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THE POTENTIAL OF AN ARTIFICIAL PANCREAS: IMPROVING CARE FOR PEOPLE WITH DIABETES

HEARING

BEFORE THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS UNITED STATES SENATE

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CONTENTS

	Page
Opening statements:	
Senator Collins	1
Senator Coburn	2
Senator Coleman	3
Senator Lautenberg	18
Prepared statement:	
Senator Lieberman	29

WITNESSES

WEDNESDAY, SEPTEMBER 27, 2006

Griffin P. Rodgers, M.D., Acting Director, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, U.S. Department of Health and Human Services	4
Chris Dudley, Chief Executive Officer, The Dudley Foundation	7
Arnold W. Donald, President and Chief Executive Officer, Juvenile Diabetes Research Foundation International	9
Caroline K. Sweeney, accompanied by her son, Aidan T. Sweeney, Gray, Maine	12

ALPHABETICAL LIST OF WITNESSES

Donald, Arnold W.:	
Testimony	9
Prepared statement	49
Dudley, Chris:	
Testimony	7
Prepared statement	43
Rodgers, Griffin P., M.D.:	
Testimony	4
Prepared statement with attachments	30
Sweeney, Caroline K.:	
Testimony	12
Prepared statement	54

APPENDIX

Andrew P. Rasdal, President and CEO of DexCom, Inc., prepared statement	58
Responses to post-hearing questions for the Record:	
Dr. Rodgers	60

THE POTENTIAL OF AN ARTIFICIAL PANCREAS: IMPROVING CARE FOR PEOPLE WITH DIABETES

WEDNESDAY, SEPTEMBER 27, 2006

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

The Committee met, pursuant to notice, at 10:03 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Susan M. Collins, Chairman of the Committee, presiding.

Present: Senators Collins, Coleman, Coburn, and Lautenberg.

OPENING STATEMENT OF CHAIRMAN COLLINS

Chairman COLLINS. The Committee will come to order. Good morning.

As the founder and co-chair of the Senate Diabetes Caucus, I have learned a great deal during the past 10 years about diabetes and the difficulties and heartbreak that it causes for so many families as they await a cure. This hearing will examine the potential that new technologies have for improving the care and quality of life for people living with diabetes.

Diabetes is a costly and devastating illness. Nearly 21 million Americans have diabetes, and one in three American children born today will develop the disease.

Diabetes is a lifelong condition that affects people of every age, race, and nationality. It is the leading cause of kidney failure, blindness in adults, and amputations not related to injury. Moreover, it is estimated that diabetes accounts for more than $132 billion of our Nation's annual health care costs and one out of every three Medicare dollars.

The burden of diabetes is particularly heavy for children and young adults with type 1, or juvenile diabetes. They not only have the disease from an early age, but must also endure a lifetime of treatment and related complications from the disease. It is a disease that they will never outgrow.

I will never forget the first family that I met who had a son with juvenile diabetes. He was, as I recall, about 10 at the time. He looked up at me and he said that he wished he could just take one day off from having diabetes, his birthday or maybe Christmas. But he knew that he could not. And that conversation with that little boy is what motivated me to be the founder of the Diabetes Caucus

in the Senate so that we could push for greater Federal investment in research.

In individuals with juvenile diabetes, the body's immune system attacks the pancreas and destroys the islet cells that produce insulin. The average child with type 1 diabetes will have to take some 50,000 insulin shots in a lifetime. Moreover, these children and adults must closely monitor their blood sugar levels throughout their lives with frequent testing.

While the discovery of insulin was a landmark breakthrough in the treatment of diabetes, insulin is not a cure, and people with diabetes face the constant threat of developing serious complications, as well as a drastic reduction in their quality of life.

Fortunately, however, there are new technologies on the horizon that hold great promise for treating diabetes.

The fact is that current diabetes technology is inadequate. Some studies have found that even patients who aggressively manage their disease—for example, those who measure their blood glucose levels an average of nine times a day—still spend less than 30 percent of their day in the normal range. The rest of the time, unfortunately, their blood sugar levels are either too high or too low.

This morning's hearing will explore the potential for the development of a closed-loop artificial pancreas that could revolutionize diabetes care. The artificial pancreas would link two existing technologies, the insulin pump and the continuous glucose monitor. This is a sensor that is used. If we could bring these technologies together, they have the potential to dramatically improve blood glucose control, which would in turn improve the quality of diabetes care and help to prevent the serious and costly complications of the disease.

In addition to testimony about the personal and economic toll that diabetes imposes, this hearing will also feature testimony about the limitations of current technologies and the promise of new technologies. We will hear why an artificial pancreas would make such a difference until a cure is found, and we will discuss the progress in its development. Finally, we will look at the ongoing collaborative efforts on the part of the Federal Government, the Juvenile Diabetes Research Foundation, and private industry to develop these innovative technologies and make them more widely available.

I look forward to hearing from our witnesses this morning about what we in Congress can do to help move this effort forward.

I am very pleased that we have with us today someone who knows very well the toll that diabetes takes on patients, a physician, our Senator, Tom Coburn. Dr. Coburn.

OPENING STATEMENT OF SENATOR COBURN

Senator COBURN. Thank you, Madam Chairman. I appreciate your having this hearing. This is a disease that affects almost every family in the country, and if you have a family member with it, you understand the nature of this disease. As a practicing physician for over 20 years, it is the most difficult disease that I deal with in my practice. I continue to see people with it on Monday mornings.

Technology is advancing, but not fast enough. The costs both in terms of time constraints to individuals and limitations on what you can and cannot do impact every family that is out there.

I think we are on the horizon of new treatments, not only in preventing juvenile diabetes, but also curing it—whether it be with ductile cell transplants for stem cells or with automated devices, such as continuous glucose and insulin pumps.

I look forward to hearing the testimony, and I thank you for having this hearing.

Chairman COLLINS. Thank you.

We are also very pleased to be joined by Senator Coleman. He has come to, I think, every single hearing that this Committee has had looking at diabetes over the years, and we are very pleased that he is able to join us this morning.

OPENING STATEMENT OF SENATOR COLEMAN

Senator COLEMAN. Thank you. Thank you, Madam Chairman, and thanks for your leadership on this issue. It is important.

We have a very active JDRF group in my State, which is wonderful. They say Washington is a town of a thousand issues and a few priorities, and an issue becomes a priority when Moms and Dads and others step forward and say, this is important and this is affecting my child. And when you look in the face of that child and others, you say we have to do better.

What I also find exciting here is the public-private partnerships. I am a big fan. We cannot do it by ourselves. We have in Minnesota, for instance, Medtronics doing, I think, some tremendous, cutting-edge research in this area. But this really is an opportunity, Madam Chairman, to pull together the public side, the tech companies, the public entities, the universities, and others.

And so I am an optimist, and I listen to my colleague Dr. Coburn and his expertise on this issue. It is probably not moving fast enough, but I am really hopeful. We have some really smart people out there, and I think forums like this, Madam Chairman, really move the ball forward and are critically important.

So I just want to thank you for your leadership, and I look forward to hearing the testimony.

Chairman COLLINS. Thank you.

I am very pleased to welcome our panel of witnesses this morning. First we will hear from Dr. Griffin Rodgers, the Acting Director of the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health. Dr. Rodgers will provide us with an overview of how the new technologies work and why they are so important. He will also give us a review of the research funded by NIH in this area.

Next we are very pleased to hear from Chris Dudley, a 16-year veteran of the NBA and the founder and CEO of the Dudley Foundation. Chris would be a stand-out in almost any crowd, and it is not just because he is almost 7 feet tall. In 1994, he founded the Dudley Foundation, which encourages all children, and particularly children with diabetes, to pursue their dreams. He will tell us about the kids at a basketball camp that he founded in Oregon for children with diabetes, and he will also share his personal story of living with type 1 diabetes.

Next we will hear from Arnold Donald, the President and CEO of the Juvenile Diabetes Research Foundation International. Mr. Donald will tell us about the JDRF's artificial pancreas project and will talk about the regulatory and reimbursement challenges that we face as we attempt to make the technologies more widely available.

And last, but in my view, first, we will hear from one of my constituents, Caroline Sweeney, who has traveled to Washington with her family all the way from Gray, Maine. She has with her today her three children, including her 4-year-old son, Aidan, who has diabetes, who was diagnosed at 22 months of age. And I think her story will tell us why this hearing matters so much. So, Caroline, thank you so much for traveling here to share your family's story with us.

We will start with Dr. Rodgers.

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

Dr. RODGERS. Chairman Collins and Members of the Committee, good morning. Thank you for the invitation to testify today on the scientific quest to develop an artificial pancreas as a treatment for diabetes, the progress we have seen, and the outlook for the future.

As the Deputy Director and the Acting Director of the National Institute of Diabetes and Digestive and Kidney Diseases, one of the institutes at the NIH, or National Institutes of Health, within the U.S. Department of Health and Human Services, I am really pleased to provide you with some brief highlights of my formal testimony, which I have submitted for the record.

Before I begin, though, I would like to acknowledge your leadership, Chairman Collins, in focusing attention on diabetes research, including the development of new technology that will benefit patients and their families.

As you indicated, diabetes affects 21 million Americans. People with diabetes are more likely to die of heart disease or a stroke, have lower life expectancy, and really face a long-term threat of severe eye disease, kidney disease, and nerve damage. Landmark NIH-supported clinical trials and other clinical studies have demonstrated that carefully controlling blood glucose or sugar is really the key to reducing the risk for these serious and costly health complications.

Yet current strategies for diabetes management are far from perfect. Less than half of diabetes patients achieve recommended targets for blood glucose control as measured by the hemoglobin A1c levels. Achieving good control is especially challenging for people with type 1 diabetes whose disease attacks the pancreas and robs the patients of their ability to produce insulin.

Intensive therapy with insulin helps patients achieve control but really requires numerous daily finger sticks to check their blood glucose levels. It also requires that patients carefully calibrate

[1] The prepared statement of Dr. Rodgers with attachments appears in the Appendix on page 30.

their food intake and physical activity to calculate their insulin doses, which are administered by a pump that delivers the insulin under the skin. Most worrisome, though, is that intensive insulin therapy raises the risk of sudden episodes of life-threatening low blood sugar, or hypoglycemia, especially at night and especially in children. Clearly, improved therapeutic options are needed.

An artificial pancreas is a device still under development that would close the loop between glucose-sensing technology and insulin-delivery technology. Patients would automatically receive the correct dose of insulin in real time in a way not currently possible, and in this way the device would mimic how a healthy pancreas senses the need for insulin and produces the right amount at the right time, around the clock, to control blood glucose levels. Some technology could potentially benefit not just type 1 diabetes but also patients with type 2 diabetes or other forms of the disease who have to use insulin to manage their disease.

Recent developments in continuous glucose-sensing technologies have vaulted us over a major hurdle toward realizing the artificial pancreas. The NIH has helped to propel this research, and casting as wide a net as possible, the NIH-supported investigators in academia and in industry have been exploring a variety of approaches to glucose sensing.

These studies are cross-cutting, bringing together basic researchers, mathematicians, engineers, and clinicians at the same table to work on these advances. As the technology has bloomed, we have also supported validation and optimization studies. These multifaceted approaches have really borne fruit already. Three new minimally invasive, continuous glucose monitors have recently been approved or are currently under study by the Food and Drug Administration.

If I can have the first slide,[1] this shows you an example of three of those continuous glucose-monitoring devices, and I think that Chairman Collins indicated one as well. We clearly know that continuous glucose monitoring facilitates tight glucose control, and the importance of that fact is indicated on the right. For every 1-percent fall in the hemoglobin A1c level, which measures the glucose over time, there is a 37-percent reduction in eye, kidney, and nerve complications. Tight glucose control cuts heart disease in half in patients with type 1 diabetes. Only about 44 percent of people with diabetes are able to achieve the recommended glucose control with the current technology.

I am pleased to note that the NIDDK helped support this technology development in two of the three devices that are currently available or being studied. These devices measure glucose every minute, day and night, from a slender sensor inserted under the skin and trigger an alarm if the glucose becomes either too high or too low.

The devices let patients see the current glucose readings, reducing the need for frequent finger sticks. Importantly, they can see whether the glucose levels are rising or falling and how quickly, thereby allowing them to take immediate action to avoid episodes of either very high blood sugars or very low blood sugars.

[1] The chart referred to appears in the Appendix on page 41.

This type of device still has limitations and is under study to assess the full range of health benefits that it may provide, but we are really encouraged by published research that shows the potential of these continuous glucose monitors to help patients achieve good glucose control and make a difference in their care now, even before we realize the artificial pancreas.

If I can have the next slide,[1] this just gives you an indication of how patients have benefited from that. If you look at the upper panel, this is a baseline profile taken for two consecutive days on a patient who had relatively good control, as indicated by a hemoglobin A1c value of 7.2. Indicated in the green box there is the healthy range that we try to achieve, and you can see that on Day 1, indicated by the green triangles, or Day 2, indicated by the pink triangles, that there was a very small period of time that the patient actually was in that healthy range.

This patient was entered into a clinical trial and was given intensive knowledge and education on the use of this device, and you can see at the 13-week follow-up profile that there is a much larger period of time in which that patient is within that healthy range. And you can see that there is only a small change in the overall hemoglobin A1c value.

These studies are especially important to continue this technology because the FDA has only approved these devices at the moment for individuals who are 18 years of age or older, and so we really need to follow through with these studies, particularly in young children. And the reason that this is so critically important is that, in collaboration with one of our sister Institutes, the National Institute of Child Health and Human Development, we have developed DirecNet, which is a way of evaluating this technology in young children. Work is already ongoing to develop information needed for complex computer programs that will be necessary, an essential step to link the sensing with the insulin delivery and thereby close the loop.

This may first be successful during the night when there are not as many major changes in either eating or physical activity that can clearly affect glucose levels. This effort will be furthered by studies using new monitors in children admitted to NIH-supported general research centers. And, finally, insulin delivery technologies are being included in studies to ensure that they will be compatible and effective in future artificial pancreases.

Our significant progress to date toward a goal of an artificial pancreas really reflects effective public-private partnerships in which NIH and other HHS agencies, working with industry and with health advocacy groups such as the Juvenile Diabetes Research Foundation, have clearly worked together very effectively. We look to continue these partnerships in the future. For example, NIDDK, together with JDRF, the American Diabetes Association, and the FDA, convened a scientific workshop in December 2005 to assess the state of the science of glucose-sensing devices and insulin-delivery technology, and we are incorporating these outcomes from that meeting into our research planning efforts.

[1] The chart referred to appears in the Appendix on page 42.

To foster new opportunities, we have just released a strategic plan for research on type 1 diabetes, which will help in the development of this research program as we move forward in the field. The plan was developed under the auspices of the statutory Diabetes Mellitus Interagency Coordinating Committee, which will continue to coordinate efforts across the NIH and with other relevant Federal agencies.

Finally, over the past several decades, technological advances have reduced the treatment burden on patients, improved diabetes management, and reduced premature mortality from type 1 diabetes. We can now foresee a future when technology will be so advanced that we will have nearly invisible technology in patients. We will continue to foster vigorous and productive research to achieve this goal. I would like to again thank you for this invitation, and I am pleased to answer any questions that the Committee may have.

Chairman COLLINS. Thank you, Doctor, for an excellent presentation. Your full statement as well as the statements of all the witnesses will be entered into the record.

Mr. Dudley.

TESTIMONY OF CHRIS DUDLEY,[1] CHIEF EXECUTIVE OFFICER, THE DUDLEY FOUNDATION

Mr. DUDLEY. Good morning, Senator Collins and distinguished Members of the Committee. Thank you for the invitation to appear before you today. Also, thank you for your tireless leadership, Senator Collins, in championing issues that will get us to our shared goal of a cure.

My name is Chris Dudley, and I played in the National Basketball Association for 16 years with Cleveland, New Jersey, Portland, and New York. I am the proud husband of a beautiful wife and father of three wonderful, healthy children, ages 7, 6, and 4. I also have been living with juvenile diabetes for over 25 years.

In 1994, I formed the Dudley Foundation. The following year we started a basketball camp for kids with diabetes. Ever since that time, I have been an outspoken advocate for encouraging kids with diabetes to pursue their passions—whether it be in sports or other activities. Our foundation emphasizes that kids can achieve their dreams to be whatever it is that they want to be, whether it is being a doctor, professional athlete, or even a U.S. Senator, provided that they take care of their diabetes. Our goal is to empower these children.

But today I want to express the challenges of having diabetes and how new technology is imperative to help diminish both the short- and long-term effects that all those with diabetes have to face.

I tell children to be proactive and positive in managing their diabetes, and I will continue empowering them. But, still, I have to acknowledge that they will face difficulties, great difficulties, and agree with them that it is a cruel disease.

I myself have been proactive with my diabetes and yet have experienced difficulties. I have tested my blood sugar over 40,000

[1] The prepared statement of Mr. Dudley appears in the Appendix on page 43.

times. I exercise, eat healthy, and follow my doctor's instructions. I, like all those with juvenile diabetes, experience unexplained high and low blood sugars. I have had double vision and have even endured violent seizures. The need for this new technology is vital. We need help in preventing erratic blood sugars. Greater control of blood sugar levels is imperative to prevent tragic accidents, seizures, and long-term complications. This disease needs to be controlled instead of it controlling us.

This is a disease you never get a break from. You have to be aware of this disease every single day. Children have to overcome the hurdle of diabetes, just as I have, but it was not and is not an easy hurdle. I have been able to fulfill my childhood dream of playing professional basketball. I have walked onto the court to hear 20,000 fans. That feeling is incredible, and I was blessed to have experienced it. But I always wished I could play one game without worrying about my blood sugar, one game where I could just concentrate on the game and not have to worry about whether my blood sugar was heading higher or dangerously low, one game where I did not have to worry about the possibility of a loss of equilibrium, lightheadedness, double vision, or even the worst case, seizure.

I tested my blood sugar level 14 times a day on game days in order to be at my peak for the games. But I still knew that there were too many variables in the control of diabetes to feel in total control. This reality is why I am so excited about today's hearing and about the promise of new technologies, like the continuous glucose sensors and the closed-loop system, to help people manage their diabetes until—until—we find a biological cure.

If I had a continuous glucose sensor when I was in the NBA, I could have seen the trends in my blood sugar levels and taken proactive action to keep myself in even better control. As valuable as the snapshot of a blood sugar test is, it would have been invaluable to see the whole picture and to know what direction my blood sugar was heading and, even more importantly, where it had been. I could have been proactive to my blood sugar level instead of having to be reactive to the symptoms.

There are even greater needs for this technology away from the court. As a potentially life-saving feature, a sensor could give a warning that the blood sugar level is or is about to be dangerously low. This would give the person the chance to adjust their blood sugar level upward, thus avoiding a potentially fatal car accident. This device could also enable parents to set the device so it alarms when a child's sugar level goes too high or too low, giving parents peace of mind and the ability to sleep through the night and not have to awake once or twice a night to test their child's blood sugar for fear of hypoglycemic reaction. Many of our campers' parents only get to sleep through the night uninterrupted 1 week a year, and that is the week when their kids are at our camp and we are the ones checking their blood sugar twice a night.

A lot has changed since I was diagnosed with diabetes, and I am excited about new technologies that will help people to better manage their diabetes and hopefully avoid the devastating complications that can occur over time.

Ultimately, what we all want is a cure, but improvements in care along the road to a cure would make a tremendous difference to so many people who struggle every day, and it is incumbent upon all of us to do our part to help accelerate the progress on both of these fronts.

I would like to close by reading an excerpt of a letter recently sent to me from a teenage boy who attended my camp in August:

"After camp each year, I return to my home in Three Rivers, California, a community of 3,000 in the southern Sierra foothills. I have always been the only one in my school with type 1 diabetes. In my elementary school, there was no school nurse. Each year since I was diagnosed with diabetes in the spring of my third-grade year, my mom and I would educate my current teacher, as well as the office staff, about type 1 diabetes and what to do in the event of an emergency. As of the 2006–2007 school year, I am a junior and travel 20 miles each day to my high school. There is a school nurse on the campus one day a week, and most of my teachers are not even aware that I have diabetes. My basketball and baseball coaches are informed that I have the disease, but most are not knowledgeable about it. During my first season of playing tackle football, my coaches did not give me playing time because they thought I was 'sick.'

"My parents are self-employed, and the medical costs have proven to be staggering and never-ending. Their monthly health insurance costs—including supplies not covered—are in excess of $1,000 per month for our family of four. Ironically, there are new products coming onto the market that could ease some of the burdens of having type 1 diabetes, but they are cost-prohibitive and our insurance company won't provide coverage on certain brands or products.

"No child deserves to live with type 1 diabetes with its risks of debilitating complications looming over them their entire life. And at a cost of more than a half-million dollars in their lifetime for medical supplies and care, no child should have to pay that price either."

Senator Collins, thank you again for this opportunity. It has been an honor to appear before you today. I worry every day that one of my kids will be diagnosed with juvenile diabetes. And even though I have been very blessed in my life and have been able to achieve great things even with diabetes, this is not the life I want for my children. I want this cure for the children who come to my camp, my children, and all of the kids who are afflicted with this disease. Thank you.

Chairman COLLINS. Thank you. Mr. Donald.

TESTIMONY OF ARNOLD W. DONALD,[1] PRESIDENT AND CHIEF EXECUTIVE OFFICER, JUVENILE DIABETES RESEARCH FOUNDATION INTERNATIONAL

Mr. DONALD. Good morning, and thank you, Senator Collins. It is truly an honor to be here before you and the other Members of the Committee, and as Senator Coburn already pointed out, about an issue that affects so many American families.

I would like to thank you not only for your work on the issue that brings us together today, the promise of a closed-loop artificial pancreas, but for your truly outstanding leadership on the wide range of issues that affect so many people with diabetes.

As you mentioned, JDRF estimates that as many as 3 million Americans now have type 1, or what was previously called "juvenile diabetes." It is an autoimmune disease in which the body attacks the cells in the pancreas that sense blood sugar and produce insulin to convert that sugar into energy. And because people with type 1 diabetes cannot produce insulin on their own, they need to

[1] The prepared statement of Mr. Donald appears in the Appendix on page 49.

inject insulin into their bodies, either using syringes or a mechanized insulin pump, throughout the day just to survive.

The financial burden of diabetes is staggering, costing the Nation and its health care system more than $130 billion a year. That is because, over time, people with diabetes are at a staggeringly high risk for complications—complications like heart disease, kidney disease, blindness, and amputation.

While JDRF's singular mission is to find a cure for type 1 diabetes, we believe that the support of rapidly emerging technology can play a crucial role in improving the lives of people with type 1 diabetes and reducing or even eliminating the complications of the disease.

JDRF has, therefore, launched a new initiative to help accelerate the availability of an artificial pancreas, and that is one of our foundation's six cure therapeutic pathways. The overall goal of the project is to accelerate the development, regulatory approval, insurance coverage, and clinical acceptance of an artificial pancreas. The long-term goal is for broad patient access and a thriving competitive market for these technologies.

An artificial pancreas, as you know, combines two pieces of technology that are actually available to people with diabetes in some form today, although separately: an insulin pump, which has long been available—though a number of developments and improvements have been made, with new pumps coming out that make quality of life a little bit better in terms of ease of use and convenience—and a continuous glucose sensor, a promising new technology which provides real-time data about trends in glucose levels, as Dr. Rodgers pointed out, and alarms if levels are heading too high or too low. Now, this information enables people with diabetes to intervene by eating food or taking insulin to prevent glucose levels from going too high or too low.

An artificial pancreas would tie these two technologies together, using a mathematical algorithm to determine how much or how little insulin is provided to maintain glucose levels in the normal range 24 hours a day, 7 days a week. There are incredibly encouraging clinical trials already underway at Yale Medical School showing that you can "close the loop," as we say. Researchers in that clinical setting have teenage patients with diabetes on a closed-loop system that maintains near perfect blood sugar levels, especially at night. JDRF is funding this research at Yale and at five other top scientific facilities throughout the country, testing a variety of ways to close the loop. Questions about miniaturization, regulatory approval, insurance reimbursement, and clinical acceptance by doctors and patients will follow quickly on the heels of the basic science and resulting medical product development.

Now, even before a closed-loop artificial pancreas is available, continuous glucose sensors show great promise in improving the health outcomes of people with diabetes. One study found patients using continuous sensors spent 26 percent more time in the normal glucose range. Another found patients had statistically significant improvements in HbA1c levels, an important measure of glucose control. Because better glucose control means fewer complications, JDRF is making accelerating the availability of continuous glucose

sensors a top priority as we work toward ultimately an artificial pancreas.

Now, over the past decade, research conducted by the National Institutes of Health and others clearly shows that blood glucose control is far and away the most important predictor of the devastating complications of diabetes. The better the control, the lower the risk of eye disease, heart disease, kidney disease, and other problems. In fact, lowering blood glucose dramatically lowers the risk of serious complications by as much as 75 percent for some of these problems. Yet recent research shows that even the best controlled patients with traditional methods are rarely within the normal blood sugar range. The test-and-inject or test-and-pump method of controlling blood sugar, though light years ahead of clinical standards from just a few decades ago, does not come close to approximating how the human pancreas really works. To significantly increase blood sugar control, you need to more closely mimic the human pancreas, and that is an issue where technology can provide startling answers in the not-too-distant future.

With tighter glucose control will come reduced risk of diabetic complications. And here is the power of this issue. Fewer complications can, arguably, lead to one of the greatest health advances and financial savings in medical expenditures in U.S. history. Consider this: Diabetes is among the leading causes of heart disease, of stroke, of kidney disease, and of peripheral nerve disease. It is the single largest cause of eye disease in the United States. It is the cause of more amputations in the United States than any other reason, save accidents. Decreasing the rate of diabetic complications in the United States can mean savings of literally billions of dollars in health care costs annually.

JDRF's role in all this is to speedup those timetables in any way possible. We are spending some $6 million on research to assess the clinical and economic benefits from use of continuous glucose sensors and testing versions of a closed-loop artificial pancreas. We are working with regulators to understand what research outcomes they need to see before approving these new technologies. We are working with private insurers and Medicare officials to make certain that when approvals come, reimbursement will be fast on its heels. And we are working with physicians and other diabetes care practitioners to ensure that when these technologies are available, they will be fully adopted and supported.

This project has in many ways been a perfect example of how medical research can and should successfully take place in the United States. The Federal Government, primarily NIH, has funded basic research showing the benefits of better glucose control and identifying promising new methods to help achieve it. Private companies have picked up the ball to begin developing products and therapeutics they could eventually bring to the market. And organizations like Juvenile Diabetes Research Foundation have been filling the gaps, funding additional research that focuses on concepts like perfecting the algorithms that can lead to commercially available artificial pancreas devices or the clinical and economic studies that can ultimately determine regulatory, insurer, and medical practitioner acceptance.

This project has also been an example of how different parts of the Federal Government can work effectively together. And as I have already mentioned, the National Institutes of Health has played a critically important role in funding research making the artificial pancreas possible. The Food and Drug Administration has made the artificial pancreas one of its Critical Path goals. The Centers for Medicare and Medicaid Services has convened an expert panel to advise on these technologies. And the Congress, under your leadership, has made this issue a priority, with 68 Senators and 245 Representatives highlighting the promise of these technologies to HHS Secretary Michael Leavitt in letters this spring.

We are profoundly grateful for your leadership—profoundly—and we look forward to continuing to work with you in the months ahead to achieve an artificial pancreas and help millions of Americans with diabetes live longer and healthier lives.

Thank you very much.

Chairman COLLINS. Thank you for your excellent testimony.

Mrs. Sweeney, we are delighted to have you here today. I think that your son may set a record in terms of the youngest witness, certainly before this Committee, if not the entire Senate. So, Aidan, we are glad to have you here, too. You are a good waver.

Mrs. Sweeney, you may proceed.

TESTIMONY OF CAROLINE K. SWEENEY,[1] ACCOMPANIED BY HER SON, AIDAN T. SWEENEY, GRAY, MAINE

Mrs. SWEENEY. Good morning, Senator Collins and Members of the Committee. I am Caroline Sweeney from Gray, Maine. I am here today with my 4-year-old son, Aidan. Before I begin, I want to say a special thank you to you, Senator Collins, for all that you do to help find a cure for diabetes. You give my family so much hope that one day my son will not have to struggle with the daily burden of diabetes. I am proud to live in Maine and to have you as my Senator. Thank you.

Chairman COLLINS. Thank you.

Mrs. SWEENEY. On February 10, 2004, my world fell apart. I had taken my son, Aidan, then 22 months old, to the pediatrician because he had been up all night drinking water and soaking diapers. Twenty-six weeks pregnant with my second child, and tired of waiting for the doctor to return to the examining room with Aidan's blood sugar results, I opened the door and was quickly escorted back into the room by the nurse. I will never forget the look on her face as I asked, "Everything is all right, isn't it?" She looked at me with tears in her eyes and shook her head, "No." Covered in urine, I held my crying son tightly and gasped for breath as I fell against the examining table. My son, the child I had longed for my entire life, was sick—sick with a disease for which there is yet no cure: type 1 (juvenile) diabetes. Aidan was in diabetic ketoacidosis, a complication which threatened his life. My life, but importantly, my son's, would never be the same. I went through every emotion. I wanted to scream; I wanted to hit; I wanted to run; I wanted to be numb. Most of all, I wanted it to go away.

[1] The prepared statement of Mrs. Sweeney appears in the Appendix on page 54.

But diabetes never goes away. Aidan is now 4 years old. He receives insulin through a pump, which he wears on a belt around his waist, 24 hours a day. The pump is connected to an inch-long catheter tunneled beneath the skin on his bottom. So far, we have changed his catheter over 500 times. Not surprisingly, he does not like the catheters. Most site changes become bargaining sessions, and despite the anesthetic cream, he feels every stick. His little bottom is studded with scars.

His fingertips are scarred from being tested up to 12 times a day. That is more than 11,000 tests in 2½ years. Like the site changes, he does not like the testing. Sometimes, Aidan will run away when it is time to test his blood sugar or hide his hands behind his back, crying for me not to test him. At preschool, he has asked his teacher to test his blood sugar in the bathroom so the other kids will not watch.

Despite his efforts, he can never escape his tests. He is forced to test his blood sugar everywhere—at preschool, at the grocery store, at restaurants, at the playground, at friends' homes, and even in his bed during sleep. The tests are constant, frustrating, and exhausting. Growth spurts and minor illnesses can cause his blood sugar levels to rise or fall unpredictably and change his insulin demands as well. His emotions shift with every blood sugar fluctuation, making it impossible to distinguish between "typical 4-year-old behavior" and "low" or "high blood sugar behavior." Often he has been unable to warn me even when his sugars are at life-threatening levels. Two and a half years into his illness, he will still sleep through dangerously low blood sugars and be asymptomatic while awake. And so I test.

And I worry. I am always fearful—fearful that my son's blood sugar will rise so high that he will enter into a coma or drop so low that he will seize or even worse. Every night, I check his blood sugar before I go to bed and pray to God that he will wake up in the morning. I never sleep through the night. I keep a baby monitor on my pillow just so I can hear him breathe. I have found myself running into his bedroom in the middle of the night, carrying glucagon and a syringe, thinking that I have heard him seizing. I am always relieved when morning comes and I hear his little footsteps entering my bedroom.

I have become not only Aidan's mother but his health care provider. With each good morning and good night kiss comes a finger stick. The responsibilities of his diabetes care are many—endless testing, counting and recording and interpreting everything that he eats, calculating insulin doses, giving insulin, changing catheter sites, keeping his supplies in stock, trying to explain to him just why it is that he cannot eat the chocolate cake that his friends are eating when his sugar is too high. The list goes on.

Still, despite diligent care and tight glucose control, I am aware my son is still more likely to suffer from heart disease, kidney failure, nerve damage, stroke, blindness, amputations, and an early death. This is most difficult to face as a parent. I try to live day by day with my son, but find myself wondering: Will he one day lose a limb? Will he end up on dialysis? Will he go blind? Will he live to see the age of 50?

Aidan can only be left in the care of others who are trained in diabetes, including babysitters and school. Fourteen weeks after Aidan was diagnosed with diabetes, I gave birth to our second son, Michael, now 2, and just 3 months ago gave birth to our daughter, Caitlin. Both deliveries put us in a state of panic over who would take care of Aidan. Families on both sides were forced to pick up their busy lives and come to Maine in the weeks before both deliveries so they could be trained in diabetes care. I can vividly remember my mother learning how to operate Aidan's insulin pump while timing my contractions. While my biggest concern should have been my unborn child, I could not seem to escape the worry about Aidan's care.

From the moment little Michael and Caitlin were born, they have never been able to have my complete attention because of Aidan's diabetes. Aidan's illness comes first—before nursing, diaper changes, cries, baths, even hugs and kisses. I recently realized the impact of this when Michael, my 2-year-old, insisted on having his blood sugar checked, claiming to have diabetes, too. Much of his life is also dependent on Aidan's blood sugars. He knows that if Aidan's blood sugar is high at dinnertime that he has to wait with the rest of the family before he can eat. He knows that sometimes Aidan needs to drink juice really fast and sometimes only he can have juice and Aidan cannot. He knows that his Mommy and Daddy sometimes stick a needle into Aidan's bottom and that Aidan does not like that. I do not know what impact this will have on Michael in the years to come. I can only try to help him understand the severity of his brother's disease, while praying that he and his sister do not one day get diabetes.

As parents, we try from the moment our children are born to protect them from any harm. Two years ago, I never felt more helpless when all I could do was hold the tiny hand of my 22-month-old son in the intensive care unit and pray he would not die. I vowed at that moment to do everything I could to find a cure for diabetes. I stand before you today with my son, my hero, asking for your support in saving his life. While the continuous glucose monitor and artificial pancreas are not cures, they can offer Aidan, and children like him, a tremendous improvement in his quality of life, free from thousands of finger stick tests, and offer me the gift of peace—peace in knowing that my son is safe and hopefully able to live a longer life with this terrible disease.

I encourage Congress to continue to show its support for these promising technologies and to help ensure that they are available and accessible to all who could benefit. Thank you.

Chairman COLLINS. Thank you so much for your eloquent testimony. It leaves me speechless, and we are not speechless very often up here, I will tell you that.

You did such a good job of explaining to us that diabetes has an impact not only on Aidan but on your entire family. And that is one reason that your testimony inspires all of us to work even harder for a cure and for the research dollars that will lead to better treatments and to support what is a truly impressive partnership with private companies, the NIH, the Juvenile Diabetes Research Foundation, all working together toward a common goal.

Mr. Dudley, your testimony also was so eloquent when you talked about not being able to play a single game without being worried about the impact on your diabetes. It really hits home also.

Mrs. Sweeney, it is my understanding that you were a dietician prior to finding out about Aidan's diagnosis.

Mrs. SWEENEY. Yes.

Chairman COLLINS. Has that made it easier for you to manage his illness than someone who did not have that background?

Mrs. SWEENEY. It probably has made it a little bit easier, but to be honest, I expected it to make a bigger difference than it has. Both my husband and I are health care professionals. My husband is an emergency room physician, the same emergency room where Aidan had to go after he was diagnosed. And we both find this just a maddening and frustrating disease. It does not work the way that we were both taught.

Chairman COLLINS. I think that is so telling, that even people with your expertise in health care have found this to be such a challenge. And when we look at the charts that Dr. Rodgers showed us and we hear the statistics, virtually everyone who has diabetes has a very difficult time controlling their blood sugar, and yet that is so critical. And that is why I am so excited about this potential technology.

We know it would help to even out the blood sugar levels for your son, but can you also give us a sense of how this technology would make your life a bit easier?

Mrs. SWEENEY. It would make my life a lot easier in numerous ways. One would be sending Aidan off to school. That has been a big concern of ours. Every day, when I drop him off at preschool, I have to meet with his teachers to make sure that they are aware as to how to check his blood sugar, correct his blood sugar if it is high or low, and give the proper insulin for his snack. I carry a cell phone with me at all times so that anyone who is with Aidan at any point can reach me with questions.

Chairman COLLINS. Dr. Rodgers, you mentioned in your testimony that the continuous glucose sensors to date have only been approved for use in adults. Are you hopeful that they can be extended so they can be used for children? What is the barrier in that area?

Dr. RODGERS. Absolutely. As you indicated, the continuous glucose monitors are only currently available or FDA-approved for individuals 18 years of age or older. It is certainly understandable that the manufacturers wanted to get their product to the market, and it is generally well appreciated that it takes much longer to get such devices FDA approved.

Your question also speaks really to the importance of having NIH-supported research to support the types of investigations that are needed, particularly in pediatric patients, to move these devices through the approval process. And it was really for this reason that we developed, in collaboration with the National Institute of Child Health and Human Development, the so-called DirecNet, because up until this time, these devices that we showed had only been tested in adults. And while we are hopeful that the results and the efficacy of this device are equally good in children, it is really im-

portant that we have that database, that knowledge to effectively determine how to best use these devices in children.

Chairman COLLINS. I think most of us are motivated by wanting to help little Aidan and wanting to help Chris Dudley live lives free of diabetes. But there are also very considerable economic consequences of this disease. Nearly one out of three Medicare dollars are spent in treatment of people with diabetes. I think the estimate that either you or Mr. Donald gave was $132 billion in health care costs. So this makes sense, even if you are putting aside your concern for people, which none of us are, but from clearly a cost/benefit analysis.

Are we giving you—"we" meaning Congress—sufficient funding for projects in this area, which are clearly going to pay off in lower health care costs down the road?

Dr. RODGERS. Well, we are certainly very appreciative of the support that you have given us over these years, and we really try to deploy those resources that the Congress has generously appropriated to us to the most cutting-edge, the highest-priority, the most innovative types of research.

I think Mr. Donald indicated in his testimony it is estimated that the direct and indirect costs of diabetes are about $132 billion a year. Actually, that number is taken from an article published in "Diabetes Care" in 2003 based upon 2002 numbers. So almost certainly that number is much higher and likely to continue to rise unless we are able to find better ways to manage diabetes care more effectively. And the human toll, as I think you have heard, the human suffering factor is also a critical point.

So we really have to think every day about the best ways to manage diabetes, both for the human toll, but also to protect against the complications which really lead to these expenditures.

Chairman COLLINS. Thank you. We are going to do a second round of questioning, so, Mr. Donald and Mr. Dudley, I will have questions for each of you on the second round.

Senator Lautenberg.

Senator LAUTENBERG. Madam Chairman, since Senator Coburn has been here and he has a professional understanding of what is taking place, I do not mind if he goes first.

Chairman COLLINS. Senator Coburn.

Senator COBURN. Thank you, Senator Lautenberg. That is very kind of you.

Dr. Rodgers, a couple of things. At the NIH, are we working on genetic identification of those more susceptible to immune destruction of the pancreas?

Dr. RODGERS. We absolutely are. We have studies currently ongoing to try to identify the genetic susceptibility factors related to the development of type 1 diabetes in particular. Some think that it may be some viral agent. Some think that it may be some food product. But we are committed to a study that will follow kids from the time of birth, looking at the most common susceptibility gene that we currently have, something related to their HLA locus.

Senator COBURN. Right.

Dr. RODGERS. We will follow them to the age of 15 for the disease onset to see whether we can determine causation, based upon very careful surveys of their food intake, viruses, and other factors. We

are collecting a number of samples very frequently to look for bacterial, viral, and other etiologies. So that is critically important.

Senator COBURN. This is just a general statement, and you can take it any way you want. Our health care system in this country is about disease treatment rather than investing in health, and we have it wrong. We should be investing in preventing juvenile diabetes. I do not disagree that we should be investing heavily in treating it with an artificial pancreas, but you all have at the NIH $7.2 billion for prevention research. When I look at diabetes in our country and you take out type 1, or juvenile diabetes, we know the vast majority of that is preventable. And yet what we are seeing is an ever increasing number of people in this country developing type 2 diabetes, and our approach seems to be to treat the disease rather than prevent it from ever occurring in the first place.

As one Senator who is working on global health care reform, it would certainly seem important to me that we look at our priorities to make sure we are investing in prevention.

You are familiar with metabolic syndrome. You are familiar with all the risk factors associated with it. And yet we do not invest the dollars both in terms of diet, in terms of education, and in terms of prevention, which is far cheaper than paying for an artificial pancreas for somebody with type 2 diabetes.

So I think it is very important that you get the message that we need to be investing in health rather than always treating disease because we are going to lose. We are never going to have the dollars to treat the disease if we fail to invest the dollars in preventing it in the first place.

The second thing, long ago when I was in the optical business, we worked on research on sorbitol and aqueous humor. Is there anything going on in that now in terms of continuous glucose monitoring or sorbitol monitoring in the aqueous humor that might make a much less invasive glucose-monitoring system?

Dr. RODGERS. We are actually investing and trying to bring in new talent and new ideas through a variety of strategies. And, in fact, that area, in actually looking at fluid in the eye, is one way to optically sort of track glucose, and those investigations are all in very early phases.

Senator COBURN. For people that are not familiar, we could actually design a contact lens to put on a child that would measure the glucose in the anterior chamber of the eye, the aqueous humor, with a little chip on it that could automatically communicate to an insulin pump. And so it would be much less invasive in terms of a device. One of the things that was not mentioned, especially for your son, is infections. You are much more prone to infection when you are a diabetic. And that is because the microvasculature is not there to fight those infections.

The other question I had on the study with the continuous glucose monitoring, was that in conjunction with an insulin pump, or was that in conjunction with individual application of insulin subcutaneously?

Dr. RODGERS. These were patients who were admitted to a general clinical research setting, and so in that context, they were being monitored very carefully, and they were being treated with an insulin pump.

Senator COBURN. So you did have glucose monitoring with the insulin pump, but not necessarily monitoring tied to——

Dr. RODGERS. That is right. The loop had not been closed.

Senator COBURN. But when we see that, what we see is that actually goes and stays in the normal range.

Dr. RODGERS. Absolutely. In fact, you can see in that slide that despite the fact that there were these wide variations—particularly in the pre-education period, there were wide variations—our overall ability to sort of measure what we think is the average value of control really did not change demonstrably. It went from 7.2 to 6.8. So we think that these fluctuations can be almost as important as the average value over a period of time, and that is why it is critically important to further research and correlate that with the specific complications.

Senator COBURN. I would just put out the challenge that outside of the NIH and outside the CDC, we spend $6.9 billion on prevention every year in this country through 19 government agencies. And I think we have it wrong. I mean, if you go out and ask a typical American, "Is my being overweight associated with me developing diabetes?" Most of them do not make that connection at all. So, therefore, they do not see an importance for exercise, weight control, and things such as that.

Madam Chairman, we are going to be working on this next year to bring bills to the floor that we are going to remodel the prevention strategy of this country to invest in health and educate the American people and give them a chance to do that.

I want to say one other thing to Mr. Dudley. One of the things that is lacking in our country is leadership, and I want to praise your leadership. You did not have to do what you are doing, but you chose to do it. And the thing that makes our country strong, that makes us greater than any other place, is when individuals stand up and take the lead. They do not wait on the government to do it. They do not wait on somebody else. They do not become a victim. What they do is they change and say, "I will defeat this by empowering other people."

And I think what you have done is very laudable. Sure, you get pats on the back for it, but the fact is that it took real courage to take this on. It took real finances of your own to take it on and invest in it. And that is what makes us great. Your model of leadership should be commended, and I do so today. I would encourage others. There is not anything that this country cannot whip if we have great leadership. That is demonstrated by what you are doing today, so I thank you.

Mr. DUDLEY. Thank you, and I would like to thank you, Senators, for your leadership as well in fighting this disease. Thank you.

Chairman COLLINS. Thank you. Senator Lautenberg.

OPENING STATEMENT OF SENATOR LAUTENBERG

Senator LAUTENBERG. Thanks very much, Madam Chairman. I think this is as important a hearing as we have ever had, and I commend you for bringing it to our attention to remind us what happens to lots and lots of people across this country. So I personally thank you and assume that Mrs. Sweeney's testimony will

wind up in the Congressional Record also so that people will read and understand what it is like to have a child with diabetes. We understand love of a child, all of us do. I am a professional grandfather, and I have 10 grandchildren. The oldest is 12 and the youngest is three, and what I think about constantly is thank goodness that they are healthy. I have one grandchild who has asthma, and we have plenty of allergies, but nothing like the kinds of things that the Sweeneys go through.

Mr. Dudley, I think you traveled around New Jersey a little bit in your professional days. We wish you were back there. [Laughter.]

And I commend each one of you for your testimony. The value that you bring to the issue is immeasurable. And to know that we face an epidemic of diabetes, with forecasts of one in three born in the year 2000 will contract diabetes before their lives are over, it is a really ominous prediction.

One thing I find, as a grandparent, I instantly fall in love with little kids, and when you see someone like Aidan, who suffers from this terrible disease, there is something fascinating about the faces of those children. They are especially beautiful, and I see it time and time again because I meet a lot with families who have a diabetic child and listen very carefully to their experiences, and I learn things about not only the pain but the interference in normal life. But these kids seem to have a special look about them, almost angelic. And I do not know whether there is just a natural plea for understanding and help, but they bring it with them. And, Mrs. Sweeney, your testimony was particularly moving, and we thank you for being so candid in talking about the experiences as clearly as you have.

One of the things that I learned when I had a group of children with diabetes in my office in Newark, New Jersey, I asked them, "Well, what is it like? And what are the things that bother you the most?" And one child said the pinprick is the thing that is most bothersome, another said getting ill, becoming ill in class and having to expose their weakness. But one little boy, 10 years old, said, "Well, I cannot go to sleepovers anymore." So I said, "Well, what do you mean?" He said, "Well, I slept over at a friend's house, and during the night I got sick. And we woke his mother, and she got mad. And my parents said I cannot ever go do that anymore." And just something as normal as that is part of the pain and the frustration.

So I ask you, Dr. Rodgers, can more funds accelerate the process? Because despite Dr. Coburn's learned view of things, do you think diverting funds from treatment to research is a good idea? I think these are all wonderful ideas, but families who are burdened with this condition are looking for relief as quickly as it can come. So it is not enough, in my view, to fund the treatment side instead of the research side; both need funding. But did you say that you had enough funding to maintain the quickest pace as thoroughly as you can, or could you use more?

Dr. RODGERS. Well, Senator, as I mentioned, we are certainly very appreciative of the funds that we have, and we really try to deploy those in the best manner, working together with our other colleagues at the NIH. There is a very broad portfolio of activity

that we try to encompass, not only in understanding better the basic biology of this disease, the treatments for people who have the existing disease, but as Senator Coburn mentioned, also trying to develop ways to actually prevent the disease.

In the case of type 1 diabetes, we know that there is a susceptibility, and those studies are the kinds of research that we would like to certainly do more of. They are long-term studies—they go out 15 years—in order to understand what makes someone susceptible to disease, what kind of environmental factors may contribute to that. And so it is not a study that you can answer very soon. These long-term studies, of course, need long-term funding, and we are really committed to them, and we would certainly like to continue these studies for the long term because our patients invest in these clinical trials, and we certainly want to see them through their fruition.

Senator LAUTENBERG. Madam Chairman, if I may extend for just a minute more?

Chairman COLLINS. Certainly.

Senator LAUTENBERG. Dr. Rodgers, how do you get data that are being compiled from commercial—from voluntary institutions, for example the pharmaceutical industry? What kind of a flow of data are there that permits you to know what is happening in the various places and how do you put that all together?

Dr. RODGERS. There are a couple of avenues in which we get input on what are really the most cutting-edge activities and what are very promising areas of exploration. There is a statutory, mandated Diabetes Mellitus Interagency Coordinating Committee in which our Institute takes the lead on, and we work with a number of people from sister agencies within HHS as well as other Federal agencies, including the VA and so forth. They bring to our attention cutting-edge research, areas that are prime for further exploration.

In addition to that, we have an Advisory Council to our Institute, oftentimes members of academia but also members of the public, who bring to our attention important developments and ideas that really are prime for exploration.

And then through frequent meetings that we fund, we bring in members of the private sector, industry as well, to learn about where we might invest. In fact, this meeting that we convened in December 2005, which was entitled "Closing the Loop," brought in a number of people from industry to discuss some of the obstacles and opportunities.

And so we get a lot of feedback, and a lot of good ideas are generated, and then it is a matter of, with consultation from outside groups and members on our own staff, really trying to prioritize, given the resources that are available, the best and most compelling areas of research to explore.

Senator LAUTENBERG. Madam Chairman, I would ask consent that my opening statement be included in the record.

Chairman COLLINS. Without objection.

[The prepared statement of Senator Lautenberg follows:]

PREPARED STATEMENT OF SENATOR LAUTENBERG

Madam Chairman, thank you for your leadership on diabetes—and for holding today's hearing on the potential for an artificial pancreas.

I have met with some great kids from New Jersey who live with Juvenile Diabetes. And an artificial pancreas holds great promise for them.

Twenty-one million Americans have diabetes, according to the CDC.

Children with diabetes are at risk for kidney failure, blindness, and losing their limbs. And diabetes lowers their life expectancy by 15 years.

In 2002—the most recent year CDC has data for—the total cost for diabetes care in the United States was more than $132 billion. And even with all that money spent, we know the current treatments are not good enough.

Thanks to science and technology, a better treatment is on the rise.

With an artificial pancreas, kids—and adults—would have their glucose monitored all day, every day—and the pancreas would send out insulin when the patient needs it.

It would help a diabetes patient maintain "normal" glucose, just like a pancreas in a person without the disease. It would reduce diabetes-related illnesses, like kidney disease and stroke. And it would give patients more freedom—and help them live their life, not live their disease.

From stem cell research to care for Americans with AIDS, we must support science anytime it can advance medicine. Today we have that opportunity. I urge my colleagues to embrace it.

Senator LAUTENBERG. I would also make another suggestion, that if we had a film of Mrs. Sweeney's presentation, just as she did it, I think it would be a wonderful tool in educating our colleagues about the toll of diabetes and the pain and the anguish that families are going through. Thank you, Mrs. Sweeny, and your family and Aidan, for your testimony. Aidan, in his silence, did more to let us know what life is about than anything else, and all of you, thank you for your testimony and your help.

Thank you, Madam Chairman.

Mrs. SWEENEY. Thank you, Senator.

Chairman COLLINS. Thank you, Senator.

Mr. Dudley, I want to echo the praise that Senator Coburn gave you for your leadership, and that includes your establishing the summer camp for children who have diabetes. You had mentioned—and certainly Mrs. Sweeney's testimony confirms—that so many parents never get a full night's sleep once their child is diagnosed with diabetes, and your camp gives them a bit of a respite.

But I think another huge benefit of your camp is it brings children who all have the same problem together so that they do not feel that they have got to go to the bathroom and hide when they are having their blood sugar checked.

Could you talk about that aspect?

Mr. DUDLEY. Sure, absolutely. When I started the camp 11 years ago, part of it was to help kids with diabetes be able to play sports and believe that they could achieve whatever it is they wanted to achieve. And at that time—it has gotten better, but some doctors were not even encouraging kids to be active. And now we know that exercise is so important for diabetes. And so I was really trying to help kids be able to do sports while having diabetes.

The bigger impact in my mind, which I did not realize when I first started, was not only helping kids have that dream that they can achieve whatever it is they want to achieve, but also it is so important to that age group—my camp is for boys and girls ages 10 through 17—to not feel alone or different. As the camper whose letter I read said, he is the only kid in his town or school that has diabetes, and so often these kids feel so isolated and so alone that

it means so much for them to come to a camp where not only everybody has diabetes, but they all love basketball, and they have so much in common. And these kids stay in touch with each other all throughout the year, and I think it really gives them hope just to see that they are not out there alone, that there are a lot of kids walking in the same shoes. I underestimated how valuable that was when I first started the camp, and it has been a tremendous blessing to just help them in their outlook on life.

Chairman COLLINS. That is great.

Mr. Donald, you mentioned that you had very encouraging results from the clinical trials at Yale that JDRF is financing. From your perspective, what are the biggest barriers that we face in getting these new technologies to the market, assuming the clinical trials continue to be so positive? Are the obstacles primarily regulatory or scientific or a matter of getting insurers to reimburse for that technology? What are the biggest barriers?

Mr. DONALD. There are a number of barriers, regulatory first. When you deal with a mathematical algorithm which will connect the continuous glucose sensor to the insulin pump and basically be an artificial pancreas, there are issues because they cover so many different aspects of regulatory approval. Getting all of the various regulatory groups within the FDA to define what it will take for them to be comfortable to approve this entire system for use is a challenge.

Now, it is something that FDA is proactive on. They are working proactively with us and our volunteers, and obviously with the medical profession as well and NIH and others, to define for safety reasons as well as efficacy how we are going to define that, what are the important measures and metrics so we can assure we can get this in the market quickly.

Then you have access issues. Let's assume this closed loop actually works, which it will eventually. Now you have the issue of access for patients, which probably will be a staged type of thing. We will have some challenges with little guys, like Aidan, versus big guys, like Chris, just to get the timing right and to make certain that we process through all that properly.

But then there is the insurance coverage. There is the cost associated with that. And then, lastly, there is the medical professionals themselves getting them up to speed, the practitioners who are going to recommend these systems for people.

In the meantime, it is all very positive. The glucose sensors themselves, as we mentioned, and as you can see from the charts,[1] offer a huge advance in terms of reducing the possibility of complications. They do not eliminate complications, but they reduce them. And just the fact we are engaged in this activity collectively, all of us together, is making a huge positive impact on the quality of life for those who suffer from the disease.

Chairman COLLINS. Thank you.

Mr. DONALD. Thank you, Senator.

Chairman COLLINS. Senator Coburn.

Senator COBURN. Mr. Donald, what can we do to streamline that once you get there?

[1] The charts referred to appear in the Appendix on page 41 and 42 respectively.

Mr. DONALD. I think there are many things we can do to streamline it. First of all—and I do have to acknowledge the FDA, in particular, has been very proactive in organizing under interim Director von Eschenbach to make certain that they have defined things well enough so there is no delay as the technology advances. So that has been very positive.

The second thing we can do is to continue to invest in the research, and we do need more research dollars. I also agree with you, Senator, that we need more education dollars, and we need more general knowledge dollars. We need more of everything, and there is a fixed pie at some point. But we definitely need dollars, more research dollars, so that we can get larger sample bases, find ways to accelerate the research, and we need some new technologies. One thing that would be a huge advance in diabetes research are biomarkers or imaging technology. Today we cannot image the disease. We cannot image the pancreas and the beta cells. Those would be huge advances. We are going to do some things to accelerate the number of people engaged in developing the mathematical algorithms so we can get more people engaged. And as you know, JDRF is the largest charitable funder of diabetes research in the world. We have given over $1 billion over the last 30 years, and we did $123 million last year, we will do $140 million this year. And we are looking for ways to leverage the dollars we spend and that NIH spends and the private companies spend to get more people engaged in developing these algorithms faster and more accurately.

Then from the insurance provider standpoint, having the economic data to demonstrate that by reducing these complications you are actually reducing medical costs will be an important metric for them to have so they can go ahead and include these devices as something that they cover.

So those would be some examples, Senator.

Senator COBURN. I note that when I first came to Congress in 1995, between now and then diabetes research has increased 250 percent to over $1 billion a year. The thing that concerns me—and the Chairman will get a tickle out of this—is that there are limited dollars, and actually the American people do not know really how severe that is going to be.

We need help from groups like the JDRF to get on the bandwagon and help us get rid of the $200 billion waste that is there now (so we can put the dollars where they will do some good) and take the conflicts of interest out of Congress. If JDRF, in their lobbying, would lobby just as hard to get rid of the $200 billion worth of waste, fraud, and abuse we have in discretionary programs, we would not have trouble spending another $10 billion or $15 billion a year at NIH, and a good portion of that on diabetes.

We hear the asking—"We need more money"—but we never hear the pressure to help us get rid of these terrible conflicts and this terrible waste that we have. I would just hope that when you lobby us, you will say, "Cut some of these programs out that are not benefiting the country." Cut some of these earmarks like building $2 million garages for museums that have $50 million in the bank—$2 million could go a long way on a contact lens measuring the aqueous humor in the eye. We do not have that kind of debate. My

hope is that we will get everybody engaged as the finances get tighter so that we really pay attention. We ought to spend the first dollar on the most important thing to this country, and then it ought to decrease in terms of priorities rather than doing what the politicians want to benefit the politicians and not the country.

So my message to you is that I hear you on wanting to send more money to NIH. Help me and the Chairman get rid of the waste and fraud so that we will not continue to waste money and dollars that could make a difference in Aidan's life because we are doing something politically expedient rather than the right thing for our country.

Mr. DONALD. Well, I assure you, Senator, families like the Sweeneys and all the families that are in the JDRF family, and as you know, there are thousands, tens of thousands of them, the constituencies all across this country of you all—resonate with the message that we need to spend on the most important things.

Senator COBURN. Just one last comment, and I have to go. Mrs. Sweeney, I want to tell you as a doctor—I remember as a resident at Oklahoma Children's Hospital staying up all night with kids just like your Aidan, pumping insulin into them, checking their sugars, keeping their fluids right, measuring their arterial blood gases, the same thing you went through doing that. And I also know that the youngest child I have ever diagnosed with diabetes was 9 months old, and there is not just a difficulty with you. It also is a difficulty for the pediatricians. This is a tough thing for them to do as they see you struggle with it, and they know you are eventually going to get to the level that you need to get to care for your child and the disease. But, I would praise the health care professionals in this country that are doing this because they are not only treating the disease and the child, they have to treat the family. And the recognition of that should go out—the kudos, especially to the pediatric endocrinologists in this country that do such a fantastic job with this in terms of supporting it. And my hope is in the future that they do not have a job. That is my hope.

And I will just end thanking the Chairman again for having the hearing. I know nobody from the HELP Committee was against us having this hearing, much like many of my Subcommittee's hearings. I want to thank you for doing it. I think it is a subject well worth our discussion and time. Thank you.

Chairman COLLINS. Thank you, Senator. Senator Lautenberg.

Senator LAUTENBERG. One of the things that you will learn in your visits here is that occasionally we have differences of opinion with one another. My distinguished colleague, Dr. Coburn, and I sometimes disagree on budgets and things of that nature, surprising as that may be. And so there is money that we spend sometimes foolishly. Our budget numbers stagger the imagination. You folks have got one tough war in front of you. Fight that war. In my view, you are going to have to depend on us, all of us, to do the right thing. And when we touch things like children's diseases, diabetes, AIDS, or asthma—we make a difference.

So we are not wasting money—we are doing all kinds of things, and we are spending a lot of money on another war, not the one that you are engaged in here, but there is another one that you read about every day when sometimes hundreds of people, Amer-

ican and otherwise, die each day as a result of violence. So maybe we can save money there, or maybe we can save some money in tax write-offs for companies or maybe tax cuts for wealthy individuals, just to keep a balance.

But I would ask the Sweeneys, was there any history, anything genetic that would lead to Aidan's illness?

Mrs. SWEENEY. No. We both do not have any diabetes on both sides of our families, so we were completely shocked with this diagnosis.

Senator LAUTENBERG. Is there evidence that there is sometimes a genetic line that comes from families where diabetes has been discovered?

Dr. RODGERS. The answer to the question is yes, but that is really the minority of cases.

Senator LAUTENBERG. I see.

Dr. RODGERS. People do inherit the susceptibility gene that I mentioned, but not everyone with that susceptibility gene—and there are quite likely to be other genes—will go on to develop diabetes, type 1 diabetes. Undoubtedly it has something to do with the environmental factors and their exposure, for example, and that is precisely the type of thing that we are trying to quantitate and get a better handle on.

Senator LAUTENBERG. Is there a program that is recommended to lessen the likelihood of a genetic transfer, a propensity for diabetes?

Dr. RODGERS. No. At the moment, until we really have a better handle on what these susceptibility genes are and how they interact with environmental exposures, it is going to be very difficult for us to make an informed decision.

If it turns out, for example, that one of these environmental factors is a virus, within the context of someone who is very susceptible, then immunizing him or her against that virus would be a very cost-effective way of preventing diabetes. But, again, those studies really need to be completed through their fruition before we are able to be able to say something definitive about that.

Senator LAUTENBERG. If the artificial pancreas is developed, is that implanted into the patient or is it an external device?

Dr. RODGERS. At the moment, the manufacturers and those developing the technologies are actually looking at both external devices as well as implantable devices. Both of these have pros and cons associated with them. In the implantable devices, at least the early ones that are in development, they can be implanted, but over time the body develops a reaction to them, and that reaction can interfere with the efficiency with which these devices can both sense the glucose level, on the one hand, and deliver the insulin, on the other hand. So people are looking to see whether there is a way to interfere with that process.

The other devices, the external devices, also have their limitations. They do not measure glucose directly. The current ones measure glucose that gets into what is called the interstitial space, and there is a lag period. Part of these algorithms that Mr. Donald has described, which is really critically important to finally closing this loop, is to have mathematical ways of predicting what is happening in real time based upon what you are able to measure with

these optical and other electrochemical sensors. That is really a critical limitation of all of these devices.

Senator LAUTENBERG. Once again, thanks, each one of you, for your contribution here today. It is very important. We have great respect for what you do and urge you to carry on. And, Mrs. Sweeney, we are going to keep on working on this, and I am sure that one day you will see a product that can make Aidan's life easier and help him live longer. We promise you that.

Mrs. SWEENEY. Thank you very much. And on another note, Aidan has asthma as well, so I do feel for your grandchild.

Senator LAUTENBERG. How come he is so beautiful? [Laughter.]

I think it is parental contribution, husband and wife. You look like you have come from Central Casting. [Laughter.]

Thank you very much.

Chairman COLLINS. It is the good Maine air. [Laughter.]

Senator LAUTENBERG. I believe that, by the way.

Chairman COLLINS. Thank you, Senator. I know you care deeply about this issue. We have worked together on juvenile diabetes projects in the past, and I know we will continue to do so.

I want to thank all of our witnesses for being here today and sharing your personal stories, your expertise, and your unique perspectives. I was hoping we could end before Aidan had to go for a walk because I was going to encourage him to wave at the cameras because he loves to wave hello and good-bye. He is an adorable little boy.

I want to end this hearing on a more upbeat note because it is hard to hear what you have been through, Mrs. Sweeney, and what you have been through, Mr. Dudley. But I also am optimistic. I believe that there are promising new technologies on the horizon that are going to make such a difference in the care of children and adults living with diabetes that will ease the burden somewhat on their families, that will reduce the likelihood of the serious complications that we know can otherwise occur. And the support that the Juvenile Diabetes Research Foundation has given to families with diabetes is just tremendous, not to mention your extraordinary financial contributions. And I am very happy to have been your partner in helping people be more aware of juvenile diabetes and of diabetes in general.

The NIH is such an essential partner in this fight in providing the funding for the basic research that then the private sector and JDRF can build on. So I want to end this hearing on a note of hope and optimism. Every time—Aidan's waving in the back there, so I am going to wave, too. Thank you, Aidan, for being here today. You were great, and you are a very brave little boy, and we are really happy to have you here. So thank you.

He is a good waver. [Laughter.]

So I leave this hearing with a renewed, stronger than ever commitment to the cause, and working together, I am confident that we can make a difference. We have already made a difference. In the time since I founded the Diabetes Caucus in 1997, we have, I think, tripled the funding for diabetes research. That makes a difference. And I am convinced that this is something where money does make a difference. Research is expensive, and I just want to assure you of my personal commitment—and I know it is shared

by Senator Lautenberg, by Senator Coburn, by Senator Coleman, and so many others on this Committee—to providing the resources that are needed. It is the least we can do to support you as you go forth and fight for people with this devastating disease.

I also want to recognize Priscilla Hanley on my staff, who has worked on this issue for 10 years as my health policy adviser. It was to Priscilla that I first said, "Why isn't there a Diabetes Caucus in the Senate?" She said, "Well, there has always been one in the House, but never in the Senate." And I said, "Well, Priscilla, it looks like we are going to have to start one." And we did, back in 1997, and I am very proud of that because I think it has made and is making a difference.

So thank you for being here today. The hearing record will remain open for 15 days for additional materials. And to the Sweeney family in particular, I cannot thank you enough for sharing your personal story. It really makes a difference as we advocate for increased funding, better technology, and better reimbursement policies. So thank you for being here.

Mrs. SWEENEY. Thank you, Senator Collins. It was an honor to be here today.

Chairman COLLINS. Thank you. This hearing is now adjourned.

[Whereupon, at 11:39 a.m., the Committee was adjourned.]

APPENDIX

PREPARED STATEMENT OF SENATOR LIEBERMAN

Chairman Collins, I would like to take a moment to thank you and your distinguished panel for taking the time to focus your expertise and the Nation's attention on the scourge of diabetes and the promise of new treatments for the disease. Every one of us here in this room knows someone with diabetes and we have taken up the fight against the disease and its frightening complications on their behalf.

The facts are compelling. Diabetes is a major risk factor for heart disease and stroke. It is the No. 1 cause of new blindness between the ages of 20–74 and responsible for 60 percent of none traumatic amputations. It is the leading cause of end stage renal disease responsible for over 44 percent of new cases.

But, it's more than the facts. The reality of diabetes in the lives of millions of children, adults, and elderly is equally compelling. Who here knows what it is like to prick your fingers four times a day until they bleed in order to check the body's sugar? Who here knows what it is like to administer insulin to the body four times a day with a needle usually stuck right here in the abdomen? And if you get it wrong and the insulin dose is too low, you feel sluggish. Or if the dose is too high you get the shakes. You may even seize. Who knows what it is like to consciously play the role of a vital organ in the body—in this case the pancreas? This is an awesome responsibility and it simultaneously amazes me and saddens me that so many Americans must do this day after day, year after year, simply to survive.

But this hearing is as much about prioritization, resolve, and team work as it is about new technologies that will prevent the complications of the chronically high blood sugar levels, which is the problem in diabetes. The Juvenile Diabetes Research Foundation (JDRF) right now is building upon the dollars invested by the National Institute of Diabetes and Digestive and Kidney Diseases' (NIDDK) to bring together people from industry, the basic science community, those affected by diabetes, and other stakeholders to tackle the problem of how to measure body sugar and respond to it with insulin in real time in the form of a small, convenient, you-don't-even-have-to-think-about-it machine. In effect, they are trying to create an artificial pancreas!

Without JDRF's initiatives those in the scientific community and in industry tend to work in silos. In the Congress, it is cubicles. New ideas only go as far as the individual or organization can and want to take them. This works for easy problems. But for complex problems like diabetes and technology to control diabetes this requires simultaneous knowledge of biology, physiology, medicine, math, computer programming, engineering, immunology, pharmacology, endocrinology, and law. Which individual or organization possesses all of this? How do you build a fast dependable car if you are only an expert in ignition systems? Or how do you get access to a better car if the car companies in your town only sell slow ones?

The answer is getting smart people from across disciplines and sectors to work together to solve important problems. JDRF is doing this. And I propose this in my American Center for Cures legislation—a $5 billion proposal introduced by Senator Cochran (R-Miss.) and myself last year. CURES establishes a new center in the NIH to develop new diagnostics, treatments, and even cures to our country's most important diseases as well as diseases poised for research promise. CURES does this by leveraging large amounts of money to encourage research collaboration that tackles diseases like diabetes once and for all. CURES addresses research and developmental barriers such as reluctance by the research community to take risks, information hoarding and industry involvement too late in the research process. It simplifies and funds large clinical trials and strengthens support of small innovative businesses critical to the innovation process.

I am excited and encouraged by what you at NIDDK, JDRF, and our universities are undertaking with families and those affected by diabetes to push innovation even faster. We in Congress are with you. We will help you with legislation like CURES that complements your work. I look forward to hearing your ideas today and promise to work with you in whatever way I can. Thank you.

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

Development of an Artificial Pancreas: Will New Technologies Improve Care for People with Diabetes and Reduce the Burden on the Health Care System?

Statement of
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Acting Director
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 a.m.
Wednesday, September 27, 2006

Chairman Collins and Members of the Committee, as Deputy Director and Acting Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), I appreciate the invitation to testify at this hearing regarding the potential of new technologies to improve care for people with diabetes and help reduce the burden of diabetes on the health care system. On behalf of the NIDDK and the other Institutes and Centers of the National Institutes of Health (NIH) within the U.S. Department of Health and Human Services, I am pleased to report to you on recent technological advances that are paving the way toward an "artificial pancreas," a treatment approach to help patients with diabetes manage their disease more effectively, and on the outlook for research furthering this technology. I would like to thank the Senate for its continuing interest in new and emerging technologies that may improve the health of many Americans with diabetes, and I would particularly like to acknowledge your leadership, Chairman Collins, in focusing the Senate's attention on biomedical research and many other issues that are important to diabetes patients and their families.

Need for Improved Treatment Options for Diabetes

Diabetes is a chronic disease affecting nearly 21 million Americans. Without medical care, people with diabetes cannot control the levels of glucose (sugar) in their blood. Diabetes lowers average life expectancy by up to 15 years, significantly increases a person's risk for heart disease and stroke, and is the leading cause of new adult-onset blindness, kidney failure, and lower limb amputations. In 2002, the total cost of diabetes was estimated at $132 billion.[1] This estimate included both direct medical costs and the

[1] Hogan P, Dall T, Nikolov P; American Diabetes Association. Economic costs of diabetes mellitus in the US in 2002. Diabetes Care. 2003;26:917–932.

indirect costs due to loss of work, disability, and premature mortality. The NIH maintains a vigorous, multifaceted research program on diabetes so that we may harness scientific discovery toward diabetes prevention, treatment, and, if possible, a cure.

Most patients struggling with blood glucose control have either type 1 or type 2 diabetes. Both forms of diabetes involve malfunctions in the body's system for maintaining appropriate blood glucose levels and both also share the same complications.

Type 1 diabetes strikes mainly in childhood and adolescence and was formerly known as juvenile diabetes. In this form of the diabetes, the body's immune system destroys its own insulin-producing beta cells, which are found in clusters called "islets" within the pancreas. Without insulin, the body cannot regulate glucose in the blood or utilize it for energy. To prevent glucose levels from rising dangerously—and threatening life—patients require administration of insulin in the form of injections or *via* an insulin pump. They must also carefully monitor their food intake and physical activity in order to manage the disease.

Type 2 diabetes is more commonly diagnosed in adulthood, although we are now witnessing an alarming increase of this disease in children. It is strongly associated with overweight and obesity, and disproportionately affects minority populations. In type 2 diabetes, the body's ability to respond to insulin is impaired. This form of the disease can often be managed with oral medications, diet, and exercise, but patients can ultimately "exhaust" their insulin-producing beta cells and become dependent upon insulin treatment to control their blood glucose levels.

Landmark NIH-supported clinical trials have proven that achieving good glucose control is vital to preventing or delaying the devastating and costly health complications

of diabetes. Results from the Diabetes Control and Complications Trial (DCCT) revealed that close control of blood glucose levels could dramatically prevent or delay the eye, kidney, and nerve complications in type 1 diabetes patients. The findings of this trial paved the way to studies that replicated these impressive results in patients with type 2 diabetes. Moreover, a follow-up investigation in the DCCT patients—the Epidemiology of Diabetes Interventions and Complications (EDIC) study—recently showed that close control could cut the risk of heart disease and stroke in half. These results are critically important because people with diabetes have a 2- to 4-fold increased risk for heart disease compared to those without the disease, and type 1 diabetes patients in particular are at a 10-fold greater risk. Unfortunately, although we possess the scientific knowledge that close glucose control can confer these tremendous health benefits, we have lacked the tools to transform this knowledge into optimal health care. Less than half of diabetes patients are able to achieve good glucose control using current treatment methods. Type 1 diabetes patients and others dependent on insulin face unique challenges. In the effort to achieve good control, every day they must endure multiple, painful finger sticks to carefully monitor blood glucose, and intensive use of insulin to control it—steps which are inconvenient, painful, and invasive. Moreover, intensive insulin treatment places patients, especially children, at increased risk for episodes of dangerously low blood sugar, or hypoglycemia. This frightening condition can lead to immediate and severe injury, coma, and even death. Hypoglycemia is particularly troublesome at night, adding to the burden of care. Thus, patients and their families must walk a tightrope between the prospect of dreaded complications on one side, and the fear of dangerous episodes of low

blood glucose on the other. Additional impediments to close glucose control include treatment costs and lack of knowledge about diabetes self-management.

To overcome the limitations of current insulin therapy, researchers have long sought to develop an "artificial pancreas." In essence, this is a system that would mimic, as closely as possible, the way a healthy pancreas "senses" changes in blood glucose levels and responds automatically to secrete appropriate amounts of insulin. As a safety feature, the device would also provide alerts when blood glucose levels drop too low or rise too high. While not a cure, an "artificial pancreas" has the potential to significantly improve diabetes care and management and to alleviate patient burden. Importantly, it could bring to full application the knowledge gained from NIH clinical trials that close glucose control can prevent or delay the devastating complications of diabetes. This is a key goal for research.

Today, I am pleased to report that—with recent technological advances, many made possible by NIH-supported research in academia and industry—the first steps have been taken toward "closing the loop" between glucose sensing and insulin delivery, thus laying the foundation for a true artificial pancreas.

Continuous Glucose Monitors: First Steps Toward An Artificial Pancreas

An artificial pancreas based on mechanical devices requires, at a minimum, three basic components: a continuous blood glucose sensor, an insulin delivery system, and a way to link the two in a loop. Such a system would automatically turn the measurement of blood glucose levels into a practical, precise, and "real-time" insulin-dosing system for patients. Technology that can replace intermittent finger sticks with continuous, accurate

measures of blood glucose levels is a key element. Whereas conventional methods of testing glucose levels provide only snapshots in time, a continuous glucose monitoring device, by contrast, can reveal the dynamic changes in blood glucose levels that are the bane of close control and, in turn, can enable responsive insulin delivery in a way that mimics the exquisitely timed responsiveness of a normally functioning pancreas.

The NIH has accelerated the pace of research on glucose sensing technologies through research solicitations and investigator-initiated projects. The NIDDK pursued these opportunities in collaboration with the National Institute of Biomedical Imaging and Bioengineering (NIBIB), the National Center for Research Resources (NCRR), the National Institute of Child Health and Human Development (NICHD), and other NIH components. Over the last decade, these efforts have led investigators in academia and industry to explore a variety of approaches to continuous glucose monitoring, including devices to measure glucose in body fluid extracted from skin, in eye fluid using a contact lens as a sensor, non-invasively with optical sensing of glucose in the blood, and with minimally-invasive sensors inserted into the skin. Researchers have also been exploring the benefits and drawbacks of sensors designed for external use versus more permanent, fully implantable devices. Studies have also focused on validating and optimizing the different technologies. These multifaceted approaches have borne fruit. New continuous glucose monitoring devices from three companies (Medtronic, Inc., DexCom, and Abbott Laboratories) have recently been approved or are currently under review by the Food and Drug Administration (FDA). These devices represent a significant improvement over the first devices approved by the FDA in 1999. I am pleased to note that NIDDK support was instrumental in technology development for two of them, the Medtronic and Abbott

continuous glucose monitors, the latter of which is still under FDA review. The devices employ a similar basic approach in their technologies: a slender sensor that can detect the biochemical reaction of glucose with an enzyme (glucose oxidase) present on the sensor tip. Inserted under the skin, these minimally-invasive sensors take glucose measurements every few minutes, whether or not the patient is awake or asleep, and trigger an alarm if levels become too high or too low. Importantly, both current glucose readings and glucose "trends" indicate whether blood glucose levels are increasing or decreasing—and how quickly—and are reported "real time" to patients. This information allows patients to take immediate action to avoid low and high blood sugar episodes. Finger sticks are not entirely eliminated because they are needed for calibrating the devices and for directly measuring blood glucose levels before adjusting an insulin dose. However, the burden of care can be significantly reduced, and additional improvements in these devices can be expected with further research and development.

One of the FDA-approved devices (Medtronic, Inc.) has been "paired" with an insulin pump through a wireless transmitter so that information about current and past glucose readings is displayed on the pump, making it easier for the patient to adjust the insulin dose. This pairing does not constitute an artificial pancreas. However, it does represent the first step in joining glucose monitoring and insulin delivery systems using the most advanced current technology. To help "close the loop," the NIDDK is supporting research on the algorithms that will be needed to enable "proactive" insulin dosing by the insulin delivery device based upon current glucose monitor data, insulin usage data, and patient trend data.

Although the new continuous glucose monitors are not fully integrated into an artificial pancreas, they represent an important opportunity, for now, to help patients implement the recommendations from the DCCT/EDIC and other clinical trials that will enable them to achieve significant risk reduction for heart disease and eye, kidney, and nerve damage. We are hopeful that, by observing how their glucose levels fluctuate throughout the day and night and by reducing their risk for the dangerous low blood glucose reactions that currently limit diabetes control, patients using these devices will be able to better manage their disease and reap the proven benefits of achieving close glucose control. Continuous glucose monitors may be especially helpful to patients to prevent "excursions" into high and low glucose levels on a daily basis, which may go undetected in long-term assessments of glucose control, but which researchers now believe may silently contribute to long-term health complications. Already, patients using the new devices have been shown to reduce time spent in excessively high and low ranges of blood glucose. For example, in one recent clinical trial in insulin-dependent patients with either type 1 or type 2 diabetes, participants who used a continuous glucose monitor spent, on average, 21 percent less time hypoglycemic, 23 percent less time hyperglycemic, and 26 percent more time in a healthy target range for blood glucose levels, when compared to trial participants not using the devices. Even more encouragingly, continuous glucose monitor use reduced the duration of hypoglycemia by 33 percent, and of severe hypoglycemia by 38 percent. However, the wealth of data these devices offer means that patients will need to be well trained in order to achieve their optimal benefits and to avoid overaggressive or lenient management.

Continuous glucose monitoring devices are currently FDA-approved for use by adults 18 years of age and older. Yet, many insulin-dependent patients are children and adolescents, who are particularly susceptible to episodes of dangerously low blood glucose, especially at night. Already new insights about this issue have been gained from the Diabetes Research in Children Network (DirecNet), a multi-center clinical research network led by the NICHD and supported by the NIDDK. DirecNet is investigating the use of technological advances in the management of type 1 diabetes in children and adolescents. It seeks to determine if the new technologies are safe and effective, particularly for use in children. Thus far, DirecNet has carried out several independent and scientifically rigorous studies to determine the true benefit of new continuous glucose monitoring technologies, including their accuracy, efficacy, and effectiveness. Using the new continuous glucose monitors, this network found, for example, that exercise much earlier in the day increases the risk of nocturnal drops in blood glucose, yielding the practical suggestion of increased bedtime snacks on days when children with diabetes were particularly physically active. Without the commitment of DirecNet to perform such research, it could be many years before studies would be conducted in the pediatric population. The initial 5-year project period for DirecNet ends in 2006, and steps are being taken to ensure that its research agenda continues to move forward.

Prospects for the Future

While currently available continuous glucose monitoring devices do not yet fully close the loop, they are an extremely important milestone in research toward developing an automated, artificial pancreas that can alleviate the burden of care for patients and

their families and reduce costly and debilitating health complications of diabetes. To continue the pace of progress toward an artificial pancreas, the NIDDK and other NIH Institutes and Centers are fostering basic and preclinical research on new technologies for both continuous glucose monitors and insulin delivery; algorithms to link glucose monitors and insulin pumps; research to better understand how the body normally senses low glucose and how this is altered in diabetes; and clinical studies to optimize and evaluate current and emerging technologies for use by patients. Recent advances on these fronts include clinical evaluation of an implantable glucose monitor for long-term use in patients and studies of first-generation closed-loop systems that use currently available technologies.

To assess the state-of-the-science of glucose-sensing and insulin-delivery technologies, the NIDDK, together with Juvenile Diabetes Research Foundation International, the American Diabetes Association, and the FDA, convened a scientific workshop in December 2005, entitled "Obstacles and Opportunities on the Road to an Artificial Pancreas: Closing the Loop." The workshop brought together basic scientists from engineering and the biological sciences, clinical investigators, and industry officials who are developing new monitoring systems. Participants discussed progress and the technical difficulties of different technologies, optimal targets for normal glucose levels, and initial testing of closed-loop systems. FDA representatives discussed the criteria and regulatory steps involved in approval of new devices. Although a fully automated closed-loop system will require more years of development, the workshop generated an insightful dialogue on the practical considerations for an intermediate artificial pancreas that may have external or internal glucose sensors and may require some patient input

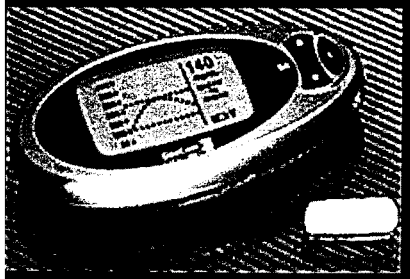
during meals and exercise, but could be automated during other activities--especially during sleep. The NIDDK is incorporating the outcomes of this meeting in its research planning efforts.

Conclusion

I am grateful for the opportunity to share with you these highlights of progress in the development of an artificial pancreas for diabetes treatment, and ongoing research efforts. The NIDDK continues to foster exciting new opportunities for the research community to intensify the study of the treatment prevention and cure of diabetes and its complications. We have just released a new Strategic Plan for Type 1 Diabetes Research that includes strategies directed at improving glucose control and reducing hypoglycemia, and that will help inform research program development for new technologies. This plan was developed under the auspices of the statutory Diabetes Mellitus Interagency Coordinating Committee, which will continue to coordinate efforts in this area across the NIH and with other relevant Federal agencies.

Diabetes can wreak havoc on a person's health, family, and finances. Over the past several decades, technological advances have reduced the treatment burden on patients, improved disease management, and reduced premature mortality from type 1 diabetes. In a lifetime, some patients went from complicated, imprecise urine-based glucose tests to accurate, though often painful, finger sticks and pager-sized blood glucose readers, and from injections of insulin extracted from animals to continuous infusion, via a pump, of optimized biosynthetic insulins. We can now foresee a future when treatment technology will be so advanced it will be nearly invisible to the patient, while providing increased health benefits. We will continue to foster research to achieve that goal. I am pleased to answer any questions you may have.

Continuous Glucose Monitoring



For every 1 percent fall in HbA1c—a measure of blood glucose control over time--there is a 37 percent reduction in eye, kidney, and nerve complications

Tight glucose control cuts heart disease in half in patients with type 1 diabetes

Only about 44 percent of people with diabetes achieve recommended glucose control with current technology and medications

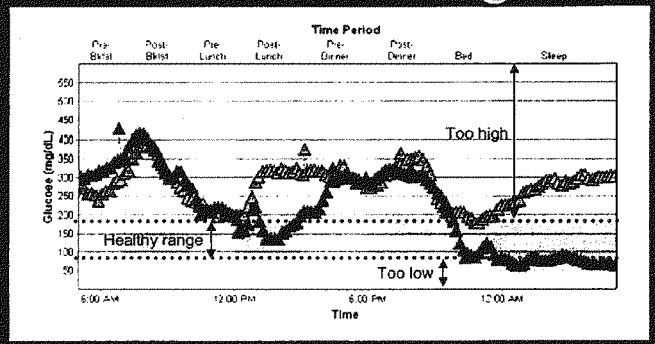
Continuous glucose monitors facilitate tight control of blood glucose levels

Improvement in Glycemic Control with Continuous Glucose Monitoring

Baseline Profile

(2 days)

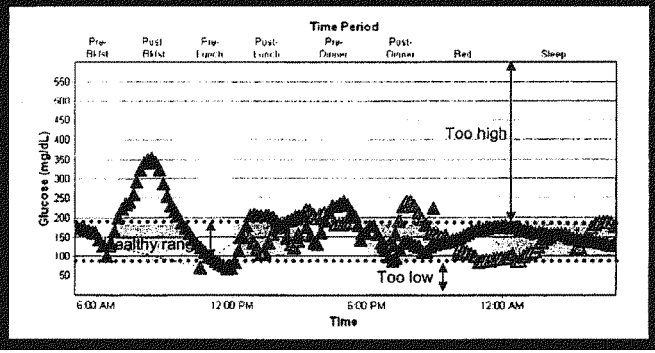
HbA1c 7.2%



13 Week Follow-up Profile

(2 days)

HbA1c 6.8%



The Potential of an Artificial Pancreas:

Improving Care for People With Diabetes

Statement of Chris Dudley
Founder and CEO, The Dudley Foundation

September 27, 2006

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

Good morning, Senator Collins and distinguished members of the Committee. Thank you for the invitation to appear before you today. Also, thank you for your tireless leadership, Senator Collins, in championing issues that will get us to our shared goal of a cure.

My name is Chris Dudley and I played in the NBA for 16 years with Cleveland, New Jersey, Portland, and New York. I am the proud husband of a beautiful wife and father of three wonderful, healthy children ages 7,6 and 4. I also have been living with juvenile diabetes for over 25 years.

In 1994 I formed the Dudley Foundation. The following year we started a basketball camp for kids with diabetes. Ever since that time, I have been an outspoken advocate for encouraging kids with diabetes to pursue their passions – whether it be sports or other activities. Our Foundation emphasizes that kids can achieve their dreams to be whatever it is that they dream of, whether it is being a doctor, professional athlete or even a United States senator – provided they take care of their diabetes. Our goal is to empower these children.

But today, I am going to talk, frankly about a dark, ever present, reality I have let few people see.

I tell children to be proactive in managing their diabetes. I tell them that they will face difficulties, but they should not let diabetes keep them

from their dreams. But what I realize and the children unfortunately have to realize: is how difficult managing diabetes actually is.

I myself have been proactive with my diabetes and have experienced difficulties. I have tested my blood sugar over 40,000 times. I exercise, eat healthy, and follow my doctors instructions. Yet, I live each day constantly worrying about what damage this cruel disease is doing to my body. I have experienced unexplained high and low blood sugars. I have administered countless injections. I have endured violent seizures. In fact one low blood sugar lead to an accident in which I drove my car into a tree at 45 mph. I had just finished a workout and had taken the necessary precaution of testing my blood sugar before I started the car. but a sudden drop in blood sugar caused what's known as a hypoglycemic reaction. The blood sugar test that I had taken had showed that I had a normal blood sugar – but it did not tell me what direction my blood sugar was heading. Thank God no one was hurt.

Aside from the many challenges, I have been able to fulfill my childhood dream of playing professional basketball. I have walked onto the court to hear 20,000 cheering fans. The feeling is incredible. But the ever present dark side was there. Even though I had tested my blood sugar 14 times each game day, the current technology of fingerstick testing didn't

give me the complete picture. It only gave me my sugar level at a particular point in time, not the all important information of what direction my blood sugar was heading. I would step onto the court and pray my blood sugar would not drop at which point I may experience loss of equilibrium, light headedness, double vision or most feared, a seizure. Thus the need to continually check to see how it was changing. Talk about a buzz kill. This is a cruel inexact disease.

The good news is, there is hope. There is technology that can help diminish this darkness. This reality is why I am so excited about today's hearing and about the promise of new technologies, like the continuous glucose sensors, to help people manage their diabetes until we find a biological cure.

If I had a continuous glucose sensor when I was in the NBA, I could have seen the trends in my blood sugar levels and taken proactive action to keep myself in better control. It would have been invaluable.

As a potentially life saving feature, a sensor would have alarmed me that I was getting low while driving, giving me the chance to pull my car off the road and avoid an accident.

From what I know about continuous glucose monitors, they enable parents to set the device so it alarms when a child's sugar level goes too high

or too low, giving parents peace of mind and the ability to sleep through the night and not have to awaken once or twice a night to test their child's blood sugar for fear of a hypoglycemic reaction. Many of our camper's parents only get to sleep through the night one week a year. When their kids are at our camp.

A lot has changed since I was diagnosed with diabetes, and I am excited about new technologies that will help people to better manage their diabetes and hopefully avoid the devastating complications that occur over time. Ultimately, what we all want is a cure, but improvements in care along the road to a cure would make a tremendous difference to so many people who struggle every day and it is incumbent upon all of us to do our part to help accelerate progress on both fronts.

I'd like to close by reading an excerpt of a letter recently sent to me from a teenage boy who attended my camp in August:

After camp each year, I return to my home in Three Rivers, California, a community of 3,000 in the southern Sierra foothills. I have always been the only one in my school with Type 1 diabetes. In my elementary school, there was no school nurse. Each year since I was diagnosed with diabetes in the spring of my third-grade year, my mom and I would educate my current teacher, as well as the office staff, about Type 1 diabetes and what to do in the event of an emergency. As of the 2006/2007 school year, I am a junior and travel 20 miles each day to my high school. There is a school nurse on the campus one day a week and most of my teachers aren't even aware I have diabetes. My basketball and baseball coaches are informed that I have the disease, but most are not knowledgeable about it. During my first season of playing tackle football, my coaches did not give me playing time because they thought I was "sick."

My parents are self-employed, and the medical costs have proven to be staggering and never-ending. Their monthly health insurance costs – including supplies not covered --

are in excess of $1,000 per month for our family of four. Ironically, there are new products coming onto the market that could ease some of the burdens of having Type 1 diabetes, but they are cost-prohibitive and our insurance company won't provide coverage on certain brands or products.

No child deserves to live with Type 1 diabetes with its risks of debilitating complications looming over them their entire life. And, at a cost of more than a half-million dollars in their lifetime for medical supplies and care, no child should have to pay that price either.

Senator Collins, thank you again for this opportunity – it has been an honor to appear before you today. I worry every day that one of my kids will be diagnosed with juvenile diabetes. And even though I have been very blessed in my life and have been able to achieve great things even with diabetes, this is not the life I want for my children. I want this cure for the children who come to my camp, my children, and all of the kids who are afflicted with this disease.

ACCELERATING THE AVAILABILITY OF AN ARTIFICIAL PANCREAS

Statement of Arnold W. Donald
President and Chief Executive Officer
Juvenile Diabetes Research Foundation International

September 27, 2006

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

Good morning, and thank you, Senator Collins. It is an honor to be here before you and the Committee this morning.

I would like to thank you, Senator Collins, not only for your work on the issue that brings us together today, but for your outstanding leadership on the wide range of issues that affect so many people with diabetes.

As you well know, JDRF estimates that as many as three million Americans now have type 1, or what was previously called "juvenile" diabetes. It is an autoimmune disease in which the body attacks the cells in the pancreas that sense blood sugar and produce insulin to convert that sugar into energy. Because people with type 1 diabetes cannot produce insulin on their own, they need to inject insulin into their bodies, either using syringes or a mechanized insulin pump, throughout the day just to survive.

The financial burden of diabetes is staggering, costing the nation and its health care system more than $130 billion a year. That's because, over time, people with diabetes are at a staggeringly high risk for complications: heart disease, kidney disease, blindness, and amputation.

While JDRF's singular mission is to find a cure for type 1 diabetes, we believe that the support of rapidly emerging technology can play a crucial role in improving the lives of people with type 1 diabetes, and reducing or even eliminating the complications of the disease.

JDRF has therefore launched a new initiative to help accelerate the availability of an artificial pancreas – one of the foundation's six cure therapeutic pathways. The overall goal of the project is to accelerate the development, regulatory approval, insurance coverage, and clinical acceptance of an artificial pancreas. The long term goal is for broad patient access and a thriving competitive market for these technologies.

An artificial pancreas combines two pieces of technology that are actually available to people with diabetes in some form today, though separately – an insulin pump, which has long been available, and a continuous glucose sensor, a promising new technology which provides real time data about trends in glucose levels and alarms if levels are heading too high or too low. This information enables people with diabetes to intervene by eating food or taking insulin to prevent glucose levels from going too high or too low.

An artificial pancreas would tie those two technologies together, using a mathematical algorithm to determine how much or how little insulin is provided to maintain glucose levels in the normal range 24 hours per day, seven days per week. There are incredibly encouraging clinical trials already underway at Yale Medical School showing that you can "close the loop," as we say. Researchers in that clinical setting have teenage patients with diabetes on a closed-loop system that maintains near-perfect blood sugar levels, especially at night. JDRF is funding this research at Yale and at five other top scientific facilities throughout the country testing a variety of ways to "close the loop." Questions about miniaturization, regulatory approval, insurance reimbursement, and clinical acceptance by doctors and patients will follow quickly on the heels of the basic science and resulting medical product development.

Even before a "closed loop" artificial pancreas is available, continuous glucose sensors show great promise in improving the health outcomes of people with diabetes. One study found patients using continuous sensors spent 26 percent more time in normal glucose range. Another found patients had statistically significant improvements in HbA1c levels, an important measure of glucose control. Because better glucose control means fewer complications, JDRF is making accelerating the availability of continuous glucose sensors a top priority as we work towards an artificial pancreas.

Over the past decade, research conducted by the National Institutes of Health and others clearly shows that blood glucose control is far and away the most important predictor of the devastating complications of diabetes. The better the control, the lower the risk of eye disease, heart disease, kidney disease, and other problems. In fact, lowering blood glucose dramatically lowers the risk of serious complications, by as much as 75% for some problems. Yet recent research shows that even the best-controlled patients with diabetes are rarely within the normal blood sugar range. The test-and-inject, or test-and-pump, method of controlling blood sugar, though light years ahead of clinical standards from just a few decades ago, doesn't come close to approximating how the human pancreas works. To significantly increase blood sugar control, you need to more closely mimic the human pancreas. That's an issue where technology can provide startling answers in the not-too-distant future.

With tighter control will come reduced risk of diabetic complications. And here's the power of this issue. Fewer complications can, arguably, lead to one of the greatest health advances and financial savings in medical expenditures in U.S. history. Consider this: Diabetes is among the leading causes of heart disease, of stroke, of kidney disease, and of peripheral nerve disease. It is the single largest cause of eye disease in the U.S. It is the cause of more amputations in the U.S. than any other reason, save accidents. Decreasing the rate of diabetic complications in the U.S. can mean savings of literally billions of dollars in health care costs.

JDRF's role in all this is to speed those timetables up, in any way possible. We're spending some $6 million on research to assess the clinical and economic benefits from use of continuous glucose sensors and testing versions of a closed loop artificial pancreas. We're working with regulators to understand what research outcomes they need to see before approving new technologies. We're working with private insurers and Medicare officials to make certain that when approvals come, reimbursement will be fast on its heels. And we're working with physicians and other diabetes care practitioners to ensure that when these technologies are available, they will be fully adopted and supported.

This project has in many ways been a perfect example of how medical research can and should successfully take place in the U.S. The federal government, primarily NIH, has funded basic research showing the benefits of better glucose control and identifying promising new methods to help achieve it. Private companies have picked up the ball to begin developing products and therapeutics they could eventually bring to market. And organizations like JDRF have been filling the gaps, funding additional research that focuses on concepts like perfecting the algorithms than can lead to commercially available artificial pancreas devices, or the clinical and economic studies that can ultimately determine regulatory, insurer, and medical practitioner acceptance.

This project has also been an example of how different parts of the federal government can work together. As I've already mentioned, the National Institutes of Health has played a critically important role in funding research making the artificial pancreas possible. The Food and Drug Administration has made the artificial pancreas one of its "Critical Path" goals. The Centers for Medicare and Medicaid Services has convened an expert panel to advise on these technologies. And the Congress, under your leadership, has made this issue a priority, with 68 Senators and 245 Representatives highlighting the promise of these technologies to HHS Secretary Michael Leavitt in a letter this spring.

We are profoundly grateful for your leadership, and look forward to continuing to work with you in the months ahead to achieve an artificial pancreas and help millions of Americans with diabetes live longer and healthier lives.

Thank you.

The Potential of an Artificial Pancreas:

Improving Care for People with Diabetes

Statement of Caroline Sweeney
Gray, Maine

September 27, 2006
10:00 a.m.

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

Good morning, Senator Collins and members of the Committee. I am Caroline Sweeney from Gray, Maine, and I am here today with my 4 year old son Aidan. Before I tell about the worst day of my life and how my son's life was forever changed, I want to say a special thank you to you, Senator Collins, for all that you do to help find a cure for diabetes. You give my family so much hope that one day my son won't have to struggle with the daily burden of diabetes and we won't have to worry about what the disease is doing to his body as he grows older and faces the reality of significant complications. I am proud to live in Maine and to have you as my Senator. Thank you.

On February 10, 2004, my world fell apart. I had taken my son, Aidan, then 22 months old, to the pediatrician because he had been up all night drinking water and soaking diapers. 26 weeks pregnant with my second child, and tired of waiting for the doctor to return to the examining room with Aidan's blood sugar results, I opened the door and was quickly escorted back into the room by the nurse. I will never forget the look on her face as I asked, "Everything is alright, isn't it" She looked at me with tears in her eyes and shook her head, "No." Covered in urine, I held my crying son tightly and gasped for breath as I fell against the examining table. My son, the child I had longed for my entire life, was sick - sick with a disease for which there is as yet no cure: Type I (Juvenile) Diabetes. Aidan was in diabetic ketoacidosis, a complication which threatened his life. My life, but more importantly, my son's, would never be the same. I went through every emotion – I wanted to scream; I wanted to hit; I wanted to run; I wanted to be numb. Most of all, I wanted it to go away.

But Diabetes never does go away. Aidan is now 4 years old. He receives insulin through a pump, which he wears on a belt around his waist, 24 hours a day. The pump is connected to an inch long catheter tunneled beneath the skin on his bottom. So far, we have changed his catheter over 500 times. Not surprisingly, he doesn't like the catheters. Most site changes become bargaining sessions, and despite the anesthetic cream, he feels every stick. His little bottom is studded with scars.

His fingertips are scarred from being tested up to 12 times a day -- that's more than 11,000 tests in 2 ½ years. Like the site changes, he doesn't like the testing. Sometimes, Aidan will run away when it is time to test his blood sugar or hide his hands behind his back, crying for me not to test him. At pre-school, he has asked his teacher to test his blood sugar in the bathroom so the other kids will not watch.

Despite his efforts, he can never escape his tests. He is forced to test his blood sugar everywhere -- at pre-school, at the grocery store, at restaurants, at the playground, at friends' homes, and even in his bed during sleep. The tests are constant, frustrating, and exhausting. Growth spurts and minor illnesses can cause his blood sugar levels to rise or fall unpredictably, and change his insulin demands as well. His emotions shift with every blood sugar fluctuation, making it impossible to distinguish between "typical 4 year old behavior" and "low" or "high blood sugar behavior." Often he has been unable to warn me even when his sugars are at life-threatening levels. 2 ½ years into his illness, he will still sleep through dangerously low blood sugars and be asymptomatic while awake. And so I test.

And I worry. I am always fearful - fearful that my son's blood sugar will rise so high that he will enter into a coma or drop so low that he will seize or even worse. Every night, I check his blood sugar before I go to bed and pray to God that he will wake up in the morning. I never sleep through the night. I keep a baby monitor on my pillow just so I can hear him breathe. I have found myself running into his bedroom in the middle of the night, carrying glucagon and a syringe, thinking that I have heard him seizing. I am always relieved when morning comes and I hear his little footsteps entering my bedroom.

I have become not only Aidan's mother, but his health care provider. With each good morning and goodnight kiss comes a finger stick. The responsibilities of his diabetes care are many – endless testing, counting and recording and interpreting everything that he eats, calculating insulin doses, giving insulin, changing catheter sites, keeping his supplies in stock, trying to explain to him just why it is that he cannot eat the chocolate cake that his friends are eating when his sugar is too high. The list goes on.

Still, despite diligent care and tight glucose control, I am aware my son is still more likely to suffer from heart disease, kidney failure, nerve damage, stroke, blindness, amputations, and an early death. This is most difficult to face as a parent. I try to live day by day with my son, but find myself wondering: will he one day lose a limb? Will he end up on dialysis? Will he go blind? Will he live to see the age of 50?

Aidan can only be left in the care of others whom are trained in diabetes, including babysitters and school. 14 weeks after Aidan was diagnosed with Diabetes, I gave birth to our second son, Michael, now 2, and just 3 months ago gave birth to our daughter, Caitlin. Both deliveries put us in a state of panic over who would take care of Aidan. Family on both sides were forced to picked up their busy lives and come to Maine in the weeks before both deliveries so they could be trained in Diabetes care. I can vividly remember my mother learning how to operate Aidan's insulin pump while timing my contractions. While my biggest concern should have been my unborn child, I could not seem to escape the worry about Aidan's care.

From the moment little Michael and Caitlin were born, they have never been able to have my complete attention because of Aidan's Diabetes. Aidan's illness comes first – before nursing, diaper changes, cries, baths - even hugs and kisses. I recently realized the impact of this when Michael, my 2 year old, insisted on having his blood sugar checked, claiming to have diabetes too. Much of his life is also dependent on Aidan's blood sugars. He knows that if Aidan's blood sugar is high at dinnertime that he has to wait with the rest of the family before he can eat. He knows that sometimes Aidan needs to drink juice really fast and sometimes only *he* can have juice and Aidan cannot. He knows that his Mommy and Daddy sometimes stick a needle into Aidan's bottom and that Aidan doesn't like that. I don't know what impact this will have on Michael in the years to come. I can only try to help him understand the severity of his brother's disease, while praying that he and his sister do not one day get diabetes.

As parents, we try from the moment our children are born to protect them from any harm. Two years ago, I never felt more helpless when all I could do was hold the tiny hand of my 22 month old son in the intensive care unit and pray he would not die. I vowed at that moment to do everything I could to find a cure for Diabetes. I stand before you today, with my son, my hero, asking for your support in saving his life. While the continued glucose monitor and artificial pancreas are not cures, they can offer Aidan and children like him a tremendous improvement in his quality of life, free from thousands of finger stick tests, and offer me the gift of peace -- peace in knowing that my son is safe and hopefully able to live a longer life with this terrible disease.

I encourage Congress to continue to show its support for these promising technologies and to help ensure that they are available and accessible to all who could benefit. Thank you.

Prepared Statement of Andrew P. Rasdal
President and CEO of DexCom, Inc.
September 27, 2006

As the President and Chief Executive Officer of DexCom, Inc., I applaud the Committee on Senate Homeland Security and Governmental Affairs for their continued willingness to explore recent technological advances to improve care and quality of life for people with diabetes. Diabetes is a chronic, life-threatening disease that affects over 20 million individuals in the U.S. and accounted for more than $132 billion of annual domestic costs in 2002. While there is no cure, there is finally a new technology available – continuous glucose monitoring - that could revolutionize diabetes care and reduce the costs and complications associated with this terrible chronic disease. As has been testified to today, combining continuous glucose monitoring and insulin delivery may ultimately lead to a closed-loop system, otherwise referred to as an "artificial pancreas."

DexCom is convinced that the cornerstone of any closed-loop system will be continuous glucose monitoring ("CGM") devices. CGM devices, which have recently been approved by the FDA and are available to patients today, have the potential to dramatically improve the ability of patients with diabetes to tightly control their glucose levels and thereby reduce the risk of diabetes-related complications. These technologies represent a revolutionary step in diabetes management, when compared to single-point finger stick devices, representing the first major improvement in glucose monitoring technology in nearly 25 years. CGM systems provide patients with continuous information about glucose levels and allow patients to continuously track trends, enabling them to accurately anticipate excursions outside of normal glucose levels and to make appropriate treatment adjustments. Alarms on CGM devices immediately alert the patient when glucose levels are outside of the target range, allowing the patient to intervene and prevent acute events, such as severe hypoglycemia, which can lead to permanent damage, coma or even death.

Data from a prospective, randomized trial published in a peer-reviewed article in the January 2006 edition of *Diabetes Care* by Satish Garg, MD, et al., showed that patients with diabetes with access to data from a CGM had a statistically significant reduction in their time spent hyperglycemic and hypoglycemic when compared to patients relying solely on single-point finger stick measurements. This improvement in glucose control, when compared to conventional single-point finger stick measurements, was achieved almost immediately – within the first six days of usage. Additional peer-reviewed data presented at the Scientific Sessions of the June 2006 Annual Meeting of the ADA from a repeated use trial that allowed patients to use a continuous glucose monitor for 90 consecutive days showed a statistically significant reduction in the patients' A1c levels with no increase in exposure to hypoglycemia. Maintaining A1c levels at or near normal (non-diabetic) levels has been shown in several landmark studies to significantly reduce the risk of common diabetic complications including kidney disease, heart disease, stroke, high blood pressure and blindness. The improvement

demonstrated in these studies was seen across a wide range of the patient population including patients with a history of poor control.

DexCom believes that these CGM devices represent an important opportunity today to help people with diabetes more conveniently and effectively manage their blood sugar levels. As several of the witnesses before you have testified, this is a disease that needs constant attention. While Mr. Dudley has had a successful career as a professional basketball player and Aiden is able to partake in many of the joys of being a four year old, neither has the luxury of putting their disease totally out of their minds. CGM devices will make this balance, between a healthy and a normal life, all the more possible.DexCom is hopeful these novel technologies will improve the quality of life for people living with diabetes. I would like to thank the Senate, and particularly Chairman Collins, for your continuing interest in CGM technologies that may improve the health of many Americans with diabetes. DexCom remains committed to developing innovative continuous glucose monitoring products to help people with diabetes live fuller and longer lives.

Post-Hearing Questions for the Record
Submitted to Dr. Griffin P. Rodgers
From Senator Pete V. Domenici

"The Potential of an Artificial Pancreas: Improving Care for People with Diabetes"
September 27, 2006

The New Mexico Department of Health estimates that approximately 130,000 New Mexicans have diabetes. Of those with diagnosed diabetes, 5 to 10 percent have Type 1 diabetes, while 90 to 95 percent have Type 2 diabetes. I am very impressed with the research and technology that was discussed at the hearing. Clearly this technology has the potential to help alleviate many of the problems facing those who are suffering from Type 1 diabetes.

1. What are the potential benefits, if any, of these new technologies for those who are suffering from Type 2 diabetes?

Because research has demonstrated that close control of blood glucose levels can prevent or delay the devastating complications of diabetes, the technologies discussed at today's hearing to improve glucose control have potential benefits for type 2 diabetes patients, as well as for those with type 1 diabetes. Although type 1 and type 2 diabetes have different underlying disease mechanisms, they both disrupt the body's system for maintaining appropriate blood glucose levels, which in turn can lead to serious health complications, such as blindness, kidney failure, and amputations. The goal for research on new technologies for diabetes management--including continuous glucose monitors and, ultimately, an artificial pancreas--is to help patients keep their blood glucose levels under control so that they can stave off debilitating diabetes complications. Our efforts are spurred by the knowledge that, at present, fewer than half of diabetes patients achieve the recommended targets for blood glucose control that have been proven to help prevent or delay diabetes complications. Among those who use insulin to control blood glucose levels, an even smaller fraction achieves these recommended targets--in large part because of the fear of drops in blood glucose to dangerously low levels (hypoglycemia), which is a risk with intensive insulin therapy.

As you point out, the new technologies have clear potential benefits for patients with type 1 diabetes. However, we are hopeful that there will also be benefits for the millions of patients with type 2 diabetes--a disease which disproportionately strikes American Indians, Hispanic Americans, African Americans, and other ethnic and racial minority groups in the U.S. Type 2 diabetes patients not only have an impaired response to the glucose-controlling action of insulin, but also--like type 1 diabetes patients--experience loss of the critical insulin-producing beta cells. However, while loss is nearly complete in type 1 diabetes and happens early in the course of the disease, the extent of beta cell loss varies in type 2 diabetes and increases with the duration of disease. The latter point is particularly important because we are now witnessing an alarming increase of type 2 diabetes in children and adolescents, especially in minority groups in the U.S., who will face potentially lifelong battles to maintain good glucose control and prevent diabetes complications. Although type 2 diabetes is often managed with oral medications, diet, and exercise, patients can ultimately "exhaust" their insulin-producing beta cells over time and become dependent upon insulin treatment to control their blood glucose levels--a risk that will be

even greater for patients diagnosed in youth. Half of type 2 diabetes patients use insulin, and for these patients--as for patients with type 1 diabetes--fear of hypoglycemia is often a problem that limits attainment of good blood glucose control. Thus, continuous glucose monitoring devices may prove very useful for type 2 patients on insulin--although how best to use them in type 2 diabetes patients, and which patients can benefit most, still need to be determined. We are encouraged by recent, published research reports of the benefits for blood glucose control achieved through the use of continuous glucose monitors by insulin-dependent type 2 diabetes patients, and we look forward to future research that may reveal further, long-term benefits.

2. Are there any new or similar technologies on the horizon to help those suffering from Type 2 diabetes better manage their conditions?

Yes. Devices for intermittent self-monitoring of blood glucose have been developed that can be used on areas of the body other than the finger. Because these areas have fewer nerve endings, testing is less painful. This approach thus helps reduce patient burden and barriers to careful monitoring. Also recently developed are "point of care" devices for measuring HbA1c levels. The HbA1c blood test indicates how well a patient has sustained blood glucose control over several months. The new devices permit rapid HbA1c testing in the doctor's office, and eliminate the need for sending a patient's blood sample to the lab. This rapid testing allows doctors to assess blood glucose control at the time that they are seeing patients, and to make adjustments to patients' diabetes medications right away, rather than having to call patients back for another visit after lab results are available. This efficient testing, in turn, encourages more timely adjustments in therapy to get blood glucose to levels associated with fewer complications. In addition to technological advancements, we are encouraged by progress in the development of new FDA-approved medications that can help type 2 patients improve management of the disease, including inhaled formulations of insulin, exenatide--an injectable drug for non-insulin-dependent patients that can help them to control blood glucose levels--and a new type of oral medication for glucose control, sitagliptin.

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