

**Testimony of Robert R. Henry, M.D.,  
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**Before the  
Subcommittee on Health  
Committee on Energy and Commerce  
United States House of Representatives**

**"The Battle Against Diabetes: Progress Made; Challenges Unmet"**

**Thursday, July 1 ~ 10:00a.m.**

Thank you for the opportunity to provide this testimony to the House Energy and Commerce Committee's Subcommittee on Health. I am pleased to testify on behalf of the American Diabetes Association (Association). I want to especially thank Chairman Pallone and Ranking Member Shimkus for holding the hearing.

I must say the Subcommittee has impeccable timing in scheduling this hearing. I have just come from the American Diabetes Association's 70<sup>th</sup> Scientific Sessions conference in Orlando, Florida, the largest diabetes research meeting in the world. Over 14,000 diabetes researchers, providers, and educators gathered to hear and discuss the very latest on research related to diabetes.

I am here today newly reenergized that outstanding studies are underway that will allow us to refine current prevention tools, improve the management of the disease, provide more effective care to individuals with diabetes, and ultimately find a cure for this devastating disease.

We cannot afford to waste time. In the five minutes I will speak to you today, fifteen more Americans will be diagnosed with diabetes. While nearly 24 million Americans have diabetes today, that number is expected to grow to 44 million in the next 25 years if present trends continue. Every 24 hours, 230 people with diabetes will undergo an amputation, 120 people will enter end-stage kidney disease programs, and 55 people will go blind from diabetes. Every single day, diabetes costs the United States over a half a billion dollars, yet, this is but a fraction of the costs that lie ahead unless we take action immediately to stop this epidemic.

The Association is grateful to the Committee for supporting 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), research translation, prevention, control and surveillance efforts through the Centers for Disease Control and Prevention's (CDC) Division of Diabetes Translation (DDT), and the development and operation of clinical and public health efforts to treat and prevent diabetes in American Indians and Alaskan Natives through the Indian Health Service (IHS), to help address diabetes. It is because of this investment that our knowledge of the disease has been expanded and the critical work towards ending this epidemic can continue.

As the nation's leading non-profit health organization providing diabetes research, information and advocacy, the Association believes that diabetes prevention and research are critical. 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. For the Association, maintaining a public health perspective reminds us of the importance of the health of patients and the communities in which they live.

In order to effectively combat the diabetes epidemic, research must be patient-centered, multi-layered and translational. That is, we must take what we learn in the laboratory and make it work both in the clinical setting and in the communities where we live. What patients and health care professionals need now is a translational diabetes GPS to help navigate and if necessary, recalculate, the curvy, often rocky road to optimal diabetes prevention and care. With this in mind, the Association remains dedicated to helping researchers, health professionals and patients connect the dots linking evidence-based studies to improved, high quality diabetes management and prevention tools.

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. We are all truly interdependent in this endeavor, and it will take a united front to stop diabetes.

I will provide the Committee with an overview of the prevalence and costs of diabetes, then discuss the Association's research program and the ways in which we support researchers to take novel, evidence-based ideas from bench to bedside. I will also highlight the partnerships we have forged with both the public and private sectors to foster cutting-edge diabetes studies in order to speed up the day that new diagnostic, prevention, and treatment tools – and ultimately a cure – will be available to people with, and at risk for, diabetes.

### **Taking a Toll: Diabetes Prevalence and Costs**

Nearly 24 million American adults and children (nearly 8 percent of the population) have diabetes, and 57 million more individuals have pre-diabetes. Of those with diabetes, almost 6 million are unaware they have this devastating disease. Together, this means a quarter of the U.S. population either has, or is at high risk for, developing diabetes.

Diabetes is a chronic condition that impairs the body's ability to use food for energy. The hormone insulin, which is made in the pancreas, is needed for the body to change food into energy. For 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 the cells are resistant to insulin, which is type 2 diabetes. Pregnant women with gestational diabetes are unable to make and use all the insulin they need during pregnancy. Without enough insulin, glucose cannot leave the blood and be changed to energy.

Diabetes results in too much glucose (sugar) in the blood stream. Insulin and some oral medications used to treat diabetes can cause blood glucose levels to become too low. Blood glucose levels that are either too high or too low can be dangerous in the short term. In the long term, it is high levels of blood glucose that cause the complications of diabetes including heart and kidney disease, blindness, and amputation.

The majority of diabetes cases, 90 to 95 percent, are type 2, while type 1 diabetes accounts for five to ten percent of diagnosed cases. Additionally, gestational diabetes affects 135,000 American women each year, or 2 to 5 percent of all pregnant women. For individuals with pre-diabetes, blood glucose levels are higher than normal; however with lifestyle intervention, many people can prevent the progression to type 2 diabetes.

Despite the many advances in diabetes research, prevention and treatment, the CDC has identified diabetes as a disabling, deadly epidemic that is on the rise. Between 1980 and 2007, the prevalence of diabetes increased by 300 percent. According to the CDC, one in three children born in the year 2000 will develop the disease in their lifetime if the number of cases of diabetes continues to grow. This number is even greater among minority populations, where nearly one in two children face a future with diabetes.

Additionally, type 2 diabetes, traditionally seen in older patients, is beginning to reach a younger population, due to the surge in childhood obesity. An alarming 2 million adolescents (or 1 in 6 overweight adolescents) aged 12-19 have pre-diabetes.

The impact diabetes has on individuals and the health care system is enormous and continues to grow at a shocking rate. Diabetes is a leading cause of kidney disease, adult-onset blindness, lower limb amputations, heart disease and stroke. Gestational diabetes is associated with health problems for both mother and child during pregnancy and childbirth, including preeclampsia and preterm delivery. Since 1987, the death rate due to diabetes has increased by 45 percent. In that same period, the death rates for heart disease, stroke and cancer have dropped.

In addition to the physical toll, diabetes also attacks our pocketbooks. A recent study by the Lewin Group found that in 2007 the total cost of diabetes in America (including both diagnosed and undiagnosed diabetes, pre-diabetes, and gestational diabetes) was \$218 billion. That year, medical expenditures due to diabetes totaled \$116 billion, which included \$27 billion for diabetes care, \$58 billion for chronic diabetes-related complications, and \$31 billion for excess general medical costs. Indirect costs resulting from increased absenteeism, reduced productivity, disease-related unemployment disability and loss of productive capacity due to early mortality totaled \$58 billion. This is an increase of 32 percent since 2002. Thus, in just five years, the cost of diabetes increased by \$42 billion, or \$8 billion per year. Added to that is another \$18 billion for costs associated with undiagnosed diabetes, \$25 billion for pre-diabetes, and \$623 million for gestational diabetes. In fact, approximately one out of every five health care dollars is spent caring for someone with diagnosed diabetes, while one in ten health care dollars is directly attributed to diabetes. Additionally, one-third of Medicare expenses are associated with treating diabetes and its complications.

### **The American Diabetes Association Research Program**

The Association's Standards of Medical Care in Diabetes, published in our journal, *Diabetes Care* in January 2010, and, developed by leading experts in the field, are the respected standard for diabetes treatment and care in our country. Diabetes is a chronic illness that requires continuing medical care and patient-management education to prevent or delay complications. As such, our guidelines cover a broad range of issues, recognizing patients, clinicians, researchers, payors and other individuals need evidence-based standards to develop patient-centered diabetes care, treatment goals, and tools to evaluate and provide quality care.

The Association brings the same comprehensive approach to our research program. Because diabetes care is so complex and requires that many issues, in addition to blood glucose, are addressed, we believe that research on diabetes must accordingly explore the full range of clinical and public health issues facing individuals with type 1, type 2, and gestational diabetes.

We realize that the federal government is, and will continue to be, by far the greatest source for diabetes research in our country. The goal of the Association's research program is to support the government's efforts by complementing and leveraging its commitment to diabetes research. We do this in several ways. First, we fund cutting edge research. We realize the importance of dedicating our public dollars to the research that has demonstrated it has the best chance of making a difference – that is, a bang for the taxpayer's buck. But we also know that a good idea does not

become a promising idea without that first infusion of funding that gets the ball rolling. Thus, the Association is dedicated to looking for the best cutting edge and novel research proposals to give them the support they need to prove their case for larger governmental funding. Second, we are committed to developing the pipeline of diabetes researchers who will ultimately work on government-funded projects by using our funds to give a start to promising young researchers and developing investigators, including more minority researchers. Thus, the Association is doing all that it can to help foster the emerging scientists interested in pursuing careers in diabetes research. We recognize that effort will require support for researchers at a number of key stages along the academic pipeline and we will continue to support promising scholars at the undergraduate, graduate, and doctorate levels, and in all stages of their professional careers, to ensure the vitality of future diabetes research. Third, we partner with the federal government to provide additional needed funds when necessary to help fully explore promising research.

#### Program Structure

Since the research program's inception in 1952, more than 4,000 research projects have been funded. Last year, there were 439 ADA-funded research projects nationwide at 164 leading research institutions throughout the country. In 2009, the Association awarded \$33.55 million in new research support. It is an understatement that we are extremely pleased with the quality and depth of the studies we have funded in the past as well as those currently being conducted.

#### From the Bench to Clinicians and Communities: Translating Our Research

The Association approaches diabetes research from the complete view of the person and the public's health, looking at multiple layers of the disease. When considering even basic research, we believe that it is just as important to provide evidenced-based treatment and management tools in clinical settings and in the community as it is to understand the causes and effects of the disease itself.

Our efforts have been significant and measurable, and have changed the way diabetes is addressed in both clinical and community settings. For example, Association-funded research developed the first hand-held blood glucose meters and established the benefits of diabetes self-management, thus giving patients key tools to enable them to control their futures with the disease.

Some examples of current research provide a window into the breadth and depth of our program. We are excited to report that research funded by the Association has found a potential new treatment for diabetic retinopathy, a common complication of the eyes that makes diabetes the number one cause of adult onset blindness. Another project is examining the influence of gestational diabetes and a serious complication of pregnancy known as preeclampsia in order to provide health care professionals and their patients with information to protect both mother and baby. Another recent grant addresses overcoming barriers to diabetes management in the elderly. And research supported by the Association is currently underway to find ways to enhance the ability of individuals with diabetes to exercise in order to improve both diabetes and cardiovascular disease outcomes.

#### Raising All Boats: Partnering with the Federal Government and Key Organizations

In addition to funding private diabetes studies, we are also actively engaged in co-supported research, providing support to select federally-funded research programs. This funding mechanism

allows us to provide additional funding to expand on a basic science study or clinical trial and obtain even more data and important research results than would have been possible without our donation.

For example, the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study, sponsored by National Heart, Lung, and Blood Institute (NHLBI) and NIDDK, was the largest clinical trial of adults with established type 2 diabetes at risk for cardiovascular disease and sought to prevent heart attack, stroke, or death from cardiovascular disease using intensive glycemic, blood pressure, and lipid management. The Association provided support for the ACCORD-MIND study of cognitive function in individuals with type 2 diabetes.

The Association is also proud to participate in TrialNet, an international network of researchers who are exploring ways to prevent, delay and reverse the progression of type 1 diabetes. We jointly fund this initiative with the NIDDK, the National Institute for Allergy and Infectious Diseases (NIAID), the National Institute for Child Health and Human Development (NICHD), the National Center for Research Resources, and the Juvenile Diabetes Research Foundation (JDRF). TrialNet was created in response to the Healthy People 2010 report, which called for more diabetes research. Clinical trials are underway in eight countries including the United States to test new treatments for, and to document the history of, type 1 diabetes in adults and children.

Additionally, the Association co-supported the groundbreaking Diabetes Prevention Program (DPP), and the long-term follow up Diabetes Prevention Program Outcomes Study (DPPOS). The DPP, which was conducted by the NIDDK, found modest weight loss through dietary changes and increased physical activity could prevent or delay the onset of type 2 diabetes by 58 percent. Work by DDT showed that this research could be translated into the community setting at the cost of less than \$300 per person. Collaboration between DDT, the YMCA, and leading researchers showed what made sense in theory and worked in the clinic could succeed in the community. This is the exact model we hope for – a progression from basic science to clinical application to community implementation – with an incredible success rate. Congress has recently recognized the value of the DPP and DPPOS by including the Diabetes Prevention Act, which creates a National Diabetes Prevention Program to expand this approach, in the Patient Protection and Affordable Care Act (P.L. 111-148). We are pleased that the Centers for Disease Control has been authorized to move forward in the effort to scale up the implementation of this successful diabetes prevention intervention and call upon Congress to quickly fund this program so this vital work can begin.

Finally, the Association values its partnerships with key health organizations that are also committed to furthering the science of diabetes prevention and treatment. I am pleased to point to our continued work with JDRF in the development of an artificial pancreas that would restore insulin production to individuals with type 1 diabetes. We have also recently teamed with the American Cancer Society in the announcement of a consensus statement acknowledging connections between diabetes and cancer and calling for further research to study the relationship between the two conditions.

## **Towards a Cure for Diabetes: What Is Needed to Defeat the Disease**

The Association looks forward to 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, prevention and treatment, there is much more to be done.

The Association is committed to continuing its diabetes research, public education and advocacy efforts. Additional studies are needed in multiple areas of diabetes research, including research into new drugs, insulin pumps and glucose sensors; gene therapy and stem cell research; new prevention trials; and population studies to help predict diabetes and better treat individuals with the disease. It is essential that diabetes funding at NIH, CDC, and IHS be increased to reflect the burden of the diabetes epidemic, both on our citizen's lives and on our nation's pocketbook. In addition, I want to outline several key next steps that must be met if we are to succeed in the battle to stop diabetes.

#### Continued Efforts to Translate Research into Health Care Delivery

We collectively must encourage more translational research to help put cutting edge research and the newest innovations into the hands of patients, providers, and the public health community as swiftly as possible. For example, the DPP is already encouraging further studies on patient-centered diabetes prevention interventions focused on lifestyle changes. According to late breaking research presented at Scientific Sessions, several similar programs, including a group setting at a primary care practice in California and in churches in Georgia and Connecticut, have shown outstanding results.

Other research presented at the Scientific Sessions conference involved African-Americans, a population that is at higher risk of developing type 2 diabetes and 3-5 times as likely as whites to develop End Stage Renal Disease (ESRD). This study found African Americans with diabetic chronic kidney disease progress faster than other races to advanced stages of kidney disease, largely due to poor glucose and blood pressure control and lower vitamin D levels. This information is critically important for patients and providers in order to maximize treatment and avoid complications.

To meet the challenge of diabetes and to begin to reflect the burden it has on this country we must significantly increase support for diabetes research programs at the NIDDK, and research, prevention, and treatment programs at the DDT, and the development and operation of clinical and public health efforts to treat and prevent diabetes in American Indians and Alaskan Natives through the IHS. For example, despite its successful research, prevention, and surveillance efforts, DDT is allotted only a little over 80 cents per year for each American with diabetes and pre-diabetes. Additionally, while the DDT has consistently comprised 10.3% of CDC's overall budget from FY 2005 to FY 2010, it has essentially been flat funded in this time period. Similarly, the NIDDK has received slight increases over the past five years, but this has not kept pace with the estimated 3.5% rate of biomedical inflation. The Association is dedicated to highlighting translational research, and stands ready to collaborate with the diabetes research community to foster these efforts, but a greater commitment from Congress is imperative.

#### Addressing the Needs of Special Populations

More must be done to address the pressing needs of special populations particularly affected by the diabetes epidemic. Diabetes disproportionately affects minority populations, including African-Americans, Latino-Americans, Asian-Pacific Americans, and American Indians and American Natives (AIAN). The Association remains steadfast in its efforts to support research that addresses people of color and disparities in diabetes care in minority communities.

With this in mind, the Special Diabetes Program (SDP) has been particularly successful in addressing the prevalence of diabetes in AIAN, as well as spurring research in type 1 diabetes since 1997. The program has demonstrated significant increases in the availability of diabetes prevention and treatment services for AIANs and has shown tangible success in preventing diabetes and its complications in AIAN communities across the country. I join my colleagues from JDRF and the National Indian Health Board in applauding Representative Diana DeGette and Representative Mike Castle for introducing legislation to reauthorize SDP, H.R. 3668, which expires in 2011. This bill will reauthorize the programs for five years and expand the funding by \$50 million per year. This increase recognizes that these programs have not seen an increase for the past six years. While the programs have continued to do amazing work without additional funding, we know this limits the reach of the research dollar and the prevention and treatment programs. I urge Congress to pass this important legislation so this work can continue to move forward.

We commend Representative DeGette for introducing H.R. 1995, the Eliminating Disparities in Diabetes Prevention Access and Care Act (EDDPAC), which seeks to reduce racial and ethnic health disparities related to diabetes prevention, care and treatment. The bill importantly requires the NIH to expand and support new and ongoing research regarding diabetes and pre-diabetes in minority populations. We also applaud Rep. Donna Christensen for her work to include EDDPAC in the Tri-Caucus's health disparities legislation. Again, I urge Congress to move quickly as the disparate impact of diabetes on minority communities stands as a high barrier to effectively stopping diabetes.

Additional research is also needed to address gestational diabetes. Greater understanding is needed by the NIH, CDC, providers and patients on how to prevent and treat this condition. New therapies and interventions to detect, treat, and slow the incidence of this condition must be identified.

That is why the Association thanks Committee members Representative Eliot Engel and Representative Michael Burgess for introducing H.R. 5354, Gestational Diabetes Act (GeDi), which aims to lower the incidence of gestational diabetes, both to protect mother and baby now and to prevent women afflicted with this condition and their children from developing type 2 diabetes. Our youngest victims of diabetes need Congress to act.

#### Preparing the Next Generation of Diabetes Researchers

The Association is doing all that it can to help foster the young scientists interested in pursuing careers in diabetes research. We recognize that these efforts will require support for researchers at a number of key stages along the academic pipeline and we will continue to support promising scholars at the undergraduate, graduate, doctorate levels and in all stages of their professional careers to ensure the vitality of future diabetes research.

### **Conclusion**

The diabetes epidemic is growing at an astonishing rate. If left unaddressed – or under-addressed – diabetes will overwhelm the healthcare system with tragic consequences. To change this future we need to increase our commitment to research and prevention in a way that reflects the burden diabetes poses both for us and for our children.

We pledge to do our part to support the young researchers, the developing investigators, and the cutting edge research that will continue to lead to major breakthroughs at NIH, CDC, and IHS. However, our fight to stop diabetes must be significantly expanded. Your leadership in combating this growing epidemic is essential.

Thank you for your commitment to the diabetes community and for the opportunity to participate in this important hearing. The Association is prepared to answer any questions you might have on these important issues.

**Robert R. Henry, MD**  
**President-Elect, Medicine and Science**  
**American Diabetes Association**

Dr. Robert R. Henry, MD, is Professor of Medicine in the Division of Endocrinology and Metabolism at the University of California, San Diego. Dr. Henry is also Chief of the Section of Endocrinology, Metabolism & Diabetes and Director of the Center for Metabolic Research at the VA Medical Center in San Diego.

He received his medical degree from the University of Manitoba Medical School, Manitoba, Canada, where he also completed his residency in internal medicine and fellowship in endocrinology. Dr. Henry has been Visiting Assistant Professor of Medicine, Diabetic Research Unit, at the University of Colorado Health Sciences Center; Visiting Assistant Research Endocrinologist at the University of California, San Diego; and Visiting Professor of Medicine at the University of Edinburgh, Royal Infirmary.

He is a member of several volunteer health organizations and professional societies including the American Diabetes Association, American Heart Association, Endocrine Society, Royal College of Physicians and Surgeons of Canada, and the American Federation for Clinical Research. Dr. Henry's honors include awards from the American Board of Internal Medicine and the American Board of Endocrinology and Metabolism. He is also a Fellow of the Royal College of Physicians and Surgeons of Canada. Dr. Henry's primary research interests involve studies in the etiology, treatment, and prevention of obesity and type 2 diabetes.

He has authored more than 200 scientific journal articles and book chapters, the most recent publications describing the metabolic and cardiovascular effects of novel therapies for insulin resistance and diabetes, as well as defects of insulin signal transduction in skeletal muscle and adipose tissue of type 2 diabetic subjects