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

JDRF Juvenile Diabetes Research Foundation International

dedicated to finding a cure

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.