jonathan, who accompanies her as a witness today, and we welcome you back, Jonathan.

He was diagnosed with Type 1 at age 6, but that has not held him down at all. In fact, I am told you are six-five—is there any truth to that?—at age 14. Outside of being an advocate, Jonathan is an impressive athlete and was a participant in the artificial pancreas trial. So we are really looking forward to your testimony.

And I also want to acknowledge that we have been joined by our colleague Senator Donnelly from Indiana, who is here today.

You will see senators in and out because of their schedules, but believe me, they care a lot about this issue.

So we will now start with Mr. Sparks.

STATEMENT OF PAUL SPARKS, ACTOR, NEW YORK, NEW YORK

Mr. SPARKS. Thank you, Chairman Collins, and thank you, Ranking Member Casey, and the members of the Committee for inviting me to testify here today. I am totally nervous, but it is a really big honor for me to be here.

I will just start by saying that I know how important the research supported by the Special Diabetes Program is because in my own lifetime personally, as a person with Type 1 diabetes, I have seen and I have benefited from the advances discovered in our labs and clinical trials and brought to market.

I was diagnosed with Type 1 diabetes when I was 28 years old. I was living in New York, working as an actor—which is code for I was living in New York working as a construction worker trying to be an actor.

Over the course of about 7 or 8 months, I lost close to 40 pounds. I had to go to the bathroom all the time. I had cramps constantly. I was thirsty, hungry, starving. I could not see very clearly. I mean, my body was completely falling apart.

Luckily, I went home to Oklahoma to visit my parents, but I was so thin, so grim, looked so unhealthy that my mother and father almost had a heart attack when they saw me.

Luckily, my brother was a medical resident at OU, Oklahoma University, and over the phone I talked about symptoms. And he said, "Well, get to a doctor because it sounds like you may have Type 1 diabetes or diabetes." I went the next day, and he was right. Thanks, David.

I spent the next few months or years trying to learn about T1D, trying to learn and figure out how to get care for myself, learn how to care for myself.

As the kids in this room and the parents know, this is a very anxiety-producing disease. You are the patient, but you are also sort of the caregiver. You have to do it yourself. You take care of yourself. You listen to yourself. You are responsible for keeping yourself healthy in many ways. And you have to stay on top of it because if you do not, you will get very sick, as you guys know, or worse.

That is why the research and the advances in care are so important. Today, nearly 20 years after my diagnosis, I use an inhaled insulin that quickly and safely brings my blood glucose back into range. I wear a continuous glucose monitor, which is awesome, and it allows me to know at all times what my glucose levels are so I do not go too high and I do not go too low. These advances have transformed my life.

I used to have to stash sugar when I would do a play on the stage somewhere in case I needed to stabilize my blood glucose. I can tell you that it is a pretty strange moment when an 18th century period drama character pulls a bottle of Tropicana orange juice out of a sofa cushion and starts drinking it mid-dialog.

But probably the most demonstrative example that I have experienced of how important these advances are: About 3 years ago, I turned my CGM off at night before I went to bed so that my very pregnant wife at that time, Annie—who is sitting right there with that little kid who was inside of her—could sleep peacefully through the night. She was struggling to do that because she was about 8 months pregnant, because the glucose monitor beeps when your blood sugar goes low. Well, because it was off, it did not beep when I went low, and I had a really severe low. And in the morning, they could not wake me up. And when I finally did wake up, I was standing in the presence of a very terrified pregnant woman and a crying 4-year-old boy, who has green hair right over there, and seven New York City EMTs.

These technologies, like the CGM, when they are turned on, and other research advances literally save my life every day. They save the lives of all these delegates. We are on the cusp of a new generation of therapies and devices and, hopefully, a cure.

That is why we cannot let up on this research. We need more advances. We need to cure and prevent Type 1 diabetes so all of us, like Charlie and Lorynn and Jonathan who are sitting here, and

all these kids, can live a life without thinking about the disease all the time.

We need to keep the momentum going. We need to renew the Special Diabetes Program before it expires at the end of September.

I am going to let the other people talk about the science and the policies that support it. But let me just say this: This research has made a difference in my life. It has made a difference in the lives of all these people in this room, and millions of people all over the United States.

So thank you, seriously, thank you, Chairman Collins, for your outstanding leadership, and thank you, Ranking Member Casey, for your support of T1D research and coverage for technologies like the continuous glucose monitor. It is great that people on Medicare can get it just like the rest of us.

Thank you and your colleagues for their bipartisan support of the Special Diabetes Program. It is doing great work for everybody.

Thank you.

[Applause.]

The CHAIRMAN. Thank you so much for your testimony, Mr. Sparks, and for your willingness to take the time out of your schedule to be with us today.

You mentioned the continuous glucose monitor, and Senator Shaheen, who has joined us and, as I mentioned earlier, is Co-Chair of the Diabetes Caucus, and I had to push so hard for CMS to cover that for people on Medicare. We are still having a problem with the Omnipod, but we are not giving up on that either.

Dr. Rodgers, thank you for being here.

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

Dr. RODGERS. Thanks so much. Chairman Collins, Senator Casey, and members of the Committee, thank you for your invitation to testify today.

Type 1 diabetes is a lifelong disease that affects Americans of all ages, including seniors. And on behalf of the National Institutes of Health, I am pleased to report that our research investments continue to improve the lives of people with Type 1 diabetes. Through coordinated efforts with research partners, such as the JDRF, the ADA, the Helmsley Charitable Trust, as well as the support of the special statutory funding program for Type 1 diabetes, we are helping the children here today and all people with Type 1 diabetes live longer, healthier lives.

Since I last testified before this Committee two years ago, significant scientific progress has been made that is putting us closer to the goal of preventing, treating, and ultimately curing Type 1 diabetes and its complications. These advances are really the fruits of the long-term sustained investment of the Special Diabetes Program in Type 1 diabetes research and a preview of what we hope will come as a result of those efforts.

First, I would like to just acknowledge the important contribution of my fellow witnesses.

Paul Sparks, you are a tireless advocate not only for a future cure but for improving people's lives today.

Charlie Albair and Lorynn Watt, your commitment to educating others and raising awareness about Type 1 diabetes is truly outstanding.

And, Jonathan and Angie Platt, I am happy to be able to share the table again with you. Without participation of you and others in clinical research, we would not be where we are today.

I would also like to thank those here today representing Americans of all ages. This is so important for people with Type 1 diabetes.

I would say that the outlook for people with Type 1 diabetes is better than ever, and one of the main reasons is the evolution of the artificial or bionic pancreas technology. This device measures blood sugar levels and automatically administers insulin and can help people with Type 1 diabetes achieve better blood sugar control and avoid the episodes of hypoglycemia, as Mr. Sparks just talked about, or dangerously low blood sugar levels.

As you have heard, a significant milestone was achieved last fall when the FDA approved the first commercial hybrid artificial pancreas device, and NIDDK supported early research that contributed to the development of the approved device and continues to vigorously support research at all stages to advance this technology.

The FDA-approved device is a first-generation device for people age 14 and older. It partially automates blood sugar sensing and insulin administration, but still requires users to count and enter mealtime carbohydrates.

Numerous improvements are on the horizon to more fully automate artificial pancreas technology, to make the devices simpler and more user friendly, to personalize care, and to bring this technology to all.

For example, the first at-home study of a bihormonal pancreas system—one which delivers not only insulin but glucagon, without the need for a mealtime carbohydrate counting—showed it improved blood sugar control better than the conventional insulin pump. And the success of this and other studies lay the groundwork for four new Special Diabetes Program-supported clinical trials to generate data toward FDA approval of other devices. These trials will bring us closer to the goal of having multiple artificial pancreas devices that are FDA-approved for all ages, allowing people with Type 1 diabetes, the caregivers, and their health care providers to choose the technology that is best suited to their needs.

And although this technology holds great promise as a near-term approach to helping people manage Type 1 diabetes, it is not a cure. Replacing the destroyed beta cells, which would be a biological cure, is another area of vigorous investigation. And one way to do this is through islet transplantation, and I am happy to report progress in this field. The NIDDK and the NIAID co-led the Clinical Islet Transplantation Consortium, completed a study of islet transplantation without accompanying kidney transplantation in people with difficult-to-control Type 1 diabetes despite expert care.

This study found two years after the transplantation that more than 70 percent of the participants were free of severe hypoglycemia events and had established near-normal control of their blood sugar levels and had restored hypoglycemia awareness.

These findings indicate that islet transplantation is an effective treatment for people whose Type 1 diabetes cannot be controlled by other means and for whom hypoglycemia events are life-threatening. These results will be the basis of an application to the FDA for licensure of a pancreatic islet product for transplantation.

Now, a current barrier to islet transplantation is the scarcity of donor islet transplants, and so the NIDDK's Human Islet Research Network, known as HIRN—everything in government has an acronym—is pursuing other strategies for replacing the lost beta cells.

Small molecules can be made into the form of drugs and hold promise for inducing beta cell replication in a patient's remaining beta cells or regenerating beta cells from related cells in the body, and HIRN scientists are pursuing these possibilities.

HIRN has also made exciting progress in identifying biomarkers of beta cell loss and developing means to measure these markers in people with Type 1 diabetes. These advances can lead to an approach to monitor people at risk for the disease and to diagnose Type 1 diabetes much earlier, perhaps when the beta cells are still present, and, therefore, they can be prevented from being completely destroyed.

I am also pleased to report important strides in combating diabetic eye disease. Nearly 35 years after the NIDDK's landmark Diabetes Control and Complication Trial, or DCCT, began, this study continues to provide critical information and insights about reducing the devastating risks of this complication. The study recently reported that people who intensively controlled their blood sugar early in life are nearly 50 percent less likely to need eye surgery. The DCCT scientists also determined that people with Type 1 diabetes should get eye exams to detect diabetic eye disease based upon their risk rather than on an automated schedule. So adjusting the frequency of eye examination and screening to a more personalized approach will result in fewer eye exams and lower costs and quicker diagnosis.

The Special Diabetes Program also provides significant funds to our sister institute, the National Eye Institute, its Diabetic Retinopathy Clinical Research Network, which also continues to report significant advances in treating diabetic eye disease. Building on the network's finding that sanative drugs are more effective than laser treatment, they compared three of these drugs with widely differing costs for treating different people with a certain type of diabetic eye disease. The results showed that in people with mild vision loss, all three drugs were equally effective after 2 years. These results can inform clinical decisions and lead to a more personalized treatment for diabetic eye disease, while having significant cost implications. Importantly, the drugs were found to improve vision, which could be the difference between whether a person can drive or not, greatly affecting the person's quality of life.

The network also showed that the sanative is more effective than laser treatment for treating patients with a more severe diabetic eye disease, so-called proliferate diabetic retinopathy. This result

gave people with diabetes and their providers the first new option for treating this disease since the 1970's, four decades. In April, based upon these results, the FDA has now approved this drug for all forms of diabetic eye disease, extending their previous approval.

Chairman Collins, Senator Casey, and members of the Committee, thank you for this opportunity to testify before you today. The NIH is grateful for the continued support of Congress, for our public and private research partners, and for the unwavering efforts of our clinical study volunteers. With the remarkable progress already achieved through the support of the Special Diabetes Program and the progress of future biomedical research, it is possible to imagine that people will lives free of the burden of Type 1 diabetes and its complications.

Thank you for your attention, and I am pleased to answer any questions you may have. Thanks so much.

The CHAIRMAN. Thank you very much, Doctor.

[Applause.]

The CHAIRMAN. Charlie, you are up.

STATEMENT OF CHARLIE ALBAIR, JDRF 2017 CHILDREN'S CONGRESS DELEGATE, GRAY, MAINE

Mr. ALBAIR. Chairman Collins, Ranking Member Casey, Senators, thank you for inviting me to speak before you today.

My name is Charlie Albair from Gray, Maine. I am 10 years old, and I will be entering the fifth grade at Gray New Gloucester Middle School.

I am just like a lot of other kids. I love sports, especially basketball and baseball. And when I grow up, I hope to play in the Major Leagues—for the Boston Red Sox.

[Applause/laughter.]

Mr. ALBAIR. The one big difference is that I have Type 1 diabetes, or T1D. I was diagnosed with T1D way back when I was 6 years old. I was in the first grade. I started not feeling like myself. I kept asking the teacher to go to the bathroom because I really, really had to. She got angry at me because she thought I just was trying to skip class.

She felt bad when she found out the real reason.

At first I was kind of confused when I was diagnosed. I did not know what it was; "diabetes" was a big word for a first-grader.

In the beginning, we treated my diabetes with syringes. And a half a year later, I got the Omnipod pump and then a CGM to monitor my sugar levels. I love it.

I do not have to be constantly stabbing myself with a needle five or ten times a day.

What does this mean for me?

When I first found out I had diabetes, I remember thinking that this would change my whole life. I thought that I would not realize my dream of being a sports star.

Now I can realize I can do whatever I want.

Sometimes my Omnipod or CGM beeps in class, and the other kids say, "Charlie, stop making noise." I just tell them that that is my natural "robot" noise.

[Laughter.]

Mr. ALBAIR. The pump and CGM are so much a part of me. But I do wish that they did not have to be.

I want my disease to go away—for me and all the other kids who suffer from it. I want us all to be able to live without thinking about it.

That is why I am here.

We need money for research.

We need money so scientists can invent new pumps and monitors better than what we have now and so they can come up with a cure for T1D.

You have supported kids like me for so many years, and all I ask is that you continue to do so. And if you do, I will invite you to a game when I am on the Red Sox.

[Laughter.]

Thank you.

The CHAIRMAN. Thank you, Charlie.

[Applause.]

The CHAIRMAN. I cannot wait to see you playing at Fenway Park. I will be there.

Lorynn, welcome.

STATEMENT OF LORYNN WATT, JDRF 2017 CHILDREN'S CONGRESS DELEGATE, STROUDSBURG, PENNSYLVANIA

Ms. WATT. Hi. Chairman Collins, Ranking Member Casey, Senators, thank you so much for inviting me to talk with you today.

My name is Lorynn Watt, as we have established. I am 17 years old, and this fall I will be a senior at Evergreen Community Charter School in Cresco, Pennsylvania.

When I was 9, I was diagnosed with Type 1 diabetes. I remember sitting on my parents' bed, just about a week before Halloween, as my Mom and step-dad told me that I had T1D. That day they loaded me into the car and took me to the hospital, where I would learn to care for myself.

At that point, I only knew about diabetes from an episode of "Hannah Montana" I saw just before I was diagnosed. That was it. What I did know was that I was scared and felt awful, and all of a sudden I was living a life where I had to inject myself with insulin multiple times a day, even though I was horrified of needles.

Then at 14, I got a continuous glucose monitor, or CGM, and an insulin pump. It made my life so much easier. Now, all I have to do is look at my phone—which kids my age do anyways—and I can see my blood sugar. It has been life-changing, and I hope this, the artificial pancreas, and other advances are small steps toward a cure.

I have heard every year since I was diagnosed that in 5 years there will be a cure. I have had this disease for almost 8 years, and you know, I am no mathematician, but I think we are behind schedule.

I believe that with your help we can have a cure. After all, we have come so far.

I know this because my biological father also had T1D. He was not in my life much, and he did not have great care—no pump or CGM or even the ability to check his blood sugar every day.

So he lost his foot and then his eyesight and then the use of his kidneys. He had to get a stent in his heart. And he died less than a year after my own T1D diagnosis, at just 38 years old.

I am here today asking you for more support and more funding for more research because no one should have to suffer and lose their life because of T1D.

I am here, inspired by his memory, and determined that none of the kids here today or sitting in a hospital room—I am sorry——

[Applause.]

Ms. WATT [continuing]. Or sitting in a hospital room right now—scared—as they get their diagnosis, will have the same fate as my father.

With your help, I know we can do it. I know we can find a cure. Thank you.

The CHAIRMAN. Thank you, Lorynn.

[Applause.]

The CHAIRMAN. Thank you so much. I know that was really hard, but your story really inspires us to work even harder.

Mrs. Platt, I know you are speaking on behalf of yourself and your son. We would love to hear your testimony.

STATEMENT OF ANGIE PLATT, CHAIR MOM OF THE JDRF 2017 CHILDREN'S CONGRESS, ACCOMPANIED BY HER SON, JONATHAN PLATT, ENCINO, CALIFORNIA

Ms. PLATT. Chairman Collins, Ranking Member Casey, Senators, thank you for inviting me to speak with you today.

I am Angie Platt from Encino, California. My husband, Jon, and I have three children, all boys: twin 4-year-olds, and this is our oldest son, Jonathan, who is 14 years old.

It is hard for me to believe that this, like you said, six-foot-five young man sitting next to me is the same boy who was here for JDRF's 2011 Children's Congress. He was only 7 years old at the time, just two years into his diagnosis.

If you watch Jonathan play in his competitive basketball tournaments, it would be very hard to believe that he is a child living with Type 1 diabetes.

I am here today to tell you and your colleagues that Jonathan is living proof that your leadership and actions have made a real difference in the lives of Jonathan and the lives of all the people with Type 1 diabetes.

In 2011, when Jonathan was here, the Type 1 diabetes community was asking for your help, and, Senators, you gave it. The Special Diabetes Program has provided hundreds of millions of dollars of crucial funding for a range of therapies and investigations, including the artificial pancreas.

In April 2016, Jonathan was enrolled in the pediatric trial for the Medtronic Hybrid Closed Loop 670G—otherwise known as the "artificial pancreas." We felt as if we had won the diabetes lottery when Jonathan got a spot on that trial.

This device has given Jonathan better blood sugar control than he has ever had in his diabetic life, and it gives our family some desperately needed peace of mind. In the past, we would wake up and check Jonathan's blood sugar at minimum three times a night, similar to the parents behind me and the parents at home caring

for children with Type 1 diabetes. Jonathan used to have to stop practicing with his team or even sit out in games because his blood sugar levels were too erratic. Now he gets to play right through crunch time, and we are so thankful for that.

As you know, last fall the FDA approved this artificial pancreas system. And, Senators, let me be clear: This would not have happened without your help and without the support of the Special Diabetes Program.

Diabetes is relentless. We all work so hard. We are so responsible. We are playing by all the rules. Jonathan is on the latest and the most advanced technology, and he doing everything right.

But the ugly reality of diabetes is that, as hard as we work, our kids are still vulnerable. This past June at Jonathan's eye exam, it was discovered that Jonathan has three dot hemorrhages. Children with Type 1 diabetes at the age of 14 should not be diagnosed with diabetes complications. And, quite frankly, there are kids who are a lot worse off than Jonathan, and those of us who are sitting here are among the lucky ones.

I know that we have made progress, and my son is wearing the very first artificial pancreas system approved in the world. But this disease does not stop, and so we cannot stop.

We need the next generation of devices that can fully automate insulin delivery.

We need to ensure that progress continues in the area of diabetes complications.

We also need to prevent others from ever developing Type 1 diabetes, including my twin sons, Jonathan's brothers, who are at a higher risk of developing Type 1. They are enrolled in TrialNet, a Special Diabetes Program-funded prevention program.

The Special Diabetes Program has done so much, but as you said, it will expire on September 30th. The SDP gives me so much hope, but it needs a hero. We need you Senators and your Senate colleagues to renew it for another three years so researchers can continue their great work.

Senators, I want to thank you for all that you have done to make my family's life and the lives of all of us here today, and the lives of all of those back at home better. Senator Collins, I particularly want to thank you for your steadfast commitment and outstanding leadership to advance Type 1 diabetes research and to help people gain access to new technologies. You have been a champion of us for a long time.

Look at Jonathan. He will not lose to Type 1 diabetes.

We will fight alongside him. We will fight alongside all these kids before you, and we will fight alongside all the kids at home.

I ask that you please continue to fight alongside with us. Thank you.

[Applause.]

The CHAIRMAN. Thank you all for such inspiring testimony. I know that it is hard to share your personal stories, and it makes such a difference because then it puts a human face on the disease, and that is what we need as we advocate for more money.

I want to start with Dr. Rodgers because I know that you will remember that 10 years ago, in September 2006, I chaired a hearing, the Children's Congress, and the topic was the artificial pan-

creas. And it was like something way in the future, but what a difference it would make. And it is so exciting when I learned of the FDA's decision last fall to see the progress that we have made. So I know that it seems hard for those of you, particularly those of you who are newly diagnosed, but the amount of progress in the 20 years that I have co-chaired the Diabetes Caucus really is encouraging. And we are going to keep working on that.

I also love, Dr. Rodgers, that you called it, instead of the artificial pancreas, the "bionic pancreas." I think I will adopt that term from now on. But I want to point out that the Special Diabetes Program has been critical to achieving many of the advances you described and was the program that spurred the development of the artificial pancreas technology.

What additional advancements is the Special Diabetes Program supporting that are in the pipeline now? Is the islet transplantation part of that?

Dr. RODGERS. Absolutely, Senator. In fact, I remember vividly. That is about 10 years ago, and that was actually the first year I was the Director of the Institute, and you really challenged us to move forward with this artificial pancreas. And it seemed at that time to sort of be a dream, but here we are.

What I can tell you is that we are actually even moving much further along in that regard with the bionic artificial pancreas. With the current funds that are remaining in the Special Diabetes Program, we are actually just launching four new clinical trials toward FDA approval of the artificial pancreas device, and one of these trials, I have already begun recruiting patients. These trials will be testing, for example, the combination of insulin and glucagon, as I mentioned, a bihormonal therapy led by researchers at Boston University.

There is a trial that is underway at the University of Virginia which is developing an intraoperative system. We understand there are going to be advances in the infusion technology as well as the sensing technology. This system will be a plug and play where it does not matter which of these devices really moves forward. This system will test that interoperability, and that is at the University of Virginia.

There is a third, which is the trial that is currently recruiting patients. That is led by investigators at the University of Cambridge in England, and they will test an artificial pancreas specifically in youth. As I said, the current device is for kids 14 and older. This is looking at a much younger pediatric group to determine its efficacy.

Then the fourth trial that we are funding is led by an international diabetes center in Minneapolis and the Schneider Children's Medical Center in Israel, and they will be testing the next generation of this currently approved device to determine its efficacy in a broader group.

The HIRN that I mentioned has also been spurred on by the Special Diabetes Program, and being able to develop a way to take the patient's cells from their skin and to induce them to actually become glucose-responsive beta-type cells and to expand them for potential transplantation is really going to be a great advance. And

we are well along the way with that with the additional and continuous funding of this Special Diabetes Program.

Having these cells available—and I do not want to go on very long, but it will also give us another advantage, because one can take these cells and culture them in a dish and put them on a chip, and this chip now, with the patient's own cells, can actually determine the effectiveness of certain drugs, for example. In this way, you can envision making therapies even more personalized.

So those are just a few of the many things that have been spurred on and we hope will continue with the Special Diabetes Program support. Thank you.

The CHAIRMAN. Thank you.

Charlie, how does having Type 1 affect you when you are playing sports, when you are on the court or in the field?

Mr. ALBAIR. Well, sometimes if my Dexcom says I am low, I have to just run out onto the sidelines, take sugar, and then wait however long I need to. And then when I go up, I can go back out and play. But the normal blood sugar that my parents want it at is 160 to 170 because it is a lot of running around, so it could make me go low, and there is a lot of adrenalin, so I could go high. And it is just hard because we do not know what way I am going to go, down or up.

The CHAIRMAN. That must be hard to constantly monitor it, and yet pay attention to the game, too. But it sounds like you do a great job doing both.

My time has expired, so Senator Casey. Thank you, Charlie.

Senator CASEY. Thanks, Chairman Collins.

I want to thank all the witnesses for being here. Your testimony is very compelling, and that is the kind of testimony that will help us win some of these legislative battles. So we are grateful you are willing to do that, and I extend that to all of the delegates. In your own ways, you will all be witnesses to bring testimony to individual Members of Congress.

Lorynn, I am especially grateful that you are here representing our state. I do have one brief suggestion. Just a thought. You do not have to answer. I know you are busy with the Prom Committee and all those other activities, but you are going to finish high school with great grades. You are going to go to college. My suggestion is become a lawyer, then become a sports agent, and get Charlie and Jonathan to play for the '76ers. OK?

[Laughter/applause.]

Senator CASEY. We could use the help.

[Laughter.]

Senator CASEY. But, Lorynn, thank you for sharing your story about your dad and about your own life. It is those stories that move the needle on these public debates. All of us will continue to make arguments. We will make speeches and all of that. If you are Senator Collins, they usually work out better than the rest of us. We know we are going to need you.

I guess the one question I had is: You have got, obviously, the benefit, and so many do, of new technology, and that is something to be positive about. And I guess part of the benefit of that is it has helped you to manage your own condition. But tell me a little bit more about how it has made your life better both at school and

at home. If you can just kind of walk us through part of your day or give us a sense of what it is like every day.

Ms. WATT. Well, a major part of it is sleep. I like to sleep, and I did not really get to do that a lot before, because my Mom would come in three times a night, four times a night, depending on how that day is going, and check my blood sugar for me, to the point where I would just sleep through it because it just became like clockwork.

But, you know, it is really cool to be in class, and all of my teachers know that I have Type 1, and so I am allowed to have my phone on the desk. And so I can look at my phone, and, you know, if I see that I am high, I can take my insulin with my pump without having to run to the nurse and do a shot. I do not really need to do a finger stick right away. I have time. And if I see I am low or if I am going down, I have the ability to treat it before it becomes a real problem for me. And so it has been really helpful. I am really grateful.

Senator CASEY. Well, that helps us as well to be able to give folks a sense of the challenge that you face every day.

Another issue that I wanted to raise is part of the debate we are having right now about programs like Medicaid. We know that living with T1D—and it is nice to have an acronym for that, too. I guess as we said, we have lots of acronyms. But living with T1D presents lots of challenges. One of the challenges, of course, is making sure that the services are there. Whether it is insulin or doctors' visits, to technology, technology like the continuous glucose monitor, those are significant costs. And I know that a lot of families here benefit not only from coverage, but I guess, Lorynn, in your case, in terms of what your Mom gets from work, that impacts you as well. Can you talk about that in terms of the coverage?

Ms. WATT. I do not know a lot about that, just because I am a minor, so I am not allowed to deal with a lot of that.

Senator CASEY. Right.

Ms. WATT. I do know that the ability to afford the technology I have is really great because a lot of people cannot afford $14,000 out-of-pocket for an insulin pump and a CGM. So the fact that we have the insurance, you know, even like a vial of insulin is about $300, and I am using about three a month. We do not have $900 a month to put toward insulin. So having the ability to know that that is going to be there and we are not going to have to worry is really relaxing to know.

Senator CASEY. Well, we will have to bring you back here when we are debating the budget with regard to NIH research dollars. So thanks for your help.

Ms. WATT. Thank you.

The CHAIRMAN. Thank you.

Senator Donnelly?

Senator DONNELLY. Thank you, Madam Chair. And I want to thank all of you for coming to the Congress today. To my Hoosier friends, Becca and Katie and everyone else, we are so excited that you are here. It is awesome to see all of you.

Charlie, my dream in life was to be a Major League baseball player, but I could not hit a curve ball, so my recommendation to you is spend a lot of time in the cage. And, actually living not too

far from Chicago, it is difficult to root for the Red Sox. However, when you get to Fenway, I will come and watch you play, and it will be awesome to see that.

And to Jonathan, I am a Notre Dame graduate and would be happy to put you in touch with the basketball coach.

[Laughter.]

Senator DONNELLY. It could be a win-win situation, my friend.

Dr. Rodgers, you talked a bit about the successful clinical trials on artificial pancreas technology, and we have all been very interested in this. Could you tell us about the future and how you think this is going to go from clinical to products in the market and where we are headed?

Dr. RODGERS. Sure. Thank you, Senator, and, again, thank you for all your support. I think, you know, again, this next generation, our goal is really to provide patients and their families with options. And while this has really been quite successful, getting this first artificial pancreas approved by the FDA, as you have heard, it still has limitations. And so really the purpose of these four trials that I just outlined a moment ago is to provide people with even more options, something that is more——

Senator DONNELLY. You are still in effect flooding the zone, so to speak, to put as many lines out there as you can.

Dr. RODGERS. Exactly right. And as I said in my opening remarks, you know, even having these available, it is still not a cure. And so we really have to make sure that we look at ways of replacing those cells that have been damaged. Ideally, actually determining the disease so early in people who are genetically at risk that we can halt the progression of the autoimmune disease and then get their own cells to repopulate and regenerate, those islet cells produce cells.

Senator DONNELLY. Now, when you do that, the islet transplantation and the work that is being done on that, would that be like a patch that would be used? Or how would it be delivered? And, you know, the magic thing that Lorynn was talking about, we are always told it is five years every year.

Dr. RODGERS. Right.

Senator DONNELLY. Where are we in terms of that? Because I know up in Harvard with Dr. Melton they are doing work, and elsewhere they are doing work.

Dr. RODGERS. That is right. They are supported by the Special Diabetes Program, and expanding these cells was really a remarkable achievement. I hate to use the word "breakthrough," but that was truly a breakthrough. Being able to take the patient's own cells and expand them in such a fashion is totally outstanding.

Of course, even if you expand those cells and transplant them back in through a variety of ways, you still have to overcome the autoimmune disease, and so you could either encapsulate these or in some way modulate the autoimmune disease to make sure that those cells remain healthy and survive.

The one aspect I do want to sort of go back to this artificial pancreas is even if we expand this technology and really achieve a lot of benefits, it really will not be to anyone's benefit if people do not use them. And so we have to make sure that these are readily available for a large number of people and for whatever barriers

that there may be to using them that we can overcome that. And one of the major things that SDP is doing, we are able to bring people into this field of research who had never envisioned going into this—chemical engineers, bioinformaticians, computer scientists, people who are involved in psychology to try to determine how one might effectively influence behaviors in terms of using these technologies. So it really does take a large number of people that we are just envisioning.

And then, finally, I just would quickly say that, as you heard, even as these technologies emerge, there are still people with the disease at risk for developing complications, so we have to put efforts into making sure that the eye disease, the kidney disease, the foot ulcers, the heart disease is appropriately managed. And we have activities underway to——

Senator DONNELLY. Well, I can tell you that on the Special Diabetes Program you have got—what is the term? "A steely eyed missile commander" in Susan Collins and Jeanne Shaheen and Bob Casey, and everybody is all in to make sure that is protected.

And to all of you young people, one of the folks who visited my office today is a fellow named Charlie Kimball. Charlie is a young man who is an IndyCar driver. Charlie has won IndyCar races. Charlie drives around the track at 230 miles an hour. And Charlie has Type 1 diabetes and has driven entire races, was ahead in the Indy 500 with about 10 laps to go a few years ago. And so any dream you have, anything you are hoping for, anything you want to accomplish, I think Dr. Rodgers and all of you would say—Dr. Rodgers, there is no reason they cannot achieve anything they want, is there?

Dr. RODGERS. Absolutely.

Senator DONNELLY. Thank you.

The CHAIRMAN. Thank you very much, Senator.

Senator Scott?

Senator SCOTT. Thank you, Chairwoman. And thank you for holding such an important hearing this morning. I will always remember growing up in South Carolina with my best friend at the time, at 13 years old was diagnosed as a child with juvenile diabetes. And the good news is that at 51 years old—I am dating myself at this point. At 51 years old now, Billy is still very healthy. So the longevity and the good health is prayerfully in the future of so many kids who have juvenile diabetes.

I do know that we have at least three delegates from South Carolina. If you are here, please stand up. Cameron. Is Cameron here? Or Julian?

The CHAIRMAN. Right here.

Senator SCOTT. A tall youngster. And Riley? All right.

[Laughter.]

Senator SCOTT. Excellent. Are there any other South Carolina delegates here? Would you stand up for me, please? Excellent. Well, thank you very much for being here. In my previous life before Congress, I served on our local Juvenile Diabetes Research Foundation for a short period of time, and I am so thankful to see this hearing and hear about the progress being made.

I thank the panelists for being here to discuss this very important issue as well.

The CHAIRMAN. Thank you very much, Senator.

I am now very pleased to call upon the Co-Chair of the Senate Diabetes Caucus, who has been a wonderful partner and leader in the fight against Type 1 diabetes and in helping us get research dollars, and that is my neighbor from New Hampshire, Senator Jeanne Shaheen.

Senator SHAHEEN. Well, thank you very much, Madam Chair, and I am honored to serve with you and appreciate the leadership that you have provided for so many years in the Senate. We would not be here where we are today without your leadership, so thank you very much for that.

I also want to recognize Anna Cook, who is here from New Hampshire, and her mother, Amy. Is Anna here in front someplace? Thank you, Anna, for being here.

And I really appreciate all of you being here because you do not know yet how much difference you have made and the Children's Congress has made in advancing research in diabetes. You are the best advocates there could be as you fan out and go meet with senators and members of the House to talk about why this is so important, and the stories that you have to tell are what has moved this debate.

I have a granddaughter, Elle, who has Type 1 diabetes. She was diagnosed a little after her eighth birthday. She is headed off to college this fall with her diabetes service dog, Coach, who went to high school with her. He graduated with his own cap and gown.

[Laughter.]

Senator SHAHEEN. And he is headed off with her, and he has made a huge difference for her. But even Coach has not been able to address the kind of issue that you all know about and that Mr. Sparks spoke to, where she has on occasion—in fact, just last week, she also turned off her CGM, and her mother was not able to wake her. And, fortunately, she did not have to go to the hospital. She was finally able to get her awake after a lot of carbohydrates.

So I appreciate and have seen how important the Special Diabetes Fund and the research it promotes is in her life.

And I hope that as you all go to offices that you will talk about this not just in the context of how important it is for you individually and what your stories are like, but you will also let people know—oh, we have a diabetes service dog in the audience. All right. What is the dog's name? Gigi? All right. Gigi is great, I bet.

But that you will let people know that this is also important to the policy of this country and to addressing a chronic illness that is not going to get any better unless we actually do the research.

Now, Dr. Rodgers, you talked about the importance of better understanding and diagnosing people who might have a proclivity to diabetes so we can address it before it becomes full-blown. Can you talk about the connection between gestational diabetes and whether that will then lead to diabetes later in life?

Dr. RODGERS. Thank you, Senator. Gestational diabetes, which is, as the Senator indicated, the type of diabetes that occurs during pregnancy, affects some five to seven percent of all pregnancies. In certain ethnic groups, it may be as high as 17 percent. As a result of NIH funding for this research, we know that the infant born during that pregnancy has a higher risk—not only does the mother

have a higher risk of developing diabetes, but the infant born of that pregnancy compared to their siblings in which the mother did not have gestational diabetes has an increased risk of developing obesity and diabetes. In this particular case, it is Type 2 diabetes.

Senator SHAHEEN. Right. Thank you. So it would behoove us to screen for gestational diabetes in every pregnant mother, right?

Dr. RODGERS. Absolutely.

Senator SHAHEEN. Mr. Sparks, you talked about inhaled insulin. I have never heard of inhaled insulin. Can you talk about how long you have had that and how that is different?

Mr. SPARKS. Yes, I can. I have been on inhaled insulin. It is called "Afrezza." It has been on the market, I think, for a little over 2 years. Aaron Kowalski, who is the chief mission officer for JDRF, turned me on to it. He said this is something that was going on. I know it is not a lot out there, but it is really simple. There are no needles. You just have these little pods, and there is a little inhaler device that goes in. I find it to be—look, I do not know the science. I am an actor. I do not even play a doctor on TV.

[Laughter.]

Mr. SPARKS. But I know that my experience of it is that it is very quick acting. It leaves the body very quickly, maybe an hour and a half after you use it. It does not store and then sneak up on you like later for some unknown reason. And it has been a big change for me. I love it. It does not seem to have the same low quality that I have had before when I was using vial insulin. So, yes, I love it. I sing its praises whenever I talk to anybody.

Senator SHAHEEN. Thank you. My time is up. Thank you, Madam Chair.

The CHAIRMAN. Thank you.

Senator Warren?

Senator WARREN. Thank you, Madam Chair. Thank you once again for having this hearing, and thank you, Ranking Member Casey.

I am going to meet with some Massachusetts folks this afternoon, but I do not know if there are any here today already. Well, there they are. OK, good. Good. I thought you would be louder than that. All right. It is good to see you. I hope I did not wake you up over there. OK, good. Good.

But I am really glad that all of you are here, and I am glad that we are getting a chance to talk about Type 1 diabetes and to meet some of the people who are speaking out for the one-and-a-quarter million Americans who have Type 1 diabetes.

I know that researchers all across the country are working hard to try to understand Type 1 diabetes and to develop better treatments on how to deal with it. There is even some talk of cure. And we have made a lot of progress with medicines and innovative devices that I think we have been talking about this morning, like insulin pumps and an artificial pancreas and inhalable insulin. That all happens because of our investments in biomedical research. But we know there is a lot more to do.

So, Dr. Rodgers, I know you have already talked some about the artificial pancreas and how it has been a game changer for many of the people in this room. And you mentioned that NIH funding has been critical for several trials that have been able to get you

in a position to push the envelope on what the artificial pancreas can do, including one led by researchers at Boston University and Massachusetts General Hospital. And I just wondered if you could just say one more word about the work that is being done, there in Massachusetts or anywhere else in the country, about how we are pushing out on the edges of research for diabetes.

Dr. RODGERS. Absolutely, Senator. And that work that they have done, particularly in Boston—and then I will talk about the other places—they really have done some critical pivotal trials sort of in the real world. So, for example, they led trials looking at the Beacon Hill area and having people in the community living as normal an existence as possible as they were being monitored. They have had summer camps for young kids using these, and a lot of these were precursors to their current study that is on the way of this bihormonal pump, which includes both insulin as well as glucagon investigators.

I had mentioned a little bit earlier but it does bear repeating that other investigators are looking at ways with the existing FDA-approved device to expand this in the pediatric population because currently it is only approved for 14 years of age. And we know that the better control of your blood sugar that you can get early on will lead to better improvements or risk reduction in complications later on in life.

Senator WARREN. I appreciate that. I think there are a bunch of people here under 14 who are rooting for you to get this done as quickly as possible. Are you guys ready for that, ready to do a little experimentation?

[Applause.]

Senator WARREN. Yes, you have got to help here.

Now, I want to put in a small plug because this research has been made possible by the National Institutes of Health, and it is vitally important that it continue, important to everyone in this room, important to all of your families, and important to people all across the country.

We are grateful for your work, Dr. Rodgers, and grateful for the work of other researchers in this area. But we are also grateful to our fellow Americans whose tax dollars help make that research possible. And it is the reason that many of us oppose cuts to the National Institutes of Health. Even if the Special Diabetes Program is reauthorized, right now there are proposed cuts of over 20 percent in a single year, and that would knock out the legs from underneath the kind of innovation we are trying to build and the kind of innovation for new treatments and even cures for diabetes.

So I just want to make the point that research takes money, and we need to support it in a sustained way. I know it is something that Senator Collins has been strong on, Senator Casey has been strong on, Senator Shaheen, Senator Donnelly. But we are going to need all of you to be out there and help support the National Institutes of Health because they support the research scientists who are going to make your lives a whole lot better. Thank you.

Thank you, Madam Chair.

[Applause.]

The CHAIRMAN. Thank you, Senator.

Before I adjourn the hearing and let all those who are sitting on the floor have an opportunity to get up and move about, I just wanted to ask Jonathan if he had anything that he would like us to know or to tell us about. I do not mean to put you on the spot, but since you did not get a chance to talk—I know that you are known for having a really positive attitude, and maybe you could share that with the other children who are here today. How do you keep such a great attitude? Sorry. I think I did put you on the spot.

[Laughter.]

Ms. PLATT. How has your device helped with basketball?

Mr. PLATT. Well, my artificial pancreas has really helped with my basketball games because now when I get pulled out of basketball games, I do not always have to check my blood sugar to make sure it is ready for me to get back in, because before this device, when I was on the CGM and the pump, when I came out of games, I would always have to check and make sure it was right. If I was high, I would stay on the bench for an extended amount of time to make sure I get my mind ready to get back in the game. And if I was low, I would not be able to get back in the game at all until my blood sugar raised up, which since I was on the court a long time running up and down, it normally took a really long time for my blood sugar to start getting up. And I would have to wait until it got to like 150 in order to get back out, because if I got back on at like 120, I would just go low again in a matter of minutes.

The CHAIRMAN. Thank you. That is really helpful.

And as I am sure everybody here knows, but maybe not everyone watching knows, the artificial pancreas is in the midst of a clinical trial for younger children, so that it would be more widely available, and I am really looking forward to the results of that clinical trial as well. So thank you for sharing.

Senator SHAHEEN. Madam Chair?

The CHAIRMAN. Yes?

Senator SHAHEEN. Could we ask Jonathan to maybe hold up his artificial pancreas? I think a lot of people do not know what we are talking about when we say that.

The CHAIRMAN. Good idea. Wow, look at how tiny it is. That is amazing.

Senator SHAHEEN. Can everybody see that? It is really small.

The CHAIRMAN. Hold it up high.

[Applause.]

The CHAIRMAN. There you go. Thank you. And, Jonathan, you now just proved that you really are six-five.

[Laughter.]

The CHAIRMAN. So thank you for sharing your personal story, and thank you, Senator Shaheen. That was an excellent idea.

I would like to thank each of our witnesses for being here today. You each added so much to our understanding.

I want to end this hearing for my part by telling you how I got involved in this issue. I do not have any family members or close friends or relatives with Type 1 diabetes. I do have some friends who have it, but what got me involved was 20 years ago, when I was a brand-new Senator, and JDRF arranged for me to meet with a family who had a 10-year-old son with diabetes. I will never forget his looking up at me and saying that he wished that he could

just take 1 day off from having diabetes, his birthday or Christmas. And that so touched me that when I came back to Washington, I said to my assistant at the time, "Is there a Diabetes Caucus in the Senate?" And she said, "No. Only in the House." And I said, "Well, guess what? There is going to be one now."

[Applause.]

The CHAIRMAN. And the reason that I share that story with you is I want you to know what a difference you make when you come to Washington and meet with your Senators and your Members of the House. When you tell them what it is like to live with diabetes, it really helps us mobilize support for the research dollars that have made the artificial pancreas, continuous glucose monitors, and better pumps possible. So you and your advocacy make such a difference, and I know that from my personal experience. So please keep up the good work. It really makes a difference.

Thank you all for traveling to Washington. Your commitment to this cause is truly extraordinary and inspiring.

I would now like to turn to Senator Casey for any final thoughts he might have.

Senator CASEY. Madam Chair, thanks very much. We want to thank all of the witnesses, to Lorynn, Charlie, and Jonathan, Angie, Dr. Rodgers, Mr. Sparks, so many others who are here.

Another suggestion I have, you know, we are worried about the budget cut to the National Institutes of Health, a big cut of billions of dollars. I thought, because Mr. Sparks is familiar with the White House, he could somehow get in there and get that and just cross it out of the budget document.

[Laughter.]

Senator CASEY. Just a suggestion.

But I am serious about the issue. In addition to the work we have to do to reauthorize the Special Diabetes Program, we have got to fight hard against the cuts to NIH. Fortunately, the opposition to those cuts is bipartisan. I think we can do that together. But all of our delegates will play a role in all of these issues.

The stories that you tell about your own lives and your own challenges are going to be critically important in this debate. We are grateful you are with us today, and this is among the more enjoyable hearings we will ever have, despite all the challenges that you have and the stories that you told. Thank you and God bless you.

The CHAIRMAN. Thank you.

[Applause.]

The CHAIRMAN. Committee members will have until Friday, August 11th, to submit questions for the record. Again, my thanks to JDRF, to all the delegates who inspire us, to our terrific panel of witnesses. Thank you so much for being here.

This hearing is now adjourned.

[Applause.]

[Whereupon, at 10:55 a.m., the Committee was adjourned.]

APPENDIX

Prepared Witness Statements for the Record

Prepared Statement of Paul Sparks, Actor, New York, New York

Thank you, Chairman Collins, thank you, Ranking Member Casey, and the members of the Committee for inviting me to testify today. It's an honor for me to be here.

I'll start by saying, I know how important the research supported by the Special Diabetes Program is because in my own lifetime as a person with type 1 diabetes, I have seen—and benefited—from the advances discovered in our labs, tested in our clinical trials, and brought to market.

I was diagnosed with T1D when I was 27, living in New York, working as an actor—which also meant that I was working as a construction worker in order to pay my bills.

Over the course of about seven or eight months, I lost about 45 pounds. I noticed that I was going to the bathroom a lot. I was having muscle cramps all the time. I started not being able to see clearly. I was very thirsty—and constantly starving.

Basically, my body was falling apart. Thankfully, I went home to Oklahoma to see my parents for Thanksgiving. I looked so grim, so thin and so unhealthy, that my mother almost had a heart attack when she saw me.

Luckily, my brother was a medical resident at the time. Via a phone call, he recommended that I see a doctor soon, because it sounded like I had diabetes.

Well, I did see a doctor the next day, and my brother was right.

I spent the next few months trying to learn about T1D and figure out how to get the care I needed.

As the kids and parents here know, this is an anxiety-producing disease. You are the patient but you are also, in many ways, the caregiver. You are responsible for keeping yourself healthy. And you have to stay on top of it; because if you don't, you will get very sick—or worse.

That's why the research and advances in care are so important.

Today, nearly 20 years after my diagnosis, I use inhaled insulin that quickly and safely brings my blood glucose back in range. And I wear a continuous glucose monitor, or CGM, that allows me to know at all times whether my glucose is going too high or too low so I can take action.

These advances have transformed the quality of my life.

I used to have to stash sugar on the set of plays I was in, in case I needed to stabilize my blood glucose. And I can tell you it's kind of strange when a character in a 18th century period drama pulls a bottle of orange juice out of a sofa cushion and starts chugging mid-dialog!

Probably the most demonstrative example of how important these advances are: Three years ago, I turned off my GCM so that my very pregnant wife, Annie, could sleep peacefully through the night without any beeping, which occurs when my glucose level goes low. Because I'd switched it off, it did not alert me, I suffered a severe low blood sugar while asleep, and woke up to a frightened pregnant wife, a crying 4-year old, and seven New York City EMTs standing over me.

These new technologies, when they are turned on, and other research advances literally save my life every day and they save the lives of every one of these delegates. And we are at the cusp of a whole new generation of therapies, devices, and dare I say, a cure.

That's why we can't let up on research. We need more advances—so we can cure and prevent T1D—so all of us, like Charlie, Lorynn and Jonathan who are here on the panel with me, can live life without thinking about this disease at all.

We need to keep the momentum going by renewing the Special Diabetes Program before it expires at the end of September.

I'll let others today go on about the science and the policies that support it. But let me just say this: this research has made a difference in my life—it has made a difference in the lives of everyone in this room—and millions more.

So thank you, Chairman Collins, for your outstanding leadership, and thank you Ranking member Casey for your strong support of T1D research and coverage for technologies like the Continuous Glucose Monitor. It's great that people on Medicare now have access to CGMs just like the rest of us.

And thank you and your colleagues for the bipartisan support of the Special Diabetes Program. It's doing great work for the millions of Americans living with this disease—like me.

Thank you.

Testimony
Before the
Special Committee on Aging
United States Senate

"Progress Toward a Cure for Type I Diabetes: Research and the Artificial Pancreas"

Statement of
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NIH National Institutes of Health

Chairman Collins, Ranking Member Casey, and Members of the Committee, as Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), thank you for your invitation to testify at this hearing on type 1 diabetes. On behalf of NIDDK and the other Institutes and Centers of the National Institutes of Health (NIH) within the U.S. Department of Health and Human Services (HHS), I am pleased to tell you about some of the significant recent scientific advances 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*).

Today I would like to update you on the following topics: improving the outlook for people with type 1 diabetes; developing technologies to improve glucose control; restoring beta cell function; preventing, treating, and reversing diabetic complications; understanding the causes of type 1 diabetes toward disease prevention; testing strategies to stop the autoimmune attack and preserve beta cells; and emerging opportunities in type 1 diabetes research.

The economic and personal toll diabetes takes on our nation is substantial, and biomedical research holds the promise to prevent, treat, and ultimately cure this disease. Toward improving the health of Americans affected by diabetes, NIH invests more than $1 billion a year in diabetes research. This investment 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 JDRF (formerly the Juvenile Diabetes Research Foundation), the American Diabetes Association (ADA), and the Leona M. and Harry B. Helmsley Charitable Trust, who share our goals to prevent, treat, and cure type 1 diabetes.

Through the invaluable support of Congress, through collaborative and coordinated research efforts, through the hard work of our researchers, and through the dedication and generosity of our clinical research participants, we have made important strides toward these goals.

Type 1 diabetes primarily strikes children and adolescents, but it may begin at any age. It is an autoimmune disease, in which the body's immune system launches a misguided attack and destroys the insulin-producing beta cells found in clusters called islets within the pancreas. Insulin is an essential hormone that helps the body regulate glucose (sugar) levels in the blood. Because their bodies no longer produce insulin, people with type 1 diabetes—or the parents of young children with the disease—must do the work of the lost beta cells. The children here today and people of all ages with the disease must closely watch their food intake and physical activity levels, monitor their blood glucose levels many times each day and night, and administer insulin through injections or an insulin pump. This is an enormous and relentless burden on them and their families, and greatly affects quality of life. Despite their vigilance, people 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. Thus, it is imperative to pursue research to identify prevention strategies and improved treatments, while striving for a cure.

IMPROVING THE OUTLOOK FOR PEOPLE WITH TYPE 1 DIABETES

Biomedical research has led to dramatic improvements in the health and quality of life of people with type 1 diabetes. A major contributor to this success is the information that has been garnered by the NIDDK's landmark Diabetes Control and Complications Trial (DCCT) and its follow-up study, the Epidemiology of Diabetes Interventions and Complications (EDIC). DCCT, which began in 1983, compared the effect of intensive blood glucose control versus what was conventional care at the time on the long-term health of people with type 1 diabetes. DCCT demonstrated that intensive control, beginning as soon as possible after diagnosis, prevented or delayed the development of complications of the eyes, kidneys, and nerves. After DCCT ended in 1993, EDIC—which began in 1994 and is ongoing—followed the original DCCT participants and demonstrated enduring protective effects of intensive glucose control on the eye, kidney, nerve, and heart complications of diabetes. These results transformed clinical care for people with type 1 diabetes: doctors now recommend that people with the disease practice intensive control as early in the course of the disease as safely possible.

Even though it has been nearly 35 years since DCCT began, this important study continues to provide critical insights. The study recently reported results related to diabetic eye disease (retinopathy), showing that people with type 1 diabetes who intensively control their blood glucose early in their disease, versus those who do not, are 48 percent less likely to need eye surgery, which reduced eye surgery costs.[1] This reduction led to eye surgery costs about 32 percent lower for people who practice early intensive glucose control. Another important recent eye finding came from analysis of about 24,000 eye exams from over three decades: DCCT/EDIC scientists determined that people with type 1 diabetes should get eye exams to detect retinopathy based on their risk, rather than on an automatic, annual schedule.[2] Adjusting the frequency of eye screenings to a personalized approach—based on risk of severe eye problems—would result in fewer eye exams at lower cost and quicker diagnosis. For example, over 20 years, the new schedule would result in eight exams on average, a greater than 50 percent reduction in eye examinations compared with annual exams.

DCCT/EDIC researchers also examined differences in cardiovascular (heart) problems, which can take many years to develop, and found that those who practiced early intensive blood glucose management had a 30 percent reduced incidence of cardiovascular disease and 32 percent fewer major cardiovascular events 30 years later.[3] Historically, people with type 1 diabetes have had a higher mortality rate than the general population. In another advance, DCCT/EDIC researchers recently found that this increased mortality rate can be reduced or eliminated through careful management of blood glucose.[4] These new findings add to DCCT/EDIC's decades of evidence demonstrating that people with type 1 diabetes can dramatically increase their likelihood of living long, healthy lives by practicing early, intensive blood glucose management. They also demonstrate the fruits of a long-term research investment—NIDDK has supported DCCT/EDIC for nearly 35 years.

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[1] https://www.ncbi.nlm.nih.gov/pubmed/25923552
[2] https://www.ncbi.nlm.nih.gov/pubmed/28423305
[3] https://www.ncbi.nlm.nih.gov/pubmed/26861924
[4] https://www.ncbi.nlm.nih.gov/pubmed/27411699

DEVELOPING TECHNOLOGIES TO IMPROVE GLUCOSE CONTROL

Results from DCCT/EDIC clearly show the importance of good glucose control to the long-term health of people with type 1 diabetes. Type 1 diabetes, however, is an extremely burdensome disease to manage for even the most vigilant, and intensive therapy brings with it potentially dangerous episodes of hypoglycemia. Thus, despite the unequivocal evidence of benefit, many people, especially teens, are not able to achieve the level of glucose control that researchers helped DCCT participants achieve. Data from the SEARCH for Diabetes in Youth study, co-led by CDC and NIDDK, showed that one out of five teenagers with type 1 diabetes have hemoglobin A1c (HbA1c) levels—a measurement of blood glucose levels over time—above 9.5 percent, which is above the 9.0 percent average level of the DCCT group that did not practice intensive control, and much higher than the recommended level for adolescents of less than 7.5 percent.[5] This is worrisome, indicating that achieving the recommended intensive glucose control and attaining its long-term protective effects is particularly challenging in this age group. Because poor glucose control may worsen the long-term health of these children, new approaches to improve glucose control are urgently needed.

NIDDK has invested significantly with resources provided by the *Special Diabetes Program* in glucose management technology, including artificial pancreas technologies. An artificial, or bionic, 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 "closes the loop" between glucose sensing and insulin delivery. This technology is designed to do the work of the pancreas with minimal human input, and holds promise not only to relieve patient and caregiver burden, but also to improve the health of people with type 1 diabetes. A significant milestone was achieved last fall when the FDA approved the first commercial hybrid artificial pancreas device.[6] NIDDK supported early research that contributed to the development of the approved device, and continues to vigorously support research at all stages to advance artificial pancreas technology.

The commercial artificial pancreas device that FDA approved last fall is a first-generation hybrid device intended for insulin delivery and continuous glucose monitoring in people ages 14 and older with type 1 diabetes. The device can be programmed to automatically adjust insulin administration; however, it still requires users to count and enter mealtime carbohydrates. An NIDDK-supported study of day and night use of another hybrid artificial pancreas device at home, without continuous monitoring by study staff, found that such use was feasible and safe in adolescents, and that it increased the amount of time these adolescents spend in the target blood glucose range.[7] The component of this device that calculates insulin requirement based on glucose sensing is designed to work with numerous sensors and pumps, so that it could potentially work with improved versions of these sensor and pump components that are subsequently developed. Numerous improvements are on the horizon which could more fully automate artificial pancreas technology, make the devices simpler and more user friendly,

[5] https://www.ncbi.nlm.nih.gov/pubmed/19643434
[6] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm522974.htm
[7] https://www.ncbi.nlm.nih.gov/pubmed/26740634

personalize care and expand the user population for this technology. It is imperative to continue pursuing additional artificial pancreas technologies through research to reach these goals, and NIDDK-supported development of many other devices is progressing rapidly. For example, the first at-home study of a bihormonal pancreas system—one which delivers both insulin and glucagon, hormones that work together to control blood glucose levels—showed that it improved glucose control better than conventional insulin pump therapy without the need for carbohydrate counting before mealtimes.[8]

The successes of these and other studies have laid the groundwork for more advanced clinical trials to generate data toward FDA approval of these devices. NIDDK, through the *Special Diabetes Program*, is supporting four new such trials that have recently begun recruitment or will begin recruiting in the next year. These pivotal studies will test the artificial pancreas technologies in larger groups, with wider age ranges, over longer periods of time, and in real world conditions. They will look at factors including safety, efficacy, user friendliness, physical and emotional health of participants.

Two of the trials build on the advances described above: one trial will test the bihormonal artificial pancreas system in 600 people, including children as young as four years of age, for six months. A second trial will test artificial pancreas use in 130 youth ages six to 18 for a full year. The third trial being supported is a trial that will compare the currently FDA-approved hybrid closed loop artificial pancreas device to a next-generation system, further refined to improve blood glucose control, particularly around mealtime, in 100 youth for three months. A fourth set of studies will test an innovative platform on smartphones with different insulin pumps and state-of-the-art glucose sensors. These trials are intended to advance the goal to have multiple artificial pancreas technologies that are FDA-approved for use in all ages, allowing people with type 1 diabetes, their caregivers, and their healthcare providers to choose the technology best suited to their needs.

NIDDK continues to support research being conducted by small businesses to develop innovative technologies to improve the components of artificial pancreas devices. For example, one small business supported by NIDDK created a computer program that runs on a mobile device linked to an insulin pump and continuous glucose monitor. The development of this technology was initially supported by grants to an academic investigator and then to the small business. The program was recently selected as the core analytic and control technology for a device in one of the new advanced trials described above.

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 regarding diabetes control, without overwhelming them with excessive data or complexity. Recently, the FDA expanded the approved use of one brand of continuous glucose monitor indicated for management of diabetes in people two years and older, enabling people to make diabetes treatment decisions using data from this device without confirming glucose levels with a painful finger stick.[9] This continuous sensor device is also

[8] https://www.ncbi.nlm.nih.gov/pubmed/28007348
[9] https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm534056.htm

being studied as part of an automated artificial pancreas. Partnerships between bioengineers designing these devices, clinicians, and behavioral scientists are key to making artificial pancreas use easier. With continued research, artificial pancreas technology may become a reality for all people with type 1 diabetes.

RESTORING BETA CELL FUNCTION

Although artificial pancreas technology represents an important and near-term approach to managing type 1 diabetes, it is not a cure. Thus, another major goal of NIH-supported type 1 diabetes research is to identify ways to replace lost beta cells and thereby restore insulin production—a biological cure for the disease. One way to restore the ability to produce insulin in response to glucose levels is to replace beta cells through islet transplantation. The current procedure involves purifying islets from a donor pancreas and transplanting them into a person with type 1 diabetes. NIDDK and the National Institute of Allergy and Infectious Diseases' (NIAID) co-led Clinical Islet Transplantation (CIT) Consortium, supported by the *Special Diabetes Program*, has been conducting clinical and mechanistic studies to test different strategies to make islet transplantation safer and more effective. One of CIT's trials, a Phase III study of islet transplantation without accompanying kidney transplantation, tested islet transplantation in 48 people with type 1 diabetes who had persistent impaired awareness of hypoglycemia and frequent severe hypoglycemia events despite expert care. For this select group of people with difficult-to-control diabetes and very high risk, frequent life-threatening hypoglycemic events, the potential benefits of this procedure could outweigh the risks of having to take immunosuppressive medicines following such a transplant.

The study found that, two years after transplantation, more than 70 percent of participants were free of severe hypoglycemic events, had established near-normal control of glucose levels, and had restored hypoglycemia awareness.[10] These findings are significant, indicating that islet transplantation is an effective treatment for people whose type 1 diabetes cannot be controlled by other means and for whom hypoglycemic episodes are life-threating. The results of this trial will be the basis for applications to the FDA for licensure of purified human pancreatic islets; licensure would allow third-party reimbursement for the pancreatic islets used during the transplant procedure, transitioning it from an experimental drug to one covered by insurers.

One barrier to islet transplantation is the scarcity of donor islets for transplant. Toward overcoming this barrier and pursuing other innovative strategies to protect and replace beta cells in people with diabetes, NIDDK launched the Human Islet Research Network (HIRN) with support from the *Special Diabetes Program*. HIRN builds on the ground-breaking successes of NIDDK's Beta Cell Biology Consortium, which focused primarily on research in mice. Now advances from the Beta Cell Biology Consortium are being incorporated into HIRN's studies of human beta cells. For example, researchers in HIRN developed a new laboratory production method to make large quantities of beta cells from the skin cells of people with type 1 diabetes.[11] This method could, with further development, be used to manufacture beta cells from a person with type 1 diabetes in the quantities needed for transplantation back into that same person. These cells would likely require protection from autoimmune attack, perhaps through a

[10] https://www.ncbi.nlm.nih.gov/pubmed/27208344
[11] https://www.ncbi.nlm.nih.gov/pubmed/27163171

bioengineered approach to encapsulation of cells, but the recipient might not require toxic immunosuppressive medications to prevent rejection of the tissue. This procedure for generating beta cells and islets from skin cells could also provide a valuable resource for drug screening and for precision medicine studies of the development of the disease.

HIRN scientists are exploring other strategies for replacing the lost beta cells, such as replication of a patient's remaining beta cells or regeneration of beta cells from related cells in the body, without the need for transplantation. Small molecules—which can be developed into drugs—hold promise for inducing beta cell replication or regeneration, and HIRN is contributing to exploration of this possibility. Scientists are identifying and studying such small molecules, like harmine[12] and SerpinB1,[13] as well as generating new small molecule screening assays,[14] to discover and develop highly potent, beta cell-specific molecules.

HIRN researchers have also made exciting progress in identifying biomarkers of beta cell death and in developing the means to measure these markers in people with type 1 diabetes.[15,16,17] For example, using the knowledge that dying cells release fragmented DNA into the blood, researchers demonstrated that beta cells release DNA with a uniquely modified pattern that can be detected in people with type 1 diabetes. At present, this research indicates these assays are sensitive enough to reliably monitor the success or failure of transplanted islets in humans, giving us a valuable new tool in transplantation research. The next generation of assays, which are in development, are designed to be even more sensitive, and could potentially detect the loss of only a very few beta cells early in the disease process, possibly before any other clinical signs can be detected. These advances could lead to a minimally invasive approach to monitor people at risk for the disease and to diagnose type 1diabetes much earlier, perhaps when the process of beta cell loss could be halted and overt disease prevented.

PREVENTING, TREATING, AND REVERSING DIABETIC COMPLICATIONS

Pursuing these promising directions for replacing lost beta cells is imperative, since chronic elevation of blood glucose levels slowly damages organs and can result in life-threatening diabetes complications. SEARCH recently reported estimates that by about age 21, approximately 32 percent of youth with type 1 diabetes would have at least one complication for the disease or would be at high risk for a complication.[18] This finding scares us all, and underscores the need for early monitoring of youth for earlier diagnosis and treatment of complications, and the critical need to pursue research toward preventing, treating, or reversing diabetes complications.

Blindness is a debilitating complication of diabetes. Laser treatment can be an effective therapy to prevent blindness in advanced cases of diabetic eye disease or vision loss from diabetic macular edema (DME), a type of diabetic eye disease. This treatment, however, causes

[12] https://www.ncbi.nlm.nih.gov/pubmed/25751815
[13] https://www.ncbi.nlm.nih.gov/pubmed/26701651
[14] https://www.ncbi.nlm.nih.gov/pubmed/27624103
[15] https://www.ncbi.nlm.nih.gov/pubmed/26976580
[16] https://www.ncbi.nlm.nih.gov/pubmed/27643615
[17] https://www.ncbi.nlm.nih.gov/pubmed/26216854
[18] https://www.ncbi.nlm.nih.gov/pubmed/28245334

some immediate and permanent scarring of the eye and worsening of vision in order to prevent future events that could cause blindness. This prompted scientists in the National Eye Institute-led Diabetic Retinopathy Clinical Research Network (DRCR.net) to seek better treatments. In 2010, a landmark DRCR.net trial demonstrated that an anti-vascular endothelial growth factor (VEGF) drug, ranibizumab injection, is a more effective treatment for DME than laser treatment.[19] This finding dramatically changed clinical practice, and ranibizumab injection quickly became one of the standard treatments for people with vision loss from DME.

Building on this result, a recent DRCR.net comparative effectiveness trial compared safety and efficacy of three anti-VEGF drugs commonly used to treat DME: Eylea® (aflibercept), Avastin® (bevacizumab), and Lucentis® (ranibizumab injection). The trial showed that, in people with DME and mild visual impairment, any of the three drugs, on average, improved visual acuity and that the drugs were equally effective after two years.[20] These results give people with diabetes and their providers more options for treating DME, specifically regarding the cost of treatment. Improving vision with anti-VEGF therapy can make the difference between being able to drive or not, which greatly affects quality of life.

DRCR.net also showed, in a separate trial, that ranibizumab was more effective than laser treatment at improving visual acuity over two years for eyes with the most severe form of diabetic eye disease—proliferative diabetic retinopathy.[21] This result gave people with diabetes and their providers the first new option for treating proliferative diabetic retinopathy in four decades. Eyes treated with ranibizumab also had fewer complications from diabetic retinopathy and required less eye surgery. In April, based on these results, FDA approved ranibizumab for all forms of diabetic retinopathy, expanding the previous approval of the drug for people with DME.[22]

With support from the *Special Diabetes Program*, the Preventing Early Renal Loss in Diabetes (PERL) trial is studying whether the inexpensive, generic medication allopurinol, currently used for treating gout, can preserve kidney function in people with type 1 diabetes who are at high risk of kidney disease. PERL recently finished recruitment and, if this inexpensive drug proves effective, it has the potential to be the first new therapy to reduce risk for diabetic kidney disease in over two decades.

UNDERSTANDING THE CAUSES OF TYPE 1 DIABETES TOWARD DISEASE PREVENTION

In parallel to efforts to improve management of type 1 diabetes, develop a cure, and prevent or treat diabetic complications, it is imperative to gain better understanding of the initiation and earlier stages of the disease. This will enable us to develop prevention strategies, so future generations do not have to be burdened with the disease like the children and adults here today are. A person's risk for developing type 1 diabetes involves both genetic and

[19] https://www.ncbi.nlm.nih.gov/pubmed/20427088
[20] https://www.ncbi.nlm.nih.gov/pubmed/26935357
[21] https://www.ncbi.nlm.nih.gov/pubmed/26565927
[22] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/125156orig1s114ltr.pdf

environmental factors. Many genes are known to contribute to disease risk, but environmental factors are not yet conclusively identified. Knowing these factors and determining their contributions is key to understanding the causes of type 1 diabetes.

We have made significant progress in understanding the genetic contributors to type 1 diabetes. Only a decade ago, just a few genes that increased risk for the disease had been identified. Today, 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 80 percent of the genetic contributors. To build on this success, NIDDK is supporting research to understand the function of identified genes to determine how they may influence disease development, which could lead to new targets for prevention or treatment.

The genetic contribution, however, is only part of the story. SEARCH recently reported that the rate of new diagnosed cases of type 1 diabetes is increasing among youth in the United States, in the first-ever estimate of incidence trends in the five-major racial/ethnic groups in the nation. The relative annual increase in the incidence of type 1 diabetes, from 2002 to 2012, was about 1.8 percent.[23] This study also found that the increase in incidence was not shared equally among racial/ethnic groups. Although historically, type 1 diabetes has been considered to affect primarily non-Hispanic white youth, the new data demonstrate that type 1 diabetes is an increasing burden for minority youth. The rate of new diagnosed cases increased most sharply in Hispanic youth, a 4.2 percent annual increase. In non-Hispanic blacks, the rate increased by 2.2 percent and in non-Hispanic whites by 1.2 percent per year. These findings generate many questions, such as why the increase in rates of type 1 diabetes development varies so greatly and is so concentrated in specific racial and ethnic groups. Further research could illuminate the factors behind these differences and provide important clues to tailoring prevention approaches.

Rising rates of type 1 diabetes suggest that there is an unknown factor—or factors—in the environment that interacts with genetic risk to trigger disease onset or protect against it. Identifying these—such as an infectious agent, dietary factors, 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. Dedicated parents and researchers are regularly collecting information about the children's diet, allergies, illnesses, and other environmental exposures. Additionally, over 3.2 million biological samples have been collected to date—the most data and samples ever collected on newborns at risk for autoimmunity and type 1 diabetes. These samples are a treasure trove now being analyzed with state-of-the-art genomic, metabolomic, and proteomic technologies to uncover possible environmental triggers and protective factors. Microbiome research—to study the microorganisms that populate the digestive tract—in TEDDY is also shedding light on the broader development of the microbiome as TEDDY is one of the largest studies of the microbiome in children. TEDDY is another example of a long-term effort that could pay major dividends and give unique insight into type 1 diabetes and children's health.

[23] https://www.ncbi.nlm.nih.gov/pubmed/28402773

TESTING STRATEGIES TO STOP THE AUTOIMMUNE ATTACK AND PRESERVE BETA CELLS

As new environmental triggers are identified by TEDDY and novel insights emerge from research on the function of risk genes, NIDDK's Type 1 Diabetes TrialNet is uniquely positioned to test promising prevention strategies. TrialNet, through the *Special Diabetes Program,* supports the development and implementation of trials to test novel strategies aimed at preventing type 1 diabetes in people at risk and slowing disease progression in people newly diagnosed. These trials go hand-in-hand: not only are TrialNet and NIAID's Immune Tolerance Network studies in people newly diagnosed potentially beneficial to participants by preserving remaining beta cell function, these studies also provide critical information for prevention research. For example, after finding that the drug abatacept was safe and preserved beta cell function in people newly diagnosed with type 1 diabetes, TrialNet investigators are now studying its use for prevention in people at high risk for the disease. Building on similar findings in other successful new-onset studies, TrialNet has also launched a prevention trial with the anti-CD3 monoclonal antibody, teplizumab. TrialNet recently announced results from a third prevention study using oral insulin: the major study population did not benefit, but in a smaller group, with more advanced disease, fewer people developed a clinical diagnosis of type 1 diabetes. Ongoing studies are comparing immune responses to different doses of oral insulin, providing new key information about this agent.

The ability to assess accurately those at risk for type 1 diabetes is critical for identifying individuals in the general population, so that as many people as possible can benefit if and when new prevention strategies are proven effective. TrialNet also supports research to understand the natural history of type 1 diabetes and identify people at risk for the disease. To date, TrialNet has screened over 160,000 individuals—and screens approximately 15,000 new individuals per year—for type 1 diabetes risk to identify those eligible for participation in TrialNet prevention studies. Data from this TrialNet study, TEDDY, and other studies demonstrated that progression of type 1 diabetes proceeds through distinct stages, allowing identification of the disease before symptoms appear. This forms the basis for a new recommendation from JDRF, the Endocrine Society, and the ADA for a type 1 diabetes staging classification in at-risk individuals that provides a framework for the research and development of preventative therapies.[24] TrialNet will begin piloting use of finger sticks to collect blood for antibody screening; this could greatly increase the number of children and ease with which they are screened for type 1 diabetes. These high-risk, high-reward studies to identify, test, and—based on advances in screening—deliver these prevention strategies are poised to inform critical future public health efforts to identify those at risk and to intervene to prevent type 1 diabetes.

EMERGING OPPORTUNITIES IN TYPE 1 DIABETES RESEARCH

The advances I have discussed today are just a few examples of the exciting progress in research on type 1 diabetes and its complications. The investments we have made in infrastructure, technology, and human potential are bearing fruit. We are learning so much so

[24] https://www.ncbi.nlm.nih.gov/pubmed/26404926

quickly, and the results of this research are improving the lives of people with type 1 diabetes. But we cannot rest yet, and we cannot slow down. To capitalize on the recent research progress I described and to take advantage of advances in cutting-edge technology, 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 April.[25] The opportunities that emerged from that workshop are extensive and exciting, such as the ability to increase understanding of the immunology of type 1 diabetes toward new prevention and cure strategies. For example, high risk for type 1 diabetes, in those with genetic susceptibility, is predicted by the presence of two or more antibodies that recognize different cellular components (autoantigens). Powerful new technologies provide opportunities to facilitate discovery and characterization of new autoantigens and the immune response to them, which could be used to monitor disease progression and response to treatment and, potentially, could lead to novel therapies. In another example, it may be possible to change the course of the disease, or to prevent it entirely, by interfering with the pathways leading to autoimmunity. Recent discoveries in the field of cancer immunology demonstrate that tumors can evolve to evade the immune system. They do this, in part, by activating the normal mechanisms by which undamaged or uninfected cells turn off immune responses after an infection. What if we could do this in type 1 diabetes? What if we could specifically and safely deactivate the "over active" immune system in type 1 diabetes? Innovative research in this area could lead to identification of compounds or development of vaccines to safely restore normal immune system functioning in people with type 1 diabetes.

The timing is also right to capitalize on advances in single-cell analysis. Many biological experiments are performed on groups of cells, assuming that all cells of a particular "type" are identical. But, we are learning that individual cells within a population may differ dramatically, and these differences can have important consequences in health and disease. Single-cell analysis promises to enhance understanding of individual cells, and we are eager to apply this to the human islet tissue environment. Detailing the identity at the cellular and molecular levels and the function of important components of islet architecture at high resolution could help to improve understanding of the early steps of the disease process toward preventative approaches, develop highly specific therapeutic strategies based on the identification of new cellular and molecular targets, and improve the design and engineering of islets for cell replacement, disease modeling, and drug discovery. These are just a few of the timely opportunities poised to accelerate discovery and development in type 1 diabetes research.

NIDDK support of type 1 diabetes research will also continue to be guided by the 2011 Diabetes Research Strategic Plan,[26] which the Institute spearheaded with broad external input, and by the input that NIDDK receives at venues such as scientific conferences and workshops. With this input, NIDDK and NIH have identified the most compelling areas of research to pursue with funds from the *Special Diabetes Program* to ensure that the *Program* continues its

[25] https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/diabetes-mellitus-interagency-coordinating-committee/Documents/DMICC_Agenda_04262017.pdf
[26] https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/Pages/advances-emerging-opportunities-in-diabetes-research.aspx

exceptional track record of supporting cutting-edge type 1 diabetes research.

NIDDK also remains committed to fostering scientific collaboration and to resource sharing to reduce duplication and maximize return on scientific research investments. We remain committed to providing access to research resources to increase understanding of type 1 diabetes and its complications. For example, NIDDK supports distribution of human islets from organ donors to researchers and ancillary studies of type 1 diabetes clinical trials. Biosamples and data from completed studies are available to the broad research community through the NIDDK Central Repositories. We also support one of our most valuable resources—young investigators—through training and career development programs to recruit and retain scientists with different areas of expertise whose talents will enhance the type 1 diabetes field.

Finally, they say that the whole is greater than the sum of its parts, and this is certainly true in type 1 diabetes research. We work together with our partners—our sister HHS agencies, academic institutions, and charitable and patient advocacy groups like JDRF, the Helmsley Charitable Trust, and ADA—and what we achieve collaboratively is changing the lives of the people with type 1 diabetes. This teamwork—like the collaboration among NIDDK, JDRF, and FDA to help advance artificial pancreas technologies—is essential and powerful, and propelled us toward the first approved hybrid artificial pancreas device, with several other promising devices in pipeline.

With the remarkable progress already achieved through support from the *Special Diabetes Program*—and the promise of future research—the goals are clear. In the near term, artificial pancreas technologies will transform the lives of people with type 1 diabetes, making blood glucose control safer and less arduous. New ways to restore and protect beta cells may yield a cure for those with the disease. Medicines that prevent life-threatening disease complications may be developed. Finding the genes and environmental factors that contribute to type 1 diabetes may produce ways to identify those at risk at birth and safely prevent the disease, thereby eliminating new cases. 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.

CONCLUDING REMARKS

I appreciate this opportunity to share with you these exciting advances, ongoing efforts, and emerging opportunities in type 1 diabetes research. We are 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 the clinical study volunteers, without whom the clinical research I described today would not be possible. Working with these partners, NIH remains steadfast in our goals of preventing, treating, and ultimately curing type 1 diabetes.

Thank you, Chairman Collins, Ranking Member Casey, and Members of the Committee for your attention. 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) at the National Institutes of Health on April 1, 2007. Dr. Rodgers served as the NIDDK's acting director March 2006 - April 2007 and was the Institute's deputy director from 2001 - 2007. Since 1998, Dr. Rodgers also serves as chief of the Molecular and Clinical Hematology Branch. The branch is now administratively managed by the NIH's National Heart, Lung, and Blood Institute.

Dr. Rodgers received his undergraduate, graduate, and medical degrees from Brown University in Providence, RI. 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/oncology was through 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, Dr. Rodgers earned a master's degree in business administration, with a focus on the business of medicine, 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. He also performed basic research that focused on understanding the molecular basis of how certain drugs induce gamma-globin gene expression. 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.

Dr. Rodgers has been honored for his research with numerous awards, among them 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. He was a 2015 finalist for The Samuel J. Heyman Service to America Medals (Sammies).

Dr. Rodgers has been an invited professor at medical schools and hospitals in France, Italy, China, Japan, and Korea. He has been honored with many named lectureships at American medical centers and as commencement speaker at many medical schools. He has published more than 200 original research articles, reviews, and book chapters; has edited four books and monographs; and holds three patents.

Dr. Rodgers served as governor to the American College of Physicians for the Department of Health and Human Services from 1994 - 1997. He is a member of the American Society of Hematology; the American Society of Clinical Investigation; the Association of American Physicians; the National Academy of Medicine (formerly the Institute of Medicine) of the National Academies of Sciences, Engineering, and Medicine; and the American Academy of Arts and Sciences. He served as chair of the Hematology Subspecialty Board and a member of the American Board of Internal Medicine Board of Directors.

Prepared Statement of Charlie Albair, JDRF 2017 Children's Congress Delegate, Gray, Maine

Chairman Collins, Ranking Member Casey, and Senators, thank you for inviting me to speak before you today.

My name is Charlie Albair from Gray, Maine. I am 10-years old, and will be entering the 5th grade at Gray New Gloucester Middle School.

I am just like a lot of other kids. I love sports, especially basketball and baseball. And when I grow up, I hope to play in the Major Leagues—for the Boston Red Sox.

The one big difference is that I have type 1 diabetes or T1D.

I was diagnosed with T1D way back when I was 6-years-old. I was in the first grade. I started not feeling like myself. I kept asking the teacher to go to the bathroom because I really, really had to. She got angry at me because she thought I just was trying to skip class.

She felt bad when she found out the real reason.

At first I was kind of confused when I was diagnosed. I didn't know what it was; "diabetes" was a big word for a first-grader.

In the beginning, we treated my diabetes with syringes. And a half a year later, I got the Omnipod pump and then a CGM to monitor my sugar levels.

I love it.

I don't have to be constantly stabbing myself with a needle—like five or 10 times a day.

What does this mean for me?

When I first found out I had diabetes, I remember thinking that this would change my whole life. I thought that I wouldn't realize my dream of being a sports star.

Now I can realize I can do whatever I want.

Sometimes my Omnipod or CGM beeps in class, and the other kids say, "Charlie, stop making noise." I just tell them that that's my natural "robot" noise.

The pump and CGM are so much a part of me. But I do wish that they didn't have to be.

I want my disease to go away—for me and all the other kids who suffer from it. I want us all to be able to live without thinking about it.

That's why I am here.

We need money for research.

We need money so scientists can invent new pumps and monitors better than what we have now—and so they can come up with a cure for T1D.

You have supported kids like me for so many years, and all I ask is that you continue to do so. And if you do, I will invite you to a game when I am on the Red Sox.

Thank you.

Prepared Statement of Lorynn Watt, JDRF 2017 Children's Congress Delegate, Stroudsburg, Pennsylvania

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

My name is Lorynn Watt, I am 17 years old, and this fall I will be a senior at Evergreen Community Charter School in Cresco, Pennsylvania.

When I was nine, I was diagnosed with type 1 diabetes. I remember sitting on my parents' bed, just about a week before Halloween, as my mom and step-dad told me that I had T1D. That day they loaded me into the car and took me to the hospital, where I'd learn how to care for myself.

At that point, I only knew about diabetes from an episode of Hannah Montana I saw just before I was diagnosed. That was it. What I did know was that I was scared, felt awful, and all of a sudden was living a life where I had to inject myself with insulin multiple times a day, even though I was horrified of needles.

Then at 14, I got a continuous glucose monitor (or CGM) and an insulin pump. It made my life so much easier. Now, all I need to do is look at my phone—which most kids my age do all the time—and I can see my blood sugar. It has been life-changing, and I hope this, the artificial pancreas, and other advances are small steps toward a cure.

I've heard every year since I was diagnosed that in 5 years there will be a cure. I've had this disease for almost 8 years. Now, I'm no mathematician, but you can see that we are a bit behind schedule.

I believe that with your help we can have a cure.

After all, we already have come so far.

I know this because my biological father also had T1D. He wasn't in my life much. He didn't have great care—no pump or CGM or even ability to check his blood sugar every day.

So, he lost his foot, then his eyesight, and the use of his kidneys. He had to get a stent in his heart. And he died less than a year after my own T1D diagnosis, at just 38 years old.

I am here today asking you to support more funding for more research because no one should have to suffer and lose their life because of T1D.

I am here, inspired by his memory, and determined that none of the kids here today or sitting in a hospital room right now—scared—as they get their diagnosis, will have the same fate as my father.

With your help, I know we can do it. I know we can find a cure.

Thank you.

Prepared Statement of Angie Platt, Chair Mom, JDRF 2017 Children's Congress, Accompanied by her Son Jonathan Platt, Encino, California

Chairman Collins, Ranking Member Casey, and Senators—thank you for inviting me to speak with you today.

I am Angie Platt from Encino, California. My husband Jon and I have three children, all boys—twin 4 year olds and meet our oldest son Jonathan who is 14 years old.

It's hard for me to believe that the 6'5" young man sitting next to me is the same boy who was here for JDRF's 2011 Children's Congress. He was only 7 years old at the time, just 2 years into his diagnosis.

If you watch him play in his competitive basketball tournaments, it would be very hard to believe that he is a child living with type 1 diabetes.

I am here today to tell you and your colleagues that Jonathan is living proof that your leadership and actions have made a real difference in our lives and the lives of all people with T1D.

In 2011, the T1D community asked you for help, and Senators, you gave it. The Special Diabetes Program has provided hundreds of millions of dollars of crucial funding for a range of therapies and investigations—including the artificial pancreas.

In April 2016, Jonathan was enrolled in the pediatric trial for the Medtronic Hybrid Closed Loop 670G—otherwise known as the "artificial pancreas." We felt as if we won the lottery.

This device has given Jonathan better blood sugar control than he has ever had—and it gives our family some desperately needed peace of mind. In the past, we would wake up at minimum 3 times a night to check my son's blood sugar. Jonathan used to have to stop practicing with his team or even sit out in a game because his blood sugars were too erratic. Now, he gets to play right through crunch time.

As you know, last fall the FDA approved this artificial pancreas system.

Senators, let me be clear: this would not have happened without your support of the Special Diabetes Program.

Diabetes is relentless. We work so hard, we are so responsible, we are playing by all the rules. Jonathan is on the latest most advanced technology. Jonathan is doing everything right.

But the ugly reality of diabetes is that as hard as we work, our kids are still vulnerable. This past June at Jonathan's eye exam it was discovered that Jonathan has three dot hemorrhages. Quite frankly, there are kids who are a lot worse off than Jonathan. Those of us here are among the lucky ones.

I know that we have made progress; my son is wearing the first artificial pancreas system approved in the world! But this disease doesn't stop, so neither can we.

We need the next generation devices that can fully automate insulin delivery.

We need to ensure that progress continues in the area of diabetes complication treatments.

We also need to prevent others from ever developing T1D—including my twin sons, Jonathan's brothers, who are at a higher risk of developing it. They are enrolled in TrialNet, an SDP-funded prevention program.

SDP has done so much, but it will expire on September 30th. The SDP gives me so much hope, but it needs a hero. We need you and your Senate colleagues to renew it for another three years so researchers can continue their great work.

Senators, I want to thank you for all that you have done to make my family's life and the lives of all of us here today better. Senator Collins, I particularly want to thank you for your steadfast commitment and outstanding leadership to advance

type 1 diabetes research and to help people gain access to new technologies. You have been a champion for us for a long time.

Look at Jonathan—he will not lose to diabetes.

We will fight alongside Jonathan.

We will fight for all of these kids.

I ask you to continue to fight along with us.

Thank you.

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