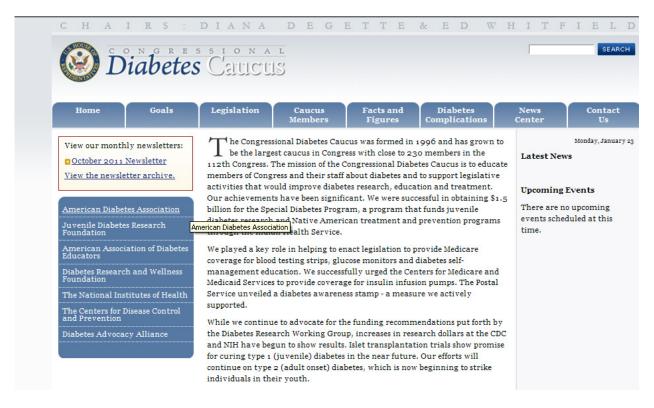


Quarterly Newsletter

112th Congress - October 2012

MESSAGE FROM THE CAUCUS LEADERSHIP

As the chairs and vice-chairs of the Congressional Diabetes Caucus, we would like to present the October edition of the Caucus Quarterly Newsletter. Below you will find the latest news in diabetes, summaries of recent diabetes events, and updates on the legislative priorities of the Caucus. We hope that you and your staff find this newsletter helpful and informative.



Can't find last quarter's newsletter? Want to learn about Diabetes Caucus legislation? Head to the Diabetes Caucus website at http://www.house.gov/degette/diabetes/. If you introduce diabetes legislation, please let emily.katz@mail.house.gov know so it can be featured on the site!

Rep. Diana DeGette	Rep. Ed Whitfield	Rep. Xavier Becerra	Rep. Tom Reed
D-CO	R-KY	D-CA	R-NY
Co-Chair	Co-Chair	Vice-Chair	Vice-Chair

November is Diabetes Awareness Month!

Did you record a Public Service Announcement with the caucus last year? Now is the time to place it again with local television channels and on social networking sites! Please check with Emily Katz at Emily.katz@mail.house.gov or Taylor Booth at taylor.booth@mail.house.gov if you would like some ideas or you would like to share an idea about how to improve Diabetes awareness during November!

News From NIH

Institute (NEI)-supported comparative effectiveness trial was an important contributor to the research base that led to the recent FDA approval of the drug Lucentis® (ranibizumab injection) for the treatment of diabetic macular edema. In this condition, blood vessels in the eye damaged by diabetes leak fluid, causing swelling and blurred vision, and can lead to severe vision loss or even blindness. The trial was conducted by the Diabetic Retinopathy Clinical Research Network (DRCR.net), which is led by NEI and receives support from the Special Statutory Funding Program for Type 1 Diabetes Research. The trial built on results from smaller, shorter studies showing benefits of eye injections of medications, such as ranibizumab, that block a chemical signal that stimulates blood vessel growth. The DRCR.net conducted a larger, longer trial that confirmed the results of earlier studies: ranibizumab eye injections, often in combination with laser treatment, result in better vision than laser treatment alone (laser treatment alone was the standard of care for over 25 years). The approval of this drug marks a major treatment breakthrough for preserving vision in people with diabetes.

Drug Approved for Treatment of Diabetic Eve Disease: An National Eye

Longer Life Expectancy for People with Type 1 Diabetes: NIDDK-supported researchers estimate that life expectancy for people with type 1 diabetes has increased by about 15 years. The researchers compared two different populations participating in the Pittsburgh Epidemiology of Diabetes Complications Study: those diagnosed with type 1 diabetes from 1950-64, and those diagnosed from 1965-80. They found that life expectancy at birth was about 15 years longer for people diagnosed during the later time period. The researchers attribute several possible factors to the increase, one of which is a decline in life-threatening diabetic complications. Key knowledge about reducing complications stemmed from NIDDK's landmark Diabetes Control and Complications Trial (DCCT) and its follow-on Epidemiology of Diabetes Interventions and Complications (EDIC) study, which showed that early, intensive blood glucose control reduces risk of long-term complications. This finding led to a paradigm shift in the way type 1 diabetes is controlled, and has resulted in greatly improved health outcomes for patients. These improvements are now being translated into longer lifespans for people with type 1 diabetes.

Improved Outcomes after Islet Transplantation: NIDDK-supported researchers have found that islet transplantation outcomes have improved in recent years. Islet transplantation is a promising therapy for people with difficult-to-manage type 1 diabetes or with kidney failure. In this therapy,

islets from a donor human pancreas are transplanted into an adult patient. The goal is that the donor islets will produce enough insulin to improve blood glucose control and, in most patients, to eliminate hypoglycemia (low blood glucose). Severe hypoglycemia is a dangerous complication of diabetes, and can lead to seizures, coma, and even death. People who are candidates for islet transplantation often suffer from repeat episodes of severe hypoglycemia, which can cause hypoglycemia unawareness. In this syndrome, patients do not recognize—and therefore cannot correct for—the low blood glucose, making it especially challenging for them to perform everyday activities, like driving. To expedite progress and promote safety in the islet transplantation field, the NIDDK, with support from the Special Statutory Funding Program for Type 1 Diabetes Research, established the Collaborative Islet Transplant Registry (CITR) to collect and analyze data on islet transplants. Many of the recent transplants were performed by the NIDDK and NIAID co-led Clinical Islet Transplantation Consortium (CIT), also supported by the Special Diabetes Program. Researchers analyzed CITR data from 677 islet transplant recipients, to identify differences between the early (1999-2002), mid (2003-2006), and recent (2007-2010) transplant eras. They found that the percent of people who did not need external insulin administration 3 years after their transplant increased over time: from 27 to 37 to 44 percent in the three eras. The transplanted islets also functioned longer in the most recent era, and the procedure protected patients from severe episodes of hypoglycemia in all eras. These findings suggest that islet transplantation is improving and continues to be a promising avenue for treating people with difficult-to-manage type 1 diabetes. Further insights are expected from a major clinical trial being conducted by the CIT. The trial has nearly reached its primary endpoint and results will be presented to the FDA for consideration of licensure of islets for therapy.



- http://well.blogs.nytimes.com/2012/08/08/diabetes-and-theobesity-paradox/ (NY Times Blog)
- http://www.newsobserver.com/2012/09/23/2364979/study-offruit-flies-brains-could.html (The News & Observer)
- http://news.health.com/2012/10/23/beans-a-boon-for-people-with-diabetes-study-finds/ (HealthDay)
- http://www.nytimes.com/2012/10/20/health/in-study-weight-loss-did-not-prevent-heart-attacks-in-diabetics.html?ref=health& r=1& (NY Times)
- http://www.nejm.org/doi/full/10.1056/NEJMp1208169 (New England Journal of Medicine)



Did You Know???

FASCINATING FACT

Prediabetes

79 million Americans—more than three times the number who have diabetes—have prediabetes and are at elevated risk for developing type 2 diabetes. Sadly, only about 7 percent even know they have

prediabetes. The good news is there is a proven, evidence-based program, showing that with modest weight loss through healthy eating and increased physical activity, individuals with prediabetes can prevent or delay the disease. The successful NIH clinical trial, the Diabetes Prevention Program, showed that people with prediabetes can reduce their risk of diabetes by 58 percent with this lifestyle intervention. The CDC further showed that this program can be effectively translated to community setting, providing the intervention to at-risk individuals for a much lower cost. This program is the basis for the national network of community-based programs called the National Diabetes Prevention Program, which was authorized by Congress in the 111th Congress. Once funded and implemented, the National Diabetes Prevention Program will provide access to this proven intervention to many of the 79 million Americans with prediabetes and bring us closer to stopping diabetes. It has been estimated that bringing this program to scale nationally will save the nation \$190 billion in heathcare costs over ten years.

RECENT EVENTS

On July 24, the Diabetes Caucus co-hosted a briefing entitled, "Diabetes: Innovative Approaches to Care, Treatment and Education" along with the California Healthcare Institute. The briefing included a distinguished panel of doctors and researchers who are working on innovative tools and programs to better understand, prevent, and treat diabetes and its related conditions.

On September 27, the Director of the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) coauthored a paper in the New England Journal of Medicine titled "What's Preventing Us from Preventing Type 2 Diabetes?" You can read the article here.

On October 9, the CDC announced \$6.75 million in grant awards to the National Diabetes Prevention Program: Preventing Type 2 Diabetes Among People at High Risk. These funds will expand the National Diabetes Prevention Program (National DPP) to help establish a network of structured, evidence-based lifestyle change program designed to prevent type 2 diabetes among people at high risk. Funding was awarded to six organizations on the basis of the number of qualified applicants, the scope of the proposals, and the geographic reach. Read more about it here.

On November 8, the Diabetes Caucus hosted a conference call with JDRF for staff of members who signed a letter to the FDA in April 2011. The letter asked for timely guidance so that clinical trials could begin on the artificial pancreas. An artificial pancreas will enable someone with insulindependent diabetes to automatically control their blood glucose levels. JDRF updated staff on the clinical trials currently under way, and explained that the artificial pancreas was a product of research funded by the Special Diabetes Program, which is set to expire in September of 2013 if Congress does not act.

On November 9, FDA finalized the guidance for the artificial pancreas (AP).



REGULATORY PRIORITIES

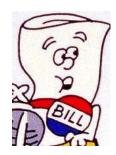
Artificial Pancreas Technology at the U.S. Food and Drug Administration (FDA)

Thank you to the 252 of our House colleagues and members of the Diabetes Caucus who signed the letter to FDA Commissioner Margaret Hamburg, 134

Democrats and 118 Republicans, in bipartisan support of advancing artificial pancreas technology guidance. The artificial pancreas is a potentially life-saving technology that would minimize dangerous high and low blood sugar levels, and would help prevent the devastating and costly long-term complications of type 1 diabetes such as: seizures, coma, kidney failure, heart disease, blindness, and amputations. The artificial pancreas draft guidance is under consideration at the agency and will allow outpatient trials to begin so that this technology can be made available to those with type 1 diabetes in the near future.

The artificial pancreas essentially combines a continuous glucose monitor (CGM) and insulin pump to act in place of a person's pancreas. When the CGM detects an abnormal blood sugar level, it speaks to the insulin pump which then automatically delivers a dose of insulin or sugar to bring blood sugar levels back to normal. This system is regarded by clinical experts as being the most groundbreaking development in type 1 diabetes care since the discovery of insulin. The Caucus' work to help it along has been noted by FDA and led to the publication of its draft guidance by its previously announced December deadline.

FDA finalized the guidance for the artificial pancreas (AP) on November 9, 2012. Research on artificial pancreas systems is continuing including for the first time a study being performed in a more real-world setting outside of the hospital.



LEGISLATIVE PRIORITIES

The **Special Diabetes Program** (SDP) is set to expire in September 2013 and needs to be reauthorized this Congress. Earlier this year, the Diabetes Caucus circulated a letter to House leadership on the importance of this program to advancing diabetes research. Thank you to all members who signed the letter. The Caucus leadership looks forward to working with all members on reauthorization by the end of the 112th Congress.

H.R. 2787, the *Medicare Diabetes Self-Management Training Act of 2011*. Introduced by Representative Whitfield. The bill would make a technical clarification to recognize certified diabetes educators (CDE) as providers for Medicare diabetes outpatient self-management training services (DSMT). CDEs are the only health professionals who are specially trained and uniquely qualified to teach patients with diabetes how to improve their health and avoid serious diabetes-related complications. The 1997 authorizing DSMT statute did not include CDEs as Medicare providers and it has become increasingly difficult to ensure that DSMT is available to patients who need these services, particularly those with unique cultural needs or who reside in rural areas.

H.R. 2741, the *Preventing Diabetes in Medicare Act of 2011.* Introduced by Representative DeGette. The bill would extend Medicare coverage to medical nutrition therapy (MNT) services for people with pre-diabetes and other risk factors for developing type 2 diabetes. Under current law, Medicare pays for MNT provided by a Registered Dietitian for beneficiaries with diabetes and renal diseases. Unfortunately, Medicare does not cover MNT for beneficiaries diagnosed with pre-diabetes. Nutrition therapy services have proven very effective in preventing diabetes by providing access to the best possible nutritional advice about how to handle their condition. By helping people with pre-diabetes manage their condition, Medicare will avoid having to pay for the much more expensive treatment of diabetes.

H.R. 3150, the *Medicare Safe Needle Disposal Coverage Act of 2011*. Introduced by Representative Whitfield. The bill would provide Medicare Part D coverage of needle disposal supplies such as sharps containers or other destruction devices. The legislation would protect type 1 and type 2 insulin-dependent Medicare diabetes patients as well as caregivers and handlers of waste from accidental needle-stick injuries

CAUCUS MEMBERS WITH DIABETES LEGISLATION

Representatives Engel and Burgess have reintroduced the *Gestational Diabetes (GEDI) Act*. H.R. 2194 directs the Director of the Centers for Disease Control and Prevention (CDC) to develop a multisite gestational diabetes research project within the diabetes program of the CDC to expand and enhance surveillance data and public health research on gestational diabetes.

Representative Waters reintroduced the *Minority Diabetes Initiative Act*. H.R. 2799 allows the Secretary of Health and Human Services (HHS) to make grants to public and nonprofit private health care providers to provide treatment for diabetes in minority communities.

Representative Pete Olsen introduced the *National Diabetes Clinical Care Commission Act*. H.R. 2960 establishes a National Diabetes Clinical Care Commission comprised of diabetes experts to provide a mechanism for federal engagement with professionals and advocates who will bring clinical expertise to implementing initiatives intended to improve diabetes care.

Representative Barbara Lee reintroduced the *Health Equity and Accountability Act.* H.R. 2954 improves and guides federal efforts in the following vital areas: data collection and reporting; culturally and linguistically appropriate health care; health workforce diversity, improvement of health outcomes for women, children and families; mental health; high impact minority diseases (hepatitis B, HIV/AIDS, diabetes, cancer); health information technology; emboldened accountability and evaluation; and, addressing social determinants of health.

Representative Lee Terry reintroduced the *Equity and Access for Podiatric Physicians Under Medicaid Act*. H.R. 3364 amends title XIX of the Social Security Act to cover physician services delivered by podiatric physicians, ensuring that Medicaid beneficiaries have access to appropriate quality foot and ankle care.