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DIABETES RESEARCH: REDUCING THE BURDEN OF DIABETES AT ALL AGES AND STAGES

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

WASHINGTON, DC

WEDNESDAY, JULY 10, 2013

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WEDNESDAY, JULY 10, 2013

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

The Committee met, pursuant to notice, at 2:10 p.m., in Room G–50, Dirksen Senate Office Building, Hon. Bill Nelson, Chairman of the Committee, presiding.

Present: Senators Nelson, Blumenthal, Donnelly, Warren, Collins, and Ayotte.

Also Present: Senator Shaheen.

OPENING STATEMENT OF SENATOR BILL NELSON, CHAIRMAN

The CHAIRMAN. The meeting will come to order.

For all of you, this is a Congressional hearing in the Senate. We have these kinds of meetings, and as you can see, this is a meeting room that is one of the large ones, and, of course, we needed a large room today because of our special guests, all in the blue shirts, and your parents, and this very fine panel of witnesses that we are going to have.

I am Bill Nelson. I am from Florida. Susan Collins is from Maine. We are in opposite parties, but that makes no difference. We work together, and that is the way it ought to be, and that is in a lot of contrast to what you see going on around here with regard to a lot of other stuff.

I am very pleased that I have a colleague who works together, and when we have differences, then what we do is we respect each other's opinion and then we work out the differences and we build consensus. And that is the essence of trying to govern in a democracy that represents a big, large, beautiful, diverse, and complicated country such as ours.

So, we want to welcome all of you, and this is a very special topic today of which you are intimately familiar.

[The prepared statement of Chairman Nelson appears in the Appendix on p. 68.]

The CHAIRMAN. And so I want to turn to our Ranking Member, Senator Collins, for her statement.

OPENING STATEMENT OF SENATOR SUSAN M. COLLINS

Senator COLLINS. Thank you very much, Mr. Chairman. You put it so well.

And when it comes to the issue of diabetes, it does not matter whether you are a Democrat or a Republican or an Independent or a Green Party member. What matters is that we all work together to focus on the estimated three million Americans with Type 1 diabetes and their families.

This is my seventh consecutive Children's Congress hearing, and I am very grateful to Chairman Nelson for allowing me to continue this tradition. I want to join him in welcoming our distinguished witnesses and the more than 160 delegates to the Children's Congress who have traveled to Washington to tell us what it is like to have diabetes, just how serious it is, and why it is so important that we fund the research that is necessary to find a cure.

I particularly want to give a special welcome to the delegate from Maine, 14-year-old Quinn Ferguson of Poland Spring, who will be speaking on our panel.

As the founder and Co-Chair with Senator Jeanne Shaheen of New Hampshire of the Senate Diabetes Caucus, I have learned a lot about this disease and the heartbreak that it causes for so many American families as they await a cure.

Diabetes is a lifelong condition that does not discriminate. It affects people of every age, race, and nationality. It is an extremely serious disease and it costs the United States an estimated $245 billion a year and accounts for one out of every three Medicare dollars. Because of the serious complications associated with diabetes, medical costs for Americans with the disease are 2.3 times higher than those incurred by individuals without diabetes.

Those statistics alone are overwhelming, but what motivates me to devote so much energy to this cause is meeting the children, the family, whose lives have been forever changed by diabetes. That is why it is so important that you have traveled here to Washington to tell your stories. You put a human face on the statistics.

When I was meeting with Quinn and he showed me his scrapbook, he said that he felt that the day he was diagnosed at age eight with diabetes was his last full day of freedom, and that really touched me. So you help us focus on what Congress can do to understand and ultimately conquer this disease.

While often associated with children, the fact is that 85 percent of those living with Type 1 diabetes are adults and many of them are seniors. An average individual with Type 1 will have to take more than 50,000 insulin shots or infusions over his or her lifetime. The discovery of insulin was a landmark breakthrough. However, it is not a cure for diabetes, as you well know.

Thankfully, there is some good news. Since I founded the Senate Diabetes Caucus, we have been successful in working together in a bipartisan manner to triple the funding for diabetes research. As a consequence, we have seen some encouraging breakthroughs and we are on the threshold of a number of exciting discoveries. Advances in technology, like continuous glucose monitors, are helping patients control their blood glucose levels, which is key to preventing the complications from diabetes.

We are also moving closer and closer to the goal of an artificial pancreas, which would revolutionize diabetes care. Recent advances also include the development of new treatments that can stop or

even reverse certain complications, such as some nerve damage and diabetic eye disease.

I am pleased to tell you that there is strong support in Congress for diabetes research funding, thanks in no small measure to the grassroots support provided by the JDRF volunteers. Earlier this year, we passed legislation to extend the Special Diabetes Program which provides $150 million a year above and over the regular appropriations for Type 1 diabetes research. This important program represents more than a third of our Federal commitment to diabetes research. As such, it is critical to our efforts to find better treatments, a means of prevention, and ultimately what we are all seeking, and that is a cure for this devastating disease.

Again, I thank the Chairman for holding this important hearing and it is wonderful to see you all here. You really inspire us to work even harder. Thank you.

[The prepared statement of Senator Collins appears in the Appendix on p. 69.]

The CHAIRMAN. As a courtesy to all of you, overflow crowd, standing, we will suspend any of our opening statements, including the Chairman's. We will insert our opening statements as a part of the official Congressional record.

And as a courtesy to you all standing, I want to invite you to come up and have a seat here at the dais and at the staff chairs, where available. I would not like any lady standing in the audience. So, gentlemen——

[Laughter and applause.]

The CHAIRMAN. As Senator Donnelly says, if there is any guy sitting down with a lady standing, the guy is going to get some dirty looks.

[Laughter.]

Okay. First, we are going to hear from Jean Smart. Ms. Smart is an Emmy winning television, film, stage actress who was diagnosed with Type 1 diabetes at the age of 13.

And then we are going to hear from Ray Allen. He is a ten-year NBA All-Star who currently plays, by the way——

[Laughter.]

And made the critical shot in Game Six——

[Applause.]

For the NBA Champions, the Miami Heat. He and his wife, Shannon——

Senator DONNELLY. Being from Indiana, can I object to that shot?

[Laughter.]

The CHAIRMAN. Well, Indiana suffered, but the ones who really suffered was San Antonio.

Ray's wife, Shannon, who serves on the JDRF's International Board, they are parents to Walker, who was diagnosed with Type 1 diabetes at 17 months, and Walker is right there with us. They will share the difficulties in managing Type 1 diabetes in very young children.

And then we will hear from Quinn Ferguson, a JDRF Children's Congress Delegate from Senator Collins's State of Maine.

And then we are going to hear from Griffin Rodgers, the Director of the National Institute of Diabetes and Digestive and Kidney Dis-

orders at NIH, the National Institutes of Health, which is one of the most fantastic research centers, all trying to do good in finding cures for the diseases that afflict us.

And then we will hear from Jeffrey Brewer. Mr. Brewer is President and CEO of JDRF.

And so let us start with you, Ms. Smart.

STATEMENT OF JEAN SMART, ACTRESS

Ms. SMART. Senator Nelson, Senator Collins, and members of the committee, thank you so much for allowing me the opportunity to appear here today and talk about an issue that is important to all these great kids and their families and their guardians and I, myself, and that is the issue of living life with Type 1 diabetes.

I was actually here in Washington, D.C. in 1965. I was 13 years old. Go ahead, do the math.

[Laughter.]

And I was waiting with my family to see the Tomb of the Unknown Soldier and I was showing all the telltale signs of Type 1 diabetes. I was so tired. I was so parched. I could not drink enough liquid to slake my thirst. It was over 100 degrees on that hot day in August, so my parents put it down to the heat. But later, after stopping, I think, at almost every gas station restroom on the drive home from D.C. to Seattle, Washington—a long drive—and after losing almost 20 pounds in a matter of weeks, my parents knew there was something seriously wrong.

So shortly after returning home, I went to the doctor and I was told I had Type 1 diabetes and I cried. I started to cry. I remember the nurse—well, it was very shocking for my parents, too, as you can imagine. I remember the nurse very quietly offering smelling salts to my poor Daddy. He did not look too good. Nobody in our family had diabetes. No one can remember of anybody in the family ever having diabetes. And all I knew about it was, at that age, that you had to take injections and you could not eat sugar, which is quite a sentence to give to a scared child.

But by the end of that day, I was actually giving myself injections, and five days later, I was released from the hospital, put on a very strict no-sugar diet. I was also told that I should not consider having children, ever, and that was a statement that would come back years later to haunt me.

But 48 years ago, there were no blood glucose meters. There were no continuous glucose monitors. If you had diabetes, you had to assess your blood sugar level by doing a urine test, which was pretty inaccurate, but it was the best we had for home testing at the time. The syringes were large. The needles were big and heavy and they had to be reused, which made for some pretty painful injections in my skinny little 13-year-old thighs. Also, you had to boil them in a pot of water before every use. Now, luckily, of course, the needles are much smaller and finer.

But even with the advent of devices like the insulin pump, it really is far from where we hope to be. My friend, Beverly, has realized much more stable blood sugars on the pump, but she still has some really frightening highs and lows if she is not ever, ever vigilant.

I have never let diabetes define me. I never really thought of myself as a sick person. But, ironically, probably one of the main reasons I am a working actress today is because of diabetes. I actually had wanted to go to college on the other side of the State, to a college that did not offer a degree in drama, but my mother had other thoughts. She really wanted me to go to the University of Washington because it was very close to home. And so I went to UW for five years. I got my BFA in acting, which kind of launched my career.

So, I was busy working as an actress and in 1989, I discovered I was pregnant. And my husband and I were quite devastated when we were advised to terminate the pregnancy because my blood sugars were not in good control, and we were reminded of the harm that Type 1 diabetes could do to myself and my baby. But I found a specialist who took me by the hand and guided me through the next eight months. I tested my blood sugar 12 times a day, with a meter at that point, fortunately. I was on the phone daily with the specialist to adjust my insulin dosages. And I was lucky enough, also, to have a husband who was very supportive and turned himself into a pregnancy diabetic specialist. And it was very, very hard work, but thankfully for myself and my strong, healthy son, Connor, it paid off.

I am sorry. I did not want to forget anything here.

But, unfortunately for a lot of people in my generation who were diagnosed as kids with diabetes, they have had a high rate of complications—heart disease, heart attacks, strokes, blindness, kidney failure, nerve damage, very complicated pregnancies.

I have had some very scary low blood sugars, and I am sure the kids will identify what I am talking about. If you have never had one, it is hard to describe. It feels to me a little bit like drowning, actually. One close call I had, I was actually on stage in front of about 900 people on Broadway, opposite Mr. Nathan Lane—name dropping—and I knew I was in trouble. It was very scary. And my mouth somehow kept saying the words, but my brain was screaming, you are in big trouble, and fortunately, that scene ended just in time. And ever since then, I have stashed jelly beans all over every set I have ever worked on. Years from now, they will find petrified jelly beans in anyplace that I have ever worked.

[Laughter.]

You know, it is hard for me to remember what life was like before I had diabetes, and sometimes, selfishly, of course, I wish that I could just remember what that was like, to feel what that was like, to not be diabetic, to go maybe a day without being diabetic, to go more than just a couple of hours without having to think about my blood sugar. But what I really pray for is that the next generation of beautiful children like these do not ever have to go through the uncertainty and the fears of being diabetic, or the physical tolls that it can take on their bodies.

You know, I never made it to the Tomb of the Unknown Soldier that day. I did not have the strength. But because I was lucky enough to be born in the second half of the 20th century, and because of the advances in diabetes care, and because Kay Smart was afraid to let me go away to college, I am able to appear here before you and to thank you and to thank Congress and to thank the

JDRF for all you have done to promote Type 1 diabetes research, and I ask that you please, please continue your efforts so that one day, we can actually all say—everybody in this room can say, remember that day that we cured diabetes?

Thank you.

[Applause.]

[The prepared statement of Ms. Smart follows:]

Testimony of

Ms. Jean Smart
Actress

At the Hearing Entitled

"Diabetes Research: Reducing the Burden of Diabetes at All Ages and Stages"

Wednesday, July 10, 2013

Before the

Senate Special Committee on Aging

Senators Nelson and Collins and members of the committee, thank you so very much for the opportunity to appear before you today to discuss an issue that all of these great kids, their families and I know all too well; living life with Type I Diabetes. I was actually here in Washington DC in 1964. I was 13 and…go ahead do the math, waiting to visit the Tomb of the Unknown Soldier with my family. I was starting to show the telltale signs of Diabetes. I was very tired and so parched I couldn't drink enough liquid to slake my thirst. It was over 100 degrees that day in August, so naturally my parents put it down to the heat. But later, after stopping at nearly every gas station restroom on the drive home from DC to Seattle, and losing almost 20 lbs. in a matter of weeks, my parents knew something was terribly wrong. Shortly after we got home we went to the doctor where I learned I had Type I Diabetes. It came as quite a shock to me as well as my parents as you can imagine. I remember the nurse very quietly offering smelling salts to my poor Daddy; he didn't look so good. No one in my family had the disease and no one could remember anyone in the family who had ever had it. All I knew about Diabetes was: you couldn't eat sugar and you had to take shots. Quite a life sentence to a scared child. But by the end of that first day I was injecting myself, then after spending five days in the hospital I was sent home on a strict sugar-free diet. I was also told to not consider having children, ever. That statement came back to haunt me years later. Forty eight years ago there were no blood-glucose meters or continuous glucose monitors. Instead, people with Diabetes had to assess what their blood sugar levels were by performing urine tests. They

weren't very accurate but it was the best we had at the time. As for the syringes, they were very large and had to be reused, which made for some pretty painful injections in my skinny 13 year old thighs. Plus, they had to be sterilized in a pot of boiling water before each use. Luckily today, we have much shorter, finer disposable needles. But even with the advent of devices like the insulin pump it is far from where we hope to be. My friend Beverly has realized much better blood sugars with the pump, but is still subject to frightening highs and lows if she is not ever-vigilant. I did my best to manage my Diabetes while growing up and did not let it define me. I have never thought of myself as a "sick" person but ironically my Diabetes is largely the reason I became an actress. I had my sights set on attending a university on the other side of the state which offered no degree in Drama but had a wonderful speech department. However, my Mom had other ideas. She wanted me to go to the University of Washington since it was closer to home. I studied at U.W for five years earning a BFA in acting and from there my career was launched. In 1989 I was enjoying life as a working actress when I found out that I was pregnant. My husband and I were panic-stricken when we were advised to terminate the pregnancy because my sugars had not been in good control and we were reminded of the harm Type I Diabetes could cause the baby and me. But I found a specialist who helped me navigate the next 8 months. I tested my blood glucose levels with a meter, fortunately, twelve times a day and was on the phone daily with my doctor to adjust my insulin needs and those of the baby growing inside me. I also had an extremely supportive

husband who immediately turned himself into an expert on pregnant diabetics. It was hard work but luckily for me and my strong, healthy son it paid off. After having Type I Diabetes for so long I am fortunate that I do not have many of the complications that can be a result of this disease. My doctor said I must have been born with some really good genes. Unfortunately, many of my generation who were diagnosed with Diabetes as children have suffered high rates of heart attacks, strokes, blindness, nerve damage, complicated pregnancies and kidney failure. Even those of us with good genes have faced risks every day from the disease. I've had some very scary low blood sugars which, if you've never experienced it, feels a little like drowning. One of my closest calls was while onstage, on Broadway, opposite Nathan Lane, my mouth was still saying the lines but my brain was telling me I was in big trouble. Luckily the scene ended just in time. Since then, I make a habit of stashing jelly beans all over the set. It's hard sometimes to remember what my life was like before Diabetes and, selfishly, I would, of course, love to know what it feels like again to not be diabetic; to go more than just a few hours without thinking about my blood sugar. But what I really pray for is that the next generation of young, beautiful children like these will never know the uncertainty and fears of being diabetic or the physical toll it takes on their bodies. I never made it to the Tomb of the Unknown Soldier that day; I didn't have the strength. But because I was lucky enough to be born in the second half of the 20th Century, because of advances in diabetes care and Kay Smart who was afraid to let me leave home for college; I am standing here today able to thank Congress,

to thank you and JDRF for all you've done to promote Type I Diabetes research and ask that you please continue your efforts so that very soon we can talk about the day we cured this disease. Thank you.

The CHAIRMAN. By the way, you all may be wondering, why is the Aging Committee having a hearing with so many young people here?

Ms. SMART. It is because of me.

[Laughter.]

The CHAIRMAN. It is simply because the physical, the economic, and the emotional toll of diabetes lasts throughout a lifetime, and when one becomes a senior citizen, you really start to see a lot of the impacts on the individual and society.

Thank you, Ms. Smart.

Next, Mr. Allen.

STATEMENT OF RAY ALLEN, PLAYER, MIAMI HEAT, NATIONAL BASKETBALL ASSOCIATION, AND FATHER OF WALKER ALLEN, JDRF CHILDREN'S CONGRESS DELEGATE FROM FLORIDA

Mr. ALLEN. Thank you. Good afternoon, everybody. It is an honor to be invited to appear before you here today to give you an understanding of what it is like for a family to live with Type 1 diabetes.

As you listen to our story, please know there is nothing special about our family, my wife, Shannon, our son, Walker, or me. Hundreds of thousands of other families across the United States and the world could tell you a story similar to ours. So, here is our story.

In 2008, I was a member of the Boston Celtics and we had a great run that year and we found ourselves in the middle of playing in the NBA Finals against the L.A. Lakers, the moment I had dreamed of since I was a little boy. There I was, competing for an NBA Championship. It was everything that I could ever ask for. There were a lot of special things about that series. It was the first time since 1986 that the Celtics won the NBA Title. It was the most watched NBA telecast in NBA history. And, personally, it was my first NBA Championship.

All of those things are very memorable, but what I remember it for is for another reason. While our family was in L.A. for Game 5, our son, Walker, who was 17 months old at the time, became very ill. My wife, Shannon, rushed him to the hospital where he was diagnosed with Type 1 diabetes. It was as if a rug was pulled from underneath us. Life as we knew it was over. You see, even though just a few days later we finished our journey, winning Game 6 and being crowned an NBA Champion, another journey began that we are still on today.

As you can see, Walker, he is six now, but he is still too young to manage diabetes on his own. No disease is easy, but managing Type 1 diabetes may be one of the most complicated and complex responsibilities facing any caregiver or person living with diabetes, or any disease, for that matter.

From the moment Walker wakes up in the morning until the moment he goes to sleep, we have to monitor everything he drinks. We have to test his blood sugar with finger pricks ten times a day. And we have to count the amount of carbohydrates he consumes. Then, do the mathematical equation required to decide how much insulin to inject. This can be as many as seven shots a day just so

the blood glucose levels remain in the safe range. Any miscalculation on our part could be life-threatening for Walker.

You might think we finally can catch our breath when Walker goes to bed. Not so. Type 1 diabetes can be at its most dangerous at night, as you all know. Blood sugars that seem fine at bedtime could suddenly come crashing down in the middle of the night. Without juice or food to restore the balance, Walker could drift into a coma and we would never know it until we tried to wake him in the morning, and that might just be too late. So we wake up every two hours throughout the night, on the clock, to check Walker's blood sugars. Shannon and I often joke that we are vampires. Neither one of us has slept through the night in five years since his diagnosis. That is a reality for all families and not just ours.

The Miami Heat, we played 106 games this past season. We had game days, practice days, travel days, even a few off days, days to rest, days to heal, days to rejuvenate, recharge. But for Walker, here, and I know a lot of the kids here in this room and a lot of the people that live with diabetes, there are no off days.

As he gets older, Walker will gradually take more charge of his Type 1 diabetes, but it will not get any easier because more and more factors will impact the blood sugar levels—exercise, stress, even normal changes in adolescent hormonal activity, changes utterly beyond Walker's control. They will all cause his blood sugars to gyrate wildly.

Shannon and I know from talking to other parents that children and young adults with Type 1 diabetes show tremendous courage, resolve, and steadfast determination not to let this disease define them. But we also know that no matter how old Walker is, no matter where he is or what he is doing every day, he has to live a new day with Type 1 diabetes, and what works one day may not work the next day, and the risks are always ever present. I doubt Shannon and I will ever go a day without just a little bit of fear and worry in the back of our minds, fear for our son's safety and his overall health that reaches his potential and is able to live his dreams.

It is not his fault that he has diabetes. There is nothing he or we did to cause it. It is not diet or lifestyle related, as is the case with Type 2 diabetes. Genetics is a part of it, but there is no history of Type 1 diabetes in our family. We do know this. Type 1 diabetes and autoimmune disease, the body launches an attack on the cells that produce insulin, eventually destroying them and leaving people with Type 1 diabetes dependent on synthetic insulin to survive. But insulin is not a cure. It is a lifeline, and there is a big difference.

That is why Shannon and I got involved with the JDRF. Shannon now serves on the Board of Directors, and we know that JDRF is working on therapies that may reduce the tremendous daily burden of living with Type 1 diabetes and that is working towards a cure. As we know, JDRF is working with Congress to make sure the government does its share and funds important programs like the Special Diabetes Program.

On the basketball court, a lot of your success comes from experience, hard work, repetition, practice, instinct, and, of course, a little luck. A rebound careens off the rim, a teammate grabs it and

passes you the ball in the corner. Without thinking, you catch it, step back, and you hit a "three." Sometimes it happens that way.

[Laughter.]

It keeps your championship hopes alive. We will need more than hard work, repetition, instinct, luck, practice, and experience, though, to beat Type 1 diabetes.

I know Type 1 diabetes will never hold Walker back, but we dream of a day when Walker can leave this disease behind with the continued support of Congress for the Special Diabetes Program, with the investment of JDRF and the private sector, and the dedication and commitment all the families in this room and all around America, all around the world, today, and hundreds of thousands of other people in other countries, that we will create a world without Type 1 diabetes. We have to, because together, we are a winning team.

Thank you.

[Applause.]

[The prepared statement of Mr. Allen follows:]

Testimony of

Mr. Ray Allen

Guard for the National Basketball Association's Miami HEAT

Accompanied by

Walker Allen

Age 6, JDRF Children's Congress Delegate from Florida

At the Hearing Entitled

"Diabetes Research: Reducing the Burden of Diabetes at All Ages and Stages"

Wednesday, July 10, 2013

Before the

Senate Special Committee on Aging

Good afternoon.

It's an honor to be invited to appear before you here today to give you an understanding of what it's like for a family to live with type one diabetes, or T1D. As you listen to our story, please know there is nothing "special" about our family, my wife Shannon, our son Walker, or me. Hundreds of thousands of other families across the United States and the world could tell you a story similar to ours. So I am here as a voice for those families and for everyone else touched by this disease. Some of these families are NBA fans, some may even be Miami Heat fans and others are certainly fans of different teams...but, today we are all united on one team with one goal in rooting on Congress to run a fast break toward curing this disease!

Here's our story.

In 2008, I was a member of the historic Boston Celtics; we had a great run that year and found ourselves playing in the NBA Finals against the Los Angeles Lakers — the moment I had dreamed of since I was a little boy. There I was, competing for an NBA championship, it was surreal.

There were a lot of special things about that series; it was the first time since 1986 that the Celtics won the NBA title; it was the most watched NBA telecast in NBA history and personally, it was my first NBA Championship. All of those things are memorable; but, I may remember it more for another reason — while our family was in LA for Game 5, our son Walker, who was 17 months old at the time, became very ill. My wife, Shannon, rushed him to the hospital where he was diagnosed with T1D. It was as if the rug was pulled out from underneath us. Life as we knew it was over; you see, even though just a few days later we finished one journey, winning Game 6 and being crowned as NBA Champions, another journey began that we are still on today.

Walker is six now.

But, he is still too young to manage his diabetes on his own. No disease is easy but managing T1D may be one of the most complicated and complex responsibilities facing any caregiver or person living with a disease.

From the moment Walker wakes up to the moment he goes to sleep we have to monitor everything he eats and drinks. We have to test his blood sugar with finger pricks 10 times a day; we have to count the amount of carbohydrates he consumes, then do the mathematical calculation required to decide how much insulin to inject — this can be as many as 7 shots a day just so his blood glucose levels remain in a safe range. Any miscalculation on our part could be life threatening for Walker.
You might think we finally can catch our breath when Walker goes to bed? Not so. T1D can be at its most dangerous at night. Blood sugars that seem fine at bedtime could suddenly come crashing down in the middle of the night. Without juice or food to restore the right balance, Walker could drift into a coma and we'd never know it until we tried to wake him in the morning when it might be too late. So, we wake up every

two hours throughout the night to check Walker's blood sugars. Shannon and I often joke that we are vampires, neither one of us has slept the night through in five years since Walker's diagnosis and that is the reality for all families, not just ours.

The Miami Heat played 106 games this past season. We had game days, practice days, travel days even a few off days; days to rest, to heal, to rejuvenate and recharge. But, for our son Walker and any family living with T1D there are no off days.

As he gets older Walker will gradually take more charge of his T1D. But it won't get any easier because more and more factors will impact his blood sugar levels. Exercise, stress, even normal changes in adolescent hormonal activity; changes utterly beyond Walker's control, will cause blood sugars to gyrate wildly. Shannon and I know from talking to other parents that children and young adults with T1D show tremendous courage, resolve, and a steadfast determination not to let this disease define them. But we also know that no matter how old Walker is, no matter where he is or what he's doing, every day with T1D is a new day, what works one day may not work the next day, and risks are ever-present. I doubt Shannon and I will ever go a day without just a little bit of fear and worry in the back of our minds. Fear for our son's safety, his overall health, that he reaches his potential, is able to live his dreams.

It isn't Walker's fault that he has T1D. There's nothing he or we did to cause it. It isn't diet or lifestyle related, as is the case with type two diabetes. Genetics are part of it but there is no history of T1D in our family. We do know this: T1D is an autoimmune disease. The body launches an attack on the cells that produce insulin eventually destroying them and leaving people with T1D dependent on synthetic insulin to survive.

But insulin is not a cure.

It is a lifeline and there is a big difference. That's why Shannon and I got involved with JDRF. Shannon now serves on their Board of Directors. We know that JDRF is working on therapies that may reduce the tremendous daily burden of living with T1D, and that it is working towards a cure. And we know JDRF is working with Congress to make sure the government does its share and funds important programs like the Special Diabetes Program.

On the basketball court, a lot of your success comes from experience, hard work, repetition, practice, instinct, and of course a little luck. A rebound careens off the rim, a teammate grabs it and passes the ball to you in the corner — without thinking you catch it, step back, and hit a 3 pointer to tie the game and keep your championship hopes alive.

We will need more than hard work, repetition, instinct, luck, practice and experience, though, to beat T1D.

I know T1D will never hold Walker back. But we dream of a day when Walker can leave this disease behind. With the continued support of Congress for the Special Diabetes Program, with the investment of JDRF and the private sector, and with the dedication and

commitment of the families surrounding us today, and hundreds of thousands of others around the country, we will create a world without T1D. We have to. Together, we are a winning team.

Thank you.

The CHAIRMAN. And, Walker, we are glad that you are here, too. Thank you for bringing your Dad here today.

Mr. ALLEN. I am glad to be here.

The CHAIRMAN. Okay. Quinn Ferguson. Now, you are a representative of all of these blue shirts out here, so tell us your story.

STATEMENT OF QUINN FERGUSON, JDRF CHILDREN'S CONGRESS DELEGATE FROM POLAND SPRINGS, ME

Mr. FERGUSON. Thank you, Senator Collins, Senator Nelson, and members of the Aging Committee, for inviting me to testify. My name is Quinn Ferguson. I am 14 years old and I am from historic Poland Spring, Maine. I have been living with Type 1 diabetes since I was diagnosed a week before my ninth birthday.

I will never forget the day I was diagnosed. Actually, I was misdiagnosed. I was at my grandparent's house when I passed out and had fallen on the ground, so my Mom drove me immediately to the hospital. On the way, I started throwing up, but my doctor said it was a concussion and sent me home.

A week later, I was still not feeling better. After looking online to find out what was causing my symptoms, my Nana brought over my Grandpa's diabetes test kit. He has Type 2 diabetes. My blood sugar was over 600, more than four times the normal range. After that, I was diagnosed with Type 1 diabetes, or T1D.

Voices have been silenced and lives have been cut short because of this disease. I am here today to speak for them as well as myself, and I am not alone in my story. People are misdiagnosed every day or not diagnosed at all, suffering the consequences and sometimes paying the ultimate price. I am here today because they cannot be and because we need to do more about this disease.

Every day since I was diagnosed, I have had to check my blood sugar at least ten times a day, even in the middle of the night. I measure everything I eat and drink and I think about my blood sugars constantly, when I am in school, on the football field, or in a chess match. If I do not, I could experience a seizure or a coma or suffer from long-term complications like eye disease, kidney failure, and heart problems.

I am fully responsible for my diabetes, from caring for myself to taking charge of my attitude on T1D. While there are times I get down, I am not out. I am a strong person for living with this disease, but every day is a trial by fire. I will never have a day off, and even as a teenager, I will never outgrow T1D.

Thanks to medical research, life will get better. It has to. I am not giving up on a cure and hope Congress will not, either, and will continue to support the Special Diabetes Program, my hope for a cure. While we wait for a cure, I am doing my part by educating others about T1D and enrolled in a TrialNet study that tests the drug Abatacept to stop or slow down destruction of insulin-producing beta cells. Those newly diagnosed with T1D who got the drug produced insulin longer than people who did not for almost one year. The study is now testing the drug in people at risk, but not yet diagnosed, to see if it can help delay or prevent T1D. Having a relative greatly increases the chance of being diagnosed. Without the SDP, TrialNet studies of almost 20,000 patients will not see results.

The SDP led us to the artificial pancreas technology now being used in—tested in T1D patients. These patients are living my dream. They do not have to worry constantly about blood sugars and can sleep through the night. The artificial pancreas is taking the guess work out of managing the disease by automatically testing blood sugars and giving insulin as needed. It will help keep people with T1D safe and healthy until a cure is found.

My Great-Grandfather Alfred Clark Ferguson came to the New World on an orphan ship when he was five years old. At that age, he could only dream of a future where the sugars would never take parents away from their children again. He lived to see science find a treatment for diabetes. Whether my generation lives to see a cure depends on research and funding. We need your help.

Today, I am surrounded by 160 delegates and their parents who represent the millions of people doing everything possible for a cure. I am grateful that Senator Collins and so many in Congress have been so supportive and I urge you to keep it up. Our hope for a full life depends on it. While the worry never goes away, we know better days are ahead. That is why we need your support for the Special Diabetes Program, so that maybe one day we can say that the world is free from T1D.

Thank you.

[Applause.]

[The prepared statement of Mr. Ferguson follows:]

Testimony of Quinn Ferguson

Age 14, JDRF Children's Congress Delegate

from Poland Spring, Maine

At the Hearing entitled:

"Diabetes Research: Reducing the Burden of Diabetes at All Ages and Stages"

Wednesday, July 10, 2013, 2:00 p.m.

Before the

Senate Special Committee on Aging

Dirksen Senate Office Building, Room G-50

Washington, D.C.

Thank you, Senator Collins, Senator Nelson, and Members of the Aging Committee for inviting me to testify. My name is Quinn Ferguson. I am 14 years old and I am from Poland Spring, Maine. I have been living with type 1 diabetes since I was diagnosed a week before my 9th birthday.

I will never forget the day I was diagnosed – actually, I was misdiagnosed. I was at my grandparents' house when I opened my eyes and I was on the ground -- I had passed out and had fallen. So my mom drove me immediately to the hospital. On the way, I started throwing up. But my doctor said it was a concussion and sent me home.

A week later, I was still not feeling better. After looking online to find out what was causing my symptoms, my nana brought over my grandpa's diabetes test kit – he has type 2 diabetes - and my blood sugar was 600 – more than four times the normal range. After that, I was diagnosed with type 1 diabetes or T1D.

Voices have been silenced and lives cut short because of this disease. I am here today to speak for them as well as speak for myself. And I am not alone in my story– people are misdiagnosed every day, or not diagnosed at all, suffering the consequences and sometimes paying the ultimate price. I am here today because they could not be, and because we need to do more about this disease.

Every day since I was diagnosed, I have had to check my blood sugar at least ten times a day -- even in the middle of the night. I measure *everything* I eat and drink, and I think about my blood sugar constantly when I am in school, on the football field, or in a chess match. If I don't, I could experience a seizure or a coma, or suffer from long-term complications like eye disease, kidney failure, and/or heart problems.

I am fully responsible for my diabetes – from caring for myself to taking charge of my attitude on T1D. While there are times that I get down, I know that I am not out. I am a stronger person living with this disease, but every day is a trial by fire. I never have a day off, and, even as a teenager, I will never outgrow T1D.

Thanks to medical research, life will get better- it has to (get better). I am not giving up on a cure, and hope Congress won't either and will continue to support the Special Diabetes Program -my hope for a cure.

While we wait for a cure, I am doing my part by educating others about T1D and enrolled in a TrialNet study that tested the drug abatacept to stop or slow down destruction of insulin-producing beta cells. Those newly diagnosed with T1D who got the drug produced insulin longer than people who did not for almost one year.

The study is now testing the drug in people at risk, but not yet diagnosed, to see if it can help delay or prevent T1D because having a relative greatly increases the chances of being diagnosed. Without the Special Diabetes Program, TrialNet studies of almost 20,000 patients will not see results.

The Special Diabetes Program investment also led us to the artificial pancreas technology now being tested in T1D patients. They are living my dream – they do not have to worry constantly about blood sugars and can sleep through the night because the artificial pancreas is managing the disease. It is automatically testing blood sugar and giving insulin as needed, and will help keep people with T1D safe and healthy until a cure is found.

My great grandfather, Alfred Clark Ferguson, came to the "new world" on an orphan ship when he was five years old. At that age, he could only dream of a future where "the sugars" would never take parents away from their children again. He lived to see science find a treatment for diabetes. Whether my generation lives to see a cure depends on research and funding. We need your help.

Today, I am surrounded by 160 delegates and their parents who represent the millions doing everything possible for a cure. I am grateful that Senator Collins and so many in Congress have been so supportive, and I urge you to keep it up. Our hope for a full life depends on it.

Thank you, Chairwoman Collins and Members of the Aging Committee, for holding this hearing and providing me the opportunity to represent those who could not be here today and give you a glimpse into life with T1D.

While the worry never goes away, we know that there are better days ahead. That is why we need your support for the Special Diabetes Program, so that perhaps one day we can say that the world is free from T1D!

I look forward to answering any questions you may have. Thank you.

The CHAIRMAN. Thank you, Quinn.

I still see some ladies standing back there, one there, one there, and I see one over here, and we have plenty of seats here, so please avail yourselves of the opportunity.

Okay, Dr. Rodgers. Tell us what is happening at NIH.

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

Dr. RODGERS. Thank you. Chairman Nelson, Senator Collins, members of the committee, thank you for giving me the opportunity to testify today.

On behalf of the National Institutes of Health, I am pleased to report that our investment in Type 1 diabetes research continues to improve lives around the country and around the world. Through coordinated efforts with research partners such as the JDRF and the ADA, as well as continuous support from the special statutory funding program for Type 1 diabetes research, we are helping people with Type 1 diabetes, such as the children sitting here today, live longer and healthier lives.

First, I would like to acknowledge the important contribution of my fellow witnesses. Ray Allen, you are a champion in basketball, but you and your family—your entire family—are truly champions in promoting efforts toward curing this disease.

I am also pleased to share the table with Jeffrey Brewer and Jean Smart, who I know share our goals of preventing, treating, and ultimately curing Type 1 diabetes.

I would also like to thank those here today representing Americans of all ages with Type 1 diabetes. Quinn, the clinical trial that you and other young people here today have participated in could not occur without your support. Our research is your research and we thank you for making it possible.

The future for those with Type 1 diabetes is brighter than ever. NIDDK-supported research has found that life expectancy for people with diabetes has increased by 15 years, and this increase is largely due to advances in technology and understanding that early glucose control is critical to reducing risk of long-term complications. This key insight was provided by the NIDDK's landmark Diabetes Control and Complication Trial, or DCCT, and its follow-up study called EDIC, E–D-I–C. Everything in government has an acronym.

[Laughter.]

This year, DCCT/EDIC celebrated its 30th anniversary, and we celebrate the great contributions to health of those with Type 1 diabetes.

Controlling blood glucose, as you all know, is very challenging, so it is critical that we continue the search for ways to prevent, treat, and cure diabetes. And we are, thus, focusing research on every stage of Type 1 diabetes development.

The first stage is the onset of auto-immunity, a stage where no symptoms are apparent, but where insulin-producing beta cells are being slowly destroyed. We have long sought to better understand what causes auto-immunity and now know that both genetic and

environmental factors play a role. We support various efforts, including a major international study involving thousands of children, to better understand these factors and we look forward to translating our discoveries into new treatments to prevent not only Type 1 diabetes, but other auto-immune diseases.

Stopping the auto-immune attack once it has begun is another focus of NIH research. The NIDDK's Type 1 Diabetes TrialNet and the NIAID's Immune Tolerance Network have identified several treatments to protect the beta cells, and studies to extend the effects of those promising results are ongoing.

Replacing or restoring the function of beta cells is another area of great interest, and one strategy is to replace the beta cells via islet transplantation, and recent progress in this area was largely made possible by NIDDK and the NIAID co-led Clinical Islet Transplantation Consortium. Today, islet transplant recipients are more likely to not need insulin at some point after their transplant. Their insulin independence lasts much longer. And they are less likely to have severe side effects than their peers receiving islet transplants just a decade ago.

We also plan to build upon the success of the NIDDK's Beta Cell Biology Consortium by creating the Human Islet Research Network, which will focus on improving methods to create beta cells and to extend their survival.

Now, we know that self-managing one's blood glucose levels is critical to long-term health, but it is also a huge burden, as you have heard from the witnesses already. A promising approach to ease this burden is an artificial pancreas, a device that can automatically sense blood glucose levels and administer insulin accordingly, and there has been tremendous progress in this area in recent years.

Preliminary studies indicate that these devices can keep blood glucose levels within an optimal range and allow the blood glucose to stay in control, much better than self-managed insulin pumps. Ongoing trials, such as devices in the real world setting, are also yielding extremely promising results. With continued research, artificial pancreas technology has tremendous potential to allow people with Type 1 diabetes to live, eat, and exercise freely without the fear of hypoglycemia.

The NIH also vigorously supports research to prevent and treat diabetes complications. For example, progress has been made by the Diabetic Retinopathy Clinical Research Network led by the NEI with support from the Special Diabetes Program. Research conducted through this network contributed to the recent FDA approval of a treatment for a serious diabetic eye complication, progress that has been hailed as the most important advanced treatment for diabetes retinopathy in the last 25 years.

Chairman Nelson, Senator Collins, members of the committee, thank you for this opportunity to speak today, and we are grateful for the continued support of Congress and for our public and private research partners and for the inspiring efforts of our clinical trial volunteers. Together, we strive to allow those of all ages with Type 1 diabetes to live longer, healthier lives, free of the burden of this disease.

Thank you for your attention. I will be pleased to answer any questions that you might have.

[The prepared statement of Dr. Rodgers follows:]

Testimony
Before the
Special Committee on Aging
United States Senate

Diabetes Research: Reducing the Burden of Diabetes at All Ages and Stages

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

For Release on Delivery
Expected at 2:00 p.m.
Wednesday, July 10, 2013

Chairman Nelson, Senator Collins, and Members of the Committee, as Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), I thank you for your invitation to testify at this hearing on type 1 diabetes. On behalf of the 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 report on our recent scientific advances and future opportunities in research on type 1 diabetes and its complications.

The NIH has long recognized the importance of diabetes research and for the past several years has invested over $1 billion each year in research investigating diabetes and its complications. This investment has been complemented by the support and efforts of our research partners around the country. These partners—including academic institutions, the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and patient-advocacy groups such as JDRF (formerly the Juvenile Diabetes Research Foundation) and the American Diabetes Association (ADA)—share our goals to prevent, treat, and ultimately cure type 1 diabetes. I am happy to report that through the invaluable support of the Congress and the Administration, through the hard work and dedication of our researchers, and, most importantly, through the generosity of our clinical trial participants, we have made important progress toward these goals. Today, I will highlight some of this progress as well as recent advances and future opportunities in type 1 diabetes research, including research supported by the Special Statutory Funding Program for Type 1 Diabetes Research.

Type 1 diabetes develops when the body loses its ability to produce the hormone insulin. Insulin is a key player in metabolism and helps the body regulate glucose levels in the blood. It is produced by the beta cells, which form clusters called islets within the pancreas. However, type 1 diabetes occurs when the body's own immune system targets and destroys these beta cells

as part of an autoimmune attack. As a result, 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 the millions of people of all ages with type 1 diabetes must monitor their food intake and physical activity, frequently monitor their blood glucose levels, and administer insulin through injections or an insulin pump in order to manage their blood glucose levels. This is a huge burden on them and their families and greatly affects their quality of life. Additionally, despite their vigilance and dedication, they are still susceptible to dangerous episodes of hypoglycemia (low blood sugar) and to developing long-term complications affecting the eyes, kidneys, nerves, heart, and other organs. Type 1 diabetes diagnoses are also becoming more common and are occurring at younger ages than before. The SEARCH for Diabetes in Youth study—supported by the NIDDK, CDC, and the Special Diabetes Program—has found that the prevalence of type 1 diabetes in people under age 20 rose by 23 percent between 2001 and 2009, highlighting the importance of identifying ways to prevent the disease and developing new therapies to manage this rising disease burden.

IMPROVING THE OUTLOOK FOR PEOPLE WITH TYPE 1 DIABETES

I am pleased to report that the future for those with type 1 diabetes is brighter than ever before. Life expectancies for those diagnosed with type 1 diabetes have risen dramatically. Recent NIDDK-supported research found that a person diagnosed with type 1 diabetes between 1965 and 1980 could expect to live a full 15 years longer than a similar person diagnosed 15 years earlier. This increase in life expectancy is largely due to advancing technology and the insight provided 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/EDIC helped define how critically important it is to control blood glucose levels early in the course of disease to reduce later development of complications. In 1983, when DCCT began, it was not known whether tightly controlling blood glucose levels helped people with type 1 diabetes reduce their risk for developing complications. The DCCT aimed to answer this question by comparing the effect of an intensive blood glucose management program versus what was conventional care at that time on the long-term health of people with type 1 diabetes. The DCCT demonstrated that intensive glucose control early after diagnosis dramatically reduced the occurrence and severity of small blood vessel damage to the eyes, kidneys, and nerves. The DCCT's follow-up study, EDIC, continued to follow the original DCCT participants and demonstrated that the protective effects of intensive glucose control persisted for decades. Those patients who had tightly controlled their blood glucose levels in the DCCT continued to have lower rates of eye, nerve, kidney, and cardiovascular complications than those who received conventional care, even though blood glucose levels of the two groups became similar after DCCT ended. In fact, over 95 percent of living DCCT participants continue to participate in EDIC today, a testament to both their remarkable altruism and to the impact the study has had on their lives and health.

As the DCCT celebrates its 30th anniversary this year, DCCT/EDIC continues to provide invaluable information on type 1 diabetes progression and complication rates. These crucial data on long-term outcomes of type 1 diabetes over an entire lifetime would not have been available without continuous NIDDK support. DCCT/EDIC is a prime example of how research findings can greatly benefit the health of the American people. Many current studies supported by NIDDK, such as clinical trials of new treatment methods to preserve beta cell function and

development of artificial pancreas technology, are based upon DCCT/EDIC's findings that maintaining normal blood glucose levels is critically important to long-term health.

Type 1 diabetes research requires collaboration and cooperation between scientists of varying disciplines from across the United States and the world. NIH and NIDDK's partnerships with other HHS agencies, with academic institutions and health providers, and with patient advocacy groups such as JDRF and the ADA have enabled us to work in synergy to support innovation and reduce duplication while taking full advantage of our scientific resources. Our most important partners, however, are our clinical research volunteers. Without them, the important clinical trials of the past, present, and future would not be possible. We applaud them for their selfless dedication to improving diabetes treatment today and for future generations.

The NIDDK and our research partners are dedicated to facilitating cutting-edge type 1 diabetes research. This mission encompasses research focusing on all the stages of disease: to protect beta cells by preventing autoimmune attack, to replace beta cells destroyed by the immune system, to improve glucose control once diabetes is established, and to eliminate diabetic complications through better prevention, detection, and treatment strategies. Understanding each of these stages will provide insight into the type 1 diabetes disease process and lay the groundwork for future advances. I would now like to share with you some of the most exciting recent progress in type 1 diabetes research.

UNDERSTANDING THE CAUSES OF TYPE 1 DIABETES

Understanding what causes type 1 diabetes is a crucial step towards developing effective treatments. Although we know that type 1 diabetes is an autoimmune disease, what causes the autoimmune attack and subsequent destruction of a person's beta cells is not completely

understood. However, we do know that a person's risk of developing type 1 diabetes involves both "nature" and "nurture"—both genetic and environmental factors—and that many genes contribute to a person's risk of developing type 1 diabetes.

Just a decade ago, only a handful of genes related to type 1 diabetes had been identified. The NIDDK-led Type 1 Diabetes Genetics Consortium (T1DGC) was formed to identify genetic regions associated with the disease. The Consortium collected over 38,000 DNA samples from families with type 1 diabetes and identified 40 new genetic regions. Thanks to the efforts of the Consortium and other researchers, we now know of over 50 genetic regions that contribute to a person's genetic risk of developing type 1 diabetes. This represents approximately 70 percent of the genetic contributions to disease, making type 1 diabetes one of the few polygenic diseases (diseases in which many genes are involved) for which most of the genetic susceptibility has been identified. The NIDDK continues to build upon this tremendous success by supporting research to identify what genes within these regions determine risk and how specific gene variants contribute to disease. Identifying particular genes and studying their functions will also teach us more about how and why type 1 diabetes occurs and may point to new targets for prevention and treatment.

However, the majority of those diagnosed have no family history of type 1 diabetes, and a high genetic risk does not guarantee that a person will develop the disease. Thus, researchers believe that there is at least one, and possibly several, environmental factors that interact with a person's genetic predisposition to determine disease risk. Some change in exposure to these factors might explain the increasing incidence of type 1 diabetes. Understanding what environmental factors contribute to disease development—whether they be a particular infection, a dietary factor, or some other as-yet-unknown agents—will allow us to prevent or reduce such

exposures and thus reduce the risk of type 1 diabetes. The NIH and the Special Diabetes Program fund research that aims to identify these causative or protective environmental factors.

One of the most ambitious of these studies is the NIDDK's The Environmental Determinants of Diabetes in the Young, or TEDDY. TEDDY is a long-term study aimed at discovering the environmental triggers of type 1 diabetes by identifying and monitoring children at high genetic risk of developing the disease. TEDDY has screened over 425,000 newborns and enrolled over 8,600 children into the study. For 15 years, TEDDY researchers and parents will collect information about possible environmental triggers in these children's lives, from their illnesses to their diet and allergies. Already, we know that the TEDDY participants are developing "autoimmunity"—a preclinical sign of type 1 diabetes—and type 1 diabetes at the predicted rates. As these children age, they will each contribute vital information on if, when, and how their disease develops.

The TEDDY families are taking part in the largest effort to identify environmental triggers of diabetes ever launched. The unprecedented scope of TEDDY is expected to contribute immensely to our understanding of type 1 diabetes, and the study is already providing important insights. For instance, TEDDY researchers have begun pilot studies using biological samples collected from the children to identify biomarkers predictive of autoimmunity and type 1 diabetes. These preliminary studies are already contributing to our understanding of what causes rapid-onset type 1 diabetes, a form of the disease that develops within 6 months after the appearance of disease markers called autoantibodies. Researchers had suspected from preliminary studies that viruses, particularly intestinal viruses called enteroviruses, might be associated with rapid-onset type 1 diabetes. However, TEDDY has recently released results from a small pilot study that found no evidence that viruses cause rapid-onset type 1 diabetes. It

remains to be determined whether viruses may trigger autoimmunity in people who develop the disease over years rather than months, and TEDDY is addressing that question as well. Importantly, TEDDY will also give us clues to what causes other autoimmune diseases, such as celiac disease, which shares some genetic susceptibility factors with type 1 diabetes and often occurs in the same individuals.

The NIH also supports a trial focusing on one possible environmental trigger of type 1 diabetes. The Trial to Reduce IDDM [insulin dependent diabetes mellitus] in the Genetically at Risk (TRIGR), led by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, is examining whether hydrolyzed infant formula compared to standard cow's milk-based formula decreases the risk of developing type 1 diabetes in at-risk children. Over 2,000 children have been enrolled in TRIGR and are being followed until age 10.

TESTING STRATEGIES TO STOP THE AUTOIMMUNE ATTACK AND PRESERVE BETA CELLS

Even after a person is diagnosed with type 1 diabetes, preserving the beta cells they have left is a critical strategy to maintain the body's ability to produce insulin, achieve good blood glucose control, reduce the risk of complications, and promote overall good health. NIDDK's Type 1 Diabetes TrialNet and the National Institute of Allergy and Infectious Diseases' (NIAID's) Immune Tolerance Network (ITN) have both tested innovative ways to slow the autoimmune attack and to protect the beta cells of people with type 1 diabetes; some agents tested thus far have shown promise. For example, in an early-stage TrialNet study, the drug abatacept preserved a measure of beta cell function in those recently diagnosed with type 1 diabetes and thus appeared to slow the progression of the disease for up to a year. In addition, ITN found that the anti-CD3 monoclonal antibody, teplizumab, could slow the loss of the ability

to secrete insulin in a subset of people recently diagnosed with type 1 diabetes. Since a person can lose beta cells for years before showing any symptoms, clinical trials being conducted by TrialNet are building on these findings in newly diagnosed patients to test whether abatacept and teplizumab can prevent or delay type 1 diabetes onset in relatives of people with the disease. Finding ways to extend the effects of these promising treatments, for instance by testing treatment combinations targeting different parts of the immune system or different stages of disease, is also a high priority for future research. TrialNet is also uniquely positioned to test new and emerging prevention approaches as we learn more about what triggers autoimmunity from long-term studies such as TEDDY.

RESTORING BETA CELL FUNCTION

One step toward developing a cure for type 1 diabetes is understanding how beta cells function and what causes them to live or die. For 14 years, the Beta Cell Biology Consortium (BCBC) has advanced our understanding of human beta cell development and function with a focus on developing new strategies to restore lost beta cells by regenerating new beta cells, replacing lost cells, or reprogramming other types of cells to create beta cells. The BCBC's work has given us invaluable insight into basic beta cell biology and pioneered ground-breaking research, including the recent discovery that the adenosine signaling pathway is a key regulator of beta cell regeneration. Due to the BCBC's efforts, scientists are now able to use precursor cell types to produce cells that make insulin, a key technological advance. Building on the BCBC discoveries, we are now transitioning to a new effort, the Human Islet Research Network (HIRN). HIRN will investigate how to improve current methods of creating beta cells and also study how to extend beta cell survival in people with autoimmunity. HIRN will also be

poised to take advantage of exciting new discoveries in the beta cell field, such as the NIDDK-supported discovery of the new hormone, betatrophin, which can promote beta cell proliferation and glucose control in mice. This new discovery is just one example of the exciting research opportunities on the horizon.

Another strategy for restoring the ability to produce insulin is beta cell replacement via islet transplantation. Islet transplantation involves transplanting purified islets from a donor pancreas into a person with type 1 diabetes, where the islets produce insulin and eliminate or reduce the recipient's need for daily insulin injections. Islet transplantation appears to be highly successful in reversing hypoglycemia unawareness, a devastating complication of type 1 diabetes in which patients are unable to recognize dangerously low blood sugar levels.

Clinical studies to improve islet transplantation procedures are ongoing. The NIDDK and NIAID co-led Clinical Islet Transplantation Consortium (CITC) is a network of clinical centers that conducts clinical and mechanistic studies in islet transplantation, with or without accompanying kidney transplantation. The CITC's goals are to make the transplantation procedure more safe and effective through improvement of the production of human pancreatic islets and investigation of novel immunosuppressive regimens, and to obtain licensure for a pancreatic islet product for transplantation. The Consortium recently reached the primary endpoint of a pivotal, Phase III islet transplantation trial. The data from this trial are being assessed, and the CITC is preparing a report for the FDA on the results, a crucial step in the development of a human pancreatic islet product for transplantation as a therapy for individuals with type 1 diabetes who suffer from severe and recurrent episodes of low blood sugar.

We already have good news about improvements in the islet transplant field, as a recent analysis of accumulated islet transplant data available through the NIDDK-supported

Collaborative Islet Transplant Registry (CITR) found that the procedure is becoming more effective and safer due to better transplantation methods. Today's islet transplant recipients are more likely to become insulin-independent (to not need insulin injections) at some point after their transplant, their insulin-independence lasts longer, and they are less likely to have adverse effects than their peers receiving islet transplants just a decade earlier.

DEVELOPING TECHNOLOGIES TO IMPROVE GLUCOSE CONTROL

Self-managing one's blood glucose levels is a huge burden on those with type 1 diabetes. Insulin pumps that continually administer low doses of insulin can relieve some of this burden, but an alternative would be the use of an "artificial pancreas", a device that can fully automate blood glucose sensing and insulin administration. These devices are designed to replace the pancreas' lost ability to secrete insulin and are comprised of three components: a sensor that monitors blood glucose levels, an insulin delivery device, and a way for the two to communicate so that glucose levels are automatically maintained within an acceptable range, a strategy described as a "closed-loop" system. Essentially, an artificial pancreas would sense when insulin is needed and automatically administer just the right dose at the right time, making it easier and safer to maintain the tight glucose control that we know helps to reduce diabetic complications. Developing safe, effective, and long-lasting artificial pancreas technologies has enormous potential to positively impact long-term health and to reduce disease burden on people with type 1 diabetes, and there has been tremendous progress in this area in recent years. For example, there is preliminary evidence that artificial pancreas technology may allow not only for avoidance of dangerously high or low blood glucose levels, but also for near-optimal blood glucose control within a tightly targeted range. A recent study tested two different closed-loop

artificial pancreas systems in a hospital setting: one that aimed to simply avoid hypo- and hyperglycemia (called standard control-to-range or sCTR) and one that aimed to keep blood glucose levels within an even tighter optimal range (called enhanced control-to-range or eCTR). Clinical trial volunteers tested both these devices and were monitored continuously for 24 hours, including during exercise and overnight. Both devices were able to reduce hypoglycemic episodes better than self-monitoring blood glucose and administering insulin via an insulin pump, particularly overnight. The eCTR device was also able to reduce average glucose levels. The results of this short-term trial are extremely promising in that blood glucose levels were kept in the desirable range without adverse effects such as hypoglycemia. As early trials support the safety and effectiveness of the technology in a controlled environment, trials are moving from hospital settings to diabetes camps, and finally to real-world settings where people with type 1 diabetes live, eat, and exercise freely. For example, FDA has approved a clinical study for an artificial pancreas that will take place at a diabetes camp. This is a major milestone for the artificial pancreas as it will be the first camp study in the United States and will allow for the study of an artificial pancreas in a camp setting where children over the age of 12 will participate in camp activities and wear the artificial pancreas during the day and overnight.

To further accelerate progress, the NIDDK has recently funded new research to encourage human studies and technological advances toward a user-friendly, wearable artificial pancreas device. In April, NIDDK, FDA, and JDRF co-sponsored a workshop on "Innovation Towards an Artificial Pancreas," which brought together scientists and other interested persons from industry, academia, and the public sector to share ideas and discuss the technological innovations occurring in this exciting field. Furthermore, the NIDDK is supporting type 1

diabetes-focused interdisciplinary bioengineering training programs. These programs will encourage the next generation of bioengineers to tackle the technological problems faced by the diabetes field. For example developing a more rapidly absorbed insulin would overcome some of the barriers to achieving a safe and effective artificial pancreas device. With continued research, artificial pancreas technology has made tremendous strides and is poised to transform the lives of people with type 1 diabetes.

PREVENTING AND TREATING DIABETIC COMPLICATIONS

Decades of scientific study have demonstrated the importance of maintaining blood glucose control in preventing diabetic complications. Because of research advances, many people with diabetes can prevent or delay the onset of these complications, but the main driver of these conditions—persistently elevated blood glucose levels—is very difficult to prevent completely with our current technology. Further limiting patients' ability to achieve good glucose control are the dangerous episodes of hypoglycemia associated with intensive glucose control. Until type 1 diabetes can be prevented or cured completely, research into how to prevent and treat diabetic complications is vitally important for those living with the disease.

As I discussed earlier, the DCCT/EDIC study has been a treasure trove of information on how and when diabetic complications arise in those with type 1 diabetes. The decades-long follow-up of the dedicated study participants have allowed researchers to track the development and progress of long-term complications. Recently, more good news was reported: after an average 22-year follow-up, EDIC demonstrated that intensive glucose control early after type 1 diabetes diagnosis prevented the development and slowed the progression of diabetic kidney disease by 50 percent. These data show that carefully managing blood glucose early in the

course of type 1 diabetes continues to yield huge dividends, preserving kidney function for decades.

One area where we are bolstering research efforts is the link between type 1 diabetes and cardiovascular disease (CVD). It is critical for prevention efforts to define the time of onset of increased CVD risk. A recent ancillary study performed by the SEARCH for Diabetes in Youth study investigated whether or not youth with type 1 diabetes were at increased risk of developing CVD. This study reported that youth who had lived with type 1 diabetes for an average of 10 years—and particularly those with poor glucose control—were likely to have asymptomatic signs of cardiac autonomic neuropathy (CAN), a serious heart condition that often progresses silently and is a significant cause of morbidity and mortality in those with diabetes. The combination of CAN—and other manifestations of CVD—can be particularly dangerous when combined with the risks of hypoglycemia. Identifying early manifestations and reliable warning signs of CVD in people with type 1 diabetes may make it possible to design and test preventative strategies.

The NIH's investments in new treatments for diabetic eye complications also continue to bear fruit. Diabetic retinopathy is the leading cause of blindness in working age adults; this blindness is due to diabetic macular edema, where fluid leaks from abnormal blood vessels and causes swelling and damage to the light-sensitive central retina. Destruction of these abnormal vessels using a laser was the standard of care until the National Eye Institute-led Diabetic Retinopathy Clinical Research Network, supported by the Special Diabetes Program, reported that the drug ranibizumab, in conjunction with laser treatment, is a more effective treatment for diabetic macular edema than laser treatment alone. I am pleased to report that ranibizumab is now the first approved medical treatment for diabetic macular edema in over 25 years.

EMERGING OPPORTUNITIES IN TYPE 1 DIABETES RESEARCH

Collaboration between various scientific fields will be key to fostering innovation and maintaining our momentum in type 1 diabetes research. Investigating new scientific findings, developing new drugs and research tools, testing new treatment regimens in clinical trials, and designing the technology required to move us toward a cure for type 1 diabetes requires an incredible breadth of knowledge. We must continue to support the next generation of clinicians, endocrinologists, behavioral scientists, bioengineers, and other researchers that will continue our fight to prevent, treat, and cure type 1 diabetes and its complications. To this end, the NIDDK is expanding its efforts to recruit and train scientists whose talents will strengthen the type 1 diabetes field. As I mentioned earlier, we are investing in the training of bioengineers interested in designing and testing new tools and devices such as the artificial pancreas. We are also training behavioral scientists to focus their skills on the particular challenges faced by those with type 1 diabetes, such as identifying strategies to improve adherence to the arduous treatment regimens required to manage the disease, particularly in pre-teens, adolescents, and young adults who often have difficulty achieving good blood glucose control. We are also continuing our exceptionally successful pediatric endocrinologist training program that provides training and career development aid to those who wish to pursue research careers focused on childhood diabetes. These programs and others like them will encourage cross-disciplinary study and collaboration that will allow the type 1 research field to grow and adapt to the ever-changing research landscape.

Furthermore, collaboration and resource sharing is critically important to maximize the return on our scientific research investment. The NIDDK is dedicated to providing access to

data and samples collected during NIDDK-sponsored clinical trials. Once these studies are completed, samples are made available to the research community for further study through the NIDDK Central Repository, aiming to leverage our existing investments to provide the most information possible. Strategies such as these aim to reduce duplicated research and ensure that we get the most science for our dollar.

As we move forward, NIDDK support of type 1 diabetes research continues to be guided by emerging opportunities outlined in a 2011 Diabetes Research Strategic Plan, which the Institute spearheaded. The statutory Diabetes Mellitus Interagency Coordinating Committee (DMICC), chaired by NIDDK, also serves as a key forum for coordinating activities and reducing duplication of effort across various HHS and non-HHS governmental entities. Under the auspices of the DMICC, we were very pleased last month to solicit the input of scientific and lay experts on ideas for the use of funds from the recently extended Special Diabetes Program. That input has allowed NIH to identify the most critical areas of current research interest and will ensure that the Program will continue its excellent track record of supporting cutting-edge type 1 diabetes research.

CONCLUDING REMARKS

Thank you for this opportunity to share with you some of the exciting advances and ongoing efforts in type 1 diabetes research. We are grateful for the continued support of Congress and the Administration that has allowed the NIH to vigorously support research to combat type 1 diabetes and its complications. We are thankful for our continuing partnerships with patient organizations, our sister federal agencies, and research institutions across the country. Finally, we are grateful for the truly inspiring efforts of our clinical trial volunteers.

Our research is their research, and we are indebted to them for their support and dedication. Together, we all strive to reach our ultimate goal of curing type 1 diabetes to allow the children at this hearing and those of all ages with type 1 diabetes to live longer and healthier lives free of the burden of disease.

Thank you, Mr. Chairman, Senator Collins, 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.

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 had served as the NIDDK's acting director since March 2006 and was the Institute's deputy director from 2001-2009. Dr. Rodgers also has been chief of the Molecular and Clinical Hematology Branch since 1998. 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.

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 to 1997. He is a member of the American Society of Hematology, the American Society of Clinical Investigation, the Association of American Physicians, the Institute of Medicine of the National Academy of Sciences, and the American Academy of Arts and Sciences. He served as chair of the Hematology Subspecialty Board and is a member of the American Board of Internal Medicine Board of Directors. Dr. Rodgers is board certified in internal medicine, emergency medicine, and hematology.

The CHAIRMAN. Thank you, Dr. Rodgers.

[Applause.]

Okay, Mr. Brewer. You brought along a lot of your colleagues today.

Mr. BREWER. I sure did.

The CHAIRMAN. Share with us, please.

STATEMENT OF JEFFREY BREWER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, JDRF

Mr. BREWER. Chairman Nelson, Senator Collins, members of the committee, I greatly appreciate the opportunity to be here today. My name is Jeffrey Brewer and I am the President and CEO of JDRF. As an entrepreneur and the father of a son with Type 1 diabetes, it is my great honor to lead the world's largest charitable funder of Type 1 diabetes research and to partner with the public and private sectors to drive progress toward our goal of a world without Type 1 diabetes.

I want to begin by thanking all the Senators who are here today for your great leadership in diabetes research. All of us at JDRF were extremely grateful in January when the Congress included a one-year, $150 million extension of the Special Diabetes Program. The SDP funds critical research upon which the private sector relies to identify in advance new therapies for Type 1 diabetes. Thanks to the SDP, scientists have identified more than 50 genes that influence a person's risk of developing Type 1 diabetes, and researchers are halfway through a 15-year study to identify what factors trigger its onset in the first place. At the same time, the SDP has helped advance important new therapies, including one that is available to patients today, one that can help reverse vision loss related to diabetes.

Last year, 72 Senators signed a letter in support of the Special Diabetes Program, and I would like to say a special thanks to Senate Diabetes Caucus Co-Chairs Collins and Shaheen, who are here today. Thank you very much for leading this effort.

As many of you know, Type 1 diabetes, also known increasingly as T1D, is a life-threatening disease that creates constant challenges for Americans of all ages. At every meal and many other times throughout the day and night, people with T1D must test their blood sugar and try to give the right amount of insulin, always at the right time. Too little insulin and high blood sugar will cause devastating complications. Too much insulin and low blood sugar will cause seizures, coma, and sometimes death, unfortunately.

In my family, my wife had to watch in horror as paramedics rushed into our home to rescue our son, who had lapsed into a coma as a result of too much insulin. Firefighters had to break down his door with an axe and rush him to the hospital, where he spent 48 hours in the ICU before recovering full consciousness. Living with T1D is a daily high-stakes challenge.

Diabetes has taken a toll on my family, the Children's Congress families here today, and many others around the world. It has also taken a toll on our nation, costing $245 billion in medical and economic expenses last year. Diabetes costs are rising rapidly, and according to a new study released today, the costs of diabetes are ex-

pected to more than double in the next eight years. The overall costs are expected to rise from $245 billion in 2012 to $512 billion in 2020. Costs to Medicare due to diabetes will also double, rising from $104 billion to $226 billion in 2020. As our population ages in the coming years, what is currently a significant problem is going to become a fiscal crisis.

Diabetes is a health crisis for patients and their families and a financial crisis for every American. Therefore, all of us, especially older Americans, have a serious stake in diabetes research. Research investments offer the only real hope for reversing these troubling trends.

Today, due to public and private research partnerships, there are new therapies in the pipeline that show great promise in improving the health of people with diabetes and reducing the costs to our nation. For example, in the last year, for the first time, people with T1D in the United States have worn artificial pancreas systems outside of the hospital as a part of groundbreaking research studies. In these studies, people with T1D have gone about daily life, going for walks, out to eat to restaurants, and to work with experimental technologies that automatically controlled their blood sugar. Less burden, better glucose control—it is not a cure, but it is great progress, progress made possible by JDRF, the National Institutes of Health, the Food and Drug Administration, various private sector companies, other research foundations, and all of you here today.

And with great progress, there is great potential for fiscal savings. For example, researchers have found that intensive glucose control over six-and-a-half years can cut in half the onset of kidney disease, and a 50 percent reduction in end-stage renal disease could save Medicare $126 billion over a term of 25 years.

With your leadership and the public-private partnership for diabetes research, potential therapies could transform millions of lives and improve the fiscal health of our nation. But we must move forward with urgency and with a long-term commitment to the investments and research that are needed to finish the job.

JDRF is funding ourselves more than $100 million in research this year and we currently have more than $500 million deployed in research programs at work today around the world. JDRF and our many volunteers will keep doing our part. But if we are to continue to make progress to advance towards desperately needed new therapies to cure, treat, and prevent T1D, we need the Federal Government to continue to do its part and that requires a long-term commitment to ensure that vital multi-year research proceeds without interruption.

I urge the Congress to fund a three-year extension of the Special Diabetes Program this year at the current funding level. We must make the promise of life saving and cost saving diabetes therapies a reality. We can make this future happen. We need your help.

Thank you, and I would be happy to answer any questions you may have.

[Applause.]

[The prepared statement of Mr. Brewer follows:]

TESTIMONY OF
JEFFREY BREWER
PRESIDENT AND CHIEF EXECUTIVE OFFICER
JDRF

BEFORE THE SENATE SPECIAL COMMITTEE ON AGING

HEARING ON

"DIABETES RESEARCH: REDUCING THE BURDEN OF DIABETES AT ALL AGES AND STAGES"

JULY 10, 2013

Chairman Nelson, Senator Collins, and Members of the Committee, I greatly appreciate the opportunity to be here today. My name is Jeffrey Brewer, and I am the president and CEO of JDRF. As a former entrepreneur and father of a son with type 1 diabetes, it is my great honor to lead the world's largest charitable funder of type 1 diabetes research, and partner with the public and private sectors to drive progress toward our goal of a world without type 1 diabetes.

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devastating complications. Too much insulin, and low blood sugar will cause seizures, coma, and/or death. In my family, my wife had to watch in horror as paramedics rushed into our home to rescue our son, who had lapsed into a coma as a result of too much insulin. Firefighters had to break down his door with an axe and rush him to a hospital, where he spent 48 hours in the ICU before recovering full consciousness. Living with T1D is a daily high-stakes challenge.

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United States have worn artificial pancreas systems outside the hospital as part of groundbreaking research studies. In these studies, people with T1D have gone about daily life—going for walks, out to eat in restaurants, and to work—with experimental technologies that automatically controlled their blood sugar. Less burden, better glucose control. Not a cure, but great progress—progress made possible by JDRF, the National Institutes of Health, the Food and Drug Administration, various private-sector companies, other research foundations, and all of you here today. And progress with great potential for fiscal savings. For example, researchers have found that intensive glucose control over 6 ½ years can cut in half the onset of kidney disease. A 50 percent reduction in end-stage renal disease could save Medicare $126 billion over 25 years.

With your leadership, and the public/private partnership for diabetes research, potential therapies could transform millions of lives and improve the fiscal health of our nation. But we must move forward with urgency, and with a long-term commitment to the investments in research needed to finish the job. JDRF is funding more than $100 million in research this year, and currently has more than $500 million deployed in research programs around the world. JDRF and our many volunteers will keep doing our part. But if we are to continue to make progress, to advance toward desperately needed new therapies to cure, treat, and prevent T1D, we need the federal government to continue to do its part. And that requires a long-term commitment to ensure that vital multi-year research proceeds without interruption.

I urge the Congress to fund a three-year extension of the Special Diabetes Program this year at the current funding level. We must make the promise of life-saving and cost-saving diabetes therapies a reality. We can make this future happen. We need you to help. Thank you. I would be happy to answer any questions you may have.

The CHAIRMAN. Thank you, Mr. Brewer.

Now, for our young friends, normally, what happens, we get into the questions. The Chairman will ask questions, the Ranking Member, and then according to the order in which the members appeared, then they are recognized. Because of my colleagues being so smart and so interested in all of this, I will defer my questions and I will do a wrap-up. So I want to call first on Senator Collins.

Senator COLLINS. Thank you once again, Mr. Chairman.

Dr. Rodgers, when Quinn was talking to me prior to the hearing, he mentioned that when he was diagnosed at age eight, he was the only person in his community with Type 1 diabetes. Now, he tells me, there are 12 or 13 children. I am very alarmed by a recent CDC study that shows that Type 1 diabetes among young people rose by a troubling 23 percent between 2001 and 2009. Do researchers have any idea why this increase?

Dr. RODGERS. Thanks for that question, Senator Collins. First, I would point out that the reason that we know that it has increased over 20 percent in that period of time is directly due to the Special Diabetes Program. The Special Diabetes Program has enabled us through a program called SEARCH in which the NIH works in conjunction with the CDC in several cities around the United States to monitor the onset of diabetes in youth. And in that group, there has been not only an increase in Type 1 diabetes at a younger age, as you indicated, but also Type 2 diabetes among adolescents and youth.

We know, as I indicated, that diabetes, especially Type 1 diabetes, is a result of a combination of genetic and environmental factors. It is quite likely that our genes have not changed over this short period of time, strongly indicating that it is quite likely some environmental factor that is increasing that is associated with that increased incidence of Type 1 diabetes.

And this long-term investment made possible by the Special Diabetes Program, a study called TEDDY, The Environmental Determinants of Diabetes of the Youth, in which we screen over 425,000 kids and we have enrolled 8,000 kids who are about halfway through the study. The hope there is to actually learn what are those environmental factors that trigger the autoimmune response to this disease.

If it turns out that it is a virus or a collection of viruses, then we would be prepared to develop vaccines to prevent this in people at youth. If it turns out that it is a dietary factor, then, obviously, avoidance of that would be important. But it is with the funding of the Special Diabetes Program that we have been able to both monitor the numbers of kids as well as be in a position to now determine what those environmental factors are.

Senator COLLINS. That is, indeed, absolutely critical research.

I know that everyone in this room is very interested in development of an artificial pancreas and much progress has been made in moving the clinical trials from hospital settings to diabetes camps and real world settings. Could you give us some idea on when you think the artificial pancreas will be more generally available.

Dr. RODGERS. Sure. Well, I would be pleased to comment on the research progress in this area. Obviously, I will have to defer to my

colleagues at the FDA to provide information on the regulatory aspects of this.

What I can say is that the FDA issued final guidance on the low-glucose suspend system, actually, in June of 2011, just a few weeks two years ago as a result of this meeting, as you remember, and for the development of an artificial pancreas system, they issued guidance in November of 2012.

What I would say is that there has been really strong research findings recently in trials conducted in Europe, in Australia, as well as in the United States that were recently published in the last six to eight months in the prestigious New England Journal of Medicine. These trials showed that this system can reduce the episodes of hypoglycemia, especially at night, which is especially worrisome, as you have heard from Ray Allen and Jeff Brewer as well as from other parents in this room.

This is an important finding, because we know that the threat of hypoglycemia is oftentimes what prevents people from very closely managing their blood sugar in tight control, which we now know definitely prevents long-term complications of the disease.

From a research perspective, I can say that the NIDDK continues its vigorous support for this artificial pancreas, both with the funds that we have in fiscal year 2013 and because the committee allowed us to move forward in fiscal year 2014. We will continue the strong support for this artificial pancreas in those years, as well.

Senator COLLINS. Thank you, Doctor, and I want to thank all of the witnesses. You are absolutely terrific.

The CHAIRMAN. Thank you, Senator Collins.

Senator Shaheen.

Senator SHAHEEN. Thank you very much, Mr. Chairman and Ranking Member Collins and Senator Warren, for allowing me to go next.

I very much appreciate the inspiring and compelling testimony from each of you on the panel, and I want to thank all of the delegates who are here with the Children's Congress. Your effort here today really makes a difference in educating us in Congress about what it is like living with Type 1 diabetes and how important it is for us to look at the policy level on things that we can do to help address Type 1 diabetes.

I have a personal window into what it is like to live with Type 1 diabetes because my oldest granddaughter has Type 1. She was diagnosed a little after she turned eight. So I have watched very directly the challenges that you all face and so appreciate your being here. Thank you very much.

Dr. Rodgers, you and Mr. Brewer and, really, everyone on the panel has talked about the importance of making investments that can help us find a cure for Type 1. Can you talk about what the impact of sequestration has been on the efforts currently underway at NIH with the Special Diabetes Fund and other efforts to try and look for therapies and a cure for diabetes.

Dr. RODGERS. What I can say is that, obviously, the more funds that we have available, obviously, we can provide progress much more rapidly. We attempt in a strategic manner to bring together external experts to sort of tell us about what it is that is critically

important to move forward with. With the possibility that funds will be limited, what would be the first studies that one might consider amplifying and what studies, of course, would either have to be scaled back or stopped completely?

The efforts for clinical research, such as the ones involving the artificial pancreas, or in the use of trials of drugs that may either prevent or delay the destruction of the beta cells, are the types of studies that we would be, from an ethical standpoint, not good judgment to move forward with if you are uncertain about having future funds. And so in opportunities in which funds are cut back, one really has to think, despite the fact that these are high priority areas, think very strongly about committing families and patients to getting involved in clinical trials that you may or may not be able to complete.

Senator SHAHEEN. Well, let me ask the question a little differently.

Dr. RODGERS. Sure.

Senator SHAHEEN. What would happen if we do not fund the Special Diabetes Program this year, if we do not fund it for another year, and if we do not fund it for the three years that you are suggesting we should do?

Dr. RODGERS. Well, let me answer that question by telling you about the progress that has been made when the committee has been able to give us three years of funding. The TEDDY program, The Environmental Determinants of Diabetes in the Young, is a program that, because of the long-term nature of it, we were able to begin it, and now with the renewal, we have been able to continue it. And TEDDY has really put us in the position now to determine what are those risk factors and how we might intervene.

TrialNet, the trial that Quinn is on, is another one of these long-term trials, and once we have an idea to move forward, TrialNet has allowed us the infrastructure to begin to address some of those questions about promising treatments. Those types of trials would be in jeopardy, those that are sort of next up, without a commitment for longer-term research funding.

Senator SHAHEEN. Thank you.

Dr. RODGERS. Thank you.

Senator SHAHEEN. Mr. Allen and Mr. Brewer, too, as parents of children with Type 1 diabetes, what would you like us as policymakers to go away from this hearing understanding and what action would you like us to take?

Mr. ALLEN. Well, first and foremost, we live with this disease every day. You know, when we look at Walker every day and he stands up and we have to give him a shot and every day he says he wants this disease to stop, he wants to not have to take a shot, and his brothers run outside and go play and he has to stay behind and he has to take a shot, he looks at us and he says, you know, "When is this going to end? When can we stop doing this?"

So we say we are going to do everything we can in our power to make this disease cease, so we are here today because we want you to understand that this is the face of our children, you know, all these kids in here, and they all feel the same way every single day, seven to ten times a day. So we are advocating for them so you understand. I am sure you have people living with diabetes every day.

So when you walk away from this, you understand that these are innocent children who had nothing to do with getting diabetes, and we want you to understand that as you make your decisions, knowing that these are our children and they are the future of our universe and future of our world.

Senator SHAHEEN. Thank you very much.

Mr. BREWER. I have a unique perspective as a father of a child with the disease but also the CEO of this organization. So I have the sense of the opportunities that we have before us to solve this problem. There are concrete opportunities that can improve the lives of people in a very substantial way, to help them to live safer and easier lives and avoid some of the adverse events that you heard about today. And they are really lying right before us. They are lying right before us as a result of previous research funding, JDRF having funded $1.7 billion of research over the last 43 years and the NIH having funded untold billions dollars of research.

We have been brought to a point where we can translate these scientific discoveries through to really meaningful impact on people living with this disease—children, adults, everybody living with the disease. It is going to take some more research funding, but it is also going to take some very close look at the regulatory challenges that are involved in translating therapies, testing therapies for safety and efficacy in order to deliver them through.

We need to take a look at the reimbursement paradigm for how Type 1 technologies for treatment are paid for, because there is a tremendous cost savings to prevent some of these catastrophic events that we are talking about. Emergency room visits are very expensive. The complications of Type 1 diabetes later in life are very expensive and burdensome on the medical system. And yet, we have such promise and opportunity to really change those outcomes.

So there is a fiscal imperative here. There is an imperative to look at how our system translates these scientific discoveries into technologies that can be used here and around the world where we have historically been a leader and where, frankly, we are now falling behind because of some structural challenges in this pipeline.

Senator SHAHEEN. Thank you very much. Thank you, Mr. Chairman.

The CHAIRMAN. Dr. Rodgers, directly to Senator Shaheen's question, the continued existence of this program, is it not absolutely critical to continue your efforts to fight the disease?

Dr. RODGERS. I could not say it better, Senator. Thanks for the question. It is. It is critically important. We have a range of areas not only in the course of the disease that I have tried to outline during my oral statement, but also a range from very basic research. We are learning quite a bit about how one could actually tease cells that are in the pancreas, that exist, and transfer them into beta-producing cells, and these discoveries which have now been found in animal models but also their equivalents exist in humans, would not have been possible. And we are on the precipice of beginning to translate these findings into clinical research, translational research as well as clinical research. All of this work over and above the regular appropriations that we get would not be possible without the Special Diabetes Program.

The CHAIRMAN. Senator Warren.

Senator WARREN. Thank you, Mr. Chairman, and I want to say to all of you at the Children's Congress, thank you very much for being here. You know, this is what democracy is about. People here in Washington will decide how we spend money and how much money goes into research for diabetes and for other medical problems. And so your coming here and making the case for why it is important that we put money into research for diabetes is really important. I am really glad you are here. I think you make a real difference.

I also want to say to Senator Collins and to Senator Shaheen, thank you very much for your leadership in creating a caucus that has made a real difference. I am a new Senator. I am just getting started, so I am learning about this. But they have shown great leadership in making sure that there is better funding, better support, better awareness here in Washington for the issues surrounding diabetes.

So, thanks for being here today. I also want to say to our panel, a terrific panel. Thank you so much. I am grateful to all of you for being here.

There are a couple of questions I want to follow up on. I want to start with you, Dr. Rodgers. This is not just about the level of funding, which I understand is critically important, but it is also the long-term commitment on funding. And what I have observed is that NIH funding, generally, and diabetes funding, has been getting shorter and shorter and shorter. That is, you cannot be sure the money is coming until just before you get it and it is for a short period of time. I suspect that has an impact on the research and on attracting more people to do more research in this field. Could you speak about that just a little bit, Dr. Rodgers.

Dr. RODGERS. Thank you, Senator. You are absolutely right in your observations. I think when one—first of all, let me start off by saying that the investments are already paying off as clearly shown in these critical studies, the Diabetes Control and Complication Trial. People are living longer and healthier lives than even a decade ago. And so if future promise—anything about past successes really point out that we are really at that point in which we are about to make major milestones and landmarks.

Now, specifically to your question about the duration of funding, as one is managing programs, one has to think about what are the feasible programs that one can begin. Clinical trials are such that without having an assurance for long-term funding, it would be, in a sense, unethical to put people into trials with all that is involved in the trials without knowing that the funding will continue through a period of time to see it successfully completed. And that is why the three-year funding that Mr. Brewer suggests, on the longer-term, makes both planning and management of clinical trials and clinical studies so vitally important.

When we get one year of funding, of course, we appreciate it and we try to manage it in a way that we can achieve it. But having longer-term trials, or longer-term funding horizons allows us not only to complete ongoing trials or ancillary trials to those trials to get really the best return on the investment, but also to begin the

planning of longer-term trials as our external experts help us with prioritizing them.

Senator WARREN. Thank you. That is very helpful, Dr. Rodgers.

You know, as much as we talk about our funding through NIH—and please count me as a supporter of substantially increasing our funding—it is also important, though, to talk about the investments that are made by the private sector in new technologies and making living with diabetes easier. And I am very proud, of course, to be from Massachusetts, where we are not only making great progress on the research, the front-end part with NIH and other support, but also that we have a medical device, pharmacology, biotechnology that we are working on in Massachusetts to try to help people who are currently living with diabetes.

And you raised the question about the Special Diabetes Program. I understand there are clinical trials going on, and I understand, Mr. Ferguson, you have been a participant in the clinical trials, is that right?

Mr. FERGUSON. Yeah.

[Laughter.]

Senator WARREN. Okay. He gets to the point.

[Laughter.]

So I have a question for you. Would you mind, just for a minute, talking a little bit about what it is like to participate in a clinical trial on diabetes?

Mr. FERGUSON. Well, it is just a great experience. Even though you are going down for a trial, it is, like, I have got to go down every month to get the drug Abatacept tested, so they would—like, I get an IV and then they put in water first to make sure I was hydrated and then they would start putting Abatacept in. And I have got to go down to Boston every time with my father, so—and it is really cool. You get to see really smart people, minds like no others, and—yeah.

Senator WARREN. All right.

[Laughter.]

Thanks, Quinn. But, you know, you are out there making a difference, and you are making a difference for everybody, everybody who has got diabetes now and people who develop it in the future.

But the question, then, that I want to ask Dr. Rodgers and Mr. Brewer, is if you can just speak briefly to the issue about barriers that are in the way of getting people into clinical trials. Mr. Brewer, would you like to start.

Mr. BREWER. Well, there are barriers in the way of information getting out to people about what clinical trials there are. We probably do not have enough clinical trial sites to be able to provide opportunities outside of concentrations like we have in Massachusetts of these kinds of resources. And, frankly, we just do not have enough things to test right now, and that is why we need the research funding, because the pipeline that is created by this research funding, the Special Diabetes Program, other NIH funding, and the funding that JDRF does, we are the feeder for those clinical trials.

Senator WARREN. Dr. Rodgers, would you like to add anything to that?

Dr. RODGERS. I would agree with that, and I would just emphasize that we—just because of the unawareness of the availability of participating in trial, we are trying to explore other avenues, such as using social media, for example, to have—instead of having doctors recommend patients, actually going directly to the patient communities, and we are working in conjunction with the JDRF to try to use social media to get patients to participate, perhaps who live in areas that are not heavily concentrated with researchers.

Senator WARREN. Well, that is very valuable. I just want to say, it is so impressive to me when you meet young people who are managing diabetes. They are not letting diabetes manage them. They are managing it and taking responsibility. And then taking that extra step to join in in part of how you find the cure, being part of the research and the clinical trial for it, good for you, Quinn. So, thank you all very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Donnelly.

Senator DONNELLY. Thank you, Mr. Chairman.

It is an honor to have all of you here. I not only have the opportunity to represent Indiana in the United States Senate, but am part of a family that has been touched by Type 1 diabetes, and so I know every day what you deal with, as well—not me personally, but a family member. My pledge to you, as I know everybody is up here, is that we will beat this. We will find a cure. We will take every step necessary along the way. And I want you to all know that you have an incredible amount of advocates here on this side who will fight for the funding that you need to make sure that you have that three-year window that you need and to—economically, it makes sense, as well, that when we cure this, we not only make everybody have a chance to be more productive, but we save so much funds, as well.

But to all of you, what we want to do is make it so you never have to think about this, so that as you live your life, this is something that you can say we beat, we cured, and it is over with, and that is the goal of what we are trying to accomplish here.

And I want to thank, also, our three participants from the Children's Congress who are from Indiana, Rebecca Moody, Claire Dunagan, and Gwen Wahler [phonetic], and just for all of you to know, another Indiana resident who is here, my friend Charlie, is an Indy car driver, and——

[Applause.]

Charlie actually almost won the Pocono Race this past weekend. Charlie has Type 1 diabetes and is an Indy car driver and almost won the Indianapolis 500. If it was for the amount of cheers given, he would have won the Indy 500.

But what I want to also do is ask you, Dr. Rodgers, in terms of an artificial pancreas, how far are we from—and, obviously, not an exact date—but how far are we from a time when we will have this available to all?

Dr. RODGERS. Again, as I—trying to answer this, I can tell you really more about the research and the great progress, and I would have to say that—again, I would leave it to my colleagues at the FDA to discuss the regulatory aspects of it, but there really have been great advances within the last—and published within the last

few months and presented at the American Diabetes Meeting just last month—about these devices.

They are much smaller. They allow for ways of actually suspending insulin injection when the glucose level reaches a critical point. Less frequent episodes of hypoglycemia at night, which is really the critical time that people worry about. There was concern, for example, from the FDA's perspective not only that the threshold was not reached and people would get seriously hypoglycemic, which was not shown, but as you suspend the insulin, of course, the glucose will begin to rise. And what these studies and presentation clearly show, that those episodes of hyperglycemia and its associated ketone production did not occur.

So from a safety perspective, trials here in the U.S. as well as in Europe and Australia are clearly pointing to a point where we are about to make major breakthroughs and allow this for more children to be able to utilize this——

The CHAIRMAN. If the Senator would yield, would you describe for the committee what the device looks like?

Dr. RODGERS. Sure. An artificial pancreas puts together two pieces of instrumentation, one that can continuously measure blood glucose levels, so a continuous glucose monitor. That glucose monitor sends signals to an insulin pump, just as your pancreas would. Your pancreas senses when there is too much sugar. It puts out more insulin. When the sugar drops too low, it puts out less insulin, and in certain instances, glucagon.

And the other aspect is the pump. These are now connected by a computerized system which now the technology is available that even on a smart phone, one can link these two together.

So this particular aspect, this insulin suspend, is a situation in which a glucose monitor indicates that the glucose levels are trending too low and, therefore, the insulin infusion in the pump is suspended, and as I said, keeps you in that critical window so that the blood sugar does not drop too low or too high.

There has been a recent report, actually, from—and that is done because it actually monitors what the glucose is. There is a second major advance in which one uses mathematical algorithms to actually predict, based upon the rate at which the glucose is falling, when it is likely to reach that critical threshold, and this is why you have to bring engineers and mathematicians into this, as well. And this has actually shown great promise, as well.

So, to answer your question, I cannot predict precisely, but I think that we are really on the precipice of this.

Senator DONNELLY. Just outside of—obviously, the FDA is critical and has an important role, but outside of their role, would you say the technology is basically just about there at this point? Obviously, we have safety tests to do, but the technology itself is there?

Dr. RODGERS. I think the components for the technology are certainly there. We can always do better. For example, I mentioned that the current artificial pancreas is actually infusing insulin. Now, to completely replicate the pancreas, one might do better with both insulin and glucagon, which is what the pancreas does, so a so-called bi-hormonal pump. And, obviously, one would have to, in a clinical setting, do trials to indicate the superiority of that over others.

There are certainly areas in which we can improve upon, but generally, the technologies have greatly advanced within the last few years, and so I think we are certainly close to being there.

Senator DONNELLY. I just want to ask one other question, and that is in regards to islet, that you discussed. There are efforts on islet transplants that are being done. Have you looked at the area of epigenetics and their possible assistance in regards to making the islets work better?

Dr. RODGERS. Epigenetics refers to changes in the DNA structure, either by the addition of methyl groups or others, that can critically influence the expression of genes leading to certain proteins, and that is certainly an area in which we are critically—we are actively involved in research findings.

One example of the importance of epigenetics is actually potentially in the development of diabetes. We talk about this gene environment interaction, but what we know, for example, is that the first environment that a developing infant is exposed to is actually the interuterine environment, and it is quite likely, and we certainly now know through a number of studies, that a woman who has diabetes, who develops in this case Type 2 diabetes, the likelihood of that infant born from that pregnancy has a greater risk of developing diabetes sometimes later in life than a sibling born to that mother under the situation in which she did not have diabetes. And it is thought that epigenetics plays an important role.

Epigenetics is a way in which the environment makes marks upon your existing genes that can change the development of cells. So that is an important area that we are looking at.

Senator DONNELLY. I want to thank all of you for being here, and to all of you young people, we promise we will be never ending in our efforts to cure this and to solve this so you never have to worry about it. And when one of you is the future President of the United States, I want to come visit you in the White House.

[Applause.]

The CHAIRMAN. Thank you, Senator Donnelly.

Senator Blumenthal.

Senator BLUMENTHAL. Thank you, Chairman Nelson, and thank you for holding this hearing. I want to join in expressing my gratitude to you for giving us this wonderful opportunity to express our determination, as my colleague, Senator Donnelly, has so eloquently and powerfully, that we will conquer diabetes. No question. We will conquer diabetes, and it will be due to the courage and strength of a lot of folks who are here today, particularly young people who have joined us, and I cannot imagine a better use of this space than for their to be visiting and sitting here. And I want to join Senator Donnelly in expressing the view that some of you, I am willing to bet a lot of money, will be sitting up here one of these days in the not too distant future.

Let me say, at the risk of offending the Chairman, that I know he has referred to Ray Allen's distinguished career as an NBA star, but I just want to remind the Chairman that before he was a winner for the Miami Heat, he was a Husky, a UConn Husky and a champion there.

Mr. ALLEN. I am always a Husky.

[Laughter.]

Senator BLUMENTHAL. And I was going to say——

Mr. ALLEN. Yes, always.

[Applause.]

Senator BLUMENTHAL. And we can applaud that, yes.

[Laughter.]

It is like being a Marine. You are always a UConn Husky.

Mr. ALLEN. Always.

Senator BLUMENTHAL. I just want to say, Couch Calhoun would be very proud of you today, and most especially proud of your son, Walker. Thank you for being here today, Walker.

Mr. ALLEN. Thank you, Senator.

[Applause.]

Senator BLUMENTHAL. Let me also thank Ms. Smart. Your work personally on this has been so valuable, and your sharing with us your story of your battle with diabetes from the age of 13, your pregnancy in 1989, your nearly succumbing on the stage. All of it shows, really, the human consequences and how even the most illustrious struggle equally with this dreaded disease.

I have been a longtime advocate of NIH funding. The costs of this disease in Connecticut and elsewhere are staggering. Two-hundred-and-sixteen thousand people in Connecticut alone have diabetes, which costs a total of $2.92 billion. That is billion with a "b." Two-point-nine billion dollars, Connecticut alone. So if we are really mindful of the costs here, we will do more and do it more effectively.

This diabetes has a face and a voice. You are here to tell us about it. I also want to thank, by the way, Sophie Brown, Harrison Zuckerberg, and Robert Miles [phonetic], who are from Connecticut. Thank you for being here. I visited with you earlier, very proud that you are here today.

[Applause.]

But I want to ask about the meaning of this NIH funding. Again, if you could explain to us—I know you have alluded to it before—the importance of sufficient funding to do the work and do it effectively and what this money actually goes to do. What is the use of this money that makes it so valuable? Perhaps you could talk about that, Dr. Rodgers.

Dr. RODGERS. Sure. Let me mention that there are a range of not only studies in terms of their design, both basic studies to understand how the beta cell works, why you lose it over time, translational studies, now understanding, for example, that there are hormones that are produced as these cells start to die that could allow for them to what is called differentiate or de-differentiate into other cells, what can allow them to proliferate, research that is currently ongoing to try to develop therapies to reverse the autoimmune attack once it has actually begun in patients or in people who are at risk, actually preventing it from ever occurring, studies that will allow us to more closely treat patients who have the disease for some time in terms of their complications—heart disease, stroke, blindness, amputations, for example.

We have made great progress, and, in fact, to a first approximation, critically, we know that just controlling the blood glucose makes major difference. But now we want to—I think everyone agrees that it is better to prevent a disease than to actually treat

long-term complications, and obviously, we have to continue efforts in all of these areas. But preventing the disease or reversing it once it is established very early on, as well as ultimately curing disease, is really what the Special Diabetes Program funds allow us to do.

Some of the studies, one can do in the short term in terms of basic studies. But the longer-term studies, the clinical studies and the clinical trials, really require long-term sustained funding in order to achieve successfully.

Senator BLUMENTHAL. So we cannot do it just by one year, by one shot. It has got to be sustained and committed.

Dr. RODGERS. Ultimately, optimally, that is the best way to approach this problem.

Senator BLUMENTHAL. Thank you. My time has expired, regretfully, but again, my thanks to this very, very distinguished panel. My thanks to the Chairman. And, again, thank you to everyone for being here today. I know you are not going away. We are not going away. We are going to win this. Thank you.

[Applause.]

The CHAIRMAN. Thank you, Senator Blumenthal. Well said, Senator Blumenthal.

Ms. Smart, tell us your lessons learned on how to stay healthy from your experiences over the years.

Ms. SMART. Oh, gosh. I think, and I do not want to make too much of this, but I do think that there is a great value in not looking upon yourself as a sick person, not thinking about being sick as a part of your identity, because we—obviously, our brain sends messages to our body. So I think that that is really, really important and I hope—and it seems like most of the kids here are pretty—incredibly sharp and have that attitude. I was reading all of your stories last night and it is impressive, to say the least. I wish that I had had that kind of gumption when I was 13.

And, again, it is just trying to do what you want to do. I mean, I never felt like there was anything I could not do. I was a cheerleader in high school and all that, and, of course, sometimes I would use my diabetes as an excuse if I did not want to do something sometimes. You know, if I wanted to take a break, I would say, oh, I need to go get a Coke. You guys go ahead without me. You know, things like that, which you have to not try to do. But, again, it is just——

[Laughter.]

Do not copy what I did. Do as I say, not as I do.

But, no, it is follow your dreams, whatever they are, but just be smart. Be wise. Do not ever feel self-conscious about letting people know what is going on with you, and never be afraid to ask for help if you need it, and just be smart. And I do not think I need to tell this group that, but maybe they can tell other kids they meet some of those messages.

And I would just like to add one little thing, too, just from what I have heard here today and what little I know. I hope and pray that the insurance business and our government and everything will not be penny wise and pound foolish, because it is, for all diseases but certainly for this one, better to try to find a cure and a

prevention than treat complications 50 years down the road. I hope that we can convince those in power that that is a huge thing.

And I think the work on beta cells and also this issue of whatever environmental causes, to me, that has got to be huge, because once we figure that out, that is going to be, it seems like, half the battle. Thank you.

The CHAIRMAN. Speaking of the cost, Mr. Brewer, Medicare in and of itself, the Medicare costs are going to double by 2020. We are estimating $226 billion. How much of that is due to Type 1?

Mr. BREWER. I am not sure I have that specific estimate to give to you today, but I can tell you that Type 1 is a disproportionate cost of the expense of diabetes because the complications tend to occur at a higher rate than in Type 2. The costs of treating the disease over a lifetime are increasingly burdensome to the system, as well. So I have seen estimates that even though Type 1 may only account for five to ten percent of the population of people who have diabetes, upwards of 30 to 40 percent of the costs that actually are absorbed by the system are driven by Type 1, which, I think, makes the argument even greater that focus on this area is going to have a very significant implication for Medicare spending.

The CHAIRMAN. Absolutely.

Mr. Allen, tell us about the resources and services that were available to you and Shannon as parents when Walker was diagnosed and how you were able to use that resource and services to manage the physical and emotional aspects of the disease.

Mr. ALLEN. Well, when Walker was diagnosed in 2008, just, I think, we talked about the environment. That was the one thing we wanted to figure out, because Walker was pre-screened when he was just one year old, or one day old. And we talked about so many things that we can do that can help him benefit, or help us help him benefit from this disease.

I think being in Boston was probably one of the best places that we possibly could have been because of the care, the hospitals there. The Joslin Center took us in immediately. They had such great doctors there and we had a huge connection with the Celtic ownership. So the minute we flew back from L.A., we had doctors waiting for us that took care of us immediately. I do not think—I can honestly say that just because I was a Boston Celtic at the time, it was not because of that. You know, they take care of all people that way. The Joslin Center there in Boston has been incredible. They continue to be incredible. Dr. Lori Laffel, who was Walker's doctor permanently, regardless of where we live, she always sees him and takes care of him and fields the phone calls from my wife.

So we feel so fortunate that we continue to learn and stay on the cutting edge because the Joslin Center is right there in Boston, and we live in Connecticut, as well, so we are a very close distance, and we have people that continually stay in contact with myself and my wife to make sure that we see and know everything diabetes-related so we can help his care over a long period of time.

The CHAIRMAN. Dr. Rodgers, how many types of diabetes are there?

Dr. RODGERS. Largely, there are two types, but there are perhaps others. Type 1 diabetes, the reason we are having this Congress,

as Mr. Brewer indicated, probably accounts for somewhere between five to ten percent of the diabetes.

The overwhelming majority is Type 2 diabetes, what we used to call adult-onset, certainly when I was in medical school. But, as I said, as a result of this SEARCH program that we were able to set up, increasingly, we are seeing more of this in children and adolescents. And Type 2 diabetes in children is a much more complicated disease to treat than even Type 1 diabetes. And because of the long nature of having complications, this really could be a major challenge for this country, and those numbers that you quoted in terms of expenditures could really increase exponentially if we do not keep an eye on this, as well.

There are rarer forms of diabetes which account for one or two percent, maturity-onset diabetes, certain genetic diseases in which insulin is not secreted well, et cetera. But the vast majority is Type 1 and Type 2 diabetes.

The CHAIRMAN. Colleagues, any further wrap-up, mindful that our young guests are still sitting horizontal?

[Laughter.]

I mean, still sitting vertical instead of horizontal.

Senator COLLINS. Or both.

[Laughter.]

Mr. Chairman, I just want to thank you so much for holding this hearing. As I mentioned in my opening statement, this is my seventh hearing of the Children's Congress and it is always so inspiring to see the young people here, to hear their stories, and to realize the progress that has been made, but also the work that must be done.

So I particularly want to thank our delegates, my constituent Quinn, who did such a great job, Walker, who puts a human face on it, as well, and did a great job sitting next to Dad for a very long time, and all of the wonderful young people that we have here today.

When I first met families whose children had Type 1, I knew that I had to get involved, and we are making a difference and I just wanted to pledge my continued support and leadership, and again, thank you, Mr. Chairman.

The CHAIRMAN. Senator Warren.

Senator WARREN. Thank you, Mr. Chairman, for doing this. Thank you.

The CHAIRMAN. Senator Donnelly.

Senator DONNELLY. It was a great honor to be part of this. Thank you, and we are going to win.

The CHAIRMAN. Amen to that.

[Applause.]

And with that statement, the meeting is adjourned.

[Applause.]

[Whereupon, at 3:41 p.m., the committee was adjourned.]

APPENDIX

Opening Statement of Chairman Bill Nelson
Senate Special Committee on Aging
Diabetes Research: Reducing the Burden of Diabetes at All Ages and Stages
July 10, 2013

Today, this committee will tackle the physical, economic, and emotional impact of Type 1 diabetes throughout the lifespan.

My partner on this committee, Senator Collins, who has been a champion for finding a cure for diabetes, will lead the committee today on the issue.

Type 1 diabetes is no longer a juvenile disease. Research advances have vastly extended the lives of the millions that have suffered with this devastating condition.
In fact, 85 percent of people in the U.S. living with Type 1 diabetes are adults.

But while those with Type 1 diabetes are able to live longer and fuller lives, we are also learning about new complications with the disease.

For instance, diabetes is the leading cause of end-stage renal disease (ESRD), which cost Medicare $29 billion in 2009.
Our research and federal efforts must keep pace with our changing understanding of this disease.

The same technologies that help children diagnosed with Type 1 diabetes, like the promising development of an artificial pancreas, are also crucial to the future economic wellbeing of the Medicare program because we know that they can help Type 1 diabetes sufferers avoid end-stage renal disease late in life.

Like any chronic disease, early diagnosis and consistent management means fewer problems later on.

That's why I believe that this hearing is so important. One in three Medicare dollars currently goes towards diabetes.

And, unlike sufferers of Type 2 diabetes which we know can sometimes be reversed with lifestyle changes, individuals with Type 1 diabetes are often diagnosed early, without a cure, and left insulin-dependent for life.

As we celebrate research advances that have made a longer, fuller life possible for those suffering from this devastating disease, we need to rethink our approach to one that truly addresses Type 1 diabetes "across all ages and stages".

UNITED STATES SENATOR
SUSAN M. COLLINS
PRESS RELEASE

For Immediate Release
July 10, 2013

Contact: Kevin Kelley or Jeremy Kirkpatrick
202-224-2523

STATEMENT OF SENATOR SUSAN COLLINS

SENATE SPECIAL COMMITTEE ON AGING

"DIABETES RESEARCH: REDUCING THE BURDEN OF DIABETES AT ALL AGES AND STAGES"

Mr. Chairman, thank you for holding this hearing to examine how diabetes affects people of all ages, with a special focus on the estimated three million Americans with type 1 diabetes and their families. This is my seventh consecutive Children's Congress hearing, and I am grateful to the Chairman for allowing me to continue this tradition.

I also want to welcome our distinguished witnesses and the more than 160 delegates to the Children's Congress who have traveled to Washington to tell Congress what it's like to have diabetes, just how serious it is, and why it is so important that we fund the research necessary to find a cure.

I particularly want to give a special welcome to the delegate from Maine, 14-year old Quinn Ferguson of Poland Spring, who will be speaking on our panel.

As the founder and co-chair of the Senate Diabetes Caucus, I have learned a lot about this disease and the heartbreak that it causes for so many American families as they await a cure.

Diabetes is a life-long condition that does not discriminate. It affects people of every age, race and nationality. It is the leading cause of kidney failure, blindness in adults, and amputations not related to injury. It is also a major cause of nerve damage, heart disease and stroke.

Moreover, diabetes costs the United States an estimated $245 billion a year and accounts for one out of every three Medicare dollars. Because of the serious complications associated with the disease, medical costs for Americans with diabetes are 2.3 times higher than those incurred by individuals without diabetes.

These statistics are overwhelming. But what really motivated me to devote so much energy to this issue is meeting more and more people – like our delegates today and their families – whose lives have been forever changed by diabetes. That is why it is so important that all of you have traveled to Washington today to tell your stories. You put a human face on the statistics. You help us to focus on what Congress can do to understand and ultimately conquer this terrible disease.

The burden of diabetes is particularly heavy for individuals with type 1 who face a lifetime of treatment and often physical complications. Usually diagnosed in childhood or adolescence, type 1 diabetes is a lifelong disease that one can never outgrow.

While often associated with children, the fact is that 85 percent of those living with type 1 diabetes are adults, and many of them are seniors. An average individual with type 1 will have to take more than 50,000 insulin shots or infusions over his or her lifetime. The discovery of insulin was a landmark breakthrough; however, it is not a cure for diabetes. People of all ages with type 1 diabetes face the constant threat of developing life-threatening complications, as well as a reduction in their quality of life.

Thankfully, there is some good news. Since I founded the Senate Diabetes Caucus, funding for diabetes research has more than tripled. As a consequence, we have seen some encouraging breakthroughs, and we are on the threshold of a number of important new discoveries.

Advances in technology, like continuous glucose monitors, are helping patients control their blood glucose levels, which is key to preventing diabetes complications.

We are also moving closer and closer to our goal of an artificial pancreas, which would revolutionize diabetes care. Recent advances also include the development of new treatments that can stop or even reverse complications such as some nerve damage and diabetic eye disease.

There is strong support in Congress for diabetes research funding, thanks in no small part to the grass-roots support provided by JDRF volunteers. Earlier this year, we passed legislation to extend the Special Diabetes Program – which provides $150 million a year over and above the regular appropriation for type 1 diabetes research – for an additional year through September of 2014.

This important program represents more than a third of our federal commitment to diabetes research. As such, it is critical to our efforts to find better treatments, a means of prevention, and ultimately a cure for this devastating disease.

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Special Diabetes Program SDP

The Economic Impact of The Special Diabetes Program

Background

In their new study, *Diabetes Research and the Public Good: Federal Support for Research on Type 1 Diabetes*, economists Robert J. Shapiro, Ph.D., and Nam D. Pham, Ph.D., analyze the extraordinary economic and human costs of diabetes and assess the likely impact of continuing the Special Diabetes Program, which funds research into treating and curing type 1 diabetes (T1D) through the National Institutes of Health (NIH), on reducing these costs. The authors conclude that failing to continue the SDP for research in type 1 diabetes would be highly ill-advised and ultimately very costly for both the tens of millions of Americans suffering from the disease and U.S. taxpayers.

According to the Centers for Disease Control and Prevention (CDC), nearly 26 million Americans had diabetes in 2011.[1] All told, more than 8 percent of all Americans have some form of the disease. Moreover, the incidence of diabetes is increasing faster than the population. From 2001 to 2009, type 1 diabetes (T1D) among youth increased 23 percent, and type 2 diabetes (T2D) among youth increased 21 percent.[2] Epidemiologists estimate that by 2020, nearly 12 percent of Americans or 39.2 million people will have diabetes, including 28.7 million diagnosed cases and 10.5 million undiagnosed cases.[3]

According to the CDC, diabetes is the underlying cause of death of over 70,000 Americans a year, and a contributor to an additional 160,000 deaths. People with diabetes are two-to-four times more likely than other people to die of heart disease. Diabetes is also the leading cause of kidney failure, accounting for 44 percent of all new cases, as well as the leading cause of new cases of blindness in adults.[4]

Key Findings

- Treating people with diabetes cost Americans $176 billion in 2012[5] or about 1.2 percent of GDP. **By 2020, these medical costs are expected to more than double**, reaching $418 billion[6] or an estimated 1.8 percent of a projected GDP of $23.1 trillion in that year.
- From 2012 to 2020, **the health-related costs of diabetes borne by taxpayers through Medicare and Medicaid are also expected to more than double**, rising from $137 billion in 2012 to $297 billion in 2020. The diabetes-related cost of Medicare alone is projected to rise from $104 billion in 2012 to $226 billion in 2020.[7]
- Diabetes also imposes large, non-medical costs on the economy. These include productivity losses associated with missed work, permanent disabilities and premature deaths from the disease and its complications. These non-medical costs totaled some $79 billion in 2012, equal to 0.5 percent of U.S. GDP in that year. Based on people's average earnings in 2007 ($45,790), the paper

estimates these costs would have covered the wages and salaries of an additional 1,738,708 full-time workers.

- By 2020, these non-medical, economic costs are expected to reach $157 billion or more than 0.7 percent of a projected GDP of $23.1 trillion in that year. Assuming historical trends in earnings continue, we estimate the foregone economic production related to diabetes in 2020 would cover the wages and salaries of 2,604,341 full-time workers in that year.

- **All told, in 2012, the medical and non-medical costs of people diagnosed with diabetes came to $245 billion. By 2020, these total costs are expected to more than double to $512 billion.**

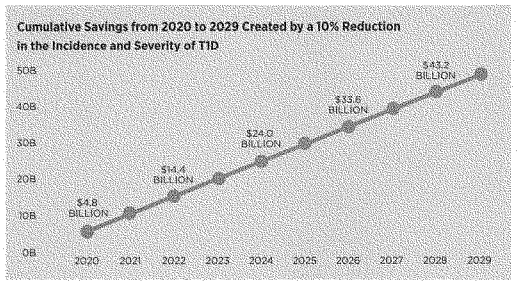
- The NIH currently provides $150 million per-year in support for T1D research through the Special Diabetes Program (SDP), as well as additional funds through other grant programs. The SDP has supported the establishment of research infrastructure and funded research programs that already have advanced our basic knowledge of diabetes and its causes, led to improved treatments and screening for T1D, and advanced research into potential cures.

- With 16 years of NIH support for T1D research, the likelihood of additional breakthroughs is rising if the program is renewed. **If those advances can reduce the incidence and severity of T1D by just 10 percent by 2020, we estimate the savings in medical costs would exceed $2.9 billion per-year**, including $2 billion in savings for Medicare and Medicaid, plus another $1.9 billion in annual non-medical economic savings, for a total savings of $4.8 billion a year. In this scenario, we estimate **the advances will produce an annual rate of return of 163%**, year after year.

- **If spillovers from these advances reduce the incidence and severity of T2D by just 5 percent in 2020, we estimate that would save nearly $17.6 billion per-year in medical costs**, including more than $12.5 billion per-year in Medicare and Medicaid costs, plus nearly $5.6 billion per-year in non-medical economic costs.

- The estimated annual savings from a 5 percent reduction in the incidence and severity of T2D by 2020 would be more than 8 times the total projected NIH funding for SDP funded research over 22 years.
- NIH support for T1D research is also critical to the progress of the diabetes R&D programs of private pharmaceutical firms: Researchers have found that a one percent increase in NIH-funded basic research leads to a 2.5 percent increase in private R&D spending, with a seven-year lag.[8]

[1] Centers for Disease Control and Prevention (2012).
[2] Mayer-Davis et al. (2012); Dabelera, D. et al. (2012).
[3] United Health (2010).
[4] Centers for Disease Control and Prevention. (2012).
[5] Yang et al. (2013).
[6] United Health (2010). To estimate the costs in 2020, Shapiro and Pham started with the 2012 costs reported by Yang et al and applied the growth rates in costs from 2012 to 2020 projected by the United Health study.
[7] Costs labeled as "Medicare" do not include those eligible for both Medicare and Medicaid.
[8] Congressional Budget Office (2006).



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Diabetes Research and the Public Good: Federal Support for Research on Type 1 Diabetes

Robert J. Shapiro and Nam D. Pham

July 2013

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Diabetes Research and the Public Good: Federal Support for Research on Type 1 Diabetes

Robert J. Shapiro and Nam D. Pham[1]

This report is an updated version of a study published in November 2012 based on the data then available, including estimates of the incidence and cost of diabetes in 2007 published in the journal Diabetes Care.[2] *Since last November, "Diabetes" has published new estimates of the incidence and cost of the disease in 2012.*[3] *This report incorporates those new estimates with certain modifications as described below.*

I. Introduction and Executive Summary

Diabetes is one of the most common, life-threatening medical conditions in the United States today. More than 30 million Americans had diabetes in 2012, up from 24.1 million in 2007.[4] All told, an estimated 9.6 percent of all Americans have some form of the disease.

As alarming is the fact that the prevalence of diabetes is increasing faster than the population. From 2001 to 2009, type 1 diabetes (T1D) among youth increased 23 percent, and type 2 diabetes (T2D) among youth increased 21 percent.[5] Epidemiologists estimate that by 2020, more than 12 percent of Americans or 40.5 million people will have diabetes, including 30 million diagnosed cases and 10.5 million undiagnosed cases.[6]

The impact of diabetes is enormous. According to the CDC, diabetes is the underlying cause of death of over 70,000 Americans a year and a contributor to an additional 160,000 deaths. People with diabetes are two-to-four times more likely than other people to die of heart disease. Diabetes is the leading cause of kidney failure, accounting for 44 percent of all new cases, and it is the leading cause of new cases of blindness in adults.[7]

The consequences of diabetes extend beyond the toll it takes on those with the disease and their families and friends. Diabetes also exacts a major toll on the U.S. economy. This study analyzes these economic effects and assesses whether continuing the Special Diabetes Program, which funds research into treating and curing type 1 diabetes through the National Institutes of Health (NIH), could materially contribute to ameliorating the adverse economic impacts associated with diabetes.

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[1] Support for research used in this study was generously provided by JDRF. The views and analyses expressed here are solely those of the authors.
[2] Dall et al. (2009).
[3] Yang et al. (2013).
[4] Yang et al. (2013); Dall et al. (2009).
[5] Mayer-Davis et al. (2012); Dabelea, D. et al. (2012).
[6] UnitedHealth (2010); Yang et al. (2013).
[7] Centers for Disease Control and Prevention. (2012).

Our key findings:

- Treating people diagnosed with diabetes cost Americans $176 billion in 2012[8], plus another $17 billion to treat undiagnosed cases, totaling $193 billion. This is equivalent to 1.2 percent of GDP and 13.2 percent of all U.S. healthcare costs. By 2020, these total medical costs are expected to more than double, reaching $418 billion[9] or an estimated 1.8 percent of a projected $23.1 trillion GDP in 2020.[10]

- From 2013 to 2020, the health-related costs of diabetes will total nearly $2.5 trillion, and taxpayers will bear 71 percent of those costs through Medicare and Medicaid, or nearly $1.77 trillion over that period. This includes $1.34 trillion from 2013 to 2020 for Medicare (54 percent), $75 billion for Medicaid (3 percent) and $348 billion for patients eligible for both programs (14 percent). In addition, private insurance will pick up $672 billion in diabetes-related medical costs from 2013 to 2020 (27 percent), and uninsured people ineligible for Medicare or Medicaid will account for $50 billion (2 percent).

- From 2012 to 2020, the health-related costs of diabetes supported by taxpayers through Medicare and Medicaid are also expected to more than double, increasing from an estimated $137 billion in 2012 to $297 billion in 2020 or nearly 117 percent. Medicare diabetes-related spending alone will increase from $104 billion in 2012 to $226 billion in 2020.

- Diabetes also imposes large, non-medical costs on the economy. There are productivity losses associated with missed work, permanent disabilities and premature deaths from diabetes and its complications. These non-medical costs totaled some $79 billion in 2012,[11] equal to 0.5 percent of GDP in that year. Based on people's average earnings in 2012 ($45,790), we estimate that these costs would have covered the wages and salaries of an additional 1,738,708 full-time workers.[12]

- By 2020, these non-medical, economic costs are expected to reach $157 billion[13] or more than 0.7 percent of a projected GDP of $23.1 trillion in that year. Assuming historical trends in earnings, we estimate the foregone economic production related to diabetes in 2020 would cover the wages and salaries of 2,604,341 full-time workers in that year.

- All told, in 2012, the medical and non-medical costs of people diagnosed with diabetes came to $245 billion.[14] By 2020, these total costs are expected to more than double to $512 billion.[15]

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[8] Yang et al. (2013)
[9] UnitedHealth. To estimate the costs in 2020, we start with the 2012 costs reported by Yang et al. (2013) and apply the growth rates in costs from 2012 to 2020 projected by the UnitedHealth study.
[10] Congressional Budget Office (August 2010).
[11] UnitedHealth (2010).
[12] Bureau of Labor Statistics (May 2012).
[13] Dall et al. (2009); Yang et al. (2013); UnitedHealth (2010).
[14] Yang et al. (2013).
[15] *Ibid.*; UnitedHealth (2010).

- The NIH provides $150 million per-year in research support for T1D through the Special Diabetes Program (SDP), as well as additional funds through other grant programs. The SDP has supported the creation of new research infrastructure and funded new research programs that have improved our basic knowledge of diabetes and its causes, led to improved treatments and screening for T1D, and advanced research into potential cures.

- With 16 years of NIH support for T1D research, the likelihood of additional breakthroughs will increase if the program is renewed. If those advances can reduce the incidence and severity of T1D by just 10 percent by 2020, we estimate that the savings in medical costs would be nearly $2.9 billion per-year, including more than $2.0 billion in savings for Medicare and Medicaid, plus another $1.9 billion in annual non-medical savings, for a total savings of $4.8 billion a year. In this scenario, we estimate the advances would produce an annual rate of return on NIH support for this research of 163 percent, year after year.

- If spillovers from these advances reduce the incidence and severity of T2D by just 5 percent in 2020, we estimate that would save nearly $17.6 billion per-year in medical costs, including more than $12.5 billion per-year in Medicare and Medicaid costs, plus $5.6 billion per-year in non-medical economic costs.

- The estimated annual savings from a 5 percent reduction in the incidence and severity of T2D by 2020 would be more than 8 times the total projected NIH funding for SDP funded research over 22 years.

- NIH support for T1D research is also critical to the progress of the diabetes R&D programs of private pharmaceutical firms: Researchers have found that a one percent increase in NIH-funded basic research leads to a 2.5 percent increase in private R&D spending, with a seven-year lag.[16]

Based on this analysis, we conclude that not continuing the SDP for research in type 1 diabetes would be highly ill-advised and ultimately very costly for both the millions of Americans suffering from the disease and U.S. taxpayers.

II. The Medical and Economic Challenge of Diabetes in the United States

The Varieties of Diabetes and the Medical Complications Associated with the Disease

"Diabetes" covers a number of different forms of the disease, although all are characterized by some defect in the production of insulin, how insulin acts in the body, or both. Type 1 diabetes, formerly called juvenile diabetes because it often is diagnosed in childhood, develops when the body's immune system destroys the beta cells in the pancreas that secrete the insulin hormone. We all need appropriate levels of insulin, because it metabolizes glucose and enables people to derive energy from food. Since pancreatic beta cells are the only cells in our bodies that produce insulin, people with T1D depend on regular injections of external insulin.[17]

[16] Congressional Budget Office (2006).
[17] Centers for Disease Control and Prevention (2012).

The most common form of the disease is type 2 diabetes, which usually manifests in adulthood, although it can also affect children and adolescents. T2D typically begins as insulin resistance, a disorder in which cells do not properly absorb and use insulin. In combination with abnormal pancreatic beta cell function, this resistance results in insulin deficiency; and as the need for insulin increases, the pancreas gradually loses its ability to produce the hormone.[18] Studies find that the onset of T2D is correlated with obesity, physical inactivity, a family history of diabetes, and impaired glucose metabolism. T2D may also be associated with a personal history of gestational diabetes, a form of glucose intolerance that can occur during pregnancy.[19]

Generally speaking, diabetes is caused by a loss of functional beta cell mass, as in an autoimmune process in T1D or the increased need for insulin seen in T2D. While T1D and T2D have different causes, the complications are often the same. Diabetes is a growing health concern, because the condition is a major cause of other serious conditions such as heart disease, stroke, kidney failure, hypertension, blindness, nervous system disorders and severe circulatory dysfunctions requiring amputations.[20] Persistent elevation of blood sugar levels slowly damages many organs including the heart, kidneys, nerves, and eyes. Given the high costs of these effects and their treatments, returns on development of new treatments for diabetes can be very large.

As detailed by the Centers for Disease Control and Yang et al.,[21] complications from diabetes include:

- *Heart disease and stroke.* Adults with diabetes die from heart disease at rates two-to-four time greater than adults without diabetes.[22] Similarly, the risk of strokes is two to four times greater for people with diabetes. These higher risks arise from the damage that a high blood glucose level does to blood vessels.

- *Kidney disease.* Diabetes is also a leading cause of kidney failure, accounting for 44 percent of new cases of kidney failure in the United States in 2008. In 2008, over 48,000 people with diabetes began treatment for end-stage kidney disease, and some 202,000 diabetics with end-stage kidney disease relied on chronic dialysis or kidney transplants. In 2012, 25,000 Americans died from diabetes-related renal disease, 55 percent of all renal disease fatalities in that year. [23]

- *Hypertension.* During the years 2005 to 2008, 67 percent of people with diabetes aged 20 years or older had blood pressure equal to or greater than 140/90 or relied on prescription medications for hypertension.

- *Blindness and eye problems.* Diabetes is the leading cause of new cases of blindness among adults aged 20-74 years. Over the years 2005 to 2008, 4.2 million people with

[18] *Ibid.*
[19] In addition, other types of diabetes can arise from certain genetic conditions, surgeries, medications, infections, pancreatic disease, and other illnesses. Centers for Disease Control and Prevention (2012).
[20] *Ibid.*
[21] *Ibid.*
[22] *Ibid.* Heart disease is noted on 68 percent of diabetes-related death certificates for people age 65 and older, and stroke is noted on 16 percent of those death certificates.
[23] Yang et al. (2013).

diabetes age 40 and older had diabetic retinopathy, including 655,000 people had advanced retinopathy that can lead to severe vision loss.

- *Nervous system disease.* Between 60 percent and 70 percent of people with diabetes also have mild to severe damage to their nervous system. The consequences of this damage include impaired sensation or pain in feet or hands, slowed digestion, carpal tunnel syndrome, erectile dysfunction, and other nerve problems.

- *Amputations.* Severe forms of diabetic nerve disease are a major contributing cause of lower-limb amputations. More than 60 percent of non-traumatic, lower-limb amputations occur in people with diabetes, including some 65,700 people in 2006.

Finally, people with diabetes are more susceptible to many other illnesses, including depression, biochemical imbalances, pneumonia, influenza, and severe gum disease.

People with T1D face additional risks. T1D is an autoimmune disorder in which a person's immune system attacks the pancreas and destroys the cells that produce insulin. People with T1D must carefully balance their insulin doses with dietary restrictions and prescribed daily activities, and they face a constant danger of life-threatening emergencies. Since many people with T1D are diagnosed as children or young adults, the disease must be managed for many decades, which increases the risks of complications. For example, women with T1D that is poorly-controlled before conception and in the first trimester of their pregnancy suffer major birth defects in 5 percent to 10 percent of cases and spontaneous abortions in 15 percent to 20 percent of cases.[24] People with T1D are also much more likely to develop celiac disease, another autoimmune disorder that affects the digestive system. People with celiac disease cannot tolerate gluten, a protein found in wheat, rye, barley and triticale; and the disease damages their intestines and ability to absorb nutrients. One in 10 people with T1D develops celiac disease, compared to one in 100 people in the rest of the population.[25] Adolescents with T1D also have an increased risk of developing eating disorders.[26] People with T1D also have a heart attack risk that is ten times more likely than those without diabetes.[27]

These various complications not only reduce the average lifespan of people with diabetes, they also increase their demands on the healthcare system and the attendant costs. Compared to the rest of America, people with diabetes, especially those with T1D, visit doctors' offices, emergency rooms, and hospitals on both an inpatient and outpatient basis more often. (Table 1, below) For example, the data show that in 2007, adults age 45 to 64 with T1D visited their physicians' offices 2.1 times for every physician office visit by an adult the same age without diabetes, entailing significant additional costs for the health care system.

[24] National Diabetes Information Clearinghouse (2011).
[25] JDRF. "Double Diagnosis: Living with Type 1 Diabetes and Celiac Disease."
[26] Rydall, Anne C. et. al. (1997).
[27] National Institutes of Health (2011).

Table 1. Ratio of Annual Heath Care Use by Adults Age 45-64 Diagnosed with Diabetes, and by Medical Complications Linked to Diabetes, Compared to Other Americans, 2007[28]

	Physician Office Visits		Outpatient Visits		Emergency Room Visits		Hospital Inpatient Days	
	T1D	T2D	T1D	T2D	T1D	T2D	T1D	T2D
Diagnosed Diabetes Patients	**2.1**	**1.9**	**2.2**	**2.1**	**1.8**	**1.9**	**3.7**	**2.7**
Complications								
Neurological	7.9	4.9	6.2	4.1	5.4	3.7	6.0	5.3
Peripheral vascular	3.5	2.9	5.6	4.3	4.0	2.5	10.9	5.8
Cardiovascular	1.7	2.0	1.9	2.1	3.1	3.0	7.1	6.1
Renal	4.1	2.9	4.0	2.9	3.1	2.8	15.3	6.7
Endocrine	1.3	1.4	1.3	1.4	14.7	8.3	23.0	9.8
Ophthalmic	5.7	3.6	6.2	4.0	2.3	2.3	7.4	7.2
Other diabetes	4.1	3.1	6.6	4.4	2.8	2.7	12.9	10.3
Other conditions	1.4	1.4	1.4	1.4	1.6	1.7	2.6	1.9

More recent data on the incidence of health care use by people with T1D and T2D, compared to other Americans, are not available. However, the 2012 data published in the journal *Diabetes* allow us to estimate the total costs of institutional care, out-patient care and medications and supplies for Americans with diabetes in 2012: In that year, medical care for people with diabetes totaled $175.8 billion or 13.2 percent of all U.S. healthcare expenditures. (Table 2, below)

Table 2. Healthcare Expenditures by Diabetes Status and Type of Service, 2012[29]

Type of Medical Service	Costs for People with Diabetes		U.S. Health Care Costs
	($ millions)	Share of U.S. Health Care Costs	($ millions)
Institutional care	$90,652	15.7%	$576,199
Outpatient care	$31,798	7.1%	$445,723
Outpatient medications & supplies	$53,369	17.1%	$311,988
Total	**$175,819**	**13.2%**	**$1,333,910**

Further, the Centers for Disease Control and Prevention (CDC) report that of the 10 leading causes of death in the United States in 2009, diabetes ranked seventh in the number of deaths and third in the number of cases. (Table 3, below) The CDC found that of 24.1 million Americans with diabetes in 2009, 68,905 died of the disease that year. Later data indicate that diabetes caused more than 70,000 deaths in 2011 and was a contributing factor in an additional 160,000 deaths.[30]

[28] Dall et al. (2009).
[29] Yang, et al. (2013)
[30] Centers for Disease Control and Prevention (2012).

Table 3. Ten Leading Causes of Death and Their Incidence, 2009, by Numbers of Deaths[31]

Cause of Death	Deaths	Cases
Heart Disease	595,444	74,521,000
Cancers	573,855	19,451,400
Chronic Lower Respiratory Diseases	137,789	35,610,000
Stroke	129,180	6,266,000
Accidents	118,043	NA
Alzheimer's Disease	83,308	5,100,000
Diabetes	**68,905**	**24,100,000**
Nephritis, Nephrotic Syndrome, Nephrosis	50,472	3,631,000
Influenza and Pneumonia	50,003	4,000,000
Suicide	37,793	1,052,000

The Incidence and Prevalence of Diabetes

The World Health Organization estimates that worldwide, some 347 million people suffer from diabetes.[32] Moreover, those numbers are expected to grow rapidly as the world's population ages, urbanization increases, and obesity and sedentary lifestyles become more common.[33] The United States has the third highest concentration of people with diabetes. Some 22.3 million Americans in 2012 were diagnosed diabetics, and another 7.8 million more Americans are thought to have diabetes but have not been diagnosed as such.[34] (Table 4, below) Based on these estimates, 7.1 percent of the current U.S. population was diagnosed with a form of diabetes in 2012, and another 2.5 percent of the population had undiagnosed diabetes. These data tell us that over 30 million Americans or 9.6 percent of the population have diabetes.

Experts from the UnitedHealth Center for Health Reform and Modernization predict that diabetes will continue to grow faster than the overall U.S. population. By 2020, estimates of the number of Americans with diagnosed diabetes will reach more than 30 million and another 10.5 million people will have undiagnosed diabetes. All told, by 2020, more than 40.5 million Americans, or 12.1 percent of the population, will have diabetes. (Table 4, below)

In our previous 2012 study, we drew on several data sources to disaggregate these estimates and estimate the incidence and costs associated with T1D, T2D, and people with yet-undiagnosed diabetes. For example, Dall et al. (2009) estimated that 17.5 million Americans has diagnosed cases diabetes in 2007, including 1 million cases of T1D and 16.5 million cases of T2D;[35] and Zhang et al. (2010) estimated that an additional 6.3 million people had undiagnosed diabetes in 2007.[36] The total number of Americans with diabetes in 2007, therefore, was estimated at 23.8 million, a total very close to the 24.1 million estimated by UnitedHealth (2010). The differences between these aggregate estimates are not significant, and here we used UnitedHealth projections for our estimates of the total number of diagnosed and undiagnosed

[31] Center of Disease Control and Prevention (2011).
[32] World Health Organization, update (March 2013).
[33] Zhang et al. (2010).
[34] Yang (2013); UnitedHealth (2010)
[35] Dall et al. (2009)
[36] Zhang et al. (2010).

cases for the years 2008-2020. However, the two studies do have significantly differences in the composition of the totals. UnitedHealth found 0.4 million cases of T1D and 17.2 million cases of T2D in 2007, compared to Dall et al.'s estimate of 1 million cases of T1D and 16.5 million cases of T2D. Our 2012 study used the Dall et al. estimate of the number of cases of T1D and T2D in 2007. We then applied the annual growth rates for those conditions projected by UnitedHealth to estimate the incidence of T1D and T2D cases for 2008-2020.

Updating these estimates introduces certain new complications. In the more recent analysis published by in *Diabetes* (Yang et al., 2013), the authors estimated that in 2012, 22,290,200 American were diagnosed with diabetes. Unlike the 2009 Dall et al. analysis for 2007, however, the Yang et al. estimate for 2012 was not disaggregated into cases of T1D and T2D. The 2010 estimate for 2012 by the UnitedHealth Center was disaggregated into cases of T1D and T2D, but its total number of cases projected for 2012 was nearly 1 million fewer than the new number Yang et al. estimated for 2012. Here, we accept the most recent estimates of total diagnosed cases for 2012 (Yang et al., 2013). We then distribute this total for 2012 into cases of T1D and T2D based on the distribution of T1D and T2D as reported by Dall et al. (2009). To estimate future incidence and costs for diagnosed cases (2013-2020), we apply the growth rates projected by UnitedHealth to the Yang et al. estimate of aggregate diagnosed cases, including the UnitedHealth projection of 1 percent average annual growth in cases of T1D from 2007 to 2020. If we assumed that T1D's share of all cases of diabetes as estimated by Dall et al. for 2007 remained constant at 5.7 percent, the number of T1D cases estimated for 2020 would be as high as 1.7 million cases, instead of 1.4 million cases reported in Table 4 below. Therefore, our estimate of future T1D cases and their consequent economic costs should be considered conservative. For undiagnosed cases, we rely on UnitedHeath's estimate for 2012-2020.

Based on these estimates and adjustments, we estimate that 22,290,200 Americans were diagnosed with diabetes in 2012, or 9.6 percent of the population, including 1,308,110 people with T1D and 20,982,090 people with T2D. In addition, there were an estimated 7,800,000 cases of undiagnosed diabetes.[37] (Table 4, below) We further project that in 2020, 40,534,213 Americans or 12.1 percent of the population, will suffer from diabetes, including 1,391,377 people with T1D, 28,642,836 people with T2D, and 10,500,000 undiagnosed cases.[38]

[37] This compares to our previous estimates of 21,300,000 in total diagnosed cases for 2012, comprised of 1,250,000 Americans with T1D and 20,050,000 with T2D, plus 7,800,000 million with undiagnosed diabetes.

[38] Only a few researchers other than those used here have projected the number of cases outwards to 2020 and beyond, and there are substantial variations in their projections of the incidence of T1D and T2D based on racial, ethnic and other demographic characteristics. For example, Imperatore et al. (2012) estimate that T1D among youths age 20 years and under will increase by an annual average rate of 1.7 percent from 2010 to 2050 under their base case scenario, and by as much as an average of 5.7 percent per-year under an "increased incidence rate" scenario. Most quantitative analyses of this sort rely on a range of distributions rather than a single projected value.

Table 4. Incidence of Diabetes in the United States, 2012 and 2020[39]

	2012		2020 (estimated)	
	Cases	Share of U.S. Population	Cases	Share of U.S. Population
Total Diabetes	**30,090,200**	**9.6%**	**40,534,213**	**12.1%**
Diagnosed diabetes	22,290,200	7.1%	30,034,213	9.0%
Type 1 diabetes	1,308,110	0.4%	1,391,377	0.4%
Type 2 diabetes	20,982,090	6.7%	28,642,836	8.6%
Undiagnosed diabetes	7,800,000	2.5%	10,500,000	3.1%
U.S. Population	313,914,000	100.0%	333,896,000	100.0%

III. The Costs of Diabetes

Diabetes imposes a large economic burden on the national healthcare systems of almost every country, with the United States spending more, both per-patient and overall, than any other nation.[40] These costs include medical costs such as hospital stays, emergency room visits, doctor office visits, drugs, and medical treatments and supplies. The economic costs of diabetes also include non-medical costs, such as lost productivity due to interruptions during the work day, absences from work, disability, or premature death.[41]

Researchers have calculated that diabetes cost Americans more than $272 billion in 2012, the equivalent of 1.7 percent of GDP in that year.[42] The total includes $193 billion in medical costs, or 1.2 percent of GDP, and $79 billion in non-medical, economic costs associated with people with undiagnosed cases of diabetes as well as those already diagnosed with the disease. (Table 5, Panel 1, below) These non-medical costs were equivalent to 0.5 percent of GDP. As these non-medical costs are estimates of foregone productivity and production, in the absence of these diabetes-related effects, GDP would have been 0.5 percent higher that year. And based on the average earnings of Americans in 2012 of $45,790, we estimate these non-medical costs would have covered or supported the wages and salaries of an additional 1,738,708 full-time workers.[43] (Table 5, Panel 2, below)

Moreover, based on projections of the growth of diabetes and its costs by the UnitedHealth Center for Health Reform and Modernization, by 2020 those U.S. costs will reach $574 billion or 2.5 percent of a GDP of $23.1 trillion in that year as estimated by the Congressional Budget Office.[44] This total includes $418 billion in medical costs, the equivalent of nearly 1.8 percent of the $23.1 trillion GDP projected for 2020, and $157 billion in non-medical costs. These $157 billion in non-medical costs would be equivalent to more than 0.7

[39] Yang et al. (2013); Dall et al. (2009); UnitedHealth (2010).
[40] Zhang et al. (2010). In terms of overall expenditures on diabetes, the United States is followed by Germany, Japan, France, and Canada
[41] Diabetes, especially T1D, also can interfere with a person's education. A 2012 study found that compared to healthy peers, people with diabetes, on average, complete 0.675 fewer years of formal education and are eight to 13 percentage points less likely to attend college. As a consequence, the annual earnings of people with diabetes, on average, are $1,500 to $6,000 less than their peers without diabetes. Fletcher and Richards (2012).
[42] Yang, et al. (2013).
[43] Bureau of Labor Statistics, Occupational Employment Statistics, May 2012.
[44] Congressional Budget Office (2010).

percent of the GDP projected for 2020. Assuming that historic trends in earnings growth persist, we further estimate that the non-medical costs or foregone economic production associated with diabetes in 2020 would cover the wages and salaries of 2,604,341 full-time workers in that year.

In our 2012 report, we used T1D and T2D medical and nonmedical costs as estimated by Dall et al. (2009) for 2007. Although Dall et al. and UnitedHealth differ on the distribution of diabetes cases into T1D and T2D patients, as noted earlier, their estimates of per-case medical and non-medical costs for T1D and T2D are virtually identical. The estimated numbers and costs of cases of undiagnosed diabetes patients in 2007 by Dall et al., Zhang et al. and United Health also are virtually the same. In our 2012 report, we applied the growth rates in annual costs per-case projected by UnitedHealth to estimate the total medical and nonmedical costs of T1D and T2D in 2020, based as noted earlier on the number of T1D and T2D cases estimated by Dall et al. We also used UnitedHealth's estimates of undiagnosed cases of diabetes in 2020 and the associated cost estimates.

The more recent analysis by Yang et al. (2013) reported that in 2012, the medical and nonmedical costs of caring for nearly 22.3 million patients diagnosed with diabetes were $175.8 billion and $68.6 billion, respectively. Based on these estimates for 2012, we find that the total costs per-diagnosed case in 2012 were $10,965, including $7,888 in medical costs and $3,078 in nonmedical costs. (Table 5, Panel 1 and Panel 3) For comparison purposes, UnitedHealth in 2010 projected $11,937 in total costs per-case in 2012, including $7,950 in medical costs and $3,987 in nonmedical costs. The major difference, therefore, involved non-medical costs.

Next, we use these new estimates of the number of diabetes patients and costs per-patient in 2012 to revise our estimates of the costs for 2013-2020. We apply UnitedHealth's projected growth rates of medical and nonmedical costs for T1D and T2D per-case to project these future costs per-patient. We also used our revised number of cases of T1D and T2D and the revised costs per-patient from Yang et al. (2013) to estimate the aggregate costs for T1D and T2D. Finally, we use UnitedHealth's forecasts of medical and nonmedical costs for undiagnosed cases.

Table 5. Economic Costs and Burdens Attributed to Diabetes, 2012-2020[45]

Panel 1:
Costs of Diabetes in the U.S., 2012 and Estimated for 2020 ($ billions)

	2012			Estimate for 2020		
	Total	Medical	Non-Medical	Total	Medical	Non-Medical
Total	**$272**	**$193**	**$79**	**$574**	**$418**	**$157**
Diagnosed diabetes	$245	$176	$68	$512	$381	$132
Type 1 diabetes	$23	$15	$7	$48	$29	$19
Type 2 diabetes	$221	$160	$61	$464	$352	$113
Undiagnosed	$28	$17	$11	$62	$37	$25

[45] UnitedHealth (2010); Dall et al. (2009); Yang et al (2013). As noted, we use the estimated medical costs and non-medical costs of T1D and T2D patients in 2007 derived by Dall et al. in their 2009 study. To estimate these costs for 2012 and 2020, we apply the projections of the likely increases in these costs from 2007 to 2012 and 2020 reported in the UnitedHealth study. Columns and rows may not add up precisely due to rounding.

Panel 2:
Costs of Diabetes, Those Costs as Shares of GDP, and Foregone Employment from the Economic or Non-Medical Costs of Diabetes, 2012 and Estimated for 2020

	2012			Estimate for 2020		
	Total	Medical	Non-Medical	Total	Medical	Non-Medical
Total Costs ($ billions)	$272	$193	$79	$574	$418	$157
Share of GDP	1.7%	1.2%	0.5%	2.5%	1.8%	0.7%
Foregone Employment	--	--	1,738,708	--	--	2,604,341

In the aggregate, T2D accounted for over 81 percent of the total costs of the disease in 2012 and almost 83 percent of the medical costs. On a per-case basis, however, the medical and non-medical costs associated with T1D, $17,148 per-case in 2012, were 62 percent greater than those arising from T2D at $10,549 per-case, reflecting mainly the complications that often accompany T1D. (Table 5, Panel 3, below) Researchers estimate that by 2020, an average case of T1D will cost $34,568 per-case as a case of T2D at $16,213.

Panel 3:
Total Costs Per-Case of Diabetes in the U.S., 2012 and Estimated for 2020

	2012			Estimate for 2020		
	Total	Medical	Non-Medical	Total	Medical	Non-Medical
Total Diabetes	**$9,057**	**$6,411**	**$2,645**	**$14,135**	**$10,303**	**$3,870**
Diagnosed diabetes	$10,965	$7,888	$3,078	$17,063	$12,673	$4,391
Type 1 diabetes	$17,148	$11,500	$5,648	$34,568	$20,637	$13,930
Type 2 diabetes	$10,549	$7,650	$2,899	$16,213	$12,286	$3,927
Undiagnosed	$3,603	$2,192	$1,410	$5,905	$3,524	$2,381

Epidemiologists predict that the total costs of diabetes will more than double from 2012 to 2020, increasing 111 percent, and the costs per case or per patient will increase 56 percent. (Panel 4, below) To begin, the number of Americans expected to be diagnosed with T1D or T2D, along with cases of undiagnosed diabetes, is expected to rise sharply. Moreover, unless new, cost-saving advances occur as a result of public and private supported research, the costs of treating the illness and its complications will grow faster than the population or economy. The result: The total costs of diabetes are expected to rise from 1.7 percent of GDP in 2012 to 2.5 percent of GDP in 2020.

Panel 4:
Projected Growth in Costs of Diabetes in the U.S., Overall and Per Patient, 2012-2020

	United States			Per Patient		
	Total	Medical	Non-Medical	Total	Medical	Non-Medical
Total Diabetes	**111%**	**116%**	**97%**	**56%**	**61%**	**46%**
Diagnosed diabetes	110%	116%	92%	56%	61%	43%
Type 1 diabetes	114%	91%	162%	102%	79%	147%
Type 2 diabetes	110%	119%	85%	54%	61%	35%
Undiagnosed	121%	116%	127%	64%	61%	69%

As noted in Panel 4, the per-patient costs of T1D are expected to increase 102 percent from 2012 to 2020, compared to 54 percent increases projected for T2D. This acceleration in the costs of T1D is driven largely by the high costs of hospital care and the fast-rising non-medical costs associated with an illness that mainly affects young people. This underscores the urgency of discovering new treatments to delay or reduce the severity of T1D, reduce the risks of medical complications, or even cure the disease could produce large economic savings and benefits.

The Components of the Medical and Non-Medical Costs of Diabetes

The current costs of the various aspects of living with diabetes are presented in Table 6 below. In 2012, the hospital-related costs of living with T1D accounted for 57 percent of all of the costs associated with the disease, premature deaths accounted for another 6.9 percent of costs, and absenteeism and other reduced productivity at work ("presentee-ism") accounted for another 7.4 percent. In contrast, hospital costs accounted for just 35 percent of all costs associated with T2D, with drugs accounting for nearly 23 percent of costs, premature deaths accounted for 7.6 percent, and absenteeism and other productivity losses accounted for 19 percent of costs.

Yang et al. (2013) estimated medical and nonmedical costs by type of service in 2012. The authors did not estimate the cost components for T1D and T2D, so we distribute the medical and nonmedical costs to T1D and T2D proportionally based on the Dall et al. estimates for 2007.

Table 6: Economic Costs Attributed to Diagnosed Cases of Diabetes in 2012[46]

	All Diagnosed Cases	T1D	T1D Shares	T2D	T2D Shares
Total Costs	**$244,419,000,000**	**$22,812,000,000**	**100%**	**$221,607,000,000**	**100%**
Medical costs	$175,819,000,000	$17,724,000,000	77.7%	$158,095,000,000	71.3%
Institutional care	$90,620,000,000	$13,080,000,000	*57.3%*	$77,540,000,000	*35.0%*
Outpatient care	$31,830,000,000	$1,731,000 000	*7.6%*	$30,099,000,000	*13.6%*
Outpatient drugs	$53,369,000,000	$2,913,000,000	*12.8%*	$50,456,000,000	*22.8%*
Non-medical costs	$68,600,000,000	$5,088,000,000	22.3%	$63,512,000,000	28.7%
Absenteeism	$5,000,000,000	$245,000,000	*1.1%*	$4,755,000,000	*2.1%*
Presentee-ism	$23,500,000,000	$1,432,000,000	*6.3%*	$21,618,000,000	*10.0%*
Disability	$21,600,000,000	$1,831,000,000	*8.0%*	$19,769,000,000	*8.9%*
Premature mortality	$18,500,000,000	$1,580,000,000	*6.9%*	$16,920,000,000	*7.6%*

Further analysis of the distribution of these costs based on age shows that the costs per patient rise sharply later in life for those with T1D, while the per-patient costs of those with T2D remain relatively stable throughout their lives. (Table 7, below) In 2007, T1D and its complications cost $36,349 per-year, per-patient for those over age 65, compared to $8,649 per-year per-patient from infancy to age 44 and $13,881 per-year per-patient for those age 45 to 64. The costs per-patient, per-year in 2007 for those with T2D were slightly greater for those age 44 and less, and significantly less for older patients and on average. The high costs of T1D in older patients are almost entirely medical-related costs, averaging $35,365 per-person, per-year, and reflect the serious, cumulative complications often associated with the condition.

[46] Dall et al. (2009); Yang et al. (2013).

Table 7: Annual Costs Arising from Diagnosed Cases of Diabetes, Per Patient, by Age, 2007[47]

	All Diagnosed Cases	T1D	T2D
Total Costs Per Case	**$9,886**	**$14,900**	**$9,584**
Age 0 to 44	$9,099	$8,649	$9,202
Age 45 to 64	$9,868	$13,881	$9,701
Age 65+	$10,473	$36,349	$9,815
Medical Costs Per Case	$6,591	$10,500	$6,355
Age 0 to 44	$3,808	$4,044	$3,755
Age 45 to 64	$5,094	$8,169	$4,966
Age 65+	$9,713	$35,365	$9,061
Non-Medical Costs Per Case	$3,295	$4,400	$3,229
Age 0 to 44	$5,291	$4,605	$5,447
Age 45 to 64	$4,774	$5,712	$4,735
Age 65+	$760	$984	$754

In their 2013 report, Yang et al. estimated medical costs by age, but not nonmedical costs. Their findings, however, confirm that the costs of diabetes rise with age. The estimated medical costs average $4,394 per-case for patients younger than 44 years old, $5,611 per-case for patients 45 to 64 years old, and $11,825 per-case for those patients older than 65. The authors' estimates do not disaggregate medical costs by age for T1D and T2D or estimate nonmedical costs by age. Drawing on the Dall et al. estimates of 2007 T1D and T2D medical costs per-case, we can estimate T1D and T2D medical costs, per-case, by age for 2012. (Table 8, below)

Table 8. Estimated Medical Costs, Per-Case of T1D and T2D, by Age, 2012

	All Diagnosed Cases	T1D	T2D
Medical Costs Per Case	$7,888	$12,566	$7,606
Age 0 to 44	$4,394	$4,666	$4,333
Age 45 to 64	$5,611	$8,998	$5,470
Age 65+	$11,825	$43,055	$11,031

All of these estimates cover only diagnosed cases of diabetes. Experts estimate, however, that nearly 10 percent of the total costs of the conditions, or about $28 billion in 2012, are associated with people with yet-undiagnosed cases of the disease. Nearly $17 billion of these costs are thought to have been medical-related, primarily hospital services. The remaining $11 billion is costs represent non-medical costs, primarily reduced performance at work.

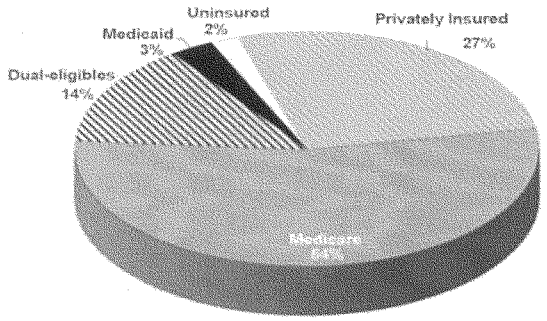
The UnitedHealth Center for Health Reform and Modernization estimated in 2012 that the health-related costs of diabetes from 2011 to 2020 would total $2.766 trillion. Using the Yang et al. estimates of per-case costs, the Dall et al. estimates of the number of cases of T1D and T2D, and UnitedHealth's estimates of the medical costs associated with undiagnosed cases of diabetes, we estimate that the health-related costs of diabetes from 2011 to 2020 will total

[47] *Ibid.*

$2.852 trillion, an increase of $86 billion over the 2010 projection. Considering only the period from this year to 2020, the medical costs of diabetes will total an estimated $2.488 trillion.

Moreover, taxpayers will bear an average of 71 percent of those medical costs through Medicare and Medicaid over this decade: Medicare will cover and average of 54 percent of these costs, or an estimated $1.34 trillion from 2013 to 2020. (Figure 1, below) Medicaid will cover another 3 percent of those costs or an estimated $75 billion from 2013 to 2020. In addition, patients eligible for both Medicare and Medicaid will account for another 14 percent of those costs or $348 billion from 2013 to 2020. Private insurance will pick up 27 percent of these costs, which will come to an estimated $672 billion from 2013 to 2020. Finally, uninsured people ineligible for Medicare or Medicaid account for 2 percent of these costs. Those costs are expected to come to more than $50 billion from 2013 to 2020 and ultimately are paid for by the patients themselves or picked up by hospitals and physicians.

Figure 1. Medical Spending on Diabetes, By Coverage, 2011-2020[48]



Using these shares and the estimated incidence and costs of treating diabetes in 2012 and 2020, we calculate that taxpayer funding to treat diabetes through Medicare and Medicaid will more than double from $137 billion in 2012 to $297 billion in 2020, an increase of $160 billion or nearly 117 percent. (Table 9, below) Moreover, because the shares are averages for 2012-2020, and because treatment costs increase with age and the number of older people is rising faster than the population, the estimates for 2020 and the percentage increase are conservative.

Table 9. Medicare and Medicaid Costs of Treating Diabetes, 2012 and 2020 ($ billions)

	2012	2020	Increase	Percentage Increase
Total Public Funding	**$137.0**	**$296.8**	**$159.8**	**116.6%**
Medicare	$104.2	$225.7	$121.5	116.6%
Medicaid	$5.8	$12.5	$6.7	116.6%
Dual Coverage	$27.0	$58.5	$31.5	116.6%

[48] UnitedHealth (2010).

IV. NIH Support for Research on Type 1 Diabetes

Since the 1990s, Congress has recognized diabetes as a major public health concern and allocated significant federal funding for research. Under the Balanced Budget Act of 1997, Congress created the Special Diabetes Program (SDP) to support basic research into ways of preventing, treating, and one day, hopefully, curing T1D and its complications. The Program is a targeted research effort designed to foster scientific collaborations among the Institutes and Centers of the National Institutes of Health, the Centers for Disease Control and Prevention, and the broader scientific research community. The Program's goals envisage research to identify the genetic and environmental causes of T1D and develop cell replacement therapies. The program also seeks to attract new talent and to apply new technologies, in order to prevent or reverse TID and reduce its complications, and prevent or reverse episodes of dangerously low blood sugar ("hypoglycemia").[49] The Program was originally funded at $30 million a year and later increased. It currently is funded at $150 million a year through FY 2014.[50]

While this analysis focuses on the cost-effectiveness of the $150 million research funding for T1D through SDP, NIH support for research into diabetes totaled some $1,076 million in FY 2011 (including the $150 million for T1D research through SDP and approximately $250 million through academic grants) or 3.5 percent of the NIH budget.[51]

A review of NIH support in 2010-2011 for the ten leading causes of death among Americans shows that NIH research support for diabetes comes to just $45 per-patient, less than any of the other leading causes of death except chronic lower respiratory diseases. (Table10, below) Based on mortality rates, however, diabetes receives the highest level of NIH research support, at $15,616 per-death.

Table 10. NIH Support for Research into the 10 Leading Causes of Death: Total Funding, Funding Per-Patient and Per-Death, 2010-2011[52]

Disease/Condition	NIH Funding (millions)	NIH Funding Per Patient	NIH Funding Per Death
Heart Disease	$3,962	$53	$6,654
Cancers	$8,046	$414	$14,021
Chronic Lower Respiratory Diseases	$351	$10	$2,547
Stroke	$317	$51	$2,454
Accidents	$734	--	$6,218
Alzheimer's Disease	$448	$88	$5,378
Diabetes	**$1,076**	**$45**	**$15,616**
Nephritis, Nephrotic Syndrome, Nephrosis	$599	$152	$11,868
Influenza and Pneumonia	$771	$193	$15,419
Suicide	$49	$47	$1,297

[49] National Institutes of Health (2011). "Special Statutory Funding Program for Type 1 Diabetes Research"; and National Institute of Diabetes and Digestive and Kidney Diseases.
[50] *Ibid.*
[51] National Institutes of Health (2010). "Special Statutory Funding Program for Type 1 Diabetes Research – Progress Report." National Institutes of Health (2012).
[52] National Institutes of Health (2012); World Trade Organization (2008); Gillum et al. (2011).

Progress in Treating and Managing Diabetes

Several decades of research into the causes, course and management of diabetes and the health conditions that often accompany it, notably heart and kidney disease, have produced important advances. Since the 1950s, the share of Americans with T1D who died within 20 years of being diagnosed has fallen from 20 percent to just 3.5 percent, and the share who die within 25 years of their initial diagnosis has declined from 33 percent to just 7 percent.[53] These major improvements have been accompanied by substantial progress in the quality as well as the length of life of those suffering from T1D.[54] T2D, which accounts for 90 percent or more of diagnosed cases of diabetes, can be managed and controlled more easily than T1D and sometimes can be prevented through diet and exercise. The likelihood of serious complications also is greater with T1D than T2D, in part because T1D strikes in childhood or adolescence.[55]

Like virtually all medical research efforts, progress in diabetes research has required considerable time and investments. For example, it took 10 years for the Diabetes Control and Complications Trial, starting in 1983, to establish that intensive blood-sugar control reduces the risks of complications involving patients' eyes, kidneys, and nerves. It took an additional decade for the follow-on Epidemiology of Diabetes Interventions and Complications trial to assess the effect on the risks of cardiovascular complications in T1D patients.

SDP Research and the Development of New Therapies for T1D

The Special Diabetes Program has provided long-term support to a large number of research projects, many of which have already produced substantial advances. For example, the Program has funded the Type 1 Diabetes Genetics Consortium, which developed new technologies that identified more than 50 genes or genetic regions that influence a person's risk of developing T1D. Identifying and understanding the genetic contributors and influencers for T1D, in turn, has helped scientists to better understand the disease, identify individuals at risk, develop and test new prevention strategies, and design clinical trials to test personalized interventions for patients with similar risk profiles. In time, these advances may enable scientists to safely prevent T1D in some people and restore normal beta cell function in others.[56] The Program also supports the Beta Cell Biology Consortium, an international collaboration studying insulin-producing cells in hopes of developing new cell-based therapies to treat T1D, as well as another consortium of research institutions working to create new animal models for the study of the onset of complications associated with T1D.[57]

In addition, the Program has provided the critical support used by the Clinical Islet Transplantation Consortium to develop new procedures that have dramatically improved the success rate of islet transplants. For example, the Program provided 98 percent of the support needed for Phase III trials that are expected to form the basis for an application for FDA

[53] National Institutes of Health (2010). "Type 1 Diabetes Fact Sheet."
[54] Lenord (2012).
[55] Dall et al. (2009).
[56] National Institutes of Health (2010). "Special Statutory Funding Program for Type 1 Diabetes Research – Progress Report."
[57] JDRF (n.d.). "The Special Diabetes Program: Advancing Research and Improving Lives on the Path to a Cure."

approval of new islet cell transplant therapy. As a result, 471 patients with T1D received islet implants from 2000 to 2005, more than the number of people with diabetes receiving islet transplants in the preceding 30 years of the procedure. Scientists hope to build on these advances in ways that may make islet transplants a common mode of treatment.[58]

Support for Early Identification and Treatment of T1D

The Program is also responsible for the TrialNet project, which screens about 20,000 people considered at risk of developing T1D each year. Screening is the first step on the pathway to prevention and provides an important opportunity for intervention at an early stage. Because persons related to people with T1D are 10-100 times more likely to develop the disease than the general population, TrialNet provides screening free of charge to all relative of people with T1D. The Program also supports SEARCH, a national multi-center study to examine the current status of diabetes among children and adolescents. SEARCH seeks to develop a uniform classification of types of childhood diabetes, estimate the number of new and existing cases of childhood diabetes, identify the clinical characteristics of the different types of diabetes in youth and how they evolve, and categorize the complications of the disease and the impact on the quality of life of children and adolescents.[59] More than 6 percent of American children aged 0 to 19 years – more than 5 million children – have participated in the program.

The Program also has provided support for the Environmental Determinants of Diabetes in the Young (TEDDY) project. This project is building the most comprehensive database of newborns at high risk of developing T1D by following more than 8,000 infants with genetic markings for the disease, from infancy to age 15. Tracking dietary and health data and collecting regular stool, blood, and other samples, the project aims to identify environmental factors that trigger the disease and, on this basis, develop strategies to prevent, delay, and reverse it. Scientists also hope to use this knowledge to develop a vaccine to prevent T1D.[60]

Other Support for New Treatments

Other projects supported by the Special Program include a network of clinical centers that are testing and evaluating new technologies for managing T1D in children.[61] In addition, the Program funds the Diabetes Retinopathy Clinical Research Network, a collaborative research network of clinicians and researchers at more than 160 institutions, which helped determine that a therapy originally developed for cancer could, in some cases, halt and even reverse the progression of diabetes-related vision loss. Numerous other Special Program-supported projects have yielded important advances. The program funded research testing the use of continuous glucose monitors, which helped demonstrate their benefits in enabling patients to maintain healthy levels of glucose and thereby reduce the likelihood of developing complications. Support from the Program was also critical to the recent success of researchers from several health centers who have developed and tested artificial pancreas systems which continuously

[58] Shapiro et al. (2005).
[59] Centers for Disease Control and Prevention, SEARCH for Diabetes in Youth. Website.
[60] *Ibid.*
[61] Juvenile Diabetes Research Foundation (n.d.). "The Special Diabetes Program: Advancing Research and Improving Lives on the Path to a Cure."

monitor glucose levels and deliver appropriate doses of insulin.[62] Research and development is underway to develop a version of this system that could be available in the future for T1D patients to use in their daily lives.

Finally, numerous studies have found a strong positive relationship between such public support for basic research and R&D investments by private pharmaceutical firms.[63] Researchers have shown that a one percent increase in NIH-funded research leads to a 2.5 percent increase in private R&D spending, with a lag of about seven years while the basic research is conducted and its findings published.[64] Studies also show that increases in public spending for basic research are associated with eventual increases in the approval of new molecular entities, with a lag of 18 years between the initial funding for the basic research and FDA approval of additional new drugs.[65] In 2011, for example, researchers reported the development of DiaPep277, a new drug currently undergoing phase three trials that may prevent beta cell destruction in T1D patients and, thereby, allow beta cells to continue to secrete insulin for up to two years following a T1D diagnosis.[66]

V. Assessing the Benefits of NIH-Supported Diabetes Research

While the Special Diabetes Program has provided support for many promising lines of research and development, quantifying the economic benefits of the Program is challenging. To begin, medical research and associated clinical trials often require many years to show results. While the Program has made significant contributions to the current basic understanding of T1D, many of its projects continue to focus on data collection, identifying basic causes, and attracting talent to research into T1D.[67] Nevertheless, we can knowledgeably speculate about some of the Program's benefits.

A Case Study: SDP & Prevention of T1D

The Special Diabetes Program is advancing research that could prevent or delay the onset of T1D. An example is TrialNet, the program that screens people at risk of developing T1D and conducts clinical trials testing potential therapies to prevent onset of the disease. TrialNet offers free screenings to relatives of people with T1D, people whose chances of developing the disease are 10-to-100 times greater than those with no family history. The screening is designed to detect the auto-antibodies that lead to T1D which, as recent clinical trials have established, may appear up to 10 years before symptoms of the disease become apparent. At the same time, TrialNet is conducting clinical trials of compounds that may enable those with antibodies to delay the onset

[62] Mayo Clinic (2011). See also, http://corporate.uvahealth.com/news-room/archives/uva-artificial-pancreas-gets-first-u.s.-outpatient-test.
[63] Congressional Budget Office (2006).
[64] Ward and Dranove (1995); CBO (2006).
[65] *Ibid.*; Toole (2000); DiMasi et al (2003).
[66] "Advances in Treating Type 1 Diabetes: Drugs Show Promise for Preserving Body's Ability to Produce Insulin," June 28, 2011, http://www.diabetes.org/for-media/2011/advances-in-treating-type-1-sci-sessions-2011.html .
[67] National Institutes of Health (2010). "Special Statutory Funding Program for Type 1 Diabetes Research – Progress Report."

of the disease, moderate its eventual severity, and avoid some of the serious complications which often accompany it.[68]

As shown earlier, total costs of T1D are estimated around $17,148 per case per year, with some 67 percent attributed to medical costs. Based on the TrialNet Progress Report, approximately 5.3 percent of those screened were found to be auto-antibody positive.[69] TrialNet has screened some 100,000 participants, which means it has identified approximately 5,300 people with the auto-antibodies that signal the development of T1D. Early results of the NIDDK studies suggest that oral insulin may delay insulin dependency for four years in people with high insulin auto-antibody levels, and TrialNet trials are currently ongoing to confirm this observation.[70] If we assume that all of those identified are young and consider only the medical costs, the annual savings from delaying the onset of T1D will be $4,666 per-person. (Table 8, above) If oral insulin therapies delay the onset for an average of four years, the four-year savings from the 5,300 people identified by TrialNet as possessing the auto-antibodies would come to $99 million. If we apply the total average economic cost of $17,970 per-person with T1D, the potential savings from this one project come to $381 million (5,300 x 4 x $17,970 = $381.0 million) or 20.2 percent of the Special Program's total 16-year funding of $2.04 billion.

In addition to TrialNet's 100,000 initial screenings, the program also screens up to 20,000 subjects per year through its "Natural History Study." This study provides the framework for the identification, risk characterization and potential recruitment of subjects into the trials. Applying the current results that have found 5.3 percent of subjects with the auto-antibodies for T1D, TrialNet should be able to identify an additional 1,060 positive auto-antibody patients each year. About 15,000 children and 30,000 people in total are diagnosed with T1D each year in the United States. TrialNet in its current form, therefore, can detect 3.5 percent of new cases years before a normal diagnosis. The economic benefits and savings associated with that early identification and appropriate intervention would come to between $4.9 million ($4,666 x 1,060) and $17.2 million per-year, or another $20 million to $69 million over four years.[71]

Spillover benefits from T1D Research and Advances

The advances in understanding the origins and mechanisms of T1D also have large, potential spillover benefits for other areas. For example, scientists believe that the artificial pancreas now being used on a small scale to regulate abnormal blood sugar levels in T1D patients may eventually be applied to people with T2D, who comprise 90 to 95 percent of all Americans with diabetes. More generally, progress in early detection of T1D enables physicians to intervene to lower blood glucose levels, blood pressure and other risk factors which otherwise would lead to circulatory system damage. Early detection also enables physicians to screen for and treat other conditions such as retinopathy.[72] Moreover, the savings will be enormous if, as

[68] Type 1 Diabetes TrialNet (2011). "TrialNet Reaches Important Milestone – Screens 100,000 People for Type 1 Diabetes." Type 1 Diabetes TrialNet (2011). "Aided by Relatives of those with Type 1 Diabetes, TrialNet Researchers Close in on Prevention."; and Lenord (2012).
[69] Type 1 Diabetes TrialNet (2011). "Progress Report – Type 1 Diabetes TrialNet."
[70] Type 1 Diabetes TrialNet, (2011). "Oral Insulin Prevention Study Surpasses Midway Enrollment Goal – Thousands More Need To be Screened."
[71] Skyler et al. (2008).
[72] World Health Organization (2011).

expected, these early interventions lead to lower rates of complications that threaten patients with T2D as well as T1D, including heart attacks, strokes, nerve damage, and the diseases of the eyes and kidneys.[73]

The NIH-supported research for T1D may produce even broader spillovers. NIH scientists have confirmed that some of the genes associated with T1D also affect the development of other autoimmune disorders, so that understanding the genetic underpinnings of T1D will provide critical insights into the genetics and pathogenesis of those other diseases. For example, scientists have found that T1D and celiac disease share many risk genes and are now investigating potentially shared environmental triggers for T1D, celiac disease and other autoimmune disorders.[74]

The Potential Benefits and Savings from Future Advances

The NIH has provided support for T1D research through the Special Diabetes program for 16 years, which suggests that the next decade may well see important, new therapeutic advances based on that research. We cannot know the precise nature and impact of those advances until they are broadly available. Recall that epidemiologists estimate that the average costs of T1D in 2020 will reach $34,568 per-patient, per-year, including $20,637 in medical-related costs and $13,930 in non-medical costs (Table 5, Panel 3, above). They further estimate that in 2020, nearly 1.4 million Americans will suffer from diagnosed cases of T1D, at a total annual cost of over $48 billion. (Table 5, Panel 1, above) If the NIH-supported research leads to advances by 2020 that reduce the incidence and severity of T1D by just 10 percent, the return on the SDP's original investments would be very large. The reduction in medical costs would come to $2.8 billion per-year, and the savings in other non-medical costs would total an additional $1.9 billion per-year. The total annual savings, therefore, would come to $4.8 billion. NIH funding for T1D research has totaled $2.04 billion over the last 16 years, and if we assume that the current support of $150 million per-year is maintained through 2020, the total support will come to $2.94 billion over 22 years. Under this scenario, the advances will produce an annual return of 163 percent, year after year.

Moreover, if the spillovers from this research reduce the incidence and severity of T2D to even a modest degree, the savings will be much larger. Epidemiologists forecast that by 2020, 28.7 million Americans will suffer from diagnosed cases of T2D (Table 3, above), and each case will involve average medical costs of $12,286, plus non-medical costs of $3,927 per-patient (Table 5, Panel 3, above). The total medical costs of diagnosed cases of T2D in 2020, therefore, will come to an estimated $352 billion in that year, and the total non-medical costs of those diagnosed in 2020 will come to an estimated $113 billion per-year. If the NIH-supported advances in T1D research lead to a 5 percent reduction in the incidence and severity of T2D, the reduction in medical costs would come to nearly $17.6 billion per-year, and the savings in other non-medical costs would come to some $5.6 billion. The total annual savings, therefore, would come to $23.2 billion per-year, or nearly 8 times the total projected NIH funding for the Special Diabetes Program over 22 years.

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[73] Mayo Clinic (2011).

[74] National Institutes of Health (2010). "Special Statutory Funding Program for Type 1 Diabetes Research – Progress Report."

Such advances based on NIH research support also would produce large savings for Medicare and Medicaid. These two programs absorb 71 percent of the medical costs of diabetes (Figure 1, above). Based on the 2020 projections, the budgetary savings for Medicare and Medicaid from a 10 percent reduction in the incidence and severity of T1D would come to nearly $2.04 billion per year or $20.4 billion over ten years. (Table 11, below) Similarly, the savings for Medicare and Medicaid from a 5 percent reduction in the incidence and severity of T2D, supported by spillovers from advances in T1D research, would come to more than $12.5 billion per-year or $125 billion over ten years. Under these scenarios, therefore, continued support for basic research in T1D could lead to savings for Medicare and Medicaid of nearly $14.5 billion in 2020 and every year thereafter, based on NIH investments of $2.94 billion over 22 years.

Table 11. Estimated Annual Costs of T1D and T1D, 2020, and Potential Annual Savings from Continued Scientific Advances

	Medical	Non-Medical	Total
T1D Costs, Per Diagnosed Case	$20,637	$13,379	$34,568
T1D Costs, All Diagnosed Cases	$28,700,000,000	$19,400,000,000	$48,100,000,000
T2D Costs, Per Diagnosed Case	$12,286	$3,927	$16,213
T2D Costs, All Diagnosed Cases	$351,900,000,000	$112,500,000,000	$464,400,000,000
Savings, 10% Reduction in T1D	$2,870,000,000	$1,940,000,000	$4,810,000,000
Medicare & Medicaid Savings	*$2,037,700,000*	--	*$2,037,700,000*
Savings, 5% Reduction in T2D	$17,595,000,000	$5,625,000,000	$23,220,000,000
Medicare & Medicaid Savings	*$12,492,245,000*	--	*$12,492,245,000*

Given the costs associated with diabetes today and for the foreseeable future, the advances which already have been achieved in its detection and treatment, based on NIH support, and the large economic and budgetary savings which could be achieved if NIH research support continues to produce advances, the economic case for continued NIH support for research in T1D is compelling.

VI. Conclusion

The fiscal pressures currently facing the federal government demand a dispassionate evaluation of the necessity and effectiveness of every program. This analysis has shown that the current NIH Special Diabetes Program of support for research into type 1 diabetes is both necessary and highly cost-effective. This conclusion is reinforced by projections that the number of people with diagnosed diabetes will increase from 22.3 million in 2012 to 30 million in 2020.

These conditions impose very large costs on government and the economy. In 2012, Americans spent $193 billion treating diabetes, on top of an additional $79 billion in economic losses from reduced work and productivity associated with the condition. By 2020, experts estimate that these costs will reach $574 billion, including $418 billion in medical costs and $157 billion in other economic costs. Taxpayers are responsible for 71 percent of the medical costs, through the Medicare and Medicaid programs, or $137 billion in 2012 and an estimated $297 billion by 2020.

The best hope for reducing the suffering from this disease and the enormous costs associated with it lies in sustained research and development into new ways of diagnosing and treating the disease. NIH support already has led to a number of breakthroughs that hold promise for better controlling the disease and its associated costs. For example, scientists recently identified a series of genes and gene regions involved in the development of T1D. These advances could soon lead to new tests to identify people at risk of developing T1D, new prevention strategies, and new treatment regimens based on a person's unique makeup. The support for basic research in TID has also funded the development of continuous glucose monitors which enable patients to maintain healthy levels of glucose and so reduce their likelihood of developing costly and potentially deadly complications. In addition, the program has produced substantial progress in islet transplants for T1D as well as the use of an "artificial pancreas," innovations which could also prove to be very important for people with T2D. The NIH funding also has led to the first large-scale screening of people at risk of developing T1D, providing new opportunities for early interventions which, based on other NIH-supported research, could delay the onset of the disease.

Not continuing the SDP also will lead to cutbacks in diabetes R&D by private pharmaceutical firms. Studies have found that a one percent increase in NIH-funded research leads to a 2.5 percent increase in private R&D spending, with a seven-year lag, as scientists working with or for private pharmaceutical companies build on the advances produced by the NIH-supported research. A reduction in NIH support for the SDP, therefore, would be expected over time to lead to even larger cutbacks in private R&D in this area.

We have further shown that if additional advances in the next seven years can lead to a 10 percent reduction in the incidence or severity of T1D, the savings in medical costs would top $2.87 billion per-year – including $2.04 billion in annual savings for Medicare and Medicaid – plus an additional $1.94 billion in annual non-medical savings. And if spillovers from these advances lead to just a 5 percent reduction in the number of Americans with T2D, the annual savings in 2020 would be come to $17.6 billion per-year in medical costs, including $12.5 billion per-year in Medicare and Medicaid savings, plus more than $5.6 billion per-year in other non-medical economic costs. The economic case for increasing NIH support for basic research in T1D, or at a minimum maintaining current levels of support, is clear and conclusive.

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