



JDRF  
Outside Witness Testimony  
Submitted to the United States Senate Committee on Appropriations  
Full Committee Hearing: *Driving Innovation through Federal Investments*  
Tuesday, April 29, 2014

JDRF is pleased to provide the Committee with testimony for the hearing titled *Driving Innovation through Federal Investments*. JDRF is the leading global organization funding type 1 diabetes (T1D) research. Until a cure is at hand, JDRF is committed to keeping individuals with T1D healthy and to reducing the daily burden of living with the disease by developing and delivering better options for managing T1D. JDRF (formerly known as the Juvenile Diabetes Research Foundation) has \$568 million invested currently in T1D research, including \$106 million in 2013. However, JDRF cannot cure, treat and prevent T1D on its own. The federal government plays an integral role in this fight by funding large-scale clinical trials and studies that could not be done otherwise, which have led and will continue to lead to innovative treatments and therapies that make a difference in the lives of those with T1D.

A continued strong federal investment in diabetes research is paramount, given the growing economic and personal burden of diabetes. Diabetes affects 25.8 million people in the U.S. The disease causes a person's blood glucose levels to be out of a healthy range, which over time often results in long-term complications such as kidney failure, nerve problems, cardiovascular disease, blindness and amputations. As a chronic disease, diabetes must be managed 24 hours a day, seven days a week. The intensive management and costly and burdensome complications cost our nation an astonishing \$245 billion in medical and economic expenses in 2012.<sup>i</sup> These costs are expected to more than double by 2020, rising to \$512 billion. Medicare bears a burden of these costs. In 2012, Medicare costs due to diabetes were \$104 billion.<sup>ii</sup> These costs are projected to increase to \$226 billion by 2020.<sup>iii</sup> In addition to the rising costs, the incidence of the disease is also rising. The prevalence of T1D in Americans younger than age 20 rose by 23 percent between 2001 and 2009<sup>iv</sup>, which, if unabated, means the prevalence of the disease would double for every future generation. The same research found that type 2 diabetes has increased 21% among American youth aged 10-19 in the same period.

Fortunately, due to public and private partnerships dedicated to diabetes innovation, there are new therapies that are available today and others that are in the pipeline that show great promise in improving the health of people with diabetes and reducing the costs to our nation. The National Institutes of Health (NIH), along with the U.S. Food & Drug Administration (FDA), are critical to catalyzing research and development of new therapies to achieve tighter blood glucose control, reduce complications and increase life expectancy. Diabetes therapies, such as faster and longer acting insulins, insulin pumps, blood glucose meters, HbA1c tests, and continuous glucose monitors (CGMs), currently help people with diabetes to better manage their blood glucose levels and live better and longer than ever before and with fewer complications. Researchers have found that intensive glucose control over 6 ½ years can cut in half the onset of kidney disease. A 50 percent reduction in end-stage renal disease could save Medicare \$126 billion over 25 years.<sup>v</sup> However, achieving such tight blood glucose control is very difficult given today's technology and treatments. We expect this will change in the future given the innovative studies underway currently and those that are on the horizon.

JDRF and our volunteers across the country are particularly excited about the development of closed loop artificial pancreas (AP) systems. The AP system will utilize a “smart” computer program involving algorithms to link an insulin pump to a CGM to dispense insulin based on changes in real-time blood sugar levels. It will make managing T1D safer, easier, simpler, and automatic – and is perceived as life changing by the T1D community.

The NIH, the FDA, and JDRF have identified an innovative continuum of AP systems. The first generation would be able to suspend insulin delivery when blood glucose levels start to fall. From there, a system would keep blood glucose levels within a certain range by turning insulin delivery on and off in response to high or low blood sugar. Finally, there would be devices capable of keeping blood sugars at specific levels, and even systems to deliver doses of key pancreatic hormones, such as glucagon or amylin, that influence glucose levels.

The NIH has supported important aspects of AP systems over the last two decades, including the development of CGMs. Since 2009, the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK) and JDRF have been funding sites in the Artificial Pancreas Consortium, made up of clinicians, engineers, and mathematicians to test AP systems. NIDDK, in partnership with the National Institute of Biomedical Imaging and Bioengineering and the Eunice Kennedy Shriver National Institute of Child Health and Human Development, has also solicited small businesses for innovative research on AP systems through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants.

In September 2013, the FDA approved the first generation AP system, known as a threshold suspend system, which is on the market today. This technology partially automates glucose control by temporarily stopping the delivery of insulin once glucose levels fall below a predetermined threshold. People using this system can avoid dangerous low blood glucose levels, particularly while sleeping at night, which could lead to seizures, comas and even death.

The next generation of AP systems is currently in outpatient clinical trials and the results are very encouraging. Supported by JDRF and NIDDK, smartphones are being used (replacing laptops which limited mobility in inpatient trials) to communicate wirelessly to CGMs and insulin pumps. People with T1D in these outpatient trials have gone about daily life—going for walks, out to eat in restaurants, and to work—with these experimental technologies that automatically controlled their blood sugar. These studies are a promising step forward towards a fully automated system. In addition to a much improved quality of life for those with T1D, such systems would keep people with T1D healthier, longer and could result in almost \$1 billion in reduced Medicare outlays over the next 25 years, according to a 2012 study.<sup>vi</sup>

Advances in AP systems represent remarkable innovation made possible, in large part, by the Congress’ continued support of the NIH and the FDA. Continued collaboration between JDRF, the NIH, the FDA, and various private-sector and research entities could make possible safe and effective automated AP systems that can be moved swiftly to market and improve lives of people with T1D, until we achieve our ultimate goal of turning Type One into Type None.

JDRF appreciates the opportunity to provide testimony for this important hearing, and encourages Congress to support strong funding for NIH and the FDA so that innovative and life-changing improvements, such as the artificial pancreas, can be made safe and available to patients sooner rather than later.

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<sup>i</sup> American Diabetes Association. (2013). Economic Costs of Diabetes in the U.S. in 2012. *Diabetes Care*, 36(4), 1033-1046. doi: dc12-2625.

<sup>ii</sup> Ibid.

<sup>iii</sup> Shapiro, R. and Pham, N. (2013). *Diabetes Research and the Public Good: Federal Support for Research on Type 1 Diabetes*. Washington: Sonecon.

<sup>iv</sup> Mayer-Davis, E., Dabelea, D., Talton, J.W., Hamman, R.F., Divers, J., Badaru, A., and Saydah, S.H. for the SEARCH for Diabetes in Youth Study Group. (2012, June). *Increase in prevalence of type 1 diabetes from the SEARCH for Diabetes in Youth Study: 2001 to 2009*. Presented at the American Diabetes Association 72nd Scientific Sessions, Philadelphia, PA.

<sup>v</sup> Winn, A., O'Grady, M., and Huang, E. (2012). *Potential Medicare Savings of Reduced End Stage Renal Disease in Patients with Diabetes*.

<sup>vi</sup> O'Grady, M., John, P., and Winn, A. (2012). Substantial Medicare Savings May Result If Insurers Cover 'Artificial Pancreas' Sooner For Diabetes Patients. *Health Affairs*, 31(8), 1822-1829.