Testimony of Elizabeth Seaquist, M.D. President, Science and Medicine, American Diabetes Association Senate Appropriations Committee Contact: Lisa Cox, Associate Director, American Diabetes Association, 703-253-4363, lcox@diabetes.org

As President for Science and Medicine at the American Diabetes Association (Association), I am pleased to testify on the Association's behalf. I especially thank Chairman Mikulski and Ranking Member Shelby for holding this hearing and for the opportunity to submit this testimony. As a medical doctor and a researcher, I can see everyday how research has improved the care of patients with diabetes, thereby allowing them to have productive and meaningful lives. Not so long ago people with diabetes who developed kidney failure were denied access to dialysis or kidney transplant – effectively sentenced to death – because of the belief that they could not benefit from such therapies. Now, because of research, they are offered these life saving treatments as a matter of course because we know they work. Just this week in clinic I saw a man who had his kidney transplant for diabetes 20 years ago. He came to clinic with his daughter and granddaughter. Without the transplant he would have never met his granddaughter, nor lived long enough to see his daughter grow up. Diabetes research directly improves patient care. I see it every day.

The topic of the hearing – the importance of investments in research and development to improve America – is a top priority for the Association. There is no question about the value of research in the effort to stop the diabetes epidemic. Our Board of Directors, our Research Policy Committee, our volunteers and staff around the country, and the researchers the Association supports all focus on the breakthroughs we can achieve with further resources and the consequences if we do not invest in diabetes research. Indeed, it is the heart of our vision: a life free of diabetes and all of its burdens.

The Association was founded in 1940 and has been funding innovative research since 1952. Beginning 70 years ago, our unit of analysis for success and our main focus has been the individual with or at risk for diabetes.

There are numerous reasons for investments in diabetes research, literally millions and billions. Most importantly, nearly 26 million Americans have diabetes today and an additional 79 million individuals have prediabetes. Every 17 seconds, someone in this country is diagnosed with diabetes. Today, 230 Americans with diabetes will undergo an amputation, 120 will enter end-stage kidney disease programs, and 55 will go blind from diabetes. In addition to the horrendous physical toll, diabetes is economically devastating to our country. A 2013 Association report found the **annual cost of diagnosed diabetes has skyrocketed by an astonishing 41 percent over the last five years** – from \$174 billion per year in 2007 to \$245 billion in 2012.

The Association is grateful to the Committee for the recent increases in funding to support vital diabetes research, including scientific studies through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH) and translational research through the Centers for Disease Control and Prevention's (CDC) Division of Diabetes Translation (DDT). It is because of this investment that our knowledge of the disease has expanded. We cannot afford to stop now; **if we do, we face a future in which one in three adults in our country will have diabetes by 2050.**

The Association believes an even deeper federal investment in diabetes research is necessary to spur the breakthroughs needed to stop the diabetes epidemic. We stand ready to collaborate with our partners in the federal government and our sister organizations and foundations in the pursuit of new and better ways to address the diabetes epidemic.

Diabetes Prevalence and Costs

Diabetes is a chronic disease that impairs the body's ability to utilize food. The hormone insulin, which is made in the pancreas, is needed for the body to change food into energy. In people with diabetes, either the pancreas does not create insulin, which is type 1 diabetes, or the body does not create enough insulin and/or cells are resistant to insulin, which is type 2 diabetes. If left untreated, diabetes results in too much glucose in the blood stream. Blood glucose levels that are too high or too low (as a result of medication to treat diabetes) can be life threatening in the short term. In the long term, diabetes is the leading cause of kidney failure, new cases of adult-onset blindness, and non-traumatic lower limb amputations, as well as a leading cause of heart disease and stroke. Additionally, an estimated 18 percent of pregnancies are affected by gestational diabetes, a form of glucose levels are higher than normal and reducing their risk of developing diabetes it is essential if they are to avoid the long term complications of the disease.

Federal Investments Must Go Forward not Backwards

The Association is working towards the day when diabetes is no longer an epidemic and, ultimately, when it ceases to exist. While we collectively have made demonstrable strides in diabetes research, there is much more to be done. The two federal agencies most important in this endeavor are NIDDK and DDT.

Additional studies are needed in multiple areas of diabetes research, including research into new drugs, improvements in measuring blood glucose and delivering insulin, gene therapy and stem cell research, primary preventions, and population studies to help predict diabetes and better treat individuals with the disease. It is essential diabetes funding at NIH and CDC be increased to reflect the burden of the diabetes epidemic, both on our citizen's lives and on our nation's pocketbook.

I want to highlight the central role NIDDK and DDT play in these biomedical and translational research efforts, the need for sustained and increased investment in innovative diabetes research studies, and the consequences if sequestration of diabetes funding continues.

National Institute of Diabetes, Digestive and Kidney Diseases

NIDDK leads the way in supporting research across the country that moves us closer to better treatments – and ultimately a cure – for diabetes. Thanks to research supported by NIDDK, people with diabetes now manage their disease with a variety of insulin formulations and regimens far superior to those used in decades past.

For example, the Institute's Diabetes Control and Complication Trial (DCCT) was a groundbreaking study which found complications such as diabetic retinopathy, diabetic neuropathy and kidney disease in individuals with type 1 diabetes can be reduced with tight blood glucose control. This finding has led to key changes in diabetes goals and management. Just this month in the New England Journal of Medicine, the CDC documented that, thanks in part to these findings and recommendations, there has been a remarkable 20-53% reduction in the prevalence of microvascular complications from the disease for persons with both type 1 and type 2 diabetes.

Individuals with diabetes can now take advantage of modern treatment regimens that have reduced the risk of costly complications like heart disease, stroke, amputation, blindness and kidney disease. NIDDK-funded innovations have spurred new drug therapies for type 2 diabetes. The Institute has also been a leader in the ongoing development of the artificial pancreas, a closed looped system combining continuous glucose monitoring with insulin delivery. NIDDK is currently supporting a range of clinical studies to foster the advancement of this promising and potentially life-changing technology.

Further, researchers all over the world have access to the broad spectrum of data the NIDDK's Environmental Determinants of Diabetes in the Young (TEDDY) research has collected, information which holds great promise in the search for triggers of type 1 diabetes so that the disease can be prevented.

NIDDK studies continue to lead to breakthroughs in understanding diabetes. For example, the Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) study recently reported valuable data on insulin resistance and secretion that suggest early and rapid deterioration of beta cell function in youth with type 2 diabetes compared with data published on adults with newly diagnosed type 2 diabetes. This is critically important information for improving interventions in children.

And NIDDK has made progress in understanding the genetics of diabetes. For example, NIDDK-supported research has identified a new class of genes called "long non-coding RNAs" that play a role in the growth of pancreatic insulin-producing cells.

Yet, this progress is in grave jeopardy. As a result of sequestration in 2013, NIDDK lost approximately \$102 million. While the Association acknowledges the \$51 million increase for NIDDK provided in FY 2014, which partially restored the sequestration cuts, this funding level still shows an enormous step backwards in the face of an epidemic that continues to grow. Sequestration affected the Institute's research efforts in multiple ways. Because of sequestration, NIDDK funded 32 fewer new and competing Research Project Grants (RPGs) and 97 fewer non-competing RPGs. NIDDK funded 14 fewer Institutional National Research Service Awards, which enable institutions to fund individuals selected for predoctoral and postdoctoral research training in specified shortage areas. Additionally, funding of applications under the Institute's Special Emphasis program was severely constrained, NIDDK's Collaborative Team Science programs were reduced, and the Institute's Core Mission Areas were underfunded.

Additional and sustained funding in FY 2015 and beyond would allow the full restoration of sequestration cuts enacted in FY 2013, enable NIDDK to support current research projects and invest in additional promising studies. For example, NIDDK would be able to continue to support a comparative effectiveness clinical trial, the Glycemia Reduction Approaches in Diabetes (GRADE) study, testing different medications for type 2 diabetes, which is instrumental in finding the most effective treatments for diabetes. The NIDDK would also be able to carry on with research to identify genes indicating risk for type 2 diabetes in multiple ethnic groups, as well as research to understand the functions of those genes in order to develop new targets for prevention and treatment. The Institute would be able to tailor type 2 diabetes prevention efforts to better reach individuals at disproportionate risk for the disease.

With increased funding, NIDDK would also be able to continue to support research toward preventing type 1 diabetes, including research to identify environmental triggers of the disease, clinical trials testing prevention approaches in relatives of people with type 1 diabetes, and research to identify immune system factors that could be potential therapeutic targets. Finally, the Institute would be able to support a clinical trial testing vitamin D therapy in the prevention of type 2 diabetes. Increased funding for NIDDK will ensure the investments made in these projects and in future studies will lead to fruitful outcomes for individuals with and at risk for diabetes.

Division of Diabetes Translation

DDT, which is a part of CDC's National Center for Chronic Disease Prevention and Health Promotion, leads efforts to prevent diabetes and its terrible complications. This includes developing and implementing prevention strategies and educational activities to address diabetes. An important component of these efforts is the work DDT undertakes to translate key diabetes research findings into practice, bringing more effective ways to prevent and treat diabetes. DDT's translational research efforts transform the wonderful work of the NIDDK into new and innovative approaches to diabetes in communities across the country. For example, the National Diabetes Prevention Program (National DPP) at CDC is based on NIDDK research showing weight loss of 5 to 7 percent of body weight, achieved by reducing calories and increasing physical activity to at least 150 minutes per week, reduced the risk of developing type 2 diabetes by 58 percent in people at high risk overall and by 71 percent for those over 60 years old. Translating the clinical trial to a community setting showed these results can be replicated for a cost of about \$400 per participant. The National DPP follows this effective low-cost community model.

Additionally, DDT collaborates with NIDDK on the Search for Diabetes in Youth study (SEARCH), which is designed to assess the impact of type 1 and type 2 diabetes in youth to improve prevention efforts aimed at young people. In addition to providing the first population-based data on rates of childhood diabetes, SEARCH also provides information on the health status of children with diabetes. Findings from SEARCH point to the need for better treatment strategies and technologies to improve diabetes management and metabolic control in children and youth.

DDT also maintains vital data on the diabetes epidemic at the state and national levels, which is used by federal, state, and local health officials and policymakers to target diabetes prevention and treatment efforts to individuals with, and at risk for, diabetes effectively and efficiently.

The Association is very appreciative of the \$137.3 million increase in FY 2014 for DDT, which restored funding lost through sequestration cuts and increased the resources available for prevention activities and translational research for the Division. For the diabetes community, this was a welcome boost of support for DDT, which has been woefully underfunded to address the diabetes epidemic. Given the ground the fight against DDT stands to gain from increased funding in FY 2014, we must ensure this level of funding continues. The ability of DDT to perform the translational studies needed to help deliver cutting-edge prevention tools to stop the diabetes epidemic depends upon it. That is why the Association recommends FY 2015 funding of \$137.3 million.

Conclusion

Americans with, and at risk for, diabetes are counting on Congress to significantly invest in diabetes research at NIDDK and DDT. We believe the best way to confront the advancing human and economic pain diabetes exacts on our country is with a deeper investment in cutting-edge medical research at NIDDK and translational research DDT. We can – and must – change our country's future with regard to this devastating disease, and we urge the Subcommittee to reflect the explosive growth of this horrendous disease in your current and future appropriations decisions. Thank you for the opportunity to submit this testimony.