



Monthly Newsletter

111th Congress – April 2010

MESSAGE FROM THE CAUCUS LEADERSHIP

As the chairs and vice chairs of the Congressional Diabetes Caucus, we would like to present the April edition of the Caucus Monthly 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.

The Congressional Diabetes Caucus website Gets a New Look!

The Congressional Diabetes Caucus recently launched a new and improved website. It can be found at

<http://www.house.gov/degette/diabetes/>. Can't find last

month's newsletter? Want to learn about Diabetes Caucus legislation? The new Web site will be up-to-date with the most recent newsletters and contain a legislative section with caucus endorsed legislation. If your Member introduces diabetes legislation, please let heather.foster@mail.house.gov know so she can feature it on the site!



Rep. Diana DeGette
Co-Chair

Rep. Michael N. Castle
Co-Chair

Rep. Xavier Becerra
Vice-Chair

Rep. Mark Steven
Kirk Vice-Chair



NEWS FROM NIH

Protein Found That Drives Development of Insulin-producing Cells: Finding ways to reduce or eliminate the burden of injected insulin therapy for people with type 1 diabetes and some with type 2 diabetes is an important goal of diabetes research. One approach to eliminating the dependency on injected insulin is to replenish a person's insulin-producing beta cells. Stem cells or reprogrammed adult cells may represent a good source of replacement tissue, but to tap their potential it is critical to

understand the developmental program that creates a functional beta cell. New research has identified a key factor necessary for making insulin-producing beta cells in both humans and mice. Previous research has identified a protein that helps trigger embryonic development of pancreatic islets, which contain beta cells and other cell types. Now, scientists have found another key protein needed for the subsequent development of distinct islet cell subtypes. Mice lacking the newly identified protein—called Rfx6—can make islets, but these islets do not contain insulin-producing cells. They also fail to make some other hormones normally made by the pancreas. Interestingly, the scientists also found that a rare form of neonatal diabetes is associated with mutations in the human gene that produces the Rfx6 protein, suggesting that Rfx6 plays a critical role in beta cell development in humans as well as mice. Researchers therefore now know they will have to ensure that Rfx6 is present in order to successfully generate beta cells from some other cell type for transplantation. This work was supported by the National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases, the Larry L. Hillblom Foundation, the Juvenile Diabetes Research Foundation International, the American Diabetes Association, the Nora Eccles Treadwell Foundation, and the Canadian Institutes of Health Research.

New Discoveries on the Genetics of Blood Glucose Regulation and Insulin Resistance: New genomic technologies have provided a wealth of data on the complex genetic underpinnings of diseases like type 2 diabetes. For example, researchers have used these technologies to compare the genomes of thousands of people with and without the disease to identify common genes that affect the likelihood of developing diabetes. Recently, researchers took a slightly different approach to shed still more light on diabetes genetics. In people without diabetes, pancreatic function tightly controls the level of glucose present in the blood, ensuring that there is always enough glucose that cells will have an adequate supply, but not so much that the excess is toxic. The new research, however, proceeds from the observation that, even among people who do not have diabetes, there is variation in blood glucose levels. One study compared genetic variants between two groups of people: people who have lower fasting blood glucose and people who have higher fasting blood glucose, but not so high they are considered to have diabetes. The researchers found nine gene locations where variation affects levels of fasting blood glucose; five of these locations are also linked to risk for type 2 diabetes. A complementary study compared genomes of people without diabetes according to how strongly and effectively they responded to oral consumption of glucose by making insulin. This study identified four gene locations affecting the insulin response, one of which was also found in the fasting blood glucose study. This variation, in the gene *ADCY5*, was among those found to be associated with type 2 diabetes in the first study. Another, in the gastric inhibitory polypeptide receptor (*GIPR*) gene, is known to influence the insulin response via other hormones called incretins. This work represents a huge collaborative effort to combine 21 studies of over 46,000 patients and helps define a new approach to identify diabetes risk genes. Some but not all the variations that influence blood glucose regulation are associated with diabetes. Further analysis of the genes near the variations found in these studies will help better explain how blood glucose levels are controlled in health and disease. By better understanding the molecular control of healthy blood glucose levels, scientists may one day be more able to predict type 2 diabetes, tailor treatment to people in particular risk categories, and better help people with diabetes keep

their glucose at an appropriate level. These studies were supported by grants from many NIH Institutes and Centers, and other funding sources.

Risks of Blood Glucose Elevation During Pregnancy, and New Definitions of Gestational

Diabetes: Gestational diabetes mellitus (GDM), is a form of diabetes which begins or is first recognized during pregnancy. GDM is common in pregnancy and significantly increases the risk of complications at birth for both the mother and the baby. Women with GDM are at high risk of developing preeclampsia a potentially fatal disorder involving dangerously high blood pressure, and type 2 diabetes. GDM can also increase later risk of obesity and type 2 diabetes in the offspring as they reach adulthood. Recent research suggests that levels of blood sugar once considered normal during pregnancy still confer clinically significant risks. The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study followed 23,000 pregnancies of women with glucose levels below those diagnostic of overt diabetes. The results showed that the higher a pregnant woman's blood glucose is, the higher her risk of pregnancy complications—whether or not her blood glucose reached the level at which GDM was diagnosed at the time of the study. Risk was increased for caesarian section and preeclampsia in mothers, as well as very high birthweight, shoulder injury, low blood sugar, and jaundice in the babies. The effect is significant enough that a recent panel of experts has recommended changing the diagnostic criteria for GDM to be less stringent, such that under the proposed new guidelines about 17 percent of pregnancies would result in GDM in the United States. (By current guidelines, an estimated 5 to 8 percent of pregnancies result in GDM.) The good news is that a healthy diet and exercise can help prevent later type 2 diabetes in women who have had GDM. Therefore, in collaboration with the Office of Research on Women's Health, the National Diabetes Education Program (NDEP) will expand its current campaign, "It's Never Too Early To Prevent Type 2 Diabetes," to raise awareness of the future health risks for women with a history of gestational diabetes and their offspring. The HAPO study received grant support from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Institute of Diabetes and Digestive and Kidney Diseases, and the National Center for Research Resources. The NDEP is a partnership between the NIH and the Centers for Disease Control and Prevention.



Diabetes News

Novo Nordisk's Victoza® receives FDA approval for adults

with type 2 diabetes: On January 25, 2010 the United States Food & Drug Administration approved the drug Victoza from Novo Nordisk. Victoza acts as an agent from diet and exercise to improve blood sugar control in type 2 diabetes adults. Victoza was evaluated in The Liraglutide Effect and Action in Diabetes phase III trials. In clinical studies submitted for FDA review, Victoza was evaluated in five trials, one of 52-weeks duration and

four of 26-weeks duration. These trials examined Victoza in monotherapy as well as in combination with one or two oral anti-diabetic medications and showed better lowering of blood glucose than active comparators such as sulfonylureas and thiazolidinediones. Victoza produced significant reductions in A1C and also was associated with weight loss.

The American Diabetes Association, the European Association for the Study of Diabetes, the American Association of Clinical Endocrinologists, and the American College of Endocrinology support the use of Victoza when blood sugar goals are not met or maintained with lifestyle adjustments and Metformin. In addition to the United States, Victoza has been approved by the European Medicines Agency (EMA) in all 27 European Union member states, Mexico, Iceland, and Japan.

For more information on Victoza please visit Novo Nordisk's website:

<http://www.novonordisk.com/press/liraglutide-press-room/liraglutide-press-room-default.asp>

JDRF Forms Partnership with Animas to Develop First-Generation Automated System for Managing Type 1 Diabetes: On January 13, 2010 the Juvenile Diabetes Research Foundation announced in conjunction with Animas Corporation that they will develop an automated system to help people with type 1 diabetes better control their disease. Their first target to help type 1 diabetes patients is the development of an artificial pancreas, a fully automated system to dispense insulin to patients based on real-time changes in blood sugar levels. "The Juvenile Diabetes Research Foundation will provide \$8 million in funding over the next three years for this project, with a target of having a first-generation system ready for regulatory review within the next four or so years," said the company's, CEO and President, Dr. Alan Lewis.

The first-generation system would be partially automated, utilizing an insulin pump connected wirelessly with a continuous glucose monitor (CGM). The CGM continuously reads glucose levels through a sensor with a hair-thin wire inserted just below the skin, typically on the abdomen. The sensor would transmit those readings to the insulin pump, which delivers insulin through a small tube or patch on the body. The pump would house a sophisticated computer program that will address safety concerns during the day and night, by helping prevent hypoglycemia and extreme hyperglycemia. It would slow or stop insulin delivery if it detected blood sugar was going too low and would increase insulin delivery if blood sugar was too high. In this early version of an automated diabetes management system, the patient would still need to manually instruct the pump to deliver insulin at times, (i.e. around meals). However, this "hypoglycemia-hyperglycemia minimizer" system would represent a significant step forward in diabetes management, and could provide immediate benefits in terms of blood sugar control, by minimizing dangerous highs and lows.

Information on the first-generation system/pancreas from the Juvenile Diabetes Research Fund and the Animas Corporation:

<http://www.jdrftalk.org/category/research-updates/artificial-pancreas-project-research-updates/>

Additional News Links for April:

- [Diabetes Know Now!](#) (Business Wire)
- [Dietary Added Sugars Pose Heart Attack, Stroke and Diabetes Risk](#) (ABC News)

- [Revealed: How genetic mutations may cause diabetes 1](#) (Business Standard)
- [FDA Weighs Halting Avandia Safety Study](#) (Wall Street Journal)



Did You Know???

is

FASCINATING FACT

MALNUTRITION DIABETES

In addition to types 1 and 2 diabetes, there is also a poorly understood form of diabetes affecting millions of children and young adults in developing countries. Characteristics include:

- Malnutrition at diagnosis, and history of childhood malnutrition
- Poor health outcomes, susceptible to severe diabetic complications
- Most patients are prescribed insulin. Insulin is not a viable solution because of cost, perishability, and unavailability. Even when it

available, consistent food often is not, leading to many deaths from low blood sugar.

It is alarming how little is known about this prevalent and devastating condition. Discovering safe and accessible treatments, such as dietary supplements and oral agents, could have tremendous impact on health and survival for millions of affected patients.

Source: Global Diabetes Initiative, Albert Einstein College of Medicine
global.diabetes@einstein.yu.edu

UPCOMING EVENTS

Caucus Briefing on the Special Diabetes Program:

The Diabetes Caucus plans to host an informative briefing on the Special Diabetes Program on May 10, 2010. Created by Congress in 1997, the Special Diabetes Program is comprised of the Special Diabetes Program for Type 1 Diabetes Research and the Special Diabetes Program for Indians.

The Special Type 1 Research Program is administered by the National Institutes of Health, which has developed a collaborative, multidisciplinary approach to diabetes research that is focused on identifying the underlying genetic and environmental causes of the disease and working to prevent, treat and reverse diabetes and its complications.

The Special Diabetes Program for Indians is administered by the Indian Health Service and has funded more than 400 community-directed programs to implement proven diabetes prevention and treatment strategies in the American Indian and Alaskan Native population, which is disproportionately burdened by diabetes.

Please be on the lookout for a formal invitation to the briefing, during which we will learn more about the successes of these programs and the tremendous impact they are having on the lives of people with diabetes.

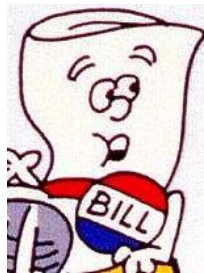
NIDDK Celebrates Its 60th Anniversary

The year 2010 marks the 60th Anniversary of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Diabetes Caucus would like to congratulate the NIDDK on six decades of medical advancement in the field of diabetes research, as well as research into other endocrine, metabolic, digestive, kidney, urologic and hematologic diseases.

In its 60 years, the NIDDK has contributed to the tremendous advances in diabetes research, including understanding and preventing diabetes, the treatment of diabetes, or the complications of diabetes. We encourage each member of the Diabetes Caucus to read about the impressive achievements in diabetes research over this time in *NIDDK: 60 Years of Advancing Research to Improve Health*, which can be found at <http://www2.niddk.nih.gov/AboutNIDDK/ReportsAndStrategicPlanning/SixtiethAnniversary/>.

The diabetes community will join with other medical research and patient advocacy organizations whose mission is aligned with the NIDDK to hold an upcoming Congressional Breakfast honoring the Institute and celebrating its decades of research achievements across its entire mission. The breakfast will take place on June 24, 2010 and will feature the NIDDK Director and key NIDDK researchers who have made significant contributions to the institute's mission to improve health for all people through medical research. For more information about the breakfast, please contact Heather Foster in Congresswoman DeGette's office at (202) 225-4431 or Olivia Kurtz in Congressman Castle's office at (202) 225-4165.

LEGISLATIVE PRIORITIES



H.R. 1995, *The Eliminating Disparities in Diabetes Prevention, Access and Care Act*. The Eliminating Disparities in Diabetes Prevention, Access and Care Act is designed to promote research, treatment, and education regarding diabetes in minority populations. This specific focus will help us address the unique challenges faced by minority populations and provide more effective treatment and education. The bill currently has 27 cosponsors.

H.R. 1625, the *Equity and Access for Podiatric Physicians Under Medicaid Act*. The bill would classify podiatrists as physicians for purposes of direct reimbursement through the Medicaid program. The Bill currently has 134 cosponsors.

H.R. 2425, the *Medicare Diabetes Self-Management Training Act of 2009*. 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. The bill currently has 38 cosponsors.

H.R. 2590, the ***Preventing Diabetes in Medicare Act of 2009***. 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. The bill currently has 11 cosponsors.

H.R. 3668, an amendment to the Public Health Service Act to ***Reauthorize the Special Diabetes Programs for Type I Diabetes and Indians***. This program provides federal funding for the Special Statutory Funding Program for Type 1 Diabetes Research at the National Institutes of Health and the Special Diabetes Program for Indians at the Indian Health Service. H.R. 3668 would extend these critical programs through 2016 and increase funding for both programs to \$200 million a year. This bill currently has 188 cosponsors.