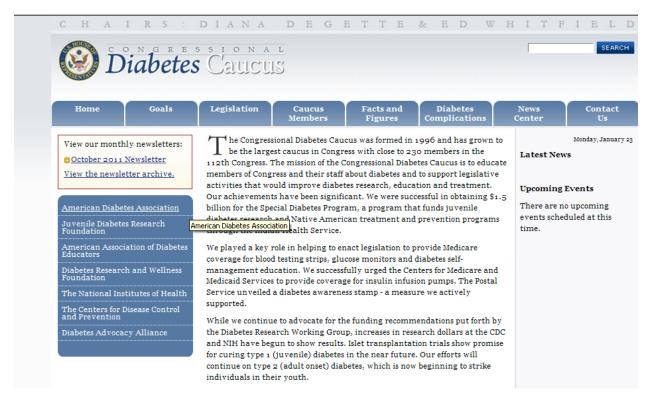


### **Quarterly Newsletter**

113th Congress - January 2013

#### MESSAGE FROM THE CAUCUS LEADERSHIP

As the chairs and vice-chairs of the Congressional Diabetes Caucus, we would like to present the January 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. Please mark your calendars to join us for a Caucus welcome reception on February 13 from 5:30-7:30 in Rayburn B-369. You will be presented with more information about the event soon.



Can't find last quarter's newsletter? Want to learn about Diabetes Caucus legislation? Head to the Diabetes Caucus website at <a href="http://www.house.gov/degette/diabetes/">http://www.house.gov/degette/diabetes/</a>. If you introduce diabetes legislation, please let <a href="maily.katz@mail.house.gov">emily.katz@mail.house.gov</a> 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 Vice-Chair Vice-Chair



Study Demonstrates Bypass Surgery Superior to Non-surgical Procedure for Adults with Diabetes and Heart Disease: Researchers demonstrated that adults with diabetes and heart disease who underwent coronary artery bypass graft (CABG) surgery, in comparison to a non-surgical procedure known as percutaneous coronary intervention (PCI), had fewer adverse events and better survival rates after 5 years. People with diabetes have a higher risk of developing

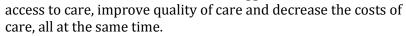
heart disease, and adults with diabetes have heart disease death rates about 2 to 4 times higher than adults without diabetes. In coronary heart disease, plaque builds up inside the coronary arteries leading to blocked or reduced blood flow to the heart. In CABG, doctors try to improve blood flow to the heart by using a healthy artery or vein from another part of the body to bypass a blocked coronary artery. PCI is a less invasive procedure in which blocked arteries are opened from inside with a balloon.

Supported by the National Heart, Lung, and Blood Institute, the Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM) study compared CABG and PCI, involving 140 international centers and 1,900 adults with diabetes. After 5 years, the group that had CABG surgery had a lower combined rate of strokes, heart attacks, and deaths (18.7 percent) than the group that received PCI (26.6 percent). Strokes, which are a well-known risk of bypass surgery, occurred slightly more often in the CABG group (5.2 percent) than in the PCI group (2.4 percent). However, more people died from any cause in the PCI group (16.3 percent) than in the CABG group (10.9 percent). The survival advantage of CABG over PCI was consistent regardless of race, gender, number of blocked vessels, or disease severity.

Identification of a Promising New Drug Target for Obesity and Type 2 Diabetes: Researchers have identified a protein in adipose (fat) tissue of mice that regulates both energy expenditure (calorie burning) and inflammation, making it a potential target for treating obesity and type 2 diabetes. A promising approach to treating obesity and related diseases is to make fat tissue that stores fat (white adipose tissue) more like fat tissue that burns fat (brown adipose tissue), thereby increasing whole-body energy expenditure. Additionally, obesity is associated with chronic, lowgrade inflammation of fat tissue, which contributes to the development of insulin resistance, a condition associated with type 2 diabetes. Therefore, identifying ways to reduce inflammation is also an important goal. Toward these goals, researchers identified a protein in mice, called TRPV4, that regulates both energy expenditure and inflammation in fat tissue, even though scientists previously thought that the molecular mechanisms regulating those processes were distinct. Because these findings suggest that TRPV4 may be a promising drug target for treating obesity, the scientists next used, as a potential drug, a chemical that inhibits TRPV4 activity in obese mice. Compared to control mice, the treated animals had improved glucose tolerance, and their fat tissue showed increased activation of energy-burning genes and decreased activation of genes involved in inflammation. These results suggest that inhibiting TRPV4 gives a two-fold benefit of increasing energy expenditure and reducing inflammation in fat tissue. If these findings are extended to humans, targeting the protein may be a therapeutic avenue for treating obesity and type 2 diabetes. New Potential Strategy To Combat Beta Cell Failure in Type 2 Diabetes: New research in mice indicates that loss of beta cell identity, not beta cell death, may be a key feature of type 2 diabetes. Diabetes is characterized by the body's failure to produce and/or respond appropriately to insulin, a hormone produced by beta cells in the pancreas. In people with type 2 diabetes, not only do cells not properly react to insulin but, gradually, the beta cells lose their ability to secrete enough insulin, resulting in beta cell failure. Researchers thought that beta cell failure is caused by a reduction of beta cell mass following cell death. This new research shows that, rather than killing beta cells, metabolic stress causes these cells to lose their ability to produce insulin and gain a new identity, and that this process is caused by loss of a protein called FoxO1. These results could lead to improved approaches to treat type 2 diabetes: treatments that salvage cells that have lost their beta cell identity and restore them to become beta cells again could be fruitful, taking advantage of the fact that the cells are still alive and present. Coupling this approach with a finite period of insulin therapy at disease onset might allow stressed beta cells to recover, enabling people with type 2 diabetes to have good glucose control without the need for continued insulin therapy. This could become an improved strategy for treating type 2 diabetes, but remains to be tested in humans.

## GUEST OPINION: CONNECTING NATIONAL POLICY AND LOCAL EXPERIENCE ESSENTIAL TO REDUCE DIABETES DISPARITIES

Health care disparities are perhaps among the most vexing problems in medicine, public health and health policy. Despite an increasing awareness of the wide gaps in health between low-income and minority populations and the rest of Americans, disparities continue to grow. This is especially true for diabetes – a chronic disease that sits at the center of America's struggle with how to increase





At the <u>Alliance to Reduce Disparities in Diabetes</u>, a national program launched and supported by <u>The Merck Foundation</u>, we are working to uncover ways to reverse this trend through a series of local health care delivery programs being run in five communities across the country. Each of the Alliance's <u>health care delivery sites</u> have implemented multifaceted, evidence-based programs

designed to improve care for those who are most likely to be burdened by diabetes.

And while Alliance sites are making progress, Alliance site leaders report facing an array of barriers in the health care delivery and financing systems that have limited the success of interventions. These include:

- The health care system's focus on payments based on units of care, on specialty care and high-cost, high-tech interventions;
- State credentialing standards that present barriers to payments for community health workers who can provide needed links to community care resources and education; and
- Technologies, costs and policies that can obstruct timely and comprehensive exchange of patient information.

Most importantly, and no matter the barrier, the site leaders emphasize how critical it is for national policies aimed at reversing diabetes disparities to consider the on-the-ground experience of people working to improve health outcomes for those most affected. For example, the Alliance program in Dallas has seen clear improvement in diabetes outcomes for its patients following the use of community health workers who follow-up with patients directly to ensure they are keeping up with their diabetes self-management practices. And at the Alliance program in Camden, data

sharing across institutions is helping to identify individuals who need the most intense case management.

A new report from the Alliance sheds light on ways to overcome these systemic and structural barriers. The Alliance's "Policy Considerations That Make the Link," connects the local experience with pressing issues facing national policymakers as they consider ways to get more value, quality, efficiency and innovation into our health care system. Leveraging the local experience to reduce disparities in diabetes is an important place to start.

 Noreen M. Clark, Ph.D., Director, National Program Office, Alliance to Reduce Disparities in Diabetes; Myron E. Wegman, Distinguished University Professor, Director, Center for Managing Chronic Disease, University of Michigan



- <a href="http://asweetlife.org/news/congress-will-not-cut-diabetes-research-program/">http://asweetlife.org/news/congress-will-not-cut-diabetes-research-program/</a> (A Sweet Life)
- <a href="http://www.pbs.org/newshour/rundown/2013/01/how-a-dying-boy-became-the-first-to-beat-diabetes.html">http://www.pbs.org/newshour/rundown/2013/01/how-a-dying-boy-became-the-first-to-beat-diabetes.html</a> (PBS)
- <a href="http://well.blogs.nytimes.com/2012/12/31/juggling-diabetes-and-cancer/">http://well.blogs.nytimes.com/2012/12/31/juggling-diabetes-and-cancer/</a> (NY Times)
- http://www.cbsnews.com/8301-204\_162-57563087/diabetes-detecting-dog-saves-mans-life/ (CBS)
- http://sports.yahoo.com/blogs/nfl-shutdown-corner/outside-game-jay-cutler-inspires-otherstype-1-181957266--nfl.html (Yahoo! Sports)



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Did You Know???

#### **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  $111^{th}$  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 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 <a href="here">here</a>.

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 <a href="here">here</a>.

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).

On January 2, 2013, President Obama signed into law H.R. 8, which included a one-year extension for the Special Diabetes Program. Thanks to all members of the Diabetes Caucus for their work on getting this critical program extended!



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

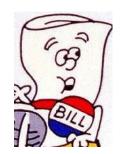
Thank you to the 252 of our House colleagues and members of the Diabetes Caucus who signed the letter to FDA Commissioner Margaret Hamburg, 134

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 FROM THE 112<sup>TH</sup> CONGRESS

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. Update: On January 2, 2013, President Obama signed into law H.R. 8, which included a one-year extension for the Special Diabetes Program!

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

## PLEASE CONTACT THE DIABETES CAUCUS WHEN YOU HAVE INTRODUCED OR REINTRODUCED DIABETES-RELATED LEGISLATION, SO WE CAN FEATURE IT HERE!

Contact <a href="mail.house.gov">mail.house.gov</a> with Congresswoman DeGette or <a href="mail.house.gov">taylor.booth@mail.house.gov</a> with Congressman Whitfield to have your legislation featured and/or to find out other ways the Caucus can help you promote and advance your diabetes legislative priorities.