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DIABETES: IS SUFFICIENT FUNDING BEING ALLOCATED TO FIGHT THIS DISEASE?

HEARING

BEFORE THE

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

OF THE

COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

JUNE 26, 2001

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DIABETES: IS SUFFICIENT FUNDING BEING ALLOCATED TO FIGHT THIS DISEASE?

TUESDAY, JUNE 26, 2001

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10 a.m., in room SH–216, Hart Senate Office Building, Hon. Carl M. Levin, Chairman of the Subcommittee, presiding.

Members present: Senators Levin, Collins, Akaka, and Carnahan.

Staff present: Linda Gustitus, Chief Counsel and Staff Director; Mary D. Robertson, Chief Clerk; Laura Stuber, Counsel; Greg Heath, Intern; Christopher A. Ford, Minority Chief Counsel and Staff Director; Claire Barnard, Investigator to the Minority; Eileen Fisher, Investigator to the Minority; Barbara Cohoon, Staff Assistant to the Minority; Bob Smith, Intern; Nancy Langley (Senator Akaka); Felicia Knight and Priscilla Hanley (Senator Collins).

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. Good morning, everybody. Diabetes is a devastating disease which affects 16 million Americans, including over 600,000 people in my home State of Michigan. Today's hearing brings together about 200 children from around the country, some very well-known Americans with household names, and some of our top scientists, to help put a human face on what it is like to live with diabetes. This hearing was initiated by Senator Susan Collins of Maine, when she chaired this Subcommittee, and it is because of that initiative that we are all here today, I was delighted to join with her, my staff, and her staff, working closely with the Juvenile Diabetes Research Foundation, to make this hearing possible. I want to give the JDRF a special thank you. I give Senator Collins a special thank you, and turn it over to her for her opening statement.

OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. Thank you very much, Mr. Chairman, for your gracious remarks. I am very honored to serve as the co-chair of JDRF's 2001 Children's Congress. I very much appreciate the Chairman agreeing to chair this important hearing to examine the impact that juvenile diabetes has had on children and their families. The work that I have done with Senator Levin and others in the Senate on behalf of the 16 million Americans with diabetes has

been so rewarding, and it has been a privilege to work in partnership with the Juvenile Diabetes Research Foundation, whose commitment to finding a cure for this devastating disease is truly inspiring.

I also want to welcome our distinguished witnesses today, and in particular the 200 delegates to the Children's Congress, who have traveled to Washington from every State in the Nation, to tell Congress what it is 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 particularly want to welcome the two delegates from the State of Maine, 11-year-old Kate Farrell, from Limestone, Maine, and 13-year-old Andy Webber of Steep Falls.

As the founder and the co-chair of the Senate Diabetes Caucus, I have learned a great deal in the last 4 years about this serious disease, the difficulty and heartbreak that it causes for so many American families as they await a cure. Diabetes is a serious, lifelong condition that affects people of every race, age, and nationality.

It is the leading cause of kidney failure, blindness in adults, and amputations not related to injury. Moreover, diabetes costs our Nation more than $105 billion a year in health-related expenditures. More than 1 out of every 10 dollars spent on health care, and about 1 out of every 4 Medicare dollars, are spent to treat people with diabetes. The burden of diabetes falls particularly heavily on children and young adults with type 1, or juvenile diabetes.

Juvenile diabetes is the second most common chronic disease affecting children. Furthermore, it is one that they will never outgrow. The statistics alone are persuasive, but what really prompted me to begin working on diabetes was meeting with more and more people, like the children who are here today, whose lives have been changed forever by diabetes. It is so important that all of you have traveled to Washington today. You put the human face on all of the statistics and all of the studies, and you children will help those of us in Congress better understand and ultimately conquer this terrible disease.

I remember very well the first meeting that I had with families in Maine, whose children had diabetes, and I will never forget the words of a little boy who told me that his greatest wish was that, just once, he could take a day off from diabetes. Despite the fact that it might be his birthday or Christmas, or another important holiday, he could never take a day off from his disease. That conversation touched me so deeply, and that is when I knew that I had to get involved, that I had to help lead the fight for more research, so that we can prevent ultimately, better treat, and eventually cure this disease, and I know that we can do it.

There is good news for people with diabetes. We have all been encouraged by the ground-breaking research last year in which 12 individuals from Canada appear to have been cured of their diabetes through an experimental treatment involving the transplantation of islet cells. I believe that it is becoming increasingly clear that diabetes is a disease that will soon be cured, and will be cured in the near future if sufficient funding is made available. There is simply no investment that promises greater returns for America than its investment in biomedical research.

I have worked with Senator Levin and others in the Senate to double our investment in biomedical research over the next 5 years, so that we can accelerate our efforts to find better treatments, a means of prevention, and, ultimately, a cure for diseases like diabetes, and we are making progress. Our efforts have resulted in an increase in the budget for the National Institutes of Health, from $13.6 billion to $20.4 billion over the past 3 years.

Last year, I worked closely with JDRF to expand and increase funding for two special programs focused on diabetes research; one that focused on juvenile diabetes, the other on diabetes affecting our Native Americans. Our efforts, due in large part to the grassroots efforts of JDRF, were successful, and the funding for those two programs was increased for each program, from $30 million a year to $100 million a year.

There is no doubt in my mind that, in the past, diabetes research was under-funded. These funding increases will help make up for some of the past funding shortfalls, and it will help ensure that more of the scientific opportunities in diabetes research are funded. Our efforts have increased diabetes funding at the National Institute of Health (NIH) from $319 million in 1997, to more than $690 million this year. That is more than double, and you are the ones who have made this possible, through your tremendous advocacy. I am particularly looking forward today, not only to hearing the testimony of those whose lives have been affected by diabetes, but also from the medical researchers, who are out there on the front lines and whose research is so promising.

Again, Mr. Chairman, I want to thank you so much for convening this hearing. I look forward to hearing the testimony from all of our witnesses, and in particular I want to thank all the children who are here today. You are the reason that we are fighting so hard to get the money necessary to combat these disease. Thank you.

Senator LEVIN. Thank you.

[Applause.]

Thank you, Senator Collins, for your wonderful statement and for your leadership. I am particularly pleased that we have three Michigan delegates in the audience who have come to Washington today to participate in the Second Juvenile Diabetes Research Foundation Children's Congress. Rachel Dudley, who will be testifying before us today, is a 15-year-old from Southfield, Michigan; Philip Porado is a 13-year-old from Rockwood, Michigan; and Mali Korc is an 8-year-old from Grand Rapids. I thank them. I thank all you young folks who are here today, and from around the country, for coming here and telling your stories of what it is like to live with diabetes.

These children and our other witnesses will testify and attest to the extraordinary difficulties that are faced because of the treatment regimens that must be followed. They will also, though, attest to the wonderful spirit that allows them to continue to pursue things that children and adults like to do; children playing sports, acting in theaters, going to sleepovers with friends; adults, for all of the joys of family and other joys that we have in this life of ours. I thank you all for coming forward today.

The payoff of the research which Senator Collins made reference to is a truly human one that touches, I think, all of us, either in our families or in some loved one that we know or in some friend that we have. In my case, my particular case, I lost my best friend from law school, to diabetes. Research that is done for type 1, that we are going to focus on today, can also help the even larger number of people who have type 2 diabetes. One of the most important aspects of diabetes research is embryonic stem cell research, and we are going to hear today from leading scientists, like Dr. Hugh Auchincloss from the Harvard Medical School, that embryonic stem cell research holds the promise of a cure, not only for diabetes, but for a range of diseases. Almost 80 Nobel Laureates recently wrote to President Bush, urging that his administration allow embryonic stem cell research to be federally funded.

I hope that he will listen to those scientists. I hope that he will listen to colleagues of ours, such as Senator Orrin Hatch, and a former colleague of ours, former Senator Connie Mack, who, while taking a very different position than I do on the issue of whether abortion should be legal, nonetheless strongly support stem cell research, as I do. I hope that this administration will take to heart the eloquence of those statements that have now been given by those pro-life supporters who are staunch in their positions relative to abortion, but who also feel it is simply inhumane for us to deny the benefits of stem cell research to those who can be saved by that research.

So I want to again thank JDRF for assembling the panel of witnesses, and again thank Senator Collins for the initiative in scheduling this hearing, and I will now turn to Senator Akaka for an opening statement.

Thank you.

[Applause.]

OPENING STATEMENT OF SENATOR AKAKA

Senator AKAKA. Thank you very much, Senator Levin and Senator Collins. It is also good to have Senator Carnahan here with us this morning. I want you to know that I am very pleased to be here to welcome our distinguished guests. I also extend my aloha to all the young people in the audience, especially Ricky and Emalia from Hawaii, who are seated in front of me. I commend the Juvenile Diabetes Research Foundation International Children's Congress for its advocacy on behalf of children with juvenile diabetes.

The foundation will be pleased to know that I have received over 250 letters from constituents in my home State of Hawaii, urging me to support increased funding for diabetes research. To you and my constituents, I will continue to work to ensure adequate funding for research on diabetes. To my good friend, the distinguished Senator from Maine, I thank you for holding today's hearing, and understand you and Senator Breaux are co-chairs of the Children's Congress. I also know that you were one of the driving forces behind the issuance of the Diabetes Awareness Stamp that was unveiled this March by the Postal Service.

Mr. Chairman, I regret that I am unable to stay. However, I want to assure Emalia and Ricky that we will have an opportunity

to sit down and talk later today in my office. Again, I applaud the efforts of the Foundation and its supporters for the outstanding work they are doing to raise awareness of a disease that afflicts 120 million people worldwide. I do not have to tell our witnesses or this audience that insulin is only life-support, not a cure, and we need to do all we can to help those who are afflicted.

Again, thank you very much, Mr. Chairman and Senator Collins.

Senator LEVIN. Thank you very much, Senator Akaka, for your statement.

Senator Carnahan.

OPENING STATEMENT OF SENATOR CARNAHAN

Senator CARNAHAN. Thank you, Mr. Chairman. I want to begin by recognizing the leadership of Senator Collins in calling this hearing today. Today's hearing holds particular meaning for me, because my father suffered from diabetes. My family and I cared for my father in our home for the last 8 years of his life, and as each of the witnesses knows well, this disease does not just impact the individual, but the entire family. I learned to measure and administer his insulin dosage. I learned to recognize the onset of an insulin reaction, and I learned to prepare healthy, well-balanced meals. In fact, Grandpa's diet and exercise routines inspired the family to a healthier lifestyle, and you might be interested to know that he lived to be 86.

As a society, we must do more to deal with this disease, particularly when it affects children. I applaud the Juvenile Diabetes Research Foundation International for organizing the Children's Congress and bringing the national spotlight to the important need for research funding. Two exceptional children are representing Missouri at the Children's Congress, Patrick Fisher and Stephanie Patton, both of whom are from St. Louis. Patrick is a 13-year-old and has been dealing with diabetes since the age of 2½. Stephanie is a 6-year-old who was diagnosed with diabetes on her fifth birthday.

In the letters that they sent to me, both children described what it means to be a child living with diabetes. They have tremendous courage. Besides from the everyday pressures all kids face, children like Patrick and Stephanie must adhere to a different eating schedule. Pricked fingers and trips to the doctor's office are as much a part of their lives as Little League or visits to the zoo. Stephanie writes, "If there was a cure for diabetes, we could eat birthday cake at parties, sleep over at a friend's house and not be scared of low blood sugar."

Patrick describes how he has to stop and think about, and plan things everybody else takes for granted—school, sports, amusement parks, parties, meals, sleepovers, and vacations. The path to a cure is through research, and I strongly support keeping the National Institutes of Health on track, by doubling its funding over 5 years. I would like to recognize each of the witnesses on our first panel, Mary Tyler Moore, Kevin Kline, Jonathan Lipnicki, and James Lovell, for the leadership and dedication that they have shown for finding a cure for this disease. Kevin Kline is a native Missourian, and I thank him especially for being here.

I look forward to learning from all of these witnesses today about what the Federal Government is doing to meet its commitment to

diabetes research, and what more can be done. Thank you very much.

[Applause.]

Senator LEVIN. Our first panel needs no introduction. They are all known and loved by millions of Americans. Today, they will be talking about something different than movie roles or what it is like to be a celebrity. They are going to tell us about their personal experiences, either living with juvenile diabetes or helping family members or friends who have diabetes. We are going to hear their stories and we are going to learn more about what it is like to live with this disease, and what more we can do in terms of research and trying to finally win a victory over it.

First, the Subcommittee is going to hear from Mary Tyler Moore, one of America's favorite stars, who lives with juvenile diabetes and has for the past 30 years. Next, we will hear from Kevin Kline, who is sitting with his 13-year-old friend, Katie Zucker, who lives with diabetes. Then we will hear from Jonathan Lipnicki, who is 10 years old, accompanied by his friend, Tessa Wick, 10 years old, and has juvenile diabetes.

Finally, we are going to hear from Captain James Lovell, who will talk about his grown son who has juvenile diabetes. We are not going to be using a timing system today, as we usually do, because our witnesses all know about our time constraints. Usually, these high-tech lights go on to give you a little warning, but they will be quiet today. We just heard that it is important that we do more, so our first witness, Mary Tyler Moore.

TESTIMONY OF MARY TYLER MOORE,[1] INTERNATIONAL CHAIRMAN, JUVENILE DIABETES RESEARCH FOUNDATION, ACTRESS, LIVING WITH DIABETES, NEW YORK, NEW YORK

Ms. MOORE. Chairman Levin, Senator Collins, and Subcommittee Members. Two years ago, I joined the 100-child delegates to JDRF's first Children's Congress, to ask you and all your colleagues to "promise to remember them" and everyone, like me, with juvenile diabetes, when making decisions that would impact funding for diabetes research. I was very proud of them, then, for finding the courage to reflect on their fears, share their hope, and reach out to you, their representatives.

Once again, it is my privilege to Chair the Juvenile Diabetes Research Foundation Children's Congress, and this year we brought twice as many delegates—200 children with type 1 diabetes—because we have twice as much to do. First, we must thank you for keeping your promise. Second, we must challenge you, just as each of us here has challenged ourselves, to do more.

First things first, thank you. We are grateful that you remembered us, last year, by approving legislation that provides a historic increase for juvenile diabetes research funding at NIH, 240 million new dollars over 3 years. We are grateful, too, that Congress and the Bush Administration, even with other program growth being constrained, have recommitted themselves to the bipartisan effort to double funding for NIH, an action that surely will result in more research to find a cure for diabetes and its complications. So, again,

[1] The prepared statement of Ms. Moore appears in the Appendix on page 53.

for all of you that have done so much to keep your promise these past 2 years, we thank you.

[Applause.]

Of course, you have not been alone in the important efforts you have made. We never ask others to do something we have not asked ourselves to do, first. So, we have been and will remain your partners in this purpose. As evidence of our dedication to finding a cure, since the last Children's Congress, JDRF has more than doubled our own funding of diabetes research, from $55 million in 1999 to $120 million in 2001. We, too, made a promise to ourselves, these children, our loved ones. The stakes for us are very real and very personal.

Many of you know that I have had juvenile diabetes for more than 30 years, and like each of these children, I struggle, everyday, to do what happens naturally for nondiabetics. So, to most of you, metabolic balance is as automatic as breathing. To people with juvenile diabetes, like me, it requires 24–7, 365-vigilance, constant factoring and adjusting, frequent finger sticks every day to check blood sugar levels, and multiple daily insulin injections, just to stay alive.

Even with the greatest of care and closest of personal scrutiny, I find that I am often unable to achieve good balance with my sugars. They are dangerously low or frighteningly high; yes, dangerous and frightening, because, frankly, serious lows can lead to seizures, coma and death, and highs over the long-term result in life-limiting and life-shortening complications like blindness, amputation, kidney failure, heart disease, and stroke. Diabetes is an all too personal time bomb which can go off today, tomorrow, next year, or 10 years from now, a time bomb affecting millions, like me and the children here today.

This reality is made all too clear by the recent sudden death of a young friend, Danielle Alberti. Danielle was 31. She was an aspiring artist and the daughter of one of JDRF's most active and generous volunteer leaders. Though rapidly losing her vision due to diabetic retinopathy, Danielle stuck to her dream of being a painter, and was pursuing her career when she recently, like too many young adults with type 1 diabetes, developed kidney failure. People with diabetes-related kidney failure do not do well on dialysis, so kidney transplant was her only real option. With her doctor's guidance, she and her mother decided to return home together to Australia, where her chances for a transplant were greater. But Danielle did not survive the flight. She died at 30,000 feet, seeking comfort in her mother's arms. Her last words were, "Mom, hold me."

Chairman Levin, Senator Collins, and Subcommittee Members, we are here again because of our children, our loved ones with diabetes, look to us for comfort, for a way to stop their suffering, and we are determined to find it.

The good news today is that since the last Children's Congress, we have achieved a critical research milestone. In May 2000, at the University of Alberta in Edmonton, Canada, and subsequently elsewhere, researchers have successfully transplanted insulin-producing islet cells into men and women with juvenile diabetes, restoring normal blood sugars. This reproducible clinical success is

the first significant proof of a scientific principle that JDRF has long led in promoting: That insulin-producing cells can be transplanted into patients with even the most severe cases of juvenile diabetes, and normal blood sugars achieved without insulin injections. Quite simply, these findings are the first real clinical evidence that a cure is within our grasp.

There is a "however" to this positive news: As encouraging as these results are, and they are, the cure will remain out of reach unless we can overcome two very important obstacles:

One, this first group of islet-transplant patients must take potentially toxic immuno-suppressive drugs for the rest of their lives, and this makes islet transplantation, in its current stage of development, too risky for children and all but those whose lives are immediately threatened.

The other major obstacle is the lack of supply. The only current source for islets suitable for transplant are cadaver pancreases, and in the United States less than 2,000 such pancreases become available for transplantation each year. If tomorrow we had the perfect solution to immune tolerance, we would still only be able to offer islet transplantation to a tiny fraction of the millions of people with diabetes who might benefit. There is hope, though, that an alternative, inexhaustible supply of islet cells can be created. Hope that very much depends on actions you, your colleagues, and the administration choose to take. The hope I refer to resides in the potential of embryonic stem cells to be coaxed to develop into any cell in the body, including islet cells. This would solve the islet cell supply problem. Of course, the promise of stem cell research is not exclusive to patients with diabetes. Stem cell research could help as many as 100 million Americans who suffer from a variety of chronic illnesses, including Parkinson's disease, Alzheimer's, heart failure and cancer. So I am here today to urge each of you, your colleagues and the Bush Administration, to support Federal funding of stem cell research. This can be done immediately, by allowing NIH to act within its ethical guidelines it approved in August 2000.

I understand the support for this research raises concern among people of goodwill, each trying to do what is right based on their very personal religious and moral beliefs. I have not shied away from this personal soul-searching, nor has JDRF in its policy-making, nor should anyone. I have found comfort in my heartfelt view that embryonic stem cell research is truly life-affirming. It is a direct outcome of a young family making a choice, without coercion or compensation, to donate a fertilized egg, not used for in vitro fertilization, for research. An egg that otherwise would have been discarded. Because of the great potential of stem cell research, donating unused, fertilized eggs is much like the life-giving choice a mother, whose child has died tragically in an automobile accident, makes when donating his organs to save another mother's child. It is the true pinnacle of charity to give life to another. Federal support for stem cell research is an extension of this affirmation of life, and is the best way to insure it is undertaken with the highest of ethical standards.

Chairman Levin, Senator Collins, and Subcommittee Members, to borrow a phrase, "diabetes ain't bean bag." My 30-plus years of diabetes has led to visual impairment, painful neuropathy, the

threat of limb loss from poorly-healing foot wounds, and peripheral vascular disease, which has started to limit how far I can walk. I push through all of this, just as each of the children here, today, push through the burdens imposed by diabetes, because we are a determined lot. None of us is willing to be deterred. We all share the firm conviction that, through our efforts, and the help of friends—like the Members of this Subcommittee—we will find a way to stop the suffering, the pain, and restore balance.

Please listen to the stories of the children here today and promise to remember all of us who suffer from juvenile diabetes, when you make decisions that will impact research. The cure is truly within our grasp. Together, we will find it. Thank you.

Senator LEVIN. Thank you so much, Ms. Moore.

Kevin Kline is a wonderful actor who has appeared in so many movies, including one in which he played a President. It was a movie called "Dave," and we do not often have a President appearing before a Subcommittee. So, Mr. President, it is your turn.

TESTIMONY OF KEVIN KLINE,[1] BOARD MEMBER, JUVENILE DIABETES RESEARCH FOUNDATION, ACTOR, NEW YORK, NEW YORK, ACCOMPANIED BY KATIE ZUCKER, AGE 13

Mr. KLINE. I think I will defer to my friend, Katie Zucker, who wants to say a couple of words by way of introduction, I believe.

Ms. ZUCKER. Hi. I am Katie Zucker. I am 13 years old and I have juvenile diabetes. I am proud to be here to meet all of you, along with my friend Kevin Kline, who is also a good friend to all of us with diabetes. Kevin has been a great JDRF volunteer, and today he is here to ask that you promise to remember us.

Mr. KLINE. Thank you, Katie.

Mr. Chairman and Members of the Subcommittee, thank you for this opportunity to speak on behalf of the Juvenile Diabetes Research Foundation and for all children with juvenile diabetes. I am honored to share the floor with these 200 extraordinary young people. Each year, approximately 30,000 Americans are diagnosed with juvenile diabetes. Over 13,000 of them are children, stricken at random, whether there is a genetic predisposition or not. No child is immune. That is 35 children every day, more than one every hour, stricken suddenly, made insulin-dependent for life, and suddenly facing the constant threat of this disease's devastating complications.

In 1999, I joined the Board of Directors of the New York chapter of JDRF, and in July 2000, I was elected to the position of Vice President of Public Outreach and Education. Through my work with JDRF, I have met countless children who have juvenile diabetes and have witnessed firsthand the devastating impact of this disease on them and their families. Children like my friend Katie Zucker. Katie and others you will hear from today are of an age where they can speak eloquently about their experience with diabetes. So I would just like to, if I may, say a few words on behalf of the children who are too young to comprehend fully their medical situation, much less be articulate about their feelings on this subject, and perhaps in the process I can also set right some popular

[1] The prepared statement of Mr. Kline appears in the Appendix on page 56.

misconceptions about how diabetes is managed with young children.

Diabetes can strike at any age, from infancy on—not everyone knows this. For these young children, whose parents become their doctors and nurses, a typical day is as follows: They will have their fingers pricked as many as 10 or 15 times throughout the day, to measure their fluctuating blood glucose levels. Then there are the injections of insulin; a shot in the morning, another at lunch, another one possibly at afternoon snack, then definitely another one at dinner, sometimes at evening snack, again at bedtime, and, if necessary, another in the middle of the night.

Each meal and snack involves exact measurements of food, based on grams of carbohydrates, fat and protein, calculated according to the amount and type of physical activity which the parent anticipates the child to be performing. Throughout these days and nights, there is an unwavering sense of dread which settles over the parents, who fear that in spite of their vigilance, their child could still have a low blood sugar, which could lead to convulsions or diabetic coma, in the worst case, or that high blood sugar levels could be damaging their child's liver, kidneys, or causing other complications, precipitating amputation, stroke, blindness, and heart attack. As Senator Collins pointed out earlier, there are no days off with diabetes.

Throughout our history, the marvelous men and women of medical science have discovered cures for what had seemed to be incurable diseases. Today, finally, the cure for diabetes is within their reach. It is within our reach. I urge you to do all that you can to speed along the necessary research for this cure, so that these brave, all-too-patient, heroic children can open their arms and embrace the long, healthy life which they deserve. Thank you.

Senator LEVIN. Jonathan Lipnicki, please go ahead. We know you as an actor, and now you are going to be a witness in front of our Subcommittee, and so it is your turn.

TESTIMONY OF JONATHAN LIPNICKI,[1] ACTOR, FRIEND OF A CHILD WITH DIABETES, NEW YORK, NEW YORK, ACCOMPANIED BY TESSA WICK, AGE 10

Mr. LIPNICKI. Mr. Chairman and Members of the Subcommittee, thank you for letting me join my friend, Tessa Wick, and all 200 of the Children's Congress delegates today to talk about juvenile diabetes. Tessa and I have been friends since we met on the set of my movie, "Stuart Little," a few years ago. Tessa and I are both 10 years old, and in a lot of ways we are very much alike. We both go to school. We love movies, and like to play sports and games. We have good friends and loving families. We both have big dreams for our futures, but Tessa happens to be different from me in one important way.

In January 1999, a doctor told her she had juvenile diabetes and a lot of things in her life would have to change, just so she could stay alive. Every day, she would have to prick her finger four or five times to check her blood glucose levels. Every day, she would have to be given two or three injections of insulin. Tessa was diag-

[1] The prepared statement of Mr. Lipnicki appears in the Appendix on page 59.

nosed with diabetes about 2½ years ago, so that means she has already had to take more than 2,738 insulin shots, and she would prick her finger to check her sugar level about 4,563 times, and even that does not make her healthy. If Tessa's blood sugar goes too low, she knows she has to take sugar right away, because if she waits even a few minutes too long, she could have a seizure or maybe even go into a coma, and she knows that high blood sugar over a long period of time can damage the organs inside her body. For 2½ years, Tessa has not been able to have a normal childhood. It has been weighed down by all the burdens of juvenile diabetes.

Everywhere she goes, she has to bring a blood sugar testing kit with her, and also shots and sugar, just in case she goes low. Like all kids of our age, Tessa wants to be independent and go to sleepovers and on class trips without her parents, but both Tessa and her parents worry when she is away from home. When Tessa goes to sleep at night, she is afraid her blood sugar could drop too low in her sleep, and she will have a seizure. Many nights, she asks her mom to wake her up at 2 a.m. to check her blood sugar, just in case.

When I am with Tessa, sometimes I forget she has juvenile diabetes. It is easy to do. She looks and acts like any other kid my age, but she can never forget that she has juvenile diabetes. If she does, she would be risking her life. I am here today because I do not want Tessa or any of the 200 kids in this room to live a life with diabetes for the rest of their lives like this. It is not fair. They do not have the same chance as other kids to live long, healthy lives and achieve all their dreams.

Recently, I was happy to have an opportunity to meet President Bush. I was so glad to hear that he and Mrs. Bush are the honorary co-chairs of the Children's Congress this year. I hope they will also promise to remember all the children with juvenile diabetes when they make decisions that will affect research. I know that I am lucky I do not have this terrible disease, but I also know that anyone can get juvenile diabetes, even me, or your kids or grandkids.

Yesterday, researchers told me that, with enough funding, a cure for juvenile diabetes is possible. Won't you please help Tessa and the children with juvenile diabetes? Please do everything you can to help find a cure.

I would like to ask my friend Tessa to conclude this testimony with a few of her words.

Ms. WICK. Hi. A few years ago, when I first got diabetes, I was embarrassed and wanted to keep it a secret. But soon, I realized that the only way to survive this disease is to be part of a cure. So my sisters and I tried to raise money thinking that we would send it to JDRF and the scientists would find a cure. But then I read that some politicians were trying to stop embryonic stem cell research, the kind of research that is our best chance for a cure. So please ask yourself: Is the life of one child with diabetes, like me or any of the other kids here, less important than a cell the size of a dot? We are scared because we are in trouble. It is hard to have diabetes, and we are scared to face the future. Won't you please help us?

Thank you, Senator Collins and Senator Hatch, who are already trying so hard to help. So please promise to remember us.

[Applause.]

Senator LEVIN. Jim Lovell is a former astronaut. He was the commander of Apollo 13, and the kind of bravery, kids, that this astronaut showed on that mission is a different kind of bravery from the bravery that you show every day, but it is something that you will read about in the history books, if you have not already done so. Jim Lovell also was famous because he was in a movie that most of us saw, and a guy named Tom Hanks played the role of Jim Lovell, and I am not sure who is more famous, but we have the real McCoy here today anyway in Jim Lovell.

Jim, welcome.

TESTIMONY OF CAPTAIN JAMES LOVELL,[1] FORMER NASA ASTRONAUT, SON WITH DIABETES, LAKE FOREST, ILLINOIS

Captain LOVELL. Thank you, Chairman Levin and Members of the Subcommittee for the opportunity to speak to you today. Unfortunately, Tom Hanks could not be here. [Laughter.]

In my professional life, though, I am president of Lovell Communications, a business devoted to disseminating information about the United States space program, and, as the Senator mentioned, you probably know me as a former member of the space program and commander of the Apollo 13 mission, and Chairman Levin also mentioned was the fact that I am the father of a grown son, Jeff, with juvenile diabetes.

When my son called, at the age of 26, to tell me that he had been diagnosed with juvenile diabetes, he began by saying, "Houston, we have a problem." At the time, I thought it ironic that he would draw a parallel between my career at NASA, especially the Apollo 13 mission, and his diagnoses with diabetes. My training at NASA gave me the confidence in my ability to overcome any obstacles that stood before my goals. When an explosion depleted our oxygen supply, forcing us to abort our voyage to the Moon and improvise a plan to get home, I never doubted that we would be successful, despite the seeming impossibility of our task.

With the combined ingenuity, the teamwork and the commitment of my crew and the team at Mission Control, we were able to successfully convert our lunar module into an effective lifeboat, which allowed us to conserve enough electrical power and water to get us safely home. But when my son was diagnosed with juvenile diabetes, the skills that I had developed at NASA suddenly seemed meaningless. I felt that I had nothing to fight this disease that was threatening my son's life. I was well aware that insulin was not a cure for diabetes, and that even if my son did everything in his power to maintain tight control of his blood glucose levels, he could still be faced with the devastating complications of this disease.

However, after joining the Juvenile Diabetes Research Foundation, I became convinced that we do have the ability to find a cure for diabetes, and that the skills that were developed at NASA, such as teamwork and ingenuity and commitment, will help us achieve this goal. The mission of the Juvenile Diabetes Research Founda-

[1] The prepared statement of Captain Lovell appears in the Appendix on page 61.

tion is constant, to find a cure for diabetes and its complications through research and support of that research. With the help of the Federal Government, private individuals willing to give their time and resources to the cause, and researchers around the world who will their careers to juvenile diabetes research, we can bring a cure in our lifetime for this disease.

I now serve as a member of JDRF's International Board of Directors, and I am pleased to report that this year, JDRF will spend over $150 million on juvenile diabetes research, an increase of $30 million from the year 2000, and up to $95 million from 1999. However, I am well aware that JDRF's budget from private donations cannot compare to the vast resources of the Federal Government. I am aware of the recent increase in juvenile diabetes research funding and the initiative to double the budget of NIH, and I really want to thank you for your commitment to this effort.

However, we must continue to increase funding for juvenile diabetes research in order to capitalize on the opportunities that have recently been presented by the breakthrough trial in Edmonton, Canada, that Mary had mentioned. The justification for increases in diabetes research has been provided by the report of the Congressionally-mandated Diabetes Research Working Group, which was released in 1999. This report, drafted by a national panel of diabetes research experts, puts forward an accelerated and expanded diabetes research program at NIH.

The DRWG report identifies numerous major opportunities not being pursued because of the lack of funds and focus. They include potential high-impact initiatives in the genetics of diabetes, the biology of the beta cell, the treatment of diabetes-related eye disease, kidney disease, nerve disease, heart disease, and the development of a vaccine for the prevention of type 1 diabetes. All of these initiatives were identified as high priorities by the DRWG and are of particular importance to the children with type 1 diabetes.

The panel recommended a Fiscal Year 2000 appropriation of $827 million for diabetes research, and a Fiscal Year 2001 appropriation of $1.07 billion, and a fiscal year 2002 appropriation of $1.3 billion. Despite the recent increases in medical research funding and juvenile diabetes research funding, diabetic research at the National Institutes of Health only came to $690 million in fiscal year 2001, $384 million short of the recommended funding level. It is evident just by looking at the children here today that the personal impact of juvenile diabetes is devastating.

The economic impact of this disease on our country is just as staggering. Diabetes accounts for more than $105 billion of health care cost annually in the United States, and approximately 25 percent of all Medicare expenditures. The numbers speak for themselves. Diabetes research is a worthwhile investment. Mr. Chairman, I know that our great Nation can solve any problem if it puts its mind to it. I ask you to promise to remember these children by supporting a cure for diabetes research.

Look at the children before you. I think you will agree that failure is not an option. Thank you.

Senator LEVIN. Thank you very much.

Senator Collins.

Senator COLLINS. Thank you very much, Mr. Chairman. I want to thank our witnesses for their heartfelt and persuasive testimony. Each of you helped us understand the human dimension of juvenile diabetes. Three of you, at least—Jonathan, Tessa and Ms. Moore—mentioned the importance of embryonic stem cell research, and I just want you to know that I wholeheartedly agree with your comments, and on June 11, 2001,[1] I wrote to the President to urge him to make the right decision in this area, and I would ask that my letter be included in the record.

Senator COLLINS. Another issue, Mr. Chairman—we have had a lot of success in increasing research going to diabetes in the last few years, but I was concerned to make sure that the additional dollars supplement, rather than supplant, other diabetes research resources. JDRF has done a wonderful job of private fund-raising, but the money that we provide at the Federal level should be in addition to that. It should not replace that in any way, or it should make sure that it supplements that.

So I wrote to the Secretary of HHS, Tommy Thompson,[2] who also is a tremendous advocate for families with diabetes, to ask him about that very issue, and he has written me back a letter assuring me that the additional resources will be used to fund new and ongoing projects,[3] that they will not be used to displace dollars already appropriated. So I would ask that be put in the record, as well.

Senator LEVIN. It will be.

Senator COLLINS. I just have one question for Ms. Moore, and that is you have lived with juvenile diabetes, as you mentioned, for 30 years. You have had a very demanding career. You have talked about how you have pushed through the medical setbacks that you have had to deal with. Do you have any advice for the children who are here today as they cope with such a strict regime in their attempt to remain healthy and the restrictions on some of their activities? Do you have any advice for them?

Ms. MOORE. When I was diagnosed with diabetes, I was an adult. So my formative years had gone into the past tense, but I think you youngsters, because of the awareness that you have had to develop, will become stronger, better human beings, because you have been there. You have been there when it is tough and when you think you want to just give up and run away, close your eyes, get under the covers. You know you cannot do that, and it is one of the best lessons you can ever learn in life. So just remember, each one of you, you are champions and you are always going to be champs.

Senator COLLINS. Thank you, Mr. Chairman.

Senator LEVIN. Let me thank the panel for coming forward. Your testimony is going to be very helpful in a number of ways, hopefully in terms of additional funding, which we are going to push very hard for, in terms of stem cell research, which we hope the President will reach the right conclusion, which will advance the

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[1] The letter to President Bush, from Senator Collins, dated June 11, 2001, appears in the Appendix on page 38.

[2] The letter to Tommy G. Thompson, from Senator Collins and Senator Breaux, dated February 21, 2001, appears in the Appendix on page 39.

[3] The letter from Tommy G. Thompson, with attachments, to Senator Collins, dated May 24, 2001, appears in the Appendix on page 40.

cause of humanity. We have got some wonderful support coming forward for stem cell research, and we hope that that is persuasive to the President, that your being here and your testimony today will also help in that cause, as well.

Tessa, you have got a wonderful friend in Jonathan. We hope that all of us can be as good a friend to diabetes research as Jonathan has been to you. We thank each and every one of you for your willingness to come forward, to share your stories and to share your thoughts with us, and what we will do now is move to our second panel.

We will have a vote in about half-an-hour, and so what we will do is we will ask our second panel to try to get all their testimony in during that period, and then we will take a recess at that time. I have a hunch that some of us here may need a recess even before that time, and if that is true, just feel free to get up and leave in the middle. We are very informal here.

Ms. Moore, you indicated we have twice the size of turnout here as we did in the first meeting of this type. If we keep going at this rate, we are going to have to double the size of this room for the next Congress, but it is because of your presence. Thank you all.

[Applause.]

You are all excused, and we will move to our second panel. We will call now on Dr. Allen Spiegel, Dr. Hugh Auchincloss, James Robbins, and Greg Brenneman. If they would come forward, our second panel. This will be the third-inning stretch. We will have a sixth-inning stretch in about half-an-hour, where we will really take a 10-minute recess. Let us proceed now to our second panel. This panel consists of two scientific experts and two fathers who have been touched by diabetes. First, the Subcommittee will hear from Dr. Allen Spiegel, who is the Director of the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health; and then, after Dr. Spiegel, we will hear from Dr. Hugh Auchincloss, who is a professor of surgery at Massachusetts General Hospital and the Harvard Medical School. We will then hear testimony from James Robbins, who is the President and CEO of Cox Communications and a father of a daughter who has diabetes. Finally, we will hear from Greg Brenneman, the former Chief Operating Officer of Continental Airlines and the father of a son who has diabetes.

So we will start with you, Dr. Spiegel.

Again, we are not going to use these lights, but we will need you to keep your statements as short as possible, less than 10 minutes in any event, please, because we now have a double problem here. Senator Collins reminds me we may have two votes at around 11:30, which means that our recess will have to be a little longer than 10 minutes. We will try to hold it to 15 minutes, but if you could keep those statements short, we will make all your statements, if longer than that, part of the record.

Dr. Spiegel.

TESTIMONY OF ALLEN M. SPIEGEL,[1] M.D., DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MARYLAND

Dr. SPIEGEL. Chairman Levin and Senator Collins, as Director of the National Institute of Diabetes and Digestive and Kidney Diseases, NIDDK, I am grateful for the opportunity to testify at this hearing on juvenile diabetes. Having spoken with many of the children yesterday at a town hall meeting held by the Juvenile Diabetes Research Foundation, I know that the Subcommittee will be hearing important testimony today directly from the kids whose lives are affected daily by diabetes.

For this reason, I would like to outline just briefly what we have learned about type 1 diabetes, the research goals we hope to pursue, and an example of the progress we are making. More complete details are in the written testimony I have provided to the Subcommittee. Approximately one million Americans have type 1 diabetes, which we now know is a slowly progressive, autoimmune illness. What do I mean by autoimmune? I mean that the body's own immune defense system attacks and destroys the beta cells in the pancreatic islets that make insulin, the hormone lacking in type 1 diabetes.

As shown on the first chart,[2] we are all born with a normal number of islets, but in some of us there is a genetic susceptibility to development of type 1 diabetes. In such individuals, some inciting event or trigger starts the immune system's attack on the islets, beginning a slow, progressive downslope and loss of the beta cells that make insulin. When this loss reaches a low enough point, diabetes, with abnormally high blood sugars, develops. It may appear to parents that their child has abruptly developed the disease, but, in fact, the process of islet loss has often been progressing for years.

Even after onset of diabetes, there are some islets left, but further loss can lead to brittle diabetes, a state in which the blood sugar is even more difficult to manage, with wide swings from high to low. We now know that the high blood sugar itself leads to the complications of diabetes affecting the kidneys, the eyes, the nerves, and the heart. With broad consultation with scientists, patients and their families, and organizations such as the JDRF, we have framed a strategic plan with six goals, as indicated on the second chart,[3] to be pursued in diabetes research.

Our first goal is to identify the genetic and environmental causes of type 1 diabetes, so that we can identify those at high risk of developing the disease and so that we can find molecular and environmental targets for prevention.

Second, we seek to prevent or, in the case of recent onset, even reverse type 1 diabetes. Basic research in immunology is leading to new insights into prevention. We hope to test new, innovative measures in a nationwide, type 1 diabetes clinical trial network, or TrialNet.

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[1] The prepared statement of Dr. Spiegel with attachments appears in the Appendix on page 63.

[2] The chart referred to appears in the Appendix on page 70.

[3] The chart referred to appears in the Appendix on page 71.

Another important goal is to prevent or reduce hypoglycemia, the low blood sugar that complicates attempts to achieve tight blood sugar control.

Likewise, we want to prevent or reduce the complications by developing better ways to identify those at risk and developing better molecular targets for drug therapies.

To attract new talent to type 1 diabetes research, it is critical that we ensure that we have sufficient numbers of researchers to bring the benefits of the Human Genome Project and other technological developments to patients.

Last, and perhaps most important, is to develop a real cure, such as cell replacement therapy, because insulin is certainly not a cure.

Let me elaborate on cell therapy. After years of frustration and failure, researchers in Edmonton, Canada, building on years of research, have developed methods for harvesting islets and transplanting them into patients with a drug treatment protocol that has enabled the majority to become insulin-independent. NIH and JDRF are supporting expanded trials of islet transplantation to replicate and build upon the Edmonton advance.

Let me describe an example from the Transplantation and Autoimmunity Branch NIDDK opened in 1999 at the National Institutes of Health Clinical Center. The next chart[1] shows results from the first of five patients in which Dr. David Harlan has performed islet transplants. The patient is a 57-year-old woman who had had type 1 diabetes for over 50 years, a brittle diabetic. Note her wildly abnormal, shown in white, and fasting blood sugars, and her total insulin dose daily, shown in black. Notice that, after the first islet transplant, the insulin requirement is already reduced. After the second transplant, she has become insulin-free, insulin-independent, and note the normalization of her blood sugars.

Since she has been off insulin for only 4 months at this point, it is too early to say she is cured, but the results are extremely encouraging. Final poster board shows schematically the islet transplant procedure. Islets, which comprise only 5 percent of the normal pancreas, are harvested from the donor cadaveric pancreas and infused into a vein directly into the liver, where they can produce and secrete insulin to normalize the blood sugar. Up until now, this experimental procedure has been performed only in adults with type 1 diabetes. When will we be able to do this in children suffering from the disease, such as the ones in this room?

There are two major hurdles to overcome. Currently, patients receiving islet transplants must receive medication daily, perhaps for the rest of their lives, to block the transplant rejection. We need to develop ways to block rejection and the autoimmunity that caused the diabetes in the first place—ways that are safe and effective for use in children. We also need to develop alternative inlet supplies, since the few thousand donor pancreases available each year will never be sufficient for the hundreds of thousands of Americans with type 1 diabetes. We at NIH are investing heavily in research to overcome both of these barriers. I can elaborate on this in the question period, and I believe Dr. Auchincloss will elaborate on these points in his testimony.

[1] The chart referred to appears in the Appendix on page 72.

On behalf of the NIDDK and the other institutes and centers of the National Institutes of Health, I hope I have been able to convey to this Subcommittee and to the children in the room today that we have a vigorous research agenda to conquer diabetes and its complications. We are eager to pursue the many scientific opportunities made possible by the biotechnology revolution. We are inspired by the dedicated efforts of the patients and their families, by organizations such as the JDRF, and by the Diabetes Caucus, which you, Senator Collins, co-chair. We are grateful for congressional interest and support, which has enabled us to undertake many of the research initiatives I have described to you.

It is a privilege for me to be able to share the vigor and promise of research in diabetes with this Subcommittee and with the children and parents affected by diabetes, who are always on our minds and in our hearts. Thank you for your attention.

Senator LEVIN. Thank you, Dr. Spiegel.

Dr. Auchincloss.

TESTIMONY OF HUGH AUCHINCLOSS, JR.,[1] M.D., PROFESSOR OF SURGERY, MASSACHUSETTS GENERAL HOSPITAL AND HARVARD MEDICAL SCHOOL, BOSTON, MASSACHUSETTS

Dr. AUCHINCLOSS. Thank you, Chairman Levin and Senator Collins. I appreciate the opportunity to speak before you. My name is Hugh Auchincloss. I am a professor of surgery and a transplant surgeon at Harvard. I am also the director of the Juvenile Diabetes Research Foundation's Center for Islet Transplantation at Harvard Medical School, and finally, for the last 3 years, I have served as the Chairman of the Medical Science Review Committee of the Juvenile Diabetes Research Foundation. That sounds like a lot of titles, but I have to tell you I feel very insignificant compared to the very eloquent witnesses you have already heard from and some of the people that you are going to hear from shortly.

Nonetheless, I do want to speak today about the extraordinary advances that have occurred recently in the effort to cure type 1 diabetes. I also want to talk about the very significant problems that remain to be overcome, and about the equally significant opportunities that are available today to solve those problems. First, let me talk about what has been accomplished. Members of this Subcommittee have already heard about the success of the Edmonton protocol for islet cell transplantation. This protocol uses a combination of immunosuppressive medicines, islet cell isolation procedures and techniques for their transportation that has led to the elimination of insulin therapy for the vast majority of patients who have undergone the full procedure.

The success of this protocol has changed the field of islet transplantation dramatically. Two years ago, the results of islet transplantation worldwide were dismal. Today, we now expect that most patients who undergo the procedure will truly be able to say that they used to have diabetes. As dramatic as this accomplishment is, much more needs to be done before we can turn to the children in this room and say that we have cured diabetes. In the first place, the patients who have undergone the Edmonton protocol or other

[1] The prepared statement of Dr. Auchincloss appears in the Appendix on page 74.

variations of this approach have actually given up one disease, their diabetes, for another one, the requirement for lifelong immunosuppression.

All of these patients will need to take a combination of several medicines which prevent rejection of their islets, but which also diminish their bodies' capacity to fight infections and the development of cancers. They will need to take these medicines for the rest of their lives if they wish to stay off of insulin. This trade-off has been justified for a very small number of adult patients who can truly no longer tolerate their insulin therapy, and for patients who already need kidney transplants and thus need immunosuppressive medicines, anyway. However, it is not a reasonable trade-off for young children.

Therefore, we need to accomplish what has been referred to as tolerance induction, the reprogramming of the immune system so that it treats the transplanted tissues from a donor as if they were a natural part of the recipient's body. The Immune Tolerance Network, sponsored jointly by NIH and the Juvenile Diabetes Research Foundation, is working to initiate clinical trials to accomplish exactly this goal. However, there is still no clear roadmap for how this can be done, and much more research will be needed to bring this effort to fruition.

The second remaining problem is that children who have type 1 diabetes face an additional immunologic problem when we attempt to replace their islets. Not only will transplanted islets be subject to rejection because they come from a different donor, they will also be subject to immunologic destruction because they are islets and thus the target of the original autoimmune condition that caused their disease in the first place. Therefore, even if we learn to accomplish transplantation tolerance and perform islet replacement without immunosuppressive drugs, we still need to learn how to reprogram the immune system so that these children no longer have autoimmunity.

The third remaining problem is that even if we could transplant islets without rejection and without recurrent autoimmunity, we do not have remotely enough islets to go around. Even if we used every available cadaver donor pancreas for islet transplantation, we would have only enough islets to cure 0.1 percent of all people with type 1 diabetes. That is the number that I want people to remember, 0.1 percent of people with type 1 diabetes.

Despite all the efforts we are making to increase the number of donors, to improve the yield of islet isolation, we still have no hope of finding enough islets from human cadaver donors to cure this disease. There are at least seven different ways in which more islets might be obtained, and scientists are exploring each and every one of them. First, we might learn to transplant islets from animal donors. This is called xenotransplantation. We have been trying this approach around the world and have so far been miserably unsuccessful.

Second, we might learn to genetically engineer other types of cells so that they produce insulin in a regulated fashion. For example, liver cells, which are abundant, might be made to secrete insulin on demand.

Third, we might develop immortalized lines of insulin-producing cells that could proliferate indefinitely. We would need, however, to learn how to shut off this proliferation reliably after transplantation to prevent what would otherwise be the transplantation of a cancer.

Fourth, we might learn to grow cultures of islets so we could increase the yield from each cadaver donor, but so far, whenever we have gotten islets to grow, they have also stopped producing insulin.

Fifth, we might learn to produce new islets from their precursors within the pancreas. So far, however, we are not even sure where these precursors are located, and our best efforts to produce new islets from them have yielded only droplets, not the bushels that we require.

Sixth, we might learn to produce islets from so-called adult stem cells. These are cells that have been found in the bone marrow, cord blood, and other sites that appear to be capable of differentiating into many different human tissues. However, despite some recent advances, scientists have been unable to turn these cells into insulin-producing cells, even after 30 years of work.

Finally, seventh, we might learn to differentiate embryonic stem cells into insulin-producing cells. We know that these ES-cell lines can be made to proliferate to produce almost unlimited quantities of offspring. In addition, during the past year, scientists have succeeded in guiding cells of this type to turn into what some have referred to as pre-islets. These differentiated offspring have produced insulin, but not yet in normal quantities. It was a dramatic step forward in this field, making this the most promising avenue of research toward developing an endless supply of insulin-producing cells for transplantation.

We do not know which of these approaches might someday solve the critical problem of islet supply. All of these approaches have been attempted. I urge you, on behalf of the JDRF and all the children with type 1 diabetes, to enable and support research in every one of these areas. Unfortunately, the most promising of these approaches, the use of embryonic stem cells, is opposed by some, and I fear that opposition is often based on misunderstandings.

First, the embryonic stem cells that are the most promising for our research are derived from the leftover products of *in vitro* fertilization. They are derived from clusters of cells that are today sitting in freezers all across this country, that are due to be discarded. Another misunderstanding is the idea that adult stem cells are just as good as embryonic stem cells. Someday, we may learn that that is true. However, we do not know today whether that is true or not. On the contrary, there is considerable scientific evidence suggesting that embryonic stem cells have major advantages over other sources of cells.

The JDRF has taken a strong leadership position, advocating the continued scientific investigation of embryonic stem cells as a possible source of new islets and of tissues to treat numerous other diseases, of both children and adults. We urge Congress and NIH to support Federal funding for this research, as well. Thank you for the opportunity to speak here today.

Senator LEVIN. Thank you, Dr. Auchincloss. Mr. Robbins.

TESTIMONY OF JAMES ROBBINS,[1] PRESIDENT AND CEO OF COX COMMUNICATIONS, DAUGHTER WITH DIABETES, ATLANTA, GEORGIA

Mr. ROBBINS. Thank you, Mr. Chairman and Senator Collins. When I have come to Washington to testify before, it is always in the field of my profession, in the telecommunications area, with Senator McCain and Senator Hollings, and those perhaps are easier jobs. This one is a much tougher one, because it involves the emotions of both being a father and particularly being a father of a 25-year-old diabetic who was diagnosed 22½ years ago.

So I speak to you from that perspective, and I want to just give you a couple of anecdotes as to how diabetes is an all-consuming, family affair. Last Saturday, my wife and I were driving to a wedding in Long Island, where we used to live, and as we were trying to find the church where this daughter of a friend of ours was being married, my wife looked over and saw a Chinese restaurant, and there said, "I remember that place, because that is where Peyson had a seizure a number of years ago." So it is that kind of experience that we go through every single day.

My entire family was on vacation the week before, and our youngest child was talking to another family that we had come across on vacation. This youngest child, a biology graduate from Dartmouth about 2 weeks ago, was very sensitive to the issue of Peyson's, at age 25—still good health, but she said to this other family the great news is that Peyson has had no complications of any serious impact yet from her diabetes. So, as a family person, you all should know that diabetes is just all-consuming.

My second and last point was that, as a businessman, I spend my life on the issue of resource allocation, where can we get the best bang for the buck that we invest in a particular area of telecommunications. Can we get it here? Can we get it there? Can we get it somewhere else? I would share with you that I do not know any place where you can get a better return on your investment than support for the kind of research work that goes on with and through the cooperation of the Juvenile Diabetes Research Foundation, if, for no other reason, than to cut down the expense on the complications that ensue as all these wonderful young people here will face other issues in conjunction and caused by their juvenile diabetes.

So, as a businessman dealing with resource allocation, I urge and urge strongly your support of the funding requests that have been made for continued research by these very distinguished colleagues on my left, including stem cell research, absolutely including stem cell research. You should know that you have a great deal of support from the business community, and I am just one small part of that, and we are committed to doing anything we can to help you urge your colleagues in Congress, as well as your colleagues in the administration, toward that end.

Thank you very much.

Senator LEVIN. Thank you very much, Mr. Robbins.

Mr. Brenneman.

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[1] The prepared statement of Mr. Robbins appears in the Appendix on page 78.

TESTIMONY OF GREG BRENNEMAN,[1] FORMER CHIEF OPERATING OFFICER OF CONTINENTAL AIRLINES, SON WITH DIABETES, THE WOODLANDS, TEXAS

Mr. BRENNEMAN. Thank you, Senator Levin and Senator Collins. I am going to shorten my testimony, as you suggested, in deference to your votes and the fact that I am between these kids and a break. Before I start the few comments that I would like to make, I would just speak as a protective parent, and I know many of you have been watching your kids up there and you have not been able to see them. I have had the benefit of seeing them, and I can assure you that what they have been pushing the button on have been their Gameboys and not their insulin pumps. [Laughter.]

So I think we will be OK. I will never forget the day, on January 20, 2000 when my 11-year-old son Andrew informed me he had diabetes. I was, until last month, the President and COO of Continental Airlines. I am now the Chairman and CEO of Turn Works. I just had arrived home from a business trip. A call from my wife confirmed what we had been suspecting, as we watched Andrew drink water like a fish and drop 20 pounds in about 3 months. I thought about what I would say to Andrew when I first saw him. I knew his first thought would be of his grandfather, who had passed away just a couple years earlier from complications of diabetes after a very long and painful fight.

Andrew had just been to the doctor for his first of thousands of blood tests and insulin shots. All my meetings had been canceled for the next day, as we were scheduled to spend the entire day at Children's Hospital in Houston, learning how to care for the disease. Our family met in the parking lot of Andrew's favorite restaurant to have our last supper before we dove head-first into our new reality. Andrew walked up to me and he put his arms around me, started crying. He said, "Well, Dad, I guess I have 17 more years to live." "17 years?" I responded, "Andrew, where did you get that idea?" "Dad, it was 17 years from the time Grandpa found out he had diabetes till the time he died."

I explained to Andrew that he had type 1 diabetes, while his Grandpa had type 2, and that treatment for the disease was a lot better than it used to be. "Dad, will you be with me tomorrow, when I learn how to treat my diabetes?" asked Andrew. "I will," I responded. "Dad, you had to turn around Continental Airlines when everybody thought it was hopeless. Now you are the best airline. Will you help me find a cure for diabetes?" asked Andrew. [Laughter.]

"Sure," I said, without really knowing what that meant. The next day at the hospital, we had one of the finest health care professionals I have ever met, Shannon Brow, take us through a mind-numbing crash course on diabetes. She explained to us that Andrew's new goal was to keep his blood sugar in a tight range, without the benefit of his pancreas, one of the body's most complicated and miraculous organs. The consequences of being outside the range were rather severe.

If Andrew's blood sugar got too low, he could pass out or go into a coma. If Andrew's blood sugar got too high, he would feel like he

[1] The prepared statement of Mr. Brenneman appears in the Appendix on page 79.

had the flu and lose control of his emotions in the short-term. He would ruin his kidneys, heart and liver over the long-term. All kinds of things, like food, exercises and hormones, would affect his blood sugar level. Thus started a regime that any parent with a diabetic child is painfully familiar with, and I will not take you through it, because you have already heard it.

With diabetes, there are no breaks. In addition, Andrew had to adjust his lifestyle. There is no snacking with friends, eating birthday cakes at parties or eating pizza late at night. He must always carry food with him in case his blood sugar drops and we must always carry a special shot with us to administer if Andrew lapses into a coma, before we call 911. That day in the hospital, I watched my son go from 11 to 18 in 1 day.

Andrew manages his care himself. I am proud of him. Some children and parents have it much worse. Like most parents, I want to do what is best for my children, so they can dream their dreams and realize those dreams, making a valuable contribution to this great Nation. In order to have a chance, these children must have a shot at a healthy and productive future. The health community and those who live with diabetes report that they have seen the future of long-term diabetics, and report back it is not a future any parent would want for their child. We know the only way to ensure these children and the millions like them to have a future is by finding a cure for this terrible disease. We need your help. Please help us give all these children a fair chance. Please help me to live up to my promise to Andrew to help him find a cure.

Thanks.

Senator LEVIN. Thank you very much, Mr. Brenneman.

Senator Collins.

Senator COLLINS. Mr. Brenneman and Mr. Robbins, I know how difficult this must be for you as fathers, to see your children go through this experience. But I want to tell you that hearing your stories only makes me want to redouble my efforts to make sure that other families in the future do not have to endure what you have had to endure, and I do feel, having heard the reports from Dr. Spiegel and Dr. Auchincloss, that there is such hope in the research.

I first visited Dr. Auchincloss a couple of years ago, I think it was at the Juvenile Diabetes Research Center at Harvard, and I was so impressed with the ground-breaking work that is being done, and I am convinced that those research efforts are going to eventually produce a cure. The challenges are daunting and the obstacles are many, but I am convinced that, as we continue to work together, we will ultimately be successful.

I want to follow up with you, Doctor, on some of the issues involving stem cell research, because that is the issue of the day. I expect decisions are going to be made very soon, and I hope today that we can build a record to help the President and the Congress reach what I believe is the right decision in this area. Could you talk to us more about the issue of human adult stem cells versus embryonic stem cells? As you know, some of the opponents of embryonic stem cell research are making the argument that adult stem cells are just as effective, and that we do not need the promise—we do not need the embryonic stem cells. Could you talk more

about your judgment on that and also the experiences that we have had in trying to get mice to produce insulin, using embryonic stem cells versus adult stem cells?

Dr. AUCHINCLOSS. Thank you very much, Senator Collins. It is possible that adult stem cells will turn out to be as effective, but at this point it is too early to make that determination, and to conclude that would be too close off an avenue of research that, at this point, in fact, looks like the more-promising approach. The simple reason for that is that we know that the proliferative capacity, the ability to make more cells from an embryonic stem cell precursor, is essentially unlimited. We can have as many cells as we need. It is not so clear that we have entirely that option from the adult stem cell sources.

The second concern is that we have thus far made more progress—and I use we in a very liberal sense, of the scientific community—in differentiating the embryonic stem cells into cells that actually have the capacity to make insulin, where that has not been accomplished from an adult stem cell source. So I think it would be a terribly sad thing to say we can do just as well with the adult stem cells, there is no need to pursue the embryonic stem cell angle.

I want to point out one of the critical lost opportunities if we make it still more difficult to pursue this avenue of research, especially with government funding. I have talked a lot to my very good friend and colleague, Doug Melton at Harvard, who is pursuing this type of research. He says, "Whether the government funds this or not is not critically important to me. I am a well-established scientist. I have other sources of funding. But when I look at younger scientists, they do not want to enter this field because they do not think they will be able to get a grant in this field from the government, which would be typically their first source of funding." It is very important for the future of this field, for the future of science, in general, that the government encourage younger scientists to move into this very promising area, not just for diabetes, but for many, many other diseases, as well.

Senator COLLINS. One follow-up question for you on that. Is the hope that using the embryonic stem cells to produce, eventually, islets that could be used for transportation, also that, with embryonic stem cells, the risk of rejection may be less, also?

Dr. AUCHINCLOSS. That is a very interesting scientific question, and there are some who believe that that is true. I do not happen to be one of them, but it is a scientific issue that is very interesting to go ahead and test further.

Senator COLLINS. Dr. Spiegel, you mentioned the obstacles that remain with the islet transplantation, which seemed so promising in the graph that you gave us,[1] where this woman apparently is cured of her need for insulin, but she will now need anti-rejection drugs for the rest of her life, which are very powerful and have consequences of their own. Where were the islet cells that were used for these transplantations obtained from? Were they obtained from cadavers?

[1] The graph referred to appears in the Appendix on page 73.

Dr. SPIEGEL. Yes, Senator Collins. The donor pancreases are from cadaveric pancreases, and just a few thousand are obtained each year.

Senator COLLINS. Is it possible to obtain islet cells from living donors?

Dr. SPIEGEL. We talked a good bit about this with the parents yesterday. I know that any parent of a diabetic child would be willing to do this. Unlike a kidney, which can be taken out whole and for which transplantation technique is the state-of-the-art, most surgeons would not want to touch the pancreas. It is a very fragile organ, filled with digestive enzymes, and to do that would probably not be a good idea in general.

Senator COLLINS. So until we come up with a way to produce an abundance of islet cells, the promising results of the transplantation research still are going to remain elusive for many people; is that accurate?

Dr. SPIEGEL. You are exactly right, and Dr. Auchincloss quantitated it for you in terms of the shortfall that we would have. There are real advances in the area of immune tolerance and I would defer to Dr. Auchincloss, who is an expert. There are animal experiments that have been done which are important for not just type 1 diabetes, but for organ transplantation, in general, suggesting that we can have a much more targeted kind of tolerance. That means we could specifically prevent rejection of the transplant, not block the whole immune system. Even then, however, we would still have the supply problem, and for this reason, it is critical that we learn everything about how these cells develop, so that we would be able to solve the supply problem.

Senator COLLINS. Thank you, Senator Levin.

Senator LEVIN. Thank you. Dr. Spiegel, I believe in your testimony you mentioned that there were reports that more and more children are being diagnosed with type 2 diabetes. Do you have any theory as to why that is happening?

Dr. SPIEGEL. We actually have striking data. Type 2 diabetes, unlike type 1, is due primarily to a resistance to insulin action followed by insufficient insulin. Like obesity, it is becoming an epidemic in this country. Type 2 diabetes disproportionately affects minority groups—Native Americans, African Americans and Hispanic Americans. We are seeing—tragically—type 2 diabetes now as a childhood disease in pubertal girls, and it is really the lack of exercise and perhaps inappropriate diet that is driving this.

Senator LEVIN. The *New York Times* reported last Friday that the National Institutes of Health (NIH), has come out with a new report that concludes that stem cells, embryonic stem cells, are even more promising for developing cures for a range of diseases than adult stem cells. Dr. Auchincloss has told us this morning that may or may not prove to be true, finally, but I gather there is a report that suggests that. Have you seen that report? We have been trying to get a copy of it.

Dr. SPIEGEL. I have seen only a draft-preliminary version of the report, which was prepared in the NIH Office of Science Policy.

Senator LEVIN. So that is still in draft-preliminary form, as far as you know?

Dr. SPIEGEL. As far as I know.

Senator LEVIN. Is the decision on stem cell research a decision which is made by an NIH directive or by an Executive Order? As I understand it, it was a NIH decision under President Clinton that allowed it go forward; is that your understanding?

Dr. SPIEGEL. With all due respect, not exactly.

Senator LEVIN. Tell it how it is. That is what I want to hear. [Laughter.]

Dr. SPIEGEL. NIH has been funding and continues to fund vigorously work on adult stem cells of all kinds, human and animal. At the same time, we are vigorously funding work on embryonic stem cells from animals, particularly mice, and that is where we have the greatest experience. Under, I believe, an amendment to the NIH appropriation bill, we are not permitted to perform human embryonic research. I believe you are referring to the NIH guidelines that would permit Federal funding of human embryonic stem cells that are derived in the private sector. These guidelines were released for public comment, and received extensive comment. The actual NIH funding, though, has not begun, and this is exactly what we are all discussing and on which we are awaiting a decision.

Senator LEVIN. Regardless of the NIH guideline, then, if the Congress maintains that prohibition, that kind of research on embryonic stem cells will not be allowed; is that correct?

Dr. SPIEGEL. That is essentially correct.

Senator LEVIN. So we need two things. We need both the congressional action, plus we need the guidelines from NIH in order for this to occur; is that accurate?

Dr. SPIEGEL. There are some subtle points, and I am not a legal expert, so I would defer to those who are. My understanding is that the work on human embryonic stem cells, if derived in the private sector, would be permissible. That is the ruling that is under review, according to the NIH guidelines. Under these guidelines, there is no congressional action required to work on the stem cells themselves, if they are not derived through Federal funding.

On the other hand, you are correct in that congressional action would be required to derive the stem cells themselves from human embryos.

Senator LEVIN. Got you.

Dr. Auchincloss, you indicated in your testimony that embryonic stem cells have major advantages over adult stem cells, or they appear to have those, and you may have, in response to Senator Collins, given us one of those advantages. But can you outline the advantages for us that the embryonic stem cells seem to have over the adult stem cells?

Dr. AUCHINCLOSS. I think that there are two primary advantages that appear at this point. One is the greater ability to produce more offspring cells, and the second is a greater knowledge of how to drive the change in those cells from the stem cells into the insulin-producing tissue. We simply know how to do that better from that stem cells source than we do from the adult stem cell source.

Senator LEVIN. Mr. Robbins, you indicated that you thought the business community would be very supportive of stem cell research.

Mr. ROBBINS. Yes, sir.

Senator LEVIN. I believe that was your reference, and it would be very helpful, I would think, if that support was sent to the White House, if it has not already gone there, because any support that we can get at the White House will be helpful. Senator Collins, Senator Hatch, and a number of other Senators have already notified the White House of our support for that research. I strongly support it, but the business community, I think, has a very unique role that it could play here for a number of the reasons that you testified to, and if you could get that information to the White House, it would be very helpful to the cause.

Mr. ROBBINS. As a fellow member of that school up in Boston that the President went to, he understands return on investment, and that is where I was coming from. I will do everything I can to get that message to the White House.

Senator LEVIN. That would be helpful. Thank you.

[Applause.]

We are not using these lights today, but those lights on that clock in the back of the room show that there are five white lights. That means that less than half of the time is left on the first roll-call vote, and we think now there are just a few minutes left on that. So you are going to see Senator Collins and I literally run out of here. This is the seventh-inning stretch, and that means we will have about 20 minutes, probably, a 15 or 20 minute break. I think that we are done with this panel. This panel is excused. We are very grateful to all of you for coming forward. Thank you very much.

[Recess.]

Senator LEVIN. Well, thank you, everybody, for your patience. These things happen in the Senate. They are out of our control, and when they do, we need everybody to do exactly what you did, to be understanding and patient with us. We thank you for that. On our final panel today, we have a number of young people who are joining us, and you are the reason, the real reason behind today's hearing, to hear from kids who live and struggle with diabetes. Our witnesses on the panel today are Rachel Dudley, from Southfield, Michigan, who we had a chance to visit with before, and her Mom; Andrew Webber, from Steep Falls, Maine; Eliza Jayne Kiley, and her Mom, Michelle; and Daniel Thaller, from Burlington, North Carolina. I do not think I mentioned that the Kileys come from Vandergrift, Pennsylvania; and finally, we have Caroline Rowley from Houston, Texas.

I think we will start with Rachel, because I know you. I would just say one thing—Rachel is 15. It has been 11 years since she was diagnosed with type 1 diabetes, an absolutely wonderful, vibrant young woman, and we are delighted to have you and your family with us today.

So, Rachel, do you want to start us off?

TESTIMONY OF RACHEL DUDLEY,[1] AGE 15, DELEGATE, JDRF CHILDREN'S CONGRESS, SOUTHFIELD, MICHIGAN

Ms. DUDLEY. Sure. My name is Rachel Dudley. I am 15 years old and live in Southfield, Michigan. Nearly 12 years and 12,300 shots

[1] The prepared statement of Ms. Dudley appears in the Appendix on page 82.

ago, I was a disease-free child. However, along came a crippling disease named diabetes to turn my world upside down. At the age of four, my mother noticed that I had lost weight, I was constantly thirsty, and my eyes were sunken in. She made an appointment with my pediatrician. After my doctor examined me, she sent us directly to the hospital. On the way, I remember asking my mother if I was going to die. She looked at me and said, "Not if I have anything to do with it."

During the 2 weeks I was in the hospital, the doctors told my mother that if she had waited any longer to bring me in, I might have gone into a diabetic coma. For the 9 years that followed, my mother had complete control of my diabetes management and I was in good health. It was not until I entered adolescence and began wanting to do things my way that my health began to deteriorate. Several times a day, my mom would ask if I had checked my blood sugar level and if I had taken my insulin. I would always tell her what she wanted to hear, even though I sometimes ignored my blood sugar reading and injected the wrong amount of insulin. Occasionally, I even injected the insulin into the toilet, instead of into my arm.

Looking back, I simply did not want to have diabetes, and I thought that I could be like a normal kid by simply ignoring the necessity of my daily routine. I wanted to eat when, where, and whatever I wanted, just like my friends. I wanted to be like them, and so I became like them. I did not take correct insulin dosages. Sometimes I did not take it at all. I did not eat according to my diet, and I ignored my mother. Because of this behavior, my body, being driven by my blood sugar, was on a wild roller coaster ride. When my blood sugar was low, my vision was blurred and I walked into things and acted as though I was drunk. When it was high, I would feel sick and have bad headaches, and I would feel terribly thirsty, and in spite of drinking quarts of water, I could never quench my thirst.

All of this was caused by my simple desire to be like other kids. This mindset earned me a 2-week stay in the hospital, including 3 days in the intensive care unit, at the age of 13. I learned that my kidneys had almost shut down. I came to understand that because of my desire to be like my friends, I had almost died. During day after day of testing and treatment and conversation and training by specialists at Children's Hospital, I finally understood that if I wanted to live, I must accept the reality of diabetes as the top priority in my life. I finally understood that anything less than the rigorous control of my diabetes management was inviting serious health problems.

I finally understood that, without insulin, I would die in a matter of days. While I was in the intensive care unit, my mother and I made a pact. My pact was if I would do everything in my power to stay healthy, she would do everything in her power to find a cure. We have both remained true to our promises. Since 1999, my mother has raised nearly $20,000 for JDRF. Me, I follow my diet, I exercise, and I always take the correct amount of insulin according to my blood sugar level. But does this make me well? Absolutely not!

Until a cure is found, I will always have diabetes. Having diabetes means that I am always just a few hours away from blurred vision, headaches and nausea, just a few days away from a hospital stay, and at this very moment, if I no longer have access to insulin, I am no more than a week away from death. At another time in my childhood, I asked my mother about the civil rights struggle and her encounters with racism. She said that she had marched and advocated for equal rights for all people so that her children would not have to. Years from now, when my children ask me about my struggles with diabetes, I will tell them about this day, and I will say I testified before the U.S. Congress in Washington, DC, and I passionately urged the leaders of this great Nation to fund the research to find a cure for diabetes, and I did that so that hundreds of thousands of kids like you, my child, would not have to.

[Applause.]

Today, I ask the men and women in this great place, those who have the power and influence to alter the direction of our Nation's resolve, would you do whatever you can, whatever it takes, whatever must be done to increase funding for research to find a cure for diabetes today? Will you remember the 200 kids who have come to this Nation's Capital to give a face and a story to this very real, very dangerous disease? Today, I ask you to promise to remember me. Thank you.

Senator LEVIN. Rachel, thank you; a very powerful statement, and I hope the response is equally powerful. You deserve it. All these kids deserve it. All Americans deserve it. Thank you. It was really quite extraordinary.

Andy.

TESTIMONY OF ANDREW WEBBER,[1] AGE 13, DELEGATE, JDRF CHILDREN'S CONGRESS, STEEP FALLS, MAINE

Mr. WEBBER. Hello. My name is Andrew Webber. I am 13 and I live in Steep Falls, Maine. Thank you for the opportunity to speak today about how diabetes affects my life. I was diagnosed in 1998. My parents thought that my weight loss, excessive thirst and stomach pains were related to my tough football workouts. But after football season was over, my condition continued to worsen. I will never forget the day that I was finally diagnosed. I felt that I would rather die than be forced to take shots for the rest of my life.

But diabetes is not just about taking shots. Having diabetes makes everything about my life more difficult, and it makes it especially hard to do the things that I love most, like playing sports. When I am playing sports, having diabetes does not just affect me. It affects my family, my coaches and my team. For example, my parents do not just go to my games. They go to all my practices, too. I would like a little independence, but most coaches either do not want to be responsible for me or they just do not "get" diabetes. Sure, my parents like to be supportive, but 3 hours a night, 6 days a week can seem to be a little over-supportive.

[1] The prepared statement of Mr. Webber appears in the Appendix on page 84.

Most of my teammates try to be helpful, but I always feel like my medical condition is on display. Other kids do not understand that diabetes does not go away when I take my insulin. They do not realize that I always have to be aware of how I feel and that I have to be ready to make the right adjustments, no matter where we are in the game, even if it means sitting out some of the game. If I am playing hard, my blood sugars might go low, and I have to stop to have some sugar. If I am not playing as hard as I expected to play, my blood sugars could go high and I could have blurred vision or lose my ability to concentrate on my coach's instructions. This is hard for a lot of people to understand.

Last year in Little League, I was having many abnormal blood sugars. My coaches did not understand how diabetes works, so they assumed that I was goofing off and I needed to take breaks. Instead of listening to my parents and allowing me the time to recover, they chose to bench me. I got a reputation for being uncooperative.

I am looking forward to a cure in my lifetime. Diabetes is a slow killer. My grandmother, aunt, and many other relatives have been diabetic. They have suffered from eye disease, nerve problems and foot trouble. They have died from heart disease, gangrene and kidney disease. I want to live to be a healthy adult with children, grandchildren, and great-grandchildren. My dream for the future is not to be "the kid with diabetes," but to just be Andy Webber.

Research is the key to a cure, but research requires money. Help me to live a long life, and to be healthy enough to enjoy it. Please promise to remember me.

Senator LEVIN. Thank you, Andy, for your wonderful statement. We read in your little bio here that you have always wanted to be a forest ranger or a game warden, and that you love the outdoors. You love to go hunting and fishing and snowmobiling, and those are the kind of wants that you are entitled to. I know that your Senator here, Senator Collins, knows where Steep Falls, Maine is, but I do not. What part of Maine is that in?

Mr. WEBBER. Well, I guess it would be like the southern part, yes, southeast, I guess, near Sebago Lake.

Senator LEVIN. You do not know where Lake Cabasi, Cabasi County Lake, is; do you? It is not near there? Nowhere near there. My expert on Maine says that I am way off. All right. Eliza, you are here with your mom, so we would like to hear from either one of you.

TESTIMONY OF ELIZA JAYNE KILEY,[1] AGE 5, DELEGATE, JDRF CHILDREN'S CONGRESS, VANDERGRIFT, PENNSYLVANIA, ACCOMPANIED BY HER MOTHER, MICHELE KILEY

Ms. KILEY. Good morning. My name is Michele Kiley and this is my daughter Eliza. She is 5 years old and we are from Pennsylvania. Thank you for allowing me to tell you a little bit about our lives today. When you plan to have children, you dream of whose eyes they will have, whose personality traits they will carry, or what they will do in their lifetime, such as being a doctor or a lawyer, or if they will have children of their own. I was diagnosed with

[1] The prepared statement of Ms. Kiley appears in the Appendix on page 85.

juvenile diabetes at the age of 3. When I was young, I was told I probably would not be able to have children. Everything I read said that women who have diabetes should not have children. It was common for diabetic mothers to see severe complications after a pregnancy, such as retinopathy and kidney disease, let alone the fears of congenital birth defects in a baby or, worse yet, a miscarriage or stillborn birth. It was just too risky for mother and child.

As I got older, there were many advances. Glucose meters and insulin pumps improved our ability to monitor and control blood glucose levels. Things have changed and, yes, I could have children if I wanted, as long as I was careful and kept myself under tight control. Well, I was thrilled. My entire life, I felt as though God put me on this earth to be a mother. To have children was my only wish. Eliza was born in 1996. All the things I dreamed of, I noticed. She has my husband's eyes. She has my smile and my personality—she is as stubborn as a bull.

But the one thing I never dreamed of giving my child was diabetes. My doctor said the chances were slim to none, so not to worry, and I did not. Well, I am here to tell you that the chances are not slim enough. One night when Eliza was 3 years old she woke at 2:30 a.m. and asked me for water, which she had never done before. I had the strangest feeling when she asked, but I let it pass. I was just being overly concerned, I thought. She was a kid who wanted a glass of water. There is nothing wrong with that.

The next morning, we went through four cups of fluid before I got up the nerve to run a blood sugar on her. The 15 seconds for that meter to count down were the longest of my lifetime. My worst nightmare was confirmed in the matter of a 15-second blood test. I diagnosed Eliza on July 11, 1999 at home with my glucose meter. My daughter Eliza now has diabetes. Talk about guilt? I hated myself for a long time. Sometimes I still do. I ask myself often, "Isn't my diabetes enough?" I have sacrificed 26 years of my life to this disease, why does she have to sacrifice her life?

Sometimes I cry myself to sleep at night, fearing the next day's insulin pump catheter insertion. I pray that she will not hate me for giving her this disease. To make matters more strenuous, in May, my other daughter, Rebecca, turned 3. The anxiety begins again. I believe that we all have a purpose in life. Sometimes people go their entire lives without knowing their purpose. I often thought that my purpose was having diabetes so I could be a role model for Eliza, but being here today has changed my belief. I see that Eliza and all of these children have diabetes so we have role models. Eliza is a brave little girl, just like all these children here today, more brave than any of us could be, facing this disease head-on. Please promise to remember Eliza and all the children here today. Please help them fight for what they have earned, a cure for diabetes.

Senator LEVIN. Thank you, Ms. Kiley, for coming forward. Your statement and Eliza's winning smile are going to help us win this war. You keep smiling, kiddo. You are doing just great.

Daniel, I understand you want to get into the Army someday. That is what it says in your little bio here. I am on the Armed Services Committee. [Laughter.]

I am Chairman of that Committee, so you have a lot going for you here today. I just want to let you know that. Your turn, Daniel.

TESTIMONY OF DANIEL THALLER,[1] AGE 12, DELEGATE, JDRF CHILDREN'S CONGRESS, BURLINGTON, NORTH CAROLINA, ACCOMPANIED BY JESSICA THALLER, AGE 13

Mr. THALLER. Hi. My name is Daniel Thaller. I am 11 years old, live in North Carolina, and I am one of the millions of Americans who has been diagnosed with juvenile diabetes.

Ms. THALLER. I am Daniel's sister, Jessica. I am 13 years old and I have had diabetes for over 7 years. My sister, Cameron, was also supposed to be here, but unfortunately she is back at the hotel, sick. She is 9 years old and has had diabetes since she was 4. We just want you to know that there are three in our family that suffer from diabetes.

Mr. THALLER. It all started for me when my mother realized my diapers had been constantly saturated and I had been very thirsty. Only at a regular checkup was it discovered that these symptoms would reveal a radical change in my and my parents' lives. With the diagnosis of diabetes came the unthinkable task of giving a toddler multiple daily insulin shots and finger pricks. If you are a parent, how do you explain to your toddler that what you are doing is what will keep them alive?

After my diagnosis, my mother did monthly blood sugar checks for both of my sisters, even though doctors told her it was highly unlikely that either would get it. Can you imagine the shock my parents felt 2 years later when they discovered a second child had diabetes, and the amazement and depression they felt 3 years later, when their third child was diagnosed? Lightning can strike twice, and even three times. Together, my sisters and I have endured more than 25,000 finger pricks.

School can be really hard for a child with juvenile diabetes. Low blood sugars can make it hard for me to concentrate, and high blood sugars make me grumpy or hyper. Sometimes diabetes affects my performance in sports, as well as my social life. If I cannot concentrate, how can I get A's? If I feel weak and dizzy, how can I hit a home run? If I feel sick to my stomach, how can I go to the movies with my friends? My friends and teachers sometimes ask, "Does that hurt?" or "What is that thing?" I get sick of the attention. Some people even know me as "the guy with diabetes."

My sister Jessica has described this as feeling like being a lab rat in a cage. Unless you have lived it, you can have no idea what living with juvenile diabetes is like. A cure for diabetes is very important for me, because I have had it for so long; 9 years is over four-fifths of my life. I cannot even remember life without diabetes. Congress should give more funds for the research to find a cure for diabetes because millions of people suffer from it; 16 million people in the United States alone have this devastating disease. Every day, 35 children are diagnosed with juvenile diabetes. That is 35 more kid who will ask themselves, "Why me?" every day for the rest of their lives.

[1] The prepared statement of Mr. Thaller appears in the Appendix on page 87.

Please remember me and my sisters, and give more money for diabetes research the next chance you get. I do not want to die a diabetic.

Thank you.

Senator LEVIN. Daniel, thank you for your very, very wonderful testimony. Jessica, I did not have a bio on you, so I did not know what your goal was. I know your brother wants to serve in the Army. Do you have a goal like that, that you would like to share with us?

Ms. THALLER. I want the freedom to be able to travel. That is really a big ambition for me, and diabetes makes that really hard.

Senator LEVIN. Thank you.

Caroline, you are our last witness, from Houston, Texas. As we heard earlier this morning, it was a reference to "We have got a problem, Houston," well, you are part of the solution.

Caroline.

TESTIMONY OF CAROLINE ROWLEY,[1] AGE 11, DELEGATE, JDRF CHILDREN'S CONGRESS, HOUSTON, TEXAS

Ms. ROWLEY. Hi. My name is Caroline Rowley and I am from Houston, Texas. I am 11 years old. The mail bags over there contain almost 60,000 letters of support on behalf of the delegates and the millions of children with diabetes. I had always heard of bad things happening to people, but I never thought anything bad would ever happen to me. Then, all of a sudden, I was diagnosed with juvenile diabetes. I was in kindergarten. My entire life changed, and being a kindergartner was suddenly full of drawing blood from my fingers and taking lots of shots every day. I could not believe this was happening to me.

In second grade, a blind woman came to speak in my school's chapel about seeing-eye dogs. I begged my teacher to ask her if she had diabetes, because she talked about having to take shots to stay alive. She was diabetic. When I got home, I asked my Mom if we would get a new dog or train our dog, Chase, to be my eyes when I went blind.

My Mom sat me down, and with tears in her eyes, she told me we were going to do everything in our power to keep me from getting complications. That is why we have to manage my diabetes so intensely. This was our first discussion about complications, but it would certainly not be our last. After having diabetes for almost 5 years, my doctor ran a routine test to be sure my kidneys were OK. She told my Mom we would not hear back from her, that it was just routine. Two weeks later, my doctor called me and asked me to re-run the test. I took the test three or four times, but every time the results were the same. I had protein in my urine, a sign of the beginning stages of kidney disease. I did not want to believe it, neither did my Mom and Dad. Now, in addition to wearing an insulin pump 24–7 and pricking my fingers, I have to take another drug each and every day for the rest of my life.

When is this all going to stop? I always thought that if I ever got complications, that I would be grown, but I would still have my youth to be normal, but diabetes has stolen my childhood and

[1] The prepared statement of Ms. Rowley appears in the Appendix on page 89.

forced me to grow up. I worry about having a seizure, going blind or losing my kidneys. The top-10 music countdown or the latest fashions at Gap, these things just do not seem that important in my life. Most people think of complications as something that happens to older people or after you have had diabetes for a very long time. I am here to tell you that it is just not true. Look around this room, there is no way for you to know how many of these children are already experiencing problems with their kidneys or their eyes, because diabetes is silent. On the outside, we look healthy. On the inside, a war is raging in our bodies, a war we cannot fight alone.

Every day I live with many fears. Every night I sit in my bed and pray for a cure as long as I can stay awake, hoping God will hear my prayers. It is my responsibility to control my diabetes everyday and try to keep my body from further complications, but you control whether or not researchers have a chance to cure diabetes. You can give me back my life and I will not have to fear if I will be blind or on dialysis. My life is already been shortened 15 years just because I was diagnosed with diabetes. I want a full life like the one most of you and your loved ones have been able to live—long, and not a life full of pain and complications. I need your help in finding a cure. Please, please promise to remember me and all children with diabetes.

Senator LEVIN. Thank you, Caroline, for your wonderful, courageous statement. We understand that you are a star soccer player. You have managed your diabetes somehow and still are out there competitively playing soccer. We are delighted with that kind of willpower and it is a real great statement about your own courage and the courage you can give to others.

Ken Bentson, who is a Congressman from Texas, from Houston, is behind you. I assume that is your Congressman, but I am not sure. Ken, we are delighted that you are with us and having your support here, as well.

Senator Collins.

Senator COLLINS. Thank you very much, Mr. Chairman. I want to thank all of you for your wonderful statements. You were so passionate and powerful in arguing for more research and you help remind us what having diabetes is really all about. I promise you that I will remember you always. I will never forget the testimony I have heard from Caroline, from Michele, from Rachel, from Andy, from Daniel, from Jessica, and all of our witnesses today.

Andy, I thought I would ask you a couple of questions about what it has been like for you to have diabetes. You live in a very small town in Maine. I have been to Steep Falls, so I know where it is, and I suspect that you did not know any other kids in your school with diabetes; is that right? Were you the only one?

Mr. WEBBER. I was the only one in my school. I think there was one other kid in the district.

Senator COLLINS. So did you have to teach your teachers and coaches about your disease?

Mr. WEBBER. Yes.

Senator COLLINS. If you had some bit of advice that you would like to give your teachers and coaches and all the teachers and coaches across America who have students with diabetes, what would that be?

Mr. WEBBER. I do not know, probably just to keep an extra eye on them, because anything can happen.

Senator COLLINS. Just sort of watch out for them and be understanding of them?

Mr. WEBBER. Yes.

Senator COLLINS. Did you get treated in Maine Medical Center in Portland?

Mr. WEBBER. Yes.

Senator COLLINS. Were you able to meet other families there who had children with diabetes?

Mr. WEBBER. No, I did not meet any other families with diabetes until a couple of weeks after I got out of the hospital.

Senator COLLINS. Has it been helpful for you to be here today and to get to meet other children who are going through the same kind of challenges that you have been going through?

Mr. WEBBER. Yes.

Senator COLLINS. I bet it has, because it must feel pretty lonesome at times, having to cope with your disease; is it, sometimes?

Mr. WEBBER. Yes.

Senator COLLINS. Yes, it feels pretty lonesome.

Mrs. Kiley, I just want to say to you that I was so moved by your statement that I think your little girl is one lucky little girl. She has a wonderful Mom. Rachel, your statement was so terrific. You will be able to tell your children that you were there, just as your mother was there for you in struggles of previous generations. I just want to thank all of our witnesses today for their testimony. Dan and Jessica, how difficult for your family to have three children struggling together with that. That is just so extraordinary, because as we have learned, a lot of times there is no family history at all and it comes as a big surprise. So I guess the one thing is at least you have been able to help each other in coping with your disease.

Jessica, has it been that way? Have you been able to help your younger brother?

Ms. THALLER. Actually, he was diagnosed first. So, he actually helped me when I was diagnosed.

Senator COLLINS. Well, Daniel, I admired that, when you talked about living four-fifths of your life with diabetes, that just seems so unfair and so difficult, but by being here today you are giving hope and education to other kids around the world. Caroline, I want to help your prayers come true, and I just want to say that all of you are an inspiration to all of us. The work of the Juvenile Diabetes Research Foundation is so wonderful and I believe that it will bring us a cure some day. Thank you for your testimony.

Senator LEVIN. Thank you, Senator Collins.

Let me just briefly conclude with the following thought. First, we owe a great deal of thanks to the families who were here, and I wonder whether the family members of these particular children, young adults, would stand if you are in the audience? I would like to give you some applause, as well.

[Applause.]

Those of us who are lucky enough to be part of a very close family know the wonders of that, and when you have diabetes, it is a particularly important part of your life that you have supportive

families, and we want to thank all of your brothers, sisters, moms, dads, grandparents, and so forth, for their work, help and their commitment and support for you.

Each of you have asked us in your own ways to remember to meet the needs for additional research—we will. Senator Collins and I and many, many other members of the Congress are determined to add research funds to the NIH budget. We will continue that struggle with your help. Your statements today, and I look at each of you as I say this, will mean, and I think Rachel made reference to this, that fewer kids are going to have to go through what you go through in future years because you came forward today. We want to thank you for that, for your courage in your daily life and for the meaning that you have given to your particular disease in terms of trying to make sure that 5 years from now we do not need to have the next generation of kids sitting here asking, but then we will have had the cure that your presence here today has helped to make possible. Thank you for coming.

[Applause.]

Senator COLLINS. I just want to not only thank the Juvenile Diabetes Research Foundation for its efforts and our witnesses, but I also want to thank Senator Levin for chairing this hearing today.

[Applause.]

Senator LEVIN. Thank you. We will stand adjourned.

[Whereupon, at 12:53 p.m., the Subcommittee was adjourned.]

APPENDIX

PPREPARED STATEMENT OF SENATOR CLELAND

I want to commend Chairman Levin and Senator Collins and the other Members of the Subcommittee for conducting today's hearing on the adequacy of diabetes research funding. In my State alone, over 420,000 Georgians are estimated to have diabetes and only half of this number have actually been diagnosed. It is the seventh leading cause of death in Georgia. In 1999, the Centers for Disease Control and Prevention (CDC) reported the prevalence of diabetes in the U.S. increased 33 percent from 1990 to 1998. We are very fortunate to have Mr. James Robbins, President and CEO of Cox Communications, and his daughter, Peyson, from Atlanta. James and Peyson will share their insights on diabetes, living with this diagnosis and their commitment to conquering this disease. I would also like to introduce Deborah Perling of Atlanta and Hunter Thomas and Keith Gonyea both of Alpharetta, Georgia. Deborah, Hunter and Keith were diagnosed with juvenile diabetes and are role models for all of us on how to cope and hope. These young people have my commitment to support the diabetes research needed to find a cure.

I fully support doubling the National Institutes of Health (NIH) budget and have also supported diabetes research conducted by the military and Veterans Affairs health care systems. The total cost of diabetes to the Nation is more than $100 billion annually. About 25 percent of all Medicare costs are spent on beneficiaries diagnosed with diabetes or diabetes-related health problems. There are many devastating diseases which need crucial research funding. However, few illnesses meet all of NIH's criteria for assigning research priorities: Number of people with the disease, number of deaths attributed to the disease, degree of disability, degree to which disease cuts short normal, productive, comfortable life span, economic and social costs, need to act rapidly to control spread, and existence of scientific opportunities related to disease.

I believe that researchers are on the verge of discovering the way to prevent and treat diabetes. I share the concerns of the Subcommittee regarding the decrease in diabetes research dollars. The proportion of NIH's budget allocated to diabetes research has fallen more than 30 percent since 1981. I urge my colleagues to support this critical funding need.

SUSAN M. COLLINS
MAINE

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COMMITTEES:
ARMED SERVICES
GOVERNMENTAL AFFAIRS
HEALTH, EDUCATION, LABOR, AND PENSIONS
SPECIAL COMMITTEE ON AGING

June 11, 2001

President George W. Bush
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mr. President:

I am writing to express my support for stem cell research and to urge you not to overturn the guidelines issued by the National Institutes of Health (NIH) last August that allow for federal funding of research on human embryonic stem cells obtained from frozen embryos slated for destruction at fertility clinics.

The promise of stem cells derived from in vitro fertilized eggs lies with their ability to differentiate into any human cell type. As a consequence, stem cell research holds tremendous potential to treat and even cure a vast array of diseases and conditions. Researchers could, for example, potentially generate insulin producing islet cells for patients with juvenile diabetes; neurons to treat Parkinson's disease, ALS, Alzheimer's disease and repair spinal cord damage; as well as bone marrow cells to treat cancer.

Some have argued that adult stem cells will be sufficient to pursue treatments or cures for disease. Experts in this field of research, however, agree that it will take years of further study to determine the therapeutic potential of adult stem cells. I am concerned that impeding human pluripotent stem cell research risks unnecessary delay for the men, women, and children who may die or endure needless suffering while the effectiveness of adult stem cells is evaluated.

While I am sensitive to the concerns raised by this research, the fact is that the embryonic stem cells being used in this research are in excess of the clinical need and will be discarded in any case. Under these circumstances, I believe that it would be tragic to waste this opportunity to pursue research that can potentially help millions of people in need. Moreover, the guidelines developed by the NIH provide clear, ethical safeguards which respect both the moral status of the embryo and public sensitivity to this issue. Given the tremendous hope that stem cell research provides to those suffering or dying from devastating illnesses, I urge you to allow this research to move forward with federal support.

Thank you for your consideration.

Sincerely,

Susan Collins

Susan M. Collins
United States Senator

SMC:phh

PRINTED ON RECYCLED PAPER

United States Senate

WASHINGTON, DC 20510

February 21, 2001

The Honorable Tommy G. Thompson
Secretary, Department. of Health and Human Services
Hubert H. Humphrey Bldg., Rm. 615F
200 Independence Ave., SW
Washington, DC, 20201

Dear Secretary Thompson:

As the co-chairs of the Senate Diabetes Caucus, we have learned a great deal about this disease and the heartbreak it has caused for millions of Americans and their families as they await a cure. We believe that it is becoming increasingly clear that diabetes is a disease that can be cured, and will be cured in the future, if sufficient funding is made available.

Diabetes is a devastating disease that affects 16 million Americans and accounts for more than 10 percent of all health care dollars and nearly a quarter of all Medicare expenditures. We, therefore, believe that increased funding for diabetes research is critical, and we strongly supported legislation passed late last year that extends and increases funding for the two diabetes research programs created by the Balanced Budget Act of 1997, one focused on juvenile diabetes and the other focused on Native Americans. The Medicare, Medicaid, and S-CHIP Benefits Improvement and Protection Act extended the funding for these two programs for one year -- through 2003 -- and increased the funding level for each program from $30 million a year to $100 million a year.

It is important to note that Congress intended that these funds be used to supplement and not supplant resources provided through the regular Labor-HHS Appropriations bill. We, therefore, urge you to ensure that funding for diabetes research from the regular appropriations stream grows in accordance with the 14.2 percent funding increase that was provided to the NIH in FY2001 and would appreciate being provided with information on the resources directed to these programs.

We strongly believe that increased funding for diabetes research will make a dramatic difference in moving our nation closer to a cure. As co-chairs of the Senate Diabetes Caucus, we look forward to working with you and hearing from you about the diabetes research being conducted at NIH.

Thank you for your support of this effort, and we hope that you will not hesitate to contact us if we may be of assistance.

Sincerely,

Susan Collins
Susan M. Collins
United States Senator

John Breaux
John B. Breaux
United States Senator

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY 24 2001

The Honorable Susan M. Collins
United States Senate
Washington, D.C. 20510

Dear Senator Collins:

Thank you for your letters urging that the budget for the National Institutes of Health (NIH) continue adequate funding in FY 2001 for diabetes research. You were concerned that funding from NIH's regular appropriations keeps pace with the growth in the total NIH budget and that the additional funds for type 1 diabetes research supplement, rather than supplant, other diabetes research resources. Let me assure you, this is the case. Our FY 2001 budget includes $596.9 million – a 16.2 percent increase -- for NIH-wide expenditures for diabetes research from its regular appropriations. This exceeds the 14.0 percent increase for NIH as a whole. When the additional $100 million Congress provided for special type 1 diabetes research is included, the increase would be 27.6 percent over the comparable FY 2000 level.

I have recently reviewed the interagency research plan for the use of the special type 1 diabetes research funds in FY 2001. This plan identifies new initiatives to help researchers take full advantage of compelling scientific opportunities, such as the findings of the Human Genome Project, to better understand how type 1 diabetes arises, to improve ways to treat it, and even to prevent it. The plan was based on the recommendations of several conferences and workshops, on priorities for type 1 diabetes research identified by the congressionally established Diabetes Research Working Group, as well as on input from the Department and the diabetes voluntary community.

Out of the total $100 million available through these special funds in FY 2001, the research plan calls for the NIH to use $93.2 million, with the remaining $6.8 million to be allocated to the Centers for Disease Control and Prevention for type 1 diabetes laboratory and epidemiology activities. These funds are being managed separately through our accounting systems. This Department's policy will be to use these special funds to supplement and not supplant diabetes research funding provided through our regular appropriations.

Your interest and support have been essential to the momentum we are now witnessing in diabetes research. We believe research currently under way and planned for FY 2001 and beyond will continue to yield the research strides we all seek in our determination to conquer this disease. I look forward to close cooperation with the Congress in our mutual support of diabetes research. Please feel free to call me if you have any questions or concerns. I am sending a similar letter to your colleague Senator John Breaux.

Sincerely,

Tommy

Tommy G. Thompson

Enclosures

Table 1 - NATIONAL INSTITUTES OF HEALTH DIABETES FUNDING
(Dollars in millions)

This table details NIH-wide diabetes research funding in millions, by institute and center, for FY 2000 and FY 2001, along with the percent change between FY 2000 and FY 2001.

Participating ICs	FY 2000 Actual	FY 2001 Estimate	
NCI	$5.5	$5.8	
NHLBI	59.0	66.9	
NIDCR	4.1	4.7	
NIDDK	313.5	364.6	
NINDS	3.3	3.7	
NIAID	18.0	20.4	
NIGMS	4.2	4.6	
NICHD	18.7	21.3	
NEI	27.3	31.0	
NIEHS	0.4	0.4	
NIA	16.2	18.6	
NIDCD	0.2	0.3	
NIMH	1.0	1.1	
NIAAA	0.9	1.1	
NINR	3.9	4.6	
NHGRI	4.1	4.6	
NCRR	31.3	34.9	
NCCAM	0.6	0.8	
NCMHD	0.0	6.7	
OD	1.4	0.9	**Percent Change**
Subtotal-Regularly Appropriated Funds	513.7	596.9	16.2
Transfer for TYPE 1 Diabetes	27.0	93.2	--
NIH TOTAL	540.7	690.1	27.6

RESEARCH PLAN
USE OF NEW SPECIAL FUNDS FOR TYPE 1 DIABETES RESEARCH

I. Goal: To identify the genetic and environmental causes of T1DM

A. Genetics of Type 1 Diabetes Mellitus

Participants: CDC, NCBI, NCI, NHGRI, NIAID, NIDDK (in alphabetical order)

Sources of recommendations:
NIDDK/JDRF Genetics of Type 1 Diabetes Workshop (11/20/2000)
FY2001 Congressional Appropriation Report Language
Diabetes Research Working Group Report (1999)
Diabetes: Challenges and Opportunities Report (1997)

Components:

- International Type 1 Diabetes Genetics Consortium

  Combined analysis of linkage data from U.S. and European family collections has the potential to identify candidate regions for further localization and positional cloning of the relevant genes. This project will provide support for a coordinated analysis of genetic linkage in the families that have been collected to date, support collection and genotyping of additional patient samples, and sequencing of the regions where the combined analysis found compelling evidence for a susceptibility gene for Type 1 diabetes.

- IHWG Type 1 diabetes SNP haplotyping and bioinformatics

  This will expand current efforts through the International Histocompatibility Working Group (IHWG) for identifying SNPs within Type 1 diabetes candidate genes. This project will accelerate the effort to establish a central repository of annotated genetic data relevant to Type I diabetes and will provide a web-based computer interface and applications for submission, storage, retrieval, and analysis of genomic data relevant to basic and clinical diabetes research.

- Identification of SNPs in the newly identified cDNAs from the pancreatic beta cell

  This will support identification of SNPs in the newly identified cDNAs from the pancreatic beta cell. One of the goals of this effort is to develop a pancreas-expression array for analysis of gene expression under different conditions including diabetes. Unique cDNAs that are expressed primarily in the beta-cell will be sequenced from several individuals to identify common SNPs. This effort will help to contribute to the genome -wide SNPs

discovery effort as well as provide SNPs that are important in the disease target for Type 1 diabetes.

- Diabetes international repositories for the study of genetic risk factors for Type 1 diabetes and its complications

  This project will store large, often population-based, samples comprising specimens from patients, unaffected family members, and unrelated control subjects. These samples will be used to identify genetic and/or environmental risk factors for type 1 diabetes and its complications.

Mechanisms of support: cooperative agreements, contracts

Allocation (millions):	FY01	$9
	FY02	$11
	FY03	$10

B. Epidemiology of Type 1 Diabetes Mellitus

Participants: CDC, NIAID, NICHD, NIDDK, NIEHS (in alphabetical order)

Sources of recommendations:
Trans-HHS Balanced Budget Act Advisory Meeting (April 2000)
FY2001 Congressional Appropriation Report Language
Diabetes Research Working Group Report (1999)
Diabetes: Challenges and Opportunities Report (1997)
International CDC workshop on Dried Blood Spots and Immunology of Type Diabetes (1999)

Components:

- Type 1 diabetes epidemiology study in families with type 1 diabetes

  This project will establish a large, cohort of siblings, offspring and parents of persons with type 1 diabetes to be followed prospectively to identify genetic and environmental causes of type 1 diabetes. By studying the interaction of genes, the environment and immune system we should identify factors that may trigger the onset of autoimmunity. Ideally this study would include identification of siblings and offspring prior to birth so that information could be collected about the pregnancy to identify potential intrauterine risk factors, since type 1 diabetes may have its roots very early in life or even in utero. This project will allow for application and testing of new genomic, proteomic, infectious disease, and immunologic approaches to study the autoimmune process early in its course and may identify new markers of autoimmunity that will allow detection and intervention earlier in the disease process. The population enrolled and followed in this epidemiologic study would be

invaluable for genetic association studies. Because the contribution of some genes contributing to the genetic risk of T1DM may be too small to be identified through linkage studies, the subjects involved in the epidemiologic study could provide a resource for more sensitive association studies.

- Population based type 1 diabetes epidemiology study

  This project will establish large, population-based cohorts of newborns identified from the general population as genetically at risk for type 1 diabetes and follow these cohorts through the high-risk age (0-15 years) to identify additional genetic and environmental causes of type 1diabetes. It will also support an initiative to develop new methods to detect, quantify, and follow infectious agents in chronic diseases such as type 1 diabetes, which have not classically been considered infectious. > 75% of all cases of type 1 diabetes occur in individuals without diabetes being present in the family. Thus, identifying potential cases from families wherein diabetes is already present will not suffice if type 1 diabetes is to be substantially controlled. One approach to identification of high risk individuals will utilize dried blood spots obtained on all newborns in the U.S. for population-based genetic screening with follow up of those individuals "at genetic risk" for autoantibody development, exposure to infection and/or toxic agents, and clinical appearance of diabetes.

- Population based registries for type 1 diabetes in children

  This project will use a standardized common methodology to (1) monitor the different types of childhood diabetes in terms of prevalence and incidence; (2) develop clinical, research, and surveillance case definitions; (3) describe the characteristics, natural history, complications, and care received by children with diabetes; and ultimately (4) provide opportunities for further research into childhood diabetes, including new approaches for prevention, diagnosis, and clinical trials.

- Diabetes autoantibody standardization program

  Development of autoantibodies is predictive of the onset of type 1 diabetes and measurement of autoantibodies is crucial for the early detection of the autoimmune disease process. Further, autoantibody measurements will assist in typology studies among various types of childhood diabetes. Antibodies include those to IA-2, glutamic acid decarboxylase (GAD_{65}), and insulin antigens. Autoantibody assays are complex and require sophisticated molecular techniques. Although much progress has been made in this area, the Immunology of Diabetes Society has emphasized that these tests do not agree well among laboratories. This project will provide standardization and proficiency testing materials for 51 laboratories throughout the world engaged in type 1 diabetes risk assessment. The project will establish reference

laboratories selected from participating laboratories on the basis of performance excellence criteria in measuring autoantibodies.

Mechanisms of support: cooperative agreements, contracts

Allocation (millions): FY01 $10.3
FY02 $12.3
FY03 $13.5

C. Animal Models for Study of Genetics and Immune Mechanisms of Type 1 Diabetes

Participants: NCRR, NHGRI, NHLBI, NIAID, NIDDK (in alphabetical order)

Sources of recommendations:
NIDDK/JDRF Genetics of Type 1 Diabetes Workshop (11/20/2000),
NIAID Expert Panel on Immune Tolerance (1998)
Diabetes Research Working Group Report (1999)

Components:

- Mouse models of type 1 diabetes repository

  The NOD mouse is an animal model of great importance to the diabetes research community. However many of the specific crosses or variants will only be utilized in type 1 diabetes research. Thus, the maintenance and distribution of these animal lines is not of sufficient scale to generate interest of commercial firms. In order to facilitate the development, maintenance and availability of NOD variants, a repository will be developed to ensure that none of these potentially valuable mice are lost to diabetes researchers.

- Identify immune system related genes for type 1 diabetes in the NOD mouse

  This project will sequence diabetes-linked regions of the NOD mouse, identify human syntenic regions, and make this resource available to the research community.

- Animal models of type 1 diabetes

  Further understanding is needed of the immune mechanisms underlying type 1 diabetes. Widely used animal models include the NOD mouse and the BB rat; however, these models do not fully reflect the immunopathogenesis of human type 1 diabetes. Examples of promising models include the humanized mouse model, adoptive transfer models, and animals transgenic for immune regulatory proteins. The recent demonstration through the generation of a GFP expressing monkey that transgenic methods can be applied to non-human

primates suggests that the above approaches may be applicable to primates as well as mice. Additional models, especially primate models, that more closely reflect the human disease will help to further our understanding of the immunopathogenesis of type 1 diabetes.

Mechanisms of support: research grants, contracts

Allocation (millions):		
	FY01	$8.5
	FY02	$2.5
	FY03	$8.0

II. Goal: To Prevent or Reverse T1DM

Participants: NHLBI, NIAID, NICHD, NIDDK (in alphabetical order)

Sources of recommendations:
Trans-HHS Balanced Budget Act Advisory Meeting (April 2000)
FY2001 Congressional Appropriation Report Language
Diabetes Research Working Group Report (1999)
Diabetes: Challenges and Opportunities Report (1997)

Components:

- Type 1 diabetes clinical trials opportunities

  An opportunity pool will support clinical trials of promising therapeutic approaches for the treatment or prevention of type 1 diabetes from individual investigators or clinical research programs/networks supported by all ICs with an interest in this disease. Potential groups for study include: patients with type 1 diabetes who have evidence of residual pancreatic beta-cell function; and individuals at various levels of risk for development of type 1 diabetes as assessed by HLA genotyping and measurement of antibodies, first phase insulin response, and other immunologic and metabolic parameters. Promising agents may first be tested in patients with type 1 diabetes with evidence of residual beta cell function. Preservation of C-peptide secretion would be a suitable design endpoint for such studies. On the basis of pilot studies, expanded intervention studies might be launched in new-onset type 1 diabetic individuals to assess beta-cell function over time and ultimately in at-risk pre-diabetic individuals to prevent development of diabetes. NIH will establish a committee to advise on the allocation of these funds based on the feasibility, merit and timeliness of clinical trial proposals submitted for support under this funding mechanism.

- Clinical and basic research in immune tolerance and prevention of autoimmune disease

This project will support a new program of research focused on development of a vaccine for autoimmune disease with an emphasis on type 1 diabetes. It will support innovative, short-term pilot projects, clinical studies other than clinical trials, and resources focused on type 1 diabetes.

Mechanisms of support: research grants, cooperative agreements, and contracts

Allocation (millions):		
	FY01	$16.5
	FY02	$13.5
	FY03	$16.5

III. Goal: Develop Cell Replacement Therapy

Participants: FDA, NCRR, NIA, NIAID, NIDDK (in alphabetical order)

Sources of recommendations:
Trans-HHS Balanced Budget Act Advisory Meeting (April 2000)
Diabetes Research Working Group Report (1999)
NIAID Expert Panel on Immune Tolerance (1998)
Report of the NIAID Expert Panel on Ethical Issues in Clinical Trials of Transplant Tolerance (1999)
NIH/JDRF Conference Gene Therapy Approaches to Diabetes and its Complications (1999)

Components:

- **Comprehensive Beta Cell Project**

  The beta cell is at the center of both pathogenesis of type 1 diabetes and its successful treatment and prevention. This comprehensive program, with both extramural and intramural components, will serve as an organizing center for several distinct initiatives which focus on the pancreatic beta cell: the Endocrine Pancreas Genomics Consortium, The Pancreas Stem Cell Consortium, the Type 1 Genetics Consortium, a Beta Cell Imaging Technologies Development Project, and numerous Islet Transplantation Projects. The Comprehensive Beta Cell Project will serve as a coordinating site and intellectual driving force to: 1) provide researchers with a comprehensive set of tools for beta cell research including cDNAs, expressed proteins, antibodies to surface proteins, and an integrated database of annotated beta cell structure and function; 2) organize and direct efforts to define the signaling networks in the beta cell which are involved in glucose sensing and insulin secretion; and 3) use high-throughput approaches to define beta cell protein structure and function. A program in Structural Genomics will define the structures of key beta cell proteins and use molecular modeling approaches to assign function to these proteins. To enable development of a range of proteomic approaches to beta cell function and type 1 diabetes, this

program will support the assembly of a library of full-length pancreatic cDNAs into vectors permitting protein expression.

- Consortium for Beta Cell Biology

  A Beta Cell Biology Consortium will provide access to information, resources, technologies, expertise, and reagents which are beyond the scope of any single research effort. Areas of focus include characterization of molecular markers for defining all stages of pancreas development; investigation of islet cell lineage, cell fate determination, and differentiation; exploration of the potential use of stem cells in the formation of pancreatic beta cells; elucidation of mechanisms underlying the regeneration of pancreatic beta cells; investigation of the role of cell-cell interactions, extracellular matrix components, differential cell adhesion, and cell motility in morphogenesis of the endocrine pancreas; prospective identification and purification of pancreatic stem/progenitor cells; development of clonogenic assays for evaluating potential stem cells; evaluation of pancreatic islets for transplantation; functional imaging of the beta cell; development of a cell culture model of the human pancreatic beta cell

- NIH/Industry partnerships: challenge grants

  A number of biotechnology companies have made significant advances in production of insulin-secreting beta cells from embryonic stem cells or pancreatic islet stem cells. These preparations have been used to cure diabetes in rodent models; however, further studies are needed to determine the function and survival of these insulin-producing cells in large animal models. It is anticipated that these pure beta-cell preparations will elicit different immune responses compared to implantation of whole pancreas or pancreas-derived islet cell preparations. The purpose of this initiative is to partner with these companies to further define the immunologic properties and recipient immune responses to these beta cell preparations. The NIH partnership will include collaboration with the Beta Stem Cell Consortium and access to the unique resources of the Immune Tolerance Network and the nonhuman primate transplant group.

- Expansion of islet isolation centers

  Establishment of up to six islet isolation centers in a wide geographic distribution across the United States is planned. These centers would be responsible for the procurement of human cadaveric whole pancreata, isolation and quality control of islet cell preparations, and distribution of islets for approved research or clinical protocols. They would also perform research and development to improve isolation techniques, cellular viability and function, and shipping procedures. Expanded support would provide for procurement of pancreata.

- Islet/beta cell transplant registry

  This will support an islet/beta cell transplant registry to collect and analyze data, both pre- and post-transplantation, from all institutions performing islet and beta cell transplants in North America.

- Consortium to foster research on transplantation in primates

  This project will expand opportunities to perform pre-clinical islet and kidney transplantation. Additional funding will accelerate pre-clinical testing of new agents and approaches to induce tolerance and evaluate the effectiveness of minimally immunosuppressive regimens to increase long-term graft survival.

- Gene therapy approaches to enhance transplantation

  This initiative will foster development of ex vivo gene therapy approaches to enhance islet viability, prevent apoptosis of the beta-cell by targeting protective genes, and reduce the number of islets required for successful transplantation.

Mechanisms of support: research grants, cooperative agreements, contracts, and intramural labs

Allocation (millions):	FY01	$14.7
	FY02	$10.7
	FY03	$20.5

IV. Goal: Reduce or Prevent Hypoglycemia in T1 DM

Participants: AHRQ, FDA, NCRR, NICHD, NIDDK, NINDS, NINR (in alphabetical order)

Sources of recommendations:
Trans-HHS Balanced Budget Act Advisory Meeting (April 2000)
Diabetes Research Working Group Report (1999)
Hypoglycemia and the Brain Workshop (2000)

Components:

- The biology of glucose sensing

  This project will foster the development of a multi-disciplinary consortium to explore the biology of glucose sensing and determine how this process is impaired in type 1 diabetes. Research will be directed toward an understanding of the mechanisms by which the brain senses glucose and other

metabolic signals, and how this information is integrated with endocrine and neural signals to regulate energy utilization. Functional MRI and PET imaging will shed light on neural activity and metabolism in the regions of the hypothalamus involved in fuel sensing as plasma glucose, lactate, and ketone concentrations change. This project will address the specific problems associated with loss of hypoglycemia awareness, including studies to define the mechanisms underlying the loss of hypoglycemia awareness as diabetes progresses and the extent and mechanism of CNS damage during recurrent or acute severe hypoglycemia

- New approaches for prevention of hypoglycemia in Type 1 DM

  This project will support clinical studies, including: the potential of continuous glucose monitoring devices to improve glycemic control and reduce the risk of hypoglycemia in children with type 1 diabetes; assessment of the extent (frequency, duration, degree) of hypoglycemia in a contemporaneously treated population of children with type 1 diabetes; and examination of the relationship between intensity of therapy or other factors and risk of hypoglycemia. This project will address the broader need for clinical studies designed to prevent or ameliorate the effects of hypoglycemia

Mechanisms of support: research grants, cooperative agreements

Allocation (millions):	FY01	$2
	FY02	$9
	FY03	$10

V. Goal: Prevent or Reduce the Complications of T1DM

Participants: NEI, NHLBI, NIDCR, NIDDK, NINDS (in alphabetical order)

Sources of recommendations:
Trans-HHS Balanced Budget Act Advisory Meeting (April 2000)
Diabetes Research Working Group Report (1999)
Diabetes: Challenges and Opportunities Report (1997)

Components:

- Development of targets for therapy and surrogate markers for clinical trials

  This initiative will include 1) identification of new targets for therapy and development of surrogate markers through expansion of the functional genomics effort to include endothelium, kidney, peripheral nerve, retina and other tissues involved in complications of type 1 diabetes; 2) development of methods to measure microvasculature blood flow, and water diffusion, tissue oxygenation and angiogenesis in peripheral tissues using MRI, optical

imaging, and/or ultrasound; 3) development of methods to non-invasively measure microvascular angiogenesis and/or inflammation for use in monitoring wound healing; and development of surrogate markers for neuropathy and nephropathy. This effort could foster the ability of NIH/JDRF as well as pharmaceutical companies to test new therapies more cost effectively.

- Clinical trial opportunities for therapy of complications of type 1 diabetes

  Several promising new drugs are under development to prevent retinopathy and other microvascular complications. This initiative would support small pilot studies of promising agents for therapy of complications to aid in the transition from bench to bedside.

- Genetics of microvascular complications

  This will support a project to identify genes for diabetic retinopathy.

- Consortium for development of improved animal models

  This project will support development of animal models of diabetes-associated micro- and macrovascular complications. The emphasis is on the mouse, but larger animals, such as swine and other species will be studied as well.

- Epidemiology of complications of type 1 diabetes

  This project will enhance support the long-term follow-up of a cohort of subjects with type 1 diabetes to allow assessment of autonomic neuropathy, including uropathy and gastropathy.

Mechanisms of support: research grants, cooperative agreements, and contracts

Allocation (millions):	FY01	$6
	FY02	$5
	FY03	$12.5

VI. Goal: Attract New Talent to Research on T1DM

Participants: NCRR, NEI, NHLBI, NIAID, NICHD, NIDCR, NIDDK, NINDS, NINR (in alphabetical order)

Sources of recommendations:
Diabetes Research Working Group Report (1999)
NIDDK Advisory Council

Components:

- Phased innovation partnerships

  This program would solicit applications for two types of research partnerships. The first would create "bench to bedside partnerships" to foster translation of basic research advances to clinical application for treatment and prevention of type 1 diabetes and its complications. For example such partnerships might support collaborations between bioengineers, with technology that might be useful in imaging or glucose sensing, and researchers with expertise in type 1 diabetes and its complications. The partnership would support a project to apply the bioengineering methodology to diagnosis or treatment of type 1 diabetes. The second type of partnership would provide a "glue grant" to support collaborations between two NIH funded laboratories—one currently pursuing research relevant to type 1 diabetes and another with expertise relevant to some aspect of type 1 diabetes which is not currently being applied to research on this disorder. This second type of partnership would not require the "bench to bedside" component. It would encourage type 1 diabetes researchers to actively identify and recruit leading scientists with relevant expertise to T1DM research. These partnerships would combine a pilot and feasibility phase with a subsequent technology development phase. The pilot and feasibility phase must have well-defined, quantifiable Milestones that will be used to judge the success of the proposed research, as well as a credible plan for the development of technology or other collaboration in the technology development phase.

Mechanisms of support: research grants, centers

Allocation (millions):		
	FY01	$3
	FY02	$6
	FY03	$9

Testimony
By
Mary Tyler Moore
New York, NY
On Behalf of
Juvenile Diabetes Research Foundation International
Regarding Federal Support of Juvenile Diabetes Research
Before the
Senate Permanent Subcommittee on Investigations
June 26, 2001

☆ ☆ ☆

Chairman Levin, Senator Collins, committee members – Two years ago I joined the 100 child delegates to JDRF's first Children's Congress to ask you and all your colleagues to "promise to remember them" and everyone, like me, with juvenile diabetes, when making decisions that would impact funding for diabetes research. I was very proud of them, then, for finding the courage to reflect on their fears, share their hope, and reach out to you, their representatives.

Once again, it is my privilege to Chair the Juvenile Diabetes Research Foundation's Children's Congress. This year we brought twice as many delegates – 200 children with Type 1 diabetes – because we have twice as much to do. First, we must thank you for keeping your promise, and second we must challenge you, just as each of us here has challenged ourselves, to do more.

First things first: Thank you. We are grateful you remembered us, last year, by approving legislation that provides a historic increase for juvenile diabetes research funding at the NIH -- $240 million new dollars over three years. We should also acknowledge, with thanks, the provision in that legislation of similar new dollars to expand the special Native Americans diabetes programs. We are grateful too, that Congress and the Bush Administration, even with other program growth being constrained, have re-committed themselves to the bi-partisan effort to double funding for the NIH -- an action that surely will result in more research to find a cure for diabetes and its complications. So, again, for all you've done to keep your promise these last two years, we thank you.

Of course, you have not been alone in these important efforts. We never ask others to do something we have not asked ourselves to do, first. So we have and will remain your partner in this purpose. As evidence of our dedication to finding a cure, since the last Children's Congress, JDRF has more than doubled our own funding of diabetes research – from $55 million in 1999 to $120 million in 2001. We too made a promise, to ourselves, these children, our loved ones. The stakes for us are very real, very personal.

Many of you know that I have had juvenile diabetes for more than thirty years. And like each of these children, I struggle, everyday, to do what happens naturally for people who don't have diabetes: achieve a balance between what I eat, what I do, and how I feel. Though to most of you, metabolic balance is as automatic as breathing, to people with juvenile diabetes, like me, it requires 24/7/365 vigilance, constant factoring and adjusting, frequent finger sticks to check blood sugars, and multiple daily insulin injections just to stay alive. Even with the greatest of care and closest of

personal scrutiny, I find I am often unable to achieve good balance, my sugars dangerously low, or frighteningly high. Yes, dangerous and frightening – because, frankly, serious lows can lead to seizures, coma and death, and highs, over time, result in life-limiting and life shortening complications like blindness, amputation, kidney failure, heart disease and stroke. Diabetes is an all too personal time-bomb which can go off today, tomorrow, next year, or ten years from now – a time bomb affecting millions, like me and the children here today, one which must be defused.

This reality is made all too clear by the recent sudden death of Danielle Alberti. Danielle was 31. She was an aspiring artist and daughter of one of JDRF's most active and generous volunteer leaders. Though rapidly losing her vision due to diabetic retinopathy, Danielle stuck to her dream of being a painter, and was pursuing her career when she recently, like too many young adults with Type 1 diabetes, developed kidney failure. People with diabetes related kidney failure don't do well on dialysis, so kidney transplant was her only real option. With her doctor's guidance, she and her mother, decided to return home, together, to Australia, where her chances for a near-term transplant were greater. But Danielle didn't survive the flight. She died at 30,000 feet, seeking comfort in her mother's arms -- her last words, "Mum, hold me."

Chairman Levin, Senator Collins, members, we're here again because our children, our loved ones with diabetes, look to us for comfort, for a way to stop their suffering, and we are determined to find it. This is the quest you have joined us on and it remains our greatest challenge. The good news, today, is we have reason to be encouraged. Since the last Children's Congress, we have achieved a critical research milestone necessary for us to make progress along our path to a cure.

In May of 2000 at the University of Alberta in Edmonton, Canada, and subsequently elsewhere, researchers have successfully transplanted insulin producing islet cells into men and women with juvenile diabetes – restoring normal blood sugars. This reproducible clinical success is the first significant proof of a scientific principle JDRF has long led in promoting: That insulin-producing cells can be harvested from cadaver pancreases and transplanted into patients with even the most severe cases of juvenile diabetes. Further, that these islet transplant patients could be treated with a less toxic regimen of immuno-suppressant drugs than whole organ transplant recipients require. And finally, that as a result of the transplant they could achieve normal blood sugars while no longer needing to take insulin injections. Quite simply, these findings are the first real, clinical evidence that a cure is within our grasp.

But there is a "however" to this positive news: as encouraging as these results are (and they are), the cure will remain out of reach unless we can overcome two very important obstacles:

First: This first group of islet transplant patients still must take potentially toxic immuno-supressant drugs for the rest of their lives. This makes islet transplant, at its current state of development, too risky for children and all but those people with diabetes whose lives are immediately threatened. To overcome this obstacle, JDRF has joined the NIH in a major research partnership – called the "Immune Tolerance Network." One of the focuses of the ITN is to support the development and testing of new non-toxic approaches to establishing immune tolerance. As progress is made in this area, new resources will undoubtedly be needed to expand opportunities for success and we will need your help.

The other major obstacle is the lack of supply of islets for transplant. The only current source for islets suitable for human transplant, are cadaver pancreases. And in the US less than 2000 such pancreases become available for transplant each year. If tomorrow we had the perfect solution to immune tolerance, we would still only be able to offer islet transplantation to a tiny fraction of the millions of people with diabetes who might benefit. There is hope, though, that an alternative, inexhaustible supply of islet cells can be created. Hope that very much depends on actions you, your colleagues, and the Administration choose to take. The hope I refer to resides in the potential of embryonic stem cells to be coaxed to develop into any cell in the body, including islet cells. This would solve the islet cell supply problem. Of course the promise of stem cell research is not exclusive to islet transplantation, or to patients with diabetes. Stem cells could, potentially, help restore vision for those with macular degeneration, prevent Alzheimers, or reverse Parkinson's disease eventually helping as many as 100 million Americans who suffer from chronic illnesses. Stem cells could improve heart muscle function after heart attack, allow spinal injury patients to walk again, or replace bone marrow in cancer patients. As a greater authority than I, Dr. Harold Varmus, former director of NIH, has stated: "it is not unrealistic to say that [stem cell] research has the potential to revolutionize the practice of medicine and improve the quality and length of life." To make our hope a reality, embryonic stem cell research requires federal support. So, I am here, today, to urge each of you, your colleagues, and the Bush Administration to support stem cell research within the framework of the ethical guidelines approved by the NIH in August of 2000.

I understand that support for this research raises concerns among people of good will, each trying to do what's right based on their very personal religious and moral beliefs. I have not shied from that personal soul searching, nor has JDRF in its policy making, nor should anyone. I have found comfort in my heartfelt view that embryonic stem cell research is truly life affirming. It is a direct outcome of a young family making a choice, without coercion or compensation, to donate a fertilized egg not used for in vitro fertilization, for research. An egg that otherwise would have been discarded or frozen forever. Because of the great potential of stem cell research, donating un-used fertilized eggs is much like the life-giving choice a mother whose child has died tragically in an automobile accident makes when donating his organs to save another mothers child. It is the true pinnacle of charity to give so totally, so freely, of ones self, to give life to another. Federal support for stem cell research is, therefore, an extension of this affirmation of life and is the best way to insure it is undertaken with the highest of ethical standards.

Chairman Levin, Senator Collins, Members, to borrow a phrase, "diabetes ain't bean bag." My 30 plus years of diabetes has led to visual impairment, painful neuropathy, the threat of limb loss from poorly healing foot wounds, and peripheral vascular disease which has started to limit how far I can walk. I push through all this, just like each of the children here, today, push through the burdens imposed by diabetes, because we are a determined lot, none of us willing to be deterred by adversity. We all share the firm conviction that through our efforts, and the help of friends --like the members of this Committee -- we will find a way to stop the suffering, end the pain, restore the balance.

Please listen to the stories of the children here today and promise to remember all of us who suffer from juvenile diabetes when you make decisions that will impact research.

The cure is truly within our grasp—together we will find it. Thank you.

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Testimony
By
Kevin Kline
New York
Accompanied by Katie Zucker, age 13
Los Angeles, CA
On Behalf of
Juvenile Diabetes Research Foundation International
Regarding Federal Support of Juvenile Diabetes Research
Before the
Senate Permanent Subcommittee on Investigations
June 26, 2001

☆ ☆ ☆

Katie Zucker

Hi, I'm Katie Zucker. I'm 13 years old and I have juvenile diabetes. I'm proud to be here and to meet all of you, along with my friend Kevin Kline, who is also a good friend to all of us with diabetes. Kevin has been a great JDRF volunteer and today he's here to ask that you "promise to remember" us!

Kevin Kline

Thank you Katie. Mr. Chairman and Members of the Subcommittee, thank you for this opportunity to speak on behalf of the Juvenile Diabetes Research Foundation and all children with juvenile diabetes. I am honored to share a stage with these 200 extraordinary young people.

Before I begin, may I direct your attention to this large pile of mailbags. These bags are filled with approximately 55,000 letters that the children have collected from friends, family members and community members, from across the United States in support of juvenile diabetes research. I congratulate and thank the delegates for this tremendous effort. Thank you, kids.

Each year approximately 30,000 Americans are diagnosed with juvenile diabetes. Over 13,000 of them are children, stricken at random. No child is immune.

That's 35 children every day. More than one every hour, stricken suddenly, made insulin dependent for life, now facing the constant threat of devastating complications.

These are statistics, numbers that impress but not like the reality of being touched personally by this dreaded disease. If it hasn't happened yet, it is very likely to happen to all of us sooner or later … someone we know, we work with, or one of our own family.

Surprisingly, many people still have strange misconceptions about diabetes. They think that it comes from eating too much sugar, or that it can be transmitted, not inherited but given, to another person, or that insulin is a cure! All of you know that none of this is the case. And those who are touched by diabetes surely know this, too.

In July of 1999, I joined the Board of Directors of the New York Chapter of JDRF and in July of 2000, I was elected to the position of Vice President of Public Outreach and Education.

Through my work with JDRF, I have met countless children who have juvenile diabetes and have witnessed firsthand the devastating impact of this disease on them and their families—children like my friend Katie Zucker.

Katie lives with her parents in Los Angeles, California. She was diagnosed with juvenile diabetes in the summer of 1999. There is no history of the disease in her family, so Katie and her parents were entirely unprepared for the daily regimen of insulin injections and finger pricks and the endless balancing act that goes with them.

Now, Katie is at an age where she can help her parents manage her diabetes. But how about younger children? For them, parents are their lifeline, taking charge of everything that must be done to keep them alive and well, in addition to the love and reassurance that are so very important. It's a 24-hour vigil! Here's what a typical day is like in the life of a child with juvenile diabetes:

7:00AM – Give blood test by pricking the child's finger. Based on the blood sugar level, insulin is measured out and injected. The amount and type of insulin is carefully measured based on how much and what type of physical activity the child will engage in. Based on all this, breakfast is measured out with carefully counted carbohydrates, proteins and fat.

Another blood test at 10AM is followed by a snack, adjusted to blood sugar level and activity level. The same routine at lunch as at breakfast.

Snack at 3:00 – same again.

5:30PM - Another finger prick and injection. Snack at 8:30PM with yet another finger prick – always alternating fingers, which have become sore and callused.

Bedtime – Shot and blood test.

2:00AM –Test again, give shot if necessary, or awaken the child to give orange juice if blood sugar level is low.

7:00AM – Begin again.

As you can see, this is far from a normal lifestyle. Everyone must feel compassion for the parents, who are doing everything in their power to make the brightest possible future for their children while coping with the emotional roller coaster that is everyday life with diabetes. But it is these children we must admire. Their honesty and bravery are models for us all. Their stories and their role here today – advocating for their cure, their own future – must be heard.

Trust me, we at the Juvenile Diabetes Research Foundation are not confused about our dream – and neither, I hope, are you. My dream, our dream – the dream of 200 children in this room and millions of children and parents across the United States, is simple: a world without diabetes. We are passionate, we are committed. But we need your help to make this dream a reality.

Thank you.

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Testimony
By
Jonathan Lipnicki
Los Angeles, CA
Accompanied by Tessa Wick, age 10
Los Angeles, CA
On Behalf of
Juvenile Diabetes Research Foundation International
Regarding Federal Support of Juvenile Diabetes Research
Before the
Senate Permanent Subcommittee on Investigations
June 26, 2001

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Mr. Chairman and Members of the Subcommittee, thank you for letting me join my friend Tessa Wick and all 200 of the Children's Congress delegates today to talk about juvenile diabetes.

Tessa and I have been friends since we met on the set of my movie, *Stuart Little*, three years ago. Tessa and I are both 10 years old and in a lot of ways, we're very much alike. We both go to school, love movies and like to play sports and games. We have good friends and loving families. We both have big dreams for our future.

But Tessa happens to be different from me in one important way. In January of 1999, a doctor told her that she had juvenile diabetes, and a lot of things in her life would have to change just so she could stay alive. Every day she would have to prick her finger 4 or 5 times to check her blood glucose levels. Every day she would have to be given 2 or 3 injections of insulin.

Tessa was diagnosed with diabetes about two and a half years ago, so that means she's already had to take more than 2,738 insulin shots and that she's pricked her finger to check her blood sugar level about 4,563 times.

And even that doesn't make her healthy. If Tessa's blood sugar goes too low, she knows she has to take sugar right away because if she waits even a few minutes too long, she can have a seizure or maybe even go into a coma. And she knows that high blood sugar over a long period of time can damage the organs inside her body.

For two and a half years, Tessa hasn't been able to have a normal childhood. It's been weighed down by all the burdens of juvenile diabetes. Everywhere she goes, she has to bring a blood sugar testing kit with her, and also shots and sugar just in case she goes low. Like all kids our age, Tessa wants to be independent and go to sleepovers or on class trips without her parents. But both Tessa and her parents worry when she is away from home. When Tessa goes to sleep at night, she is

frightened that her blood sugar could drop so low in her sleep that she will have a seizure. Many nights she asks her mom to wake up at 2:00am to check her blood sugar, just in case.

When I am with Tessa, sometimes I forget that she has juvenile diabetes. It is easy to do. She looks and acts like any other kid my age. But she can never forget that she has juvenile diabetes. If she does, she would be risking her life.

I am here today because I don't want Tessa or any of the 200 kids in this room with diabetes to live the rest of their lives like this. It's not fair that they don't have the same chance as other kids to live long, healthy lives and achieve all of their dreams.

Recently, I was happy to have the opportunity to meet President Bush. I was so glad to hear that he and Mrs. Bush are the Honorary Co-Chairs of the Children's Congress this year. I hope that they will also promise to remember all children with juvenile diabetes when they make decisions that will affect research.

I know that I'm lucky that I don't have this terrible disease, but I also know that that anyone could get juvenile diabetes—even me, or your kids or grandkids.

Yesterday, researchers told me that with enough funding, a cure for juvenile diabetes is possible. Won't you please help Tessa and all children with juvenile diabetes? Please do everything that you can to help find a cure.

Now, I'd like to ask my friend Tessa to conclude this testimony with a few of her words.

Tessa Wick

As someone who has diabetes, I believe that "the only way to survive is by being part of the cure." I want a cure so badly! My friends with and without diabetes want a cure, too! And I know that right now, somewhere there's a little kid – a normal kid, just like I used to be – who's sitting in some classroom and their parents are about to rush in and take them to some hospital where they will get the news that they have diabetes. And that kid is going to need a cure too.

Thank you.

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Testimony
By
Captain James Lovell
Lake Forest, IL
On Behalf of
Juvenile Diabetes Research Foundation International
Regarding Federal Support of Juvenile Diabetes Research
Before the
Senate Permanent Subcommittee on Investigations
June 26, 2001

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Thank you Chairman Levin and Members of the Subcommittee for the opportunity to speak to you today. In my professional life I am President of Lovell Communications, a business devoted to disseminating information about the United States Space Program, but you probably know me as a former member of the space program and the commander of the Apollo 13 mission. What you may not know is that I am also the father of a grown son, Jeff, with juvenile diabetes.

When my son called at the age of 26 to tell me that he had been diagnosed with juvenile diabetes, he began by saying, "Houston, we have a problem." At the time I found it ironic that he would draw a parallel between my career at NASA, especially the Apollo 13 mission, and his diagnosis with diabetes.

My training at NASA gave me confidence in my ability to overcome any obstacles that stood before my goals. When an explosion depleted our oxygen supply on the Apollo 13 mission, forcing us to abort our voyage to the moon and improvise a plan to get home, I never doubted that we would be successful, despite the seeming impossibility of our task.

With the combined ingenuity, teamwork and commitment of my crew and the team at Mission Control, we were able to successfully convert our lunar module into an effective lifeboat, which allowed us to conserve enough electrical power and water to get us safely home.

But when my son was diagnosed with juvenile diabetes, the skills that I had developed at NASA suddenly seemed meaningless. I felt that I had nothing to fight this disease that was threatening my son's life. I was well aware that insulin was not a cure for diabetes and that even if my son did everything in his power to maintain tight control of his blood glucose levels, he could still be faced with the devastating complications of this disease.

However, after joining the Juvenile Diabetes Research Foundation, I became convinced that we do have the ability to find a cure for diabetes and that the skills that I developed at NASA, such as teamwork, ingenuity and commitment, will help us achieve this goal.

The mission of the Juvenile Diabetes Research Foundation is constant: to find a cure for diabetes and its complications through the support of research. With the help of the Federal government, private

individuals willing to give their time and resources to the cause, and researchers around the world who dedicate their careers to juvenile diabetes research, we can bring about a cure in our lifetime.

I now serve as a member of JDRF's International Board of Directors and am pleased to report that this year JDRF will spend over $150 million on juvenile diabetes research—an increase of $30 million from the year 2000 and up $95 million from 1999.

However, I am well aware that JDRF's budget from private donations cannot compare to the vast resources of the Federal government.

I am aware of the recent increase in juvenile diabetes research funding and the initiative to double the budget of the NIH and I thank you for your commitment to this effort. However, we must continue to increase funding for juvenile diabetes research in order to capitalize on the opportunities that have recently been presented by the breakthrough trials in Edmonton, Canada that Mary mentioned.

The justification for increases in diabetes research has been provided by the report of the congressionally mandated Diabetes Research Working Group, which was released in 1999. This report, drafted by a national panel of diabetes research experts, puts forward an accelerated and expanded diabetes research program at the NIH.

The DRWG report identifies numerous major opportunities not being pursued because of lack of funds and focus. They include potential high impact initiatives in: the genetics of diabetes; the biology of the beta cell; the treatment of diabetes related eye-disease, kidney disease, nerve disease, and heart disease; and the development of a vaccine for prevention of Type 1 diabetes. All of these initiatives were identified as high priorities, by the DRWG and are of particular importance to children with Type 1 diabetes.

The panel recommended an FY 2000 appropriation of $827 million for diabetes research, a fiscal year 2001 appropriation of $1.07 billion and a fiscal year 2002 appropriation of $1.3 billion. Despite the recent increases in medical research funding and juvenile diabetes research funding, diabetes research at the National Institutes of Health only came to $690 million in fiscal year 2001, $384 million short of the recommended funding level.

It is evident just by looking at the children here today that the personal impact of juvenile diabetes is devastating. The economic impact of this disease on our country is just as staggering. Diabetes accounts for more than $105 billion of health-care costs annually in the U.S. and approximately 25 percent of all Medicare expenditures. The numbers speak for themselves—diabetes research is a worthwhile investment.

Mr. Chairman, I know that our great nation can solve any problem if it puts its mind to it. I ask you to promise to remember these children by supporting a cure through diabetes research. Look at the children before you. I think you will agree that failure is not an option.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

National Institute of Diabetes and
Digestive and Kidney Diseases
Bethesda, Maryland 20892

For Release Upon Delivery

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Juvenile Diabetes Research

Witness appearing before the
Senate Permanent Subcommittee on Investigations
Governmental Affairs Committee

Allen M. Spiegel, M.D.
Director
National Institute of Diabetes and Digestive and Kidney Diseases

June 26, 2001

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Statement of the Director

National Institute of Diabetes and Digestive and Kidney Diseases

Chairman Levin, Senator Collins, and Members of the Subcommittee: As Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), I appreciate the opportunity to testify at this hearing on childhood diabetes, which is being held in conjunction with the "Children's Congress" of the Juvenile Diabetes Research Foundation International (JDRF). I know that the Subcommittee will be hearing important testimony today directly from children whose lives are affected by diabetes. On behalf of the NIDDK and the other institutes and centers of the National Institutes of Health (NIH), I am pleased to report to this Subcommittee and to the children and parents in the room today that we have a vigorous research agenda to conquer diabetes and its complications. We are increasing our knowledge of the disease. We are well on our way to developing more effective treatment and prevention strategies. We are working diligently toward a true cure.

One of the most important health care issues facing our Nation is the increasing burden of diabetes. According to the Centers for Disease Control and Prevention (CDC), diabetes affects an estimated 16 million Americans, including both genders, the young and the old, all races and ethnic groups, the rich and the poor. Consistent with the topic of today's hearing, I will focus my testimony on diabetes in children, who, in many ways, suffer most from the disease. They have the disease from an early age and must endure lifelong treatment. They must carefully adjust what they eat and everything they do--from schoolwork to sports--in order to manage their disease. Even with a continuous struggle to follow such regimens, they may still develop serious, long-term complications of diabetes.

Approximately one million Americans have type 1 diabetes, which is typically diagnosed in childhood, adolescence or young adulthood. They must have daily insulin administration to survive, and must monitor their blood glucose levels throughout the day and night. While the value of maintaining blood glucose control in preventing or delaying the onset of complications has been demonstrated through NIH research, this therapy is extremely difficult and is not without risks.

We are also very concerned about reports that more and more children are being diagnosed with type 2 diabetes. While patients with type 2 diabetes usually do not lose all of their insulin-producing ability and thus may not require insulin administration, they are susceptible to the same complications as those with type 1 diabetes.

The NIH has established a broad consultative process to frame a productive diabetes research agenda for fiscal year (FY) 2001 and beyond. Critical to this process is

the scientific advice NIH has garnered from a variety of workshops and conferences, from the Strategic Plan of the congressionally established Diabetes Research Working Group, from our National Advisory Councils, and from the Juvenile Diabetes Research Foundation International (JDRF), with whom we have excellent interactions and complementary research programs. In addition to the growth in diabetes research through regularly appropriated funds, the NIH has effectively deployed the separate, special funding stream for research on type 1 diabetes for the launch of major new initiatives. We are focusing our research agenda for type 1 diabetes around six important goals: to understand the genetics and epidemiology so that we can identify who is at risk for developing diabetes, to prevent or reverse the disease, to develop cell replacement therapy as a true cure for diabetes, to prevent or reduce hypoglycemia (low blood sugar) which limits tight control of blood sugar, to prevent or reduce complications, and to attract new research talent to the field.

Understanding the Genetics and Epidemiology of Type 1 Diabetes

Type 1 diabetes has strong genetic determinants; over the last few years, several genes have been linked to type 1 diabetes, and several chromosomal regions have been identified that harbor additional genes that confer susceptibility to type 1 diabetes. The NIDDK is launching major new research initiatives related to the genetics of type 1 diabetes, in conjunction with the National Institute of Allergy and Infectious Diseases (NIAID), the CDC, and the JDRF. We are forming an International Type 1 Diabetes Genetics Consortium to analyze genetic data from U.S., European and Australian family collections. These data have the potential to identify the additional genes that confer susceptibility to type 1 diabetes. A related research initiative will expand current efforts to establish a central repository of genetic data relevant to type 1 diabetes and provide an Internet-based information service for researchers through the International Histocompatibility Working Group.

We are also stepping up research to uncover the environmental "triggers" that, in combination with a genetic predisposition, may make some individuals especially prone to developing the disease. In order to understand the interplay of genetic and environmental factors in type 1 diabetes more fully, the NIDDK is bolstering research on the epidemiology of the disease, in collaboration with the CDC, the NIAID, the National Institute of Child Health and Human Development (NICHD), and the National Institute of Environmental Health Sciences (NIEHS). One project will establish a large population of siblings, children, and parents of individuals with type 1 diabetes to identify genetic and environmental causes of the disease. By studying the interaction of genes, the environment, and the immune system, we may be able to identify factors that trigger the onset of autoimmunity in type 1 diabetes--the destructive process in which the body's immune defense system destroys its own insulin-producing cells. Given that type 1 diabetes may have its roots very early in life, another project will identify newborns genetically at risk for type 1 diabetes and follow them through the high-risk age (from 0 to 15 years) to identify additional genetic and environmental causes. Current research will be expanded at several sites, including Colorado, Florida and Washington. The CDC and NIDDK are also supporting a population-based registry to define the

prevalence and incidence of diabetes in children. This project, entitled "SEARCH," will identify all children with diabetes in six regions of the country and will help us understand trends in disease development.

Genetic clues can also be derived from animal models, which are essential tools for understanding health and disease in humans. They help clarify the function of genes and provide systems for testing possible treatments that are not yet ready for human trials. Widely-used animal models of diabetes include the non-obese diabetic (NOD) mouse and the BB rat.

Reversing or Preventing Type 1 Diabetes

The foregoing genetic and epidemiologic studies should facilitate identification of those at high risk for development of type 1 diabetes. This identification, in turn, will allow us to intervene in an effort to prevent the disease. To spur the testing of promising new strategies to prevent or delay progression of type 1 diabetes, the NIDDK, in collaboration with the NIAID and NICHD, is creating a clinical trials network, the "Type 1 Diabetes TrialNet," a major recommendation of the Diabetes Research Working Group.

To develop a therapeutic or preventive vaccine, the NIH is actively pursuing research along several fronts. The NIDDK supports basic research to facilitate the establishment of a solid knowledge base enabling the selection, development and testing of promising candidate agents for the treatment and/or prevention of type 1 diabetes. Building on this knowledge base, the NIAID and NIDDK soon will be launching a program with the long-range objective of developing prevention strategies, including vaccines for autoimmune diseases, with emphasis on type 1 diabetes. This new research program is being co-sponsored by NICHD, the National Institute of Dental and Craniofacial Research (NIDCR), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the NIH Office of Research on Women's Health (ORWH), and the JDRF.

Developing Cell Replacement Therapy

Cell-based therapy offers the hope of a real cure for type 1 diabetes and would be far superior to the two current alternatives: daily insulin administration or whole pancreas transplantation. Insulin administration via multiple daily injections or through an insulin pump is an extraordinarily difficult therapy and a poor substitute for the body's own finely tuned mechanism for releasing insulin only at the times and in the amounts necessary to maintain normal blood glucose levels. Whole pancreas transplantation is also problematic. It is major surgery, is usually done only in conjunction with a kidney transplant, and is not a feasible therapy for young children. In contrast to these current treatments, cell-based therapy would have many advantages for patients, including ease of administration--an important factor in the medical treatment of children.

Gaining knowledge about the genes of the insulin-producing beta cells of the pancreatic islets is also critical to combating type 1 diabetes. These cells are the key to insulin production and resulting glucose control. Thus, a new initiative will support the

development of a gene expression array--a tool used to analyze which genes are turned "off and on" under different conditions, including diabetes. We expect that this research will provide important insights about possible new molecular targets for the treatment and prevention of type 1 diabetes.

Recent advances have sparked an exciting wave of new hope that a cure for type 1 diabetes can be realized through pancreatic islet transplantation. The crest of that wave is a promising study in Edmonton, Alberta, Canada, in which islet transplantation permitted a small number of people with type 1 diabetes to remain healthy for over a year without daily insulin injections. The NIH is now expanding clinical studies to exploit and extend these impressive findings. One major NIH effort, the Immune Tolerance Network (ITN), is a consortium of research institutions, led by the NIAID, which seeks to replicate the successful results of the Edmonton protocol in a larger number of patients.

In complementary research, the NIDDK, in conjunction with the Department of the Navy, has established a Transplantation and Autoimmunity Branch, in which several islet transplants have been performed in adult patients with severe type 1 diabetes. The Walter Reed Army Medical Center and the University of Miami's Diabetes Research Institute are also collaborating in this research. The National Center for Research Resources (NCRR) also plans to establish up to six islet isolation centers across the U.S. to coordinate procurement of pancreatic tissue, isolation of islets, and their distribution for use in research protocols. These centers would also perform research and development to improve islet isolation techniques. In addition, the NIDDK will support an islet/beta cell transplant registry to collect data from all institutions performing islet and beta cell transplants in North America. As islet transplantation continues to be perfected, we will need to address two issues that could limit its widespread clinical application: (1) inadequate supplies of islets and (2) imperfect methods to prevent transplant rejection. We have several initiatives under way to resolve these issues.

First, we are accelerating research on many aspects of beta cell development and function so that we can increase supplies of donor pancreatic tissue for transplantation, possibly by developing alternative sources of islet beta cells. With NIDDK leadership, the NIH is taking a significant step in the development of cell-based therapy by establishing a new comprehensive beta cell project, as recommended by the Diabetes Research Working Group. The consortium approach will provide scientists with access to information, resources, technologies, expertise, and reagents that are beyond the means of any single research effort. A comprehensive understanding of the molecular basis of beta cell development and function will then help to generate new research tools and to provide critical insights into the prevention and treatment of type 1 diabetes. Another approach to cell-based therapy is research on laboratory-generated replacement cells.

Second, we are supporting research on alternatives to the lifelong immunosuppressive drug treatments that are currently required to prevent rejection of transplanted islets and kidneys. One innovative research program, led by the NIAID and NIDDK, is developing methods to induce immune tolerance to transplanted kidneys and islets in non-human primates so that the grafts will be accepted by the recipient's immune system without the need for global immunosuppression. Because of the similarities between the human and non-human primate immune systems, results from

this program will directly influence studies in the Immune Tolerance Network, TrialNet, and other NIH and JDRF supported clinical trials in islet and kidney transplantation. Such novel approaches to educating the immune system not only increase the likelihood of achieving a true cure for type 1 diabetes, but may also offer hope of preventing the disease in those at risk. Through these combined efforts, we are hopeful that islet transplantation can become the real cure we are all seeking for patients with type 1 diabetes, many of whom are children and young adults.

Reducing or Preventing Hypoglycemia in Type 1 Diabetes

The medical management of children with type 1 diabetes is particularly challenging. The occurrence of low blood sugar is a major factor limiting the ability to achieve good metabolic control and thus reduce the risk of complications. Very young children cannot be taught the symptoms of low blood sugar or to alert their parents to take action when sugar levels drop dangerously low. Symptoms of severe low blood sugar can include seizures or loss of consciousness, which can be very frightening and may cause permanent problems. The NIDDK, in conjunction with the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Nursing Research (NINR), NICHD and the JDRF, is expanding research to understand the pathways involved in being aware of hypoglycemia, and clinical research on methods to reduce or prevent hypoglycemia. In addition, NICHD and NIDDK are collaborating on a new initiative to encourage research on subcutaneously implanted glucose sensors in children with diabetes to monitor their blood sugar levels around the clock. Clearly, this advance would mean a substantial improvement in the quality of life for these children and their families, especially avoiding night-time hypoglycemia and elevated blood sugar levels immediately following meals.

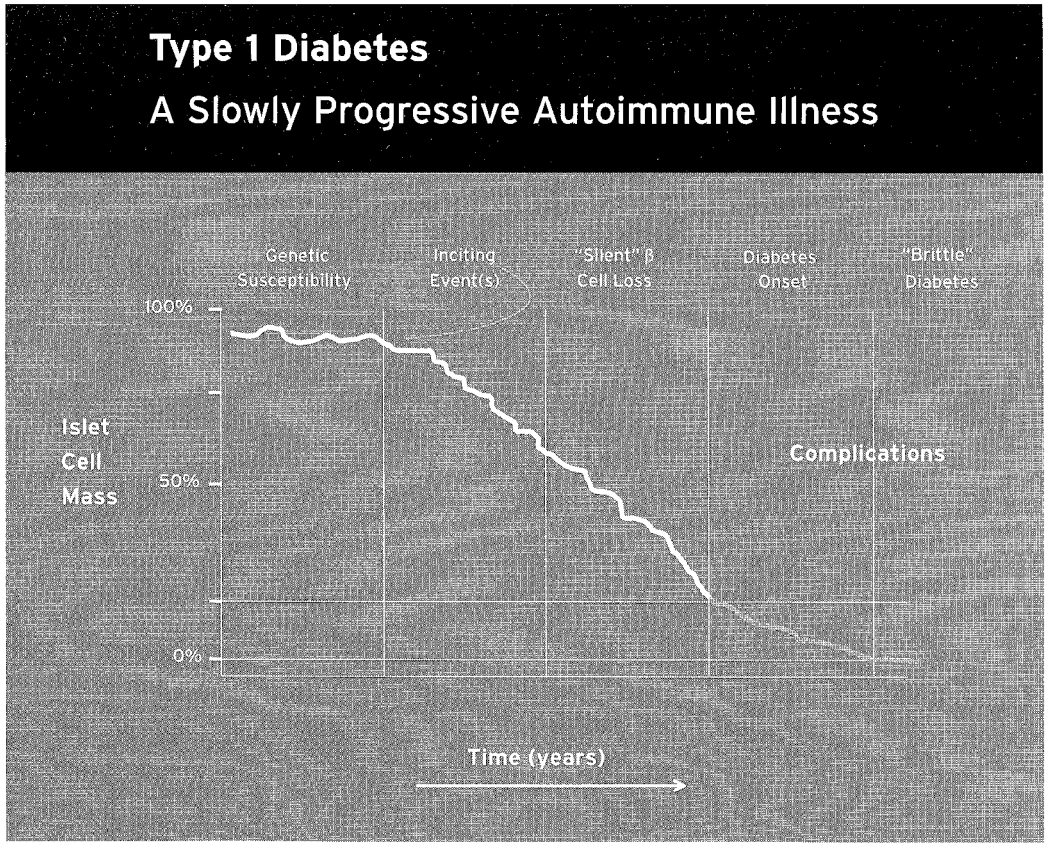
Preventing or Reducing the Complications of Type 1 Diabetes

The complications of diabetes affect virtually every system of the body. Diabetes is the leading cause of kidney failure, new blindness in adults, and non-traumatic amputations. It is a major risk factor for heart disease, stroke, and birth defects; shortens average life expectancy by up to 15 years; and costs the nation in excess of $100 billion annually in health-related expenditures. The NIDDK, in collaboration with the National Eye Institute (NEI), NIDCR, NHLBI, and NINDS, is supporting numerous initiatives to reduce and prevent the complications of diabetes. We are increasing research efforts to identify new targets for therapy. We are encouraging the development of surrogate markers for clinical trials by expanding the study of how genes function in tissues commonly involved in diabetes complications and by the development of improved diagnostic techniques. The NEI is initiating clinical trials relevant to diabetic eye disease. Several promising new drugs are under development to prevent diabetic eye disease and other complications involving the small blood vessels. We are also working to identify genes that may increase susceptibility for the development of the eye and kidney complications of diabetes.

Attracting New Talent to Research on Type 1 Diabetes

In order to accelerate the pace of research, a cadre of exceptionally talented and dedicated researchers is needed to bring the power of their intellects and expertise to bear on understanding, treating, preventing and curing type 1 diabetes. As the base of fundamental knowledge about type 1 diabetes grows, the opportunities also increase to translate this information into new diagnostic, preventive and therapeutic strategies. The NIDDK is supporting initiatives to foster the development of "bench to bedside" research through a partnership of both basic and clinical scientists in order to bring discoveries in the laboratory more rapidly to a clinical setting in which the patient can benefit. In addition, we are encouraging diabetes researchers to act as "talent scouts" to identify leading scientists with expertise or cutting-edge technology and bring them into type 1 diabetes research. New awards will support partnerships between such scientists and type 1 researchers.

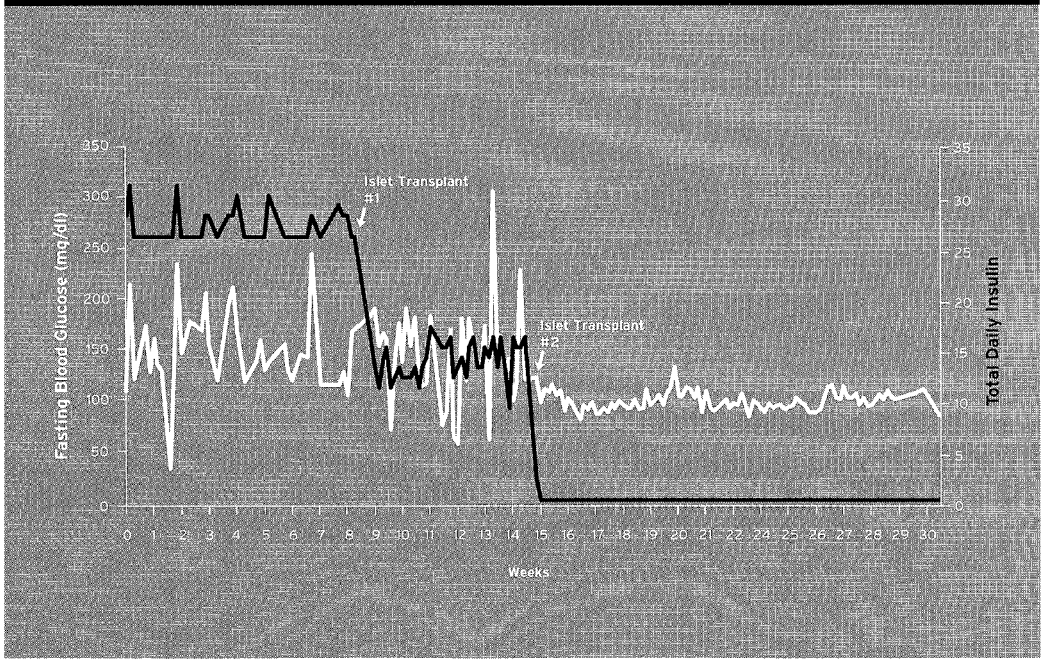
I am grateful for the opportunity to share with you these examples of the many exciting NIH research efforts directed toward conquering diabetes in children. Diabetes places a tremendous burden on patients and their families, especially when it strikes in childhood. Through research, we will find the means of lifting the strain of this disease from their shoulders. Today, there is an unprecedented sense of enthusiasm and momentum in the diabetes community. We are eager to pursue the many scientific opportunities made possible by the biotechnology revolution. We are encouraged by the dedicated efforts of patients and their families, by organizations such as the Juvenile Diabetes Research Foundation International, and by the Diabetes Caucus. We are grateful for congressional interest and support, which have enabled us to undertake many of the research initiatives I have described to you. It is a privilege for me to be able to share the vigor and the promise of diabetes research with this Subcommittee, and with the children and parents affected by diabetes--who are always on our minds and in our hearts. I am pleased to answer any questions you may have.

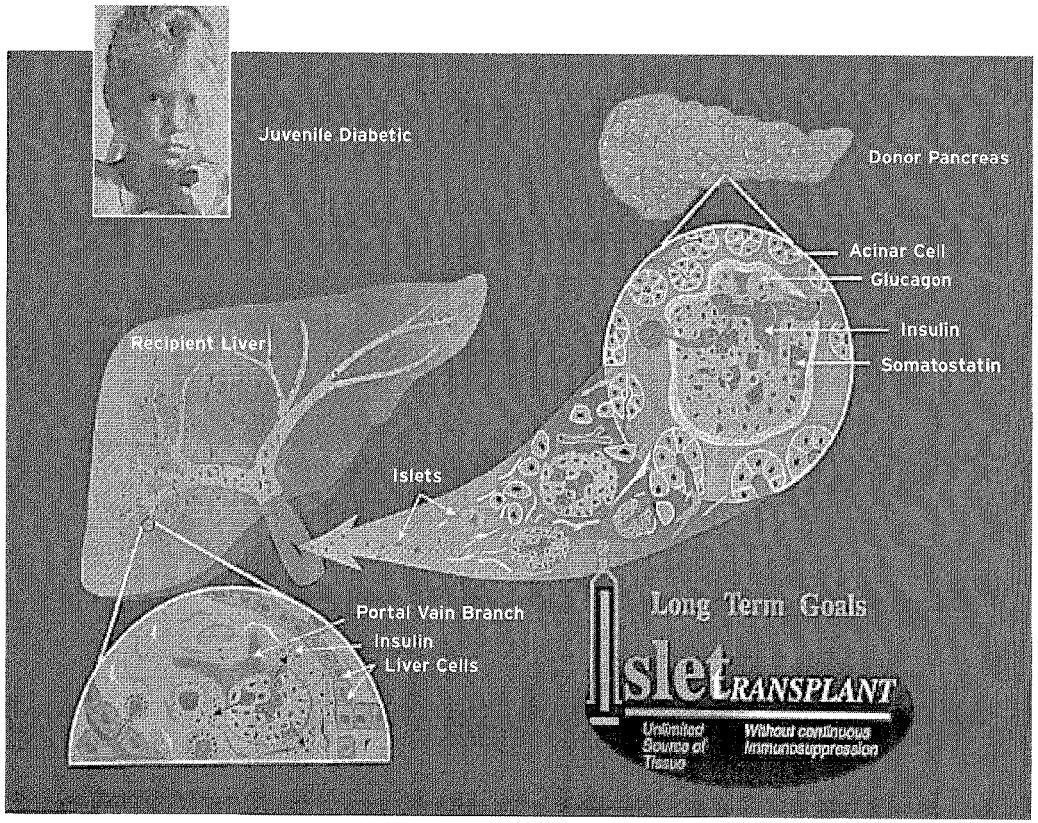

Type 1 Diabetes
A Slowly Progressive Autoimmune Illness
Genetic Susceptibility
Inciting Event(s)
"Silent" β Cell Loss
Diabetes Onset
"Brittle" Diabetes
100%
50%
0%
Islet Cell Mass
Complications
Time (years)

Goals to be Pursued in Type 1 Diabetes Research

- Identify the genetic and environmental causes of T1DM
- Prevent or reverse T1DM
- Develop cell replacement therapy
- Prevent or reduce hypoglycemia
- Prevent or reduce complications
- Attract new talent to T1DM research

Fifty-seven Year Old Woman Diagnosed with T1DM in 1950 (Brittle)




Juvenile Diabetic
Donor Pancreas
Acinar Cell
Glucagon
Insulin
Somatostatin
Recipient Liver
Islets
Portal Vain Branch
Insulin
Liver Cells
Long Term Goals
Islet TRANSPLANT
Unlimited Source of Tissue
Without continuous Immunosuppression

Testimony
By
Hugh Auchincloss, MD
Boston, MA
On Behalf of
Juvenile Diabetes Research Foundation International
Regarding Federal Support of Juvenile Diabetes Research
Before the
Senate Permanent Subcommittee on Investigations
June 26, 2001

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Introduction:

I would like to thank Chairman Levin, Senator Collins, and distinguished members of the subcommittee for this opportunity to speak before you. My name is Hugh Auchincloss. I'm a Professor of Surgery and a transplant surgeon at Harvard. I'm also the Director of the Juvenile Diabetes Research Foundation Center for Islet Transplantation at Harvard Medical School. Finally, I have served for the past three years as the Chairman of the Medical Science Review Committee of the Juvenile Diabetes Research Foundation.

I want to speak today about the extraordinary advances that have occurred recently in the effort to cure type one diabetes. I also want to talk about the very significant problems that remain to be overcome, and about the equally significant opportunities that are available today to solve these problems.

What has been accomplished?

Let me talk first about what has been accomplished. Members of this committee have already heard about the success of the "Edmonton Protocol" for islet cell transplantation. This protocol uses a combination of immunosuppressive medicines, islet cell isolation procedures, and techniques for their transplantation that has led to the elimination of insulin therapy for the vast majority of patients who have undergone the full procedure. The success of this protocol has changed the field of islet transplantation dramatically. Two years ago the results of islet transplantation were dismal. Today, we now expect that most patients who undergo the procedure will truly be able to say that they <u>used</u> to have diabetes.

What remains to be done?

As dramatic as this accomplishment is, much more needs to be done before we can turn to the children in this room and say that we have cured diabetes.

1. In the first place, the patients who have undergone the Edmonton protocol, or other variations of this approach, have actually given up one disease (their diabetes) for another one (the requirement for life-long immunosuppression). All of these patients will need to take a combination of several medicines which

prevent rejection of their islets but which also diminish their body's capacity to fight infections and the development of cancers. They will need to take these medicines for the rest of their lives, if they wish to stay off insulin. This trade-off has been justified for a small number of adult patients who truly can no longer tolerate their insulin therapy and for patients who already need kidney transplants (and thus need immunosuppressive treatment anyway). However, it is not a reasonable trade-off for young children. Therefore, we need to accomplish what is referred to as "tolerance-induction": the re-programming of the immune system so that it treats transplanted tissues from a donor as if they were a natural part of the recipient's body. The Immune Tolerance Network, sponsored jointly by the NIH and the JDRF, is working to initiate clinical trials to accomplish this goal. However, there is still no clear road map for how this can be done and much more research and effort will be needed to bring this effort to fruition.

2. The second remaining problem is that children who have type one diabetes face an additional immunologic problem when we attempt to replace their insulin-producing cells. Not only will transplanted islets be subject to rejection because they come from a different donor, they will also be subject to immunologic destruction because they are islets, and thus the targets of the original autoimmune condition that caused the disease in the first place. Therefore, even if we learn to accomplish transplantation tolerance and perform islet replacement without immunosuppressive drugs, we will still need to learn how to reprogram the immune system so that these children no longer have autoimmunity.

3. The third remaining problem is that even if we could transplant islets without rejection and without recurrent autoimmunity, we do not have remotely enough islets to go around. Even if we used every available cadaver-donor pancreas for islet transplantation, we would have only enough islets to cure 0.1% of all the people with type one diabetes. Despite all the efforts that we are making to increase the number of donors and to improve the yield of islet isolation, we still have no hope of finding enough islets from human cadaver donors to cure this disease.

There are at least seven different ways in which more islets might be obtained. Scientists are actively exploring all of them.

1. We might learn to transplant islets from animal donors. This is called xenotransplantation. We have tried this approach, and have, so far, been miserably unsuccessful.

2. We might learn to genetically engineer other types of cells so that they produce insulin in a regulated fashion. For example, liver cells (which are abundant) might be made to secrete insulin on demand.

3. We might develop immortalized lines of insulin-producing cells that could proliferate indefinitely. We would need, however, to learn how to shut off this proliferation reliably after transplantation to prevent what would otherwise be a transplanted cancer.

4. We might learn to grow cultures of islets so that we could increase the islet yield from each cadaver donor. But so far, whenever we have gotten islets to grow, they have also stopped producing insulin.

5. We might learn to produce new islets from their precursors within the pancreas. So far, however, we're not even sure where these precursors are located and our best efforts to produce new islets from them have yielded only droplets, not the bushels that we need.

6. We might learn to produce islets from so-called adult stem cells. These are cells that have been found in bone marrow, cord blood, and other sites that appear to be capable of differentiating into many different human tissues. However, despite some recent advances, scientists have been unable to turn these cells into insulin-producing cells, even after thirty years of work.

7. Finally, we might learn to differentiate embryonic stem cells into insulin-producing cells. We know that these ES cell lines can be made to proliferate to produce almost unlimited quantities of offspring. In addition, during the past year, scientists have succeeded in guiding cells of this type to turn into what have been called "pre-islets". These differentiated offspring have produced insulin, but not yet in normal quantities. It was a dramatic step forward in this field, making this the most promising avenue of research toward developing an endless supply of insulin-producing cells for transplantation.

We do not know which of these approaches might someday solve the critical problem of islet supply. All of these approaches have been attempted. I urge you, on behalf of the JDRF and all the children with type one diabetes, to enable and support research in every one of these areas.

Unfortunately, the most promising of these approaches - the use of embryonic stem cells - is opposed by some. I fear that the opposition is often based on misunderstandings. First, the embryonic stem cells that are most promising are derived from the left-over products of in vitro fertilization. They are derived from clusters of cells that are today sitting in freezers all across this country that are due to be discarded. Another misunderstanding is the idea that adult stem cells are just as good as embryonic stem cells. Someday, we may learn that that is true. However, we do not know today whether it is true or not. On the contrary, there is

considerable scientific evidence suggesting that embryonic stem cells have major advantages over any other source of cells.

The JDRF has taken a strong leadership position advocating the continued scientific investigation of embryonic stem cells as a possible source of new islets and of tissues to treat numerous other diseases of both children and adults. We urge Congress and the NIH to support federal funding for this research as well.

Thank you for the opportunity to speak to you today. I would be happy to answer any questions.

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Testimony
By
James Robbins
President and CEO – Cox Communications
Before the
Senate Permanent Subcommittee on Investigations
June 26, 2001

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Thank you for the opportunity to testify today. I am here today because my daughter, Peyson, lives with diabetes and has done so since she was a youngster. Peyson has developed into a wonderful young adult, works in the stimulating atmosphere of New York City and looks forward to building her own family someday. But I was reminded of what is involved in maintaining a life with diabetes when we recently took a family vacation together. While I am filled with admiration for her, I also have deep concerns about her future. There are no two ways about it; diabetes compromises one's future.

You have heard from Drs. Auchincloss and Spiegel that we are at a critical juncture in diabetes research. The interdisciplinary approach, drawing researchers from various disciplines to attack a problem, is working. Islet cell transplantation is moving forward rapidly, and stem cell research stands to move us to the next level of making this research available to all people with diabetes, including our children.

As a person who has been involved in corporate leadership most of my life, I know that investments based on strategic initiatives pay off, and I am here today to applaud your support of medical research and to seek further assurances that we, as a society, will explore all scientifically-sound research to find a cure. The main thrusts of diabetes-related research fall within the areas of transplantation and immunology, and breakthroughs promise broad benefits. I implore you, therefore, not only to maintain your long-term support of medical research, in an environment admittedly oriented toward the immediate, but to increaser your commitment.

What this could mean to society is far-reaching, and would provide the ultimate gift we could provide our children—an even playing field, hope for tomorrow, and a future toward which they can build their lives.

I commit to you today that I will work at your side to bring this about and feel confident that I can offer the same commitment from fellow parents of children with diabetes. In a civil society, we can do no less.

Testimony
By
Greg Brenneman
The Woodlands, TX
On Behalf of
Juvenile Diabetes Research Foundation International
Regarding Federal Support of Juvenile Diabetes Research
Before the
Senate Permanent Subcommittee on Investigations
June 26, 2001

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I would like to begin by thanking the members of both houses of Congress for warmly embracing our children as they have courageously brought their story to the leaders of our great country. These 200 children are advocates for millions of others whose minute-by-minute, day-by-day existence is impacted by diabetes.

As we all know, diabetes is one of the fastest growing and most costly diseases facing our society. It has no cure. Sixty years ago it was fatal, 20 years ago it was manageable but shortened a person's normal lifespan by 20-30 years, today new tools (such as the insulin pump) and new types of insulin have improved the overall health of those with the disease. With your help, we can find a cure for this diabetes in the next decade.

I'll never forget the day, January 20, 2000, when I found out my 11-year-old son, Andrew, has diabetes. I was, until last month, president and COO of Continental Airlines and had just arrived home from a business trip. A call from my wife confirmed that what we had been suspecting as we watched Andrew drink water like a fish and drop 20 pounds in just over three months.

I thought about what I would say to Andrew when I first saw him. I knew his first thought would be of his grandfather who passed away a few years earlier from complications of diabetes after a long, painful fight. Andrew had just been to the doctor for his first of thousands of blood tests and insulin shots. All of my meetings had been canceled for the next day as we were scheduled to spend the entire day in Children's Hospital in Houston learning how to care for the disease.

Our family met in the parking lot of Andrew's favorite restaurant to have our "last supper" before we drove head first into our new reality.

Andrew simply walked up to me and put his arms around me. He started crying. "Well, Dad," he said, "I guess I have 17 more years to live."

"Seventeen years to live?" I responded. "Andrew, where did you get that idea?"

"Dad, it was 17 years from the time Grandpa found out he had diabetes until the time he died."

I explained to Andrew that he had type one diabetes while his grandpa had had type two, and that treatment for the disease was a lot better than it used to be.

"Dad, will you be with me tomorrow when I learn how to treat my diabetes?" asked Andrew.

"I will," I responded.

"Dad, you led the turnaround of Continental Airlines when everyone thought it was hopeless and now you're the best airline. Will you help me find a cure for diabetes?" asked Andrew.

"Sure," I said, without really knowing what he meant.

The next day at the hospital, we had one of the finest health care professionals I have ever met, Shannon Brow, take us through a mind-numbing crash course on diabetes. She explained to us that Andrew's new goal was to keep his blood sugar in tight range without the benefit of his pancreas, one of the body's most complicated and miraculous organs. The consequences of being outside the range were rather severe. If Andrew's blood sugar got too low, he could pass out or go into a coma. If Andrew's blood sugar got too high, he would feel like he had the flu and lose control over his emotions in the short term, and would ruin his kidneys, heart, and liver over the long term. All kinds of things like food, exercise, and hormones would affect his blood sugar level.

Thus started a routine that any parent with a child with diabetes is painfully familiar with. Six-thirty a.m.: blood test and insulin shot carefully calculated to have just the right amount of carbohydrates. On any given day, he may feel like his blood sugar is high or low. If high, he drinks water and is excused from class to "exercise it down". If low, he eats a variety of snacks at his desk depending on how low it is and tests his blood sugar again in 15 minutes. Twelve-noon: blood test in the school nurse's office and carefully calculated lunch. Three-thirty p.m.: blood test and carefully calculated snack. If he has basketball practice, he mixes Gatorade with water to offset the effects of the exercise. Six-thirty p.m.: blood test and insulin shot with a carefully calculated dinner. Eight-thirty p.m.: blood test and insulin shot with a carefully calculated snack. If Andrew's blood sugar is low in his evening test, which happens once of twice a week, we must get him up every two hours in the night to test his blood sugar and force him to eat as necessary.

The process starts over again the next morning. With diabetes, there are no "breaks".

In addition, Andrew had to adjust his lifestyle. There is no snacking with friends, eating birthday cake at parties, or eating pizza late at night. He must always carry food with him in case his blood sugar drops. And we must ALWAYS carry a special shot with us to administer to administer in Andrew lapses into a coma BEFORE we call 911.

That day in the hospital, I watched my son turn from 11 to 18 in one day. Andrew manages to care for himself. I'm so proud of him. Some children and parents have it much worse.

Like most parents, I want to do what is best for my children so that they can dream their dreams and realize those dreams, and make a valuable contribution to this great nation. In order to have a chance, these children must have a shot at a healthy and productive future. The health care community and those that have lived with diabetes report that they have seen the future for long-term diabetes and it is not a future any parent would want for their child.

We know that the ONLY way to ensure that these children and the millions like them a future is by finding a cure for this terrible disease. We need your help. Please help us to give all these children a fair chance. Please help me to live up to my promise to Andrew to help him find a cure.

Thank you.

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Testimony
By
Rachel Dudley
Southfield, MI
On Behalf of
Juvenile Diabetes Research Foundation International
Regarding Federal Support of Juvenile Diabetes Research
Before the
Senate Permanent Subcommittee on Investigations
June 26, 2001

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My name is Rachel Dudley. I'm 15 years old and live in Southfield, Michigan. Nearly 12 years and 12,300 shots ago I was a disease free child. However along came a crippling disease, named diabetes, to turn my world upside-down.

At the age of four, my mother noticed that I had lost weight, I was constantly thirsty, and my eyes were sunken in. She made an appointment with my pediatrician. After my doctor examined me, she sent us directly to the hospital. On the way, I remember asking my mother if I was going to die. She looked at me and said, "Not if I have anything to do with it." During the 2 weeks I was in the hospital, the doctors told my mother that if she had waited any longer to bring me in, I might have gone into a diabetic coma.

For the 9 years that followed, my mother had complete control of my diabetes management and I was in good health. It was not until I entered adolescence and began wanting to do things my way that my health began to deteriorate. Several times a day my mom would ask if I had checked my blood sugar level and if I had taken my insulin. I would always tell her what she wanted to hear even though I sometimes ignored my blood sugar reading and injected the wrong amount of insulin. Occasionally, I even injected the insulin into the toilet instead of into my arm. Looking back, I simply did not want to have diabetes and I thought that I could be like a "normal" kid by simply ignoring the necessity of my daily routine. I wanted to eat when, where, and whatever I wanted, just like my friends. I wanted to be like them and so… I became like them. I didn't take correct insulin dosages—sometimes I didn't take it at all—I didn't eat according to my diet and I ignored my mother.

Because of this behavior, my body – being driven by my blood sugar - was on a wild roller-coaster ride. When my blood sugar was low, my vision was blurred and I walked into things and acted as though I was drunk. When it was high, I would feel sick and have bad headaches. And, I would feel terribly thirsty and in spite of drinking quarts of water, I could never quench my thirst. All of this was caused by my simple desire to be like other kids.

This mindset earned me a two-week stay in the hospital, including 3 days in the intensive care unit, at the age of 13. I learned that my kidneys had almost shut down. I came to understand that because of my desire to be like my friends, I had almost died.

During day after day of testing and treatment and conversation and training by specialists at Children's Hospital, I finally understood that if I wanted to live, I must accept the reality of diabetes as the top priority in my life. I finally understood that anything less than rigorous control of my diabetes management was inviting serious health problems. I finally understood that without insulin, I would die in a matter of days.

While I was in intensive care, my mother and I made a pact. Our pact was: if I would do everything in my power to stay healthy, she would do everything in her power to find a cure. We have both remained true to our promises. Since 1999, my mother has raised nearly $20,000 for JDRF. Me? I follow my diet, I exercise, and I always take the correct amount of insulin according to my blood sugar level. But, does this make me well? Absolutely not! Until a cure is found, I will always have diabetes. And, having diabetes means that I am always just a few hours away from blurred vision, headaches and nausea… just a few days away from a hospital stay. And at this very moment, if I no longer have access to insulin, I am no more than a week away from death.

At another time in my childhood, I asked my mother about the civil rights struggle and her encounters with racism. She said that she had marched and advocated for equal rights for all people so that her children would not have to. Years from now, when my children ask me about my struggles with diabetes, I will tell them about this day and I will say, "I testified before the United States Congress in Washington D.C. and I passionately urged the leaders of this great nation to fund the research to find a cure for diabetes. And I did that so that hundreds of thousands of kids like you would not have to."

Today, I ask the men and women in this great place, those who have the power and influence to alter the direction of our nation's resolve… will you do whatever you can… whatever it takes… whatever must be done… to increase funding for research to find a cure for diabetes?

Today, will you remember the two hundred kids who have come to the nation's capital to give a face and a story to this very real, very dangerous disease?

Today, I ask you to promise to remember us!!

Thank You!

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Testimony
By
Andrew Webber
Steep Falls, ME
On Behalf of
Juvenile Diabetes Research Foundation International
Regarding Federal Support of Juvenile Diabetes Research
Before the
Senate Permanent Subcommittee on Investigations
June 26, 2001

☆ ☆ ☆

Hello, my name is Andrew Webber. I'm thirteen and live in Steep Falls, Maine. Thank you for the opportunity to speak today about how diabetes affects my life.

I was diagnosed in 1998. My parents thought that my weight loss, excessive thirst and stomach pains were related to my tough football workouts, but after football season was over my condition continued to worsen. I'll never forget the day that I was finally diagnosed. I felt that I would rather die than be forced to take shots for the rest of my life.

But diabetes isn't just about taking shots. Having diabetes makes everything about my life more difficult, and it makes it especially hard to do the things that I love most… like playing sports.

When I'm playing sports, having diabetes doesn't just affect me. It affects my family, my coaches, and my team. For example, my parents don't just go to my games; they go to all of my practices too. I'd like a little independence, but most coaches either don't want to be responsible for me, or they just don't "get" diabetes. Sure, my parents like to be supportive, but three hours a night, six days a week can seem to be a little over-supportive. Most of my teammates try to be helpful, but I always feel like my medical condition is on display. Other kids don't understand that diabetes doesn't go away when I take my insulin. They don't realize that I always have to be aware of how I feel, and that I have to be ready to make the right adjustments, no matter where we are in the game even if it means sitting out some of the game. If I'm playing hard, my blood sugars might go low, and I have to stop to have some sugar. If I'm not playing as hard as I expected to play, my blood sugars could go high, and I could have blurry vision or lose my ability to concentrate on my coach's instructions.

This is hard for a lot of people to understand. Last year in Little League, I was having many abnormal blood sugars. My coaches didn't understand how diabetes works, so they assumed that I was goofing off when I needed to take breaks. Instead of listening to my parents and allowing me time to recover, they chose to bench me. I got a reputation for being uncooperative.

I'm looking forward to a cure in my lifetime. Diabetes is a slow killer. My grandmother, aunt and many other members of my family have had diabetes. They have suffered from eye disease, nerve problems and foot trouble. They have died from heart disease, gangrene and kidney disease. I want to live to be a healthy adult with children, grandchildren, and great grandchildren.

My dream for the future is to not be "the kid with diabetes" anymore but to just be Andy Webber. Research is the key to a cure but research requires money. Help me to live a long life and to be healthy enough to enjoy it. Please promise to remember me.

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Testimony
By
Michelle Kiley
Eliza Jayne Kiley
Tarentum, PA
On Behalf of
Juvenile Diabetes Research Foundation International
Regarding Federal Support of Juvenile Diabetes Research
Before the
Senate Permanent Subcommittee on Investigations
June 26, 2001

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Good afternoon. My name is Michelle and this is my daughter Eliza. Thank you for allowing me to tell you a little bit about our lives.

When you plan to have children, you dream of whose eyes they will have; whose personality traits they will carry; or what they will do in their lifetime, such as becoming a doctor; or if they will have children of their own.

I was diagnosed with Juvenile Diabetes at the age of three. When I was young, I was told that I probably wouldn't be able to have children. Everything I read said that women who have diabetes shouldn't have children. It was common for diabetic mothers to experience severe complications after a pregnancy such as retinopathy and kidney disease. Let alone the fears of congenital birth defects in a baby, or worse yet, a miscarriage or a stillborn birth. It was just too risky for baby and mother.

As I got older, there were many advances. Glucose meters and insulin pumps improved our ability to monitor and control blood sugar levels. Things have changed. Yes, I could have children if I wanted, as long as I was careful and kept myself under tight control.

Well, I was thrilled. My entire life, I felt as though God put me here on earth to be a mother. To have children was my only wish.

Eliza was born in 1996. All the things I dreamed of, I noticed. She has my husband's eyes. She has my smile and my personality—as stubborn as a bull! But the one thing I never dreamed of giving her was diabetes. My doctor said the chances were slim to none, so not to worry. And I didn't.

Well, I'm here to tell you that the chances aren't slim enough. One night, Eliza got up at about 2:30 a.m. and asked me for water, which she had never done before. I had the strangest feeling when she asked, but I just let it pass. I was just being overly concerned, I thought. She was a child who wanted a glass of water . . . what could be more normal, right? The next morning, we went through

four cups of fluid before I got up the nerve to test her. Those 15 seconds, while waiting for the meter to count down, were the longest of my lifetime. My worst nightmare was confirmed in a matter of a 15-second blood test. I diagnosed Eliza on July 11, 1999 at home with my glucose meter. My daughter Eliza has diabetes.

Talk about guilt. I hated myself for a long time. Sometimes I still do. I ask myself often, isn't my diabetes enough? I have sacrificed 26 years of my life to this disease. Why does she have to sacrifice hers? Sometimes I cry myself to sleep at night, fearing the next day's insulin pump catheter insertion. I pray that she won't hate me for giving her this disease. To make matters more strenuous, in May, my other daughter, Rebeka, turned three. The anxiety begins again.

I believe that we all have a purpose in life. Sometimes people go their entire lives without knowing their purpose. I often thought that mine was having diabetes so I could be a role model for Eliza.

But being here today has changed my beliefs. I see that Eliza and all these children have diabetes so that WE have role models. Eliza is a brave little girl, just as all the children here today. More brave than any of us could ever be, facing this disease HEAD ON.

Please promise to remember Eliza and all the children here today. Please help them fight for what they have earned. A cure for diabetes.

Eliza Kiley

Please promise to remember me. Help me and my mom find a cure for diabetes.

Michelle Kiley

Thank you.

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Testimony
By
Daniel Thaller
Burlington, NC
Accompanied by
Cameron Thaller
Jessica Thaller
Burlington, NC
On Behalf of
Juvenile Diabetes Research Foundation International
Regarding Federal Support of Juvenile Diabetes Research
Before the
Senate Permanent Subcommittee on Investigations
June 26, 2001

☆ ☆ ☆

Daniel Thaller

My name is Daniel Thaller. I am twelve years old, live in North Carolina and I am one of the millions of Americans who has been diagnosed with juvenile diabetes.

Cameron Thaller

I'm Daniel's sister, Cameron. I'm 9 years old and I was diagnosed with juvenile diabetes when I was four.

Jessica Thaller

My name is Jessica Thaller. I'm 13 years old and I've had diabetes for over 7 years.

Daniel Thaller

It all started for me when my mother realized my diapers had been overflowing and I had been very thirsty. Only at a regular checkup was it discovered that these symptoms would reveal a radical change in my and my parents' lives. With the diagnosis came the unthinkable task of giving a toddler multiple daily insulin shots and finger pricks. If you are a parent, how do you explain to your toddler that what you are doing is what will keep him alive?

After my diagnosis my mother did monthly blood sugar checks for both of my sisters, even though doctors told her it was "highly unlikely" that either would get it. Can you imagine the shock my parents felt two years later when they discovered a second child had diabetes, and the amazement

and depression they felt three years later when their third child was diagnosed. Lightning CAN strike twice (and even 3 times).

Together, my sisters and I have endured more 25,000 finger pricks.

School can be really hard for a child with juvenile diabetes. Low blood sugars can make it hard for me to concentrate, and high blood sugars make me grumpy or hyper. Sometimes, diabetes affects my performance in school and sports, as well as my social life. If I can't concentrate, how can I get A's? If I feel weak and dizzy, how can I hit a homerun? If I feel sick to my stomach, how can I go to the movies with my friends?

My friends and teachers sometimes ask, "Does that hurt?" or "What's that thing?" I get sick of the attention. Some people even know me as "the guy with diabetes." My sister Jessica has described this as feeling like being a lab rat in a cage. Unless you've lived it, you can have no idea what living with juvenile diabetes is like.

A cure for diabetes is very important to me because I have had it for so long! Eight years is 4/5ths of my life! I can't even remember what life was like without diabetes. Congress should give more finds for the research to find a cure for diabetes because millions of people suffer from it. 16 million people in the United States alone have the disease. Every day, 35 children are diagnosed with juvenile diabetes. That's 35 more kids who will ask themselves "why me?" every day for the rest of their lives. Please remember me and my sisters and give more money for diabetes research the next chance you get.

Thank you.

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Testimony
By
Caroline Rowley
Houston, TX
On Behalf of
Juvenile Diabetes Research Foundation International
Regarding Federal Support of Juvenile Diabetes Research
Before the
Senate Permanent Subcommittee on Investigations
June 26, 2001

☆ ☆ ☆

Hi. My name is Caroline Rowley and I am from Houston, Texas.

I've always heard of bad things happening to people, but I never thought anything bad would happen to me. Then all of a sudden I was diagnosed with juvenile diabetes. I was in kindergarten. My entire life changed and being a kindergartner was suddenly full of drawing blood from my fingers and taking lots of shots every day. I couldn't believe this was happening to me.

In 2nd grade, a blind woman came to speak at my school's chapel about guard dogs. I begged my teacher to ask her if she had diabetes, because she talked about taking shots to stay alive. She **was** diabetic. When I got home, I asked my mom if we would get a new dog or train our dog, Chase, to be my "eyes" when I went blind.

My mom sat me down, and with tears in her eyes, she told me we were going to do everything in our power to keep me from getting complications … that is why we have to manage my diabetes so intensely. This was our first discussion about complications, but certainly would not be our last.

After having diabetes for almost 5 years, my doctor ran a routine test to be sure my kidneys were ok. She told my mom we wouldn't hear back from her, it was just routine. Two weeks later, my doctor called and asked me to rerun the test. I took the test 3 or 4 times, but every time the result was the same.

Protein in my urine – a sign of the beginning stages of kidney disease. I didn't want to believe it…neither did my mom or dad. Now, in addition to wearing an insulin pump 24/7 and pricking my fingers, I have to take another drug each and every day for the rest of my life. When is all this going to stop?

I always thought that if I ever got complications that I would be grown, that I would still have my youth to be normal, but diabetes has stolen my childhood and forced me to grow up. I worry about having a seizure, going blind or losing my kidneys. The top ten music countdown, or the latest fashions at the GAP - these things just don't seem that important in my life.

Most people think of complications as something that happens to older people or after you've had diabetes for a very long time. I'm here to tell you **that is just not the truth.** Look around this room … there is no way for you to know how many of these children are already experiencing problems with their kidneys or their eyes.

Because diabetes is silent …. on the outside we look healthy … on the inside a war is raging our bodies, a war we cannot fight alone.

Every day I live with many fears, every night I sit in bed and pray for a cure as long as I can stay awake, hoping God will hear my prayer. It is my responsibility to control my diabetes every day and try to keep my body from further complications, but you control whether or not the researchers have a chance to cure diabetes. You can give me back my life and I will not have to fear when or if I'll be blind or on dialysis.

My life has already been shortened 15 years just because I was diagnosed with diabetes. I want a full life like the one most of you and your loved ones have been able to live, long…. and not a life full of pain and complications.

I need your help in finding a cure.

Please, please Promise to Remember Me …..

and all children with diabetes.

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