

Testimony of

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At the Hearing Entitled

“Transforming Lives Through Diabetes Research”

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Before the

**Senate Committee on Homeland Security and
Governmental Affairs**

Senator Collins, Senator Lieberman, and Members of the Committee, thank you for inviting me to appear before you today with such a distinguished panel and with such remarkable kids.

Ten years ago, I had the honor of joining Mary Tyler Moore and the 100 plus delegates at the 2001 JDRF Children's Congress. Since then, we have made remarkable progress in understanding type 1 diabetes. We are many steps closer to a cure and new tools are being developed to improve the day-to-day management of this disease. But we still have work to do and I thank you for sticking with us to get the job done.

Today, these great delegates are getting all of the attention, as they well deserve. But I'd also like to recognize all of the moms, dads and other special people these kids brought with them today. When a child is diagnosed with type 1 diabetes, parents must take on additional roles immediately as doctors, nurses, nutritionists, teachers and even psychologists. They are on duty, 24/7, 365 days a year, monitoring their child's blood sugars, counting the carbohydrates in food, calculating insulin dosages, educating others about their child's diabetes, and managing the emotions from dealing with the daily rigors of the disease. Each day brings its own special challenge to control blood sugar levels, even with the best of plans and use of the latest technology.

And with each exciting new stage that children with type 1 diabetes reach – whether it be starting kindergarten, going to summer camp, learning to drive or going off to college – there is a mom, dad or loved one looking over their shoulder worrying about their safety. Many of these parents have become advocates so that one day their child won't have to deal with diabetes anymore. They, like me, joined JDRF and the fight to cure diabetes.

As JDRF's National Walk Chairperson, I had the great pleasure of telling people to lace up their shoes and walk – one foot in front of the other, walking the walk to raise money to find a cure for type 1 diabetes. We have raised a lot of money with the Walk to Cure Diabetes, and JDRF has put this money to excellent use. The federal government has also played a critical role in the fight to cure diabetes, in particular with the strong bipartisan support for the Special Diabetes Program. I thank you, Senator Collins, for your leadership, and thank your colleagues who recognized the great return on the investment from the Special Diabetes Program and supported the two-year, \$300 million extension last December.

Together JDRF and the federal government for years have made and will continue to make terrific partners in advancing research to cure, treat and prevent type 1 diabetes. Since I testified before this panel ten years ago, more than 40 of the genes have been discovered which put people at risk for type 1 diabetes. Multiple therapies to halt the autoimmune attack which causes type 1 diabetes have been tested in human clinical trials. New therapies have been shown to not only halt the progression of diabetic eye disease but to improve vision in those who have it. And the artificial pancreas has gone from being a theory to a technology that has been shown in early trials to prevent dangerous low and high blood sugars.

Aside from a cure, the artificial pancreas is a parent's dream. Imagine going to bed at night without having to worry about dangerous nighttime high or low blood sugar levels that could result in a seizure, or a coma – or worse. Or knowing that your child will have a great day at school without the burden of poking his or her fingers, counting carbohydrates, taking the right amount of insulin, and treating high and low blood sugars – or forgetting to do all that and coming home from school dangerously ill. Or sending your child off into the world as an adult, without having to worry about who will look after him or her all of the time. Best of all, knowing that your child will live a long, productive life since these artificial pancreas technologies have the potential to keep him or her healthier, longer, until a cure is found.

I know the Food and Drug Administration (FDA) has made the artificial pancreas a priority, and I commend the agency for that. But there is more the FDA needs to do. Many of these children here today are wearing the components of an artificial pancreas – insulin pumps that deliver insulin and continuous glucose monitors which give sugar readouts every few minutes. The challenge, however, is that these devices don't yet work together to automatically control their blood sugar levels. In other countries, there are devices available that take the first step, by automatically shutting off the insulin pump when someone is low. This is an important first step we need in the United States now.

But we can do more than that. JDRF and federally funded research have, in hospital settings, tested artificial pancreas technologies that automatically turn insulin both on and off – and the results have been amazing. The next step is testing these artificial pancreas devices in real-world settings. To do this without delay, however, the FDA needs to provide clear and reasonable guidance. Many of the world's best diabetes researchers and leading clinician organizations have joined together with JDRF to propose artificial pancreas guidance to the FDA. And the majority of the Senate and the House have urged the FDA to give this proposal immediate consideration. Now we need the FDA to act.

Parents who are up every night and worrying every day about their children simply cannot afford to wait any longer. It is past time for artificial pancreas technologies to be tested in real world settings. We urge the FDA to issue draft guidance for public comment on the artificial pancreas so outpatient trials can begin and the burdens of type 1 diabetes can be lifted from millions of Americans as soon as possible.

Thank you for the opportunity to participate in this hearing today. I would be pleased to answer any questions you may have.