

**TYPE 1 DIABETES RESEARCH: REAL PROGRESS
AND REAL HOPE FOR A CURE**

HEARING

BEFORE THE

COMMITTEE ON
HOMELAND SECURITY AND
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

OF THE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

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JUNE 24, 2009
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**TYPE 1 DIABETES RESEARCH: REAL
PROGRESS AND REAL HOPE FOR A CURE**

WEDNESDAY, JUNE 24, 2009

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 8:51 a.m., in room SD-342, Dirksen Senate Office Building, Hon. Susan M. Collins, presiding.

Present: Senators Lieberman, Akaka, Burris, and Collins.
Also Present: Senators Specter, Lautenberg, and Shaheen.

OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. Good morning. The hearing will come to order. I so appreciate this opportunity to hold this hearing to examine the devastating impact that juvenile diabetes has on children and their families. This is the fifth Juvenile Diabetes Research Foundation (JDRF) Children's Congress that I have had the honor to Chair, and I am particularly grateful to my good friend, the Chairman of the Committee, Senator Lieberman, for turning the gavel over to me this morning. He will be joining us shortly, as will other Members. But we are starting a bit early because at 10 a.m., unexpectedly, we are going to have an impeachment proceeding begin in the Senate. This was totally unanticipated, so it makes the schedule a bit harder this morning. So what we will do is we will go up until that time, then we will take a break, and then we will reconvene. So we are going to try to start early and get as much done as we can.

I want to begin by welcoming the delegates who are here today. It is wonderful to see all the boys and girls who have come from every State in the Union to be with us today, and we also have some students from foreign countries as well. We have 150 delegates who have traveled to Washington from every State in the country and from around the world. They are going to help those of us who serve in Congress better understand just what it is like to have diabetes, how serious it is, and how important it is that we all work together to try to find a cure. I also want to give a special welcome to the delegates from my home State of Maine: 11-year-old Hannah Ryder of Cumberland is here, she is sitting in the first row; and 8-year-old Cole Buchanan of Falmouth is here. And, Cole, why don't you put your hand up so we can see you. Very good. Thank you.

(1)

Also here today are the grandchildren of two Senators, Senator Lautenberg and Senator Shaheen, and the Senators are going to be joining us as special members of the Committee just for today.

As the founder and Co-Chair of the Senate Diabetes Caucus, I have learned so much about this disease during the past 12 years and the heartbreak and difficulties that it causes for so many families as they await a cure. Diabetes is a life-long condition that affects people of every age, race, and nationality.

Moreover, it is estimated that diabetes accounts for more than \$174 billion of our Nation's annual health care costs. Health spending for people with diabetes is almost double what it would be if they did not have the disease.

These statistics are overwhelming, and they compel us to act. But what really motivated me to devote so much energy and time to diabetes is meeting more and more families—like our delegates today—whose lives have been forever changed by diabetes. I will never forget, back in 1998 when I was a newly elected Senator, meeting with a family from Maine whose son had diabetes. At that time, I did not know anything about the disease, but this family taught me so much. And I will never forget this 10-year-old boy looking up at me and saying, “I wish I could just take one day off from having diabetes.” And I bet the children who are here today feel like that, too.

So that is why it is so important that you have traveled to Washington today to tell your stories. You put a human face on all of the statistics, and you help us focus better on what Congress must do to ultimately conquer this terrible disease.

Juvenile diabetes is the second most common chronic disease affecting children. Moreover, it is one that they never outgrow. An average child with diabetes will have to take more than 50,000 insulin shots in a lifetime. Moreover, these injections must be balanced with regular meals and daily exercise, and blood sugar levels must be closely monitored throughout their lives through frequent testing.

While the discovery of insulin was a landmark breakthrough in the treatment of diabetes, it is not a cure, and people with Type 1 diabetes face the constant challenge of working to avoid life-threatening complications.

Thankfully, there is good news for people with diabetes. Since I founded the Senate Diabetes Caucus, funding for diabetes research has more than tripled, and last year we spent more than \$1 billion on diabetes research. As a consequence, we are seeing some encouraging breakthroughs, and we are on the threshold of a number of important discoveries.

Advances in technology, like continuous glucose monitors, are helping patients better control their blood glucose levels. These advances are also moving us closer to our long-term goal of an artificial pancreas. And drugs originally designed for cancer therapy are showing tremendous potential for treating diabetic eye disease.

While we can be pleased at the progress we are making, this is no time to let up. We have two choices: We can either sit back and continue to pay the bills and endure the suffering, or we can aggressively pursue a national strategy aimed at curing this disease.

The good news is that there is strong support for more research funding in Congress, and that is thanks to all of you who are here today. It is that strong grass-roots effort that is led by JDRF that has helped to convince so many Members of Congress. That is why we were able to extend the Special Diabetes Program for 2 more years through September 2011. It is critical to our efforts to find better treatments, a means of prevention, and, ultimately, a cure.

I am hopeful that this morning's hearing will help us generate even more support, and you are so key to that effort.

Again, I want to thank our Chairman, who has been such a wonderful advocate, for allowing me to hold this hearing this morning. Chairman Lieberman, thank you, and forgive me for beginning early because of the schedule.

OPENING STATEMENT OF CHAIRMAN LIEBERMAN

Chairman LIEBERMAN. Thank you, Madam Chairman.

I just want to indicate for the press here that Senator Collins has not pulled off a coup. [Laughter.]

She is chairing this meeting at my request in recognition of her principled and really passionate leadership here in Congress, along with others like Senator Lautenberg, on behalf of the recognition of the impact of diabetes, particularly juvenile diabetes, and really extraordinary advocacy, effective advocacy for Federal support for the kind of research that is leading to dramatically improved treatment and I know with a certainty will lead us to a cure one day. So I am just very honored to be able to sit here today with Senator Collins.

This is actually a very exciting day in this Committee every year—exciting because of the feeling of progress we have every year; frankly, exciting just because, no matter how attractive the witnesses are, we never have as beautiful a group as we have to look at today.

I will also say that the witnesses on the first panel generate a lot of excitement. I do find that it is generationally affected. [Laughter.]

For instance, the younger members of my office, pages and interns, are quite excited that Nick Jonas is here.

I am thrilled to be in a room with Mary Tyler Moore and Sugar Ray Leonard.

I do not want to date myself, Sugar, but I would be excited to be in a room with Mr. Robinson. [Laughter.]

Anyway, your presence means a lot, and, Dr. Rodgers, obviously yours does as well.

Just to say very briefly, this is an extraordinary story about the blessings of life that each of us receive from God, and the fact that we are given these amazing bodies that are miraculous, but not perfect, and sometimes a lot of us have a problem with our bodies. This one goes back a long ways in history—diabetes. But what is amazing are two things.

One is the extraordinary technological research, unimaginable just a short time ago, that is allowing so much better treatment and will get us to a cure.

The second is the absolutely inspirational message that all of you and, frankly, all the people that all of us know who have diabetes—

there is hardly a person that I know in the Senate or just anywhere who does not have family members or friends who are dealing with diabetes. I bet that is true of all of us here on the panel, and the way in which you manage this problem every day is an inspiration to all of us. Because somebody once said to me a long time ago, in life there is no one who does not either get pushed down or stumble sometimes. It is just the nature of life. The question is: Do you get up? And how do you get up? And the reality is, as I look at the panel and the beautiful, exuberant, slightly restless faces in front of me, that is what this is all about. So you are all winners, and together, under the leadership of Senator Collins, we will be winners in this fight against diabetes.

Thank you, Madam Chairman. I look forward to hearing these witnesses and, of course, the second panel of witnesses, including a celebrity of our own from Connecticut. Thank you.

Senator COLLINS. Thank you, Mr. Chairman. I would now like to recognize Senator Lautenberg. Senator Lautenberg, thank you for joining us this morning.

OPENING STATEMENT OF HON. FRANK R. LAUTENBERG, A U.S. SENATOR FROM THE STATE OF NEW JERSEY

Senator LAUTENBERG. Thank you, Senator Collins, for inviting me to the Committee today. It is a deeply personal issue for me, and I appreciate the chance to work with you and Senator Lieberman, and I thank you not only for the invitation but for the work you have chosen to do here. It touches so many of us. As Senator Lieberman said, there is not anybody that I know who does not know someone who suffers from diabetes. And I am delighted to be here, honored to be here with these young people and with our friends at the witness table. It takes a lot to turn a struggle into strength, but all of you have done that, and we all benefit from your strength, like our witnesses.

The issue is very personal to me. I am deeply committed to keeping our children in this country of ours healthy, and I love and care deeply for my diabetic grandchild. Her name is Maddie Birer. Maddie, raise your hand, please. And she came down with the disease unexpectedly, as it probably always happens, but she is like many others. She has turned to treatment. She has proven something. She is doing well. She is energetic. She plays soccer. She even scores goals—doing everything an 11-year-old girl dreams of doing.

We are inspired by those of you who are at the witness table, and Mary Tyler Moore and Nick Jonas visited with me in the office today, and I never knew I was that popular. [Laughter.]

But the crowd was at my door, and when I tried to sing, Nick suggested I stick with my day job and not bother.

Mr. Leonard and Dr. Rodgers, thank you all because one of the things that you are doing by your presence here is establishing the fact that life continues, that life can be terrific, and that all of these beautiful children who are here get an inspiration from you, as all of us do. And we have to get to work, my friends on this Committee, Senator Collins and the other Members of the Committee, and make sure that we teach America how to save money and how to save heart because if we do the things that are nec-

essary, do the research that is necessary, we can change all of this, and we will not be sitting around mentioning the statistics of \$174 billion a year just to care for diabetics. If we want to do something smart, we have to put the effort in. And I am grateful to you and to all of you, especially to you guys, for being as inspirational as you are this day. Thank you very much.

[Applause.]

Senator COLLINS. Senator Burris.

OPENING STATEMENT OF SENATOR BURRIS

Senator BURRIS. Thank you very much, Madam Ranking Member, and Chairman Lieberman, Members of the Committee. It is certainly an opportunity for me to be able to address this issue with this importance and being impressed by this distinguished panel, Madam Chairman. I must apologize because I am due at another hearing in about 10 minutes, so my leaving will not be any reflection on my support for this major issue.

It is a pleasure to be here to witness the relationship that exists between Congress and the Juvenile Diabetes Research Foundation. It is an effort like this and the continued work of the National Institute of Diabetes and Digestive and Kidney Diseases that give diabetes research and education such a bright future.

I understand that 24 million families are affected by diabetes. I use the term "families" because diabetes does not only affect individuals; it also affects their support groups and all the families that are associated with them.

I am especially concerned about the impact of diabetes on the minority population. Twenty-five percent of African Americans in this country have been or will be diagnosed with diabetes. We need to continue to educate and reach out to minorities that have not had access to the benefits of the research being conducted today.

I want to thank all of the witnesses who appeared here today as well as the delegates from the Children's Congress, this tremendous group of our future right in front of us, who came here today to raise awareness about this issue.

And, Dr. Rodgers, I just hope that there is some way we can reach those African American males who fail to really own up to the fact that they have diabetes and that we can certainly save ourselves tremendous dollars in health care costs by early intervention, early treatment, and early diagnosis.

So I certainly will be doing everything I can, and I want to extend my heartfelt thanks to our witnesses on panels 1 and 2.

Thank you very much, Madam Chairman.

Senator COLLINS. Thank you. Senator Shaheen, we are delighted to welcome you today, too.

OPENING STATEMENT OF HON. JEANNE SHAHEEN, A U.S. SENATOR FROM NEW HAMPSHIRE

Senator SHAHEEN. Thank you very much, Senator Collins. Thank you for your leadership in addressing diabetes, and I thank you and Senator Lieberman for holding this hearing today.

I am very honored to be here to have an opportunity to say a few words at this hearing. I had the opportunity Monday night to be at the JDRF dinner and hear from all of you young people who are

here and know what compelling witnesses you are to what we have to do to find a cure for diabetes.

Like most of us involved in health policy, I have long supported the importance of research to find cures for diabetes and other diseases, but this issue really became personal for me when my granddaughter Ellie was diagnosed about a year and a half ago. Ellie, where are you?

And so I have seen the challenges that Ellie and her family face. I know what it is like to test multiple times a day, to deal with daily injections, to figure out whether you are eating too many carbohydrates and whether the exercise that you are doing and the other challenges of daily life are affecting what kind of injections you need to do, and I know, like all of you, that a cure is within our reach. And we just have to support research. We have to make sure that help is there to find this cure.

I want to thank also the panelists who are here for your willingness to talk about what it is like to live with diabetes on a daily basis and what a difference that has made for everyone who has juvenile diabetes.

I remember when Ellie was diagnosed and thinking about what her future was going to be, and when she found out Nick Jonas had diabetes, she realized that everything would be OK, that she could deal with this.

So thank you all very much for your participation here and for all of the Children's Congress who are here. Thanks for the work that you are doing because together we are going to find a cure for this disease.

[Applause.]

Senator COLLINS. Thank you. Senator Akaka, I am pleased to call on you for your remarks.

OPENING STATEMENT OF SENATOR AKAKA

Senator AKAKA. Thank you very much, Ranking Member Collins and Chairman Lieberman. Thank you for conducting this hearing today, and thank you for your leadership on this important issue.

Diabetes is a very serious health problem in my home State of Hawaii. Diabetes is a disease that disproportionately affects Native Hawaiians, Pacific Islanders, and Asian Americans. In Hawaii, Native Hawaiian, Japanese, and Filipino adults are twice as likely to be diagnosed with diabetes as compared to Caucasian residents.

Diabetes can be extremely difficult for patients to manage. Taking insulin injections and carefully monitoring blood sugar levels are not easy tasks. Even with careful management, diabetes contributes significantly to other health problems, such as heart disease, stroke, eye disease and blindness, and kidney disease. However, there are promising research efforts underway which we will learn more about today. We must continue to increase the funding for diabetes research to develop improved methods to treat, manage, and prevent diabetes.

I also want to thank Ms. Moore and the Juvenile Diabetes Research Foundation for all of their efforts to improve the lives of so many people. In addition, I thank all of the witnesses for appearing today, including Dr. Rodgers, Mr. Leonard, Mr. Jonas, and our JDRF advocates who are seated here. I am particularly pleased to

see one of my constituents, Devin Rettke. Will you raise your hand? Hi, Devin. All the way from Hawaii.

I look forward to hearing from the witnesses who will share their experiences in managing their diabetes. Again, Chairman Lieberman, Ranking Member Collins, thank you for holding this hearing. I look forward to continuing to work with all of you to improve the lives of individuals suffering from diabetes.

Thank you very much.

Senator COLLINS. Thank you very much.

Leading off our first panel this morning is Mary Tyler Moore. Although many of us know her from her extensive work on television and in film and in the theater, her strong advocacy on behalf of people with diabetes is why she is here today. And it has been such a pleasure to work with Mary Tyler Moore over the years. She is always our lead-off witness every time we convene the Children's Congress. She serves as the International Chairman of the Juvenile Diabetes Research Foundation, so it is a great honor to have her with us today.

Next we will hear from Dr. Griffin Rodgers, who is the Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH). Dr. Rodgers will highlight the advances and opportunities in the area of juvenile diabetes research and will provide us with some examples of the research that is supported by the Special Diabetes Program.

Our next witness, Sugar Ray Leonard, is one of the legendary sports icons. A winner of the gold medal in boxing in the 1976 Olympics, Mr. Leonard's illustrious career also includes three National Golden Glove titles, two Amateur Athletic Union championships, and the 1975 Pan-American Games crown. A champion in the ring, Mr. Leonard is also a champion for people with diabetes, and he has served as the International Chairman of the Juvenile Diabetes Foundation Walk for a Cure.

And last, but certainly not least, what has set young hearts aflutter in the Congress today, we will hear from Nick Jonas of the phenomenally successful Jonas Brothers. Nick was diagnosed with Type 1 diabetes in 2005, but that certainly has not slowed him down at all. In the last 2 months, Nick and his brothers have launched a new TV show, released their third album, and begun a world concert tour.

So we are delighted that all of these distinguished witnesses could be with us today, and, Ms. Moore, we are going to start with you. Thank you.

**TESTIMONY OF MARY TYLER MOORE,¹ INTERNATIONAL
CHAIRMAN, JUVENILE DIABETES RESEARCH FOUNDATION**

Ms. MOORE. Good morning to all of you, Senator Collins, Senator Lieberman, and Members of this Committee. I want to thank you for your leadership and commitment to sustaining robust Federal funding for diabetes research. Your efforts are resulting in real progress and real hope for millions of Americans personally affected by Type 1 diabetes.

¹The prepared statement of Ms. Moore appears in the Appendix on page 30.

I am honored to be accompanied today by all of these terrific young delegates and special guests who surround us in this chamber and join me on the panel. We sincerely thank you for providing us the opportunity to testify about the issues that we know all too well—life with Type 1 diabetes and our hope for a cure.

Ten years ago, Tommy Solo—an 8-year-old JDRF volunteer from Boston—had a big idea. He was looking for something he could do to move us closer to a cure, and he thought, “Why not have kids with diabetes, like me, go to Washington, DC, and tell Congress we need their help?”

Even at age 8, Tommy understood, intuitively, what JDRF’s Moms and Dads and people personally affected by Type 1 had always known: When confronted by challenges to our personal well-being, the solution starts with our willingness to share our stories, make our case, and ask others to join us as partners in our cause.

Senators, we are grateful to you for welcoming our Children’s Congress delegates to these rooms over the years since, for listening to us, and for remembering us and our partnership for a cure with your legislative leadership and support.

But because our work together will not be done until we have found a cure, here we are again today. More than 150 child delegates from across the United States and several countries join me to participate in the 10th anniversary Children’s Congress. We acknowledge the remarkable progress we have made, and we reflect on the challenges which remain.

As many of you know, I have endured the ups and downs of Type 1 diabetes for almost 40 years. And as all of these children and their families can attest, every day tests our determination to lead a normal life. Each day I check my blood sugar several times. I count the carbohydrates of what I am going to eat, I take multiple insulin injections, and I exercise.

Even with this structured regimen, terrific doctors, and the loving support of my husband, Robert, my blood sugars can still fluctuate tremendously. If I do not take enough insulin, my sugars can go dangerously high—which, over time, can lead to long-term complications such as blindness, nerve damage, kidney failure, and a host of other serious ailments. If I take too much insulin, my sugars can drop frighteningly low, which can acutely lead to feeling really sick and cold and anxious and lost and, in turn, lead to unconsciousness, seizures, or worse.

I actually had my first hint of impending long-term complications of diabetes in 1981 after only about 11 years of having this disease. I truly wish the technology that is available today and the understanding that we now have about how to manage diabetes was available when I was first diagnosed. Back then, to get an idea of what your blood sugar was, we relied on urine tests. They were not all that accurate, timely, or helpful. I did the best that I could to control my blood sugars, but it was a really difficult task. And my doctors, even if they wanted to, could not really push me to do what was, as a practical matter, not really doable. As a result, by 1981, I was well on my way to having vision-threatening diabetic retinopathy.

I was not alone. Diabetic retinopathy is the leading cause of adult onset blindness.

I was terrified. How was I going to continue the things I loved most—dancing, horseback riding—if I went blind?

At the time I was diagnosed with Type 1, there was no simple treatment to prevent diabetic retinopathy. But when my retinas started to show evidence of damage due to diabetes, there was, thankfully, a new procedure that was available called “laser photocoagulation.”

It was not without its costs, however, because in order to halt the progression of diabetic retinopathy and save the “central vision,” the laser must literally burn holes in the peripheral retina.

So the combination of the disease itself and its vision-preserving treatment has resulted in my having a difficult time seeing when it is dark or when I am in a room that is not well lit. My peripheral vision, and vision below my waist, is also very limited. Simple things like navigating curbs on a street or changes in levels between rooms in an unfamiliar home, or seeing one of my precious pups taking a nap in an unexpected, unusual place, or recognizing a welcoming hand that has been extended patiently waiting for me to shake it are all challenges of the first order.

For years, I kept the full impact of my diabetes under wraps. While people knew I had Type 1 and that I was a long-time, outspoken advocate for a cure and International Chairman of JDRF, the general public did not know the extent to which diabetes affected my day-to-day life.

But recently, at the prompting of a lovely young woman named Diane Revzin, and her father, Phil, I wrote a book about living with diabetes. Diane is a 19-year-old fellow diabetic; Phil is a book publisher.

My book is titled “Growing Up Again: Life, Loves, and Oh Yeah, Diabetes.” It chronicles my battles with Type 1 in the context of my broader life experience and career, and I hope it informs and even inspires people facing similar challenges. Though I am not here to promote my book, I am happy to note that all my proceeds from its sale will be donated to JDRF to advance research for a cure.

As JDRF’s International Chairman, I am actually just one volunteer in an army of determined moms, dads, children, loved ones, and friends personally affected by diabetes. We are not sitting back waiting for the cure. These children before you have built lemonade stands, created walk teams, held bake sales, and organized car washes. Most importantly, they have spoken out about their lives with diabetes and shown, by their courage and hard work, that they can accomplish anything—including being an important part of finding their own cures. Overall, JDRF’s efforts have enabled us to contribute over \$1.3 billion to diabetes research since our founding in 1970 and over \$150 million last year alone. But curing diabetes is an enormous task. We cannot do it alone. And that is why we are here.

We are so grateful that this Committee and Congress as a whole have been our true partners in the fight to cure Type 1 diabetes and its complications. The Special Diabetes Program, which has been renewed by Congress four times since it was first enacted in 1997, currently provides \$150 million a year for Type 1 diabetes research. This critical funding has led to some remarkable ad-

vances—including real progress in developing new therapies that are potentially life-changing for all of us sitting before you today.

Dr. Griffin Rodgers, the Director of the NIDDK, will elaborate more on the scientific progress that we have seen, thanks to the Special Diabetes Program funding. But there are a few areas of research that I would like to touch on today myself.

Researchers are using the Special Diabetes Program funds to find a way to prevent and reverse diabetic retinopathy. This is very exciting work, and it gives me great hope, especially for children and young adults with Type 1. As a result of these advances, people with diabetes may be able to live with far less fear of visual loss and have an alternative to laser surgery.

Major advances are also being made in the development of new devices called continuous glucose monitors (CGMs). By measuring blood sugars automatically every few minutes and graphically showing the results and the up and down trends, CGMs help people to better understand their diabetes and to avoid extreme highs and lows.

Teams of researchers are now working hard to connect CGMs with insulin pumps via a control algorithm—I need to brush up on my science—thereby creating a truly automated system, an artificial pancreas. This will closely mimic the blood sugar control workings of a human pancreas. This intelligent pump will administer insulin based on a person's blood sugar level and whether it is rising or falling. Human clinical trials are already underway, and the early results are very encouraging.

In short, with your help, we are making real progress toward discovery, development, and delivery of cures and significantly improving on our health outcomes. To keep this progress, however, Congress must renew the Special Diabetes Program in 2010. Without your help, we face a 35-percent cut in Federal funding for Type 1 diabetes—a cut that could turn hope into despair. With your help, new life-changing therapies and cures will finally be within our reach.

Every parent of these delegates here today, every parent of every child ever diagnosed with Type 1 diabetes makes a promise to them. We will do everything we can to find a cure for you. We promise.

As their Chairman and “oldest delegate,” I am proud to be leading our 2009 Children's Congress Delegates in their efforts this week. As we have started to do in this special hearing, today our goal is to persuade our Senators and Representatives to also make a promise. We hope you will “promise to remember us” when you vote on the Special Diabetes Program and other important issues that affect all of us with diabetes.

The energy and commitment of families affected by Type 1 and the strong support of champions like you on Capitol Hill make me certain that we will soon be able to turn the promising research made possible by JDRF and the Special Diabetes Program into our “promises kept for a cure.”

Thank you from the bottom of my heart for all that you do for these children, for me, and for all others who are touched by Type 1 diabetes. I look forward to continuing to work with you as we pursue our mutual goal of a cure. And I will be with you, I promise.

Thank you.
[Applause.]

Senator COLLINS. Thank you so much, Ms. Moore, for an excellent statement. Dr. Rodgers, welcome.

TESTIMONY OF GRIFFIN P. RODGERS, M.D.,¹ DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. RODGERS. Thank you. Mr. Chairman, Senator Collins, and Members of the Committee, as Director of the National Institute of Diabetes and Digestive and Kidney Diseases, I want to thank you for your invitation to testify at this hearing on Type 1 diabetes. And on behalf of NIDDK and the other Institutes and Centers at the National Institutes of Health, I am pleased to report that we are vigorously pursuing research into Type 1 diabetes and its complications—along with the Juvenile Diabetes Research Foundation and other research partners with whom we share these important goals.

As Ms. Moore mentioned, support provided by the Special Statutory Funding Program for Type 1 Diabetes Research has led to exciting progress, even since I had the privilege of testifying before you in 2007. But before I tell you about some of that progress, I would like to take a moment to recognize the extraordinary efforts and contributions of others who are testifying here today.

Ms. Moore has been a tireless leader in the fight against Type 1 diabetes and is a great inspiration to patients, to advocates, and to researchers around the world. Following his boxing career, Mr. Leonard turned his attention to another fight—the fight against diabetes—and has been the JDRF’s International Chair of the Walk for the Cure. And Mr. Jonas has become a national advocate for young people with diabetes. In fact, Nick recently worked with our National Diabetes Education Program to create a new public service announcement campaign, and he has also teamed up with our Type 1 diabetes TrialNet investigators to develop a public service announcement on the importance of participating in research studies.

I also want to acknowledge the children and their parents who will testify today and who are attending this hearing and, indeed, the millions of other children and parents across the country. They are our true heroes in advancing the cause of diabetes research, and many are taking part in government-sponsored trials that would not be possible without their desire and commitment to help prevent and find a cure for diabetes.

Mr. Chairman, Senator Collins, the need to pursue the prevention and cure of diabetes through research is greater than ever. New data clearly indicate that the incidence of Type 1 diabetes is rising in some populations, and this is supported by evidence from the Search for Diabetes in Youth study, which is providing the first comprehensive incidence and prevalence data for diabetes among American children.

¹The prepared statement of Dr. Rodgers appears in the Appendix on page 34.

And so we are thinking big, working toward a hope for a cure for those who have Type 1 diabetes and an effective approach to prevent diabetes in those at risk. It is through research that we will work toward these goals and have already made great progress.

This past year, astonishing advances were reported in the genetics of Type 1 diabetes. Today at least 40 genes are known to influence the likelihood of developing Type 1 diabetes. That is four times the number that were available 2 years ago when I testified before this Committee.

Why is this important? Well, because identifying genes may lead to potential new avenues for therapeutic and preventive advances and treatments, and even on a personalized and more customized basis, it may allow us to direct therapy. Moreover, because we have identified genetic variants that account for more than half of the genetic risk, we can identify individuals at high risk of developing Type 1 diabetes and, thus, give them the opportunity to enroll in clinical trials aimed at preventing the disease.

We have also laid the groundwork to discover the environmental factors that have led some but not all people with a genetic predisposition to Type 1 diabetes to develop the disease. The Environmental Determinants of Diabetes in the Young (TEDDY) has screened over 350,000 newborns for the presence of the most important genetic risk factor for Type 1 diabetes and has identified 17,000 with this risk factor and has enrolled now 6,670 children in this study. These children will be followed until they are 15 years of age so that we can discover the environmental contributors to Type 1 diabetes.

This achievement represents tremendous progress toward amassing the most data and samples on newborns at risk for autoimmunity and Type 1 diabetes in the world.

Discovery of an infectious trigger could lead to a vaccine to prevent Type 1 diabetes, or the development of dietary factors could yield a simple dietary intervention to lower the risk in those at risk for the disease.

In another clinical effort, our TrialNet researchers have just reported that therapy used in the treatment of non-Hodgkin's lymphoma and rheumatoid arthritis can substantially preserve the function of insulin-producing beta cells in people recently diagnosed with Type 1 diabetes. Patients taking the medication rituximab had better blood sugar control and required less insulin than those who took a placebo. We are now considering how to build on this success and to test whether rituximab and other treatments with agents called anti-CD3 can actually prevent Type 1 diabetes.

Other researchers are working toward intervention to treat and ultimately cure diabetes, such as new sources of insulin-producing cells. These include induced pluripotent stem cells which could be derived from a patient's skin, triggered to develop into insulin-producing cells or pancreatic cells that do not normally produce insulin but could be programmed to do so.

This research is at a more preliminary stage in its investigation, but it is already yielding very promising results. Approaches such as these could ultimately lead to a day when people with Type 1 diabetes have easier and better diabetes control and perhaps are

entirely free of injected insulin, where their bodies once again can produce the insulin that they need to regulate blood glucose, to avoid both the acute episodes of low blood sugar, or hypoglycemia, and the long-term complications associated with high blood sugar.

At the same time, we are working to help those with Type 1 diabetes take the fullest advantage of existing technologies to control their diabetes. For example, recent data from a JDRF-funded study showed that CGMs were a valuable tool in patients 25 or older to achieve an impressive lowering of their blood hemoglobin A1c levels. And new NIH initiatives will study the way that people use data from these monitors, ultimately to help them use the devices more effectively.

I would like to close by mentioning the success story of a person who has reached, I think, the pinnacle of a remarkable career after 46 years with Type 1 diabetes. Supreme Court nominee Sonia Sotomayor offers a striking portrait of success that stems not only from her achievements in the legal arena, but also from her remarkable vigilance with regard to her health and the high quality of care made possible by Type 1 diabetes research. Her story reminds us that a diagnosis of Type 1 diabetes in no way defines or limits the remarkable potential of children in this room. And it is not a story that could have been possible decades ago. People with Type 1 diabetes are living longer, healthier lives today than ever before. Current research offers hope for continuing improvements in care and perhaps even suggest that we may one day be able to prevent or cure this disease.

I am grateful for the opportunity to share with you these few examples of recent advances and ongoing research efforts, many of which are made possible by the Special Diabetes Program. We continue to be inspired by the dedicated efforts of individuals affected by Type 1 diabetes and by organizations that represent them, such as the JDRF.

We look forward to continuing to partner with the JDRF in research to combat Type 1 diabetes and its complications, and we continue to press forward in the fight against diabetes so that we can help all the children in this room and the many other Americans whom they represent here today. Improving their quality of life with the ultimate goal of curing their disease is the driving force behind all of our efforts.

Thank you, Mr. Chairman and Senator Collins, for your leadership in calling for this hearing to continue focusing attention on the importance of Type 1 diabetes research and, of course, for your continued support for NIH research. And I will be pleased to answer any questions that you might have. Thank you.

[Applause.]

Senator COLLINS. Thank you, Dr. Rodgers. That is a very encouraging report. Mr. Leonard, thank you for being here today. Please proceed.

**TESTIMONY OF SUGAR RAY LEONARD,¹ RETIRED
PROFESSIONAL BOXER**

Mr. LEONARD. Good morning Senator Collins, Senator Lieberman, and Members of the Committee. I truly appreciate this opportunity to appear before you today, and I would like to testify about the burden of diabetes and the need for continued research funding to cure this devastating disease.

Once again, I would like to personally thank Senator Collins for her unwavering dedication to people with diabetes. And as a diabetes advocate, I know how grateful we are to have you as one of our champions.

It is so wonderful to be here in Washington, DC, as part of the Juvenile Diabetes Research Foundation's Children's Congress. I grew up not too far from here, in Palmer Park, Maryland. My teenage years were spent in the boxing ring.

During this time of personal accomplishments in the ring, privately my family faced challenges as my father struggled to manage his diabetes. We are not alone in this fight. Nationwide, more than 24 million people have diabetes, a chronic disease that imposes a huge emotional and financial burden on patients and their families.

I know the toll that diabetes can take on a family. As I closed the book on my amateur boxing career, I planned to begin a new chapter in my life as a college student at the University of Maryland, but I had to face the reality of my father's illness and the incredible medical bills that resulted from his life with diabetes. My decision to turn professional was based on the desire to help my family cover the costs of my father's care.

Due to the long list of complications associated with diabetes, the cost of this disease is overwhelming for any family. But it is also overwhelming for the Nation and our health care system. Diabetes costs are currently estimated at \$174 billion each year—\$116 billion in direct medical costs and \$58 billion in lost productivity and disability. In California, where I now live, the direct and indirect costs of diabetes totaled more than \$24 billion in 2007.

Thankfully, the Juvenile Diabetes Research Foundation has partnered with the Federal Government to make a meaningful investment in diabetes research. I was proud to serve as an International Walk Chairman for JDRF, which has provided more than \$1.3 billion in funding for Type 1 diabetes research over the years. And as Ms. Moore stated, last year alone, JDRF funded more than \$150 million in diabetes research.

With the leadership of Senator Collins and our many other diabetes champions on Capitol Hill, the Federal Government has been a key partner along our path toward a cure for diabetes. We are so thankful to Congress for renewing the Special Diabetes Program. That program provides \$150 million each year for diabetes research at the National Institutes of Health and an equal amount for the treatment and prevention of diabetes in American Indian and Alaska Native populations.

Since its inception in 1997, the Special Diabetes Program has funded research that has shed light on the causes of Type 1 diabe-

¹The prepared statement of Mr. Leonard appears in the Appendix on page 51.

tes, as well as who is at risk for developing the disease. The research funded by the Special Diabetes Program is unique because its discoveries are important not only to people with Type 1 diabetes but also to people who suffer from similar autoimmune diseases. The therapeutic advances in diabetes complications made possible through the Special Diabetes Program also apply to people with Type 2 diabetes, making this program a critical component of any effort to fight diabetes. Help us keep up the momentum behind this research by ensuring the renewal of the Special Diabetes Program.

Life with diabetes is like life in the boxing ring. Some days you just do not have your "A" game and your opponent can get the best of you. Other days you are managing the fight well and able to outsmart and outbox your opponent. One of my most memorable fights was my re-match against Roberto Duran. I lost my welterweight crown to Duran just a few months earlier, and I could not wait to get my title back. In the re-match, I fought a smart and skillful match. With just seconds left in the eighth round, Roberto Duran turned his back, walked to his corner, threw his hands up, and said, "No mas." He quit.

Now, it would be easy for these children here today to say "No mas." The fight against diabetes is a tough one. Some days nothing seems more difficult, more impossible, to battle. There are days we all think about saying "No mas." But it is totally clear that these children have fight in them. They are willing to go as many rounds as it takes to beat this formidable opponent. And we have you in our corner. Thanks to congressional support for the Special Diabetes Program, the advancements made through research are bringing us closer to the cure that will allow these children to finally knock out diabetes.

Once again thank you, and God bless.

[Applause.]

Senator COLLINS. Thank you, Mr. Leonard. Thank you so much for an inspiring statement.

Mr. Jonas, it is great to have you here.

**TESTIMONY OF NICHOLAS J. JONAS,¹ SINGER, SONGWRITER,
AND ACTOR, JONAS BROTHERS**

Mr. JONAS. Good morning. My name is Nick Jonas, and I would like to thank you for having me here today. I would like to share my story of living with Type 1 diabetes and talk about the need to fund research to find a cure.

First, I would like to thank you, Senator Collins, Senator Lieberman, and other Members of the Committee, but specifically Senator Collins for being such a champion for all of us with diabetes. Everyone here today for the Juvenile Diabetes Research Foundation's Children's Congress is grateful for your leadership on the Senate Diabetes Caucus and your commitment to people with Type 1 diabetes. We are lucky to have you pushing for policies that will bring us closer to a cure.

Senator COLLINS. Thank you.

¹The prepared statement of Mr. Jonas appears in the Appendix on page 53.

Mr. JONAS. In one way or another, I have spent most of my life performing. I have been writing songs since I can remember, and I love sharing my passion for music. As a little kid, I sang in the choir at my dad's church and then performed on Broadway. As the Jonas Brothers, my brothers Joe, Kevin, and I have written songs, made albums, and toured the country, playing our music for people all over America.

It was during a concert tour in 2005 that I was diagnosed with Type 1 diabetes. My brothers were the first to notice that I had lost a significant amount of weight—15 pounds in 2 weeks. I was thirsty all the time, and I had a bad attitude, which is unlike me. [Laughter.]

It would have been easy to blame my symptoms on a hectic schedule. But my family knew I had to get to a doctor.

The normal range for blood sugar is anywhere between 70 and 120. When we got to the doctor's office, we learned that my blood sugar was over 700. The doctor said that I had Type 1 diabetes, but I had no idea what that meant. The first thing I did was ask her, "Am I going to die?" She assured me that I was not going to die, but that I would have to manage this disease for the rest of my life. We went right to the hospital that night where I spent 3 days, including a crash course on getting my blood sugar in range and learning all about diabetes.

It has not been easy, but diabetes technology has really helped me to manage my diabetes. At first, I took insulin shots, but it was just too hard on the road to give myself shots. I switched to a pump, which has been great. Since then, my A1c has come down, and I have been able to use the pump to better estimate how much insulin I need based on the carbohydrates I eat. I am also considering getting a continuous glucose monitor, but for now, I still prick my finger. I do that up to 12 times a day, including right before I began this testimony.

While technology has made it much easier to manage my diabetes, technology is not a cure. Insulin is not a cure. Like everyone here today, I know that the promise of a cure lies only in research. I am grateful that Congress renewed the Special Diabetes Program last year, which has helped researchers make important discoveries into what causes Type 1 diabetes. This vital program has also funded research to test new drugs and therapies that could treat or cure patients with Type 1 diabetes and may even lead to an artificial pancreas one day. I ask that each of you join me in supporting the renewal of the Special Diabetes Program next year so that the researchers can continue their work on a cure for diabetes. My life depends on it. All of our lives depend on it.

After I was diagnosed with Type 1 diabetes, I wrote a song called "A Little Bit Longer" about dealing with diabetes. I would like to submit a copy of the full song for the record,¹ but I would like to read one of the verses, which explains my outlook on living with diabetes:

"All this time goes by / Still no reason why / A little bit longer / And I'll be fine. / Waitin' on a cure / But none of them are sure. / A little bit longer / And I'll be fine."

¹The song submitted by Mr. Jonas for the record appears in the Appendix on page 55.

Diabetes has changed my life. But I know that I have benefited from the government's investment in diabetes research. With the help of Congress, I will only have to wait a little bit longer for a cure.

In the meantime, I have decided not to let diabetes slow me down. In just the last 2 months, my brothers and I launched a new TV series, released our fourth album, and began a world concert tour. My approach to managing my diabetes is to focus on simple wins—little things I can do each day to achieve my goals. Over time, these everyday victories can make a big difference in your life—just like every research advancement moves us along on our path to find a cure. While on that path, I want to be a positive face for diabetes. I want to show kids with Type 1 diabetes—like all the kids sitting with me today—that they can live their dreams while living with diabetes.

Thank you for the opportunity to appear before you today, and thank you for your commitment to diabetes research. With your help, a little bit longer and we will all be fine.

[Applause.]

Senator COLLINS. Thank you for that. Thank you so much, Nick. Your song really sums it up so well and is great and inspiring advice for all the young people who are here.

I want to acknowledge that we have been joined by Senator Arlen Specter from Pennsylvania. He has been a leading advocate of NIH funding, and we are delighted that he has joined us this morning. Senator Specter, thank you for being here. If you would like one minute, we will give you a moment.

**OPENING STATEMENT OF HON. ARLEN SPECTER, A U.S.
SENATOR FROM THE STATE OF PENNSYLVANIA**

Senator SPECTER. I do not think I will need all of the minute. Thank you, Mr. Chairman and Ranking Member, for convening this important hearing. This is quite a demonstration, and juvenile diabetes is an ailment that ought to be conquered, and can be. And I wanted to come, even though I am not on this Committee, just to say a word to urge you as advocates, urge you as lobbyists to get behind additional funding for the National Institutes of Health.

Ms. Moore joined this crusade about 20 years ago. I have some pictures of her hanging in my office. And with the concurrence of Senator Harkin, we have increased NIH funding from \$12 to \$30 billion and added \$10 billion in the stimulus package. I would like to see the floor set at \$40 billion, so I came to urge you to utilize your efforts to help raise that money, which is the best way to cure juvenile diabetes. Thank you very much.

Senator COLLINS. Thank you.

Senator Lieberman, do you want to start with questions? We are going to do very limited questions because we shortly are going to have to go to the floor.

Chairman LIEBERMAN. Thanks, Senator Collins. I just want to say a word about Senator Specter. Politics gets a bad name often for good reason, particularly the kind of legislative horse trading that goes on here. But earlier this year, when the so-called stimulus package was up to try to help our economy recover, create jobs, improve the quality of life, the truth is that the Democratic

Majority Leader was about three votes short of the 60 votes needed to pass that program. It was very important to our country. Senator Specter was one of those potential votes, and Senator Collins was right there with him. And Senator Specter, supported by Senator Collins, did not ask for some sort of parochial project. He said, "I am not going to vote for this unless you increase funding for NIH up to \$10 billion." And he was so stubborn. He is really an ornery guy. [Laughter.]

And supported again by Senator Collins, in the end, to get their votes, the leadership along with President Obama had to raise, I think, from \$3 or \$4 billion up to \$10 billion the amount of money given to NIH. Think of all the good that will do in supporting research that will lead to better treatments and cures for diseases like diabetes.

So I want you to join me in a round of applause for Senator Specter.

[Applause.]

Senator SPECTER. Thank you.

Chairman LIEBERMAN. Senator Collins, these three witnesses have been so eloquent. Mary Tyler Moore, Sugar Ray Leonard, and Nick Jonas, your stories make you not just role models for people with Type 1 diabetes but really inspirations for anybody who listened. I do not have a question to ask. I want your words to stand. I am going to yield to you, Madam Chairman.

Senator COLLINS. Thank you, Senator Lieberman. I, too, found the statements so eloquent that there is little to ask. But let me, nevertheless, just ask a couple of questions.

Mr. Leonard, you brought up a very good point about the impact of diabetes on the whole family. Could you talk in a little more detail about your family's struggle in coping with your father's illness?

Mr. LEONARD. When I returned home from the Olympics in 1976, I was ready to attend the University of Maryland. But we noticed that there was a change in my father's attitude, his personality, and once he was diagnosed as being diabetic, the medical bills were astronomical. And for some reason, a friend of mine told me, he said, "Ray, if you turn professional, you can make some money."

So I turned professional. I became a professional boxer—because I had no intentions whatsoever. I became a professional boxer to pay the medical bills. And thank God my father regained his health, and I said to myself, this is not a bad career. So I continued. [Laughter.]

I continued on and had an illustrious career.

Senator COLLINS. Thank you. Dr. Rodgers, I am going to submit a question to you for the record. It is fascinating learning about the 40 genes that have been identified. I am also very interested in environmental triggers and whether the NIH has been able to isolate any environmental triggers. But I am going to ask that for the record because I know that is a long subject.

Let me just thank this panel for your outstanding testimony and commitment. It really could not have been better. You helped put a human face on the issues that we are discussing. The updates on the medical research are inspiring to all of us and very encouraging, and, of course, Ms. Moore, your being a champion for juve-

nile diabetes for so many decades means so much. Mr. Jonas, your sharing your personal experience I know is so encouraging to these young people.

So thank you all for being here. We are going to recess for a half-hour. We will try to reconvene with the second panel at 10:30, or as soon as we can get back. Thank you so much.

[Applause.]

[Recess.]

Senator COLLINS. The hearing will come back to order. You are an obedient group. We got it instantly quiet. That is very impressive. I am delighted to welcome our next panel of witnesses this morning. It consists of children and family members who know firsthand what it is like to live with diabetes.

Our witnesses on this panel are Hannah Ryder of Cumberland, Maine; Patrick Lacher of South Glastonbury, Connecticut; Asa Kelly of Charlotte, North Carolina; and Ellen Gould of Nashville, Tennessee, who will be testifying on behalf of her children—Patrick, Samuel, Sarah, and Oliver.

So I am delighted to welcome all of you here today. Your panel is so important to all of us. And, Hannah, because you and I are both from the great State of Maine, I am going to call on you first. [Laughter.]

Thank you, Hannah, go ahead.

**TESTIMONY OF HANNAH RYDER,¹ DELEGATE, JDRF
CHILDREN'S CONGRESS, CUMBERLAND, MAINE**

Ms. RYDER. Thank you for inviting me to testify. I am Hannah Ryder, and I am from Cumberland, Maine. Three years ago my life changed forever when I was diagnosed with Type 1 diabetes.

After being in the hospital for 4 days, I hoped that I was cured when I got home. But I soon figured out that this was not going away when my parents kept checking my blood sugar, giving me shots, and measuring all my food. Everyone kept asking me how I was feeling. Before I could go back to school or play on a sports team, we had to meet with all of the nurses, teachers, and coaches, and anyone else that my parents thought could help keep me safe.

Sometimes I do not like all the attention, but I know it is the attention that is going to keep me safe, and it is the attention like this that is going to help find a cure.

Diabetes not only affects me physically, it affects me emotionally as well. Sometimes I get mad, especially when people say things like I am lucky I missed a class because my blood sugar got too low. Or I get sad when people eat some of my favorite foods and say how good they are, and I cannot eat them because I have celiac, which a lot of people with Type 1 diabetes have too.

But I feel happy to have family and friends that help me out, like my walk team, Hannah's Heroes. This year my team did a bunch of fundraisers. We walked in the Diabetes Walk. We had a yard sale with all of the stuff my family does not use. We had a bake sale and a lemonade stand. So far, we have raised over \$5,000. I hope that we raised enough money with our team, and I hope that

¹The prepared statement of Ms. Ryder appears in the Appendix on page 56.

Congress gives scientists the rest of the money that they need because I really do not want other kids to get diabetes.

In school this year, I had to write a paper about what I would do if I was President of the United States. One thing I said I would do is have more walks to raise money to help find a cure for diseases like diabetes. My mom says that a cure can be found soon and that doctors and scientists get money that they need to work on it from walks and from Congress.

So I am doing my part, and my family and friends are, too. Someday I hope to go to culinary school and open my own small restaurant. I am really hoping that I will not need to include a carbohydrate count on the menu.

Thank you, Members of the Committee, and particularly my Senator, Senator Collins, for helping in the fight to cure Type 1 diabetes. Please keep up the good work, and I will, too.

[Applause.]

Senator COLLINS. Thank you, Hannah. That was great. Patrick, please go ahead.

TESTIMONY OF J. PATRICK LACHER III,¹ DELEGATE, JDRF CHILDREN'S CONGRESS, SOUTH GLASTONBURY, CONNECTICUT

Mr. LACHER. Senator Collins and Senator Lieberman, thank you for inviting me to testify today. My name is Patrick Lacher. I am 13 years old, and I have had juvenile diabetes for over 3 years.

My family and I decided to participate in the 2005 JDRF Walk to Cure Diabetes near my home town in South Glastonbury, Connecticut, to support my dad, who has had juvenile diabetes since he was 19. Little did I know that just 2 weeks later, I would be diagnosed with juvenile diabetes.

The next 2 days became the hardest in my life. I had a crash course in how to manage my diabetes. The last thing in the mind of a 9-year-old is managing diabetes, but I had to accumulate all that knowledge practically over night.

Even though I had watched my dad take care of his diabetes, I never realized how much of my day would be spent dealing with this disease. Though over time it has become easier, I can never cease to pay attention to diabetes and the daily challenges it brings. When I go to a friend's house, even for just a few hours, I have to have a plan. I have to know how active I am going to be, what I am going to eat, and how both will affect me. I have to bring my blood sugar tester and other supplies, such as juice, snacks, or glucose tablets, so I am always prepared for anything that can happen. My bag that carries all of these items is like my right arm. I can never leave it behind. All of this responsibility has been mine since I was a 9-year-old.

There are many reasons why a cure is important to me. The most important reason is that it would help not just me, but the millions of other people living with this disease. Just think, if we could improve the lives of millions of children and adults around the world, why wouldn't we? Curing diabetes would also save our

¹The prepared statement of Mr. Lacher appears in the Appendix on page 57.

country a lot of money since the cost of diabetic supplies and health care is enormous.

Another reason a cure is important to me is that it would make my life a whole lot easier. I would be able to sleep over at a friend's house without worrying about my blood sugar, not to mention how worried my parents are when I am away from home. I would be able to eat just as much as my friends do at birthday parties, and I would even be able to order dessert all the time like my little brother does. I cannot wait for that day. I would not have to carry a bag everywhere I go. I could be free.

Like Hannah, I am doing my part to help find a cure. With the support of my family and friends, I have had over 100 walkers on my team in the 2008 Walk to Cure Diabetes. I have also spoken at the walk and other JDRF functions to help people understand just how difficult it is to live with diabetes and how they can help.

From the day I was diagnosed, I always knew in my heart and believed passionately that we would cure this. And now with all the advances I have seen in just the past 3 years, I know a cure is within our grasp. And that is what keeps me vigilant every day so that my body is ready when a cure is found.

It is my hope that one day I can tell my children and grandchildren, "Can you believe I had diabetes?" And they will say, "What is diabetes?" And I can tell them about how Congress and JDRF worked together to fund research for the cure.

Thank you for letting me share my story with you. I look forward to answering any questions you may have.

[Applause.]

Senator COLLINS. Thank you, Patrick. Great job. Asa, we are delighted to have you here today. Please go ahead.

**TESTIMONY OF ASA KELLY,¹ DELEGATE, JDRF CHILDREN'S
CONGRESS, CHARLOTTE, NORTH CAROLINA**

Ms. KELLY. Good morning. I am Asa Kelly. I am 16 years old and from Charlotte, North Carolina. And like my friends Hannah and Patrick, I am relatively new to the diabetes world. Just over a year ago, on May 29, 2008, I went to the doctor because I was tired and thirsty all the time. The doctor ran some tests, which showed my blood sugar was 362, about three times the normal. I was diagnosed with Type 1 diabetes and was immediately admitted to the hospital.

At the hospital, I learned about the different types of insulin I would have to take until there is a cure. The diabetes educator taught me how to check my sugar, draw up insulin, and give myself a shot. She taught me the warning signs of high and low blood sugar and how to treat them. From then on I realized that I was in control of my health and that diabetes is very manageable—a little scary, but manageable.

At first when I was discharged, I was scared about giving myself insulin without someone constantly watching me, but I quickly learned. Type 1 diabetes called for some major changes in my life. Testing blood sugar many times daily, counting carbohydrates, and checking ketones are just a few things that I go through.

¹The prepared statement of Ms. Kelly appears in the Appendix on page 58.

Finding a cure would relieve a lot of the stress it takes me and others to be healthy. I could focus on my school work better and not have to step out of class to deal with a bout of hypoglycemia, which makes my teachers nervous. A cure would also take a load off my parents. My parents trust the workers at my church, the friends who I hang out with, and my school to take care of me because they are not always present to do so.

Diabetes is a disability, but I am not disabled. Many people treat me different and feel like I have to be watched more often. But the truth is I am an active teenager, a diehard Carolina Panther and North Carolina Tar Heel fan, a scholar, and a good friend. One of my major goals in life is to actually go to the University of North Carolina at Chapel Hill to become a doctor.

I am not going to let diabetes ruin my life. But I deep down hope that I do not have to contend with the daily challenges for much longer.

I ask you, as Members of Congress, to support research issues to find a cure. Over 3 million Americans suffer from this disease, and many of them are children and teens just like me and my friends here. A cure would give us freedom to carry on a normal life without taking a break to check our blood or have a snack. I want Congress to feel the urgency of this issue, that it is a daily struggle not just something we can take a break from doing. It is our life style and all choices are made due to it. Please continue to support research efforts to find a cure. A cure would truly change my life, my family's life, and the lives of almost everyone in this room today.

Thank you.

[Applause.]

Senator COLLINS. Thank you. Nice job, Asa. That was terrific. Mrs. Gould, welcome.

TESTIMONY OF ELLEN GOULD,¹ MOTHER OF DELEGATES PATRICK, SAMUEL, SARAH, AND OLIVER GOULD, JDRF CHILDREN'S CONGRESS, NASHVILLE, TENNESSEE

Mrs. GOULD. Good morning. Thank you for the opportunity to speak to you today about my family's story of living with Type 1 diabetes and our hope for a cure. I am Ellen Gould from Nashville, Tennessee, and joining me are my children: Patrick, who is 17 today.

Senator COLLINS. Happy Birthday, Patrick.

[Applause.]

Mrs. GOULD. And Sam, who is 12; Sarah, who is 10; and Oliver, my 5-year-old.

Yes, all four of them have Type 1 diabetes, and helping them manage their disease can be quite a challenge. Our journey with Type 1 diabetes started in July 2004 when Patrick was diagnosed. My husband and I had noticed he was rapidly losing weight, constantly thirsty, and unusually tired. A trip to the pediatrician turned into a hospital stay, with the required boot camp of sorts, where we received a crash course on diabetes management. And we needed one. There was no diabetes in our family history.

¹The prepared statement of Mrs. Gould appears in the Appendix on page 59.

Patrick quickly learned how to manage his blood sugar, but for an active teenager going through growth spurts, controlling his blood sugar was often a challenge. Today, Patrick uses shots because the years of having diabetes has left scar tissue where he would insert his infusion sets, so a pump is not his best option.

Type 1 diabetes hit home again in January 2006. Sarah began to show the similar symptoms as Patrick had just 2 years earlier. We were devastated all over again.

Fortunately, her brother was and still is an excellent role model, and we had a lot of experience with highs, lows, and sick days under our belt. So she was able to quickly adapt to the routine. Unlike her brother, she wears a pump, which requires different prescriptions and different management.

Shortly after Sarah's diagnosis, my husband and I learned about a clinical trial called TrialNet, which is funded by the Special Diabetes Program. Researchers were looking for children whose siblings had Type 1 to see if the children were at risk for developing Type 1. We immediately enrolled our family.

The initial screening required a blood test. My heart sank when Sam and Oliver's results came back positive for diabetes antibodies, meaning they were clearly at risk of developing full-blown Type 1. Later tests indicated that Sam did have Type 1, although he was not showing the classic symptoms at that time.

While we were dealing with helping a third child manage diabetes, at the age of 3, Oliver started taking a pill as part of the TrialNet study to see if the full onset of Type 1 could be delayed by months or years. We do not know if he received a placebo or oral insulin, but last fall he too was diagnosed with Type 1. He is a real trooper; he tests his own blood sugar and has learned to handle all the injections.

As you can see, my husband and I have our hands full. While the kids are very responsible with their diabetes care, they still need oversight. We are constantly filling prescriptions, scheduling doctors' appointments, filling out forms for school and various activities, educating others, and making sure our kids are safe. We have four other children at home, so you can only imagine how busy our lives are.

Finding a cure means everything to our family, and we are willing to be part of the solution even with juggling our already busy life. We are very active in our local JDRF chapter. We will do all we can to educate others and raise funds for a cure. We have participated in research studies and will continue to do so.

This is not just about the Gould family. It is about the thousands of children who have to live with this terrible disease every day. It is about the thousands of children who are going to be diagnosed with this disease.

While insulin therapy helps us manage this disease, insulin is not a cure. On many occasions, we carefully measure blood sugars, count carbohydrates, and inject what we think is just the right amount of insulin. And it is so discouraging when we measure just a few hours later and their blood sugar is way above the normal range. How many high blood sugars are too many? When will the long-term complications with their eyes, kidneys, or heart start to show? Sometimes we have to deal with the low blood sugars, like

the Saturday morning several months ago when we were awakened by Sam, who had collapsed in his room, incoherent, because of a dangerously low blood sugar. It took us 20 minutes to get him back to normal. What happens the next time if we do not hear him?

As their mother, I just want to reach out and make it better. I cannot. I cannot cure this disease, I cannot make it better for my kids. I need help.

We are so very grateful that so many Senators and Representatives have been doing their part by being strong and vocal supporters of the Special Diabetes Program. It is our hope that the Special Diabetes Program will continue well into the future so that clinical trials, such as TrialNet, can continue and lead to better treatments and eventually a cure for Type 1 diabetes.

Thank you.

[Applause.]

Senator COLLINS. Thank you very much. Mrs. Gould, you gave such moving testimony.

One of the things I have learned about juvenile diabetes is it affects not just the child or, in your case, the children who suffer from the disease, but it has an impact on the whole family. Could you talk to us a little bit more about the impact on your other four children who do not have diabetes? What is the impact on their lives?

Mrs. GOULD. Well, they know just as much about counting carbohydrates and giving shots, and they help us, especially Oliver, test his blood sugar. He is learning to do it on his own, but sometimes he needs a little help. And Nicholas and Andrew, who are here with me today, both help a lot. They are 15 and 13. Our two youngest are 3 and 2. So they always ask, "Well, when am I going to get diabetes, too?" It is definitely part of our family.

I think they feel very fortunate that they do not have it yet, but they go through the trials and tribulations with us all. And they are each tested every year through TrialNet for the presence of antibodies, and we are praying every time—we were just tested 2 weeks ago, the four who are not diabetic—that they will not have it. But if they do test positive, we will also enroll them in the study because we are very committed that research has to have people to participate. And it is not everybody else's job to cure this. We have to be part of the cure.

Senator COLLINS. Thank you.

[Applause.]

Senator COLLINS. Asa, I loved it when you said that you have diabetes and it is a disability, but that you are not disabled. And you have set such high goals for yourself, and I cannot wait someday to call you "Dr. Kelly." I think that is just wonderful.

Does it help you keep those high goals to hear from successful people like Mary Tyler Moore and Nick Jonas and Sugar Ray Leonard about how they have coped with diabetes themselves or in their family? Does that help encourage you?

Ms. KELLY. Most definitely, it helps encourage me that this is not like a life sentence or whatever. I can still live my life. I think it actually speaks more to the outside public because a lot of people do not know about Type 1 diabetes because most of them just know about Type 2, because Type 1 is less common. It helps them to real-

ize that we are just normal or whatever, that we had nothing to do with it, that it is just something that we are just composed of.

Senator COLLINS. Thank you.

Patrick, could you tell us what you would like people who do not have diabetes to know about what it is like for those of you who do, such as your classmates or your teachers? What would you like them to know?

Mr. LACHER. Well, I do not think a lot of people actually understand just how much work and effort goes into even just a normal day with diabetes. You have to test your blood sugar. You have to count your carbohydrates. You have to bolus or give yourself a shot, whatever the case may be. And then you have to also manage your blood sugars in one way or another.

So if everybody could even just understand how hard it is, I think it would make a whole lot of difference.

Senator COLLINS. I think you are right. Do you think that it helped you adjust that you had seen your father cope with diabetes?

Mr. LACHER. I think my dad's support and having seen him do it definitely had positive effects because I knew that my dad has done it, he seems all right. [Laughter.]

Senator COLLINS. I bet he is better than all right. That is helpful. Thank you.

Hannah, what is the hardest part of having diabetes for you?

Ms. RYDER. Probably that you can never take a break. It is always with you, and my blood sugar never is really in the middle. I am always really high or kind of low. I think yesterday was the first good blood sugar I have had in a week.

Senator COLLINS. That has to be difficult. It really must be.

Is it also more complicated for you because you have celiac disease as well? Could you talk to us a little bit about that?

Ms. RYDER. Well, since I cannot have wheat, sometimes if I feel low, I am at a place where I cannot find food that does not have wheat in it. So I have to eat glucose tabs or juice, and that is all I can have if I am low.

Senator COLLINS. That is a challenge.

I want to thank all of you for coming here today. We are about to have yet another vote, so rather than trying to go vote and come back, I think I will just give each of you an opportunity for any additional comments or anything else that you would like us to know.

Hannah, is there anything else that you would like us to know?

Ms. RYDER. No.

Senator COLLINS. You are all set. Patrick.

Mr. LACHER. No.

Senator COLLINS. Asa.

Ms. KELLY. No.

Senator COLLINS. Mrs. Gould. Would any of your children like to say anything for us?

Mrs. GOULD. What would you like to say, Oliver?

Senator COLLINS. You do not have to. It is not required.

Mrs. GOULD. Well, he had asked, "Well, when is it going to be my turn to talk?" So it is your turn, if you would like to say something, Oliver.

Oliver GOULD. I will let Patrick say something.

Mrs. GOULD. You want Patrick to say something?

Senator COLLINS. Oliver has passed the microphone to Patrick.
[Laughter.]

Patrick GOULD. I just want everybody to know that a cure is coming and to hang in there, just hang tight. That is what keeps me going, is that I know that it will be cured eventually and it will be cured soon. So everybody just needs to hang in there and do your best until we do not have to worry about this anymore.

Senator COLLINS. Those are great words for us to close on.

[Applause.]

Senator COLLINS. Well, I, too, have some final words, and Hannah really reminded me of it, and that is, I know the theme of this Children's Conference is to promise to remember you, and I just want to give you my personal promise that I will remember you, and I will continue to do everything that I can to advance the research that will indeed someday lead to a cure.

We have already seen such tremendous progress in better means of diagnosis, better means of treatment, and ultimately, if we all continue to push for more research and to work with the scientists, to participate in clinical trials, and if Congress continues to listen to you, the advocates, the families, I am confident that one day when we convene the Children's Congress, it will be to celebrate a cure.

So thank you, particularly all the children who have come from all over the country. I want to tell each and every one of you how important you are to the search for a cure. When you go see your Senators and your Members of Congress, you help them understand just how important this is. So you are great advocates and ambassadors for the cause of juvenile diabetes. Thanks to your work, we were able to get the research dollars tripled in the last decade, and with your continued help, we one day will be here in this very room celebrating a cure.

So thank you very much for your advocacy. It has been a great honor to be with you here this morning. This hearing is adjourned.

[Applause.]

[Whereupon, at 11:02 a.m., the Committee was adjourned.]

A P P E N D I X

**Type I Diabetes Research: Real Progress and Real Hope for a Cure
Hearing Statement before the Homeland Security and Governmental Affairs
Committee Chairman Joe Lieberman
June 24, 2009**

Thank you Madame Chair. I just want to indicate for the press here that Senator Collins has not pulled off a coup, that she is chairing this meeting at my request in recognition of her principled and really passionate leadership here in Congress, along with others like Senator Lautenberg, on behalf of a recognition of the impact of diabetes particularly juvenile diabetes and really extraordinary advocacy, effective advocacy, for federal support for the kind of research that is leading to dramatically improved treatment that I know with certainty will lead to a cure one day. So I am just very honored to be able to sit here today as Chairman Collins' ranking member.

This is actually a very exciting day in the Committee every year. Exciting because of the feeling of progress we have every year, exciting just because no matter how attractive the witnesses are, we never have as beautiful a group as we have to look at today. I will also say that the witnesses on the first panel have generated a lot of excitement. I do find that it is generationally affected. For instance, the younger members of my office, pages and interns, are quite excited that Nick Jonas is here. I, myself, am thrilled to be in a room with Mary Tyler Moore and Sugar Ray Leonard. I don't want to date myself Sugar, but I would be excited to be in a room with Sugar Ray Robinson. Anyway, your presence means a lot. Dr. Rodgers, obviously, yours does as well.

Just to say briefly, this is an extraordinary story about the blessings of life that each of us receive from God, and the fact that we are given these amazing bodies that are miraculous but not perfect, and sometimes a lot of us have a problem with our bodies - this one goes back a long ways in history, diabetes. But what is amazing is two things: One is extraordinary research, technological research, unimaginable just a short time ago, that is allowing so much better treatment and will get us to a cure. The second is the absolutely inspirational message from all of you, and frankly, all the people who all of us know who have diabetes. There is hardly a person that I know in the Senate, or just anywhere, who doesn't have family members or friends who are dealing with diabetes. I bet that is true for all of us here on the panel, and the way in which you manage this problem everyday is an inspiration to all of us. Somebody once said to me a long time ago: In life there is no one who doesn't either get pushed down or stumbles sometimes. It's just the nature of life. The question is, do you get up? And how do you get up? And the reality is - as I look at the panel and the beautiful, exuberant, slightly restless faces in front of me - that's what it's all about. So you are all winners, and together, under the leadership of Senator Collins, we will be winners in this fight against diabetes. Thank you Madame Chair. I look forward to hearing from our witnesses and of course the second panel of witnesses, including a celebrity of our own from Connecticut.

Statement of Senator Susan M. Collins

Type 1 Diabetes Research: Real Progress and Real Hope for a Cure

I appreciate the opportunity to hold this hearing to examine the devastating impact that juvenile diabetes has had on children and their families. This is the fifth Children's Congress that I have had the honor to chair, and I am particularly grateful to my good friend, the Chairman of the Committee, for turning the gavel over to me this morning.

I also want to welcome our distinguished witnesses, especially the more than 150 delegates to the Children's Congress who have traveled to Washington from every state in the country and from around the world to tell the Congress what it's like to have diabetes, just how serious it is, and how important it is that we fund the research necessary to find a cure. I also want to give a special welcome to the delegates from Maine - 11-year old Hannah Ryder of Cumberland and 8-year old Cole Buchanan of Falmouth.

As the founder and Co-Chair of the Senate Diabetes Caucus, I have learned a lot about this disease and the difficulties and heartbreak that it causes for so many American families as they await a cure. Diabetes is a life-long condition that 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.

Moreover, it is estimated that diabetes accounts for more than \$174 billion of our nation's annual health care costs, and that health spending for people with diabetes is almost double what it would be if they did not have the disease.

These statistics are overwhelming. But what really motivated me to devote so much energy to this issue was 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 you have all traveled to Washington today to tell your stories. You put human faces on all of the statistics. You help us to focus on what Congress can do to better understand and ultimately conquer this terrible disease.

Juvenile diabetes is the second most common chronic disease affecting children. Moreover, it is one they never outgrow.

In individuals with Type 1 diabetes, the body's immune system attacks the pancreas and destroys the islet cells that produce insulin. An average child with diabetes will have to take

over 50,000 insulin shots in a lifetime. Moreover, these injections must be balanced with regular meals and daily exercise, and blood sugar levels must be closely monitored throughout their lives through frequent testing.

While the discovery of insulin was a landmark breakthrough in the treatment of diabetes, it is not a cure, and people 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 good news for people with diabetes. Since I founded the Senate Diabetes Caucus, funding for diabetes research has more than tripled from \$319 million in 1997 to more than a billion dollars last year. As a consequence, we have seen some encouraging breakthroughs in diabetes research, 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. These advances are also moving us closer to our long-term goal of an artificial pancreas. And drugs originally designed for cancer therapy are showing tremendous potential for treating diabetic eye disease, the leading cause of blindness in working-age adults.

While we are making progress, this is no time to take our foot off the accelerator. We have two choices. We can sit back and continue to pay the bills and endure the suffering, or we can aggressively pursue a national strategy aimed at curing this terrible disease.

The good news is that there is strong support in Congress for increased funding for diabetes research, thanks in no small part to the strong grass-roots support provided by JDRF volunteers. Last year, we were able to pass legislation to extend the Special Diabetes Program for two years through September of 2011. This critical program provides \$150 million a year for juvenile diabetes research, over and above the regular appropriation for diabetes research at the National Institute of Health. It is critical to our efforts to find better treatments, a means of prevention, and ultimately, a cure for this terrible disease.

I am hopeful that this morning's hearing will help us to generate even more support to extend this important program far into the future.

Testimony of**Ms. Mary Tyler Moore
International Chairman, Juvenile Diabetes Research Foundation**

Good morning Senator Collins, Senator Lieberman, and members of this committee.

As International Chairman of the Juvenile Diabetes Research Foundation, I want to thank you for your leadership and commitment to sustaining robust federal funding for diabetes research. Your efforts are resulting in real progress and real hope for millions of Americans personally affected by type 1 diabetes.

I am honored to be accompanied today by all of the terrific young delegates and special guests who surround us in this chamber and join me on this panel. We sincerely thank you for providing us the opportunity to testify about an issue that we know all too well – life with type 1 diabetes and our hope for a cure.

Ten years ago, Tommy Solo -- an 8 year old JDRF volunteer from Boston -- had a big idea. Tommy was frustrated with his Type 1 diabetes and was looking for something he could do to move us closer to a cure. He thought, "Why not have kids with diabetes, like me, go to Washington, D.C. and tell Congress we need their help?"

Even at age 8, Tommy understood, intuitively, what JDRF's Moms and Dads and people personally affected by Type 1 had always known: When confronted by challenges to our personal well-being, the solution starts with our willingness to share our stories, make our case, and ask others to join us as partners in our cause.

Senators, we are grateful to you for welcoming our Children's Congress delegates to these rooms over the years since, for listening to us, and for remembering us and our partnership for a cure with your legislative leadership and support.

But because our work, together, will not be done until we have found a cure, here we are again today. More than 150 child delegates from across the United States and several countries join me to participate in the 10th anniversary Children's Congress, acknowledge the remarkable progress we've made, and reflect on the challenges which remain.

As many of you know, I have endured the ups and downs of type 1 diabetes for almost 40 years. And as all of these children and their families can attest, every single day with type 1 diabetes tests our will and determination to live a normal life. Each day I check my blood sugar several times, count carbohydrates in what I am going to eat, take multiple insulin injections, and exercise.

Even with this structured regimen, terrific doctors, and the loving support of my husband Robert, my blood sugars can still fluctuate tremendously. If I don't take enough insulin, my sugars can go dangerously high – which, over time, can lead to long-term complications such as blindness, nerve damage, kidney failure and a host of other serious ailments. If I take too much insulin, my sugars can drop frighteningly low, which can acutely lead to feeling really sick and cold and anxious and lost and, in turn, lead to unconsciousness, seizures or worse.

I actually had my first hint of impending long-term complications of diabetes in 1981 – after only about 11 years of having the disease. I truly wish the technology that is available today and the understanding that we now have about how to manage diabetes was available when I was first diagnosed. Back then, to get an idea of what your blood sugar was, we relied on urine tests. They were not all that accurate, timely or helpful. I did the best that I could to control my blood sugars, but it was really difficult. And my doctors, even if they wanted to, couldn't really push me to do what was --as a practical matter -- not really doable. As a result, by 1981, I was well on my way to having vision-threatening diabetic retinopathy.

I wasn't alone. Diabetic Retinopathy is the leading cause of adult blindness.

I was terrified. How was I to continue doing the things I loved most – dancing, horse back riding, window shopping on Madison Avenue – if I went blind?

At the time I was diagnosed with Type 1, there was no simple treatment to prevent diabetic retinopathy. But when my retinas started to show evidence of damage due to diabetes, there was, thankfully, a new procedure available called “laser photocoagulation” that was able to keep me from going blind.

But not without costs. Because, in order to halt the progression of diabetic retinopathy and save your “central vision,” the laser must literally burn holes in your peripheral retina.

So the combination of the disease itself and its vision preserving treatment has resulted in my having a difficult time seeing when it is dark or when I'm in a room that isn't well lit. My peripheral vision, and vision below my waist, is also very limited. Simple things like navigating curbs on a street or changes in levels between rooms in an unfamiliar home, or seeing one of my precious pups taking a nap in an unusual place, or recognizing a welcoming hand that's been patiently waiting for me to shake it, are challenges of the first order!

For years, I kept the full impact of my diabetes under wraps. While people knew I had type 1 and that I was a long-time, outspoken advocate for a cure and International Chairman of JDRF, the general public didn't know the extent to which diabetes affected my day-to-day life.

But recently, at the prompting of a lovely young woman named Diane Revzin, and her father, Phil, I wrote a book about living with diabetes. Diane is a 19-year-old fellow diabetic; Phil is a book publisher.

My book is entitled “Growing Up Again – Life, Loves, and Oh Yeah, Diabetes.” It chronicles my battles with type 1 in the context of my broader life experience and career, and I hope it informs and even inspires people facing similar challenges. Though I am not here to promote my book, I'm happy to note that all my proceeds from its sale will be donated to JDRF to advance research for a cure.

As JDRF's International Chairman, I am, actually, just one volunteer in an army of determined moms, dads, children, loved ones and friends personally affected by diabetes. We are not sitting back waiting for the cure. These children before you have built lemonade stands, created walk teams, held bake sales, and organized car washes. Most importantly, they have spoken out about their lives with diabetes and shown, by their courage and hard work, that they can accomplish anything-- including being an important part of finding their own cures. Overall, JDRF's efforts have enabled us to contribute over \$1.3 billion to diabetes research since our founding in 1970, and over \$150 million last year alone. But curing diabetes is an enormous task. We can't do it alone. And that's why we're here.

We are so very grateful that this committee and Congress as a whole, have been our true partners in the fight to cure type 1 diabetes and its complications. The Special Diabetes Program -- which has been renewed by Congress four times since it was enacted in 1997 -- currently provides \$150 million per year for type 1 diabetes research. This critical funding has led to some remarkable advances...including real progress in developing new therapies that are potentially life-changing for all of us sitting before you, today.

I will ask our friend, Dr. Griffin Rodgers the Director of the NIDDK, to elaborate more on the scientific progress we've seen, thanks to the Special Diabetes Program funding. But there are a few areas of research that I would like to touch upon today, myself -- areas that affect me, personally.

Researchers are using the Special Diabetes Program funds to find a way to prevent and reverse diabetic retinopathy. This is very exciting work and it gives me great hope, especially for children and young adults with Type 1. As a result of these advances, people with diabetes may be able to live with far less fear of visual loss and have an alternative to laser therapies' "burn the village to save the village" approach.

Major advances are also being made in the development of new devices, called Continuous Glucose Monitors or CGMs. By measuring blood sugars, automatically, every few minutes, and graphically showing the results and the up and down trends, CGMs help people to better understand their diabetes, and avoid extreme highs or lows.

Teams of researchers are now working hard to connect CGMs with insulin pumps via a control algorithm --- thereby creating a fully automated system that can closely mimic the blood sugar control workings of a human pancreas. This intelligent pump would automatically administer insulin based on a person's blood sugar level and whether it was rising or falling. Human clinical trials are already underway, and the early results are very encouraging.

In short, with your help, we are making real progress towards discovery, development and delivery of cures and significantly improving the health outcomes of people with type 1 diabetes and its complications. To keep up this progress, however,

Congress must renew the Special Diabetes Program in 2010. Without your help, we face a 35% cut in federal funding for type 1 research – a cut that could turn hope into despair. With your help, new life-changing therapies and cures will, finally, be within our reach.

When a child is diagnosed with diabetes, it is a hectic, crazy time. There are ambulances or emergency rooms. You hear medical terms you never knew existed. Days blur into nights. But one thing is common at every diagnosis. Every parent of these delegates here today, every parent of every child ever diagnosed with type 1 diabetes makes a promise to them. We'll do everything thing we can to find a cure for you. We promise.

As their Chairman and “oldest delegate” – by just a year or two – I'm proud to be leading our 2009 Children's Congress Delegates in their efforts in DC this week. As we have started to do in this special hearing, today our goal is to persuade our Senators and Representatives to also make a promise. We hope you will “promise to remember us” when you vote on the Special Diabetes Program and other important issues that affect all of us with diabetes.

The energy and commitment of families affected by type 1 and the strong support of champions like you on Capitol Hill make me certain that we will, soon, be able to turn the promising research made possible by JDRF and the Special Diabetes Program into our “promises kept for a cure.”

Thank you from the bottom of my heart for all that you do for these children, for me, and for all others who are touched by type 1 diabetes. I look forward to continuing to work with you as we pursue our mutual goal of a cure. I promise.



**Testimony
Before the
Committee on Homeland Security and
Governmental Affairs
United States Senate**

**Recent Advances and Future Opportunities
in Type 1 Diabetes Research**

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 9:00 a.m.
Wednesday, June 24, 2009**

Chairman Lieberman, 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 that we are vigorously pursuing research on type 1 diabetes and its complications—along with research partners with whom we share important goals. Such partnerships have helped to synergize and propel research to combat this disease. In FY 2008, NIH invested over \$1 billion on diabetes research. Through collaborative and coordinated research efforts, we are gaining important insights into the molecular mechanisms underlying disease development, testing promising therapies to prevent and treat the disease and its complications, and striving for a cure. Today I will discuss 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 strikes mainly in childhood and adolescence. It is an autoimmune disease, in which the body's own immune system attacks and destroys the insulin-producing beta cells found in clusters called islets within the pancreas. To survive, people with type 1 diabetes require daily administration of insulin in the form of injections or via an insulin pump. They must also monitor their food intake and physical activity in order to manage their blood glucose levels. Even with continuous and vigilant management, patients are still susceptible to developing serious, long-term complications that can damage the eyes, kidneys, nerves, heart, and other organs. Moreover, we now

know that type 1 diabetes diagnoses are on the rise, and that the disease is occurring in younger children than before—often appearing during infancy.

Today, I will be describing some of the strides that we have made in improving the lives of people with type 1 diabetes. Importantly, because of continued improvements in therapy, people with type 1 diabetes are living longer, healthier lives than ever before. For example, improved therapy is reducing rates of diabetic kidney disease in people with type 1 diabetes. Further improvements in health and well-being are expected, as new continuous glucose monitoring technologies are helping patients better control their blood glucose levels, which is key for preventing disease complications. Blood tests can predict the risk of developing the disease in relatives of people with type 1 diabetes; this knowledge has enabled the launch of clinical trials testing new prevention strategies. We are working to build on these successes and continue basic and clinical research to further improve patients' quality-of-life and to seek ways to prevent and cure type 1 diabetes.

How are we going about this? The NIH is focused on six broad goals in type 1 diabetes research, which are: (1) to understand the genetic and environmental causes of type 1 diabetes; (2) to prevent or reverse the disease; (3) to develop cell replacement therapy as a cure; (4) to avert hypoglycemia (low blood sugar), which limits tight control of blood glucose; (5) to pre-empt complications; and (6) to harness new technologies and empower talented researchers to pursue these opportunities.

Through this multifaceted approach, we can achieve a comprehensive understanding of the disease process, and form the foundation for future advances in treatment, prevention, and approaches to a cure.

Pursuit of the six goals I just mentioned has involved not only partnerships among scientists with complementary expertise from many academic institutions, but also partnerships among many of the Institutes and Centers of the NIH, HHS's Centers for Disease Control and Prevention (CDC), and patient-advocacy groups, which have played an instrumental role in facilitating and in contributing support to many of these collaborative research endeavors.

Of course, the most important partners in these efforts are those people with or at-risk for type 1 diabetes who participate in clinical research to help improve diabetes care, not only for themselves but for future generations. The clinical research we conduct would not be possible without their enthusiastic participation and dedication.

I would now like to tell you about some of the exciting progress that has been made in type 1 diabetes research.

Understanding the Genetic and Environmental Causes of Type 1 Diabetes

Type 1 diabetes is caused by a combination of genetic and environmental factors, and it is the genetic arena that has seen some of the most impressive advances in recent years. Today, at least 40 genes are known to influence the likelihood of developing type 1 diabetes--four times as many as were known only two years ago. Why is this important? Identifying genes may lead to potential avenues for therapeutic or preventive treatments, and even on a personalized or customized basis. Moreover, because we have identified genetic variants that account for more than half of the genetic risk for type 1 diabetes, we can identify these high-risk individuals for entry into prevention trials. Since the sequencing of the human genome a few years ago, a new research method

called “genome-wide association” has emerged, where specialists in genetic research scan the DNA of patients and search over 500,000 common genetic variations for markers of disease. Most genes influencing the likelihood of developing type 1 diabetes were discovered using this technology.

In addition, our understanding has grown deeper as well as broader by studying genes that are already known, such as through the fine mapping of the *HLA* locus (also known as MHC), the gene which has the greatest single impact on susceptibility to type 1 diabetes. Such research is helping to explain how it is that *HLA* exerts its strong effect on type 1 diabetes susceptibility. Other research has shown that a different diabetes gene, *PTPN22*, influences progression from autoimmunity to full-fledged type 1 diabetes in people who have a family history of the disease, while the gene *CTLA-4* plays a similar role in children without a family history of the disease. A drug directed at *CTLA-4* is now in clinical trials to slow progression of type 1 diabetes. Indeed, the next great strides in the genetics of the disease are likely to come from understanding the roles of the diabetes genes we already know, and leveraging that knowledge to fight the disease. A new initiative, “Fine Mapping and Function of Genes for Type 1 Diabetes,” seeks to do just that. The Type 1 Diabetes Genetics Consortium, a group of researchers from around the world who have come together to collect samples and information from families with type 1 diabetes, has helped to drive these recent advances, and will be in the vanguard to answer key remaining questions about diabetes genetics.

We know much less about the environmental factors that trigger onset of type 1 diabetes in genetically-susceptible individuals. The rise in rates of type 1 diabetes around the world is presumably the result of a change or changes in the environment, which we

hope to identify through research. The discovery of a precipitating viral infection could lead to a diabetes-preventing vaccine; the identification of a dietary trigger or protector could be addressed through a dietary intervention. To address this crucial issue, an international consortium is identifying infants at high-risk for developing type 1 diabetes and following them through adolescence to search for environmental factors that may trigger disease. This long-term NIDDK-led study, called The Environmental Determinants of Diabetes in the Young, or TEDDY, has screened almost 350,000 newborns for the presence of the most important genetic risk factor for type 1 diabetes, identifying over 17,000 with this risk factor and enrolling over 6,670 of the children in the study. This achievement represents tremendous progress toward amassing the largest set of data and samples anywhere in the world on newborns at risk for autoimmunity and type 1 diabetes. To maximize the return on the investment in TEDDY, samples from the study will be made widely available to researchers worldwide. Importantly, TEDDY may also contribute to understanding the development of celiac disease, which is an autoimmune disease primarily affecting the gastrointestinal tract. Some genes confer susceptibility to both celiac disease and type 1 diabetes, and many people have both diseases. Thus, TEDDY may benefit not only people with, or at-risk for, type 1 diabetes, but also people with celiac disease and other autoimmune diseases. As the powerful research tool that the TEDDY samples will represent continues to be assembled, new data are beginning to shed some light on environmental variables that can affect incidence of diabetes. Among the most striking of these findings in the last year is the discovery that healthy bacteria in the gut can potentially help blunt the autoimmune attack that causes diabetes in an animal model.

A clearer understanding of why diabetes strikes will also come in part from a fuller perspective on where, when, and how often it does. Thus, CDC and NIDDK support the Search for Diabetes in Youth Study, an epidemiologic effort which has recently reported the most complete picture to date on the incidence and prevalence of both type 1 and type 2 diabetes in five major racial/ethnic categories in the United States. These data show that type 1 diabetes is present at significant rates in youth under age 20 in all of these groups. In Colorado, where data exist for the period of 1978-1988, we now know that incidence of type 1 diabetes climbed 2.3 percent per year over the past three decades, rising both among Hispanic and non-Hispanic white children. We also know that the largest part of that increase came among children diagnosed very early, within their first 4 years. This research will also help to evaluate key risk factors for the disease, and for its complications.

Preventing or Reversing Type 1 Diabetes

To spur the testing of promising new strategies to prevent type 1 diabetes in those at elevated risk of the disease, and to slow or reverse its course in those recently diagnosed, the NIDDK leads a clinical trials network, the Type 1 Diabetes TrialNet. TrialNet researchers have just reported exciting data that rituximab, a therapeutic agent currently in use for non-Hodgkin's lymphoma and rheumatoid arthritis, can substantially preserve the function of insulin-producing beta cells in people with recently diagnosed type 1 diabetes. Patients taking the drug had better glycemic control and required less insulin than those who took a placebo over a one year follow-up to their treatment. Other TrialNet studies include a trial to test whether oral insulin administration can prevent type

1 diabetes in a group of people who have high levels of anti-insulin antibodies, a certain marker of pre-clinical type 1 diabetes. The TrialNet infrastructure is critically important for testing emerging therapies for disease prevention and early treatment.

The Immune Tolerance Network (ITN), sponsored by NIH's National Institute of Allergy and Infectious Diseases (NIAID), is also conducting several clinical trials to test therapies to reverse disease in newly-diagnosed patients with type 1 diabetes. ITN and TrialNet work in partnership, and currently between the two have nine trials in progress, with several others scheduled to launch soon.

Evidence from observational studies suggests it may be possible to use dietary interventions to lower the risk that people born with the genetic predisposition to developing type 1 diabetes will go on to develop the disease. Indeed, TrialNet is currently doing a pilot trial of omega-3 fatty acid supplements to help lower the odds of developing type 1 diabetes in those at elevated genetic risk. NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) leads an effort, called the Trial to Reduce IDDM [insulin-dependent diabetes mellitus] in the Genetically At Risk, or TRIGR, which is examining a specific environmental factor, cows' milk, in development of type 1 diabetes. That international study has recently completed recruitment of 2,160 newborns at high risk for type 1 diabetes and is comparing standard formula with a formula in which cows' milk proteins are broken down into smaller pieces.

NIDDK also leads an international effort to standardize autoantibody measurements, which has helped to characterize childhood diabetes and distinguish between type 1 and type 2 diabetes. Increasingly, beta cell inflammation, and in some

cases autoimmunity, is being recognized as contributing to type 2 diabetes.

Standardizing antibody measurement is important to help understand this phenomenon as well as to identify participants at high risk of type 1 diabetes for participation in TrialNet trials.

Developing Cell Replacement Therapy

Insulin therapy for type 1 diabetes is a less than ideal substitute for the body's exquisitely precise regulation of blood glucose by insulin-producing pancreatic beta cells. In contrast to insulin administration, a real cure could emerge from cell-based therapy, such as the transplantation of insulin-producing cells. Developing this type of therapy has proven challenging: clinicians must have an adequate supply of healthy islets for transplantation; they must inhibit the autoimmune attack that destroyed a patient's original islets; and they must inhibit the body's defense mechanisms that can lead to graft rejection. This last point is a particular challenge in the case of diabetes, because many of the best medications for preventing tissue rejection are toxic to beta cells. However, researchers are collaborating to achieve this goal. For example, scientists from the Clinical Islet Transplantation Consortium, a network of clinical centers sponsored by NIDDK and NIAID to conduct studies of islet transplantation in patients with type 1 diabetes, are comparing the current state of the art procedure for islet transplantation with several new protocols that may yield improved insulin production over the longer term with fewer side effects. The Collaborative Islet Transplantation Registry, initiated and supported by NIDDK, is tracking approaches to and outcomes of such procedures. Scientists are hard at work overcoming technical difficulties to islet transplantation, and

increasing the available supply of transplantable islets. A powerful new tool recently developed through the Beta Cell Biology Consortium, established by NIDDK to facilitate interdisciplinary approaches that will advance our understanding of pancreatic islet development and function, is a mouse model that facilitates testing of medications used in people with diabetes to find those that are benign in their effects on islets.

Recent research from the Beta Cell Biology Consortium also suggests that an exciting alternative therapy may one day replace beta cells without the need for transplants: converting exocrine cells in a patient's own pancreas into insulin-producing cells. Scientists found that this was possible in diabetic mice by infecting the exocrine cells with a virus carrying genetic signals that trigger the cells to act like beta cells and produce insulin in response to rising glucose levels. In the mice, the insulin production was sufficient to "cure" them of their diabetes. There are a considerable number of technical hurdles and safety questions that must be addressed before such an approach can be tested in people with type 1 diabetes, and an additional intervention may be required to keep the immune system from attacking the new insulin-producing cells just as they attacked the patient's original islets. But this exciting approach could avoid some of the problems associated with immune rejection of transplanted tissue.

Such research also provides fundamental new insights into the biology of the beta cell, which is of great importance not only to help improve treatment for patients with type 1 diabetes, but also for millions of Americans with type 2 diabetes or with pancreatic cancer. Thus, research projects such as these, made possible by the Special Statutory Funding Program for Type 1 Diabetes Research, have a broader impact on biomedical research than some may realize.

By studying the beta cell in detail, scientists are also gaining new insight into the autoimmune process that leads to type 1 diabetes and discovering new biomarkers that can predict disease onset. Biomarkers are measurable molecular, biological, or physical characteristics that indicate a specific underlying physiologic state. Biomarkers are critically needed to predict disease risk, to monitor disease, and to monitor autoimmune responses during therapeutic intervention. Autoantibodies, which are antibodies that react with the cells, tissues, or native proteins of the individual who produce them, are the most important biomarkers used for detecting the earliest stages of autoimmunity, and recent research has identified a new autoantibody that improves the sensitivity and specificity of such predictive tests. Better testing for autoimmunity before onset of diabetes can identify those at risk, help catch the disease before blood glucose gets dangerously high and could lead to interventions that prolong beta cell life, reduce the need for injected insulin, and lower the risk of complications. As therapies improve, autoantibody screening may one day make it possible for health care providers to reverse the course of diabetes entirely in patients whose diabetes risk is caught early enough.

Preventing or Reducing Hypoglycemia in Type 1 Diabetes

Research is pointing the way to exciting new interventions that may one day lead to prevention or reversal of type 1 diabetes or to the development of an artificial pancreas. But just as important are key findings that give patients and their families practical solutions to the problems posed by the disease every day. Perhaps the most distressing acute complication in people with type 1 diabetes is hypoglycemia—low blood sugar. It is caused by greater-than-necessary treatment with insulin relative to food

intake and physical activity. The potential for hypoglycemic episodes has challenged the use of intensive insulin therapy even though major clinical trials have shown that intensive therapy can significantly reduce the risks of longer-term diabetic complications. Another worry has been the fear that recurrent episodes of hypoglycemia might lead to a decline in cognitive skills. Again, good news comes from NIH research. Scientists have found that tight control of blood glucose does not lead to cognitive decline, even when it is accompanied by recurrent episodes of hypoglycemia, and in fact is significantly associated with better preservation of fine motor control.

Nevertheless, hypoglycemia remains a serious concern for people with diabetes and their loved ones, and the NIH is deeply committed to helping ease the difficulties of glucose control. Within the last few years, continuous glucose monitors have been developed and approved for use, which can help remove some of the guesswork from insulin therapy. Research from the DirecNet Consortium, led by NICHD, has yielded practical suggestions for people with diabetes and their parents or caregivers to help maintain healthy glucose levels more safely and effectively by managing diet and exercise. To better understand the way patients and caregivers utilize continuous glucose monitors, the NIH has developed an initiative to study the way data from the monitors is used.

Having supported the research that led to development of continuous glucose monitors, the NIH is committed to capitalizing on this technology to achieve a new option in diabetes clinical care: an “artificial pancreas” that will tightly control a person’s blood glucose, like the biological pancreas naturally does in people without diabetes. Strides in improved accuracy of continuous glucose monitoring, together with new

algorithms to predict insulin requirements based on trends in glucose levels, have allowed researchers to begin careful studies to “close the loop” and link insulin delivery to continuous glucose measurements. The NIH is working with the business community to help bring about the required technology through the Small Business Innovation Research to Develop New Therapeutics and Monitoring Technologies for Type 1 Diabetes initiative, a new grant program that will award its initial funding later this year.

Preventing or Reducing the Complications of Type 1 Diabetes

The complications of diabetes affect virtually every system of the body; diabetes and its complications can shorten average life expectancy by up to 15 years. Recent studies have brought good news: people with type 1 diabetes are living longer and healthier lives than ever before. The landmark NIDDK-supported Diabetes Control and Complications Trial (DCCT) demonstrated that intensive control of blood glucose levels is extremely effective in preventing complications affecting the eyes, kidneys, and nerves. Long-term results from the follow-on study to the DCCT now show that intensive therapy also dramatically reduces the risk of heart disease, which is the leading cause of death in people with diabetes. Results also showed that a finite period of good glucose control provides benefits years down the road, with enduring protection from complications of the eyes and kidneys, and from cardiovascular disease. Thus, patients and physicians are advised to start intensive therapy as early as possible following diagnosis.

Despite these gains, type 1 and type 2 diabetes together are the leading cause of new blindness in people 20-74 years old. To combat this devastating complication, NIH’s

National Eye Institute (NEI) supports the Diabetic Retinopathy Clinical Research Network, which is conducting multiple protocols to identify new prevention and treatment strategies for diabetic eye disease. The NEI is also leading an effort to involve small businesses in Innovative Patient Outreach Programs and Ocular Screening Technologies to Improve Detection of Diabetic Retinopathy. This funding opportunity is intended to help detect retinopathy in its early stages, when it is still possible to prevent blindness.

To better understand why diabetes leads to devastating complications like retinopathy and kidney disease, researchers from the Family Investigation of Nephropathy and Diabetes (FIND) consortium have compared the genomes of thousands of people with diabetes who either do or do not have kidney disease. The study identified four genetic regions where subtle differences correlate with increased risk of diabetic kidney disease. Other scientists looked carefully at specific genes they thought might contribute to the development of complications and found that a genetic region that controls production of the hormone erythropoietin leads to too much of the protein in people who develop proliferative diabetic retinopathy (the abnormal growth of blood vessels in the eye) and diabetic nephropathy. These results may one day help clinicians head off complications before they happen, and suggest novel therapeutic approaches for treating and preventing the devastating complications of both type 1 and type 2 diabetes.

**Attracting New Talent and Applying New Technologies to Research on Type 1
Diabetes**

A critical goal of the *Special Statutory Funding Program for Type 1 Diabetes Research* is to draw talented young investigators into the field, and help establish them as productive members of the scientific community. Many young investigators have innovative research ideas, but they lack the preliminary data required to compete in the traditional NIH peer review system. Therefore, the NIDDK established the Type 1 Diabetes Pathfinder Awards to help overcome this impediment. By providing multi-year support to new researchers with highly innovative projects, we hope to attract and retain high-caliber investigators to research careers in type 1 diabetes.

In October 2008, ten scientists won Pathfinder Awards for highly innovative research studies that offer exceptional promise for improving the understanding, prevention, and treatment of type 1 diabetes and its complications. The recipients, all new researchers who have never been principal investigators on an NIH-funded grant, will receive about \$1.5 million each over a 5-year period to pursue their work. Their studies span a wide range of topics, from the development of a vaccine to prevent autoimmune diabetes to methods that speed wound healing and prevent recurrent injury.

Because type 1 diabetes research spans a broad range of scientific disciplines, a cadre of exceptionally talented and dedicated researchers is needed to bring expertise to bear on scientific challenges. As more and more exciting discoveries are made in the laboratory – at the “bench” – there is a need to rapidly move those results to the clinic – to the “bedside” – to benefit patients directly. Thus, the NIH is sponsoring “bench-to-bedside” initiatives, in which teams of basic scientists and clinical researchers work together on translational research projects focused on type 1 diabetes.

New technologies are driving many of these efforts. Genome-wide association studies have yielded powerful new findings that I previously mentioned in the contexts of both Goal I and Goal V. Closing the loop for the artificial pancreas and developing new cell-based therapies will help prevent hypoglycemia, while also improving glucose control and preventing long-term complications from hyperglycemia (elevated blood sugar). New technologies for imaging islets and beta cells have the potential to transform not only research but also care, as a clearer picture of what is happening in the pancreas may be possible. Another important translational research effort is the Type 1 Diabetes-Rapid Access to Intervention Development (T1D-RAID) program. T1D-RAID has provided resources for preclinical development of therapeutic agents to move them along the pipeline to clinical trials. For example, a drug produced under the T1D-RAID program is currently being tested in clinical trials of islet transplantation. Efforts in these diverse scientific disciplines combine to help move the field forward, and bring life-extending and improved health care to people with diabetes.

Conclusion

Looking to the future, in order to inform the program development process for NIH-supported type 1 diabetes research in the years ahead, the NIDDK is spearheading development of a *Diabetes Research Strategic Plan*, with extensive input from external scientific and lay experts. The Plan will help to synergize diabetes research, and bring benefit to all people with diabetes by identifying gaps, and finding solutions to help fill them.

For now, I am grateful for the opportunity to share with you these few examples of recent advances and ongoing research efforts. We continue to be inspired by the dedicated efforts of individuals affected by type 1 diabetes, and by organizations that represent them. We look forward to continuing to partner with these organizations on research efforts to combat type 1 diabetes and its complications. We are grateful for the full range of support that NIH has received for type 1 diabetes research. We continue to be diligent in our fight against diabetes so that we can help all the children at this hearing and the many other Americans whom they represent here today. Improving their quality of life—with the ultimate goal of curing their disease—is the driving force behind our efforts.

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.

Testimony of**Mr. Sugar Ray Leonard
World Champion Boxer**

Good morning Senator Collins, Senator Lieberman, and members of the Committee. I am Sugar Ray Leonard, and I appreciate this opportunity to appear before you today. I would like to testify about the burden of diabetes and the need for continued research funding to cure this devastating disease.

First, I would like to thank Senator Collins for her unwavering dedication to people with diabetes. As a diabetes advocate, I know how grateful we all are to have you as one of our champions.

It is wonderful to be here in Washington, DC as part of the Juvenile Diabetes Research Foundation's Children's Congress. I grew up not far from here, in Palmer Park, Maryland. My teenage years were spent in the boxing ring, winning a number of amateur boxing championships. I won National Golden Glove Championships, AAU championships, and gold medals at both the Pan American Games and the 1976 Olympics in Montreal.

During this time of great personal accomplishment, privately my family faced tremendous challenges as my father struggled to manage his diabetes. We are not alone in this fight. Nationwide, more than 24 million people have diabetes, a chronic disease that imposes a huge emotional and financial burden on patients and their families.

I know all too well the toll that diabetes can take on a family. As I closed the book on my amateur boxing career, I planned to begin a new chapter in my life as a college student at the University of Maryland, but I had to face the reality of my father's illness, and the incredible medical bills that resulted from his life with diabetes. My decision to turn professional was based largely on the desire to help my family cover the costs of my father's care.

Due to the long list of complications associated with diabetes, the cost of this disease is overwhelming for any family. But it's also overwhelming for the nation and our health care system. Diabetes costs are currently estimated at \$174 billion each year -- \$116 billion in direct medical costs and \$58 billion in lost productivity and disability. In California, where I now live, the direct and indirect costs of diabetes totaled more than \$24 billion in 2007.

Thankfully, the Juvenile Diabetes Research Foundation has partnered with the federal government to make a meaningful investment in diabetes research. I was proud to serve as an International Walk Chairman for JDRF, which has provided more than \$1.3 billion in funding for type 1 diabetes research over the years. Last year alone, JDRF funded more than \$150 million in diabetes research.

With the leadership of Sen. Collins and our many other diabetes champions on Capitol Hill, the federal government has been a real partner along our path toward a cure for diabetes. We are so thankful to Congress for renewing the Special Diabetes Program. That program provides \$150

million each year for diabetes research at the National Institutes of Health and an equal amount for the treatment and prevention of diabetes in American Indian and Alaska Native populations.

Since its inception in 1997, the Special Diabetes Program has funded research that has shed important light on the causes of type 1 diabetes, as well as who's at risk for developing the disease. The research funded by the Special Diabetes Program is unique because its discoveries are important not only to people with type 1 diabetes but also to people who suffer from similar auto-immune diseases. The therapeutic advances in diabetes complications made possible through the Special Diabetes Program also apply to people with type 2 diabetes, making this program a critical component of any effort to fight diabetes. Please help us keep up the momentum behind this research by ensuring the renewal of the Special Diabetes Program.

Life with diabetes is sort of like life in the boxing ring. Some days, you don't feel on top of your game, and your opponent can get the best of you. Other days, you're managing the fight well and able to outsmart and outbox your opponent. One of my most memorable fights was my rematch against Roberto Duran. I lost my welterweight crown to Duran just a few months earlier, and I couldn't wait to get my title back. I fought a smart and skillful match. With just seconds to go in the 8th round, Duran suddenly walked back to his corner, threw up his hands and said, "*no mas.*" No more. He gave up.

Now, it would be easy for these children here today to say "*no mas.*" The fight against diabetes is a tough one. Some days, nothing seems more difficult, more impossible, to battle. There are days we all think about saying "*no mas.*" But it's clear these children have fight in them. They're willing to go as many rounds as it takes to beat this formidable opponent. And we have you in our corner. Thanks to Congress' support for the Special Diabetes Program, the advancements made through research are bringing us closer to the cure that will allow these children to finally knock out diabetes.

Thank you again for having me here to testify today, and I look forward to answering your questions.

Testimony of**Mr. Nick Jonas
Musician, Jonas Brothers**

Good morning. My name is Nick Jonas, and I'd like to thank you for having me here today. I'd like to share my story of living with type 1 diabetes, and talk about the need to fund research to find a cure.

First, I would like to thank you, Senator Collins, for chairing this hearing and for being such a champion for all of us with diabetes. Everyone here today for the Juvenile Diabetes Research Foundation's Children's Congress is grateful for your leadership on the Senate Diabetes Caucus and your commitment to people with type 1 diabetes. We are lucky to have you pushing for policies that will bring us closer to a cure.

In one way, or another I have spent most of my life performing. I've been writing songs since I can remember, and I love sharing my passion for music. As a little kid, I sang in the choir in my dad's church, and then performed on Broadway. As the Jonas Brothers, my brothers Joe, Kevin and I have written songs, made albums and toured the country, playing our music for people all over America.

It was during a concert tour in 2005 that I was diagnosed with type 1 diabetes. My brothers were the first to notice that I had lost a lot of weight – fifteen pounds in two weeks. I was thirsty all the time and had a bad attitude, which isn't like me at all because I'm a really positive person. It would have been easy to blame my symptoms on a hectic schedule. But my family knew I had to get to a doctor.

The normal range for blood sugar is between 70 and 120. When we got to the doctor's office, we learned that my blood sugar was over 700. The doctor said I had type 1 diabetes, but I had no idea what that meant. The first thing I asked her was, "Am I going to die?" She assured me that I wasn't going to die, but that I'd have to manage this disease for the rest of my life. We went right to the hospital where I spent three days, including a crash course in getting my blood glucose levels in control and living with diabetes.

It hasn't been easy, but diabetes technology has really helped me to manage my diabetes. At first, I took insulin shots, but it was just too hard on the road to give myself shots. I switched to a pump, which has been great. Since then, my average blood glucose levels have come down, and I'm able to use the pump to better estimate how much insulin I need based on the carbs I eat. I am also considering a continuous glucose monitor, but for now, I still prick my finger to check my blood sugar. I do that up to 12 times a day, including right before I began this testimony.

While technology has made it much easier for me to manage my diabetes, technology is not a cure. Insulin is not a cure. Like everyone here today, I know that the promise of a cure lies only in research. I am grateful that Congress renewed the Special Diabetes Program last year, which has helped researchers make important discoveries into what causes type 1 diabetes. This vital program has also funded research to test new drugs and therapies that could treat or cure patients with type 1 diabetes, and may even lead to an artificial pancreas one day. I ask that each of you join me in supporting the renewal of

the Special Diabetes Program next year so that the researchers can continue their work on a cure for our disease. My life depends on it. All our lives depend on it.

After I was diagnosed with type 1 diabetes, I wrote a song called *A Little Bit Longer* about dealing with diabetes. I'd like to submit a copy of the full song for the record, but I'd like to read one of the verses, which explains my outlook on life with diabetes.

*All this time goes by
Still no reason why
A little bit longer
And I'll be fine
Waitin' on a cure
But none of them are sure
A little bit longer
And I'll be fine*

Diabetes has changed my life. But I know that I've benefited from the government's investment in diabetes research. With the help of Congress, I'll only have to wait a little bit longer for a cure.

In the meantime, I've decided not to let diabetes slow me down. In just the last two months, my brothers and I launched a new TV show, released our third album and began a world concert tour. My approach to managing diabetes is to focus on simple wins -- little things I can do each day to achieve my goals. Over time, these everyday victories can make a big difference in your life -- just like every research advancement moves us along on our path to a cure. While on that path, I want to be a positive face for diabetes. I want to show kids with type 1 diabetes -- like all the kids sitting with me today -- that they can live with diabetes and still make their dreams come true.

Thank you for the opportunity to appear before you today, and thank you for your commitment to diabetes research. With your help, a little bit longer and we will all be fine.

"A Little Bit Longer"*Words and music by Nick Jonas*

Got the news today
 Doctor said I had to stay...
 A little bit longer and I'll be fine

When I thought it'd all been done
 When I thought it'd all been said
 A little bit longer and I'll be fine
 But you don't know what you got till it's gone
 And you don't know what it's like to feel so low
 And every time you smile or laugh you glow
 You don't even know (no, no)
 You don't even know

All this time goes by
 Still no reason why
 A little bit longer and I'll be fine

Waiting on a cure
 But none of them are sure
 A little bit longer and I'll be fine
 But you don't know what you got till it's gone
 And you don't know what it's like to feel so low
 And every time you smile or laugh you glow
 You don't even know (no, no)
 You don't even know (no, no)
 You don't even know (no, no)

(2,3,4!) Yeah!

And you don't know what you got till it's gone,
 And you don't know what it's like to feel so low
 And every time you smile you laugh you glow
 You don't even know! No!

So I'll wait till kingdom come
 All the highs and lows are gone
 A little bit longer and I'll be fine
 I'll be... fine

Testimony of**Hannah Ryder
Age 11, JDRF Children's Congress Delegate
Cumberland, ME**

Thank you for inviting me to testify. I'm Hannah Ryder and I'm from Cumberland, Maine. Three years ago my life changed forever when I was diagnosed with type 1 diabetes.

After being in the hospital for 4 days I hoped I was cured when I got to go home. But I soon figured out that this wasn't going to go away when my parents kept checking my blood sugar and giving me shots and measuring all of my food and everyone kept asking how I was feeling. Before I could go to school or play on a sports team or join a club we had to have meetings with the nurse, teachers, coaches, and anyone else that my parents thought could help keep me safe. Sometimes I don't like all the attention. But I know it is the attention that is going to keep me safe and it is attention like this that is going to help find a cure.

Diabetes not only affects me physically, it affects me emotionally as well. Sometimes I get mad; especially when people say things like that I'm lucky I missed a class because my blood sugar got too low. Or I get sad when people eat some of my favorite foods and say how good they are and I can't eat them because I have celiac, which a lot of people with type 1 diabetes have too. But I feel happy to have family and friends that help me out, like with my walk team, Hannah's Heroes.

This year my team did a bunch of fundraisers. We walked in the diabetes walk, had a yard sale with all of the toys and stuff that my sisters, brother and I don't use anymore, we sold lemonade at a parade and we had a bake sale. So far we have raised over \$5,000. I hope that we raised enough money with our team and I hope that Congress gives scientists the rest of the money that they need because I really don't want other kids to get diabetes.

In school this year I had to write a paper about what I would do if I was the President of the United States. One thing that I said I would do is have more walks to raise money to help find a cure for diseases like diabetes. My Mom said that a cure could be found soon and that doctors and scientists get the money that they need to work on it from walks and from Congress. So I'm doing my part and my family and friends are too.

Someday I hope to go to culinary school and open my own restaurant. I'm really hoping that there won't be a need to include carbohydrate counts on the menu!

Thank you Members of the Committee and particularly my Senator -- Senator Collins -- for helping in the fight to cure type 1 diabetes. Please keep up the good work and I will too.

J. Patrick Lacher III
Age 13, JDRF Children's Congress Delegate
South Glastonbury, CT

Senator Collins and Senator Lieberman, thank you for inviting me to testify today. My name is Patrick Lacher, I am 13 years old, and I have had juvenile diabetes for over three years.

My family and I decided to participate in the 2005 JDRF Walk to Cure Diabetes near my hometown of South Glastonbury, Connecticut, to support my dad who has had juvenile diabetes since he was nineteen. Little did I know that just two weeks later, I would be diagnosed with juvenile diabetes.

The next two days became the hardest of my life. I had a crash course in how to manage my diabetes. The last thing in the mind of a 9-year old is managing diabetes, but I had to accumulate all that knowledge practically overnight.

Even though I had watched my dad take care of his diabetes, I never realized how much of my day would be spent dealing with this disease. Though over time it has become easier, I can never cease to pay attention to diabetes and the daily challenges it brings. When I go to a friend's house, even for just a few hours, I have to have a plan. I have to know how active I'm going to be, what I'm going to eat and how both will affect me. I have to bring my blood sugar tester and other supplies, such as juice, snacks or glucose tablets so I'm always prepared for anything that can happen. My bag that carries all these items is like my right arm; I can never leave it behind. All this responsibility has been mine since I was a 9 year old.

There are many reasons why a cure is so important to me. The most important reason is that it would help not just me, but the millions of other people living with this disease. Just think - if we could improve the lives of millions of children and adults around the world, why wouldn't we? Curing diabetes would also save our country a lot of money since the cost of diabetic supplies and healthcare is enormous.

Another reason a cure is important to me is that it would make my life a whole lot easier. I would be able to sleep over at a friend's house without worrying about my blood sugar - not to mention how concerned my parents are when I'm away from home. I would be able to eat just as much as my friends do at birthday parties, and I would even be able to order dessert all the time like my little brother does. I can't wait for that day! I wouldn't have to carry a bag with me everywhere I go. I could be free.

Like Hannah, I am doing my part to help find a cure. With the support of my family and friends, I had over 100 walkers on my team in the 2008 Walk to Cure Diabetes. I've also spoken at the Walk and other JDRF functions to help people understand just how difficult it is to live with diabetes and how they can help.

From the day I was diagnosed, I always knew in my heart and believed passionately that we would cure this, and now, with all the advances I've seen in just the past three years, I know a cure is within our grasp. That is what keeps me vigilant every day so that my body is ready when a cure is found.

It is my hope that one day I can tell my children and grandchildren "Can you believe I had diabetes?" and they'll say, "What's diabetes?" And then I can tell them about how Congress and JDRF worked together to fund research for the cure.

Thank you for letting me share my story with you. I look forward to answering any questions you may have.

Testimony of

Asa Kelly
Age 16, JDRF Children's Congress Delegate
Charlotte, NC

Good morning. I am Asa Kelly. I am sixteen years old and come from Charlotte, North Carolina. Unlike my friends Hannah and Patrick, I am relatively new to the diabetes world. Just over a year ago on May 29, 2008, I went to the doctor because I was tired and thirsty all of the time. The doctor ran some tests, which showed my blood sugar was 362, about three times the normal. I was diagnosed with type 1 diabetes and was immediately admitted to the hospital.

At the hospital, I learned about the different types of insulin I would have to take until there is a cure. The Diabetes Educator taught me how to check my sugar, draw up insulin and give myself a shot. She also taught me the warning signs of high and low blood sugar and how to treat them. From then on I realized that I was in control of my health and that diabetes is very manageable – a little scary but manageable. At first when I was discharged I was scared about taking my insulin without someone constantly watching me, but I quickly learned.

Type 1 diabetes called for some major changes in my life. Testing blood sugar many times daily, counting carbohydrates, and checking ketones are just a few things that I go through. Finding a cure would relieve a lot of the stress it takes me and others to be healthy. I could focus on my schoolwork better and not have to step out of class to deal with a bout of hypoglycemia, which makes my teachers nervous.

A cure would also take a load off my parents. My parents trust the workers at my church, my friends who I hand out with, and my school to take care of me because they are not always present to do so.

Diabetes is a disability, but I am not disabled. Many people treat me different and feel like I have to be watched more often. But the truth is I am an active teenager, a diehard Carolina Panthers and UNC Tar Heel Fan, a scholar, and a good friend. One of my major goals in life is to go to UNC Chapel Hill to become a doctor. I am not going to let diabetes ruin my life. But I deep-down hope that I don't have to contend with the daily challenges for much longer.

I ask you as members of congress to support research issues to find a cure. Over three million Americans suffer from this disease and many of them are children and teens just like me and my friends here. A cure would give us freedom to carry on a normal life without taking a break to check our blood or have a snack. I want Congress to feel the urgency of this issue that it is a daily struggle, not just something you can take a break from doing. It is our lifestyle and all choices are made due to it.

Please continue to support research efforts to find a cure. A cure would truly change my life, my family's life and the lives of almost everyone in this room today. Thank you!

Testimony of**Ellen Gould****Mother of JDRF Children's Congress Delegates****Patrick, Samuel, Sarah and Oliver****Nashville, TN**

Good morning and thank you for the opportunity to speak to you today about my family's story of living with type 1 diabetes and our hope for a cure. I am Ellen Gould from Nashville, Tennessee and joining me are my children, Patrick who is 17, Sam who is 12, Sarah who is 10 and Oliver my five-year old. Yes, all four of them have type 1 diabetes and helping them manage their disease can be quite a challenge.

Our journey with type 1 diabetes started in July of 2004 when Patrick was diagnosed. My husband and I had noticed that he was rapidly losing weight, constantly thirsty and unusually tired. A trip to the pediatrician turned into a hospital stay with the required boot camp of sorts where we received a crash course on diabetes management. Patrick quickly learned how to manage his blood sugars but for an active teenager going through growth spurts, controlling his blood sugars was often a challenge. Today Patrick uses shots because the years of having diabetes left scar tissue where he would insert his infusion sets, so a pump isn't his best option.

Type 1 diabetes hit home again in January of 2006. Sarah began to show similar symptoms as Patrick had just two years earlier. We were devastated all over again. Fortunately her brother was and still is an excellent role model and we had a lot of experience with highs/lows and sick days under our belt so she was able to quickly adapt to the routine. Unlike her brother, she wears a pump which requires different prescriptions and management.

Shortly after Sarah's diagnosis, my husband and I learned about a clinical trial called TrialNet, which is funded by Special Diabetes Program. Researchers were looking for children whose siblings had type 1 to see if the children were at risk for developing type 1. We immediately enrolled our family. The initial screening required a blood test. My heart sank when Sam and Oliver's results came back positive for diabetes antibodies, meaning they were clearly at risk of developing full-blown type 1. Later tests indicated that Sam did have type 1, although he was not showing the classic symptoms at that time.

While we were dealing with helping a third child manage diabetes, at the age of 3, Oliver started taking a pill as part of the TrialNet study to see if the full onset of type 1 could be delayed by months or years. I don't know if he received a placebo or oral insulin, but last fall he too was diagnosed with type 1. He's a real trooper – he tests his own blood sugar and has learned to handle the injections.

So, as you can see, my husband and I have our hands full. While the kids are very responsible with their diabetes care, they still need oversight. We're constantly filling prescriptions, scheduling doctors' appointments, filling out forms for school and various activities, educating others and making sure our kids are safe. We have four other children at home so you can only imagine how busy our lives are.

Finding a cure means everything to my family and we are willing to be part of the solution even with juggling our already busy life. We are very active in our local JDRF chapter, and do all that we can to educate others and raise funds for a cure. We have participated in research studies and will continue to do so.

This isn't just about the Gould family. It is about the thousands of children who have to live with this terrible disease every day. It is about the thousands of children who are going to be diagnosed with the disease.

While insulin therapy helps us manage this disease, insulin is not a cure. On many occasions, we carefully measure blood sugars, count carbs and inject what we think is just the right amount of insulin. It is so discouraging when we measure just a few hours later and their blood sugar is way above normal range. How many high blood sugars are too many? When will long term complications with their eyes, kidneys or heart start to show? Sometimes we have to deal with the low blood sugars. Like the Saturday morning several months ago when we were awakened by Sam, collapsed in his room, incoherent, because of a dangerously low blood sugar. It took us 20 minutes to get him back to normal - but what happens the next time if we don't hear him? As their mother, I just want to reach out and make it better – but I can't. I can't cure this disease, I can't make it better for my kids. I need help.

We are so very grateful that so many Senators and Representatives have been doing their part by being strong and vocal supporters of the Special Diabetes Program. It is our hope that the Special Diabetes Program will continue well into the future so that clinical trials, such as TrialNet, can continue and lead to better treatments and eventually a cure for type 1 diabetes.

Thank you.

QUESTIONS SUBMITTED FOR THE RECORD
HEARING ON
"TYPE 1 DIABETES RESEARCH: REAL PROGRESS AND REAL HOPE
FOR A CURE"
COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
U.S. SENATE
JUNE 24, 2009

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NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Post-Hearing Questions for the Record
Submitted
From Senator Susan M. Collins

Question 1

Senator Collins: There currently are a number of new technologies on the horizon that hold great promise for people with diabetes. A few years ago, you testified at a hearing I chaired in the Committee to explore the potential for the development of an artificial pancreas, which would link two existing technologies – the insulin pump and continuous glucose monitors. Used together, these two technologies have the potential to dramatically improve blood glucose control, which would greatly improve the quality of diabetes care and prevent deadly and costly complications. Would you please give us an update about where we are with these technologies?

Dr. Rodgers: I am pleased to share with you the latest advances in our quest for an artificial pancreas. As you noted, a mechanical artificial pancreas will rely on two devices that are still being studied and improved—the insulin pump, which has been in use for many years, and the continuous glucose monitor (CGM), a more recent technology that allows patients and their physicians to “see” and respond to rapid changes in glucose levels on a near-constant basis. A third piece to an artificial pancreas is the complex computer programs, or algorithms, that are needed to “close the loop” between glucose sensing and appropriate insulin delivery. Since I testified before this Committee about the artificial pancreas in September 2006, we have seen tremendous progress on a variety of fronts. First, the Food and Drug Administration (FDA) has approved the use of CGM devices for children, an important step in making this diabetes management option more widely available for children and their families. Second, we have seen very encouraging results regarding the utility of CGM devices for improving health outcomes in diabetes patients. A recent study in children and adults with type 1 diabetes, funded by the Juvenile Diabetes Research Foundation (JDRF), that showed that patients 25 years of age or older who used CGMs (versus standard blood glucose monitors) showed significant improvement in glucose control as measured by hemoglobin A1c (HbA1c). Importantly, this improvement was observed without an increase in hypoglycemia often seen in intensively managed patients trying to achieve improved glucose control. In all ages, patients who used CGM at least six days a week had substantially improved HbA1c levels. Because improvement

was associated with the degree of use, we, with co-sponsorship by NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), have solicited research studies exploring methods to make these devices more acceptable to patients, which we anticipate funding later this year.

Even more encouragingly, we have seen the first human studies of a closed loop system in which CGM is combined with pump therapy. Experience is very preliminary, but so far in these very carefully conducted studies there have not been problems with hypoglycemia or other safety issues. We continue to advance research on component devices and algorithms. For example, NIDDK recently issued a Small Business Innovation Research program solicitation to support development of innovative technologies that can overcome current device limitations. Finally, to help speed movement of promising technologies into actual products and practice, in July 2008 we held a two-day scientific workshop on artificial pancreas technologies in partnership with the FDA and the JDRF. This meeting brought together leaders in the field from the U.S. and abroad. One of the workshop's goals was to identify obstacles along the pathway to regulatory approval of future artificial pancreas devices that need to be overcome by research. The outcomes of that meeting are helping to guide our research plans for the artificial pancreas.

The NIH, the FDA, the JDRF, academia, and industry have individually and collectively catalyzed very intensive and productive activity toward the development of an artificial pancreas. I am very hopeful that, with each step we take towards this goal, we will continue to see greater improvements in patient glucose control, reduced burden of care for children and adults, and improved long-term health outcomes.

Question 2

Senator Collins: In your written testimony, you point out that Type 1 diabetes is caused by a combination of genetic and environmental factors. Would you please elaborate a bit more on the research that is currently being conducted on the environmental factors that trigger onset of Type 1 diabetes in genetically-susceptible individuals; what kinds of environmental factors are you looking at?

Dr. Rodgers: Although genes associated with type 1 diabetes have been identified, much less is known about the environmental factors that increase a person's risk of developing the disease. Recent data that rates of type 1 diabetes are increasing by as much as 5% annually and that type 1 diabetes is developing sooner after birth than in the past points to the importance of uncovering environmental factors. These environmental factors could be dietary in nature, an environmental toxin, an infectious agent, or stress. It is imperative to uncover these environmental triggers, so we can develop approaches to prevent the disease, such as, for example, with a vaccine for an infectious agent or a dietary change. The NIDDK's Environmental Determinants of Diabetes in the Young (TEDDY) study is designed to do just that. TEDDY is following over 7,000 high-risk infants until they are 15 years of age, collecting dietary and health data and stool, blood, and other samples to identify a factor or factors that lead some genetically predisposed children to develop the disease while others do not. This study represents tremendous progress toward amassing the most data and samples on newborns at-risk for autoimmunity and type 1 diabetes anywhere in the world and is poised not only to uncover environmental triggers for type 1 diabetes, but also for celiac disease, which shares many risk genes with type 1 diabetes and which is also becoming more common over time.

Already, elimination of early exposure to one potential dietary trigger of type 1 diabetes--cow's milk-based formula--is being tested in a clinical trial. Over 2,000 newborns are enrolled in the NICHD's Trial to Reduce IDDM [insulin-dependent diabetes mellitus] in the Genetically at Risk (TRIGR). Half were weaned to the usual cow's milk-based formula and half to a special infant formula. Recruitment is completed and the children will be followed for 10 years to determine whether they are protected from the disease. Similarly, the NIDDK's Type 1 Diabetes TrialNet has completed a pilot study of omega-3 fatty acids given to pregnant women in their third trimester or added to the formula of at-risk newborns to determine if the children are protected from developing early markers of type 1 diabetes. If these studies are successful, dietary interventions could be a possible approach for preventing type 1 diabetes.

TEDDY, TrialNet, and TRIGR all receive funding from the Special Statutory Funding Program for Type 1 Diabetes Research.

Question 3

Senator Collins: On our second panel, we heard testimony from Mrs. Ellen Gould of Nashville, Tennessee. Four of the Gould family's eight children have Type 1 diabetes, which would seem to show that there is a strong genetic link. Yet Mrs. Gould says that -- apart from her children -- there is no history of Type 1 diabetes in either her husband's family or her own. What are some of the possible explanations for this situation?

Dr. Rodgers: Type 1 diabetes has a strong genetic component, which is why the disease sometimes runs in families and why it may affect more than one sibling. The efforts of the Type 1 Diabetes Genetics Consortium (T1DGC), a group of international researchers sponsored by the NIDDK, National Institute of Allergy and Infectious Diseases (NIAID), National Human Genome Research Institute (NHGRI), and JDRF, bring the total number of genes or gene regions that are involved in type 1 diabetes to 40 or more. The T1DGC receives funding from the Special Statutory Funding Program for Type 1 Diabetes Research. We have learned that it is not a single gene, but rather a combination of genes, that determines the risk of disease. In the case of the Goulds, the children may have inherited some risk genes from each parent. While having a family member with type 1 diabetes increases the risk by as much as 10-fold, the great majority of children affected with type 1 diabetes do not have a family member with the disease. This is one reason why it is so important to find the genes for type 1 diabetes. In the future we want to be able to prevent type 1 diabetes not only in children born to families with type 1 diabetes but also in those with no family history. Already our knowledge of the genetics of type 1 diabetes has allowed us to identify high-risk newborns with no family history of type 1 diabetes, so they can enroll in studies to find environmental factors contributing to diabetes risk. Even though the Gould family had no family history of type 1 diabetes, the children carried genes that made them susceptible to the disease, and something in their environment could have triggered disease onset.

It is critical to identify the culprit environmental trigger or triggers. The NIDDK is aiming to do just that through a study called The Environmental Determinants of Diabetes in the Young, or TEDDY. TEDDY has enrolled children from families with type 1 diabetes and those with no family history who were identified as being at high risk based on genetic testing. They will be

followed from birth to age 15 to pinpoint environmental triggers of type 1 diabetes. This long-term study, supported by the Special Statutory Funding Program for Type 1 Diabetes Research, could help revolutionize our ability to prevent disease. By identifying environmental triggers, we hope to find new ways to intervene before disease onset, preventing children from ever getting this terrible disease.

Question 4

Senator Collins: The Gould family is enrolled in the TrialNet clinical trial, which is funded by the Special Diabetes Program and is testing some promising new strategies to prevent Type 1 diabetes in those who are at an increased risk of the disease, and to slow or reverse its course in those recently diagnosed. How important is it for families, like the Goulds, to volunteer to participate in these kinds of clinical trials?

Dr. Rodgers: It is critically important. Simply put, without the participation and dedication of families like the Goulds, the NIH could not conduct clinical trials that are testing novel ways to prevent or reverse type 1 diabetes.

The NIH vigorously supports basic research to understand the underlying mechanisms of disease, which leads to the discovery of new therapeutic targets and strategies for intervention. However, the only way that therapies discovered in the laboratory can be translated to improve people's health is if we determine if they work in people through clinical trials. Type 1 Diabetes TrialNet is testing novel therapies for type 1 diabetes, but the only way we will know if these therapies are effective is if families like the Goulds participate in clinical trials to test them.

Importantly, research has shown that there is a benefit to families who participate in clinical trials that follow children at high risk for developing type 1 diabetes. Because children may not develop symptoms of type 1 diabetes until the blood sugar is very high, close follow-up in studies like TrialNet allows earlier detection and prompt treatment of type 1 diabetes. Sometimes the first hint that a child is ill may occur when he or she develops diabetic ketoacidosis, a life-threatening condition requiring hospitalization. In this condition, due to insufficient levels of insulin, glucose is unavailable as an energy source for the body; therefore, the blood sugar level rises, but also the body begins to break down fat for energy, which produces toxic acids known as ketones that build up in the body. Fewer children who participate in clinical research studies need to be hospitalized at disease onset, and death from ketoacidosis is markedly reduced. Thus, families also benefit from participating in these types of studies.

We are extremely grateful to the Gould family and to the thousands of other families participating in NIH-supported type 1 diabetes clinical trials and clinical research studies. Through their dedication and passion, we are moving closer toward preventing and curing type 1 diabetes.

