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THE BATTLE AGAINST DIABETES: PROGRESS MADE; CHALLENGES UNMET

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

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THE BATTLE AGAINST DIABETES: PROGRESS MADE; CHALLENGES UNMET

THURSDAY, JULY 1, 2010

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:05 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. [Chairman of the Subcommittee] presiding.

Members present: Representatives Pallone, Dingell, Engel, Green, DeGette, Capps, Schakowsky, Baldwin, Barrow, Christensen, Castor, Space, Sutton, Waxman (ex officio), Shimkus, Whitfield, Burgess, Blackburn, and Gingrey.

Staff present: Karen Nelson, Deputy Committee Staff Director for Health; Sarah Despres, Counsel; Purvee Kempf, Counsel; Emily Gibbons, Professional Staff Member; Katie Campbell, Professional Staff Member; Stephen Cha, Professional Staff Member; Virgil Miller, Professional Staff Member; Anne Morris, Professional Staff Member; Alvin Banks, Special Assistant; Allison Corr, Special Assistant; Karen Lightfoot, Communications Director, Senior Policy Advisor; Lindsay Vidal, Special Assistant; Clay Alspach, Minority Counsel, Health; and Ryan Long, Minority Chief Counsel, Health.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. The meeting of the Health Subcommittee is called to order.

Today we are having a hearing on our collective battle against diabetes, the progress we have made so and the challenges that remain. Over 30 years ago, Congress passed the National Diabetes Research and Education Act, the first significant legislation directed at coordinating and expanding the government's research and prevention efforts related to diabetes. While we have made tremendous progress in understanding and treating diabetes, it remains a significant public health epidemic. It is staggering to realize that over 23 million Americans have some form of diabetes today, and the number is growing. Even more troubling is that 57 million Americans are at serious risk for developing type 2 diabetes including women with gestational diabetes.

Until recently, kids were rarely diagnosed with anything but Type 1 diabetes, and the increasing rate of childhood obesity is changing the face of diabetes though, and certainly not for the bet-

ter. And as we will hear today from our esteemed panels, diabetes is a leading cause of heart disease, stroke, blindness and kidney failure.

As is often the case, diabetes disproportionately affects racial and ethnic minorities. American Indians have the highest prevalence of diabetes, nearly four times those of white Americans, with Hispanics and African-Americans close behind.

Moreover, there is a clear economic cost. It has been estimated that over $220 billion in medical expenses in 2007 can be attributed to diabetes.

These are serious problems which need aggressive and innovative action. Today we are going to hear from two of our government witnesses from the National Institute of Diabetes and Digestive and Kidney Diseases, located at NIH, and the Centers for Disease Control. Both will speak to their agencies' roles in doing landmark research and surveillance work related to diabetes, and how this information has been translated into more effective prevention and treatment strategies, including the development of key therapies and technologies. I should add that NIDDK has recently celebrated its 60th anniversary conducting and supporting biomedical research to improve health care across the nation. NIDDK leads the Nation's federal commitment in research, education and health information dissemination with respect to diabetes, and supports investigators who continue to make strides in research toward understanding, preventing and treating type 1 diabetes, type 2 diabetes and gestational diabetes. It is for these reasons that the ranking member, Congressman Shimkus, and I recently introduced a resolution honoring the NIDDK for its outstanding work.

Now, on our second panel, comprised of leaders from the American Diabetes Association, the Juvenile Diabetes Research Foundation and National Indian Health Board, will also be able to shed light on the partnerships they have with government and in the community to maximize technology, translating to improved health outcomes. Lessons learned from innovative research such as that funded by the Special Diabetes Program, have informed our efforts to address the epidemic today and will continue to do in the future. I have to mention my home State and say that innovative, exciting and collaborative work on diabetes research is taking place across the country in public-private partnerships, and I am proud that New Jersey's life sciences industry continues to play a strong role in contributing to our ability to address the epidemic today and will do so in the future.

Before I turn it over to Mr. Shimkus—she is here. I wanted to mention that there were many members who asked for this hearing but the most persistent one was certainly the gentlewoman from Colorado, Ms. DeGette, but I know that many members have asked that we have this hearing today. Also, my Native American friends have been asking that we have this for some time because of the high incidence of diabetes in American Indian populations.

So with that, I will turn it over to Mr. Shimkus.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. Thank you, Mr. Chairman. I do want to recognize Diana DeGette, also, Ed Whitfield and Freddy Upton and Zach Space, and Diana is a rabid supporter and well known for her hard and diligent work, so there is a story we tell only to ourselves about our first term when we sat together way up front and they moved us, so—they moved me.

Let me just welcome folks here, and as a member of the very large Diabetes Caucus and the work from all the whole community to help educate us, to educate, really, children and parents and that whole plethora, it is a success story. Obviously we would like to have the final success which would be, you know, cure and that is the research and that is the disease management and that is what we should be focusing on.

We will continue to express concerns about spending and the debt because budgetarily it will affect our ability to get money for research and development. If we continue to spend more and more money on interest on the debt, then the discretionary money and the accounts that we have to do NIH, do CDC, to do all the things that we need to do gets limited. In fact, USA Today in their article the federal debt will represent 62 percent of the Nation's economy by the end of this year, the highest percentage since just after World War II, and that is according to the CBO.

So when we raise issues about the new health care law, when we raise issues about spending and dollars, we are putting ourselves in a bad position to really focus on the things we want to do and set priorities interest payments will start consuming that. So as we make those cases, we do that with the best intention.

This hearing is a result of a letter that was sent by Diana and her colleagues. We have sent other letters on the law that we hope will be well received too, whether it is the CMS actuary or of concern now are high-risk pools which were promised in the new health care law which some States can't fully fund and operate or the States that have turned it over to the federal government because they are not going to manage it themselves, we have no idea what we are going to do, and those are promises we made as a Nation with the passage of the law and the signing by the President. So we have to figure out how we can keep our promises.

So I have a lot more I would want to say but I know time is short, and I will yield back my time and thank the chairman for letting me use his big chair.

Mr. PALLONE. Thank you, Mr. Shimkus.

Next is the gentlewoman from Colorado, Ms. DeGette.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you so much, Mr. Chairman, and thanks to Mr. Shimkus for his I think allegedly kind words.

I really want to thank Mr. Space and Mr. Whitfield and Mr. Upton for requesting this hearing with me, and I also want to thank Mr. Green and all the rest of the members of this committee because we all share a collective commitment to addressing the

issues of diabetes. The 250-member Congressional Diabetes Caucus is the largest caucus in Congress, and we strive hard to keep it that way. The reason is because diabetes is the fastest growing epidemic in this country and it affects everybody, young and old. Twenty-four million people have diabetes in this country. Fifty-seven million people, which is a quarter of all American adults, have pre-diabetes. So one of our tasks as well as giving quality care and management to the people who already have one of the various forms of diabetes is to try to get these other people back from the brink, and this is something that is difficult because most of those people don't even know that they are pre-diabetic.

Have we made progress? Yes, we have made some. We know that effective patient self-management of an individual's own diabetes is arguably the most crucial part of an overall care regimen and there is now a substantial body of evidence that diabetes self-management training is effective but only if the patient has access to it. We also know that medical nutrition therapy can have a significant impact on preventing pre-diabetes from becoming full-blown diabetes.

One issue that I have been increasingly concerned about and I have talked to a lot of folks about this is access to technology because as the mother of a 16-year-old with type 1 diabetes, I see the wonderful care advances that she has access to but these advances are very, very expensive. She now has a continuous glucose monitor, and the sensors that she puts in once or twice a week each cost $80 before insurance. So I say to myself and the members of the Diabetes Caucus, how can we make those wonderful advances in care and technology available to every diabetic, not just those who are fortunate enough to have parents with good health care coverage. We also know that disparities in minority populations are too prevalent but we haven't done enough research to figure out how to mitigate the disparities in prevention, access and treatment for these populations.

So we have made progress but when the incidence of diabetes in the United States continues to rise unabated, it is clear that diabetes has become as described in this week's Lancet a public health humiliation for our Nation. The Diabetes Caucus is unwaveringly committed to tackle these challenges that are still unmet and to remove this humiliation. We will continue to press forward on all of the priorities including making our hard-fought efforts to include certified diabetes educators as Medicare providers, to classify podiatrists as physicians under Medicaid, and many, many other priorities. The caucus is going to host a briefing on July 12th to address the growing epidemic of pre-diabetes so we can start thinking about ways to pull those 57 million people back from the brink.

For pre-diabetes, type 1 diabetes to type 2, to gestational diabetes and even malnutrition diabetes, this condition comes at us in different forms but the urgency mandates that we continue to work tirelessly to tackle the issue, and Mr. Shimkus is right. It is a health issue and also a cost issue because if we don't start putting the research into this issue now, it is going to overwhelm our health care system, as my two young girls become adults.

So I want to thank the witnesses on both panels for coming today. This testimony really helps us set our course as we move

forward the rest of this year and into the next year to set our policy as a caucus but also as a Health Subcommittee, and with that, I yield back.

Mr. PALLONE. Thank you.

Ms. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Mr. Chairman, I do thank you for calling the hearing, and I want to welcome Mr. Buford Rolin, who is chairman of the Poarch Band of Creek Indians and the national area representative for the National Indian Health Board and say a special welcome to him for coming in today and to all of our witnesses. We thank you for coming in today and to all of our witnesses, we thank you for attending, we thank you for the preparation that you put into the hearings as you come to us.

Diabetes presents serious financial burdens and cost patients in Tennessee more than $3 billion in 2007. I had the pleasure of meeting the Gould family from Middle, Tennessee, last year during the JDRF fly-in. Four of eight children in their family suffer from type 1 diabetes. It is impossible to imagine the financial and emotional toll that this disease takes on each and every day for that family. With the sixth highest rate of diabetes in the Nation, this is a very important issue to our State of Tennessee.

According to the JDRF, over 10 percent of Tennessee's population is diabetic. In an annual obesity report released Monday by the Robert Wood Johnson Foundation, Tennessee was ranked the second most obese State in the country. A direct link between diabetes and obesity exists. We all are aware of that, and it appears that Tennessee is on their way to a diabetes epidemic. Due to the prevalence of this disease, the research, treatment and prevention efforts are a significant focus for our Tennessee medical researchers. In fiscal year 2009, NIH—and we thank you—granted over $17 million for research in Tennessee. The American Diabetes Association has eight active research grants in the State. Most are focused on type 2 diabetes. Vanderbilt University Medical Center's Eskin Diabetes Clinic is in the midst of 10 clinical trials to develop treatments and learn more about the disease. And finally in my district, we have two wonderful JDRF chapters. They are working actively to support those with type 1 diabetes and the organization who has given more than, get this, $55 million to Tennessee researchers. They are doing great work.

So for all of our agencies that are in the room, we thank you for the working that you are putting in, and these volunteers with associations are doing an incredible job in our State. So I join my colleagues in saying this is an area we want to heighten awareness. We want to be more proficient in our education efforts and we hope that we provide the proper support for the researchers who are trying to find a cure, a treatment and disease management programs for this disease.

I thank you, and I yield back.

Mr. PALLONE. Thank you, Ms. Blackburn. I am told we are OK now with the mics, so we will see.

Next is our chairman, Mr. Waxman.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Chairman Pallone, for convening today's hearing.

The term "diabetes" describes a host of related health conditions that are familiar to us, and the facts are staggering. More than 20 million Americans have diabetes, almost 60 million more at risk for diabetes, the leading cause of blindness and kidney failure. People with diabetes are at least twice as likely to die of heart disease or have a stroke, and diabetes is the seventh leading cause of death. It affects all age groups, both sexes and every race and ethnicity. However, older Americans and certain racial and ethnic groups are several times more likely to have diabetes than others. That is why I am glad that we are taking the opportunity to learn about landmark research accomplishments, ongoing efforts to translate what we know works into practice and research questions we have yet to answer.

Research has shown genetic causes, effective prevention for type 2 diabetes and ways to delay and prevent complications. NIDDK, CDC and other agencies within the Department are working to ensure that our government has a coordinated effort to advance diabetes research and improve the health of those affected by this condition.

Still, there is work to be done. We must continue our efforts to prevent women with gestational diabetes from developing type 2 diabetes later in life. We are not yet able to prevent type 2 diabetes nor have we perfected the link between the continuous monitoring of blood glucose and the administration of insulin, the so-called artificial pancreas. And just this week, two new studies on the drug Avandia underscore the need to better understand and better treat type 2 diabetes.

Underpinning all of this is the importance of a broad public health approach to this disease. We need sustained investments in research. We need people who have information to be emphasizing the point that diabetes is 24 hours, 7 days a week. That is why we support what health providers, families, and what is going on workplaces to maximize each person's health and well-being.

I want to thank the witnesses for appearing before us today and I look forward to hearing their testimony. With that, Mr. Chairman, I yield back my time.

Mr. PALLONE. Thank you, Chairman Waxman.

Next is the gentleman from Georgia, Mr. Gingrey.

OPENING STATEMENT OF HON. PHIL GINGREY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. GINGREY. Thank you, Mr. Chairman.

The World Health Organization has found that more than 150 million people suffer from diabetes and it is estimated that this number will actually double by the year 2025. For at least the last 20 years, diabetes rates in North America have been increasing substantially with about 18.2 million Americans living with the

disease in 2002. Of those, roughly 90 percent have type 2 diabetes, which costs the United States as much as $132 billion a year. These statistics are a stark reminder of the impact the disease has on our Nation but also reminds us that the onset of diabetes for some Americans can be prevented.

A majority of the patients with type 2 diabetes are obese, the connection being that chronic obesity leads to increased insulin resistance that can then develop into diabetes. Obesity in many forms is a gateway from which diabetes, heart disease and other chronic conditions can strike American patients. Therefore, as we look at the federal response to diabetes, I would suggest that we also consider the root cause of obesity, reassessing the food stamp program so that healthy foods are encouraged, ensuring access to local parks and recreational programs and promoting employer wellness programs, all the things that the federal government can and should do to encourage healthy lifestyles.

We should also ensure that Americans with chronic diseases have access to quality health care. Unfortunately, President Obama's health care reform bill will make it hard for many Americans with chronic diseases to find care when in need. As many of you know, the preexisting condition insurance plan passed as part of President Obama's health care bill, Patient Protection Affordable Care Act of 2010, will begin accepting applications in many States today. However, according to an AP article that ran just yesterday, and I quote, "Premiums will be a stretch for many and the $5 billion that Congress allocated to the program through 2013 could run out well before that." The Congressional Budget Office in a report released last week supported this finding when stating that the program's funding will not be sufficient to cover the cost of all applicants.

Mr. Chairman, Ranking Member Shimkus has repeatedly called for hearings on the new health care law because it is deeply flawed and certainly can and I think will hurt our country. Since the day the bill was enacted, we have been reminded how this bill fails everyday Americans, companies filing billion-lawsuits with the SEC, the Department of Labor reporting that half of all workers will actually lose the health plan that they have today, and many Americans with chronic illnesses will be offered health insurance that they just simply cannot afford. Mr. Chairman, I would urge this committee to act and hold hearings on the problems in the bill, President Obama's health care law.

That being said, however, Mr. Chairman, I really do want to single out and commend Congresswoman DeGette for her efforts in addressing the incidence of diabetes in this country. She represents and is I think chairperson of the largest caucus in Congress today with over 250 members. Her leadership in this area is laudable and worthy of recognition by this committee and by myself, a practicing physician before I got this job.

And with that, Mr. Chairman, I yield back.

Mr. PALLONE. Thank you, Mr. Gingrey.

Next is our chairman emeritus, Mr. Dingell.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, I thank you for your courtesy and I commend you for this hearing.

First, I wish to recognize the many members of this committee who have continued to beat the drum on this disease, and I thank them for their leadership.

It is safe to say that we have a diabetes epidemic on our hands. More than 24 million Americans are afflicted with the disease. That is more than twice the number of people with diabetes in 1997. In my home State of Michigan, more than 680,000 people, 8.6 percent of our population, struggle with the disease daily. In addition to the major health complications caused by diabetes, the economic toll of the disease is considerable. Diabetes costs the U.S. economy $174 billion every year. One-third of every Medicare dollar is spent on people with diseases and already stretched State Medicaid programs are confronted with the growing costs of diabetes care.

Since the passage of the National Diabetes Research and Education Act in 1974, the federal government has worked to coordinate diabetes activities amongst the various responsible agencies. Most notably, the work of the Centers for Disease Control and Prevention and the National Institutes of Health have tossed a tremendous amount on the causes of this disease and ways to control and prevent it. Because of our surveillance, education and treatment activities, individuals today with diabetes live longer and healthier lives than people were diagnosed with the condition in prior decades. However, the rate of new cases of diabetes continues to increase. As a result, the gains in control and treatment are being overtaken and submerged by the increase in the number of people acquiring the condition.

The recently enacted health reform law will address the many abuses employed by insurance companies to discriminate against those with diabetes, and I am extremely proud of that fact. Additionally, the new law provides access to the necessary tools to manage and prevent diabetes and its complications including the creation of a National Diabetes Prevention Program, a national report card on diabetes to be updated every 2 years, and State grants to provide healthy lifestyle incentives for Medicare beneficiaries. Now, these steps will go a long way in our fight against diabetes but more can and should be done. We must ensure our approach is consistent with current science and with understanding the disease. Our approach needs to be comprehensive and it must ensure that all we do and that we do all we can to prevent the onset of the disease to ensure the diagnosis of the disease is conducted in the most efficient and accurate manner, and to ensure that our people have the best methods available to control the disease and ensure that diabetics have the best treatment and medications available to prevent complications. These efforts we make in defeating diabetes will have an enormous impact on the health of our Nation.

Thank you again, Mr. Chairman. I yield back the balance of my time.

Mr. PALLONE. Thank you, Chairman Dingell.

Let me now—they just called three suspension votes but I would like to take one more speaker and then we will recess and come back, which should be about half an hour or so. And next on my list is the gentleman from Kentucky, Mr. Whitfield.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Thank you very much, and I certainly want to thank the witnesses for being here today. We appreciate very much the commitment that you have made to help us find a cure for this disease and to reduce the number of people that unfortunately have it, and I also hope that those in the audience are not disillusioned that Republicans and Democrats are so joined together on this issue.

I do want to thank Diana DeGette and Henry Waxman and Frank Pallone as well as John Shimkus, Joe Barton, Fred Upton, Zach Space and all of those who are involved and interested in this issue.

Two months ago, I was down in my district and I met with the parents and six teenagers who all had diabetes, and we frequently, those of us who are layman, think that what you eat and your weight is the determining factor of whether or not you have diabetes but when you talk to these young teenagers, all of whom are very thin, very energetic, all of them have diabetes, and then you realize what they go through every single day with the testing that they do, with the monitoring that they do, watching the foods that they eat, the emergency runs to the hospital they make and the impact it is going to have on their entire life, it does bring home very clearly the impact that this disease has. Other speakers have talked about the statistics and the costs and the impact on the number of people in our country, and so I think this hearing is very important. I certainly want to thank Diana DeGette for sort of leading the charge. I know that all of our physicians on this panel, Dr. Gingrey and our friend from Texas, Dr. Burgess, have particular interest as well.

So we look forward to your testimony to help guide us as we move forward, and I also want to point out that while the federal government is spending a lot of money on research, we also have some private companies that are spending a lot of money on research, and one that I would like to particularly mention is Novo Nordisk, which happens to be a company in Denmark but they have 4,000 employees in the United States, and the U.S. federal government is the only entity that is spending more money on research on diabetes than is Novo Nordisk, so I want to thank them and their leadership team for their commitment to this disease as well

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Whitfield.

We have time for one more before we break, so I am going to ask our vice chair, Ms. Capps, to do an opening statement.

OPENING STATEMENT OF HON. LOIS CAPPS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mrs. CAPPS. Thank you, Chairman Pallone, for holding this hearing, and it gives me an opportunity to thank my suitemate here, my colleague, Diana DeGette, as well, for bringing us all together around this issue, and on behalf of the entire diabetes community because as I was just mentioning to her, this is a very well-organized group with juvenile diabetes and make visits to their Members of Congress regularly, and I want to applaud them for doing that.

It really has an impact on us. I look forward to an update today from our esteemed witnesses on the progress of diabetes research. After all, despite all the promising discoveries over the past several decades, there still is no cure, no surefire way to prevent the development of diabetes, especially type 1. As many of my colleagues know, I was a school nurse for many years, and if there is one disease that is sure to make a student a frequent visitor into the nurse's office at school is diabetes, so I certainly became very familiar with the maintenance of type 1 diabetes and I have been hopeful that by now we would have something in place but there are many promising things on the horizon which is exciting to know about or what we are going to learn today.

The sad truth, however, as my colleagues have indicated, is that children don't suffer today just from type 1 diabetes. There is such an increase now in the incidence of type 2 diabetes. I know there are definite steps to prevent the onset of type 2 we can take in our communities such as increased physical activity and better nutrition but we need also to be creative in how we get the message out to at-risk populations, especially minority ones, and design programs targeted for those populations. I think particularly of programs in my district such as St. John's Latino Health Diabetes League, an initiative in Oxnard, California, which is tailored educational programming to at-risk communities. But they can only do this with the right type of evidence-based research being conducted at the institutions represented here today.

So I am especially curious today to learn more about how you are working to equip our local communities with the tools that they need to address diabetes prevention and management. I look forward to hearing from our witnesses about the exciting work you are doing now and how Congress can better work with you and help you achieve our shared goal of finding a cure.

I yield back.

Mr. PALLONE. Thank you, Ms. Capps.

So we will now take a recess for the three votes. The committee stands in recess.

[Recess.]

Mr. PALLONE. The committee hearing will reconvene, and we will begin with the gentleman from Texas, Mr. Burgess.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Well, I thank the chairman for yielding.

The hearing this morning focuses on an important public health issue, obviously a significant impact on our Nation and a crippling

effect on our budgets, and we have already heard statistics from a number of members this morning so I won't repeat those, only to mention that in my home State of Texas over 1–1/2 million people over the age of 18 have diabetes, and in our State, it is the sixth leading cause of death.

Two bills which I would like this committee to consider to move expeditiously and mark up, of course, we have already heard about H.R. 3668, Representative DeGette, would reauthorize the special diabetes programs for type 1 diabetes. This program was started back in the 1990s under the guidance of then-Speaker Newt Gingrich, and he continues, as do I, to support the innovative work of this program. In fact, there have been some rather dramatic things that have come out of this program including auto transplantation of beta cells from people who have had a dramatic disruption of the pancreas.

Now, I also have a bill with Eliot Engel, the Gestational Diabetes Act of 2009. Having practiced as an OB/GYN for over 25 years, I am clearly well aware of the problems of untreated gestational diabetes affecting over 200,000 pregnancies a year, over 7 percent of the pregnancies in this country, and they can have significant impact on both the mother and child because they are at significant risk of developing type 2 diabetes, and mothers are almost three times more likely to have a recurrence of gestational diabetes in future pregnancies. As with other diabetes trends, the rates of gestational diabetes are higher among women of African American, Hispanic, Asian and Native American descent. H.R. 5354 creates a research advisory committee headed by the CDC to expand monitoring including coordinating efforts to help mothers avoid contracting type 2 diabetes.

So I would urge members of the committee to cosponsor this legislation. It does just so happen that I have a signup sheet for anyone interested in cosponsoring this bill, and I Mr. Engel and I would be happy to take that to the floor to save you the trouble.

While we hear about the increase of obesity in the United States that has raised the prevalence of diabetes generally, we also need to hear about the impact of genetics, ethnicity and maternal age, particularly in the case of gestational diabetes, and focus our research on how diabetes cost can be reduced through better lifestyle choices. With the correlation between obesity and lower income levels and diabetes, this committee really needs to stress being involved in encouraging proper nutritional choices for our populations that we serve under Medicare, which is under our jurisdiction.

So I thank you, Mr. Chairman. I will unbelievably yield back the balance of my time.

Mr. PALLONE. I am supposed to take notice, I guess, right? All right. Thank you.

Next is the gentlewoman from the Virgin Islands, Ms. Christensen.

OPENING STATEMENT OF HON. DONNA M. CHRISTENSEN, A REPRESENTATIVE IN CONGRESS FROM THE VIRGIN ISLANDS

Mrs. CHRISTENSEN. Thank you, Mr. Chairman, and Ranking Member Stupak for holding this hearing today to discuss the yet

unmet challenges facing us regarding diabetes, and thank you also to Diana DeGette for her leadership on this issue.

I would like to welcome our witnesses today on both panels and recognize in addition the 60th anniversary of the National Institute of Diabetes and Digestive and Kidney Disease and wish you many more years of leadership and conducting and supporting biomedical research.

I too also want to thank Novo Nordisk for their work on diabetes both in the lab and in communities like mine, which has a prevalence of diabetes that is far higher than the national average.

Diabetes is a disease that strikes at every age level and every racial and ethnic group in America, and while it does still disproportionately affect the elderly, the fact remains that its prevalence is growing among all groups. In addition to the nearly 24 million people currently living with diabetes, there are 57 million estimated to have pre-diabetes, putting them at increased risk for developing diabetes and complications therefrom. Particularly disturbing to me is the increase in type 2 diabetes in children and the racial and ethnic differences in prevalence of diagnosed diabetes. When nearly 12 percent of non-Hispanic blacks, more than 10 percent of Hispanics and an unacceptable 16.5 percent of Native Americans and Alaska Natives have been diagnosed with diabetes compared to 6.6 percent in non-Hispanic whites and 7.5 percent in Asian Americans, it is undeniable that aggressive action must be taken to address these disparities. It is also alarming that the prevalence of a disease which 100 years ago was unknown to them affects now Native Americans and Alaska Natives at a rate that is more than twice that of their white counterparts.

It is because of these disturbing facts that I am especially pleased to see that Mr. Buford Rolin is present from the National Indian Health Board. Although the diversity that exists among Native Americans, Alaska Native populations must be recognized. Your presence here is certainly a step in the right direction, and giving these populations a voice on this issue and ensuring that the diversity that exists on every American health issue is not overlooked or forgotten.

It has been over 35 years since the Interagency Committee to Coordinate Diabetes was set up at HHS, and while advances have been made, in that time diabetes has exploded, especially in the South, and racial and ethnic minorities and type 2 in children, so I look forward to exploring today what is going to change forward so we can reverse this really terrible trend that we are seeing in our country.

Mr. GINGREY. Will the gentlelady yield to me before she yields back just for a friendly purpose?

Mrs. CHRISTENSEN. Certainly.

Mr. GINGREY. I thank the gentlewoman.

Earlier a member on our side of the aisle recognized a couple of physicians on the committee and on the subcommittee, and he failed to mention Dr. Christensen, who has come to this Congress from the Virgin Islands, having practiced family medicine there for many years, and she knows of what she speaks, so I just wanted to recognize that fact.

Mrs. CHRISTENSEN. Thank you for that. I yield back. Thanks.

Mr. PALLONE. I thank the gentlewoman.

Next is the gentleman from Ohio, Mr. Space.

Mr. SPACE. Mr. Chairman, I will enter my opening statement into the record on the condition that I will be allotted time for my questioning.

Mr. PALLONE. Absolutely. That is how we work.

Mr. SPACE. I would like to thank you, however, for calling this very important hearing, and my gratitude should also go out to Diana DeGette for her leadership and to Ed Whitfield and Fred Upton for joining me in the request for this hearing.

[The prepared statement of Mr. Space follows:]

OPENING STATEMENT: "THE BATTLE AGAINST DIABETES: PROGRESS MADE, CHALLENGES UNMET"

July 1, 2010

Thank you, Mr. Chairman, for holding this hearing. I am most grateful for your attention to an issue so important to me.

I want to thank Rep. DeGette, the co-chair of the Diabetes Caucus, and Reps. Upton and Whitfield for joining me in requesting this hearing. It is refreshing to see bipartisan attention to an issue that so strongly affects our nation.

During the 111th Congress, this Committee has taken on a number of critical issues. Energy, health care, food safety, chemical security – the list goes on and on.

Yet, I have not looked forward to a hearing with such anticipation and such excitement as I have this one.

That is because diabetes – just one, simple disease – is rapidly becoming one of the biggest threats to our nation's health care system and, more importantly, our nation's health.

We have all seen the statistics –

- 26 million Americans have diabetes, a number that is certain to continue to skyrocket
- As the ADA points out in its testimony, diabetes is costing our nation $218 billion/year in health care costs and lost productivity.
- Most astounding – that number boils down to more than half a billion dollars per day.

But let's stop for a second and put that in perspective – this week the House is scheduled to vote on dedicating $33 billion to the wars in Afghanistan and Iraq.

In 2009 total, we spent $148.2 billion on the two wars (according to CRS).

Look at the differential! $218 billion to fight one disease, $148 billion to fight two wars.

These figures are war-like. We are at war with diabetes.

Today, this Subcommittee will have the opportunity to learn about how we – the United States Congress and the Federal Government – are addressing this ever-growing crisis.

Advances in medical technology and our understanding of diabetes have radically improved the quality and length of life for people it afflicts.

A prime example of such advances would be an insulin pump. The pump has helped countless Americans suffering from diabetes take control of their own lives by providing a more precise mechanism to track insulin intake, as well as a convenient medium to do so.

Innovations like the pump have helped to grow the expected life span of those afflicted with diabetes, as scientific research continues to provide progressively more detailed information about how diabetes affects the body.

But I fear that success will breed complacency. While these advances are certainly cause for cheer, they are not cause for an end in our pursuit for a better life for every American with diabetes.

As a moderate Congressman who seeks to find the center on the issues we tackle, I am well versed in the practice of pragmatism.

Yet, on the issue of medical research, I believe that we cannot fear to dream. We cannot afford to be bound by the restraints of the pessimists – we must strive to achieve that which seems unachievable.

We must work to find a cure.

Imagine a world where anyone afflicted with diabetes can be treated and cured. A world where the issue is not how best to manage the disease, but how quickly it can be expelled from the body.

I believe that we can achieve this goal, with the commitment of this body.

Congress must also begin thinking about diabetes in a comprehensive fashion. While I commend the work of many of my colleagues in advancing critical bills that make a difference in the lives of diabetics every day, how long has it been since we examined the full scope of how we treat diabetes?

From public health initiatives of the public, prevention, early diagnosis to treatments, there are many questions to ask.

As many of you know, this battle is a personal one for me. My son Nick was diagnosed with Type 1 diabetes (or juvenile diabetes) just over a decade ago.

Any parent who has received the news of their child's illness understands what I felt the day he received his diagnosis – panic, fear, and hopelessness.

Nick has been the beneficiary of innovations like an insulin pump that help him to track his disease more carefully than he could have 50 years ago.

However, my family still worries for his future. Even with all the advances we have now, Nick still faces an uncertain road, as do the tens of thousands of type 1 diabetics across the country.

In closing, I'd like to again offer my thanks to Chairman Pallone for hosting this hearing. I yield back the balance of my time.

Mr. PALLONE. OK. Next is the gentlewoman from Ohio, Ms. Sutton.

OPENING STATEMENT OF HON. BETTY SUTTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Ms. SUTTON. Thank you, Mr. Chairman, and I too appreciate you holding this hearing today. This is an incredibly important to have. I, like so many members of the subcommittee, care deeply about diabetes and I am a member of Ms. DeGette's Congressional Diabetes Caucus, and I thank her very much for her tremendous leadership.

Yesterday a young woman from northeast Ohio, Selena Williams, came into my office. Selena is a 15-year-old and was diagnosed 2 years ago with type 2 diabetes. As you can imagine, and as some of you in this room have experienced personally, this was an incredibly scary time for Selena and her parents. She was very lucky to be able to participate in a treatment program at Rainbow Babies and Children's Hospital, which is home to a center for excellent for childhood diabetes, activity and nutrition, and through Rainbow Babies Selena and her family joined a program called the TODAY program, which stands for Treatment Options for Type 2 Diabetes in Adolescents and Youth. The TODAY program's goal is to study the best ways to treat type 2 diabetes in children, and in the TODAY program Selena and her family learned the basic skills that she would need as a diabetic—how to test her blood on a home meter, give insulin shots and manage high and low blood sugars. And she also learned through home visits with a certified diabetes nurse how to make lifestyle changes to help her and her entire family be healthier such as how to read food labels, manage portions and stay active. And through the TODAY program, Selena has improved her health and she recently did something that she said she never thought she would do. She tried out for the freshman basketball team, and I am proud to report that she made it. Sadly, there are millions of children like Selena but not all children have the same treatment opportunities or educational programs that Selena has had but all of those children have great potential, and the fact that they don't have that opportunity is heartbreaking.

So I look forward to hearing about the progress that has been made in the battle against diabetes and about the work that still needs to be done and what we can do to help.

Thank you, and I yield back.

Mr. PALLONE. Thank you.

Next is the gentlewoman from Illinois, Ms. Schakowsky.

OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

You know, if for no other reason, we should as policymakers and as taxpayers pay very close attention to diabetes. According to a Mathematica report by Drs. Marsha Gold and Ronette Briefel, diabetes costs the government, just the government cost, $80 billion a year in medical costs. That is Medicare and Medicaid, and I am sure veterans health care, etc. The CDC's testimony reports that national costs for 2007 exceeded $218 billion. That includes private

insurance. So if we were to really target diabetes in terms of research, in terms of the kinds of public education programs that Congresswoman Sutton talked about in controlling this disease, we would also be able to save billions of dollars and change lives forever.

Diabetes is really a very cruel disease that affects 23.6 million Americans. It is cruel to young children who have to draw blood every day, monitor their sugar and their diet, which is a good thing for all children but in the ways that diabetic children have to do, it is really difficult, and to millions of adults who develop diabetes later in life particularly for type 2 where there really are lifestyle kinds of changes that can be made. We need to invest in public health programs, and for all the rest of diabetes type 1 and also type 2, we need to invest in research.

So I want to thank Congresswoman DeGette, who has been a champion throughout her career here and even earlier on addressing this important disease, important in so many ways, and a disease that we can in so many ways effectively address. So let us do it. I yield back.

Mr. PALLONE. Thank you.

And next is the gentlewoman from Wisconsin, Ms. Baldwin.

OPENING STATEMENT OF HON. TAMMY BALDWIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WISCONSIN

Ms. BALDWIN. Thank you, Mr. Chairman and Ranking Member Shimkus for calling this hearing today, and I too want to echo my colleagues' comments of gratitude for the leadership of my friend Diana DeGette on this issue.

I also want to welcome all the witnesses that we have today. We are very much looking forward to hearing your testimony.

Diabetes clearly has a sweeping impact on our society, and in that vein I would like to share the story today of a very brave family making a tremendous difference in my district and across the State of Wisconsin. The Wickmans are just like many other American families. They love the outdoors, they love to take road trips on weekends, and they would do anything for their children. Yet this family has really been ravaged by diabetes. Grandpa Rick has type 2 diabetes and just had to have his foot amputated recently. Their daughter, Stella, just 4 years old, has type 1 diabetes and has to have her finger pricked dozens of times each day to make sure that her blood sugar level is at a safe level. This disease infiltrates every waking moment of their lives. You know, the Wickmans discovered that Stella was sick on a family trip to the upper peninsula of Michigan after a midnight ambulance ride and an admission to a pediatric ICU. Since that day they really could have sat back and bemoaned their fate but instead they have really thrown themselves into helping Stella and the many children like her across the country by championing the Juvenile Diabetes Research Foundation of Western Wisconsin. They also carry the torch of another Wisconsin hero, Jesse Alswager. Jesse traveled extensively in his young life educating others about diabetes. He even testified before a panel here in Congress in support of stem cell re-

search. Jesse died due to complications of juvenile diabetes in February of this year at age 13 but his legacy clearly lives on.

In my hometown at the University of Wisconsin, the progress towards better treatment is real. An FDA-approved clinical trial is currently underway for the use of adult stem cells in the treatment of type 1 diabetes. This study is cosponsored jointly by Osiris Therapeutics and the Juvenile Diabetes Research Foundation. Researchers are specifically targeting newly diagnosed type 1 diabetes patients who still have some functioning beta cells left. An infusion of targeted stem cell therapy could stop the immune destruction and preserve individuals' remaining ability to make insulin.

Perhaps the most exciting news for both the Wickmans and researchers in the district that I represent is the passage of the comprehensive health care reform legislation earlier this year. This year, the bill bans insurers from citing preexisting conditions as a reason to refuse to insure children in America and to ensure that a child like Stella will never be without health care coverage, and this year that piece of legislation invests $126 million through the new prevention and public health fund to help create the necessary infrastructure to prevent, detect and manage chronic diseases like diabetes. Clearly, much work remains to be done.

So as we work to implement this legislation, we must remember the toll that diabetes takes on our families and on our health care system but we must also work to improve and expand existing federal programs that are making a difference today, and I am glad that our witnesses are here to help inform that process.

Thank you, Mr. Chairman, and thank you again to our witnesses.

Mr. PALLONE. Thank you, and I think that concludes our members' opening statements. We will now move to our witnesses. Let me introduce, well, first welcome you both and introduce the two of you. On my left is Dr. Judith Fradkin, who is director of the Division of Diabetes, Endocrinology and Metabolic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health. Fradkin—did I pronounce that properly? OK. And then is Ann Albright, who is director of the Division of Diabetes Translation of the Centers for Disease Control and Prevention, and thank you both for being here. I think you know the drill, 5-minute speeches, and then if you want to submit additional written comments, you can, and I will start with Dr. Albright.

STATEMENTS OF ANN ALBRIGHT, PH.D., R.D., DIRECTOR, DIVISION OF DIABETES TRANSLATION, CENTERS FOR DISEASE CONTROL AND PREVENTION; AND JUDITH FRADKIN, M.D., DIRECTOR, DIVISION OF DIABETES, ENDOCRINOLOGY AND METABOLIC DISEASES, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, NATIONAL INSTITUTES OF HEALTH

STATEMENT OF ANN ALBRIGHT

Ms. ALBRIGHT. Mr. Chairman, Mr. Shimkus and distinguished members of the subcommittee, thank you for the opportunity to participate in the hearing. I am Dr. Ann Albright. I am the director

of the diabetes division at CDC. I am trained as an exercise scientist and nutritionist but I also live with type 1 diabetes for 42 years.

The diabetes division at CDC translates the science of diabetes into practical strategies to control and prevent diabetes in the U.S. population and I will be describing some of our work in surveillance to define and monitor diabetes, the reduction of the risk factors, the prevention of type 2 diabetes, and management of this disease.

The ability to identify the magnitude of a problem through ongoing surveillance is a foundation of CDC's work. CDC developed and maintains the National Diabetes Surveillance System. It is the world's first system for monitoring diabetes. It relies on national and State-based household telephone and hospital-based surveys, vital statistics to monitor trends in diabetes. In the last 2 years, CDC has developed a methodology to estimate levels of diabetes and obesity at the county level, providing policymakers and communities with new information to guide programming and resource allocation.

CDC in collaboration with NIH has also initiated the largest major surveillance system to quantify and track type 1 and type 2 diabetes in those under 20 years of ago called Search for Diabetes in Youth. Among other things, Search allows us to clarify the degree to which type 2 diabetes is affecting youth of different racial and ethnic backgrounds.

Findings from our national surveillance system document several increases or successes in the public health response to diabetes over the past decade but have also revealed areas of major concern and continuing threats to the public's health. Rates of blood glucose being out of control, amputations and end-stage renal disease among adults have declined. However, considerable variation and disparities in diabetes care and outcomes remain.

CDC does work to impact and improve outcomes for women with and at risk for gestational diabetes. In collaboration with the National Association of Chronic Disease Directors and the Agency for Health Care Research and Quality, we have established a five-State collaboration to identify, catalog and validate routinely collected data about gestational diabetes, identify gaps and documenting prevalence and determine implications for care.

Our greatest concern, though, is the continued increase in the rate of new cases of diabetes. This is evident in virtually all segments of society. This continued increase in the rate of development of new cases is unfortunately negating many of the successes that clinical and public health efforts have achieved in reducing the rates of complications. The continued increase in diabetes incidence calls for a comprehensive implementation of a diabetes prevention strategy.

So CDC is engaged in risk-reduction efforts on multiple levels including focus on obesity for the general population but the diabetes division focuses on those at highest risk for diabetes, so there are very complementary efforts, and in fact we have focused much of our work in the Native American community, helping many members achieve vouchers for nutritious foods, particularly fruits and vegetables, and the use of those vouchers have been in excess of

50 percent, so a very tangible, concrete example of a way to reduce those risk factors.

Based on the findings of the NIH-led diabetes prevention program clinical trial, CDC is now actually translating those findings into practice. We are able to do this with our partners. At the top of the leading role is the YMCA of USA and United Health Group, and we are able to offer this for about $250 to $300 a person. This is the first time ever that a private health insurer has joined forces with a national community-based organization not deliver this work, and we are focusing on training the workforce, on recognizing those programs for quality assurance, for actually investing in delivery of the programs, and for health marketing so people know where to go and how to get those programs.

We are also preventing complications of diabetes, and we have research trials that we have been doing, the Triad study. We are taking those findings and we are working with our State-based diabetes prevention and control programs to actually put those into practice and change what health care systems are actually delivering as a result of that study.

I want to just close with two new projects that we have going on that are exciting, and one is the national program to eliminate diabetes-related disparities in vulnerable populations. We will now be funding six organizations that will focus on reducing the mortality and premature mortality and morbidity, and we will be helping this by helping these communities to organize, plan and implement effective strategies. And finally, we will also be initiating a new platform of research studies to examine the impact of population-targeted policies emanating from health systems, business and community organizations and the government.

So several steps have been taken to stem the diabetes epidemic. Work in risk factor reduction must continue so fewer people develop pre-diabetes. The programs and policies for obesity prevention and control are critical. There is a critical need for effective programs that prevent people with pre-diabetes from developing a disease and the first steps have been taken in the form of the National Diabetes Prevention Program. The complications of diabetes have a very high cost in terms of dollars and human suffering, and while improvements have been made, much work remains to be done, especially in those vulnerable populations. Thank you.

[The prepared statement of Ms. Albright follows:]

Testimony before the
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives

The Battle Against Diabetes: Progress Made, Challenges Unmet

Statement of
Ann Albright, PhD, RD
Director, Division of Diabetes Translation
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

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For Release on Delivery
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Introduction

Mr. Chairman, Mr. Shimkus, and distinguished members of the Subcommittee, thank you for the opportunity to participate in this hearing. I am Dr. Ann Albright, Director of the Division of Diabetes Translation at the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services (HHS). CDC's Diabetes Program translates the science of diabetes into practical strategies to control and prevent diabetes in the U.S. population and implements these strategies through leadership, research, programs, and policy. Our work stretches from surveillance and reduction of diabetes risk factors, to prevention of diabetes, to management and surveillance of diabetes and complications in those who already have the disease. Today, I will describe how we accomplish this work, and how our work complements that of our sister divisions and agencies.

Background

Diabetes is a group of diseases marked by high blood glucose (sugar) resulting from a shortage of insulin, a decreased ability to use insulin, or both. When diabetes is not controlled, glucose and fats remain in the blood and damage vital organs. Diabetes is the leading cause of new cases of blindness, kidney failure, and non-traumatic lower-extremity amputations among adults. Women of childbearing age with diabetes and who become pregnant are at increased risk of having babies with major birth defects, a major cause of infant mortality and life-long disabilities. In addition, children born to women with diabetes are at increased risk for developing diabetes as adolescents or adults. Adults being treated for diabetes are just as likely to have a heart attack or stroke or die from cardiovascular causes as people who have had a prior heart attack, and are twice as likely to die following a heart attack as people without diabetes. [1]

Medical costs associated with diabetes are substantial. Total national cost associated with diabetes in 2007 exceeded $218 billion. Pre-diabetes (a condition in which blood sugar is elevated but has not reached the levels that would result in a diagnosis of diabetes) costs $433 annually per person (medical costs only); undiagnosed diabetes, $2,864; type 2 diabetes, $9,677; and type 1 diabetes, $14,856. Gestational diabetes cost per case averaged $3,514 in 2007 - $3,305 in higher pregnancy cost and $209 additional cost during the newborn's first year of life. [2] Diabetes was the seventh leading cause of death listed on U.S. death certificates in 2007. [3]

Diabetes has changed from a public health concern to a widespread epidemic. Data from CDC's 2003 - 2006 National Health and Nutrition Examination Survey (NHANES) reveal that nearly 24 million Americans now have diabetes [4], as compared to 10.2 million in 1997. [5] One in three children born in 2000 are at risk of developing diabetes during their lifetime. [6]

Diabetes can be in the form of type 1 (shortage of insulin), type 2 (decreased ability to use insulin), or gestational diabetes (GDM) (diabetes first diagnosed during pregnancy). Type 1 diabetes usually is first diagnosed in children and young adults, although it can occur at any age. Type 1 diabetes, an autoimmune disease that is not currently preventable, accounts for 5 percent of diabetes cases. [6] People with diabetes diagnosed before the age of 20 years have a life expectancy that is 15 to 27 years shorter than people without diabetes. [7] Until recently, diabetes diagnosed in children and adolescents was almost entirely considered to be type 1. However, while still rare, type 2 diabetes in youth is increasingly occurring in those under 20 years of age, particularly minority youth, probably due to obesity in youth. Type 2 diabetes is also increasing among women of childbearing age.

Type 2 diabetes accounts for 90 to 95 percent of diabetes cases. [6] Data from the 2004 – 2006 National Health Interview Survey (NHIS) for people 20 years and older indicate that 6.6 percent of non-Hispanic whites, 7.5 percent of Asian Americans, 10.4 percent of Hispanics, and 11.8 percent of non-Hispanic blacks had diagnosed diabetes. [8] Risk factors associated with type 2 diabetes include increasing age, family history of diabetes, history of gestational diabetes, race, and ethnicity. These are risk factors that we cannot change. Type 2 diabetes is closely linked to obesity and physical inactivity. These risk factors can be changed. The vast majority of cases of diabetes in the U.S. today are preventable.

Gestational diabetes is of concern because of potential consequences for both the mother and the baby. For the mother, this includes an increased risk for high blood pressure and eclampsia, a condition that causes seizures. For the baby, potential consequences include, increased birth weight, increased risk for birth trauma, and low blood sugar. Gestational diabetes affects 3 to 7 percent of all pregnancies in the United States. [9] An estimated 40 to 60 percent of women with gestational diabetes will develop type 2 diabetes within ten years. [10] Because women with type 2 diabetes are at increased risk for having babies with birth defects, women with a history of gestational diabetes should receive targeted intervention strategies to prevent

type 2 diabetes before they become pregnant, during pregnancy, postpartum and between pregnancies.

Defining and Monitoring Diabetes

The ability to identify the magnitude of a problem through ongoing surveillance is a foundation of CDC's work. CDC developed and maintains the National Diabetes Surveillance System, the world's first system for monitoring diabetes. It relies on national and state-based household, telephone, and hospital-based surveys, and vital statistics to monitor trends in diabetes, its risk factors, levels of care, and complications. In collaboration with the National Institutes of Health (NIH), CDC has also initiated the largest major surveillance system to quantify and track the diabetes burden in those under 20 years of age, the SEARCH for Diabetes in Youth study. This study provides population-based information on the underlying factors, trends, impact, and levels of care provided to American youth who develop either type 1 or type 2 diabetes. Among other things, SEARCH allows us to clarify the degree to which type 2 diabetes is affecting youth of different racial and ethnic backgrounds.

CDC uses its surveillance data to understand the diabetes epidemic, identify vulnerable at-risk populations, set prevention objectives for the nation, and monitor success of our programs over time, all at the national level. The system also provides essential data on the levels of behavioral risk factors, preventive care practices, and prevalence (percent of the population who has diabetes) and incidence (fraction of the population that develops a new case of diabetes in any given year) at the state level. It uses a variety of mechanisms, such as fact sheets, publications, and the internet, to provide data on diabetes to a variety of audiences, including policymakers, professional organizations, and state health departments. In the last two years, CDC has developed a methodology to estimate levels of diabetes and obesity at the county level, providing policy makers and communities with new information to guide program planning and resource allocation.

Findings from the National Diabetes Surveillance System document several successes in the public health response to diabetes over the past decade but have also revealed areas of major concern and continuing threats to the public's health. Rates of blood glucose being out of control and cardiovascular disease risk factors, as well as incidence of amputations, end stage renal disease, and deaths due to high blood sugar among the adult U.S. population with diagnosed diabetes, have all declined. These findings suggest that people with diabetes live

longer, healthier lives than people who were diagnosed with the condition in prior decades. However, these improvements hide considerable variation and disparities in diabetes care and outcomes across the country. For example, CDC's recently published county level estimates of diabetes and obesity indicate that wide sections of the Southeast, Appalachia, and some tribal lands in the West and Northern Plains have the nation's highest rates of obesity and diabetes. [11] In many counties in those regions, rates of diagnosed diabetes exceed 10 percent and obesity reaches more than 30 percent. [11] Concerning disparities also persist in the levels of risk for complications. For example, African Americans have notably increased risk of high blood pressure, diabetes-related kidney disease, and diabetes itself. In addition, people of lower education and income have higher risk for diabetes and numerous complications. [12]

Various factors influence low levels of testing and post partum care for women with a history of GDM (e.g., gaps in surveillance system, lack of awareness about GDM and future risk for type 2 diabetes, health system infrastructure challenges). Through strategic collaborations, research and education, CDC works to impact and improve outcomes for women at risk for and with GDM. In collaboration with the National Association of Chronic Disease Directors' Women's Health Council and the Agency for Healthcare Research and Quality, we are working to conduct a GDM validation project to: 1) establish a 5-state collaboration to identify, catalogue, and validate routinely collected data about GDM; 2) identify gaps in quality of GDM prevalence data; and 3) determine implications for care.

Our greatest concern is the continued increase in the rate of new cases of diabetes. This is evident in virtually all segments of society, regardless of age, race/ethnicity, and gender. This continued increase in the rate of development of new cases is unfortunately negating many of the successes that clinical and public health efforts have achieved in reducing rates of complications among people with diabetes. The continued increase in diabetes incidence calls for two major efforts in public health., First, the trends indicate a need for improved surveillance at regional, state, and local levels to improve the ability of programs to put resources where they can be most effective; second, these findings indicate a need for comprehensive implementation of a multi-tiered diabetes prevention strategy.

Reducing Risk Factors for Type 2 Diabetes

CDC is engaged in risk reduction efforts on multiple levels, including a focus on obesity, nutrition, and physical activity for the general population. CDC is actively working with the

First Lady on the *Let's Move!* initiative, providing scientific expertise in the areas of healthy eating and physical activity, and communication support to the campaign's public service advertising efforts. Additionally, CDC, in collaboration with HHS, is implementing the Communities Putting Prevention to Work (CPPW) program as part of the American Recovery and Reinvestment Act. Through CPPW, CDC is funding communities, states, and territories to advance nutrition, physical activity, and obesity-related policy and environmental strategies with the goal of stabilizing or beginning to decrease adult and youth overweight/obesity, thus reversing long term trends of obesity and related chronic diseases.

CDC's Division of Diabetes Translation focuses on obesity, nutrition, and physical activity in those with or at risk for diabetes. American Indians and Alaska Natives are at extremely high risk for diabetes. [13] About16 percent of American Indians and Alaska natives have diabetes. [13] CDC focuses on American Indians with its Native Diabetes Wellness Program. The Native Diabetes Wellness Program works with 17 American Indian and Alaska Native communities to improve access to local, fresh produce, including traditional foods like squash and berries. For many people living on reservations, grocery stores can be dozens of miles away. These efforts focus on preserving and renewing cultural identity. For example, CDC is providing funds to the Standing Rock Nation, bordering North and South Dakota, in partnership with the U.S. Department of Agriculture, to offer fresh-produce vouchers that the elderly can use at local farmers markets. Redemption rates for these vouchers are more than 50 percent. [14]

Preventing Diabetes

Several research studies, including the NIH-led U.S. Diabetes Prevention Program, have demonstrated that a structured lifestyle program, which results in a modest weight loss of 5 to 7 percent while encouraging a healthy diet and increasing physical activity, can reduce risk for type 2 diabetes by 58 percent in those at high risk for diabetes or who have pre-diabetes. Based on the findings of the Diabetes Prevention Program clinical trial and subsequent NIH-supported studies that have translated these research findings into real world settings, CDC and our partners are implementing the National Diabetes Prevention Program. This program focuses on delivering the proven intervention in group settings for a cost of about $250 to $300 per person per year. The National Diabetes Prevention Program takes a four-pronged approach: training the

workforce, a recognition program for quality assurance, funding sites to deliver the intervention, and health marketing to increase the program's utilization.

In partnership with Emory University, CDC established the Diabetes Training and Technical Assistance Center which is developing a Diabetes Prevention Program Master Trainer Curriculum to educate master trainers who train lifestyle coaches. The lifestyle coaches will deliver the evidence-based structured lifestyle intervention in group settings across the country. This systematic training will help build a workforce that can sustain the National Diabetes Prevention Program and prevent or delay type 2 diabetes in high-risk individuals.

The recognition program sets recognition standards for diabetes prevention programs, monitors recognized diabetes prevention programs, and maintains a national registry of recognized diabetes prevention programs and a master trainer directory. The recognition process assures the quality and fidelity of the National Diabetes Prevention Program and provides a registry to track and report data, performance, and outcomes of the National Diabetes Prevention Program for quality assurance, monitoring, and reporting purposes.

The National Diabetes Prevention Program is currently offered in select communities across the country. CDC convened public and private partners, including the YMCA-USA, UnitedHealth Group, University of Pittsburgh, and Indiana University to ensure successful uptake, referral, and delivery of the National Diabetes Prevention Program. In the first phase, CDC is funding ten YMCA sites, and UnitedHealth Group is funding six YMCA sites to deliver the lifestyle program. This program will be systematically rolled out, scalable, and sustainable. In future phases, other organizations will also deliver the intervention as they become CDC-recognized. Sustainability is particularly important. UnitedHealth Group will cover the cost of participation for its beneficiaries. This represents the first time private insurance, in this case UnitedHealth Group, has entered into a partnership to cover prevention of diabetes to a community-based national organization. Work is under way to bring on additional organizations and third party payers to fund the intervention.

A CDC-NIH collaboration, the National Diabetes Education Program's 2008 Survey of the Public's Knowledge Attitudes, and Practices Related to Diabetes, revealed significant gaps between perceived and actual risks. For example, only 29 percent of the people at high risk for diabetes understood their risk for the disease, and only about a third of people with pre-diabetes understood that they were at risk for diabetes. NHANES data from 2005 – 2006 show that 30

percent of U.S. adults 20 years or older had pre-diabetes. Only 7 percent of those determined by the medical exam portion of this survey to have pre-diabetes reported that they had been told that they had the condition, and 48 percent of adults with pre-diabetes reported a test for diabetes or high blood sugar in the past three years. [15] These numbers clearly indicate the need for education, both for people at risk for diabetes and for clinicians. A CDC-led strategic marketing effort will focus on increasing the understanding of diabetes among people at risk for diabetes, such as women with a history of GDM, and referring clinicians.

Diabetes Management

CDC is active in preventing complications among people who already have diabetes. Control of A1c (a measure of average blood sugar over the last three months), blood pressure, cholesterol, and smoking cessation are crucial, and are emphasized in all our efforts.

The CDC-led Translating Research into Action for Diabetes project is a ten-year, six-center study of managed care and diabetes quality of care. The Translating Research into Action for Diabetes project was created to determine the key factors in managed care systems and patients that influence the progression and outcomes of diabetes care. The ultimate goal is to provide practical information on how to better implement effective treatment in managed care settings. The Translating Research into Action for Diabetes project has taught us that, among other things, greater out-of-pocket costs are associated with lower rates of both eye exams and blood sugar monitoring and that physician reimbursement by salary or capitation is associated with better care than fee for service. [16] We, along with the CDC-funded state and territorial-based Diabetes Prevention and Control Programs, are using these findings to advance our work in improving the health care delivery system. For example, the Utah Diabetes Prevention and Control Program has partnered with nine major health care plans to improve diabetes care for state residents. Together, these partners developed initiatives to improve the quality and performance of important aspects of diabetes care. The health care plans that participated in the initiatives worked together to increase patient and provider awareness of key clinical targets and indicators for diabetes; increase systems-based support for the delivery of diabetes care and the measurement, tracking, and reporting of key health indicators; and implement patient reminder/call back systems that focus on key health indicators and medication adherence. Between 2004 and 2009, all diabetes quality of care measures improved as a result of the partnership efforts. These outcomes included increase in average blood glucose control (A1c

<7%) from 23 percent (baseline) to 43 percent; increase in lipid control from 18 percent (baseline) to 45 percent; increase in eye examination rates from 42 percent (baseline) to 64 percent; and increase in screening to assess kidney function from 33 percent to 69 percent. [16]

In addition, we have a special focus on vulnerable populations. For example, the Florida Diabetes Prevention and Control Program, in collaboration with Florida's Office of Minority Health, administers the Closing the Gap project in eight disease areas, including diabetes. Community-based organizations provide diabetes self management education, wellness education, community health worker services, and/or assist faith-based agencies with health ministry capacity building. This program has reached over 12,000 persons with diabetes. Results achieved include reductions in body mass index, lowering of A1c, and an increase in such preventive care services as foot exams, eye exams, and receipt of flu shots. [14]

Chronic kidney disease is the ninth leading cause of death in the United States, and diabetes accounts for nearly half of all new cases of people requiring dialysis or a kidney transplant. People with diabetes are at substantial risk for diabetic retinopathy, cataracts, and glaucoma, all of which can cause blindness. CDC's Congressionally-mandated Vision Health and Chronic Kidney Disease Initiatives develop partnerships with federal and non-federal organizations to establish new surveillance systems and integrate them with public health, effectiveness, and economic studies. These initiatives help prioritize interventions that reduce or prevent the development or progression of these complications.

Future Work

We are continuing to explore new frontiers of diabetes prevention and control. We have two new projects that will begin by September 30, 2010. In the National Program to Eliminate Diabetes-Related Disparities in Vulnerable Populations, CDC will fund six organizations to reduce morbidity, premature mortality, and eliminate health disparities associated with diabetes. This will be achieved by mobilizing community partners and assisting them to effectively plan, develop, implement, and evaluate community-based interventions to reduce the risk factors that influence the disproportionate burden of diabetes that vulnerable populations bear.

Beginning in 2010, CDC will initiate a new platform of research studies to examine the impact of population-targeted policies emanating from health systems, business and community organizations, and governments. The impetus behind this work is that many innovative public

health policies are initiated every year, but the true impact of these initiatives can only be fully assessed with further study.

Conclusion

People with diabetes now live longer than in the past. Improved awareness of diabetes has contributed to improved diagnosis. These factors, combined with our aging population, means that the percentage of the population with diagnosed diabetes will rise over the coming years. As recognized in Healthy People 2020 goals, reducing new cases of diabetes (incidence) requires an increased focus, while at the same time we continue to make advances in improving the health outcomes for those with diabetes.

Several steps must be taken to stem the diabetes epidemic. Work in risk factor reduction must continue so that fewer people develop pre-diabetes. The programs and policies for obesity prevention and control, both in the general population and those at risk for diabetes, are central to this effort. There is a critical need for effective programs that prevent people at high risk for diabetes from developing the disease. The first steps have been taken, in the form of the National Diabetes Prevention Program. The complications of diabetes have a very high cost, both in dollars and human suffering. While improvements have been made, much work remains to be done, especially in vulnerable populations.

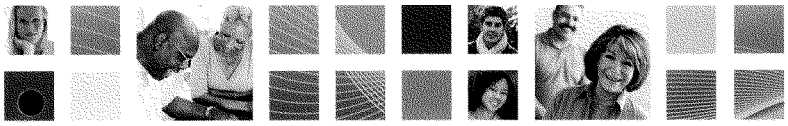
The increasing number of new cases of diabetes demands an urgent response. CDC will continue to increase the reach of the National Diabetes Prevention Program by increasing the number of master trainers and lifestyle coaches who can implement the National Diabetes Prevention Program as resources permit and by managing the recognition program to assure quality and effectiveness. We will work with other organizations to expand the delivery and reimbursement for the National Diabetes Prevention Program.

Thank you for your attention. I will now take your questions.

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DIABETES

SUCCESSES AND OPPORTUNITIES FOR POPULATION-BASED PREVENTION AND CONTROL

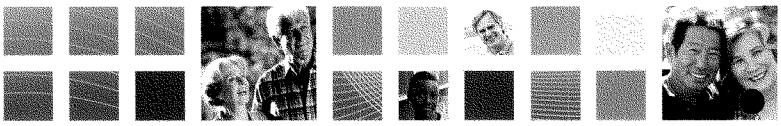
AT A GLANCE

2010

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

IMPROVING HEALTH AND QUALITY OF LIFE FOR ALL PEOPLE

CDC



What Is Diabetes?

Diabetes is a disease in which the body has a shortage of insulin, a decreased ability to use insulin, or both. Insulin is a hormone that allows glucose (sugar) to enter cells and be converted to energy. When diabetes is not controlled, glucose and fats remain in the blood and, over time, damage vital organs.

- **Type 1 diabetes** usually is first diagnosed in children and young adults, although the disease can occur at any age. Type 1 may be autoimmune, genetic, or environmental and accounts for 5% of diabetes cases. There is no known way to prevent this type of diabetes.
- **Type 2 diabetes**, which is linked to obesity and physical inactivity, accounts for 90%–95% of diabetes cases and most often occurs in people older than 40. Type 2 is associated with older age, obesity, family history of diabetes, history of gestational diabetes, impaired glucose metabolism, physical inactivity, race, and ethnicity. Type 2 diabetes in children and adolescents, although still rare, is being diagnosed more frequently among American Indians, African Americans, Hispanics/Latinos, and Asians/Pacific Islanders.
- **Prediabetes** is a condition in which a person has blood glucose levels higher than normal but not high enough to be classified as diabetes. An estimated 57 million American adults had prediabetes in 2007. People with this condition have an increased risk of developing type 2 diabetes, heart disease, and stroke.
- **Gestational diabetes** is a form of glucose intolerance diagnosed during pregnancy. Gestational diabetes occurs more frequently among African Americans, Hispanics/Latinos, and American Indians. It is also more common in obese women and women with a family history of diabetes. Gestational diabetes requires treatment to normalize maternal blood glucose levels to avoid complications in the infant. Women who have had gestational diabetes have a 35%–60% chance of developing diabetes during the 10–20 years following their pregnancy.
- **Other types of diabetes** result from specific genetic conditions (such as maturity-onset diabetes of youth), surgery, medications, infections, pancreatic disease, and other illnesses. Other types of diabetes account for 1%–5% of all diagnosed cases.

Diabetes Is Common, Disabling, and Deadly

- 23.6 million people in the United States (7.8% of the total population) have diabetes. Of these, 5.7 million have undiagnosed diabetes.
- In 2007, about 1.6 million new cases of diabetes were diagnosed in people aged 20 years or older.
- African American, Hispanic, American Indian, and Alaska Native adults are twice as likely as white adults to have diabetes.
- If current trends continue, 1 in 3 Americans will develop diabetes sometime in their lifetime, and those with diabetes will lose, on average, 10–15 years of life.
- Diabetes is the leading cause of new cases of blindness, kidney failure, and nontraumatic lower-extremity amputations among adults.
- Diabetes was the sixth leading cause of death on U.S. death certificates in 2006. Overall, the risk for death among people with diabetes is about twice that of people without diabetes of similar age.
- In 1999–2000, 7% of U.S. adolescents aged 12–19 years had impaired fasting glucose (prediabetes), putting them at increased risk of developing type 2 diabetes, heart disease, and stroke.

Diabetes Is Costly

- Total costs (direct and indirect) of diabetes: $174 billion.
- Direct medical costs: $116 billion.
- Indirect costs (related to disability, work loss, premature death): $58 billion.
- People with diagnosed diabetes have medical expenditures that are about 2.3 times higher than medical expenditures for people without diabetes.



DIABETES
SUCCESSES AND OPPORTUNITIES FOR POPULATION-BASED PREVENTION AND CONTROL
2010

Success Stories

Utah: A Health Plan Partnership Helps Improve Diabetes Care Measures

The Utah DPCP partnered with nine major health care plans (six commercial and three Medicaid) to improve diabetes care for state residents. Together, these partners developed initiatives to improve the quality and performance of important aspects of diabetes care. Because the initiatives were systems-based, the Utah DPCP was able to reach approximately 90% of state physicians and the majority of people seeking diabetes care, regardless of their insured status.

These initiatives encouraged providers to adopt Utah's Diabetes Practice Recommendations, collect data on a uniform set of diabetes quality assurance measures, and complete yearly quality improvement projects. The health care plans that participated in the initiatives worked together to accomplish the following:

- Increase patient and provider awareness of key clinical targets and indicators for diabetes.
- Increase systems-based support for the delivery of diabetes care and the measurement, tracking, and reporting of key health indicators.
- Implement patient reminder/call back systems that focus on key health indicators and medication adherence.
- Provide feedback to patients about their health and to providers about their medical performance.
- Implement comprehensive and standardized data collection, evaluation, and reporting methods.

The partners used data on diabetes quality of care to identify joint objectives and targets for diabetes-related clinical indicators. They also established a 3- to 5-year work plan with annual goals. All media, awareness, and clinical interventions were coordinated across the health care plans. The Utah DPCP, together with CDC's Division of Diabetes Translation, conducted an evaluation of the partnership to determine whether these efforts were impacting provider care practice and patient health outcomes.

Results showed that from 2004 through 2009, all diabetes quality of care measures improved as a result of the partnership efforts. These measures included average blood glucose control (A1c <7%), 23.5% to 42.7%; lipid control (low-density lipoprotein <100), 17.8% to 45.2%; eye examination rates, 41.9% to 64.0%; and screening to assess kidney function, 33.3% to 69.3%.

Eye examinations rates in Utah also were trended year-to-year and compared with national rates. The results of the evaluation indicated that the rate of diabetes eye examinations in Utah improved at a significantly greater rate than national rates during the same period (41.9% to 50.3%).

In 2008, the DPCP invited the Utah Heart Disease and Stroke Prevention Program to join the partnership to improve measures for cardiovascular care. The new partnership has added the goal of reducing high blood pressure for fiscal year 2010 and has established baseline and target rates related to this measure.

Texas: Creating a Diabetes Self-Management Pilot Project for Medicaid Recipients

In Texas, about 1.8 million adults have diagnosed diabetes, and an estimated 460,040 have undiagnosed diabetes. People who receive Medicaid benefits make up a significant portion of Texans with diabetes. However, it is unclear whether those who receive benefits and have diabetes are receiving adequate self-management training to control their disease and prevent costly and dangerous complications.



Regulated insurance plans and Medicare require that recipients complete a specified number of hours of patient education with qualified providers. However, the quantity and quality of diabetes education provided under Medicaid varies. This disparity can significantly affect the ability of Medicaid recipients to control their diabetes and its complications.

CDC provided the Texas Diabetes Prevention and Control Program (DPCP) with funding to collaborate with the Texas Diabetes Council to develop a strategic plan to reduce the health and economic burden of diabetes. One of the six priority areas identified in the plan involved changing public policy to ensure that all people with diabetes have access to adequate care and self-management education.

The Texas DPCP worked with statisticians at the Texas Health and Human Services Commission to collect data on Medicaid recipients with diabetes. The program also was a resource for legislators as they drafted legislation that would allow a minimum of 10 hours of self-management education to be covered by Medicaid, with the option for follow-up education.

As a result of these efforts, in 2009, state legislators passed a law that created a Medicaid pilot project to make self-management education a covered benefit for about 2,000 people with diabetes. Through this pilot project, participants will have access to self-management education that meets state and national standards.

The Texas DPCP and partner organizations will monitor the progress of the project, and information learned from the project will shape future efforts to make the service available to all Medicaid recipients with diabetes in Texas.

Kentucky: Forming a Partnership to Improve Work Site Wellness

Trane Commercial Systems offered employees at its Lexington, Kentucky, location the opportunity to participate in an annual health assessment. The results of the assessment showed that numerous employees had diabetes, heart disease, or related risk factors, which increased their risk for heart attack and stroke. These conditions resulted in health-related absences from work and increased employer health care costs. To address this problem, the company planned to launch an onsite wellness program to promote heart-healthy behaviors for all of the 1,100 employees working at its Lexington factory. However, company officials realized that they lacked the subject matter expertise, materials, and community resources needed to develop the program.

Trane received help from the Kentucky DPCP, which is funded by CDC, to overcome this problem. Regional DPCP staff at the Lexington-Fayette County Health Department provided Trane with diabetes educators to help plan and conduct its employee wellness program. The educators used evidence-based materials, including the National Diabetes Education Program's tool kit, Diabetes at Work, to design the program.

Educational sessions were developed and made available during all three work shifts. Trane provided in-house marketing and support, including a location for blood pressure monitoring, a walking program, and various employee incentives. These incentives included a new policy that granted employees 30 minutes of paid leave per month to participate in wellness program activities.

Staff at the Kentucky DPCP also helped Trane connect with other community partners. A new advisory board with representatives from the American Diabetes Association and other organizations provided educational materials, speakers, and incentives, which contributed to the program's sustainability.

After the first year of the program, Trane officials noted several improvements in employee health. For example, 57% of employees reported improved eating habits, and 52% reported an increase in physical activity. The percentage of employees with desirable blood pressure values of less than 120/80 more than doubled, from 26% to 53%. The percentage with high-risk high-density lipoprotein (HDL) levels (<40 mg/dl) decreased from 58% to 52%, while the percentage with desirable HDL levels increased from 5% to 10%.

Because of the program's success, Trane added a full-time wellness coordinator to its Lexington location, and the company began supporting efforts to duplicate the model at its other factories.



Diabetes Is Preventable and Controllable

Recent studies show that lifestyle changes can prevent or delay the onset of type 2 diabetes among people at high risk.

- For people with prediabetes, lifestyle changes, including a 5%–7% weight loss and at least 150 minutes of physical activity per week, can reduce the rate of onset of type 2 diabetes by 58%.

Disability and premature death are not inevitable consequences of diabetes. By working with their support network and health care providers, people with diabetes can prevent premature death and disability by controlling their blood glucose, blood pressure, and blood lipids and by receiving other preventive care in a timely manner.

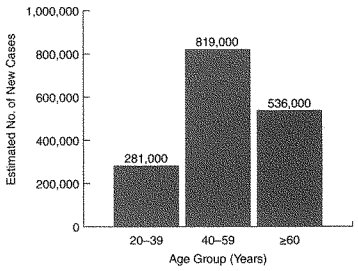
- Blood glucose control reduces the risk for eye, kidney, and nerve diseases among people with diabetes by about 40%.
- Blood pressure control reduces the risk for heart disease and stroke among people with diabetes by 33%–50%. It reduces the risk for eye, kidney, and nerve diseases by about 33%.
- Detecting and treating diabetic eye disease with laser therapy can reduce the risk for loss of eyesight by 50%–60%. Comprehensive foot care programs can reduce amputation rates by 45%–85%.

Important Achievements, But More to Do

There are encouraging outcomes to report in the effort to control the epidemic of diabetes. People with diabetes are living longer. The following also have decreased:

- The percentage of people with diabetes who are unaware that they have the disease.

New Cases of Diagnosed Diabetes in People Aged 20 Years or Older, by Age Group, United States, 2007



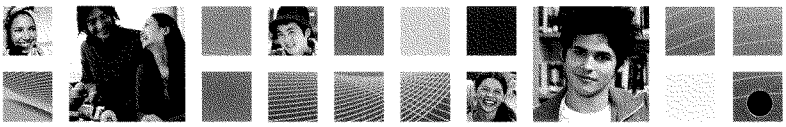
Source: 2004–2006 National Health Interview Survey estimates projected to year 2007.

- Hospitalizations among people with diabetes.
- Cardiovascular disease death rates among people with diabetes.
- The prevalence of visual impairments among people with diabetes.
- The rate of new cases of kidney failure among people with diabetes.

CDC's Response

CDC works to reduce the preventable burden of diabetes through public health leadership, partnerships, research, policies, and programs that translate science into practice. Through its Division of Diabetes Translation (DDT), CDC is conducting the following activities to achieve this goal:

- Using public health surveillance to monitor the burden of diabetes across the United States.
- Conducting research that helps communities deliver findings in clinical and public health practice.
- Developing and maintaining effective state-based diabetes prevention and control programs.
- Closing health gaps among populations most severely affected by diabetes.



CDC's Response (continued)

Defining the Diabetes Burden

CDC's National Diabetes Surveillance System (NDSS) maintains diabetes-related data from national and state-based surveys. NDSS data are not available from any other source. They have been used to determine trends in diabetes and its complications, identify diabetes health service research needs, develop and monitor national health objectives, detect changes in health care practices, facilitate program planning and educational materials, and allocate resources. To view trends in national data, as well as data about your state or county, visit http://apps.nccd.cdc.gov/DDTSTRS.

Translating Research and Conducting New Research

CDC translates research findings from scientific studies and clinical trials for use by health care systems and communities. Special emphasis is placed on the elimination of health disparities among populations at higher risk. Examples of this translation include the following:

- **Translating Research Into Action for Diabetes (TRIAD).** A national, multicenter study, TRIAD aims to provide practical information on how to better implement effective treatments and provide better care for patients with diabetes in managed care settings in the United States.
- **Primary Prevention for People Most at Risk.** Building on information learned from past projects that translate research into action, CDC is establishing an evidence-based National Diabetes Prevention Program that will recognize and certify community-based lifestyle intervention programs for people who have a high risk of developing type 2 diabetes.

Developing Programs in States and U.S. Territories

CDC provides funding and technical assistance for diabetes prevention and control programs (DPCPs) in all 50 states, the District of Columbia, and 8 current and former U.S. territories. These programs implement public health strategies such as

- Preventing diabetes among people at highest risk.
- Adopting diabetes care guidelines in health care delivery settings.
- Helping state Medicaid programs monitor quality care outcomes among people with diabetes.
- Educating providers and the public about optimal diabetes care and self-management.
- Involving communities in diabetes control activities.

Providing Education and Sharing Expertise

The National Diabetes Education Program (NDEP) and the Native Diabetes Wellness Program (NDWP) are two programs in DDT that focus on disparate populations. The NDEP, jointly led by CDC and the National Institutes of Health, develops and disseminates educational information on the prevention and control of diabetes for populations affected by diabetes, health care professionals, employers, and insurers.

The NDEP's educational resources and tools are available online in English, Spanish, and 15 Asian and Pacific Islander languages at http://www.ndep.nih.gov. The NDEP Web site also provides resources for specific audiences, such as health care professionals, businesses, schools, and community organizations.

The NDWP focuses on American Indian/Alaska Native and Pacific Islander populations who are disproportionately affected by diabetes. The NDWP and its partners are developing a series of books and graphic novels that use the native art of storytelling to teach adolescents about returning to traditional, healthy lifestyle practices. This series will complement the *Eagle Books* series for younger children. More than 2 million copies of the *Eagle Books* have been provided to schools, libraries, and other organizations. For more information on the books, go to http://www.cdc.gov/diabetes/pubs/eagle.htm.

For more information, please contact the Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion
4770 Buford Highway NE, Mail Stop K-10, Atlanta, GA 30341-3717
Telephone: 800-CDC-INFO (232-4636) • TTY: 888-232-6348
E-mail: cdcinfo@cdc.gov • Web: http://www.cdc.gov/diabetes

Mr. PALLONE. Thank you, Dr. Albright.
Dr. Fradkin.

STATEMENT OF JUDITH FRADKIN

Dr. FRADKIN. Thank you, Mr. Chairman and members of the subcommittee, and I also want to thank you for your congratulations on our 60th anniversary and particularly to thank Congresswoman DeGette and Mr. Space and Mr. Green, who actually participated in our celebratory breakfast, and Ms. DeGette in particular made some remarkably inspiring remarks at that event, and I want to thank her. I am also very pleased to testify with Dr. Albright, because our two agencies work so effectively together on multiple efforts to combat diabetes including our National Diabetes Education Program which is co-led by the two agencies.

On behalf of NIDDK and the NIH, I am pleased to report that we are vigorously pursuing research on diabetes and its complications and today I would like to tell you about some of NIH-supported research including research supported by the special statutory program for type 1 diabetes research, which is administered by NIDDK and has resulted in many scientific advances that are improving the health and quality of life of people with diabetes. A parallel funding stream for a special diabetes program for Indians is administered by the Indian Health Service and has led to substantial improvements in diabetes care in American Indians.

Mr. Chairman, the need to pursue research on prevention, treatment and cure of diabetes is greater than ever because the rates of several types of diabetes are rising. The good news is that we have made tremendous progress in recent years which has led to improvements in survival and quality of life for people with diabetes. For example, now thanks to continuous glucose monitoring technology, some parents of young children with type 1 diabetes can sleep through the night without having to rise repeatedly to check their child's blood glucose level. The device measures glucose every several minutes and sounds an alarm if the levels are too high or too low, a technological peace of mind allowing parents to sleep more soundly.

Because genetic and antibody tests can predict with great accuracy which children will develop type 1 diabetes, we can now test prevention strategies and are doing so. To find new approaches to prevention, we launched the TEDDY study. TEDDY researchers screened over 400,000 newborns to find 8,000 who had genes that put them for particularly high risk of type 1 diabetes. Those children are now enrolled in the study and are being followed until age 15 with a goal of identifying environmental triggers of type 1 diabetes. For example, if we could find an infectious trigger, we must develop a vaccine to prevent the disease. To date, the number of children who have developed autoimmunity in type 1 diabetes are exactly as predicted in the study, showcasing the tremendous power of these predictive tests.

We can prevent or delay the development of type 1 diabetes in people at high risk for the disease as demonstrated by the NIDDK-led landmark diabetes prevention program clinical trial that Dr. Albright mentioned. A modest amount of weight loss through diet changes and moderate exercise substantially reduced the occur-

rence of type 2 diabetes at 3 years and now in the most recent report at 10 years after enrollment in the trial. This intervention worked in all the ethnic and racial groups studied in both men and women and in women with a history of gestational diabetes.

Building on this success, NIDDK supports research to translate these results to people who can benefit from them. For example, just this week NIDDK-supported scientists announced exciting results from research in which community health workers effectively delivered a group-based lifestyle intervention to people at high risk for type 2 diabetes. At 1 year, the participants lost as much weight as was observed in the diabetes prevention program, suggesting that this approach may be a low-cost way to reach Americans.

Another NIDDK-supported pilot study is already having a far-reaching impact. Researchers successfully utilized local YMCAs to deliver a lower-cost group-based DPP lifestyle intervention, and Dr. Albright has provided information about how the CDC is building on the results of this NIDDK-supported research to improve the public health by implementing a National Diabetes Prevention Program.

Diabetes during pregnancy brings risks to mother and child. Because of the NIH-supported hyperglycemia and adverse pregnancy outcome study, we now have precise information on what blood glucose levels should be during pregnancy to avoid complications near birth.

These are just a few examples of how far we have come in recent years through vigorous supported research toward increasing knowledge about diabetes and improving the health of people with diabetes. However, much work remains to be done to curb the diabetes epidemic. For example, it is critical to move beyond continuous glucose monitoring technology and link glucose monitoring to insulin delivery to create the so-called artificial pancreas. This technology could help patients achieve blood glucose control that has been shown to reduce complications and also alleviate the burden of self-care. Now that we have thousands of samples collected through the TEDDY study, it is vital to use new and emerging technology to analyze those samples and identify an environmental trigger of type 1 diabetes. Building on the success of the many new available therapies for type 2 diabetes, comparative effectiveness research can help inform doctors' decisions about what medications to prescribe for their patients and when.

Loss of the insulin-producing beta cells underlies both type 1 and type 2 diabetes. Research through NIDDK's beta cell biology consortium may develop new approaches to treatment by providing insights on how to reprogram cells to become insulin-producing cells, stimulate beta cell replication or replace lost beta cell function with cells derived from stem cells. Complementing these efforts, clinical research can provide information on how best to preserve beta cell function in people newly diagnosed with type 1 or type 2 diabetes.

Perhaps most important to combating the diabetes epidemic is reversing the trend of both type 1 and type 2 diabetes occurring at younger ages because earlier disease onset means earlier development of complications and premature mortality. For women, earlier development of diabetes also endangers her offspring. The intrauterine environment plays an important role not only in problems

at the time of birth but also in the future development of diabetes and obesity, a finding observed among the Pima Indians in Arizona. Thus, it is critical to pursue research to break the vicious cycle of ever-growing rates of diabetes by preventing or mitigating the effects of diabetes and obesity during the childbearing years and pregnancy.

Implementing research findings into clinical practice has led to reductions in rates of heart disease, kidney failure and blindness in people with diabetes. By building on recent advances in diabetes research, we are poised to realize even greater improvements in health and quality of life for people with diabetes. We have come far but we must go farther.

Thank you, Mr. Chairman, for your leadership in calling this hearing to focus attention on the problem and for your continued support of NIH research.

[The prepared statement of Dr. Fradkin follows:]

Testimony
Before the
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives

Testimony for hearing entitled,
"The Battle Against Diabetes: Progress Made; Challenges Unmet"

Statement of
Judith E. Fradkin, M.D.
Director, Division of Diabetes, Endocrinology, and Metabolic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
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July 1, 2010

Mr. Chairman and Members of the Committee: I am Judith Fradkin, Director of the Division of Diabetes, Endocrinology, and Metabolic Diseases of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Our Institute has primary responsibility for diabetes research at the National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services (HHS).

On behalf of the NIDDK and the other Institutes and Centers of the NIH, I am pleased to report that we are vigorously pursuing research on diabetes and its complications. Through collaborative and coordinated research, we are gaining important insights into the molecular mechanisms underlying disease, identifying and testing promising therapies to prevent and treat the disease and its complications, and striving for a cure. In these efforts, we are fortunate to often partner with other HHS agencies, such as the Centers for Disease Control and Prevention (CDC) and the Indian Health Service (IHS), and other non-federal diabetes organizations.

ADVANCES FROM DIABETES RESEARCH

This year marks the NIDDK's 60th anniversary of conducting and supporting research to combat debilitating diseases within its mission, including diabetes. Diabetes is characterized by the body's inability to produce and/or respond appropriately to insulin, a hormone that is necessary for the body to absorb and use glucose, or sugar, as a cellular fuel. The most common forms of the disease are type 1 diabetes, in which the body loses its ability to produce insulin; and type 2 diabetes, which is due to a combination of insulin resistance and insufficient insulin production. Women can also develop gestational diabetes, a risk factor for type 2 diabetes, during pregnancy. Rarer forms of diabetes also exist.

To appreciate the tremendous progress that has been achieved in recent decades, we can look back at how diabetes was treated in 1950, at the inception of the Institute. Sixty years ago, patients monitored their blood glucose levels with urine tests, which recognized high but not dangerously low glucose levels and reflected hours-old, not current, glucose levels. People with type 1 diabetes relied on painful injections of animal-derived insulin. People with type 2 diabetes had few treatment options: injections of insulin or drugs that stimulated insulin release from the beta cells of the pancreas. Both of these therapies had associated risks. No proven

strategies existed to prevent disease complications, such as blindness, heart disease, kidney disease, and nerve damage.

Insights gained from NIDDK and NIH-supported research over the past 60 years have contributed to a knowledge base leading to improvements in survival and quality of life for people with diabetes. Doctors now use simple blood tests to diagnose diabetes and to assess long-term blood glucose control. People at high risk for type 2 diabetes can prevent or delay disease onset by losing a modest amount of weight through dietary changes and moderate exercise. People with type 1 diabetes can reduce their risk for complications by intensively controlling blood glucose levels. Doctors can prescribe new classes of oral drugs and combinations of drugs to treat people with type 2 diabetes. Patients can use new technologies, such as insulin pumps and continuous glucose monitors, to manage their diabetes. As a result of these past accomplishments, people with diabetes are living longer and healthier lives than ever before. I am pleased to provide you with a few specific examples of how NIH-supported research has contributed to these tremendous improvements in the health and quality of life of people with diabetes.

RESULTS OF MAJOR CLINICAL TRIALS AND TRANSLATING THOSE RESULTS TO IMPROVE PUBLIC HEALTH

One approach to combat the diabetes epidemic in the U.S. is to prevent the disease. A landmark clinical trial studying type 2 diabetes prevention was spearheaded by the NIDDK. The Diabetes Prevention Program (DPP) clinical trial showed that people with pre-diabetes–defined as having blood glucose levels that are higher than normal but not yet high enough to be diagnosed as diabetes—can dramatically reduce their risk of developing type 2 diabetes through lifestyle changes that achieve modest weight loss or through treatment with the drug metformin, although the metformin intervention was much less effective than the lifestyle intervention.[1] The interventions worked in all ethnic and racial groups studied, in both men and women, and in women with a history of gestational diabetes. Research now shows that, after a 10-year period of following DPP participants, the interventions result in long-term benefits: people still had a

[1] Knowler WC, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 346:393-403, 2002.

lower risk of developing type 2 diabetes and those who made lifestyle changes also had reduced cardiovascular risk despite taking fewer drugs to control their heart disease risk factors.[2]

Building on these critically important results, the NIDDK supports research to translate DPP findings to improve public health and benefit the approximately 57 million Americans with pre-diabetes.[3] One successful research effort utilizes local YMCAs for delivering a group-based DPP lifestyle intervention. A pilot study showed that this group-based approach reduces costs to deliver the intervention, while achieving similar levels of weight loss in participants;[4] a larger trial is ongoing. The impressive findings of this pilot study serve as the basis for a new partnership established earlier this year among the UnitedHealth Group, the National YMCA, and the CDC to offer a diabetes prevention program in sixteen U.S. cities, with plans for a national roll out over the next couple of years.

Another way that the DPP results are being translated to the public and health care providers is through the National Diabetes Education Program (NDEP), which is a partnership between the NIDDK and the CDC. The NDEP developed the "Small Steps. Big Rewards. Prevent Type 2 Diabetes" education campaign to disseminate the DPP results. The NIDDK and its collaborators remain dedicated to building on the tremendous successes to date in order to take advantage of new and emerging opportunities to expand type 2 diabetes prevention efforts.

Another NIDDK-led clinical trial has changed the face of type 1 diabetes management. The Diabetes Control and Complications Trial (DCCT), and its follow-on, the Epidemiology of Diabetes Interventions and Complications (EDIC) study, conclusively demonstrated that early and intensive blood glucose control prevented or delayed the debilitating complications of type 1 diabetes involving the heart, eyes, kidneys, and nerves.[5] These impressive findings have revolutionized the management of type 1 diabetes, as physicians now recommend that people control their disease as early and intensively as possible. Intensive treatment is being translated

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[2] Diabetes Prevention Program Research Group, et al. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study. Lancet 374:1677-86, 2009.

[3] CDC. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2007. Atlanta, GA: U.S. Department of Health and Human Services, CDC, 2008.

[4] Ackermann RT, et al. Translating the Diabetes Prevention Program into the community. The DEPLOY Pilot Study. Am J Prev Med. 35: 357-63, 2008.

[5] The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 329: 977–986, 1993; Nathan DM, Cleary PA, Backlund JY, et al. Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group. Intensive diabetes treatment and cardiovascular disease in type 1 diabetes mellitus. N Engl J Med 353: 2643–2653, 2005.

into improved health, as researchers recently reported that the outlook for people with longstanding type 1 diabetes has greatly improved in the past 20 years.[6]

The NIDDK-supported United Kingdom Prospective Diabetes Study showed that people with type 2 diabetes also benefit from improved glucose control early in the course of the disease with respect to reducing rates of disease complications.[7] However, in people with long standing type 2 diabetes who also are at high risk for heart disease, more intensive blood glucose control than is currently recommended by treatment guidelines can be dangerous, as demonstrated in the ACCORD clinical trial, which is led by the National Heart, Lung, and Blood Institute.[8] The trial found that lowering blood pressure to normal levels did not significantly reduce the risk of cardiovascular events overall, although it may reduce the risk of stroke. In the lipid trial, combination therapy of a statin and a fibrate appeared to be safe, but did not lower the risk of heart attack, stroke, or death from heart disease more than statins alone. The ACCORD findings indicate that people who have longstanding type 2 diabetes and are at high risk for a cardiovascular event and are well controlled as per current recommendations do not need to be treated more intensively to reduce heart attacks, strokes, and other cardiovascular events. Thus, the patients can be spared from unnecessary additional medications. These key results from type 2 diabetes clinical trials suggest that, rather than a one-size-fits-all approach, recommendations for treating people with type 2 diabetes can be personalized.

Further insights into the management of type 2 diabetes are expected to emerge from the NIDDK-led Look AHEAD (Action for Health in Diabetes) clinical trial, which is examining the health effects of a lifestyle intervention designed to achieve and maintain weight loss over the long term in over 5,000 overweight and obese adults with type 2 diabetes. Encouraging results are already emerging. After following participants for 1 year, researchers found that people in the intensive lifestyle arm showed improved diabetes, blood pressure, and lipid control, with

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[6] DCCT/EDIC Research Group, et al. Modern-day clinical course of type 1 diabetes mellitus after 30 years' duration: the diabetes control and complications trial/epidemiology of diabetes interventions and complications and Pittsburgh epidemiology of diabetes complications experience (1983-2005). Arch Intern Med 169:1307-16, 2009.

[7] Holman RR, et al. 10-year follow-up of intensive glucose control in type 2 diabetes. N Engl J Med 359:1577-89, 2008.

[8] Action to Control Cardiovascular Risk in Diabetes Study Group, et al. Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med 358: 2545-49, 2009; ACCORD Study Group, et al. Effects of intensive blood-pressure control in type 2 diabetes mellitus. N Engl J Med 362:1575-85, 2010; ACCORD Study Group, et al. Effects of combination lipid therapy in type 2 diabetes mellitus. N Engl J Med 362: 1563-74, 2010.

reduced medication use and costs.[9] After 4 years, researchers observed a sustained effect of the lifestyle intervention on weight loss, as well as improved glucose control with reduced medication use.[10] Participants continue to be followed to assess longer-term outcomes. These are just a few examples of the NIH-supported clinical trials that have provided unprecedented insights into diabetes prevention and management.

DISPROPORTIONATE IMPACT ON MINORITY POPULATIONS

Type 2 diabetes occurs more frequently among racial and ethnic minority groups in the U.S., including American Indians, African Americans, Hispanic/Latino Americans, and Asians/Pacific Islanders.[11] Because of this disparity, the NIH has included large numbers of minority participants in its type 2 diabetes studies. For example, nearly half of the DPP participants were from minority groups, and the interventions worked in all groups. Those results are being translated in culturally appropriate ways through the NDEP and other translational research efforts.

Type 2 diabetes is an emerging health problem in youth, particularly minority youth, being driven by the obesity epidemic. The NIH and its partners are tackling this issue on many fronts. For example, just this week, researchers announced results from the NIDDK-led HEALTHY clinical trial, which examined whether a middle-school based intervention could lower risk factors for type 2 diabetes. The study was conducted in schools with a high enrollment of minority children and youth from low-income families. The intervention was found to lower the obesity rate in students at highest risk for type 2 diabetes—those who started out overweight or obese in sixth grade. However, schools that implemented the program did not differ from comparison schools in the study's primary outcome—the prevalence of overweight and obesity combined—which had declined by 4 percent in both the intervention and control schools by the end of the 3-year study.[12] These results are important for informing future school-based efforts to reduce overweight and obesity in children.

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[9] Redmon JB, et al. Effect of the look AHEAD study intervention on medication use and related cost to treat cardiovascular disease risk factors in individuals with type 2 diabetes. Diabetes Care 33: 1153-8, 2010.
[10] The Look AHEAD Study: Design of the Lifestyle Intervention and Four-Year Weight Losses. Presented at the American Diabetes Association 69th Scientific Sessions, June 2009. Publication in press, Archives Int Medicine.
[11] CDC. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2007. Atlanta, GA: U.S. Department of Health and Human Services, CDC, 2008.
[12] Presented at the American Diabetes Association 70th Annual Sessions, June 2010.

Another school-based effort is the Diabetes Education in Tribal Schools (DETS) Project, on which NIDDK and IHS partner. The DETS Project is a K-12 curriculum focused on increasing American Indian/Alaska Native students' understanding of health, diabetes, and maintaining life in balance; understanding and application of scientific and community knowledge; and interest in science and health professions. The NIDDK is currently building on the success of the DETS Project to develop a K-12 curriculum for African American and Hispanic students.

For children who already have type 2 diabetes, the NIDDK supports the Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) clinical trial at centers around the country to test three different treatment regimens. A large percentage of children who are enrolled in this study are from minority groups disproportionately burdened with type 2 diabetes. Through TODAY and other studies, the NIDDK hopes to ameliorate type 2 diabetes and its complications in this most vulnerable population.

Gestational diabetes mellitus (GDM) also disproportionately affects minority groups. Although this form of diabetes generally goes away after the baby is born, it leaves both mother and child at increased risk for developing type 2 diabetes. Important insights about GDM have emerged from the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study, which is led by NIH's *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). The HAPO study 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.[13] 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, the prevalence of GDM will more than double.[14] The good news is that the DPP showed that a healthy diet and exercise can help prevent later type 2 diabetes in women who have had GDM. For this reason, the NDEP, in collaboration with the NIH Office of Research on Women's Health, recently expanded its

[13] HAPO Study Cooperative Research Group, et al. Hyperglycemia and adverse pregnancy outcomes. N Engl J Med 358: 1991-2002, 2008.

[14] International Association of Diabetes and Pregnancy Study Groups Consensus Panel. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. Diabetes Care 33: 676-82, 2010.

educational campaign for women with a history of GDM to raise awareness of the health risks for these women and their offspring.

CURRENT RESEARCH

The NIDDK and other NIH Institutes and Centers are supporting a wide range of diabetes research efforts that are having a far reaching impact. For example, the NIH supports research to improve diabetes treatment strategies, to help patients achieve blood glucose control associated with reduced rates of complications and to reduce the burden of diabetes self-care. NIH-supported research contributed to the development of continuous glucose monitoring technologies, which reveal dynamic changes in blood glucose levels by assessing glucose levels hundreds of times per day and displaying trends. The NIH is committed to capitalizing on this technology and supports research on "artificial pancreas" technology to "close the loop" and link insulin delivery to continuous glucose measurements. This technology has the potential to benefit people with both forms of diabetes.

The NIDDK also supports research on cell replacement therapy for people with diabetes, which could potentially restore the body's ability to produce sufficient levels of insulin and properly control blood glucose levels. The NIDDK-led Beta Cell Biology Consortium is making significant progress in understanding beta cell biology and development toward the goal of generating unlimited supplies of beta cells in the laboratory for transplantation, or promoting growth of new beta cells in the pancreas. Because impaired function of the beta cell is central to both type 1 and type 2 diabetes, this research can inform treatment strategies for people with both forms of the disease.

Although the DPP identified effective strategies to prevent or delay type 2 diabetes, disease prevention remains a major goal of type 1 diabetes research. The NIDDK-led Type 1 Diabetes TrialNet is tackling this goal by conducting prevention trials, including a trial testing whether oral insulin could prevent the disease in people who have high levels of antibodies to insulin (a pre-clinical marker of disease). TrialNet plans to launch a second prevention trial with an agent proven to slow beta cell loss in new onset type 1 diabetes. An NICHD-led clinical trial, called TRIGR (Trial to Reduce the Incidence of Type 1 Diabetes in the Genetically at Risk), is determining whether weaning newborns at risk for type 1 diabetes to extensively-hydrolyzed

formula, as compared to standard cow's milk formula, will reduce the risk of developing type 1 diabetes.

Diabetes has a strong genetic basis that is modified by environmental factors. The last few years have seen unprecedented discoveries in diabetes genetics research. Recent research has identified over 40 genes or genetic regions associated with type 1 diabetes,[15] and 38 associated with type 2 diabetes.[16] The NIDDK is now supporting research to pinpoint the exact genes involved and to understand their function in health and disease. New insights about the genetic underpinnings of diabetes can inform new strategies for prevention or treatment, and even on a personalized or customized basis.

With respect to environmental factors, The Environmental Determinants of Diabetes in the Young (TEDDY) study has recently completed recruitment of over 8,000 newborns at high genetic risk for type 1 diabetes and is now following them to age 15 to identify environmental triggers of disease. Identification of a dietary or infectious cause of type 1 diabetes could have an enormously positive impact on public health through a diet change or vaccine for disease prevention, for example. Importantly, TEDDY may also contribute to understanding the development of celiac disease, which is an autoimmune disease primarily affecting the gastrointestinal tract. Some genes confer susceptibility to both celiac disease and type 1 diabetes, and many people have both diseases. Thus, TEDDY may benefit not only people with, or at-risk for, type 1 diabetes, but also people with celiac disease and other autoimmune diseases.

New insights about diabetes in youth are stemming from the SEARCH for Diabetes in Youth study, which is supported by CDC and NIDDK. SEARCH is defining the incidence and prevalence of diabetes in youth, which is important for informing public health efforts. Because of SEARCH, for the first time we now can estimate how many children in the U.S. have diabetes, and we will be able to see how the rates are changing over time. This knowledge could help to explain the findings from HEALTHY showing that overweight and obesity rates seemed to fall in both the intervention and control schools; SEARCH could help us determine if this trend is also being seen on a broader level.

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[15] Barrett JC, et al. Genome-wide association study and meta-analysis find that over 40 loci affect risk of type 1 diabetes. Nature Genetics 41: 703–707, 2009.

[16] Personal communication; unpublished data.

Another high impact program conducted jointly by NIH and CDC is improving standardization of hemoglobin A1c (HbA1c), which is a measurement that provides information on a person's average blood glucose levels for the past 2-3 months. This program has been important for translation of the good glucose control proven so beneficial in DCCT and other trials nationwide. I am pleased to testify today with Dr. Ann Albright, Director of the CDC Division of Diabetes Translation, because our agencies work so effectively together on efforts to combat diabetes, such as on this standardization program, the SEARCH study, the NDEP, and several other efforts.

COORDINATING RESEARCH ACROSS THE GOVERNMENT

Diabetes research is effectively coordinated throughout the government toward a common goal of improving health. One important venue for coordination is the statutory Diabetes Mellitus Interagency Coordinating Committee (DMICC), which is chaired by the NIDDK and includes other components of NIH and other HHS and federal agencies that support diabetes-related activities. The DMICC facilitates cooperation, communication, and collaboration on diabetes among these government entities. DMICC meetings help members identify emerging issues and opportunities and develop ways in which different government components can work together and build upon each other's expertise and resources. This approach helps ensure that federal diabetes activities are coordinated and not duplicated, and also stimulates collaborations.

The DMICC, with leadership by the NIDDK, has undertaken a diabetes research strategic planning process to help guide the federal investment in diabetes research. The draft Plan is currently posted on the NIDDK website and is expected to be finalized later this summer. The Plan was developed as a collaborative effort across federal agencies and with input from the external research and patient advocacy communities. The Plan will guide the NIH, other federal agencies, and the investigative and lay communities in our pursuit of a common goal of conquering diabetes.

FUTURE DIRECTIONS FOR RESEARCH

As the NIDDK reflects on the past 60 years of supporting and conducting research on diabetes, it is clear that the scientific progress achieved during that time period has been remarkable. People with the disease are living longer and healthier lives than they did a few short decades ago. However, diabetes still places an enormous personal and economic toll on our country, so it is critically important to continue the pursuit of research to make further improvements in patients' health and quality of life.

For example, it is critical to link glucose monitoring to insulin delivery to create an artificial pancreas, which can help people with diabetes achieve blood glucose control associated with reduced complications, as well as alleviate the everyday burden of self-care. Now that we are collecting thousands of samples through the TEDDY study, researchers can use new and emerging technologies to analyze those samples and identify an environmental trigger of type 1 diabetes. We must break the link between diabetes and its complications, and prevent the disproportionate burden that heart disease places on people with the disease. With the availability of many new medicines for type 2 diabetes, comparative effectiveness research can help inform doctor's decisions about what medicines to prescribe for their patients at different stages of disease to achieve the best health outcomes. Research can identify new strategies to help people maintain weight loss that is needed to prevent or delay development of type 2 diabetes.

Vital to these and other research efforts is the continued vigorous support of basic, pre-clinical, and clinical research, including research to address disparities in minority populations disproportionately burdened by diabetes. We will also continue to develop educational materials to disseminate new research findings to patients, their families, and health care providers. Strategic planning, including the new Diabetes Research Strategic Plan, will continue to guide future research directions. The NIH will remain steadfast in our goal to support and conduct research that can continue to improve the health of people with and at risk for diabetes.

In closing, thank you Mr. Chairman and members of the Committee for the opportunity to share with you a few highlights of NIH-supported diabetes research efforts. I am pleased to answer any questions you may have.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Diabetes and Digestive and Kidney Diseases
Biographical Sketch
Judith E. Fradkin, M.D.

Dr. Judith E. Fradkin became the Director of the Division of Diabetes, Endocrinology, and Metabolic Diseases (DEMD) at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) in 2000. She had previously served as the Deputy Director of the Division, Chief of the Endocrinology and Metabolic Diseases Programs Branch, Acting Chief of the Diabetes Research Programs Branch, and Director of the Cystic Fibrosis Research Program within the Division.

Dr. Fradkin graduated magna cum laude from Harvard College, received her medical degree from the University of California at San Francisco, and completed her internship and residency in internal medicine at Harvard's Beth Israel Hospital in Boston. She came to NIDDK as a clinical associate in 1979 after an endocrinology fellowship at Yale University. Dr. Fradkin is board-certified in Internal Medicine and in Endocrinology and Metabolism.

In her 31-year career at NIDDK, Dr. Fradkin has created or directed a diverse array of high-impact clinical and basic research programs, including multi-centered clinical trials to evaluate new approaches to prevent and treat diabetes and its complications, scientific consortia to define the genetic and environmental triggers of diabetes, and diabetes research centers. She is responsible for a major series of diabetes initiatives focused on beta cell development and function, improved glucose control through development of continuous glucose monitors and an artificial pancreas, and research on obesity, insulin action, and animal models of diabetes.

Under Dr. Fradkin's leadership of DEMD, major new clinical research networks have been created to conduct trials for prevention or delay of progression of type 1 diabetes, prevention of development of risk factors for type 2 diabetes in children, and comparison of treatment approaches to type 2 diabetes in children, and the landmark Diabetes Prevention Program clinical trial was successfully completed.

Dr. Fradkin serves as Chair of the Diabetes Mellitus Interagency Coordinating Committee, which is charged with facilitating collaboration on diabetes among Federal entities.

She also serves the on the Executive Committee providing leadership for the National Diabetes Education Program.

In addition to her oversight of major biomedical research programs, she has served as an endocrinology consultant at the National Naval Medical Center in Bethesda, Maryland, since 1984.

The recipient of numerous NIH and Public Health Service awards, Dr. Fradkin is also the 2003 recipient of the American Medical Association's Dr. Nathan Davis Award for outstanding public service in the advancement of public health.

Mr. PALLONE. Thank you, Dr. Fradkin.

Now we are going to have questions now from the members of the subcommittee, and I will start with myself for 5 minutes.

As you both know, the Diabetes Mellitus Interagency Coordinating Committee is in the midst of finalizing a diabetes research strategic plan. It is the first comprehensive research plan to be released in several years. I understand it is going to describe the future direction for 10 major diabetes research areas, and Dr. Fradkin, if I could start with you, can you briefly summarize the major focus areas of this report, and then I was going to ask Dr. Albright, she identifies the increasing rate of new diabetes cases as an area of great concern for CDC, so how do you think that plan will help stem the diabetes epidemic? I will start with Dr. Fradkin.

Dr. FRADKIN. Thank you. So NIDDK is pleased to chair the DMICC, which includes participation from CDC and multiple agencies across HHS and throughout the government and really serves as a very effective organization to bring us together to share information and develop plans. So we have developed with the help of over 100 external researchers chapters focusing on each of 11 critical opportunities, and these range from very basic areas such as autoimmunity and the beta cell function that I was telling you about to needs with regard to comparative effectiveness research and translational research to build translation from clinical research into translational research, and we have identified a number of opportunities for important clinical trials that we would like to undertaken if funds are available as well as some key opportunities utilizing new genomics, proteomics technologies to try to elucidate the basis of diabetes so that we can develop new strategies for prevention and cure.

Mr. PALLONE. All right. Thanks.

Dr. Albright, as I mentioned, how is this new plan going to stem the diabetes epidemic looking at the rate of new diabetes cases?

Ms. ALBRIGHT. There certainly is continued research that needs to be done in developing ways to reduce the onset of diabetes in those that have pre-diabetes and reducing the risk factors so people don't even into the world of pre-diabetes. So particularly the trend. There will be certainly chapters in this plan that will help with those more basic biologic mechanistic work, which is critical, but importantly, this plan also includes a chapter on translational research and that is an area that CDC and NIH and others share. We both have a role to play in the translation of the basic science into practice. So there will be questions and guidance in that chapter for how to identify those areas that are real world in which you take what we learn in a laboratory or in a contained setting and now you have got to take it out to the real world. So it important that we have studies that allow us to make those transitions, and then certainly from CDC's perspective, we then take that information and try to scale it and sustain it and be sure that there is a much broader research. Otherwise the discoveries that we made end up with a very limited reach, and that is not effective for the investment in research. We need to be sure that we get it out to as many people as we possibly can.

Mr. PALLONE. All right. Dr. Albright, let me ask you this. You talked about, you know, trying to promote fresh vegetables, fresh

fruit, that type of thing. I actually am still the vice chair of the Native American Caucus and I have taken an interest in diabetes as it pertains to Native Americans in particular, and also in urban areas, and I have always felt that the biggest problem is not having access to fresh fruits and vegetables. I remember when I went to the Tahona Odem reservation years ago, they were a desert people that relied on just, you know, nuts and fruits and things they gathered in the desert, and all of a sudden they are eating processed cheese and tacos and all this kind of stuff, and I know that they have made an effort there to try to go back to some of the subsistence agriculture, but it is often difficult for people. Like I take my kids to McDonald's. One day I was at McDonald's, and McDonald's is now starting to offer salads and fruits and different things that are better, but if you stand there for a half an hour, nobody orders any of that. They still order the burgers and everything. So how do you promote this effectively? And also, are there alternatives? Like some people have suggested that maybe use dietary supplements, vitamins, because if people aren't going to eat the fresh fruits and vegetables, there is some other way to supplement their diet through vitamins or whatever, I don't know. It just seems like even though there are a lot of people out there trying to promote the fresh fruits and everything that we continue to lose the battle, not just amongst Native Americans but just in general. I mean, it is sort of a comment, but if you could just—how do we get there and are there alternatives like supplements that could be used instead?

Ms. ALBRIGHT. I think that some of the things that we are trying that have an evidence basis behind them, and that is first important, that what we do try has an evidence basis behind it. I think part of the challenge is that we haven't been able to implement these on a large enough scale to have the kind of impact. We do have to change the culture and change the environment so that the healthier choice is the easier choice for people, and that can have to do with pricing strategies and other kinds of things that make it easier, so it is availability both from a geographic—you don't have to hike 10 miles to get an orange and you can reach right next to you and get a 52-ounce soda. So we have really got to make access to those things easier. That can be supported by policies and by pricing, other sorts of things that may help with that. So it is going to require a culture change.

As far as supplements, they may have a role to play if people are not getting adequate nutrition but really our major challenge is that people are overconsuming calories. So we do have to consider ways to reduce caloric consumption and that is what is resulting in the obesity epidemic and increase the physical activity opportunities which again is another situation where people need to have safer places to be physically active and know what they can do to improve their health. So while there certainly may be a role for supplements and vitamins and minerals, as a dietician I often recommend that people are taking those but they are not a replacement or an answer for reducing caloric intake and increasing physical activity.

Mr. PALLONE. Thank you very much.

Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. I have to continue my role as the burr underneath the saddle of the majority and the loyal opposition sometimes, but I need to stand up for McDonald's and understand the market. If they are not making any profit off those salads, they just wouldn't be selling them.

Mr. PALLONE. But they don't sell that many.

Mr. SHIMKUS. They must be selling enough to keep it on the menu board. My son used to get the apples over the fries but now he is older, he is moving to the fries now. But that is a real issue. They wouldn't—they are marketing and they are selling, and if they weren't—you know, they are doing it for the bottom line, but it is an educational aspect, so when parents are taking their kids in, you know, the parents can also choose healthy. They can set the example for the kids. But I just wanted to put that aside there.

And I also want to put down, the first of the health law's $569 million in tax increases starts today with the $2.7 billion tax on tanning services, so I just got a little blurb on that and wanted to put that on the record. We can celebrate.

Now, this is more in line with your visit here, and I do appreciate it, and it is a little technical so I have got to read some of this. You all, CDC and NIH through this section shows the positive benefits of lifestyle intervention, diet and physical exercise to individuals with type 2 diabetes, plus it has been known that diet plays a major role in treatment and management of type 1 diabetes, and we were talking about that. In fact, insulin's effectiveness requires diet interventions to manage diabetes and slow the progression of diabetes comorbidities, primarily cardiovascular, kidney and eye complications, again something that you were just referring to, Mr. Chairman. So this is a question directing about the registered dieticians who provide medical nutrition therapy which for a decade since the Benefits Improvement Protection Act, BIPA, as a lot of us like to say, passed has been a Medicare Part B-covered intervention for diabetes chronic kidney disease. Under the health care law, the Affordable Care Act, states that copayment and deductible fees are waived for prevention and interventions recommended by the U.S. Preventive Services Task Force with a grade A or B. CMS recently released proposed rules for section 4104 of the medical nutrition therapy, was given a grade B. So the U.S. preventive Services Task Force recommends intensive behavioral diet counseling for cardiovascular and other diet-related chronic diseases. Does CDC believe diet interventions for cardiovascular risk factors such as high blood pressure and high cholesterol for pre-diabetes and other diet-related chronic diseases should be included with diabetes and chronic kidney disease in Medicare Part B medical nutrition therapy? I know it is a lot. I had to read it. And if this is too big and voluminous, you know, if you could respond in writing or get back to us, unless you know the answer.

Ms. ALBRIGHT. Sir, I can't speak to the specific official position of our agency. What I would offer, though, is to think about those services that you are describing which are education and counseling. Those are important services. They will have limited impact if they are not undergirded and supported by other interventions that focus on making the opportunities for people easier to get to so the advice they get from their dietician, and I advise patients

as a dietician, they have to go home to their settings, and if those do not support easier opportunities to get those healthy foods and to participate in physical activity, it makes it more difficult to implement the advice that they are being given by their registered dietician whether it is for hypertension or for diabetes. So there are other opportunities to help support that education and counseling so it can actually have the best impact it could possibly have. But it does need to be supported by these other options and other sorts of things that allow people to make that choice, the healthy choice, much easier for them to make.

Mr. SHIMKUS. And if I may, has the Common Fund, which was established in the NIH reauthorization law, been used to coordinate diabetes research across NIH? Dr. Fradkin, do you know?

Dr. FRADKIN. So the Common Fund is actually focused on things that are of broad interest and are not disease specific with the idea that it is, for example, developing new technologies that will be applied to diabetes. But over half of the institutes, in fact, a great majority of the institutes and centers at NIH do participate in the Diabetes Mellitus Interagency Coordinating Committee which is the major coordinating function. Could I just speak to your previous question briefly also?

Mr. SHIMKUS. Oh, yes, if the chairman will allow.

Dr. FRADKIN. The study that I just mentioned that was just reported actually 2 days ago on a more cost-effective way to deliver the diabetes prevention program intervention, it provided people with three sessions with a dietician and then all the rest of the sessions were with low-cost community caseworkers, and they found a very dramatic reduction in weight. So that is an example of the kind of study that we support, you know, which does provide evidence for the value of dieticians. And if I could just make one additional comment? When the U.S. Preventive Services Task Force gives something a relatively low grade, that could be because it doesn't work, but often it is because it simply hasn't been studied.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Shimkus.

Next is the gentlewoman from Colorado, Ms. DeGette.

Ms. DEGETTE. Thank you.

Dr. Fradkin, my first questions nicely piggyback on Mr. Shimkus's question because one of the big concerns of the Diabetes Caucus for a long time has been the disparities between minority populations like African Americans, Latinos and American Indians and Alaska Natives and Anglos, and we are not really sure why those disparities exist other than a combination of factors of health access, community, environment, genetics, so I am wondering if you can talk a little bit more about any ongoing research by NIH to address the cause of the disparities because until we find out the cause, we can't really address how to deal with it.

Dr. FRADKIN. So first of all, we make a big effort to include minorities in all of our clinical research and in fact to over-represent minorities because they are disproportionately affected by diabetes, and in a study such as the diabetes prevention program, the interventions worked just as well in minority participants as in non-minority participants, but we do see some differences. So, for example, there has been research recently, for example, suggested that

African Americans may have higher hemoglobin A1C values at the same level of glucose values.

Ms. DEGETTE. Right.

Dr. FRADKIN. We need more research to look at that, but if that is the case, what it means is that they aren't necessarily getting worse glucose control but it is the measure of the glucose control that could potentially——

Ms. DEGETTE. Right, which means you are going to have different therapies for those groups. And then we have some groups like the Pima Indians we were talking about earlier where they have a huge percentage of their populations with type 2 diabetes and it could be that not necessarily those groups, dietary habits or exercise habits are that much worse than a comparable other population but that there is some kind of genetic propensity or something else that we could use. Is that right?

Dr. FRADKIN. Absolutely, and so most of the studies that have up to now been done in terms of genetics of type 2 diabetes have looked at Caucasian largely European populations and the NIDDK just established a very major genetics consortium to look specifically at genes for type 2 diabetes in high-risk minorities.

Ms. DEGETTE. And just for the commercial portion of my questioning, we have this minority disparities legislation which has attempted to deal with this exact issue, and Dr. Christensen has been a huge help and some of the other caucuses, Mr. Chairman, so we should really look at that bill too as we move along.

I want to ask you, Dr. Albright, very briefly about this new report that came out from the Robert Wood Johnson Foundation this week. Unfortunately, it is called F is for Fat and it says that the intensity, the rate of obesity continues to increase in 2010, particularly in the Hispanic and African American subpopulations, and this is despite all of CDC'S public health campaigns to improve diet choices and activities and everything else. I am wondering what CDC's strategy is to try to reverse this trend. I know CDC has been working assiduously on it but it just seems every time we get one of these reports, it is worse and worse. My State of Colorado is almost always the vast State but that doesn't mean it is good because it just means that the rate of obesity is lower than other places. It doesn't mean people aren't obese. I am wondering if you can talk about how we can ramp up our efforts to reverse these trends.

Ms. ALBRIGHT. It is certainly a significant issue and one that is going to require a multi-pronged approach. I think that is one of the things we all have to remember is that there isn't a simple single answer for this, it is multifactorial. Other divisions within CDC and other agencies in the federal government are certainly tackling and taking on obesity, particularly working on childhood obesity so starting early in life and trying to change those habits early in life. They are also working on things related to adult obesity prevention and treatment issues. Much of the focus is turning toward policies and changing the built environment that will help with that. There will need to be some time in order to determine the impact of those broader changes in policy that should have a much bigger impact on a larger segment of the population.

Ms. DEGETTE. Thank you. One last question for you, Dr. Fradkin. Going back to the special diabetes funding that we are trying to get reauthorized, what benefits, if any, does the multiyear funding stream in that program provide to the ability to fund the most promising research in the field and how important is that multiyear funding aspect of the special diabetes program?

Dr. FRADKIN. Let me give you an example of one thing that we did with the special funding that absolutely required multiyear funding. We created a program for career development, research career development for researchers studying childhood diabetes so we gave funds to the institutions that had very, very strong programs in pediatric diabetes research which enabled them to recruit in promising new investigators with the promise of 5 years of career support, and I can tell you that some of the people supported through that program have already made tremendous contributions so, for example, at Yale one of the investigators who was supported through that program has already got NIH funding and is working on trying to close the loop, and in fact three out of four of the people supported at Yale are now junior faculty there. We had to stop that program because we don't have 5 years of funding remaining and so as a result we couldn't offer people 5 years of career development support. That is just a specific kind of an example but I think it kind of gives the favor of why it is important, and many of things that we are doing like TEDDY where we have to follow kids until they are 15 just clearly require a sustained stream of funding.

Ms. DEGETTE. Thank you very much.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

The gentleman from Georgia, Mr. Gingrey.

Mr. GINGREY. Thank you, Mr. Chairman.

Dr. Fradkin, you responded to one of my colleagues just a few minutes ago, and this is not an exact quote but you essentially said when the United States Preventative Services Task Force gives something a low grade, it often means that it hasn't been well studied. I would like to ask your opinion in regard to the low grade that they, the U.S. Preventive Services Task Force, gave regarding screening mammography for women in their 40s to either prevent or early detection of breast cancer. Do you have any thought on that?

Dr. FRADKIN. I really have not followed screening mammography closely. That is not in my area.

Mr. GINGREY. But you are a medical doctor.

Dr. FRADKIN. So, you know, I think probably the grade that concerns us in particular relates to their grade on screening for identifying people with diabetes and with pre-diabetes where the quality of evidence that it would require for them to recommend supporting that would require many, many years because simply identifying people with diabetes or pre-diabetes doesn't rise to the status that they require to find something effective. You have to actually——

Mr. GINGREY. Well, let me pull back just for a second and then I will let you continue, because the reason I ask you that, I do have some real serious concerns, because you know that in the Patient

Protection and Affordable Care Act of 2010, sometimes referred to as Obamacare, that this task force will begin pretty darn soon to not just recommend but to mandate, and I think it is really important that we take a very, very close at that. But let me go ahead and shift to the area in which you are now involved of course.

With some 57 million Americans estimated today to have pre-diabetes, strategies to prevent or delay the progression to type 2 diabetes are critical to stemming the burden of diabetes on patients and our health care system. Do you think the existing guidelines sufficiently address the needs of patients with pre-diabetes or is it more important or more attention needed to ensure these patients have access to the most appropriate treatment options? My concern being that, you know, we know a lot of people have pre-diabetes. You gave a figure, an astoundingly large figure, but are we doing enough to really prevent them from progressing to full-blown type 2 diabetes?

Dr. FRADKIN. So I think this is where the kind of joint effort that Dr. Albright and I have been talking about is particularly important. We at NIH are doing research to try to figure out how to most cost-effectively prevent diabetes in those patients. We have a very strong program looking at multiple different ways to achieve prevention and specifically looking at culturally sensitive approaches, looking at what works best in particular populations and then CDC and actually it is wonderful to see even private payers, you know, building on the results of our research to try then to create public health programs that give people access to the things that the research has shown was effective. But clearly our research shows that about 90 percent of people with pre-diabetes don't even know that they have pre-diabetes and most of them are not taking effective steps to try to reduce their risk.

Mr. GINGREY. Thank you, Dr. Fradkin.

Dr. Albright, again, regarding that, and you mentioned the vast majority of cases in the United States today are preventable and certainly these many people with pre-diabetes. What are the top things that can be done to prevent these cases from progressing?

Ms. ALBRIGHT. At this point the evidence that we have suggests really scaling up and making this National Diabetes Prevention Program widely available to people. We are now offering it. CDC is providing funding to 11 sites. United Health Group is providing it to six. They have agreed to take over coverage of their beneficiaries so it is a very good public-private model. We will get the ball rolling in some of these locations and the private insurer can take over and continue to reimburse as time goes on, and so that is a nice combination. But we do need to get to more places and get to more locations, particularly harder to reach places. We need more entities that can deliver this in addition to the YMCA USA, who is outstanding, and other additional third-party payers. So we have got the beginning infrastructure there and it is time now for us to expand that infrastructure and allow it to reach across the country.

Mr. GINGREY. Thank you, Dr. Albright, Dr. Fradkin, and I will yield back. Thank you both.

Mr. PALLONE. Thank you, Mr. Gingrey.

Next is the gentlewoman from the Virgin Islands, Ms. Christensen.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman, and I want to thank you both for your testimony and your answers thus far.

Dr. Albright, you mentioned working with five States and six organizations. Do they have a good mix of the population, a good population mix?

Ms. ALBRIGHT. Yes, they——

Mrs. CHRISTENSEN. I don't know if you had mentioned what States they are or——

Ms. ALBRIGHT. Yes. We can't publicly announce them yet because the reviews have just been done, but we work to pay special attention to that. We first look for the best applicants. Certainly that is number one. But we are working and always seek to assure a wide representation of States and more territories and Pacific jurisdictions as well. We do provide funding to all of the U.S.-affiliated territories, so we are eager to have them involved as well.

Mrs. CHRISTENSEN. I just wanted to make sure that there was diversity represented in those States and organizations.

Ms. ALBRIGHT. Yes.

Mrs. CHRISTENSEN. Both of you have talked about the importance of the social and economic determinants of health, and certainly that is some of the reason why we haven't been able to make the impact in the African American, Native American, Hispanic communities. I have been supporting having an executive order similar to the one that President Clinton had issued back in 1998, I guess, around environmental justice requiring that all agencies of government, all departments do health impact assessments on their policies and programs and actually go beyond that to try to address some of the social and economic environmental issues through their policies. Is that something that you could support? Because it seems as thought we are not going to make any progress as long as people live in food deserts, have, you know, all of the social and economic and environmental barriers to improving their health.

Ms. ALBRIGHT. I can certainly say that CDC's focus is growing in that area under the leadership of our agency director, Dr. Tom Frieden. We certainly are focused on policies and environmental changes that will support that, and really one of the themes that CDC is really seeking help in all policies. It is going to take—because it is so multifactorial of a problem, we do have to consider and evaluate the kinds of things that we are doing to try to make inroads in these very broad areas in our society but it is critical that we do investigate them and find solutions within these multiple areas.

Dr. FRADKIN. Maybe I could just speak to one specific investigation that we have done in this regard that we actually just reported the results on this past week, and that was a huge study in which we looked at the environment in 42 middle schools focusing on the schools that predominantly serve minority and low-income students. Fifty percent were Hispanic, over 20 percent were African American. Most of them were on free or reduced lunch. And we looked in those schools at changing the food services, increasing physical activity, and also promoting behavioral change, and we got

some positive results. We didn't get everywhere we wanted to be but we saw reductions in obesity in the kids who started overweight or obese, which was half the kids in these schools were overweight or obese, and those children had reduced obesity as a result of this intervention, decreased waist circumference, decreased levels of insulin. So some positive impacts on risk factors for type 2 diabetes, and this is the kind of societal intervention that I think, you know, NIH likes to do research to test and then when we see results from studies like this, you know, then the public health agencies move to try to translate that.

Mrs. CHRISTENSEN. Thank you. I yield back, Mr. Chairman.

Mr. PALLONE. Thank you.

Mr. Space for 8 minutes.

Mr. SPACE. Thank you, Mr. Chairman, and thank you again for exhibiting your commitment to such an important issue by convening this hearing.

Where to begin? Dr. Albright, your testimony, and actually both of your testimonies, I think, underline the increase that we are seeing all types of diabetes and your testimony briefly alludes to, and I think some of my colleagues have referenced it very specifically, the cost that this is visiting upon our country, and just doing a little bit of quick math, assuming that we are somewhere north of $200 billion a year now, which I know is probably true. I know the ADA's study from a couple years ago, 2007, was at $174 billion. That computes to over a half a billion dollars a day that this disease is costing our society, and as Ms. Schakowsky pointed out, much of that is a direct governmental expenditure, and to put it in perspective, in 2009 we spent $148 billion on two wars in this country, and now we are spending upwards of $200 billion a year dealing with the effects of this one disease that has taken several different forms. Is it a safe assumption that with the increase in incidence of diabetes that these costs will continue to escalate?

Ms. ALBRIGHT. Yes. That would be the short answer.

Mr. SPACE. And much of the costs associated with diabetes consist of treating the complications of diabetes, correct?

Ms. ALBRIGHT. They certainly are associated with the costs of treatment. Fortunately, as we have said, there are ways for us now to prevent, and we have been trying to work to get those to be delivered as cost-effectively as possible.

Mr. SPACE. Right. So with the delivery of those preventive mechanisms and maintenance mechanisms, in the end you will mitigate the total cost associated with treating the complications that you can prevent or reduce through effective maintenance and treatment, and in the end, dollars spent today will result in a significant decrease in dollars spent tomorrow. Is that a safe statement?

Ms. ALBRIGHT. I think there are some little parameters you have to put around there when you are looking at cost-effectiveness. You are very right, that you have to look at the time horizon and you have to look at the assumptions, but there certainly are opportunities for us to drive the costs down in treatment and prevention so that we can indeed have more productive citizens who can be contributing to the economy in successful ways, so there is certainly benefit to doing that.

Mr. SPACE. If we were to develop a cure for diabetes, and I want to on subsequent panels maybe talk a little bit about we might better do that, but just hypothetically if we were to develop a cure for diabetes, and that cure can take many different forms, it could be an artificial cure like the closed loop system that you have referenced or it could be a more natural cure, perhaps some day some embryonic stem cell research, if you have got a young person that develops diabetes at the age of 6 or 7 years old was diagnosed with type 1, the complications that that child is likely to experience as a result of the disease are not likely to manifest themselves for decades, correct?

Ms. ALBRIGHT. That is right.

Mr. SPACE. So by the that child is 40 or 50 years old, his risk for heart disease, blindness, stroke, kidney disease, amputation is much, much higher than it would be for someone who is not diabetic at that age.

Ms. ALBRIGHT. Absolutely.

Mr. SPACE. What I am trying to drive at here is the future costs of this disease, as debilitating as they are today, you know, society in a country that can't afford the luxury of $200 billion a year in one disease, as debilitating as these costs are today, can you give us some projection as to where may be in 20 years or 30 years given the rather rapid increase in incidence of both type 1 and type 2 diabetes in the event that we do not see a cure and we do not see the implementation on a wide scale of some of the measures that you are testifying about today with maintenance? What will be the implications economically to the society in 20 years if we continue to go the way we are going now without massive intervention and maintenance and/or cure?

Dr. FRADKIN. Well, I think obviously the CDC is predicting that one in there children born today and one in two minority children born today will develop type 2 diabetes if we don't intervene and change things, but I would like to point out that things actually—there are some very real improvements in terms of the prognosis for people with diabetes that have effects on health care costs, so because rates of diabetes are increasing so fast, if it weren't for some of the effective things that we are doing to bring down the complications of diabetes, we would be seeing even greater costs than we are seeing today. So, for example, even though rates of end-stage kidney disease, which is a huge expense for Medicare, are going up, the actual proportion of people with diabetes who develop end-stage renal disease is falling. So if we weren't doing those effective interventions as diabetes is increasing, we would be seeing even greater increase in the cost than we are seeing.

Ms. ALBRIGHT. And I think this is definitely a combination of we are—this is—where we are seeing a greater number of people with diabetes, and that is because as people live longer, as we diagnose them earlier, as we catch them, people have undiagnosed diabetes, we are going to have a bigger total prevalence or total population. We want to drive that number down by reducing the new cases so that what resources we have can be delivered to effectively manage those people that have the disease and then hopefully over time not have a future of one in three and the devastating complications so we have got to make headway in preventing all forms of diabetes

and better treating diabetes because it also is where we will spend the cost. Yes, it does cost to take care of people with the disease, it does cost to prevent, but the opportunity to not have people suffer the ravages of this disease and continue to be productive members of society is a critical piece to be sure we keep in the discussion about the economics of diabetes.

Mr. SPACE. Thank you, Doctor. Thank you, Doctor.

I regret that I have no additional time.

Mr. PALLONE. No, that is all right. I mean, I am glad you don't because we are going to have a vote. We have three votes. I am going to try to get in our other two people here.

Ms. DEGETTE. Mr. Chairman, before you recognize, can I just ask unanimous consent to submit a folder of different statements by different groups about their activities for the record? And this has been cleared with the minority.

Mr. PALLONE. We will take a look at it first.

Ms. DEGETTE. They have seen it.

Mr. PALLONE. You have?

Ms. DEGETTE. Yes.

[The information appears at the conclusion of the hearing.]

Mr. PALLONE. Without objection, so ordered, and I am going to try to get in Ms. Schakowsky and Mr. Engel and then we will let you go and we will come back after the votes for the second panel. I recognize the gentlewoman from Illinois.

Ms. SCHAKOWSKY. I really—I think this is a quick question. There has been a lot of recent news about Avandia, the drug that is used to treat type 2 diabetes by increasing the body's sensitivity to insulin. Two new studies released earlier this week add to the body of evidence about the risk of heart attack, stroke and heart failure among people who take these drugs and those are of course the very things we are trying to prevent by treating diabetes. The FDA is holding an advisory committee meeting in July where the safety of Avandia will be under review, and I think this is an appropriate action at this time. While the FDA deliberates on the safety and effectiveness of this drug, I wanted to ask about the underlying research and public health implications. Dr. Fradkin, in your professional opinion, what are the implications of the recent studies? And Dr. Albright, if you have anything else to add.

Dr. FRADKIN. Well, let me just say that there are now multiple different classes of drugs that are available to treat type 2 diabetes as a result of research, and rosiglitazone, Avandia and pioglitazone are members of one of those classes of drugs. Most of the drugs have been approved based on relatively short-term studies that show that they are effective in reducing glucose but I think what we really need and what the strategic plan that the chairman referred to that the DMICC is developing is what we really need to head-to-head comparisons of the various drugs that are available for treating type 2 diabetes with longer-term time frames looking not simply at glucose lowering but looking at what they do over the course of diabetes in terms of heart disease, in terms of weight gain, in terms of quality of life for people, and we don't have those head-to-head comparisons and so most of the data like these current studies that you are referring to are basically analyses of observational studies. They aren't the ideal rigorous kind of research

that you need to answer the question, and the rigorous research is something that we need.

Ms. SCHAKOWSKY. So let me ask you, Dr. Albright, then what advice would you have for people who are taking Avandia right now? Because it appears that not only do we have to reduce the blood sugar but how we do it is very important, and obviously more and more research and studies scientifically based studies have to be done. But in the meantime, what do we tell them?

Ms. ALBRIGHT. Well, our response when we are asked, and we are asked these questions, is that it is critical that people have the discussion with their health care professional because as Dr. Fradkin referenced, there are other treatments. Their particular risks can be very carefully examined and determined. So it is important that people have a conversation with their health care provider because diabetes is a disease where you have to make lots of decisions and it is imperative that you have a good discussion with your health care provider to make those decisions for you as an individual.

Ms. SCHAKOWSKY. Well, all of this really is a humbling reminder that we still have a lot to learn about diabetes and that we need to do that, so thank you very much.

I yield back.

Mr. PALLONE. Thank you.

Mr. Engel.

Mr. ENGEL. Thank you, Mr. Chairman. I will try to speak very fast.

A hundred and thirty-five thousand women are diagnosed with gestational diabetes each year as well. I know that Dr. Burgess spoke about it. He and I have introduced the Gestational Diabetes Act, H.R. 5354, and we have gotten many cosponsors and I hope people on this subcommittee will all cosponsor it in a bipartisan way. And what our Act aims to do is lower the incidence of gestational diabetes and prevent women afflicted with this condition and their children from developing type 2 diabetes, and the legislation creates a research advisory committee headed by CDC to develop multi-site gestational diabetes research projects to enhance surveillance, provides demonstration grants to focus on reducing the incidence of gestational diabetes and expands basic clinical and public health research investigating gestational diabetes and current treatments and therapies, and I ask unanimous consent for my opening statement to appear in the record.

[The information was unavailable at the time of printing.]

Mr. PALLONE. Without objection, so ordered.

Mr. ENGEL. Thank you, Mr. Chairman.

Let me ask first Dr. Fradkin, and I will ask each of you one question. First of all, Doctor, congratulations on the NIH National Institute of Diabetes and Digestive Kidney Diseases 60th anniversary.

Dr. FRADKIN. Thank you.

Mr. ENGEL. It is because of the tremendous support of the National Institute's research toward understanding, preventing and treating diabetes that we are closer than ever to better fighting and curing the disease, so congratulations.

Could you tell me more, please, about the results of the hyperglycemia and adverse pregnancy outcome study? I guess it is the

HAPO study. And do you find that expansion of basic clinical and public health research investigating gestational diabetes and obesity during pregnancy such as our Act would be useful to further develop the insights gained from the hyperglycemia and adverse pregnancy outcome study?

Dr. FRADKIN. I can't speak specifically to the Act but I can tell you that I think gestational diabetes is one of the most important problems confronting us in the area of diabetes because not only does it cause problems at the time of birth for both the mother and the child, increasing rates of cesarean section and injury to the child but also it puts the mother at increased risk for subsequent diabetes but also we have data suggesting that the intrauterine environment puts the offspring at increased risk for diabetes and obesity. So you can imagine the vicious cycle that can occur as type 2 diabetes occurs at younger and younger ages moving toward people developing gestational diabetes or even type 2 diabetes during their childbearing years, then the offspring of that pregnancy not only has the genetic risk that it gets from the parent but also has the increased risk conferred by this adverse metabolic environment that also then increases the risk, so you can imagine sort of a vicious cycle where rates of diabetes will increase at expanding rates. So this is a cycle that we really need to break and I think the HAPO study has given us some extremely important information showing that adverse effects of hyperglycemia in pregnancy occur at much lower levels of glucose than we previously appreciated.

Mr. ENGEL. Thank you. Very well said.

Dr. Albright, you mentioned in your testimony that women with type 2 diabetes are at increased risk for having babies with birth defects and women with a history of gestational diabetes should receive targeted intervention strategies to prevent type 2 diabetes before they become pregnant, during pregnancy, postpartum and between. Can you please describe some of the intervention and educational outreach strategies the CDC is undertaking to increase awareness of gestational diabetes and the risks associated with it?

Ms. ALBRIGHT. Yes. Briefly, we are making special effort in the National Diabetes Prevention Program that we mentioned earlier to really put recruitments efforts and raising the awareness of women of childbearing years and their risk if they have had for GDM for developing type 2 diabetes and special efforts will be made to really try to seek to get them involved in this program. They are a terrific candidate for the National Diabetes Prevention Program. We also as part of the National Diabetes Education Program that Dr. Fradkin and I have the honor of working on together, we are working on some more gestational diabetes education efforts. We have received some funding from HHS and NIH will be taking the lead in doing some comparative effectiveness work with our NDEP materials. So we are continuing to work together in that area.

Mr. ENGEL. Thank you. And before I yield back, I just want to throw a little accolades to our counsel here to my left, Emily Gibbons. I am going to thoroughly embarrass her, but she was my long-term legislative director and health person, and Mr. Pallone stole her from me.

Mr. PALLONE. With permission.

Mr. ENGEL. With permission, and she does marvelous work and has done the work for both of us on gestational diabetes. So now that I have thoroughly embarrassed you, I yield back the balance of my time.

Mr. PALLONE. I will second that.

Thank you, Mr. Engel, and thank you both of you. This was very helpful. We really appreciate it, and obviously something that we have to deal with long term, but we appreciate your testimony.

And what we are going to do is take—we are voting now. We have three votes. It should take us to approximately 1:30. So if anybody wants to have lunch, we will reconvene at 1:30 and we will have our second panel. Thank you.

The committee stands in recess.

[Recess.]

Mr. PALLONE. The subcommittee will reconvene, and as I promised, we will begin with our second panel. Let me introduce each of you. First is Chairman Buford Rolin, who is vice chairman and national area representative for the National Indian Health Board and also chairman of the Poarch Band of Creek Indians. Thank you for being here. Then we have Dr. Robert Goldstein, who is senior vice president for Scientific Affairs of the Juvenile Diabetes Research Foundation, and Dr. Robert R. Henry, who is president-elect, Medicine and Science for the American Diabetes Association, professor of medicine at the University of California, Department of Medicine, and chief of the section of endocrinology, metabolism and diabetes at the VA Medical Center in San Diego.

I need to mention to the panel that Chairman Rolin is going to testify and then leave because he has to catch a plane and pervious commitments, but he will take written questions, and the way we work, as I think you know, we have 5 minutes' opening from each of you and then we take questions, but you can submit additional written statements if you like and then members may also follow up with some written questions as well.

So we will start with Chairman Rolin. Nice to see you again.

STATEMENTS OF BUFORD ROLIN, VICE CHAIRMAN AND NASHVILLE AREA REPRESENTATIVE, NATIONAL INDIAN HEALTH BOARD, AND CHAIRMAN, POARCH BAND OF CREEK INDIANS; ROBERT A. GOLDSTEIN, M.D., PH.D., SENIOR VICE PRESIDENT, SCIENTIFIC AFFAIRS, JUVENILE DIABETES RESEARCH FOUNDATION; AND ROBERT R. HENRY, M.D., PRESIDENT-ELECT, MEDICINE AND SCIENCE, AMERICAN DIABETES ASSOCIATION, PROFESSOR OF MEDICINE, UNIVERSITY OF CALIFORNIA DEPARTMENT OF MEDICINE, AND CHIEF, SECTION OF ENDOCRINOLOGY, METABOLISM AND DIABETES, VA MEDICAL CENTER IN SAN DIEGO

STATEMENT OF BUFORD ROLIN

Mr. ROLIN. Thank you, Mr. Chairman and members of the subcommittee. I am Buford Rolin, chairman of the Poarch Band of Creek Indians and vice chairman of the National Indian Health Board. I also serve as the co-chair of the Tribal Leaders Diabetes Committee and——

Mr. PALLONE. I am not sure, Chairman, that your mic is on. Is it green?

Mr. ROLIN. It is green.

Mr. PALLONE. Then you have to bring it a little closer.

Mr. ROLIN. Can you hear me?

Mr. PALLONE. That is better. Thanks.

Mr. ROLIN. I will just begin again.

Good afternoon, Mr. Chairman and members of the subcommittee. I am Buford Rolin, chairman of the Poarch Band of Creek Indians and vice chairman of the National Indian Health Board. I also serve as the co-chair of the Tribal Leaders Diabetes Committee, and on a personal note, I have lived with diabetes for the last 6 years. Thank you for inviting NIHB to participate in this important hearing. I apologize, but I must leave early to catch a flight.

Today, American Indians and Alaska Natives suffer disproportionately from diabetes. Indian adults are two times more likely to have diabetes compared with the non-Hispanic whites. In some tribal communities, more than half of the adults have been diagnosed with diabetes. Sadly, the highest rate of diabetes diagnosis has appeared among our young children and young adults. From 1990 to 2009, young native people ages 25 to 34 years experienced a 161 percent increase in diagnosis of type 2 diabetes. In addition, diagnosis of diabetes rose 110 percent in our teenagers 15 to 19 years old during the same period.

Despite these alarming statistics, progress is being made. This progress would not have been possible without the Special Diabetes Program for Indians. Congress created the SDPI in 1997 in the wake of increasing public concern about the burden of diabetes in native communities. In 1998, the Indian Health Service established the Tribal Leaders Diabetes Committee to provide guidance on SDPI, diabetes and related chronic diseases. Today, through SDPI, IHS provides funding in support for diabetes prevention and treatment programs, services and activities to over 450 IHS tribal and urban Indian SDPI programs, and it is working. Diabetes-related health outcomes have improved significantly in native communities since the launch of SDPI. For example, there is 11 percent decrease in the blood sugar level A1C in Indian people who have been diagnosed with diabetes. This decrease translates to a 40 percent reduction in diabetes-related complications such as blindness, kidney failure, nerve disease and amputations, 16 percent in total cholesterol level and a decrease of 20 percent in bad cholesterol. Research has shown that lowering cholesterol levels reduces the risk of developing complications associated with diabetes such as heart attacks, stroke or heart failure, 32 percent decrease in the prevalence of protein in urine and a risk of kidney disease. New cases of diabetes-related dialysis in Indian people decreased 31 percent between 1999 and 2007 while remaining relatively unchanged in other races. Preventing kidney failure is critical to help people with diabetes, avoid needing dialysis or kidney transplants. In addition, SDPI has enabled the IHS tribal and urban Indian programs to provide expanded screening, prevention and diabetes treatment services as well as to build a desperately needed infrastructure.

The committee should also know that the outcomes of the SDPI and knowledge gained through these scientific-based programs have helped to inform and advance other IHS diabetes programs such as the model diabetes program established under the Indian Health Care Improvement Act. The 19 model diabetes programs in the Indian health system have made significant contributions including state-of-the-art comprehensive clinical diabetes care through a multidisciplinary preventive and treatment approach. The Special Diabetes Program for Indians has been lifesaving to people who have diabetes, life-changing to those who have avoided diabetes because of early detection and prevention efforts, and perhaps most importantly, it is helping to ensure a diabetes-free future for our children and future generations. Making real progress in this area and ensuring that future generations will be free of the burden of this disease requires federal and tribal government collaboration. We have shown it can work. Now we need to recommit ourselves and this hearing is a good first step.

On behalf of the National Indian Health Board, thank you for this opportunity to address the subcommittee regarding this important issue. Thank you.

[The prepared statement of Mr. Rolin follows:]

National Indian Health Board

TESTIMONY OF BUFORD ROLIN
CHAIRMAN, POARCH BAND OF CREEK INDIANS,
VICE-CHAIRMAN, NATIONAL INDIAN HEALTH BOARD &
CO-CHAIRMAN, TRIBAL DIABETES LEADERS COMMITTEE

BEFORE THE HOUSE COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH
FOR THE HEARING ON
THE BATTLE AGAINST DIABETES: PROGRESS MADE; CHALLENGES UNMET
THURSDAY, JULY 1, 2010, AT 10:00 A.M.
2322 RAYBURN HOUSE OFFICE BUILDING

Good Morning Mr. Chairman, and Members of the Subcommittee:

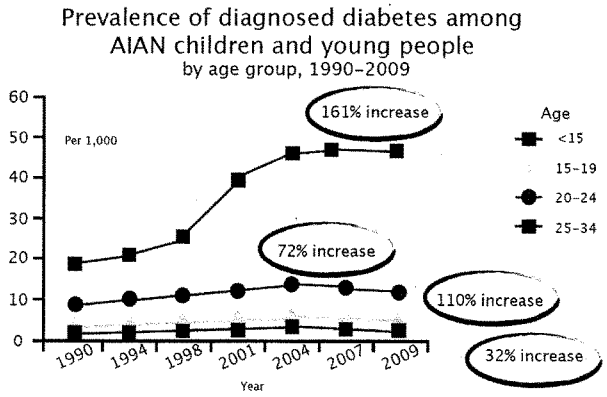
I am Buford Rolin, Chairman of the Poarch Band of Creek Indians and Vice-Chairman of the National Indian Health Board (NIHB). Thank you for inviting the NIHB to discuss the crisis of diabetes facing our American Indian and Alaska Native (AI/AN) people.

Established in 1972, the NIHB serves all 564 federally recognized AI/AN Tribal Governments by advocating for the improvement of health care delivery, as well as upholding the federal government's trust responsibility to AI/ANs. We strive to advance the level and quality of health care and the adequacy of funding for health services delivered directly by the Indian Health Service (IHS) or directly operated by Tribes and Tribal Organizations. Our Board Members represent each of the twelve IHS Areas and are generally elected at-large by their respective Tribal Governmental Officials within their regional area. The NIHB is the only national organization solely devoted to the improvement of Indian health care on the behalf of the Tribes.

AI/AN people suffer disproportionally lower health status and experience higher health disparities. In many tribal communities, diabetes is three to five times the national average. I am pleased that your Committee is working to both elevate this issue in Congress and to develop and support policies and programs to address the problem.

Diabetes in Indian Country

Less than 100 years ago, diabetes was virtually unknown in Native communities. Today, AI/AN communities suffer disproportionately high rates of type 2 diabetes. AI/AN adults are 2.2 times more likely to have diabetes compared with non-Hispanic whites.[1] Furthermore, in comparison with 8.7% of non-Hispanic whites, 16.3% of AI/AN adults have been diagnosed with diabetes.[2] In some AI/AN communities, more than half of the adults aged 18 and older have been diagnosed with diabetes, with prevalence rates reaching as high as 60%.[3] Adding to these troubling statistics is the rise of obesity and type 2 diabetes among our young people. The highest rate of increase has occurred among AI/AN young adults aged 25-34 years, with a 161% increase from 1990-2009. Alarmingly, type 2 diabetes rose 110% in AI/AN adolescents, 15-19 years old.



Source: IHS Diabetes Program Statistics

AI/AN people are also more likely to die from diabetes or diabetes related causes than other Americans. The diabetes mortality rate is nearly three times higher in the AI/AN population than the general U.S. population (2003-2005)[4]. The diagnosis of diabetes also leads to diagnosis of other diseases, which lead to further health complications. For example, AI/ANs have a 3.5

[1] Indian Health Service (June 2008). *Diabetes in American Indians and Alaska Natives: Facts at a Glance.* Retrieved from http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=resourcesFactSheets_AIANs08.
[2] Id.
[3] *Special Diabetes Program for Indians: Together We Fight Diabetes for our Ancestors, Our Communities and Future Generations* citing the Indian Health Service Report to Congress, 2007.
[4] Indian Health Service (January 2010). *Indian Health Service Factsheets: Indian Health Disparities.* Retrieved from http://info.ihs.gov/Disparities.asp.

times higher of rate of diabetes-related kidney failure compared to the general U.S. population in 2004.[5]

The Special Diabetes Program for Indians

Despite these alarming statistics, there is progress being made that, if continued, will help to stem the tide of diabetes in Native communities. It is difficult to highlight this progress without calling attention to the Special Diabetes Program for Indians (SDPI). That is because prior to the creation of SDPI, there was no focused federal effort to address diabetes in tribal communities. Moreover, in the twelve years since SDPI began providing support to communities for diabetes treatment, prevention and education, data has been collected that shows real progress.

Congress created the SDPI in 1997 in the wake of increasing public concern about the human and economic costs of diabetes in the U.S. and its growing prevalence among the AI/AN population. The SDPI was implemented through consultation with Tribes to develop the methodology and the process for distribution of the funds. In 1998, the IHS formally established the Tribal Leaders Diabetes Committee (TLDC) to provide advice and recommendations on policy and issues concerning diabetes and related chronic diseases. The TLDC is comprised of an elected Tribal Leader from each of the 12 IHS Areas, one IHS representative and one representative from five national organizations, including the NIHB. Currently, I have the honor to serve as the Co-Chair of the TLDC along with Dr. Kelly Acton with the IHS Division of Diabetes Treatment and Prevention.

The TLDC's collaborative effort with the IHS has been an important factor of the SDPI. The IHS recognized from the start of this program that it would have to make careful choices about where to invest these funds and knew these choices would best be made with input from Tribal leaders who serve on the TLDC. In addition, the TLDC plays a key role in ensuring that the IHS consults with Tribes before making decisions on diabetes treatment and prevention efforts.

Growth and Impact of SDPI

In the beginning, the SDPI funds provided funding to 333 non-competitive grant programs to IHS, Tribal, and urban Indian health programs in 35 states to begin or enhance diabetes treatment and prevention programs in Indian communities. The result has been the creation of innovative, culturally appropriate strategies that address diabetes. The Community-Directed Diabetes Programs continue today with 385 grant programs funded. The IHS encourages the use of the Indian Health Diabetes Best Practices and promotes the development of local programs based on local community needs and priorities. This focus on the local priorities and community centered has been the key to the success of the program as the local tribal community designs the program based on the needs of their community.

In 2004, at the direction of Congress, the SDPI expanded with the addition of two demonstration projects, which included 66 competitive grants. Thirty-six grantees participated in the Diabetes Prevention Demonstration Projects, which focused on preventing diabetes through lifestyle changes, such as exercise and weight loss. The remaining 30 grantees participated in the Healthy

[5] See note 1.

Heart Demonstration project that targets Indian people who have been diagnosed with diabetes by treating for related cardiovascular diseases.

Today, the IHS provides funding and support for diabetes prevention and treatment programs, services, and activities to over 450 IHS, Tribal and urban Indian program, serving nearly all federally recognized tribes. The following is a sample of some of the prevention, screening, and treatment services provided by the IHS, Tribal, and urban diabetes programs:

- Clinical annual examinations of the eyes, teeth, and feet to prevent diabetes-related complications
- Laboratory tests to assess diabetes control and complications
- Nutrition education and counseling services by registered dieticians
- Culturally appropriate diabetes education and awareness activities
- Diabetes primary prevention programs for children and families
- Community-based healthy eating programs at area schools and nursing homes
- Community physical fitness activities

Diabetes-related health outcomes have improved significantly in AI/AN communities since the inception of the SDPI. For example:

- One of the most important improvements is an 11 percent decrease in the mean blood sugar level (A1C) of AI/ANs with diagnosed diabetes, a major achievement over 12 years. Decreases of this magnitude translate to a 40% reduction in diabetes-related complications such as blindness, kidney failure, nerve disease and amputations.[6]
- The mean total cholesterol level has decreased by 16% from 1997-2009, and mean LDL cholesterol ("bad" cholesterol) has been reduced 20%. Research has shown that lowering cholesterol levels may help reduce the chance of developing cardiovascular complications associated with diabetes such as heart attacks, stroke or heart failure.
- The prevalence of protein in the urine (a sign of kidney dysfunction) was reduced by 32% between 1997-2009.[7] New cases of diabetes-related dialysis in AIANs decreased 31% between 1999 and 2007, while remaining relatively unchanged in whites and blacks. Preventing kidney failure is critical to preventing people with diabetes from needing dialysis or kidney transplants.[8]

The SDPI has allowed many of the IHS, Tribal and urban programs to provide preventive and other basic elements of diabetes care that was not available to AI/ANs prior to the SDPI. In fact, it is proving to be both a successful effort and a good investment. The SDPI funding has enabled the IHS, Tribal, and urban Indian programs to provide expanded prevention, screening and treatment diabetes services. Through an increase in prevention and screening activities, the economic costs of treating diabetes and diabetes-related complications in Indian communities

[6] *Special Diabetes Program for Indians: Together We Fight Diabetes for our Ancestors, Our Communities and Future Generations* citing Indian Health Service Report to Congress, 2007.
[7] *Special Diabetes Program for Indians: Together We Fight Diabetes for our Ancestors, Our Communities and Future Generations* citing Indian Health Service, DDTP Fact Sheet.
[8] *Special Diabetes Program for Indians: Together We Fight Diabetes for our Ancestors, Our Communities and Future Generations* citing 2009 USRDS Atlas available at http://www.usrds.org/atlas.htm.

should be lessened. However, more importantly, the SDPI funds have significantly enhanced diabetes care and education in AI/AN communities, as well as built a desperately needed infrastructure for diabetes programs.

The outcomes of the SDPI have helped to advance other IHS diabetes programs such as the Model Diabetes Program, which was established under the Indian Health Care Improvement Act. The Model Diabetes Program also promotes collaborative strategies with Tribes for the prevention and treatment of diabetes. The 19 Model Diabetes Programs in the Indian health system have made significant contributions, including state-of-the-art comprehensive, clinical diabetes care through a multidisciplinary preventive and treatment approach, and education and nutritional counseling services.

The Future

The vision of the TLDC is to empower AI/AN people to live free of diabetes through healthy lifestyles while preserving cultural traditions and values. The SDPI is a vital program that is fulfilling this mission of the TLDC. I am proud of what the SDPI has accomplished. This program has been life saving to people who have diabetes, life-changing to those who have avoided diabetes because of early detection and prevention efforts, and perhaps most importantly, it is helping to ensure a diabetes-free future for our children and future generations.

Diabetes is one of the greatest public health challenges facing Native communities as well as our country as a whole. Making real progress in this area and ensuring that future generations will be free of the burden of this disease will take the federal government and tribal governments working together. We have shown it can work. Now we need to recommit ourselves and this hearing is a good first step.

On behalf of the National Indian Health Board, I appreciate having this opportunity to provide this testimony. Thank you for inviting me here and I am happy to answer your questions.

Mr. PALLONE. Thank you, Chairman, and thank you. I know that you have to leave but I do appreciate your testimony, and I want you to know that I speak for myself but I think I can speak for everyone in saying that you were particularly conscious of the impact of diabetes on the Native American community and want to help in any way we can to deal with this epidemic. I appreciate your comments.

Dr. Goldstein.

STATEMENT OF ROBERT A. GOLDSTEIN

Dr. GOLDSTEIN. Chairman Pallone, Ranking Member Shimkus and members of the subcommittee, thank you for the opportunity to testify before you today. I am Robert Goldstein, senior vice president of Scientific Affairs for the Juvenile Diabetes Research Foundation. I am honored to be here today before this distinguished committee with my colleagues from the diabetes ct.

JDRF is the largest charitable funder and advocate of diabetes research worldwide. Since our founding 40 years ago by parents of children with type 1 diabetes, JDRF has awarded more than $1.4 billion to diabetes research.

Type 1 diabetes, also known as juvenile diabetes, is an autoimmune disease for which there is no cure, at least not yet. It is the second most common chronic disease affecting children. It is growing rapidly, particularly in our youngest children. Diabetes overall costs our Nation more than $174 billion a year and one in three Medicare dollars is spent on people with the disease. But the good news is that we are moving faster toward a cure for type 1 diabetes than ever before, thanks to a strong federal commitment to diabetes research funding as well as JDRF's private investment.

A key component of the federal investment is the Special Diabetes Program, which provides a critical 35 percent of NIH funding for type 1 diabetes research and supports the multicenter human clinical trials that are contributing to discovering better treatment. Let me highlight some of the key advances which benefit not only those with type 1 diabetes but those with type 2 diseases and other autoimmune diseases.

Researchers have discovered ways to slow the autoimmune attack that causes type 1 diabetes. Charlotte Cunningham, a 15-year-old from Maryland, was able to produce her own insulin for 3 years after receiving a drug treatment called anti-CD3, and today is better able to control her blood glucose levels. Great strides have been made in investigating therapies to regenerate and replace insulin-producing cells. Thanks to this research, Anne Sidell Demarek of Texas and now California, who received an islet transplantation, no longer suffers from frequent low blood sugar episodes which impacted her ability to care for her young son who unfortunately also has type 1 diabetes. Researchers have paired continuous glucose monitors with insulin pumps to develop an artificial pancreas to help those with type 1 more easily and accurately control their blood glucose levels. A study recently published in the Lancet found an early artificial pancreas system lowered the risk of low blood sugar emergencies in children and teenagers while they were asleep. Researchers have recently found a way to reverse diabetic eye disease, the leading cause of adult-onset blindness. Sally Cart-

wright, a 66-year-old type 2 patient, can now drive thanks to a treatment combining a drug and laser treatment.

As this progress shows, diabetes research is one of the world's most effective public-private partnerships focused on curing a particular disease, yet despite tremendous advances, there is still much work to be done. On behalf of JDRF and the millions of families affected by diabetes, I thank the committee for its leadership and strong support for the Special Diabetes Program, which is a key element of our continued success. We deeply appreciate your commitment and look forward to continuing to work with you to cure this devastating and costly disease.

Thank you again for holding the hearing. I will be happy to answer questions.

[The prepared statement of Dr. Goldstein follows:]

TESTIMONY

BY

ROBERT A. GOLDSTEIN, M.D. PH.D.

SENIOR VICE PRESIDENT, SCIENTIFIC AFFAIRS

FOR THE

JUVENILE DIABETES RESEARCH FOUNDATION INTERNATIONAL

AT THE HEARING ENTITLED

THE BATTLE AGAINST DIABETES:
PROGRESS MADE; CHALLENGES UNMET

BEFORE THE

HOUSE ENERGY AND COMMERCE COMMITTEE

SUBCOMMITTEE ON HEALTH

July 1, 2010

Chairman Pallone, Ranking Member Shimkus and Members of the Subcommittee, thank you for the opportunity to testify before you today on the state of type 1 diabetes research, the progress to date and the need for continued research along our path to a cure for this disease. I am Dr. Robert Goldstein, Senior Vice President of Scientific Affairs for the Juvenile Diabetes Research Foundation International (JDRF), and I am honored to be here today. I am also privileged to sit on the same panel with my colleagues – the American Diabetes Association and the National Indian Health Board – who are tremendous partners of JDRF's in the fight against diabetes.

JDRF is the largest charitable funder and advocate of diabetes research worldwide. Our mission is to find a cure for type 1 diabetes and its complications through the support of research. Until there is a cure, JDRF is also committed to working tirelessly to develop better treatments to improve the lives and health of people who have type 1 diabetes.

Since our founding four decades ago by parents of children with type 1 diabetes, JDRF has awarded more than $1.4 billion to diabetes research, including more than $100 million last year. To fund this research, JDRF volunteers and staff do their part every day to raise money through walks, galas and other events in communities across the nation. We are moving faster towards a cure for type 1 diabetes than ever before, thanks to the combination of federal diabetes research funding and JDRF's private investment, which is one of the world's most effective public-private partnerships focused on curing a particular disease.

Diabetes: Background on a Complex, Chronic, and Demanding Disease

About Type 1 and Type 2 Diabetes

Type 1 diabetes, often referred to as juvenile diabetes, is an autoimmune disease that causes the destruction of pancreatic beta cells, the cells in the body that make the hormone insulin. Insulin is required for people to get energy from food; therefore, people with type 1 diabetes must take multiple injections of insulin each day or continually infuse insulin through an insulin pump in order to survive. They must also monitor their blood glucose levels closely with frequent blood testing throughout the day and night and adjust their insulin levels, food intake and amount of exercise accordingly. Even with the most rigorous attention, many other factors can adversely affect a person's blood glucose levels, including stress, hormonal changes, growth spurts, medications, illnesses, and fatigue. The management of this disease is a constant battle, not only for the patients but also for their families and loved ones – low glucose causes potentially deadly medical emergencies such as seizure and coma, while high glucose causes debilitating and sometimes fatal health problems such as kidney failure, blindness, nerve damage, amputation, heart attack, stroke and pregnancy complications.

Typically, type 1 diabetes strikes in childhood, adolescence or young adulthood; however, it is not a disease one can outgrow. Warning signs of the disease include extreme thirst, frequent urination, drowsiness or lethargy, increased appetite, sudden weight loss, and vision changes. Unfortunately, diet and exercise cannot prevent the

onset of type 1 diabetes as is often the case with type 2 diabetes. Today, nothing can prevent the onset of type 1 diabetes.

Type 2 diabetes typically affects adults, although it is an increasing public health problem facing children. Injections are usually not required for people with type 2 diabetes because the pancreas produces insulin; the body just cannot process it effectively. Obesity and lack of exercise are important risk factors for type 2 diabetes. While the causes and management of type 1 and type 2 diabetes are different, the complications associated with the disease are the same. People with diabetes are two to four times more likely to have a heart attack or stroke than those without the disease. Diabetes is the leading cause of kidney disease, adult onset blindness, and non-traumatic amputations and is a leading cause of nerve damage. Overall, the risk of death for people with diabetes is about double that of people of similar age without the disease.

Incidence of Diabetes

Type 1 diabetes is the second most common chronic disease affecting children. Each year more than 15,000 children are diagnosed with diabetes in the U.S. Unfortunately, the number of new diagnoses of type 1 is increasing annually at an unprecedented rate. Historically, the diabetes research community has estimated the incidence of type 1 diabetes to increase, on average, by 2 percent per year. Currently, however, researchers believe increased incidence to be as high as 4 percent each year, with incidence of the disease rising particularly in children under the age of four.

In total, diabetes affects more than 24 million adults and children in the United States, and one out of every three Americans born in 2000 is predicted to develop some form of diabetes during his or her lifetime. Despite the staggering statistics of today, the outlook for the future is even bleaker: over the next 25 years, the number of Americans with diabetes is predicted to nearly double, while the cost of diabetes will almost triple.

Economic Impact of Diabetes

Diabetes is one of the costliest chronic diseases. In 2007, diabetes accounted for $174 billion in costs in the U.S, and 1 in 3 Medicare dollars is spent on people with the disease. The nation spends $11,744 for medical care for each person with diabetes, compared to $2,935 on people without diabetes, as of 2007. These increased costs are attributable to diabetes' role as the leading cause of kidney failure, adult blindness, and non-traumatic amputations, and a leading cause of nerve damage, stroke, and heart attacks. Continued research to better prevent, treat and cure diabetes will significantly reduce the incidence and economic impact the disease has on this country.

Progress in Type 1 Diabetes Research

Research offers the best hope for a cure for a patient with type 1 diabetes. In the forty years since JDRF's founding, we have not yet achieved a cure for this devastating disease, but investments in research have yielded new and improved therapies and treatments that now give people with type 1 diabetes greater quality of life and longer life expectancy. Today, people with type 1 diabetes have better tools to test and control

blood sugar, and significant progress has been made towards an artificial pancreas. The risks of complications are now lower than ever before, and thanks to research, doctors are beginning to have better ways to diagnose complications, slow their progression, and lessen their impact. And research has put us on a pathway towards therapies to restore the function of insulin-producing beta cells and stop the autoimmune attack that damages them. Many of the advances on the horizon would benefit not only those with type 1 diabetes but those with type 2 diabetes or other autoimmune diseases as well.

These many advances would not have been possible without the public-private partnership and steadfast commitment to diabetes research by the Congress and the federal government. On behalf of JDRF and the millions of families affected by diabetes, I want to thank the committee for its leadership in advancing diabetes research. Among your many contributions is your leadership in the Special Diabetes Program, a congressionally-mandated type 1 diabetes research program administered by the National Institutes of Health (NIH). The Special Diabetes Program provides a critical 35 percent of NIH funding for type 1 diabetes research and dedicates funding for the innovative and collaborative multi-center human clinical trials that are contributing to better therapies and treatments for people with type 1 diabetes. This public-private partnership must remain strong and stable if we are to capitalize on the advances to date and achieve our mutual goal of a cure for people with diabetes.

Immune Therapies: Research to Prevent Type 1 Diabetes
To prevent type 1 diabetes, one must know how the disease develops. Current evidence indicates that both a genetic pre-disposition and an environmental trigger cause type 1. Currently, by the time patients recognize the symptoms and receive a type 1 diabetes diagnosis, they have already suffered the devastating autoimmune attack that has destroyed most of the insulin-producing beta cells in the pancreas.

Research funded by JDRF and NIH could vastly improve the current standard of care. Thanks to research, we now know of about 40 gene regions associated with type 1 diabetes and can identify those who are genetically at risk. Long term studies are being conducted to identify the environmental trigger(s) of type 1 diabetes. And new therapies are being developed and tested to help prevent the disease altogether and enable newly diagnosed patients to preserve remaining insulin-producing beta cells and possibly even regenerate new ones. Promising research results in this area include:

- **Antibody Treatment Slows Autoimmune Attack in New Onset Type 1 Diabetes Patients:** NIH-funded researchers first identified a drug – a monoclonal antibody named anti-CD3 – that can slow the progression of type 1 diabetes. Together, JDRF and NIH funded the proof-of concept clinical trial that showed that a short 1-2 week treatment with anti-CD3 helps patients maintain or increase their ability to produce insulin naturally for several years after diagnosis. Patients on anti-CD3 therapy use less insulin and have more stable blood glucose levels for an extended period of time.

For example, Charlotte Cunningham from Maryland enrolled in the anti-CD3 trial soon after her diagnosis at the age of 10. While Charlotte now requires insulin at 15 years old, she produced her own insulin for three years after her diagnosis – helping her to better control her blood glucose levels and protect her from the complications that accompany type 1 diabetes. This success could not have been achieved without several Special Diabetes Program-funded programs at NIH, including the Immune Tolerance Network (which develops new therapies to treat/prevent autoimmune disease and to prevent or treat graft rejection in transplantation by inducing immune tolerance) and Type 1 Diabetes TrialNet (which also supports studies aimed at both preventing further destruction of insulin-producing beta cells in those newly diagnosed with type 1 diabetes, as well as developing the therapies to prevent the disease altogether).

Despite this tremendous progress, our work is not done. Pivotal phase III clinical trials on two different anti-CD3 drugs are now underway to further test their effectiveness. Continued federal support will allow for the additional research needed to determine how to prolong the effectiveness of the treatment, whether early treatment prior to disease onset can prevent diabetes or whether these therapies can be successful when given years after the onset of type 1 diabetes.

- **Vaccine to Prevent Type 1 Diabetes Onset:** Research toward the development of a vaccine to reverse the immune attack that causes diabetes holds great promise for type 1 diabetes patients. NIH- and JDRF-funded researchers have successfully cured and prevented type 1 diabetes in mice using a vaccine made of nanoparticles thousands of times smaller than the size of a cell, coated with proteins involved in immune cell communication. Thanks to NIH funds from the Special Diabetes Program, researchers have shown that these particles are safe for use in humans.

  The NIH, JDRF and privately-funded researchers are also working on promising vaccine therapies to preserve beta cell function in people newly diagnosed with type 1 diabetes.

Beta Cell Therapies: Research to Restore Insulin Production
Therapies to restore insulin production by beta cells in the pancreas would benefit all patients with type 1 diabetes and many with advanced forms of type 2. Researchers are focusing on replacing diseased beta cells with functioning ones from a human donor or from animals like pigs, as well as by changing different types of cells, such as liver cells, into becoming insulin-producing cells. Researchers are also investigating therapies to regenerate insulin producing cells either by copying existing cells or encouraging the pancreas to create new ones. While more work is needed to fulfill the promise of regenerative medicine, recent research toward that end includes:

- **Continued Progress in Islet Transplantation:** Researchers continue to improve the efficiency of procedures for transplanting islets from human donors to people with difficult-to-control or "brittle" diabetes. Thanks to efforts by the NIH and

JDRF, islet transplantation researchers worldwide are sharing information learned with each new procedure, and helping to quickly disseminate this knowledge.

- **Identification of the Gene Critical to Beta Cell Development:** Researchers have identified a gene, called Rfx6, which is required for the development of insulin-producing beta cells and other cell types in the pancreas. Mice lacking the gene failed to regenerate beta cells and most other cells in the pancreas. In people, deficiency of the gene resulted in diabetes in newborns. Research on beta cell development may help identify potential new treatments that could be used in both type 1 and type 2 diabetes.

- **Potential of Other Pancreas Cells to Convert into Insulin-Producing Cells:** A JDRF-funded researcher recently found that "alpha" cells in the pancreas – specialized cells that produce glucagon, not insulin – can spontaneously convert into insulin-producing beta cells without genetic manipulation. This finding is significant, especially since the alteration of genes is a process that cannot be easily translated into therapies for people. More research into alpha cells would be particularly beneficial for people who have long struggled with diabetes and have few or no remaining beta cells.

Glucose Control: Research to Advance an Artificial Pancreas

Until there is a cure, people with diabetes will need better tools to control their blood glucose levels, as better control will keep people healthier and help them avoid diabetic complications. The federally-funded Diabetes Control and Complications Trial (DCCT), a clinical trial of almost 1,500 people with type 1 diabetes conducted between 1983-1993, demonstrated that tight control of blood glucose levels through intensive insulin therapy could significantly reduce or delay many diabetic complications. A follow-up study – which was funded by the Special Diabetes Program and the results of which were published in *The New England Journal of Medicine* – found that intensive diabetes therapy aimed at achieving better glucose control reduced the risk of any heart disease event by 42 percent, and the risk of nonfatal myocardial infarction, stroke, or death from heart disease by 57 percent.

Despite the clear benefits of glucose control demonstrated by these studies, far too many patients with diabetes cannot achieve tight glucose control with traditional diabetes tools. For example, a 2005 study found diabetes patients who tested their blood glucose on average of nine times a day – far above the national average – spent less than 30 percent of the day in normal glucose range (between 90-130). These patients had higher than acceptable blood glucose ranges (over 180) for eight hours of the day and low ranges (less than 90) for two hours per day.

JDRF is working in partnership with the National Institutes of Health and private sector partners to accelerate the development and availability of new technologies to improve glucose control. These devices include the continuous glucose monitor (CGM) and the artificial pancreas (a closed-loop device that will consist of a continuous glucose monitor, an insulin pump and software to link the two) and will enable a person with diabetes to

maintain normal glucose levels by providing the correct amount of insulin at the appropriate time. Promising research includes:

- **Advancements in Glucose Monitoring Technologies:** Just within the past few years, new glucose sensing technologies that can monitor glucose levels continuously have come on the market. These CGM devices are a critical part of an artificial pancreas system, and have been shown to improve glucose control when used alone. NIH funded the original glucose sensor research which was developed by the private sector into CGM products. The NIH DirecNet program then tested the products and demonstrated benefits in children. JDRF then funded a larger trial including children and adults with type 1, whose results were published in *The New England Journal of Medicine*, which led to insurance coverage by major health plans. This public-private effort by NIH, JDRF and the private sector has enabled wide spread adoption of this beneficial technology. However, research has also shown there are limits to the benefits of CGM technology, which require the patients to respond manually to the data, something difficult to do continuously throughout the day and especially at night while sleeping. Thus, a parallel effort has been underway to accelerate the development of an automated artificial pancreas system.

- **Accelerating the Development of an Artificial Pancreas:** Early research funded by JDRF at Yale had shown that, by using sophisticated software in a hospital setting, CGM data could be used to effectively direct insulin delivery, creating an early artificial pancreas system. In 2006, JDRF funded a worldwide consortium of diabetes researchers, mathematicians, and engineers to develop and test the software algorithms for a first generation artificial pancreas. This consortium has developed, tested, and refined algorithms needed to automatically deliver insulin in various situations (e.g., during overnight, meals, exercise) in hospital-based clinical trials, and results to date show a first generation artificial pancreas system can improve glucose control throughout the day and lower the risk of blood glucose emergencies at night. Additional research is underway to further hone these software algorithms so they can be used in real life situations and tested to ensure safety and effectiveness. In 2009, the NIH funded multiple grants to help accelerate this process which are complementary to the JDRF funded research and funded through the Special Diabetes Program. As a result of this promising research, companies have announced plans to develop and commercialize artificial pancreas systems, a development that holds great promise for those with type 1 diabetes.

Complications Therapies: Research to Reverse Costly Diabetes Complications
Thanks to the public-private diabetes research partnership, diabetic complications are declining, and people with diabetes are living longer. The introduction of longer and shorter acting insulins and improved technologies – such as insulin pumps and CGMs – are helping many patients avoid unexpected and dangerous low blood sugars. Research funded by JDRF and the federal government has increased our understanding of how diabetes causes complications, and led to the development of new drugs and treatments to

stop, prevent or reverse the various complications. These complications include eye disease, nerve damage, kidney disease, heart disease and stroke, and they place a tremendous economic burden on society. Some of the exciting recent advances in this field include:

- **Reversing Diabetic Eye Disease:** Recent research has confirmed the ability to halt and reverse diabetic eye disease, a major complication of diabetes and the leading cause of adult-onset blindness. Research supported by the Special Diabetes Program and JDRF has shown that a treatment combining a drug and laser therapy is almost twice as likely to improve vision in people who have diabetic macular edema as laser therapy alone (50% vs. 28%). Improved vision was defined as being able to read two lines better on the eye chart, an improvement that could be the difference between being able to see well enough to drive, or hold a job – or not. The result of this research brings us one step closer to a new and much-needed treatment for diabetic eye disease, the first in almost 25 years.

- **New Gene Identified with Diabetic Kidney Disease:** Kidney disease is a devastating complication of diabetes and develops in 40 percent of patients with the disease. Researchers have identified a gene, called ELM01, that identifies people with type 1 diabetes who are at greater risk of developing kidney disease. More research is needed so that doctors can eventually identify type 1 patients with low, medium, and high risk for kidney disease and take steps earlier to mitigate the onset of kidney disease and its progression.

- **Reversing and Repairing Nerve Damage:** Research has shown the ability to reverse and repair diabetic nerve disease in the legs. People with diabetic neuropathy who were given a drug therapy had a significant increase in the number of small nerve fibers in the skin, which are responsible for sensation and motor function and are lost in diabetes patients with neuropathy complications.

Conclusion

As JDRF looks back on the last forty years since its founding, there is much to be proud of in the field of type 1 diabetes research. Tremendous research advancements have produced a number of new therapies and technologies that are undoubtedly improving the lives of people with type 1 diabetes. This progress, however, has yet to lead us to a cure for this devastating disease. We must redouble our efforts on both the federal level and in the private sector to ensure continued momentum toward our goal of a cure.

The renewal of the Special Diabetes Program is a key element of our continued success, and I would like to thank Rep. Diana DeGette for introducing H.R. 3668, which would provide a multi-year renewal of the program. I would also like to thank Ranking Member Shimkus for his contribution to the program's success, as he was the lead sponsor of legislation to renew the Special Diabetes Program in 2002. Additionally, JDRF is grateful to the majority of the Energy and Commerce Committee for co-sponsoring the bill and for the tremendous support you have given patients with type 1 and their loved

ones. JDRF wholeheartedly endorses this legislation, which has currently 281 bipartisan cosponsors, and knows all too well the program's importance in our mutual effort to understand, treat and eventually cure type 1 diabetes. JDRF will keep doing its part in this fight, and we hope that we can count on Congress to continue funding the medical research that will be necessary to maximize research opportunities and capitalize on the federal investment made in type 1 diabetes research to date. We have come too far along our path to a cure to turn back now.

Thank you again Chairman Pallone, Ranking Member Shimkus and Members of the Subcommittee for holding this hearing. I am happy to answer any questions you may have.

Mr. PALLONE. Thank you, Dr. Goldstein.
Dr. Henry.

STATEMENT OF ROBERT R. HENRY

Dr. HENRY. Well, thank you for the opportunity to testify today and to Chairman Pallone and Ranking Member Shimkus for holding this hearing. I am pleased to be here on behalf of the American Diabetes Association. My full written testimony has been submitted for the record, and in the 5 minutes I have, I will summarize it.

I have just come from the American Diabetes Association's 70th scientific sessions conference in Orlando, Florida, the world's largest diabetes research meeting, where over 14,000 diabetes researchers, providers and educators gathered to hear and discuss the latest in diabetes research. The CDC has identified diabetes as a disabling, deadly epidemic that is on the rise. Between 1980 and 2007, the prevalence of diabetes has increased by 300 percent. Its total cost is over $218 billion a year.

The Association is grateful to the committee for supporting vital HHS diabetes programs including the NIDDK, CDC'S DDT and the Indian Health Service. Because of this investment, our knowledge of the disease has been expanded and the critical work towards ending this epidemic can continue.

Our efforts have significantly changed the way diabetes is addressed in both the clinical and community settings. Since 1952, more than 4,000 research projects on type 1, type 2 diabetes and gestational diabetes has been funded by the American Diabetes Association. In 2009, the Association awarded $33.55 million in new research support. We strive particularly to bring research from bench to the bedside and swiftly into the hands of patients and care providers. We fund cutting-edge research. Association-funded work developed the first handheld blood glucose meters, a key tool to achieving diabetes control. Currently, our research has found a potential new treatment for diabetic retinopathy, a complication that makes diabetes the number one cause of adult-onset blindness.

We value our partnerships with key health organizations, and I am pleased to point to our continued work with JDRF in the development of an artificial pancreas that holds the promise of revolutionizing diabetes management for type 1 diabetes. We are committed to developing the pipeline of diabetes researchers including funding younger researchers and more minority investigators to ensure the vitality of future research. We have made great progress but more has to be done.

With this in mind, I want to outline several key next steps in the battle to stop diabetes. More attention must be paid to the pressing needs of special populations particularly affected by the diabetes epidemic including minority populations. We remain steadfast in our effort to support research that addresses these disparities. H.R. 3668, sponsored by Representatives Diana DeGette and Mike Castle, helps address this issue by renewing the Special Diabetes Program. SDP programs in American Indians and American Native communities and SDP-funded type 1 are highly successful. The pro-

gram expires in 2011, and I urge Congress to pass this legislation soon so this work can continue.

H.R. 1995, the Eliminating Disparities and Diabetes Prevention Access and Care Act, also seeks to address racial and ethnic health disparities related to diabetes. We thank Representative DeGette again for introducing this bill and Representative Donna Christensen for including it in the tri caucuses health disparities legislation.

We also must increase efforts to prevent and treat gestational diabetes. Representatives Eliot Engel and Michael Burgess have sponsored H.R. 5354, the Gestational Diabetes Act, which aims to lower the incidence of gestational diabetes in order to protect mother and baby and prevent future cases of type 2 diabetes.

Our collective fight to stop diabetes must be continued. Your leadership in combating this growing epidemic is absolutely essential. Thank you for your commitment to the diabetes community and it will be my pleasure to answer any questions you might have on these important issues. Thank you again.

[The prepared statement of Dr. Henry follows:]

American Diabetes Association.

Cure • Care • Commitment

Testimony of Robert R. Henry, M.D.,
President-Elect, Medicine and Science, American Diabetes Association

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 70th 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 our 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

Mr. PALLONE. Thank you, Dr. Henry.

We are going to have questions from the panel, and I will start with myself.

Dr. Goldstein, can you explain how the promising research you are doing with the NIH and the private sector on initiatives like the continuous glucose monitor, artificial pancreas was mentioned several times, how these are going to be better control diabetes and the disease's associated costs and complications? Because we know the costs are unbelievable. One out of three Medicare dollars is spent on diabetes.

Dr. GOLDSTEIN. Mr. Chairman——

Mr. PALLONE. And I ask Dr. Henry to comment as well.

Dr. GOLDSTEIN. The NIH-supported DCCT study in 1993 for the first time demonstrated that high-quality tight control of the blood sugar variations resulted in improvements. Over time, those patients have now been studied for 20 years and the complication rates have just dropped from very large numbers to 15 and 20 percent numbers so that the reduction in complication rate from just exerting tight control has been enormous. With the continuous glucose monitors, we have upped the ante because patients can now achieve high-quality tight control with lower risk for getting blood sugars that are too low and with just an improvement in the overall quality of life because they don't have to concern themselves so much with measuring blood sugars six, seven, eight times a day. So the JDRF supported a study that was published a couple of years ago that showed you could drive the hemoglobin A1C down which is directly correlated to reduction in complication rates, and we are in the phase now where we are working with everybody we can find, industry, other organizations, to implement high-quality tight control in as many patient populations as possible ranging from children, adolescents, pregnancy—we are just beginning to start there—and the idea is, while we are waiting for a cure, we want people to implement very high-quality control of their diabetes so that they will be in good enough health when the cure does appear.

Mr. PALLONE. Dr. Henry, you can answer that. Also, I wanted to ask you a question too separately about the Association's role as a government partner and how you strike a balance in addressing the needs of the different types of diabetes, you know, type 1, type 2, gestational. So if you want to follow up on him and then get into that.

Dr. HENRY. Well, I would say I agree with everything that Dr. Goldstein has stated, and clearly the goal for an artificial pancreas is to make it easier to be able to regulate the blood sugar within the normal limits and as you heard, complications are minimized by good glycemic control, particularly low blood sugars, hypoglycemia, which can have devastating consequences, as well as persistent high blood sugars, which leads to complications. So these can be minimized by feedback between understanding the blood glucose levels and injections of insulin.

The other thing that we found that the DCT research, the long term funded by the NIDDK data showed is that there was a legacy effect so that controlling diabetic patients today with type 1 diabetes had effects on cardiovascular disease, beneficial effects on car-

diovascular disease 10 years later so that there was this short-term—the study lasted for several years but even 10 years later there were significant benefits. So I think that it emphasizes that good control now will not only reduce the long-term consequences but they will have sustained benefits for many, many years.

In terms of the second question, can I ask you to repeat that?

Mr. PALLONE. I may forego that because I did want to ask something else. I am so interested in the issue as it affects the Native Americans, and Chairman Rolin left, but I just wanted to ask, he gave me the impression that we really were getting a handle on diabetes amongst American Indians. Is that—I mean, obviously there is some success but my recollection just talking to different tribes is that the incidence of diabetes is still on the increase and particularly amongst younger people. How do I reconcile that with what he said? I mean, he is not here so it is difficult but——

Dr. HENRY. Sure. I would be happy to. I think you are correct that the prevalence continues to rise in the Indian and the Native Alaskan population. However, we are doing a better job of taking control of those people so they are living longer but we are doing a better job of preventing the complications.

Mr. PALLONE. So more people are still contracting diabetes but you are able to control it and make them live longer?

Dr. HENRY. And many of the complications of the nerves and of the kidneys and the eyes, we have made substantial progress in reducing those so while there has been significant progress, as he states, the prevalence of the disease does continue to rise, though.

Mr. PALLONE. Thank you very much.

Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Dr. Goldstein, and Dr. Henry, you can chime in too, you talked about the islet technology and use, and I know in the early part of the decade there was widespread media reports on the promise of this, especially those with type 1 diabetes, and the hope was that they would be able to live without daily injections of insulin. You briefly mentioned one case. What is the promise of the islet use?

Dr. GOLDSTEIN. So the pancreatic islet transplantation study you are referring to, which was reported from Canada in the year 2000, was widely heralded and adopted and NIH studied it and the initial promise probably exceeded what could be delivered, but the long-term promise is quite interesting. So if we prepare islets from a donor, a cadaveric donor pancreas, and transplant that into somebody who has got relatively severe disease, typically with what is called hypoglycemia unawareness where they don't know that they are getting low blood sugars and could be prone to seizures and that sort of thing. The islet transplant actually reverses the hypoglycemia unawareness, even if you still have to take insulin, and for those patients who have had to continue to take insulin, the quality of their treatment has improved so much and two complications have begun to reverse, one in the eyes and one in the nerves. So it has had an important conceptual effect which we would call a proof of therapy that cell therapy or replacement therapy can actually work. That kind of replacement therapy requiring lifelong immunosuppression to prevent graft rejection is not exactly what we would like to give to our children, so we made improve-

ments on that and hopefully this will lead the way towards the next generation of productivity.

Mr. SHIMKUS. Great.

Dr. Henry, do you want to add anything to that?

Dr. HENRY. Well, I would only say that there was a large number of symposia at this recent ADA meeting in Orlando which addressed islet cell rejection and techniques to prevent rejection, techniques to stimulate other cells to become islet cells and so I think that this is a very sort of stimulating area of research that is currently ongoing.

Mr. SHIMKUS. Dr. Goldstein, you mentioned also in your statement, not the written but when you were talking, anti-CD3. Can you elaborate on that?

Dr. GOLDSTEIN. Can I divert your attention for 30 seconds?

Mr. SHIMKUS. It happens all the time.

Dr. GOLDSTEIN. Dr. Burgess talked about a soldier who was injured by a blast injury and was losing his pancreas surgically to save his life in other ways. That pancreas went to one of the islet transplantation programs in Miami. They recovered the islets from this soldier's damaged pancreas, sent them to Walter Reed. They were transplanted back, and he now has function and doesn't have diabetes because of that traumatic event. That couldn't have happened if there weren't a facility that understood how to prepare those islets.

Let me tell you about anti-CD3 in a moment, please. So type 1 diabetes is an autoimmune disease where the immune system reacts in an abnormal way. If we could stop that autoimmune response, we presumably can stop the attack on the insulin-producing cells. Anti-CD3 is a monoclonal antibody which blocks the autoantibody response. If you give it to Charlotte Cunningham within 4 or 5 weeks of the time she got the disease and blocked that autoimmune response, her body stops destroying insulin-secreting cells and she keeps them functional now almost up to 4 years.

Mr. SHIMKUS. Great. That is good news on hopefully future uses. And I will just end with this.

Dr. Goldstein, I know that the charity, JDRF, has a good ratio of money spent out versus overhead costs, and I was going to ask questions but I will just place that in the record because we do know that you are good stewards of the donations and I put on the record a family who especially since I got elected to the Congress has just been all over me, and they have two—their youngest boy is Kevin Covarubius. He has been up here for the Congress years ago. And what was challenging is that he as a young, young body was identified. Then his brother, who is older, only was identified in his late teens, like 18 or 19 years old, which I guess had Ryan appreciate what Kevin went through for all those years. So my hats off to the Covrarubius family for doing the work in the field, and I yield back, Mr. Chairman. Thank you.

Mr. PALLONE. Thank you.

Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman, and I want to thank both of you for coming and for all of the work of your organizations. I was getting a lot of thanks up here but really it is you and your

partners at the federal agencies that are doing all the work and all of the families too. Whenever Mr. Space and Mrs. Capps and the chairman and I and everybody will tell you that—even Mr. Shimkus will tell you that when these families come up to the Hill to testify and to talk to members, it is the most powerful evidence that we get up here. So thank you for that.

I want to follow up on a couple of questions. Both of you were talking about the islet cell transplantation work that has been done, and I just think it is worth noting as well as the anti-rejection issues, the other issue that we have right now with using the islet cells from cadavers is that the supply is—even if you could figure out the rejection issues, you would have such a low supply of existing islet cells that you couldn't possibly treat the existing populations. I am wondering if either of you or both of you would like to comment on that.

Dr. HENRY. Well, my comment would be that is likely to be true. The options of stem cells I think is really a true one, and while we still have to get around the rejection issue, because that has been sort of the thorn in the side of getting a cure, I think that stem cells still hold significant promise.

Ms. DEGETTE. And that is because with the stem cells you can actually make new cells versus the existing research where you have to just collect——

Dr. HENRY. Right, and hopefully immune tolerant so that they don't get rejected.

Ms. DEGETTE. Right. Let me ask you along those lines, the NIH recent work of trying to improve new cell lines, is that sufficient to be doing the research that is out there right now on the stem cell research and what about this issue of having cell lines that might have the genetic predisposition towards diabetes? What is the status from your perspective as private organizations?

Dr. GOLDSTEIN. There are now many approved lines for NIH funding. We think that is terrific. There are alternative sources for new lines from induced pluripotent stem cells, which are excellent resources, and disease-specific lines are being produced, for example, at the Harvard Stem Cell Institute with the technique of induced pluripotent stem cells and they are making the cells available for study by researchers. They include rare genetic disorders as well as things like type 1 diabetes. So I would say the rate-limiting event today is funding for research to take advantage of the available material more than we need to make even more material this week.

Ms. DEGETTE. Yes, because not only did we have President Obama's expansion of the embryonic stem cell research but just in the last few years we had discovery of the IPS cells and so now we need the funding to capitalize on that.

I just have one more question for both of you, which is, a lot of your testimony and the previous panel's testimony was around this concept of an artificial pancreas, and of course, as the parent of a diabetic, I follow these research developments with interest, and I think the closed loop system will be the next big step. How far away are we, though, from really developing, to being able to get clinical trials of the closed loop system and then to actually have it be widely available for folks?

Dr. HENRY. Well, there have been some clinical trials that are already being conducted and have shown efficacy in small numbers of patients. I think the difficulty right now is having sufficient funds to be able to do in larger populations of patients, and of course to research to make it more user friendly. Right now the artificial pancreases that have been studied are still bulky and large and they are very effective but not particularly adaptable to everyday life, and that is what we have to strive to do. But I think we are certainly heading in the right direction, moving quickly but perhaps not quickly enough.

Ms. DEGETTE. Dr. Goldstein?

Dr. GOLDSTEIN. The technology is a bit cumbersome at the moment. Not every teenager likes to wear it. And if we can package that and shrink it and make it more user friendly and get more widespread use, we will be able to take advantage of current technology. We need improvements. We are funding work that is going ahead full blazes in terms of understanding how to set an algorithm to describe exercise situation or sleeping at night situation with the infinite variety of details that a person might go through. But our notion is that to whatever extent we can automate the technology, we will get those tough-to-treat patient populations like adolescents and teenagers to use the technology, and that will make it better for everybody.

Ms. DEGETTE. Thank you.

Mr. PALLONE. I am going to try to finish, guys. You have 5 minutes each, which is fine. Because we have not only a series of votes but also a motion to recommit, so it will probably be at least an hour, so we are going to try to finish. So we will go to Ms. Capps next.

Mrs. CAPPS. Thank you very much for your testimony and also for your patience getting through this very long day. Two questions for each of you, and they can be brief and we can go to Mr. Space.

A couple for Dr. Goldstein. In your testimony, you state that type 1 diabetes typically strikes in childhood, adolescence or young adulthood, then you note that the incidence has increased particularly among children under 4. I wonder if you could briefly give us a couple of reasons for that if they are known.

Dr. GOLDSTEIN. I wish I could give you a couple.

Mrs. CAPPS. Or some kind of——

Dr. GOLDSTEIN. I should say two things quickly. About half the cases come in people 20 years old and older, so type 1 diabetes is not strictly speaking only a disease of children.

Mrs. CAPPS. Right.

Dr. GOLDSTEIN. What has happened from the epidemiologic studies in the past 5 years from both Europe and the United States is unfortunately we are seeing it in younger and younger children in a more aggressive version, and since nothing much has changed in the genetic structure of people, the assumption is that it is related to something in the environment, so studies are focusing on identifying a theoretical virus that could do that, some antigen within your body that——

Mrs. CAPPS. So there is no clear path or—and therefore we need a lot more research in this area.

Dr. GOLDSTEIN. We do.

Mrs. CAPPS. Let me move on, because you described also the disproportionate burden of type 2 and gestational diabetes on certain groups. I wonder if this also holds true for type 1 and can you tell us whether there are certain age groups beyond children under 4 that are particularly affected by type 1 diabetes, you know, with ethnic, racial, whatever kind of groups that you——

Dr. GOLDSTEIN. Well, type 1 diabetes appears to be an equal opportunity disease, and the numbers are fairly similar across ethnic groups. Where it is extremely important, for example, as in, let us say, Los Angeles, if we would like to get the technology into certain areas of Los Angeles to treat ethnic groups with type 1, that is a tour de force because that is not easily done without an army of educators and third-party pay, etc. So we have some of our artificial pancreas researchers working there on that. That is the hope for the future.

Mrs. CAPPS. I see. So it is going to depend on some other things. Maybe that will segue into questions that I have for you, Dr. Henry. These could have been interchanged with each of you.

Earlier today, Dr. Albright was talking about in testimony that CDC is actively working with the First Lady and Let's Move, that campaign to provide expertise in healthy eating and physical activity as a way to deal with diabetes, and they are also sponsoring the diabetes—CDC is—the diabetes prevention program Master Training Curriculum. I am particularly interested in types of prevention research and activities that will really work and that ties into areas like that they would work with particular community groups, and Dr. Henry, maybe you can tell us more about some efforts that your organization is getting behind and the advocacy community is working on in terms of outreach, specifically, how they are being tailored to meet the needs of individual communities.

Dr. HENRY. I think one of the major ways is in the application of the diabetes prevention program information which was highly effective, as you know, a 58 percent reduction in the development of diabetes in individuals who are able to lead a healthy lifestyle, so clearly one can make big inroads in that. The task has now been to take it to the community level, and that has been done. The translational part of that program has been initiated and we are obviously very supportive of that and has been done for a reasonable amount of money, as you heard, in the range of $250 to $300 per year per person, which is, I think, a reasonable amount of an expenditure. So I think that that is right now where our major efforts are going. But there are also many preventive efforts that are being directly truly at the pancreatic beta cell, which not only does it decline and cease in type 1 diabetes but it declines progressively in type 2 and is a major contributor to many of the complications through poor glucose control. So there is again a great deal of research focusing on preserving the beta cell, preserving and also treating the insulin resistance that you heard about because we now know that efforts directed at treating the insulin resistance, whether it be through lifestyle modification or through medications, prolongs the pancreas and gives it a longer period where it can produce sufficient insulin to maintain glucose control.

Mrs. CAPPS. Thank you very much.

Mr. PALLONE. Thank you.

Mr. Space.

Mr. SPACE. Thank you, Mr. Chairman.

Thank you both for being here today, and I certainly want to echo the remarks of my colleague, Mrs. DeGette, regarding how valuable the work that both your agencies do is. I have, Dr. Henry, for you first. Your testimony references special populations as being especially prone to contracting diabetes, and there has been some talk today about ethnic minorities and Native Americans, and there hasn't been much said, however, about geographic and demographic breakdowns. My district in southeastern Ohio, it is Appalachian Ohio. It is a very poor, very rural district. Some of my counties have actually twice the incidence of diabetes than the national average or even the statewide average, and I would be interested in your thoughts as to whether those types of demographics, location or access to health care facilities or poverty, whether or not they have negatively influenced the diabetes incidence rate and whether your studies are accounting for that and what can be done to offset that.

Dr. HENRY. I think that it seems unquestionable that is the case, and access to care is definitely one of the limiting factors because in many cases there is prodrome, not only obesity but different forms of obesity, that precede the development of at least type 2 diabetes and individuals at risk for gestational diabetes, and certainly those populations, they need to be effectively treated and have access to care. Just as well, I think that healthy lifestyles are difficult when you are poor. It is very difficult to eat the fruits and vegetables that we have talked about, and I think that that also increases the likelihood that individuals with a genetic risk of diabetes which it clearly has a genetic component are more likely to develop diabetes. So I think that those are real issues that have to be addressed, and I think that better access to preventive technology as well as better treatment of the comorbidities will translate to a reduction in the development of diabetes.

Mr. SPACE. Thank you.

And Dr. Goldstein, thank you, by the way, for meeting with me earlier today and taking time out of your busy schedule. We have about 2 minutes, and if you could give us just a very brief account of how the NIH funding works in conjunction with foundational funding that comes from sources like ADA and JDRF and how it works in conjunction with industry sources of funding for research and development from biotech and pharmaceutical companies.

Dr. GOLDSTEIN. So here is the 2-minute version. We work very closely with the NIH to do complementary things so we are not funding the same things, and I would say that most important piece of information is that the NIH, which has made a historically important investment in basic science and discovers new things, to develop those things, you have to pass that off as you go along. So initially new discoveries get in the hands of small companies. NIH has a modest program. JDRF has a modest program to encourage small companies to develop things. We like to nourish them along the pathway to get into proof-of-concept clinical trials, which is about the first place that large pharma becomes interested after you have already got some data. And once you have got the data and a phase III trial, large pharma becomes very interested. So, for

example, the anti-CD3 I spoke about, two large pharmaceutical companies are both taking that to market, and it costs lots of money to do that. We can't afford to do it nor can the ADA probably.

Early on, NIH gets us the discovery, but once you hit the small company level and the small biotech and the small investigators, the handful of people who are moving the next generation of science along, it is really hard to get money to do that these days. Venture capital has dried up, and the foundation world has said that is a gap we need to think about filling, how could we do it wisely, and that is exactly where we are focusing our more limited resources in a more strategic way. So we frankly pick and choose. We try to take something more promising and try to move it along to the point where it can either move or not, and that is a partnership that I would argue has served the United States of America very well in terms of being a model for how to do things for people, and at some point the big clinical translation apparatus comes into play and NIH has played an important role in doing that as well.

Mr. SPACE. Thank you very much.

Mr. PALLONE. We are going to have to end, otherwise we are going to miss the votes.

I thank my colleagues and both of you for your presentations. It was very helpful. The way we work is, we have about 10 days to submit written questions and particularly since Chairman Rolin had to leave, I am sure there will be some, and the clerk will send you those and then we ask you to get back to us as quickly as possible. But again, thank you, and I know there is a lot more to be done on this issue but at least we had a beginning here today.

And without objection, this meeting of the subcommittee is adjourned.

[Whereupon, at 2:18 p.m., the Subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Statement of the Honorable Anna G. Eshoo
Committee on Energy and Commerce, Health Subcommittee
Hearing on "The Battle Against Diabetes: Progress Made; Challenges Unmet"
July 1, 2010

Mr. Chairman, thank you for holding this important hearing on the progress of diabetes in our country. This is a critical public health issue.

According to the CDC, an estimated 23.6 million Americans—or 7.8% of the country's population—have diabetes. Another 57 million Americans have pre-diabetes. With 1.6 million new adult cases being diagnosed each year, we simply can't afford to continue down this path.

The vast majority of diabetes cases in this country are preventable. While a small percentage of diabetes patients are Type I diabetic (autoimmune disorder) at least 90% have Type II diabetes, characterized by "insulin resistance." Type II diabetes is most often caused by obesity, which has skyrocketed in the U.S. with no signs of slowing. Obesity rates in the United States are on the rise amongst every sector of the population, including children.

I commend the efforts of First Lady Michelle Obama with her "Let's Move!" campaign. The campaign brings national awareness to the issue of childhood obesity, while encouraging parents, parents, schools, and kids themselves to make healthy choices. Mrs. Obama spearheaded a task force which recently released a "Childhood Obesity Action Plan" with recommendations on how to prevent obesity. This is an excellent step in the right direction and I'm eager to hear from our witnesses about how we get people to actually *follow* these recommendations.

Addressing the obesity epidemic in our country is no easy endeavor. It requires a multi-pronged approach, including communities, schools, families, advertising, and personal choices. We've come leaps and bounds in the last century at closing the hunger gap, but we haven't done so with an eye toward health. The accessibility of cheap and unhealthy food, especially in low-income communities, without healthier alternatives, is a major contributing factor to the prevalence of obesity.

I want to thank our witnesses for being here today and I look forward to learning more about the progress of research in the area of obesity and diabetes.

Statement of Congressman Gene Green
House Committee on Energy and Commerce
Subcommittee on Health
"Battle Against Diabetes: Progress and Challenges"
July 1, 2010

Thank you Mr., Chairman for holding this hearing today on diabetes. I'm interested in hearing from our witnesses on the status of research at the CDC, NIH, and the National Institute of Diabetes and Digestive and Kidney Diseases.

I don't need to tell any of you here that diabetes is a serious, costly, and life-threatening chronic illness that affects more than 23 million Americans.

There are three types of diabetes: Type 1 diabetes is a chronic, genetically determined, and debilitating disease, Type 2 diabetes, formerly called adult-onset or noninsulin dependent diabetes, and gestational diabetes that some women develop late in pregnancy.

Diabetes is one of the most costly chronic diseases, costing the United States economy more than $174 billion annually in direct and indirect health care costs.

On average, individuals with diabetes pay $13,000 in annual health care costs, compared to $2,600 for individuals without diabetes. Insulin treats but does not cure this potentially deadly disease or prevent the complications of diabetes, which include blindness, heart attack, kidney failure, stroke, nerve damage, and amputations.

Diabetes is more prevalent in women than men and among certain racial and ethnic groups, including Native American, African American, and Hispanic and Latino populations. Our district, which is nearly 70% Hispanic, and Texas in particular have high rates of diabetes and pre-diabetes.

Approximately 1,727,000 Texans—10.4% of the state's population—had diagnosed diabetes, and many of them suffer from serious diabetes related complications or conditions.

The financial burden diabetes places on the health system in Texas is high—in 2007, the direct and indirect cost of diabetes in Texas was approximately $12.46 billion.

With diabetes as widespread as it is, I don't doubt that every one of us knows someone with the disease, either a friend, a neighbor, or a loved one. So we all know how much individuals with diabetes struggle to control their illness.

Their lives are dictated by a regimen of strict diets, painful blood sugar tests, multiple medications, and sometimes insulin, which they must rely on in order to survive.

Just as troubling is that almost 6 million individuals with diabetes do not know they have the disease, and won't learn it until they develop one of its life threatening complications.

An additional 57 million Americans suffer from a condition known as "pre-diabetes" that, when left untreated, will develop into diabetes.

We need to do more to educate people about the risks of diabetes, so they know what to look out for. There is also more we can and should do to screen for and diagnose the millions of individuals with undiagnosed diabetes and pre-diabetes.

Additionally, we need to ensure we continue funding research programs like those at CDC, NIH, the National Institute of Diabetes and Digestive and Kidney Diseases, and the Special Diabetes Program.

Promising advances have been made in determining root causes of the disease and finding a cure will depend on funded research initiatives and training the next generation of diabetes researchers, but Congress can do more to advance the research on diabetes.

Thank you Mr. Chairman and I want to thank the witnesses for appearing before the committee. I yield back my time.

U.S. Representative Kathy Castor
Committee on Energy and Commerce - Subcommittee on Health
Hearing on "The Battle Against Diabetes: Progress Made; Challenges Unmet"
July 1, 2010

- Thank you Mr. Chairman for holding this morning's hearing on a critical issue that every member of this subcommittee cares about a great deal.

- Each of us is affected in some way by diabetes. We all have a family member, friend, sibling or neighbor who struggles with diabetes. Many of us can remember a childhood friend growing up that may have been insulin dependent and relied on blood sugar tests throughout the school day to stay healthy.

- This disease affects more than 24 million adults and children and one of every three Americans born just 10 years ago will develop some form of diabetes during his or her lifetime.

- In my home state of Florida, just over 8% of the population has diabetes. In 2007 alone, the direct and indirect costs of diabetes in Florida were more than $12 billion.

- It is estimated that diabetes costs the U.S. economy $174 billion annually and one third of every Medicare dollar is spent on diabetes.

- I am particularly concerned about the trends in childhood obesity that are a head start for becoming an overweight or obese adult and increase the risk for type 2 diabetes later in life and gestational diabetes for pregnant women.

- In Florida, more than 33 percent of children are overweight or obese, which is higher than the national average. As the numbers of children who are overweight have increased in

recent years, campaigns to fight childhood obesity have sprouted around the country. I am encouraged by the First Lady's decision to make the fight against childhood obesity her priority by creating the Let's Move initiative.

- It is critical that we continue to fight known risk-factors for type 2 diabetes and some gestational diabetes cases that may be preventable by maintaining a healthy weight.

- As type 1 diabetes - an autoimmune disorder different from the other forms of diabetes - often affects children, it is also important that families are able to count on school nurses and faculty to be aware of warning signs of the adverse effects of type 1 diabetes, so that problems can be detected and treated before tragedy strikes.

- Just recently, in Pinellas County near my home, a young high school student passed away after going into a blood sugar "low" at school. No one at the school was able to recognize warning signs or detect his symptoms – he died overnight after slipping into a diabetic coma and never recovering. This student's death could have been prevented if appropriate education for school faculty was provided and someone was able to recognize his symptoms before it was too late.

- Again, thank you Mr. Chairman for holding today's hearing. I look forward to hearing from our witnesses about what is currently underway to address some of these issues and the work ahead to combat diabetes.

The Honorable Joe Barton
Committee on Energy & Commerce
Subcommittee on Health
The Battle Against Diabetes: Progress Made; Challenges Unmet
July 1, 2010

Thank you, Mr. Chairman for holding this hearing today. In this country, there are an estimated 24 million people afflicted with diabetes, a number that is projected to double in the next twenty-five years. Diabetes is a lifelong disease marked by elevated levels of sugar in the blood. The complications can be devastating, ranging from heart disease, stroke, blindness, to kidney disease.

Type one diabetes results from the body's failure to produce insulin -- the hormone that "unlocks" the body's cells, allowing sugar to fuel them. The most common form of type one diabetes is caused when the body's immune system attacks and destroys the insulin-producing cells of the pancreas. Although the common name for type one diabetes is juvenile diabetes, our witnesses from the Juvenile Diabetes Research

Foundation can attest that it is a disease individuals must manage their whole lives.

Type two diabetes, sometimes known as adult-onset diabetes, results from the body's inability to make enough or properly use insulin. Type two diabetes is the most common form of diabetes and its prevalence is rising every year. Approximately 57 million American are thought to have early signs of type two diabetes.

People at risk of type two diabetes can take steps to avert the onset of the disease and mitigate the effects of it. Balanced diets and increased physical activity can prevent the disease or its complications. Those individuals with histories of diabetes in their families must be especially vigilant. Mr. Buyer and others on this Committee advocate allowing employers and health plans to provide incentives to those who join wellness programs. I believe such incentives could go a long way to reversing the current trend in the growth of type two diabetes.

I look forward to hearing from our witnesses on the advances in medical technology for diabetes treatment. Several years ago, the promise of islet cell transplantation led many to believe that a major breakthrough in diabetes was near. However, we hear little about the potential breakthrough now. There have also been reports about the development of a vaccine to prevent type one diabetes. I look forward to asking the witnesses whether islet cell transplants are as promising as once thought, and I look forward to hearing from the witnesses on when and if a type-one vaccine will be available.

As promising as these new therapies are, it is unfortunate that the health reform bill passed by this Congress will make these therapies more expensive for consumers. In an April 22nd letter, the Administration's own actuary stated, "we anticipate that [the] fees and the excise tax [in the Act] would generally be passed through to health consumers in the form of higher drug and device prices and higher insurance premiums." I do not see how higher drug and device prices and higher insurance premiums fit the definition of reform. I am also

concerned that these new taxes will reduce investment in research and development that could yield future therapies and cures.

I want to thank the American Diabetes Association for being here today. The ADA has an office in Dallas, and I have participated in many of their events in the Metroplex. I would also like to thank the Juvenile Diabetes Research Foundation for testifying. Every year JDRF representatives from Texas come to Washington, and they always have a remarkable story to tell about the research their foundation supports. Thank you again Mr. Chairman for holding this hearing and I yield back the balance of my time.

July 1, 2010

Opening Statement of
Congressman John Sullivan
House Energy and Commerce Subcommittee on Health
"The Battle against Diabetes: Progress Made; Challenges Unmet"
2322 Rayburn House Office Building

Chairman Pallone,

Thank you for holding this important hearing on our nation's battle against Diabetes.

Diabetes is a terrible disease that is the leading cause of kidney failure, new adult blindness and amputation. This disease also takes a tremendous toll on the personal lives and families of its victims who must often times administer life-sustaining insulin injections and strictly monitor their diet and physical activity of those with the condition.

According to the Kaiser Family Foundation, my state of Oklahoma ranks sixth in the nation in our diabetes rate with 10% of our population afflicted. This is a public health crisis that must be addressed. According to the journal *"Diabetes Care,"* it is predicted that diabetes levels in the United States are likely to double in the next 25 years, resulting in 44.1 million sufferers by 2034! It is imperative that we explore our current understanding of the causes and consequences of diabetes and evidence-based prevention and management strategies used to combat the disease.

Being overweight is a risk factor for developing this disease, but other risk factors such as family history, ethnicity and age also play a role. In an era when we are faced with less time for

physical activity and the temptation and convenience fast food, it is important for all Oklahomans and Americans to take simple steps to live longer and healthier lives. By exercising regularly and maintaining healthy eating habits, individuals can feel better and control their diet and exercise, which will reduce their risk of chronic health conditions like, diabetes.

As a member of the bipartisan Congressional Diabetes Caucus, I am an advocate for finding a cure and for utilizing best practices with our public health efforts to combat the disease. I look forward to hearing the testimony of our witnesses today on examining research advances into type 1, type 2 and gestational diabetes so we can better fight this terrible disease that is a leading cause of death and disability in our nation.

I yield back the balance of my time

July 1, 2010

The Honorable Frank Pallone
Chairman, Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable John Shimkus
Ranking Member, Energy and
Commerce Subcommittee on Health
2322A Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Co-Chair, Congressional Diabetes
Caucus
2335 Rayburn House Office Building
Washington, DC 20515

The Honorable Mike Castle
Co-Chair, Congressional Diabetes
Caucus
1233 Longworth HOB
Washington, DC 20515

Dear Chairman Pallone, Ranking Member Shimkus, Co-Chair DeGette, and Co-Chair Castle:

We are grateful that the Subcommittee on Health has scheduled the hearing "The Battle Against Diabetes: Progress Made, Challenges Unmet." As you know, Novo Nordisk is a healthcare company with 87 years of innovation and leadership in diabetes care, and the U.S. leader in insulin. We welcome the opportunity to bring a few issues to your attention.

The timing of this hearing coincides with an editorial published in the medical journal *Lancet* which calls the explosion of diabetes in America "a public health humiliation" while calling for "a strong, integrated, and imaginative response." We agree wholeheartedly on the need for dramatic action and look forward to working with the committee to defeat this disease.

The Explosion of Type 2 Diabetes in America

With 24 million Americans already living with diabetes (a quarter of whom do not know they have the disease) and 57 million more with prediabetes and at risk for developing the disease, diabetes could reasonably be called the most important critical public health issue currently facing our country. Within the last 30 years, since 1980, the percentage of Americans diagnosed with diabetes has more than doubled. On its current course, by 2034, the number of people with diabetes will nearly double again to 44.1 million.

Diabetes is the leading cause of new cases of blindness, kidney disease and amputations. Research also suggests a relationship between diabetes and depression, Alzheimer's disease and other conditions. Thus, some clinicians and public health officials are increasingly referring to diabetes as a "gateway disease."

Overall, the risk for death among people with diabetes is about twice that of people without diabetes of similar age. In 2006, diabetes was the sixth leading cause of death on U.S. death certificates. Given the fact that the Centers for Disease Control has estimated that diabetes is vastly underreported as a cause of death, in reality, diabetes is one of the top killers in America – and its death rate continues to rise.

Already, diabetes is one of the most costly diseases in America. Factoring in the previously unidentified costs of undiagnosed diabetes, prediabetes, and gestational diabetes, the total diabetes-related costs in the United States in 2007 amounted to $218 billion. One in every 10 health care dollars is spent on diabetes and its complications, and one in every three Medicare dollars is spent on people with diabetes. According to a recent study by Thorpe et al published in *Health Affairs*: "Much of the recent growth in spending among Medicare beneficiaries is attributable to rising spending on chronic conditions—specifically diabetes and hypertension, both of which rose considerably in treated prevalence over the past two decades."

A report issued by HHS in November 2009, Preventing and Treating Diabetes in America: Health Insurance Reform and Diabetes in America, highlighted as a problem that "diabetes prevention and early treatment are under-emphasized" in the U.S.

Nowhere is this more evident than when examining federal funding for diabetes.

Inflation-adjusted, the combined federal NIH and CDC funding for diabetes has been *decreasing* since 2004, dropping from $1.009 billion in 2004 to $850 million in 2010 based on CPI-adjusted 2003 dollars. HIV/AIDS, on the other hand, received more than $4.6 billion in funding in 2010 (CPI-adjusted 2003 dollars), a funding level nearly 5 times higher than diabetes—for a disease whose prevalence is less than 1/10th that of diabetes. The important and necessary progress against HIV/AIDS is proof that we can make a difference in the fight against a disease state when we make it a national priority.

Among the chronic diseases, estimated per capita federal spending on diabetes prevention and research lags far behind that of heart disease, cancer, and HIV/AIDS. Per capita spending for diabetes is $55, vs. $111 for heart disease, $665 for cancer, and $3,609 for HIV/AIDS.

This disparity does not look to change soon, as the CDC budget request for FY 2011 for diabetes was $64.7 million, a *decrease* of $1.3 million below the FY 2010 Omnibus. Indeed, diabetes funding at CDC – the world's premier prevention agency – has been stagnant in real dollars since 2004, which has meant a significant decrease in real spending power over this time. During this same period of prevention funding stagnation, the prevalence of diabetes has increased by over 50%.

Without a significant national investment in the prevention of diabetes and diabetes complications, Americans, especially those who are disproportionately impacted by the disease - those in the Hispanic, African American and Native American communities - will continue to needlessly develop blindness and kidney disease, and be at far greater risk for amputation and early mortality from heart attack and stroke.

The Importance of Diabetes Screening

While every disease is important, not every disease is a public health crisis. Diabetes is a gateway disease that leads to many other health complications. Health reform will not be successful unless it succeeds at changing the way the country prevents diabetes and treats people who are diagnosed with diabetes. Novo Nordisk strongly supported the creation of the Public Health Fund and believes, if properly utilized, it could create a sea change in the care and treatment of diabetes and other chronic diseases.

We believe that as health reform is implemented, Congress and the Administration should place a high priority on ensuring a new, aggressive approach to screening people at risk for diabetes, along with prevention and treatment of diabetes. We have strong concerns that this priority is not yet reflected in several initiatives that should give more attention to diabetes.

First, we believe that HHS, CMS and CDC must make a commitment to promote diabetes screening and prevention for the Medicare population. Efforts to date to implement the Medicare diabetes screening benefit the Congress passed as part of the Medicare Modernization Act have been minimal at best. In addition, it is

critically important that community-based efforts to implement the Diabetes Prevention Program for the Medicare population is a clear government priority – and that it receive the funding necessary to make prevention a reality.

The Committee may be interested to know that people 65 and older have the highest prevalence of diabetes and prediabetes of any age group: Thirty-two percent of adults 65 and older have diabetes and 46% of them are undiagnosed. An additional 40% of those 65 and older have prediabetes. Taken together (and subtracting those with diagnosed diabetes), approximately 6 out of 10 remaining Medicare beneficiaries qualify for the Medicare screening benefit because they have diabetes risk factors.

Diabetes screening tests are covered once per year for all Medicare beneficiaries 65 years of age and with any one of the following risk factors:

*High blood pressure
*High cholesterol
*Obesity or overweight
*Family history of diabetes
*History of gestational diabetes

Two screening tests per year are allowed for those diagnosed with prediabetes. No co-payment or deductible is required.

The Diabetes Prevention Program, a major NIH clinical trial, found participants in the lifestyle intervention group—those receiving intensive individual counseling and motivational support on effective diet, exercise, and behavior modification—reduced their risk of developing diabetes by 58 percent. Lifestyle changes worked particularly well for participants aged 60 and older, reducing their risk by 71 percent. Follow-up studies show prevention or delay of diabetes with lifestyle intervention can persist for at least 10 years.

As such, it is particularly disturbing that the free, annual screening benefit is being vastly underutilized, especially given the large percentage of Medicare beneficiaries who are at risk. According to CMS data, in 2008 just 11.5% of beneficiaries used the Medicare diabetes screening preventive benefit.

To help address the critical need to promote diabetes screening and prevention for Medicare beneficiaries, the "Medicare Diabetes

Screening Project: A National Drive to Find the Undiagnosed" was created in 2006. The Medicare Diabetes Screening Project is a coalition of more than 20 national partners, co-chaired by the American Diabetes Association, the Healthcare Leadership Council, and Novo Nordisk, and supported by Novo Nordisk as a *Changing Diabetes*© leadership initiative. These organizations have worked with patient and senior organizations, providers, industry, and government agencies to promote the benefits of screening and prevention and to create local organizing models and messages that can be replicated across the country. It works.

For example, data available from CMS shows that the utilization rate of the Medicare diabetes screening benefit has increased by 16.2% from 2005 to 2008. In our pilot city of Columbus, Georgia, the screening rate increased by 50% from 2005 to 2008! And the Columbus rate was more than 60% higher than the statewide Georgia utilization rate.

It may interest you all to know that the Committee can take action today to help address the diabetes screening issue. Language in H.R. 1402, introduced last year through the leadership of Congressman Zack Space, Congresswoman Diana DeGette, Congressman Bruce Braley, Congressman Lee Terry, and Congressman Don Manzullo would evaluate why the uptake of the Medicare diabetes screening benefit has been so low and create a public/private outreach program to reduce the number of undiagnosed seniors with diabetes and prediabetes. This legislation has been scored at zero by CBO, and we urge the Committee to move it as soon as possible. The other provisions of H.R. 1402 are now law thanks to the leadership of Congressman Space and Senator Hagan; the bill's screening provisions should be passed by Congress as soon as possible.

Secondly, we are concerned that the current drafts of the Healthy People 2020 (HP2020) objectives - which represent the federal government's official stand on what needs to be achieved in diabetes over the next 10 years - do not include a specific recommendation to increase testing of people at risk for diabetes. Diabetes stands out among major chronic conditions in terms of its growing prevalence and climbing mortality rates— yet, unlike many others, it lacks a Healthy People 2020 screening objective around it. Other important areas of public health, such as HIV/AIDS, some forms of cancer, and cholesterol, all have specific screening or testing objectives proposed for Healthy People 2020.

Given the size and impact of the diabetes epidemic among the U.S. population, we believe there is a need to increase the proportion of at risk adults screened for diabetes. The inclusion of a diabetes screening test objective in the set of HP2020 Diabetes Objectives is crucial to establishing such testing as critical to the health of the nation. We have formally commented and met with the relevant HHS staff, but at this point, we have not received a positive response. We would welcome the opportunity to work in concert with like-minded Members on the Committee and the Diabetes Caucus to communicate the importance of having a screening objective in HP2020.

Prediabetes and the Promise of Prevention

According to the Centers for Disease Control and Prevention, 57 million Americans had prediabetes in 2007. In prediabetes, blood glucose levels are higher than normal but not high enough for a diagnosis. A patient with a fasting plasma glucose (FPG) test result of 100-125 may be diagnosed with prediabetes, versus 99 or below (normal) or 126 and higher (diabetes).

Individuals with prediabetes have an increased risk of heart disease and stroke. Many people with prediabetes develop type 2 diabetes within 10 years. As noted earlier, the good news is that lifestyle interventions including individual counseling and support towards effective diet, exercise and behavior modification have been shown to reduce the risk of diabetes onset.

H.R. 2590, the Preventing Diabetes in Medicare Act and introduced by Congresswoman Diana DeGette and Congressman Mike Castle, calls for covering medical nutrition therapy (MNT) for these beneficiaries, giving them the evidence-based tool they need to reduce the risk of diabetes onset. We urge Congress to pass this important legislation as soon as possible.

However, the opportunity exists for the Obama Administration to make this important change on its own accord. Currently, Medicare covers medical nutrition therapy (MNT) - nutritional diagnostic, therapy and counseling services from a registered dietitian or qualified nutrition professional - for beneficiaries with diabetes or renal disease who are referred by a doctor. However, until the enactment of the Patient Protection and Affordable Care Act (ACA), the Centers for Medicare & Medicaid Services (CMS) lacked the authority to extend the MNT benefit to beneficiaries with prediabetes: those most at risk of developing diabetes. Without nutritional counseling to promote

changes in diet, beneficiaries with prediabetes lack the most potent tool to reverse their condition and prevent the onset and enormous costs associated with ongoing treatment of diabetes.

Now, under current law, the Secretary would be authorized to modify the *current* coverage of MNT services such that the benefit is covered for both beneficiaries with diabetes or renal disease *and* beneficiaries with prediabetes. Novo Nordisk encourages the Secretary (or CMS) to adopt this common sense step to preventing diabetes in Medicare.

Diabetes and Minority Populations

Racial and ethnic minority communities are disproportionately affected by diabetes, at a rate nearly two times higher than their non-Hispanic white counterparts. Compared to almost 7 percent of non-Hispanic White Americans living with diabetes, nearly 15 percent of African Americans, over 10 percent of Hispanic/Latino Americans, and 16.5 percent of American Indians and Alaska Natives live with diabetes. If the rate of diabetes in minority communities is not improved, according to the Centers for Disease Control, 1 in 2 minority children born after 2000 will develop diabetes in his or her lifetime.

At Novo Nordisk, we believe that everyone should have appropriate diabetes prevention and treatment strategies regardless of race or ethnicity. Today, there are barriers that prevent racial and ethnic groups from taking better control of their health. There must be better interventions that are culturally sensitive and population specific, better cultural sensitivity training for health care professionals, and more career pipelines that lead doctors to work in underserved, high minority-populated areas.

There is legislation before the Committee, H.R. 1995, the Eliminating Disparities in Diabetes Prevention, Access and Care Act (EDDPAC) introduced by Diabetes Caucus Co-Chairs Congresswoman DeGette and Congressman Castle, which must be a high priority if we are to improve the rate of diabetes in minority communities. More research is necessary to understand the environmental and genetic predispositions that make the prevalence of diabetes higher in some racial and ethnic groups. More effective treatment and prevention strategies are necessary to better curb the onset of diabetes and empower those most affected to be responsible for their diet and lifestyle.

EDDPAC calls various federal agencies to action. The National Institutes of Health, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, and other federal health agencies would focus on researching the disparity in diabetes, stimulate culturally appropriate public dialogue on diabetes, and initiate programs to increase participation from minority health care professionals.

Without adequate funding and resources, diabetes and its complications will continue to ravage racial and ethnic minority communities. Data from diabetes prevention programs show that with the appropriate policy changes and long-term financial investment, diabetes rates will improve and lives will be saved. Novo Nordisk remains committed advocating for appropriate legislation and increased federal funding to eliminate the disparity in diabetes prevention, detection and treatment.

The Promise of Implementing the Diabetes Prevention Program

The National Diabetes Prevention Program (NDPP), a provision included in the recently-passed ACA, is targeted at adults at high risk for full onset of type 2 diabetes. Such adults are often overweight or obese, and therefore also at high risk for hypertension and high cholesterol. NDPP authorizes support for community efforts to establish, run, monitor, and evaluate affordable programs modeled upon the groundbreaking clinical trial, the Diabetes Prevention Program (DPP). The DPP intervention is an intensive overall lifestyle intervention, which although designed to be specific for people with prediabetes, will also positively impact other conditions, disease states, and outcomes. This community-based lifestyle intervention:

*Promotes weight loss;
*Encourages an increase in physical activity levels;
*Facilitates healthier eating habits;
*Improves the risk factors for cardiovascular disease; and
*Improves health-related quality of life.

As indicated earlier, the original DPP study found that individuals diagnosed with prediabetes that lost a moderate amount of weight (5 to 7 percent) and engaged in regular physical activity reduced their chances of developing type 2 diabetes by 58 percent. The Diabetes Prevention Program Outcomes Study (DPPOS), a 10-year follow-up of the DPP, shows that prevention or delay of diabetes and its complications persisted through the decade.

A report issued by HHS in November 2009, *Preventing and Treating Diabetes in America: Health Insurance Reform and Diabetes in America*, highlighted as a problem that "diabetes prevention and early treatment are under-emphasized" in the U.S. Solutions do exist that can be implemented today. YMCA of the USA, in conjunction with a host of public and private partners, has transformed the delivery of primary prevention programs for diabetes at the community level by translating the Diabetes Prevention Program through a community-based program, first in Indianapolis and soon in 17 sites across the country, together with the NIH, CDC and UnitedHealth Group. Novo Nordisk was the first private partner approached by UnitedHealth Group to join this initiative and we are actively working to put activities by our employees in place to support these efforts. We urge the Committee to further examine these and other successful prevention models that are on the ground, today, making a difference in people's lives.

While we recognize that this committee does not have direct jurisdiction over funding, the Committee Members can make a difference in the overwhelming need to fund the National Diabetes Prevention Program (NDPP) which falls under the jurisdiction of this committee. We urge committee members, individually or together, to support $80 million from the Public Health Fund to fund the NDPP and thereby support these cost-effective, community-based prevention interventions - precisely the kind of interventions the fund was created to support.

State and Local Resources Falling Short

It is important for Congress to seriously consider the impact of diabetes on our country's states and localities, and then act to provide the resources necessary to battle the scope of the epidemic. Research conducted last year by the National Conference of State Legislatures (NCSL) strongly suggests that current resources are falling far short of what is required to credibly prevent diabetes, diagnose the disease, and address its complications.

In 2009, the NCSL published a report entitled "Diabetes Health Coverage, State Laws & Programs." This review found the Centers for Disease Control and Prevention to be the primary source of support from the government for state and national activities associated with battling and preventing diabetes. The assessment found that of the approximately $60 million available to fight diabetes through the CDC during the last fiscal year, only $28.4 million in grants was available to

the states and territories to battle diabetes, control the disease and prevent it. This represents a 4.3% decrease in funds from the prior fiscal year. The balance of the CDC diabetes funding was used for surveillance or other activities. Further impacting resources available to states is a new funding formula that ultimately reduced diabetes funding available last year to 40 states and government entities including Tennessee, Colorado, New Jersey, Utah, Illinois, Pennsylvania and Arkansas. Some states experienced a 14% reduction in funding or more. The NCSL publication also suggests that the mandated state match is often not met, further limiting state commitment to diabetes public health activities.

The funding provided by CDC to states represents essentially the entire universe of public health resources available nationwide to battle diabetes. Responding to the data provided by NCSL, state and local legislators from across the country are requesting that Congress provide adequate resources to battle diabetes. Since July 2009, NCSL, Native American interests, the National Black Caucus of State Legislators and others have adopted resolutions calling for new resources dedicated specifically to helping people diagnosed with diabetes and its complications. A question for the Committee to consider is how seriously America can battle diabetes, diagnose the disease and prevent it when public health programs in communities across the nation have less than $28 million available. Put another way, does Congress believe that America can control a diabetes epidemic that currently impacts about 24 million Americans and their families, is increasing in numbers 7 – 8% per year, and costs nearly $13,000.00 per capita with a budget for state and local diabetes control activities that totals less than $28 million?

We believe it is imperative for Congress to provide funding and resources necessary to control diabetes as well working to prevent the disease, commensurate with the reach and scope of the epidemic.

Modernizing Congressional Budget Office Scoring

Novo Nordisk believes that our country is on the cusp of a new era in prevention, but such advances for people with diabetes and other chronic diseases will be muted if we do not update our budget laws to incorporate rigorous, credible disease-progression analysis into our official cost estimates. Official budget estimating process conducted at OMB and CBO tends to be narrowly focused on provider and institution payments, and are tied to a narrow budget window of 10 years. This limits the federal government's ability to consider more fully the long-

term savings from certain chronic disease interventions when estimating the budgetary impact of proposed legislation, rules, or waivers. Within health care, and specifically chronic disease treatment and prevention, the federal scoring process does not make use of disease-based modeling to inform projections of federal health spending. We believe this approach does not serve Congress or the nation well.

Research published in *Health Affairs* in 2009 by O'Grady Health Policy, LLC assessed current cost estimating models and recommended ways to change current practice by adding cost-estimating approaches that more explicitly incorporate projections of the disease burden in the future and the expected health care spending as a result. Diabetes serves as the model in this ground-breaking study.

Following the publication of this research, in July 2009, the Preventive Health Savings Act of 2009 (H.R. 3148) was introduced by Congresswoman Donna Christensen (D-VI), with support from Congressman Michael Burgess (R-TX) and 42 co-sponsors. H.R. 3148 will update existing budget law by directing the CBO to provide information, in certain circumstances, on the potential cost offsets of preventive health investments by: 1) using epidemiological data to model the progression of chronic illness; and 2) looking beyond the first 10-year window after an investment in preventive health is made. We believe Congress would benefit by having more long-term information on the impact of legislation which affects people with diabetes and other chronic diseases, and we urge all members of the Committee to consider this important legislation.

The Only Conclusion: It's Time to Modernize the 1974 National Diabetes Mellitus Research and Education Act

There is a wide-swath of diabetes-related legislation before the Subcommittee, evidence that a comprehensive approach is needed to address this crisis in America. Diabetes, particularly type 2 diabetes, has exploded since 1974 when Congress last addressed this issue in a comprehensive way through the passage of the National Diabetes Mellitus Research and Education Act (NDMREA). Today, we are fighting type 2 diabetes – which constitutes 90%-95% of all diabetes in the 24 million Americans who have the disease - with most of the same public health programs created in 1974, when there were only 4 million people diagnosed with diabetes.

Thirty-six years ago, Congress took bold, comprehensive action to make diabetes a national priority by passing the NDMREA. Congress' action resulted in a long-range plan with resource recommendations to combat diabetes. In 1974, no one could have envisioned the scope of the diabetes crisis as it exists today. We owe it to the millions of families who are living with diabetes everyday, and the tens of thousands of people who are fighting this disease on the frontlines, to ensure that our government's research and public health efforts match the challenge at hand. As such, Novo Nordisk strongly urges the Committee to act to bring the nation's diabetes infrastructure into the 21st Century this year by modernizing the National Diabetes Mellitus Research and Education Act.

Thank you for the opportunity to comment on this important hearing. We look forward to working with you on this critical issue in the days and months ahead. If we can be of further assistance, please do not hesitate to contact me or Christopher Porter in our Washington office at 202-626-4524.

Sincerely,

Michael Mawby

Michael Mawby
Chief Government Affairs Officer
Novo Nordisk

American Dietetic Association

1120 Connecticut Avenue NW
Suite 480
Washington, D.C. 20036
800/877-0877
www.eatright.org

June 30, 2010

The Honorable Diane DeGette
United States House of Representatives
Washington, DC 20515

Dear Mrs. DeGette:

RE: Energy and Commerce Subcommittee Hearing on Diabetes, July 1, 2010

On behalf of the American Dietetic Association, the largest professional organization of food and nutrition professionals, I am writing to share ADA's concerns and issues regarding the lack of coverage for interventions aimed at reversing pre-diabetes. ADA's more than 71,000 members, most of whom are registered dietitians, thank you for your ongoing support to secure coverage for medical nutrition therapy (MNT) for pre-diabetes.

For almost a decade, the Centers for Medicare & Medicaid Services has covered Medicare, Part B MNT outpatient services by a registered dietitian for diabetes and for chronic kidney disease and renal transplantation. CMS has just issued proposed rules for Affordable Care Act Sec. 4104, Removal of Barriers to Preventive Services in Medicare. ADA is pleased that CMS has awarded a grade of "B" to MNT based on U.S. Preventive Services Task Force recommendations. For one, this means that coinsurance/deductibles have been waived for Medicare beneficiaries to improve access to MNT.

ADA remains concerned cautiously optimistic that CMS's decision in the proposed rules to designate MNT as a USPSTF "B" service, translates to includes pre-diabetes. The optimism is based on USPSTF's recommendation in its 2003 report titled "Behavioral Counseling in Primary Care to Promote a Healthy Diet," the basis for MNT's "B" grade.[1] The recommendation is more expansive, stating that USPSTF "*recommends intensive behavioral dietary counseling for...known risk factors for...diet-related chronic disease.*"

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[1] **The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians.**

Rating: B Recommendation.

Rationale: The USPSTF found good evidence that medium- to high-intensity counseling interventions can produce medium-to-large changes in average daily intake of core components of a healthy diet (including saturated fat, fiber, fruit, and vegetables) among adult patients at increased risk for diet-related chronic disease. Intensive counseling interventions that have been examined in controlled trials among at-risk adult patients have combined nutrition education with behavioral dietary counseling provided by a nutritionist, dietitian, or specially trained primary care clinician (e.g., physician, nurse, or nurse practitioner).

Accessed June 28, 2010: http://www.ahrq.gov/clinic/3rduspstf/diet/dietrr.htm

ADA would greatly appreciate you agreeing to confirm that CMS will act on Congress' intent to expand and cover MNT to help Medicare beneficiaries manage diet-related risk factors for chronic disease such as hypertension, pre-diabetes, obesity and chronic conditions such as cardiovascular disease, diabetes, kidney disease and others. CMS needs to clarify in the Medicare final rule for CY 2011 that MNT and intensive behavioral counseling provided by RDs are covered for these conditions recommended by USPSTF, including pre-diabetes.

ADA supports your efforts to cover appropriate interventions for pre-diabetes. Please feel free to contact me at mhager@eatright.org or (202) 775-8277.

Best regards,

Mary H. Hager

Mary H. Hager, PhD, RD, FADA
Director, Regulatory Affairs

C: Heather Foster

July 1, 2010

The Honorable Frank Pallone
Chairman, Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable John Shimkus
Ranking Member, Energy and Commerce
Subcommittee on Health
2322A Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Co-Chair, Congressional Diabetes Caucus
2335 Rayburn House Office Building
Washington, DC 20515

The Honorable Mike Castle
Co-Chair, Congressional Diabetes Caucus
1233 Longworth HOB
Washington, DC 20515

Dear Chairman Pallone, Ranking Member Shimkus, and Co-chairs DeGette and Castle,

Diabetes, as a chronic disease affecting nearly 24 million Americans and often leading to multiple chronic conditions or co-morbidities, is a critical public health issue for the nation. Within the last 30 years, the percentage of Americans diagnosed with diabetes has more than doubled. On its current course, by 2034, the number of people with diabetes will nearly double again to 44.1 million.

Enclosed are several documents from members of the Diabetes Action Alliance (DAA) which have been sent to various agencies and officials in our efforts to gain funding for the National Diabetes Prevention Programs (NDPP), as well as to include an objective focused on diabetes screening in Healthy People 2020. We believe these two areas are critical in the efforts to help properly manage and prevent the diabetes epidemic and ultimately its related conditions.

The DAA is made up of nine diverse organizations who have come together to speak in one strong voice with the vision of changing how the nation perceives and approaches the problem of diabetes. Our current members include the American Association of Clinical Endocrinologists, American Association of Diabetes Educators, American Clinical Laboratory Association, American Diabetes Association, American Optometric Association, Medicare Diabetes Screening Project, Novo Nordisk Inc, The Endocrine Society, and Vision Service Plan.

Already, diabetes is one of the most costly diseases in America. Direct and indirect costs for diabetes and prediabetes were estimated at $218 billion in 2007. The good news is that we have proven interventions, such as the NDPP, that lead to therapeutic weight loss and reduction in diabetes risk factors. What's more, we have shown that these evidence-based interventions can be offered affordably.

We appreciate the opportunity to provide these letters and comments to you. If we can work together to change diabetes, we will at last make a significant change to the health of our nation.

Sincerely,

Diabetes Action Alliance

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

March 23, 2010

Dear Secretary Sebelius:

Thank you for your leadership during American Diabetes Month in November 2009 and on related efforts to bring attention to the needs of those with diabetes. As leading organizations in the diabetes community, we write to request a meeting with you and your team so we can discuss the significant burden diabetes poses to the nation and ways the federal government can make an impact.

Before taking office, President Obama highlighted the need to reorient our health care system "towards prevention and public health" in his *Plan for a Healthier America*. Health reform legislation just passed by Congress would allocate at least $15 billion over 10 years to prevention and wellness efforts—which represents an important step toward this reorientation.

As you consider the implementation of Administration or Congressional funds for disease prevention and health promotion, we urge you to **provide substantial resources toward diabetes**, given the magnitude and the seriousness of the disease in the US population, and its disproportionate impact on minority populations.

Every day, diabetes continues to exact a significant human and financial toll.

- Some 4,400 Americans develop diabetes each day. In fact, almost every 20 seconds someone is newly diagnosed with diabetes.
- Nearly 24 million Americans already have diabetes and another 57 million have pre-diabetes and are at risk of developing the disease.
- Within the last 30 years, since 1980, the percentage of Americans diagnosed with diabetes has more than doubled. On its current course, by 2034, the number of people with diabetes will nearly double again to 44.1 million.
- Already, diabetes is one of the most costly diseases in America. Factoring in the previously unidentified costs of undiagnosed diabetes, pre-diabetes, and gestational diabetes, the total diabetes-related costs in the United States in 2007 amounted to $218 billion.
- One in every 10 health care dollars is spent on diabetes and its complications, and one in every three Medicare dollars is spent on people with diabetes.

- According to a recent study by Thorpe et al published in *Health Affairs*: "Much of the recent growth in spending among Medicare beneficiaries is attributable to rising spending on chronic conditions—specifically diabetes and hypertension, both of which rose considerably in treated prevalence over the past two decades."

The potential availability of funds designated for disease prevention and wellness offers an unprecedented opportunity to address diabetes, one of our nation's most prevalent and costly chronic diseases. Diabetes is a chronic condition that presents a great opportunity for targeted interventions to: save lives and reduce incidence of co-morbidities; reduce health care costs and increase economic productivity; support prevention and wellness across the lifespan—from children and adolescents to adults and seniors—and reduce geographic, racial, and ethnic disparities.

We ask that you make diabetes a priority and commit $5 billion of the prevention and wellness funds over 10 years to diabetes prevention and management.

Reversing the trend of rapid growth of diabetes in America is certainly being held out as a key metric of success for health care reform. In fact, in your November 2009 report, *Preventing and Treating Diabetes in America; Health Insurance Reform and Diabetes in America*, you highlight as a problem that "diabetes prevention and early treatment are under-emphasized" in our health care system. In addition, President Obama, in speaking about the need for health care reform, has consistently pointed out diabetes as a chronic disease that requires the nation's attention; First Lady Michelle Obama spoke of the specter of diabetes being the future for one third of our children unless we change course when introducing her childhood obesity initiative; and Surgeon General Benjamin's *Vision for a Healthy and Fit Nation* calls out the epidemic of diabetes. Moreover, a recently released report from the National Business Council on Health shows that employers have identified diabetes as a priority area for prevention. According to the report, "Employers are increasingly seeing that it is a bottom line issue to prevent diabetes, identify it early, and treat it 'to goal' in their employee population."

Despite all the attention being showered on the many problems associated with diabetes, the means to address this crisis are simply not in evidence. Relative to the impact of diabetes in America, the federal commitment to diabetes falls woefully short of what is needed. The prevention and wellness funds offer a significant opportunity to right this wrong.

Without a significant national investment in the prevention of diabetes and diabetes complications, Americans, especially those who are disproportionately impacted by the disease, particularly those in the Hispanic, African-American and Native American communities, will continue to needlessly develop blindness and kidney disease, and be at far greater risk for amputation and early mortality from heart attack and stroke.

As leading organizations in the diabetes community, we urge that diabetes prevention and management—specifically evidence-based clinical and community-based interventions to reduce rates of diabetes and improve diabetes care management—be considered a top priority when the prevention and wellness funds are allocated.

Fortunately, much is known about how to prevent type 2 diabetes, and how to treat type 1 and type 2 diabetes to avoid costly complications. Already, significant evidence exists that community-based and clinical interventions are making a difference.

Therefore, we recommend the following ways in which prevention and wellness funds can be used to address diabetes:

- **Implement community prevention programs based on the groundbreaking clinical trial, the Diabetes Prevention Program (DPP).** The DPP found that individuals diagnosed with pre-diabetes who engage in moderate lifestyle changes can reduce their chances of developing type 2 diabetes by 58 percent. Research has shown that these positive results can be replicated in a community setting for far less cost than the original clinically-based DPP. Senators Franken and Lugar introduced legislation that will support community efforts to establish, run, monitor and evaluate such affordable programs. This language, included in the health reform legislation signed today by President Obama, will go a long way in preventing type 2 diabetes at the community level.

- **Support other effective, culturally appropriate community-based interventions** such as the Asheville project, REACH, Bridges to Excellence, Project Dulce, Peers for Progress, and the Stanford Chronic Disease Self- Management Program.

- **Improve and expand efforts for early detection** through greater utilization of current diagnostic testing methodologies and promotion of already existing Medicare benefits.

- **Support the proposed HP 2020 diabetes objectives** that call for: 1) increasing the proportion of adults with diabetes whose condition has been diagnosed, and 2) improving glycemic control among the population with diagnosed diabetes.

- **Support research, treatment programs, public education programs, and diabetes health promotion and prevention programs for minority populations.**

We respectfully request a meeting with you this month to discuss how we can work together to accomplish our mutual goals. We look forward to working

with you to improve our nation's health, beginning with changing the way we approach diabetes prevention and treatment.

Sincerely,

American Academy of Physician Assistants

American Association of Clinical Endocrinologists

American Association of Diabetes Educators

American Clinical Laboratory Association

American Diabetes Association

American Dietetic Association

American Medical ID

American Optometric Association

Center for Health Transformation

Diabetes Hands Foundation

diaTribe

Medicare Diabetes Screening Project

National Black Nurses Association

National Minority Quality Forum

Novo Nordisk Inc.

Results for Life: Lab Testing - Better Health, Improved Outcomes

Tethys Bioscience

The Endocrine Society

Vision Service Plan (VSP)

XL Health

CC: Ann Albright, Thomas Frieden, Dora Hughes, Kaya Lewis

Dr. Howard Koh, MD, MPH
Assistant Secretary of Health
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

May 4, 2010

Dear Dr. Koh:

We are writing to express our concern that the recently released Healthy People 2020 diabetes objectives, which represent the federal government's official stand on what needs to be achieved in diabetes over the next 10 years, do not include an objective related to screening for diabetes. We have formally commented and met with the relevant HHS staff, and look forward to our meeting with you to directly discuss the need to include this as a key objective rather than just a strategy.

In December 2009 some 20 organizations and companies, including the American Diabetes Association, American Medical Association, National Black Nurses Association, National Council on Aging, Novo Nordisk, and the Partnership for Prevention submitted written comments to recommend that the Healthy People 2020 Diabetes objectives include an objective related to screening for diabetes, specifically to: "Increase the proportion of adults who have been tested for diabetes." In fact, among all the comments on the 16 diabetes objectives posted to the Healthy People 2020 website, approximately 50% urge the Federal Interagency Workgroup to include screening language.

More recently, we met with key staff at CDC and NIH to discuss this issue and they agreed that it is both appropriate and timely to include screening language within one of the Healthy People 2020 diabetes objectives. In fact, they brought proposed language before the Federal Interagency Workgroup.

Diabetes stands out among other major chronic conditions in terms of its growing prevalence—and precisely because of **the lack of a Healthy People 2020 screening objective around it.** Other important areas of public health, such as HIV/AIDS, some forms of cancer, and cholesterol, **all have specific screening and testing objectives proposed for Healthy People 2020**. Given the size and impact of the diabetes epidemic on the U.S. population, we believe there is a need to increase the proportion of adults screened for diabetes, and thus merits the inclusion of diabetes screening as an HP2020 Diabetes Objective, and not as a strategy contained within other objectives.

In 2010, diabetes screening was clearly acknowledged in the preamble to the diabetes section and in the 2010 Midcourse Review as one of the "four transition points" that offers an "opportunit(y) to reduce the health and economic burden of diabetes." But no steps were taken then or since to include diabetes screening within Healthy People objectives.

Over the two decades since the inception of Healthy People, diabetes has relentlessly continued to exact a significant human and financial toll nationwide.

- Nearly 24 million Americans already have diabetes, **a quarter of whom do not know they have the disease**, and another **57 million have pre-diabetes and are at risk of developing the disease.**
- Within the last 30 years, since 1980, the percentage of Americans diagnosed with diabetes has more than doubled. **On its current course, by 2034, the number of people with diabetes will nearly double again to 44.1 million.**
- The rising prevalence of diabetes is contributing to increasing numbers of disabling conditions such as blindness, limb amputations and kidney disease, as well as more premature deaths.
- Already, diabetes is one of the most costly diseases in America. Factoring in the previously unidentified costs of undiagnosed diabetes, pre-diabetes, and gestational diabetes, the total diabetes-related costs in the United States in 2007 amounted to $218 billion.
- One in every 10 health care dollars is spent on diabetes and its complications, and one in every three Medicare dollars is spent on people with diabetes.

The Healthy People 2020 website clearly states that "Healthy People 2020 will **reflect assessments of major risks to health and wellness**..." In addition, during the July 10, 2009 Healthy People 2020 Planning Meeting, Dr. Jonathan Fielding and others talked about making Healthy People 2020 the **cornerstone of prevention.**

The statistics on diabetes are compelling—and demonstrate that it *certainly* qualifies as a major risk for the American public and therefore demands a better preventive response from the public health and clinical care communities. One particularly potent response would be to include a screening objective in Healthy People 2020. Doing so could help increase awareness around this critical component in addressing the overall problem and pave the way for appropriate action by the diabetes community in advocating for change.

Clinical research has conclusively shown that early diagnosis and intervention in type 2 diabetes can significantly reduce the development of long-term complications and mortality rates. Moreover, conclusive landmark clinical trials—both the Diabetes Prevention Program and the Diabetes Prevention

Program Outcomes Study—have demonstrated that, among people with pre-diabetes, type 2 diabetes can be prevented or delayed in both the short term and the long run through lifestyle modification. We have an evidence base of programs to prevent, manage and reverse diabetes. Thus, there is a medical, if not a moral, imperative to identify people with undiagnosed diabetes and pre-diabetes.

Some of these proposed screening and testing objectives in Healthy People 2020 are in accordance with recommendations set forth by USPSTF, while others are not. Nonetheless, it is our understanding that you are looking to a broader evidence base for objectives proposed for Healthy People 2020, including CDC's *Guide to Community Preventive Services*, studies funded by and reported on by the Robert Wood Johnson Foundation, Cochrane reviews, practice-based evidence, and the like.

Lack of baseline data on diabetes screening is not a stumbling block for a diabetes screening objective because a national data source *already* exists. Beginning with the 2005-2006 NHANES survey, and continuing on the 2007-2008 survey and the questionnaire for 2009-2010, there is a diabetes screening/testing question.

In light of the preponderance of support and evidence—and the critical need to proactively address the ever growing diabetes epidemic—we urge you, the Secretary's Advisory Committee and the Federal Interagency Workgroup, to include diagnostic testing for diabetes within the objectives proposed for Healthy People 2020. Thank you for your time and attention.

Sincerely,

American Association of Clinical Endocrinologist

American Association of Diabetes Educators

American Clinical Laboratory Association

American Diabetes Association

AmericsourceBergen Corporation

American Optometric Association

diatribe/Close Concerns, Inc.

Medicare Diabetes Screening Project

Novo Nordisk, Inc

Obesity Action Coalition

Results for Life - Lab Testing: Better Health, Improved Outcomes

The Endocrine Society

VSP Vision Care

June 10, 2010

The Honorable Tom Harkin
Chairman
U.S. Senate Appropriations Committee
Subcommittee on Labor, HHS, and Education
131 Dirksen Senate Office Building
Washington, DC 20520

The Honorable Thad Cochran
Ranking Member
U.S. Senate Appropriations Committee
Subcommittee on Labor, HHS, and Education
The Capitol, S-206
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Cochran:

Before taking office, President Obama highlighted the need to reorient our health care system "towards prevention and public health" in his *Plan for a Healthier America*. The recently enacted Patient Protection and Affordable Care Act (hereafter referred to as the Affordable Care Act or ACA), which contains many provisions to increase health promotion and disease prevention in the U.S., represents a dramatic shift in this direction. **We are writing to respectfully urge you to provide $80 million from the Prevention and Public Health Fund in ACA to fund the Franken-Lugar Amendment; $20 million to initiate the provisions authorized through the Catalyst to Better Diabetes Care Act in ACA; and $10 million for HHS to develop and implement a public action initiative around existing Medicare Diabetes Screening coverage.**

Given the magnitude of the diabetes epidemic, this funding must not supplant current funding for essential diabetes programs and research.

Any solution to America's current health challenges must include what public health professionals call "upstream" interventions, which engage and enable local communities to make environmental changes that will allow and encourage more people to live healthier lives. The good news is that we have proven interventions that lead to therapeutic weight loss and reduction in diabetes risk factors. What's more, we have shown that these evidence-based interventions can be offered affordably.

To this end, Senator Al Franken (D-MN) and Senator Richard Lugar (R-IN) co-authored the National Diabetes Prevention Program (NDPP), a provision included in ACA, which is targeted at adults at high risk for full onset of type 2 diabetes. Such adults are often overweight or obese, and therefore also at high risk for hypertension and high cholesterol. The legislative language for NDPP authorizes support for community efforts to establish, run, monitor, and evaluate affordable programs modeled upon the groundbreaking clinical trial, the Diabetes Prevention Program (DPP).

The DPP intervention is an intensive overall lifestyle intervention, which although designed to be specific for people with pre-diabetes, will also positively impact other conditions, disease states, and outcomes. This community-based lifestyle intervention:

- Promotes weight loss;
- Encourages an increase in physical activity levels;
- Facilitates healthier eating habits;

- Improves the risk factors for cardiovascular disease; and
- Improves health-related quality of life.

The original DPP study found that individuals diagnosed with pre-diabetes who lost a moderate amount of weight (5 to 7 percent) and engaged in regular physical activity reduced their chances of developing type 2 diabetes by 58 percent. The Diabetes Prevention Program Outcomes Study (DPPOS), a 10-year follow-up of the DPP, shows that prevention or delay of diabetes and its complications persisted through the decade.

Recent research has shown that these positive clinical trial results can be replicated cost effectively in a community setting at an annual per-person cost of less than $300. In fact, Senator Harkin, you characterized these programs in a press release from your office, as such: "...Programs like those offered through the YMCA help rein in chronic diseases like diabetes, which will mean less health spending down the road."

Already, UnitedHealth Group has announced its intent to partner with YMCAs in Cincinnati, Columbus and Dayton, Ohio; Indianapolis, Indiana; St Paul, Minnesota and Phoenix, Arizona to reimburse participants in these DPP-like programs. In a recent editorial in the *New England Journal of Medicine*, Assistant Secretary for Health, Dr. Howard Koh, comments that the rising prevalence of diabetes "means that even greater attention must be paid over the next decade to scaling up evidence-based diabetes prevention interventions in high-risk populations."

1. As you craft the Fiscal Year 2011 Labor, Health and Human Services, and Education (LHHS) Appropriations bill, we urge that you provide $80 million from the Prevention and Public Health Fund to fund the Franken-Lugar Amendment and support these cost-effective, community-based prevention interventions. Supporting this proven lifestyle modification intervention will not only result in healthier lives for participants, but is instrumental in lowering the staggering economic toll that diabetes currently takes on our country, estimated at $218 billion each year.

2. We also urge that you include in the LHHS Appropriations bill a total of $20 million to initiate the provisions authorized through the Catalyst to Better Diabetes Care Act, under section 10407 of the Affordable Care Act. The Catalyst Act, like DPP, has the potential to go a long way towards your goal of reining in chronic disease and its associated health care spending by raising awareness about the state of diabetes care in the U.S.; the impact of diabetes on morbidity and mortality; and the quality of medical education around the disease. **We specifically request:**

- **$10 million to HHS to work with the states and appropriate agencies to educate providers on the proper reporting of information on death certificates,** including data on diabetes.
- **$5 million to HHS to prepare a National Diabetes Report Card** every two years with aggregate health outcomes related to diabetes and pre-diabetes.
- **$5 million to the Institute of Medicine to conduct a study and report to Congress on the impact of diabetes on medical practice in the United States** and whether there is an appropriate amount of diabetes medical education prior to licensure, board certification, and board re-certification.

3. In addition, we ask for $10 million for HHS to develop and implement a public action initiative around the Medicare Diabetes Screening coverage The Medicare Modernization Act (P.L. 108-173) included a new diabetes screening benefit to help identify the thousands of

seniors on Medicare with undiagnosed diabetes. However, according to the Centers for Medicare and Medicaid Services, in 2007 only 12.2 percent of Medicare beneficiaries took advantage of this diabetes screening benefit. Given the new annual wellness visit and personalized prevention plan services provided under ACA, it is important to ensure beneficiaries know of and utilize the Medicare Diabetes Screening coverage. **Therefore, we urge you to provide funding to increase awareness and utilization of this important benefit.**

In addition, Senators Harkin and Cochran, we respectfully request a meeting with each of you sometime during the next month to discuss the epidemic of diabetes in the U.S. and the asks outlined in this letter.

Thank you for your consideration of our requests. Changing the way we approach diabetes prevention and treatment in the U.S. is another significant step toward re-orienting our health care system, and thereby improving our nation's health.

Sincerely,

American Association of Clinical Endocrinologists

American Association of Diabetes Educators

American Diabetes Association

American Dietetic Association

American Optometric Association

Healthways

Novo Nordisk, Inc.

Obesity Action Coalition

The Endocrine Society

Vision Service Plan (VSP)

Science at the heart of medicine

Meredith Hawkins, MD
Director
Global Diabetes Initiative
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Jack and Pearl Resnick Campus
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718.430.3186 fax 718.430.8557
meredith.hawkins@einstein.yu.edu

EINSTEIN

Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

July 1, 2010

The Honorable Diana DeGette
2335 Rayburn House Office Building
Washington, DC 20515

Dear Congresswoman DeGette,

Given your remarkable commitment to tackling the diabetes epidemic, I want to bring to your attention an emerging problem plaguing developing countries around the world. "Malnutrition-modulated diabetes mellitus" is a devastating form of diabetes affecting millions of people globally, yet virtually unknown in the Western medical literature. Chronically malnourished individuals present in adolescence or early adulthood with severe diabetes, often following a stressful life event. These patients tend to have very poor outcomes. High blood sugar levels and coexisting vitamin deficiencies make them particularly susceptible to complications of diabetes. Since so little is known about this condition and its management, many such patients are labeled as type 1 diabetes and are prescribed insulin. Unfortunately, when insulin is actually available in these settings, taking insulin when food is scarce causes many of these impoverished patients to die from low blood sugar.

It is intriguing, in the twenty-first century, to encounter a condition as prevalent and devastating as malnutrition diabetes, yet about which so much remains to be learned. Building on Einstein's strength in complex metabolic research studies, the Global Diabetes Initiative is collaborating with researchers at the world-renowned Christian Medical College (CMC) Vellore in South India to carefully characterize this condition. Specifically, knowing whether these patients have defects in insulin secretion, insulin sensitivity, and/or fat metabolism could point towards the use of safer, cheaper oral agents and nutritional approaches. The tremendous research sophistication of CMC Vellore together with its poor patient population provides a unique opportunity to carefully research this condition.

Additionally, CMC Vellore has developed an outstanding diabetes education program that has already trained health care professionals at 120 hospitals around India in comprehensive diabetes management. This very successful program includes a textbook, a series of workbooks, and videoconferencing in addition to highly focused training sessions. CMC has approached Einstein to perform a careful monitoring and evaluation of this program. Additionally, the Global Diabetes Initiative has numerous contacts with institutions in Nepal, Bangladesh, Afghanistan, Thailand, Jordan, Kenya, Ethiopia and Uganda, and is in the process of partnering with CMC to adapt their program for diverse settings beyond India.

It has been a pleasure to communicate with Heather Foster in your office, and we would be delighted to provide you with any additional information and materials that might be helpful.

Thank you for your strong leadership in the fight against diabetes. Your efforts and energy are truly appreciated.

Sincerely,

Meredith Hawkins, MD
Professor of Medicine
Director, Global Diabetes Initiative

National Indian Health Board

July 1, 2010

Dear Representative DeGette:

We understand that today the Energy and Commerce Subcommittee on Health is holding a hearing focused on diabetes and the progress being made in turning the tide of this public health crisis. We applaud the Committee for focusing on this critical issue and your leadership in requesting this hearing. You have been a strong champion for people with diabetes, and we are grateful for your efforts.

As you know, American Indians and Alaska Natives (AIAN) suffer in greater numbers from diabetes than any other U.S racial and ethnic group. Among AIANs, diabetes is four to eight times more common than in the general population. And perhaps most alarming is the fact that diabetes prevalence rates continue to rise in AIAN youth.

But real progress is being made, in large part due to the Special Diabetes Program for Indians (SDPI). SDPI funding has allowed Indian health programs and tribal communities to develop vital resources and tools to both prevent and treat diabetes. SDPI currently funds 450 programs in 35 states, allowing local tribes and health programs to set priorities that meet their needs, whether it is prevention activities or treatment.

SDPI has increased diabetes treatment and prevention programs for American Indians and Alaska Natives, and has become one of the most strategic and comprehensive diabetes treatment and prevention programs in the country. Key health indicators – including blood sugar control, cholesterol levels, and kidney function – have improved among American Indians and Alaska Natives with diabetes each year since this program was created.

These are among the successes that demonstrate that this program is yielding real returns on the federal investment and should continue to receive broad congressional support. SDPI is a model of what we can accomplish when the Federal and Tribal governments work together. Renewing the program this year will ensure continuity in the programs so that tribal communities can continue to build upon the successes achieved. Congress has recognized the importance of this and has acted under a similar timeline in the past. We greatly appreciate the historical support Congress has provided for this program and look forward to working with you to secure a multi-year renewal this year.

Sincerely,

Reno Franklin, Chairman
NIHB

Jefferson Keel, President
NCAI

Dr. Patrick Rock, President
NCUIH

HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

JOE BARTON, TEXAS
RANKING MEMBER

ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225-2927
Minority (202) 225-3641

July 21, 2010

Ann Albright, Ph.D., R.D.
Director, Division of Diabetes Translation
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS K-10
Atlanta, GA 30333

Dear Dr. Albright:

Thank you for appearing before the Subcommittee on Health on July 1, 2010, at the hearing entitled "The Battle Against Diabetes: Progress Made; Challenges Unmet."

Pursuant to the Committee's Rules, attached are written questions for the record directed to you from certain Members of the Committee. In preparing your answers, please address your response to the Member who submitted the questions.

Please provide your responses by August 4, 2010, to Earley Green, Chief Clerk, via e-mail to Earley.Green@mail.house.gov. Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,

Henry A. Waxman
Chairman

Attachment

CDC Responses to Questions for the Record
Health Subcommittee of House Committee on Energy and Commerce Hearing
July 1, 2010
The Battle Against Diabetes: Progress Made, Challenges Unmet

The Honorable Henry A. Waxman

1. As your testimony states, improved diabetes surveillance is one of the most important initiatives in which CDC is engaged. We need to continue to understand who is affected by diabetes, particularly as we've seen a sizeable increase in the rate of cases. It is also important for us to know which groups are most impacted by this disease.

    a. Please summarize for the record the process by which CDC goes about collecting data on diabetes.

    A key component of CDC's diabetes surveillance activities is the National Diabetes Surveillance System (NDSS) as well as dissemination of data from this system such as the National Diabetes Fact Sheet. The NDSS is a comprehensive assembly of diabetes-related data from national and state-based surveys like the National Health and Examination Survey (NHANES) and the Behavioral Risk Factor Surveillance Survey (BRFSS) and other data systems. For example, NHANES findings over the past decade have been widely disseminated in research publications and the public media. Among its communications are reports on 1) the increase in the United States of a major risk factor for developing diabetes, that is obesity; 2) change in the percentage of people in the United States with diabetes; and 3) how well people with diabetes are controlling their condition. Other data collection mechanisms obtain data on the changing pattern of diabetes treatment (National Health Interview Survey); diabetes hospitalizations (National Hospital Discharge Survey); and diabetes deaths (National Vital Statistics System). CDC has maintained and adapted these systems to meet the expanding diabetes surveillance needs. It has done this in partnership with many Federal agencies, including within HHS the National Institutes of Health's (NIH) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) which has provided ongoing support for NHANES and NHIS. This broad, complex, and dynamic system has proven successful at monitoring trends in the magnitude of diabetes and its complications, identifying diabetes health service research needs, developing and monitoring national health objectives, detecting changes in health care practices, facilitating program planning and educational materials, and allocating resources. Most recently, CDC also developed a methodology to estimate levels of diabetes and obesity at the county level, providing policy makers and communities with new information to guide program planning, resource allocation and develop long term strategies.

    b. Can you explain why CDC has selected this surveillance strategy over other available methods?

    Because diabetes is a complex disease affecting nearly every organ system of the body, the scope of diabetes surveillance is broad. No single survey or data system can provide CDC with all the important data needed. Specifically, NHANES can provide laboratory and examination measures of a national sample of people with diabetes. The BRFSS can provide telephone interview information from people at a state-level. CDC's priorities have been to collect data that provide the most comprehensive national and state-level

picture possible of major health outcomes of importance, modifiable risk factors, and the degree to which evidence-based interventions are delivered. There is, however, unfortunately a gap in our ability to characterize the levels of variation in care and risk factors around the country. For these reasons, an important priority is to improve the regional and local surveillance of levels of risk factors and care, ideally with integration of electronic health records.

2. You describe the work that your agency is doing with respect to the three forms of diabetes that were the subject of our hearing: type 1, type 2, and gestational diabetes.

    a. Given that you have finite resources to devote to diabetes research, how do you strike a balance in addressing the research and other public health needs of each type of diabetes?

CDC works diligently to strike a balance in addressing the pressing needs of all types of diabetes and has strategically chosen to distribute resources where we can achieve the greatest impact. Type 2 diabetes accounts for 90 to 95 percent of all diagnosed cases of diabetes. CDC provides funding and technical assistance to state grantees to enable them to implement local, regional and statewide, multi-level public health approaches to affordable, high-quality type 2 diabetes prevention and control care and services, with priority on reaching high-risk and disproportionately affected populations.

CDC has made a significant investment in translating the science from the NIDDK-led Diabetes Prevention Program (DPP) into public health practice through cost-effectiveness research and community interventions aimed at exploring the efficacy of community-based lifestyle modification programs. The National Diabetes Prevention Program (NDPP) is CDC's current effort and is the most ambitious of its decade-long commitment to translating the science of type 2 diabetes prevention. The program is built on results from NIDDK-supported research to translate the results of the DPP. The goal of the program is to systematically scale the adapted cost-effective model of the DPP research trial for high risk persons. Through a four-pronged approach that includes training, a recognition program, model sites, and health marketing, CDC is partnering with public and private industry leaders, aimed at collectively maximizing the opportunity for successful outcomes.

Though type 1 diabetes accounts for 5 to 10 percent of all diagnosed cases of diabetes, CDC is able to dedicate significant resources to research that is identifying cases of diabetes in those younger than 20 years of age through the Search for Diabetes in Youth Study (SEARCH). SEARCH, which is also supported by the Special Diabetes Program and the NIDDK, is the most comprehensive study of its kind and will yield valuable information: 1) the number of children and youth younger than 20 years of age who have diabetes (prevalence) and the number who develop diabetes each year (incidence); 2) an understanding of how type 1 diabetes and type 2 diabetes differ, including how they differ by age, sex, and race/ethnicity; 3) better understanding of the risk for acute and

chronic complications of diabetes in children and youth; 4) data about the different types of care and medical treatment that these children and youth receive; and 5) insight into how diabetes affects the daily lives of children and youth in the United States.

Gestational diabetes (GDM) presents a unique case for mother and child. Approximately 5 to 10 percent of women with gestational diabetes are found to have diabetes, immediately after pregnancy, usually type 2 diabetes. CDC is working with other organizations to 1) establish a five-state collaboration to identify, catalogue, and validate routinely collected data about GDM; 2) identify gaps in quality of GDM prevalence data; 3) develop recommendations for improving data quality; and 4) determine implications for care for those with GDM.

b. How will investments in research, not specifically directed at diabetes or one of the specific types of diabetes, benefit each form of diabetes?

Diabetes is a very complex disorder affecting nearly every organ system of the body. As a result, research examining vision health, kidney, cholesterol, smoking cessation, and other topics will contribute to prevention or delay of diabetes and its complications. As examples:

- Research conducted on hypertension prevention and control is beneficial. Individuals with sustained high blood pressure, treated or untreated, are at high risk for type 2 diabetes. A CDC supported report by the Institute of Medicine outlines the need for a population based approach to policy interventions to address hypertension in the United States. If manufacturers gradually reduced the amount of sodium in processed and prepared foods, public consumption of sodium could be reduced to safer levels with little or no behavior changes needed on the part of the individual consumer.
- Research conducted by other CDC divisions and NIH on environmental issues, policies, health disparities, and health behaviors provides the basis for strategies and potential interventions for managing, preventing, and controlling diabetes and its complications. Often, people with type 2 diabetes are able to lower their blood glucose by losing weight and increasing physical activity.

CDC Responses to Questions for the Record
Health Subcommittee of House Committee on Energy and Commerce Hearing
July 1, 2010
The Battle Against Diabetes: Progress Made, Challenges Unmet

The Honorable Diana DeGette

Medical Nutrition Therapy & Diabetes Self-Management Education

1. Dr. Albright, you are here today in your capacity as Director of DDT, however, I understand that you have worked extensively with both the American Association of Diabetes Educators and the American Dietetic Association. I have also done significant work with both of these groups in my role as Co-Chair of the Congressional Diabetes Caucus. Could you please elaborate on the role you see for both diabetes self-management therapy (DSMT) and medical nutrition therapy (MNT) in the quest for addressing the unmet challenges in the battle against diabetes?

Medical nutrition therapy (MNT) and diabetes self management education (DSME) are central to improving diabetes outcomes and should be supported in medical and community-based settings across the United States. DSME can be delivered by a variety of health professionals including Registered Dietitians (RDs), pharmacists, nurses and other health professionals. RDs play a vital role in the delivery of MNT and are an integral part of the diabetes care team. Community health workers have also been shown to be effective in supporting and reinforcing DSME and MNT.

CDC uses a variety of approaches to integrate both MNT and DSME into its programs for people with diabetes. For example,

- CDC works with 59 state and territorial Diabetes Prevention and Control Programs (DPCPs) to support efforts to increase diabetes self management education programs across the country, to improve nutrition, to increase physical activity, to increase smoking cessation, and to increase wellness for people with or at risk for diabetes.

- The National Diabetes Education Program (NDEP), which is co-led by CDC and NIH, consists of more than 200 public and private organizations concerned about diabetes. NDEP has developed several resources in multiple languages that include information about making healthy food choices and increasing physical activity for people with and at risk for diabetes. More information can be found on the website at: www.yourdiabetesinfo.org.

CDC funds 17 American Indian/Alaska Native communities, tribal organizations, and tribal colleges to increase access to traditional local healthy foods and physical activities for diabetes prevention and health promotion. CDC also developed and distributes *The Eagle Books*, a series of four children's books for Native American children and those interested in healthy living. The books promote diabetes education and encourage a return to traditional ways, including physical activity and healthy eating. For more information on CDC's activities with tribal communities, visit: http://www.cdc.gov/diabetes/projects-wellness.htm

Providers

CDC Responses to Questions for the Record
Health Subcommittee of House Committee on Energy and Commerce Hearing
July 1, 2010
The Battle Against Diabetes: Progress Made, Challenges Unmet

2. I am aware that there is a group called PPOD (pharmacists, podiatrists, optometrists, and dentists) within CDC that actively engage in educational efforts to the public and other providers to help prevent drug interaction, foot ulcers and amputations, and oral and vision complications. How effective has that group been in helping educate providers and the public about prevention of the complications of diabetes?

Often allied health professionals, such as pharmacists, podiatrists, optometrists, and dentists, are the first providers to see people with diabetes. They are an essential part of the important team care approach to treating diabetes. A 2008 *Healthstyles* survey of 5399 American adults found that approximately 40 percent of those with pre-diabetes or diabetes used pharmacists as sources of information about diabetes and 64 percent of both groups said they trusted recommendations from their local pharmacist. As co-sponsors of the National Diabetes Education Program (NDEP), CDC has and NIDDK have guided the PPOD work group in creating and promoting materials for PPOD professionals and their patients, such as:

- *Working Together to Manage Diabetes: a Guide for Pharmacy, Podiatry, Optometry, and Dental Professionals* and its *Diabetes Medication Supplement*
- *I can control my diabetes by working with my health care team,* a poster available in English and Spanish for people with diabetes
- A checklist to help coordinate care between PPOD and other health care professionals so that people with diabetes receive all of the recommended standards of care (currently being piloted tested for incorporation into an electronic medical record)

NDEP and its PPOD partners have been actively promoting these materials to all of the specialty organizations and their constituents. The *Working Together* training guide was requested by over 9000 professionals, is in its second printing, and currently is being updated and reformatted for the web and new technologies to enable NDEP to reach more PPOD professionals. NDEP is conducting a limited evaluation to measure the use and impact of PPOD resources with relevant audiences.

CDC Responses to Questions for the Record
Health Subcommittee of House Committee on Energy and Commerce Hearing
July 1, 2010
The Battle Against Diabetes: Progress Made, Challenges Unmet

The Honorable Zack Space

1. Too often, I hear horror stories from health care providers in my district who receive visits from patients suffering from diabetes they didn't even know they had. Please discuss some of the efforts the CDC and NIDDK have undertaken to improve early detection efforts across the country.

Evidence from the Diabetes Prevention Program (DPP) a randomized controlled clinical trial, led by NIDDK and supported by CDC, indicated that weight loss of 5 to 7 percent while encouraging a healthy diet and increased physical activity can reduce risk for type 2 diabetes by as much as 58 percent in those who have pre-diabetes. CDC is further translating what is known from this study to the public by implementing the National Diabetes Prevention Program. Currently, CDC is working with the YMCA USA and UnitedHealth Group to identify those at risk and refer them to programs in 17 communities throughout the United States. This program delivers the proven intervention in group settings and is built on results of NIDDK-supported research in which scientists successfully utilized local YMCAs for delivering a lower-cost, group-based DPP lifestyle intervention. Elements of the program include:

- **Health Marketing** to inform populations at highest risk for diabetes about risk factors for pre-diabetes and to raise awareness among both providers and high risk populations of referral to and availability of diabetes prevention programs.
- **National Recognition Program** for community-based lifestyle programs to ensure that interventions to prevent diabetes in high risk persons are of high quality and evidence-based. This initiative includes development of a national registry of CDC-recognized diabetes prevention programs accessible to the general public, third party payers, and clinicians that documents and reports the performance of community-based diabetes prevention programs.
- **National Training and Outreach Program** to develop a workforce of competent Lifestyle Coaches that deliver lifestyle interventions to high risk persons served by CDC-recognized programs.
- **Model Sites** to establish sustainable community-clinical partnerships for the delivery of structured lifestyle interventions to persons at high risk for developing type 2 diabetes.

Another collaboration between CDC and NIDDK is the National Diabetes Education Program (NDEP). NDEP consists of more than 200 public and private organizations concerned about diabetes and the health status of their members. NDEP develops and disseminates educational information on the prevention and control of diabetes for various target audiences. NDEP has developed several resources in English and Spanish for people at risk for diabetes that includes a risk assessment to determine individual risk for type 2 diabetes. This tool is available on the NDEP website at http://www.ndep.nih.gov/resources/ResourceDetail.aspx?ResId=252

2. My Congressional District falls directly into the heart of Appalachia. We face all of the same challenges of a rural area when it comes to access to care. Some recent figures I have seen indicate that Appalachia has a much higher prevalence of diabetes than other areas. For

obvious reasons, I find this extremely troubling. I worry that public health/education efforts in my Congressional District may be more difficult than in some urban and suburban areas. Have you seen any evidence that suggests your education efforts are more effective in urban rather than rural settings?

Currently, CDC does not have any evidence that suggests education efforts are more effective in urban than in rural settings. CDC materials are tested and adapted for targeted audiences.

For the past 10 years, CDC has supported the Appalachian Diabetes Control and Translation project to prevent and control diabetes through developing coalitions in poor, rural Appalachian counties. These community projects help people with type 2 diabetes control their disease and prevent the disease in people who may be at risk for developing type 2 diabetes.

Additionally, the CDC and NIDDK co-led National Diabetes Education Program has recently developed a number of educational resources that are ideal for addressing diabetes prevention and control in rural areas, such as Appalachia, and will be promoting and evaluating their use in the next year. These include:

- Road to Health Toolkit
- Capacity Building for Diabetes Outreach Tool Kit

Beginning in FY2011, CDC will fund six organizations to work with diverse communities in Appalachia and other rural areas such as the Mississippi Delta through the National Program to Eliminate Diabetes-Related Disparities in Vulnerable Populations. This program will address both rural and urban settings and will help CDC to understand more fully the types of approaches that work best in these different communities or vulnerable populations.

3. Can you share with the Subcommittee what you think are the most pressing diabetes research needs that must be met if we are to build on past successes, improve prevention and treatment and ultimately close in on a cure?

Type 2 diabetes is a disease that results from multiple factors rooted largely in our culture and lifestyle. Fortunately, the evidence for prevention of diabetes and its complications is now very strong. Better outcomes for diabetes require the collaboration of health related sectors and non-health related sectors to modify our health systems and change the characteristics of our communities to promote prevention of type 2 diabetes and improve treatment for all forms of diabetes.

Areas of public health research that are crucial to realize these changes include:

1. Studies that prioritize modifiable risk factors, stimulate new interventions, and examine the causes of disparities in diabetes risk. Such studies would help clarify the best ways to reduce the race/ethnic, income, sex, and age-related disparities that remain in diabetes prevention and control and improve our understanding of how mechanisms and risk factors for disease vary across the lifespan.

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2. Improved local and regional diabetes surveillance tools. Better surveillance systems feed programmatic efforts by helping to identify and target the populations at risk, but they are also a crucial base for research efforts because they uncover the factors that have the largest proportional influence on the population as a whole. New surveillance tools should go beyond traditional health surveys and make use of electronic health records, registries, and community-level information where available.

3. Research efforts that test population-targeted policy interventions to prevent and control of diabetes. Although there is clear evidence that intensive lifestyle interventions can prevent type 2 diabetes for high risk individuals, there is a need to study policies that support cost-effective diabetes prevention and control. The diabetes problem is now large enough that we need to have solid evidence around not only the biological processes that influence diabetes risk, but also the public policy approaches for delivering intervention.

4. Public health research that improves measurement and our understanding of the best practices to promote healthy nutrition and physical activity lifestyles. We know that excess caloric consumption and insufficient physical activity can result in weight gain, which is a major risk factor for developing diabetes. We also know that unbalanced nutritional intake (e.g. consuming excess saturated fats) or a sedentary lifestyle may increase the risk of diabetes related complications such as heart attacks or strokes. We also know that nutrition and physical activity patterns can vary considerably by demographic characteristics (i.e. age, sex, race, etc) in the United States. Further research is needed to understand if healthy nutrition and physical activity lifestyles are being achieved in the various population subgroups, to determine approaches that are successful in achieving improvements, and to identify remaining barriers to healthy nutrition and physical activity.

CDC Responses to Questions for the Record
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The Battle Against Diabetes: Progress Made, Challenges Unmet

The Honorable Bruce Braley

1. Currently Medicare Part D plans are required to establish medication therapy management (MTM) programs. Plans are required to make MTM available to targeted beneficiaries – those with multiple chronic conditions who take multiple prescription drugs, and whose drug spending is likely to reach a designated amount. Congress recently took steps to strengthen the MTM program by codifying into statute changes that will help in standardizing benefits. Unfortunately, under current law, fewer than 13% of all Medicare beneficiaries have access to the MTM benefit due to the eligibility requirements.

   As you know, of the 24 million Americans with diabetes, approximately 20-25% of them are Medicare beneficiaries. Pharmacies are often the most accessible healthcare providers and pharmacists can play a critical role in helping patients to manage their diabetes. Are you familiar with MTM and what can Congress do to better utilize trusted healthcare professionals like pharmacists to combat diabetes?

CDC is aware of MTM and supports the important role of pharmacists in helping prevent the complications of diabetes. A 2008 *Healthstyles* survey of 5399 American adults found that approximately 40 percent of those with pre-diabetes or diabetes used pharmacists as sources of information about diabetes and 64 percent of both groups said they trusted recommendations from their local pharmacist.

Since 1997, through its support of the NDEP's Pharmacy, Podiatry, Optometry, and Dental work group, CDC and NIDDK have been promoting the role of pharmacists in the prevention and control of diabetes. Selected activities include:

- Developing and promoting guidance materials for pharmacists – *Working Together to Manage Diabetes: a Guide for Pharmacy, Podiatry, Optometry, and Dental Professionals* and its *Diabetes Medication Supplement* (currently in its 2nd printing and being updated) and informational brochures targeting each profession about diabetes prevention
- Creating and disseminating a poster (in English and Spanish) urging people with diabetes to "Team up with your pharmacist" and providing steps to do this
- Collaborating with primary and specialty healthcare professionals to develop and promote a checklist for the entire diabetes healthcare team that includes a section for pharmacists to record vital information about medications and ensures that other healthcare providers and patients are aware of the need to consult with pharmacists

CDC Responses to Questions for the Record
Health Subcommittee of House Committee on Energy and Commerce Hearing
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The Battle Against Diabetes: Progress Made, Challenges Unmet

The Honorable Michael C. Burgess

1. What is being done to research the correlation between gestational diabetes and the mother or child developing type 2 diabetes?

The association between gestational diabetes (GDM) in the mother and risk of developing type 2 diabetes in the offspring is not well understood. Numerous studies have addressed the risk of overweight, obesity, and of diabetes in offspring of women with diabetes, but these studies have numerous methodological limitations, including lack of inclusion of a control group, combining women with chronic diabetes and women with GDM, lack of control for relevant confounders, and small sample size. In the NIH-led Diabetes Prevention Program (DPP) trial, women with impaired glucose tolerance (IGT) and a history of GDM had a higher incidence rate of diabetes compared with women with IGT and no history of GDM, and a 50 percent reduction in diabetes risk with lifestyle or metformin therapy. Women with GDM are at increased risk for type 2 diabetes and should receive postpartum screening and appropriate prevention referral and follow-up. CDC is addressing these needs by:

- Working to identify strategies to increase postpartum screening in collaboration with Los Angeles County and University of Southern California Women and Children's Hospital by conducting a randomized trial of an intervention using a promotora to educate Latina women with GDM about their risk of developing diabetes and to facilitate their return for postpartum testing vs. usual care.

- Collaborating with Kaiser Permanente Northwest to evaluate the effects of systems-based changes (including reminder systems for clinicians and reminder calls to affected women) on postpartum diabetes testing rates.

- Supporting the development and evaluation of a DPP-style intervention, modified for postpartum women, to help develop diabetes prevention guidelines for the Massachusetts Department of Public Health. Funds were awarded to Brigham and Women's Hospital to assess, through informant interviews and focus groups, interest in participating in a diabetes prevention study and the preferred format.

- Collaborating with the National Association of Chronic Disease Directors' Women's Health Council to conduct a GDM validation project to: 1) establish a five-state collaboration to identify, catalogue, and validate routinely collected data about GDM; 2) identify gaps in quality of GDM prevalence data; 3) develop recommendations for improving data quality; and 4) determine implications for care.

- Translating what is known from the DPP and NIDDK-supported translational research utilizing YMCAs to deliver a cost effective program based on the DPP to the public by implementing the National Diabetes Prevention Program. Currently, CDC is working with the YMCA USA and UnitedHealth Group to identify those at risk, including women with a history of GDM, and refer them to evidenced-based programs in 17 communities throughout the United States.

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2. In June, it was recently announced that HHS will spend $250M to increase the number of healthcare providers and strengthen the training of the primary care workforce. What steps are being taken to ensure appropriate diabetes-related education for these new providers?

CDC recognizes that healthcare providers are an essential and trusted source of information for people with diabetes and those at risk for diabetes. The National Diabetes Education Program (NDEP), a collaboration between CDC and NIH, provides a wide range of up-to-date information and resources available to primary care and other healthcare professionals through a website tailored to healthcare professionals (www.betterdiabetescare.nih.gov). This site provides tools to help healthcare professionals improve diabetes prevention and care in the health care delivery system and is updated annually.

NDEP actively promotes these resources through exhibits at major medical meetings, newsletters, conferences, webinars, and organizational websites and works with partners from all of the major healthcare professional organizations to educate providers.

CDC's funded state and territorial Diabetes Prevention and Control Programs will continue to work with academic medical centers to teach students, residents and faculty about the planned care model and diabetes as part of the American Association of Medical Colleges Academic Chronic Care Collaborative. Training programs in primary care require trainees to learn about systems change such as the planned care model, especially for people with chronic conditions like diabetes.

QUESTIONS SUBMITTED FOR THE RECORD
HEARING ENTITLED,
"THE BATTLE AGAINST DIABETES: PROGRESS MADE, CHALLENGES UNMET"
SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES
JULY 1, 2010

Questions for Judith E. Fradkin, M.D.
Director, Division of Diabetes, Endocrinology, and Metabolic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Department of Health and Human Services

The Honorable Henry A. Waxman

1. In your testimony you state that diabetes has a strong genetic basis, which is modified by a person's environment. You describe The Environmental Determinants of Diabetes in the Young (TEDDY) study, which will identify environmental triggers of type 1 diabetes among at-risk children.

    a. What do we already know about how the environment increases one's risk of developing type 2 diabetes?

FRADKIN: Diabetes has a genetic basis that is modified by environmental factors. For type 2 diabetes, these environmental factors include diet, physical activity, and being overweight or obese. The intrauterine environment during pregnancy also plays an important role in future development of diabetes and obesity for the child.

    b. Are there ongoing trials that will yield more information on this topic?

FRADKIN: Yes. For example, the NIDDK's landmark Diabetes Prevention Program, or DPP, clinical trial showed that type 2 diabetes could be prevented or delayed in people at high risk for the disease if they lost a modest amount of weight by making diet changes and engaging in moderate exercise. The ongoing DPP Outcomes Study continues to follow participants and has found that benefits persist for at least 10 years. For overweight or obese adults who already have type 2 diabetes, the NIDDK's ongoing LookAHEAD clinical trial is examining the health effects of a lifestyle intervention designed to achieve and maintain weight loss over the long term. The results can shed light on new management strategies for adults with type 2 diabetes.

Very recently, researchers announced the results of the NIDDK-supported HEALTHY clinical trial, which focused on the school environment. Scientists tested the ability of a middle-school based intervention to lower risk factors for type 2 diabetes. The intervention was found to lower the obesity rate in students at highest risk for type 2 diabetes, but the intervention schools did not differ from comparison schools in the prevalence of overweight and obesity combined. These results are important for informing future school-based efforts to reduce overweight and obesity

in children. The NIH is also bolstering research on the intrauterine environment to further understand how it contributes to future development of type 2 diabetes and obesity. Research is also ongoing to combat obesity and its associated health consequences, including type 2 diabetes.

2. You describe the work that your agency is doing with respect to the three forms of diabetes that were the subject of our hearing: type 1, type 2, and gestational diabetes.

    a. Given that you have finite resources to devote to diabetes research, how do you strike a balance in addressing the research and other public health needs of each type of diabetes?

FRADKIN: The NIDDK considers many factors in addressing diabetes research and public health needs. For example, the NIDDK not only considers the number of people suffering from a disease, but also the associated morbidity and premature mortality. Therefore, diseases that often strike in childhood, such as type 1 diabetes, may get particular emphasis because of the earlier potential onset of health complications, including those that may lead to premature mortality. Another consideration is the impact of the disease on future generations, so research on gestational diabetes is particularly important because of the health implications for both mother and child. Along with considering these types of factors, the NIDDK continually seeks external input from scientists, professional organizations, patient advocates, and the public to help inform strategic planning for diabetes research. The federal government's statutory Diabetes Mellitus Interagency Coordinating Committee, which is chaired by the NIDDK, also plays a key role in coordination and strategic planning. For example, the Committee is now finalizing a new Diabetes Research Strategic Plan, for publication later this year, that highlights numerous scientific opportunities that will help to guide the NIH, other federal agencies, and the scientific community on future directions for diabetes research.

Because different forms of diabetes share common features, research findings are often relevant to more than one form of the disease. For example, research on beta cell biology can benefit people with all three forms of diabetes. Research to mitigate overweight and obesity can help to reduce risk for type 2 and gestational diabetes. Research on complications benefits people with type 1 and type 2 diabetes who share some of the same complications. Emerging research shows that factors in the immune system are not just important in type 1 diabetes, but are also involved in childhood type 2 diabetes and "hybrid" forms of diabetes that have characteristics of both type 1 and type 2. Thus, research on the immune basis of diabetes broadly benefits children with diabetes.

    b. How will investments in research, not specifically directed at diabetes or one of the specific types of diabetes, benefit each form of diabetes?

FRADKIN: Success has already been realized in the genetics field with the identification of numerous genes and gene regions associated with type 1 or type 2 diabetes. These discoveries were possible because of the Human Genome Project. We also expect that diabetes research will benefit from several ongoing broad initiatives. One example is research supported by the NIH Common Fund on the Human Microbiome Project, which is identifying and characterizing the microorganisms found in the body. Technologies stemming from that research could be used to

analyze samples being collected in the TEDDY study to uncover possible environmental triggers of type 1 diabetes. Another example is the Common Fund program on epigenetics, which involves the study of changes in the regulation of gene activity and expression that are not dependent on gene sequences. Research on epigenetics may provide insights into how intrauterine environmental factors contribute to risk of obesity and type 2 diabetes in offspring of gestational diabetes pregnancies. A final example is the Common Fund program to establish a national resource for induced pluripotent stem cells. These cells have potential for being used as a source to make insulin-producing beta cells for treating people with type 1 diabetes or severe cases of type 2 diabetes. Therefore, many of the broad initiatives supported by NIH have enormous potential for benefiting people with different forms of diabetes.

The Honorable Gene Green

1. We have heard about the recent activities of the NIDDK regarding research in diabetes prevention and treatments. With the need to put research into practice to enhance quality of life and decrease health care costs, can you elaborate on how NIDDK engages the health professions community to ensure that important research findings in the area of diabetes are translated to the physician practice so that patients receive the benefits of this important research?

FRADKIN: The NIH and the Centers for Disease Control and Prevention co-sponsor the National Diabetes Education Program (NDEP) (http://ndep.nih.gov/) in order to translate the latest science, spread the word that diabetes is serious, common, and costly, yet controllable and, for type 2, preventable. Thus, the NDEP helps to maximize the benefits of NIH investments in diabetes research. In addition to a copious array of culturally tailored publications for patients, translated into a variety of languages, NDEP features a series of important resources for health care professionals (http://ndep.nih.gov/hcp-businesses-and-schools/HealthCareProfessionals.aspx). These resources include:

- Guiding Principles for Diabetes Care, outlines patient-centered principles for people with diabetes and pre-diabetes: http://www.ndep.nih.gov/publications/PublicationDetail.aspx?PubId=108
- Diabetes Numbers at a Glance gives health care providers the clinical recommendations to diagnose and treat diabetes and pre-diabetes: http://www.ndep.nih.gov/publications/PublicationDetail.aspx?PubId=114
- The Support for Behavior Change resource (http://www.ndep.nih.gov/sbcr/Index.aspx) is a searchable database of research articles, tools and programs to help health care providers help their patients with the "how-to" make and sustain lifestyle changes to cope with diabetes and make lifestyle changes for people with pre-diabetes.
- NDEP recently created the Transitions from Pediatric to Adult Care tool to help teens, their families and their health care team make the transition from pediatric to adult care: http://www.ndep.nih.gov/whats-new/posting.aspx?id=5
- Working Together to Manage Diabetes: A Guide for Pharmacists, Podiatrists, Optometrists, and Dental Professionals (http://www.ndep.nih.gov/publications/PublicationDetail.aspx?PubId=26) provides resources for other key professionals in the diabetes care team.
- And to help health care professionals help their patients take steps to prevent or delay type 2 diabetes, the GAMEPLAN toolkit is available at: http://www.ndep.nih.gov/publications/PublicationDetail.aspx?PubId=118

Another valuable resource for primary care providers is the Better Diabetes Care website (http://www.betterdiabetescare.nih.gov/), which focuses on helping health care providers assess and evaluate systems of care, or how they deliver care to their patients with diabetes.

The NIDDK is also working to dramatically expand access to lifesaving diabetes research in a way that is cost-sustainable through its Translational Research for the Prevention and Control of Diabetes and Obesity program. This initiative has funded exciting research to deliver proven

diabetes prevention methods cheaply and efficiently by community health workers and at YMCAs.

The Honorable Diana DeGette

Technology

1. I read about the exciting results released this week on the STAR-3 study which demonstrated improved blood glucose control with glucose sensors and insulin pump therapy. Can you describe the results from this trial and its potential significance for diabetes management?

FRADKIN: Yes. The goal of this industry-supported study, the Sensor-Augmented Pump Therapy for A1C Reduction (STAR) 3 clinical trial, was to see if new diabetes management technologies could help people with type 1 diabetes who had inadequate glucose control improve their hemoglobin A1C levels. The trial compared strategies for intensive blood glucose control in two groups of adults and children. One group used an insulin pump paired with a continuous glucose monitor, enabling users to adjust insulin doses based on glucose sensor values. The other group used a standard regimen of multiple daily injections of insulin and monitoring by finger sticks—an approach that has been in use since the NIH-supported Diabetes Control and Complications Trial (DCCT) showed that it could help reduce or delay complications. The STAR 3 study found that sensor/pump technology resulted in much greater improvement in A1C than the standard injection regimen. Most significantly, more people achieved recommended A1C targets with sensor/pump technology than with injection therapy, with no increase in hypoglycemia. It was especially encouraging that children had many fewer hypoglycemia episodes with the sensor/pump strategy than were seen, for example, in the DCCT. However, although these results are promising, this approach still does not represent a panacea. A number of people enrolled in this and similar trials have had difficulty with the new technologies and consider them a burden, sometimes dropping out of studies or not using the devices consistently during a study. NIDDK-supported research contributed to the development of the currently approved continuous glucose monitoring devices, and the Institute is now working on improving the technology so that future devices will be more accurate and less burdensome.

Disparities in Minority Populations

2. From your perspective, are there gaps in the ongoing NIH research in terms of the disparate effect of diabetes? What further research do we need to initiate in order to fully address the problem of diabetes in every community and how can we eliminate any gaps in the current research?

FRADKIN: We are making great strides in our efforts to understand and address diabetes health disparities. For example, the Diabetes Prevention Program showed that interventions to prevent or delay type 2 diabetes were effective across a racially and ethnically diverse population of women and men, laying the groundwork for a multicultural health campaign that has reached out with important diabetes prevention messages for Americans from all communities. Similarly, the Look AHEAD clinical trial involves a diverse population in a study of the benefits of weight loss in people with type 2 diabetes. Our efforts to prevent or treat type 2 diabetes in youth, such as the HEALTHY study and the TODAY trial, have focused on children and adolescents from racial and ethnic minorities that are the hardest hit by this disease.

On a more fundamental level, we are closing gaps in what we know about type 2 diabetes risk genes outside of people of Western European descent—for example, NIDDK has collaborated with the National Human Genome Research Institute to establish a Multiethnic Study of Type 2 Diabetes Genes. NIDDK-supported research also led to a recent report that the results of hemoglobin A1C tests may differ based on race, such that African Americans in the study had higher A1C values, on average, than their white counterparts when they had the same blood glucose values—a disparity that was most apparent among people with the highest glucose levels. We are exploring this surprising finding further, as it could have important implications for the use of A1C tests in issues such as diagnosing diabetes, setting glucose control targets, and evaluating health disparities. Finally, while disparities in access to health care have been a significant barrier to appropriate diabetes care, there are also factors within care systems that may affect diabetes outcomes for different populations. Thus, we have been collaborating with the Centers for Disease Control and Prevention on a study called Translating Research into Action for Diabetes, or TRIAD, to examine quality of diabetes care in a very diverse population of people enrolled in managed care systems, to identify these factors and determine if there are practical steps that can be taken to improve treatment processes and outcomes. These are just a few examples of our many current efforts to address biologic and environmental factors contributing to diabetes health disparities so that we may see improved health for all Americans.

Special Diabetes Program

3. The multi-year funding stream for diabetes research is a unique feature of the Special Diabetes Program. What benefits, if any, does the multi-year funding stream provide to your ability to fund the most promising research in the field, and how important is this factor in the success of the program moving forward?

FRADKIN: Multi-year funding benefits research supported by the Special Diabetes Program. For example, because type 1 diabetes is a chronic disease in which outcomes develop over a long time period, clinical trials studying this disease require many years to complete. In particular, trials to prevent type 1 diabetes require substantial timeframes and screening of tens of thousands of people. Thus, clinical trials to prevent and treat type 1 diabetes and its complications benefit from multi-year funding. Another example of the benefit of multi-year funding is research to identify environmental triggers of type 1 diabetes. Such studies require the coordinated efforts of research teams capable of identifying newborns at high genetic risk for type 1 diabetes and collecting clinical data and biosamples over many years. This type of coordinated effort is now being done by the Special Diabetes Program-funded TEDDY study, which has enrolled over 8,000 newborns and is following them to age 15 to identify environmental triggers of type 1 diabetes.

Diet & Lifestyle Changes

4. NIDDK's Diabetes Prevention Program is widely recognized as strong evidence that Type 2 Diabetes can be prevented or delayed with a 7 percent reduction in body weight. Its follow-up trial, the DPP Outcomes Study data showed that even after a 10-year period the benefits

of lifestyle changes yielded long-term health benefits. What will it take to let Americans everywhere have the chance to benefit from these same interventions?

FRADKIN: One way to reach as many of the 57 million Americans with pre-diabetes as possible is to develop lower cost adaptations of the Diabetes Prevention Program lifestyle intervention that maintain efficacy, and to make such efforts widely available, particularly in communities with high rates of diabetes. The NIH is pursuing this goal through its Translational Research for the Prevention and Control of Diabetes and Obesity program. This initiative has funded exciting research to deliver proven diabetes prevention methods efficiently and at relatively low cost. Studies funded through this program include research to use a group-based lifestyle intervention delivered by professional and lower cost lay health counselors in a community setting via innovative expansion of an existing diabetes education program. This pilot project achieved excellent results, and is being expanded to a larger trial. It could be scalable to thousands of community care centers certified by the American Diabetes Association nationally. Another exciting project is testing a similar group-based approach delivered at YMCAs. Based on the results of this NIH-supported research, the Centers for Disease Control and Prevention (CDC) is implementing the National Diabetes Prevention Program to deliver this evidenced-based intervention. The initial phase of this implementation includes a unique partnership with the UnitedHealth Group, a private insurance company, and the YMCA to deliver this intervention cost effectively. Additionally, CDC is in discussion with other health care payers and community based organizations who can deliver the intervention.

The NIH also collaborates with the Centers for Disease Control and Prevention through the National Diabetes Education Program (http://ndep.nih.gov/) to disseminate the latest science, spread the word that diabetes is serious, common, and costly, yet controllable and, for type 2, preventable. The NDEP provides culturally tailored publications for patients, translated into a variety of languages, and features a series of important resources for health care professionals (http://ndep.nih.gov/hcp-businesses-and-schools/HealthCareProfessionals.aspx).

5. In 2003, the U.S. Preventative Services Task Force (USPTF) recommended intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dieticians USPTF awarded a B grade for these services. In the same document, USPTF concluded that such counseling is likely to improve health outcomes and that benefits outweighed potential harms.

   It is now 2010. Is there sufficient data to recommend similar intensive counseling for children? If not, when can we expect to have such information?

FRADKIN: People with diabetes manage their disease every day. This is a burden and challenge for even the most vigilant, and especially for children. Patient education plays an important role in effective disease management. For example, data from the NIDDK's Diabetes Control and Complications Trial (DCCT) showed that the intensive therapy intervention, which included intensive education and counseling, benefited the adolescent type 1 diabetes

participants. Data are expected in 2012 from the NIDDK's TODAY clinical trial on the importance of intensive counseling for lifestyle change in children with type 2 diabetes.

A need for tools to help patients manage their diabetes and achieve and sustain intensive blood glucose control associated with reduced rates of complications led to the development of new technologies such as continuous glucose monitors and insulin pumps. Enabling patients and providers to make optimal use of these technologies and the vast amounts of information these tools provide, requires additional knowledge, skill, training, and motivation. Until these technologies are automated, people, especially children, will need significant counseling to use the devices and benefit from their promise. To optimize the potential impact of these technologies, the NIH is supporting research on behavioral aspects that may enhance or constrain the sustained use of these technologies toward the goal of fully automating the system and relieving the burden associated with their use. Results from this research could lead to improved understanding of how to help people, including children, better manage their diabetes. To educate youth with diabetes in disease management, the National Diabetes Education Program (NDEP), jointly led by the NIDDK and Centers for Disease Control and Prevention, has developed materials specifically for children and teenagers to help them take appropriate actions to manage their disease for a long and healthy life. The NDEP also recently developed a Web site resource with materials to help teens transition from pediatric to adult health care and assume responsibility for and management of their own health and health care needs.

Stem Cell Research

6. As you know, I have been a proponent of embryonic stem cell research, which has the potential to unlock a cure or treatment for diabetes. Can you speak to any research the NIDDK is doing with stem cells? Do you know whether there is a need for diabetes-specific stem cell lines before research to this effect can proceed?

FRADKIN: The NIDDK is supporting research on stem cells through the Beta Cell Biology Consortium (BCBC), which just began its third award cycle. BCBC investigators work collaboratively toward the goal of developing cell-based therapies for type 1 diabetes, including research on stem cells. For example, these researchers are working to generate the insulin-producing beta cells lost in type 1 diabetes directly from stem or progenitor cells, so that they can be transplanted into people with type 1 diabetes. They are also conducting research to identify stem cells within humans that are capable of becoming beta cells, as it may be possible to stimulate these cells to regenerate beta cells. BCBC scientists are also exploring ways to increase the numbers of beta cells in people with diabetes by reprogramming other adult cells to become beta cells.

As it is not yet known which types of stem cells will lead to an effective cell-based therapy, research on all types of stem cells, including induced pluripotent stem cells and approved embryonic stem cells, is being pursued. It is critically important that research to produce beta cells for cell-based therapies is coupled with research on ways to control immune system responses. As type 1 diabetes results from an inappropriate attack by the immune system on a person's beta cells, it will be necessary to ensure that a similar attack does not destroy any newly generated beta cells.

The Honorable Zack Space

1. Too often, I hear horror stories from health care providers in my district who receive visits from patients suffering from diabetes they weren't aware they had. Has the NIDDK done any research into the benefits of early detection? Or, conversely, has the NIDDK done any research into the cost of treating patients who failed to detect their diabetes early on?

FRADKIN: NIDDK-supported research has provided us with the tools to delay or prevent type 2 diabetes in people at risk, and to prevent or delay complications of all diabetes. Because diabetes is a progressive disease, earlier intervention can lead to better health outcomes. It may also help in terms of health care costs. Just this month, NIDDK-supported investigators published an analysis suggesting that screening for diabetes and pre-diabetes, combined with preventive management, could be cost-effective for the health care system. NIDDK has supported a number of efforts to facilitate diabetes detection. For example, NIDDK-supported research led to the use and standardization of the hemoglobin A1C marker that is used to monitor diabetes control. The American Diabetes Association has now recommended using the A1C test as a diagnostic test for diabetes and pre-diabetes in many individuals. This eliminates a barrier to detection due to the inconvenience of tests requiring fasting. We are also pursuing new biomarkers for detecting pre-diabetes, diabetes, and complications. For example, an NIDDK-supported team recently reported promising results of a pilot study that could lead to a simple blood enzyme test to detect pre-diabetes. However, even when it is caught early, there are still questions about the best way to treat and manage diabetes. Along those lines, we are currently planning an initiative to determine whether there are long-term benefits to early aggressive treatment of type 2 diabetes, which could potentially encourage efforts in early detection.

For type 1 diabetes, relatives of type 1 diabetes patients are participating in research studies and can be identified early in the course of the disease when autoimmunity first develops. Through the Special Diabetes Program, tens of thousands of family members are being screened and their risk assessed. People who know they are at high risk for type 1 diabetes are less likely to present with life threatening ketoacidosis at disease onset.

2. Would you agree that early detection of diabetes can be an important way to mitigate the suffering of the patient and minimize costs to the system?

FRADKIN: Many health complications of diabetes start developing well before diabetes is diagnosed or detected, so the earlier we can detect either diabetes risk factors or its onset, the better chance people have to preserve their health and possibly lower health care costs.

3. I have been working with a number of my colleagues to advance legislation that would improve utilization of screening benefits under Medicare and Medicaid. Would you agree that mechanisms that would encourage seniors to be screened early for diabetes would have a positive effect on their health?

FRADKIN: Older Americans are at high risk for diabetes, and nearly a quarter of people 60 and over have the disease, so screening is very important for people over 60. Older individuals are also at high risk for pre-diabetes and older participants had the best results with lifestyle change to prevent or delay type 2 diabetes in the Diabetes Prevention Program clinical trial. Because the same test that finds type 2 diabetes also finds pre-diabetes, testing can help identify people who can benefit from prevention efforts. Diabetes presents a number of challenges to seniors, who often have other medical conditions that require medication or that could interfere with diabetes care. Thus, the NIDDK-CDC National Diabetes Education Program has developed efforts tailored to seniors, encouraging them to be aware of their diabetes risk and providing information on the Medicare benefits related to diabetes.

4. Can you talk about some of the efforts the NIDDK has undertaken to improve early detection efforts across the country?

FRADKIN: Our most important efforts in this area come from the National Diabetes Education Program. The NDEP has developed a number of tailored publications for multiple audiences. The NDEP's "Am I At Risk?" publication gets at the heart of improving our ability to find people with diabetes and pre-diabetes, by encouraging people to consider their possible risk factors and get tested. Currently, the NDEP is also partnering with the NIH Office of Research on Women's Health on a new campaign to increase awareness of diabetes risk among women with a history of gestational diabetes and their children, who are at greater risk for diabetes and obesity in the future.

5. As you may know, my District falls directly into the heart of Appalachia. We face all of the same challenges of a rural area when it comes to access to care. Some recent figures I have seen indicate that Appalachia has a much higher prevalence of diabetes than other areas. For obvious reasons, I find this extremely troubling. Can you talk about any efforts the NIDDK has undertaken to investigate geographic disparities in the prevalence of diabetes? Were significant conclusions drawn about this divide between rural areas and the rest of the country?

FRADKIN: The Centers for Disease Control and Prevention (CDC) monitors trends of diabetes and its complications over time on a nationwide, state-wide, and county-wide level. CDC maps showing the number of adults with diagnosed diabetes overlap significantly with maps showing the number of obese adults, reaffirming the close association between obesity and type 2 diabetes. The maps indicate that diabetes and obesity tend to be more prevalent in rural and poor areas. The NIDDK supports research to identify ways to translate the results of our diabetes clinical trials to reach communities at risk, including rural populations. For example, researchers are studying telemedicine approaches to reach rural populations.

6. I worry that public health/education efforts in my Congressional District may be more difficult than in some urban and suburban areas. Have you seen any evidence that suggests your education efforts are more effective in urban rather than rural areas?

FRADKIN: It is more challenging to reach people who live in rural areas, so the NIH is specifically supporting research that can benefit rural populations. For example, the National

Eye Institute, with support from the Special Diabetes Program, is supporting studies to develop new tools and technologies that can be used to increase patient access to eye exams for detecting diabetic retinopathy, a complication of diabetes that can lead to blindness. A major goal of the research is to identify ways to reach rural populations who do not have easy access to eye specialists. For example, researchers are developing cameras that can be used by non-eye specialists, such as primary care physicians, to take retinal images that can be sent to a remote processing site for interpretation and diagnosis by retinal specialists. This research could help to improve detection of diabetic retinopathy because patients would not necessarily have to make a trip to an eye specialist for an exam.

The NIDDK also supports translational research on the prevention and control of diabetes and obesity, including research on telemedicine approaches to reach rural communities at particularly high risk of developing type 2 diabetes. NIH-supported research is also focused on developing computer-assisted programs to promote weight loss and improve management of diabetes, which could be utilized by people living in rural areas. The NIDDK and the Centers for Disease Control and Prevention also make educational materials developed by the National Diabetes Education Program available on the Internet, to reach as broad an audience as possible.

7. Can you share with the Subcommittee what you think are the most pressing diabetes research needs that must be met if we are to build on past successes, improve prevention and treatment and ultimately close in on a cure?

FRADKIN: There are many exciting scientific opportunities in diabetes research, the results of which could greatly improve prevention, treatment, quality-of-life, and potentially lead to a cure. These opportunities have been outlined in a new Strategic Plan to guide diabetes research that is being developed under the auspices of the Diabetes Mellitus Interagency Coordinating Committee and with leadership from NIDDK. For example, the beta cell—the cell in the pancreas that produces insulin—is central to all forms of diabetes. Therefore, research toward replenishing, replacing, or regrowing beta cells can benefit people with type 1, type 2, or gestational diabetes. The NIH vigorously supports research on the beta cell to enhance understanding of disease and help inform new cell-based therapies. The NIH also supports research to develop an "artificial pancreas"—a mechanical system that will couple glucose monitoring with insulin delivery. We know that control of glucose soon after diabetes diagnosis can prevent complications, but many people cannot achieve it. An artificial pancreas could have a tremendously positive impact on patients' health and quality of life, and alleviate an enormous amount of the burden of diabetes care. We now have many drug classes available to treat type 2 diabetes, but comparative effectiveness research would help to personalize medicine so providers know which medication will work best in particular patients and stages of disease.

The Honorable Bruce Braley

1. Currently Medicare Part D plans are required to establish medication therapy management (MTM) programs. Plans are required to make MTM available to targeted beneficiaries – those with multiple chronic conditions who take multiple prescription drugs, and whose drug spending is likely to reach a designated amount. Congress recently took steps to strengthen the MTM program by codifying into statute changes that will help in standardizing benefits. Unfortunately, under current law, fewer than 13% of all Medicare beneficiaries have access to the MTM benefit due to the eligibility requirements.

   As you know, of the 24 million Americans with diabetes, approximately 20-25% of them are Medicare beneficiaries. Pharmacies are often the most accessible healthcare providers and pharmacists can play a critical role in helping patients to manage their diabetes. Are you familiar with MTM and what can Congress do to better utilize trusted healthcare professionals like pharmacists to combat diabetes?

FRADKIN: You have identified a very important problem. Many people with diabetes have high blood pressure, high cholesterol, and other health problems requiring multiple medications. Team care involving multiple health professionals has proven enormously valuable in helping people with diabetes manage their disease and adhere to complex medical therapies. Pharmacists and other health care professionals can play critical roles in helping diabetes patients achieve treatment goals, including through MTM partnerships. Indeed, the Asheville Project, a study funded and run by the city of Asheville, NC, showed that the pharmacist can make a tremendous difference in outcomes for people with diabetes. In this study, participants were paired with pharmacists, who met with them to discuss goals, and monitor progress. Over 14 months, participants experienced significant improvement in important measures of their health, including lower hemoglobin A1C levels, and improvements in their blood cholesterol levels. Building on this small study, NIDDK is supporting a larger trial assessing a clinical pharmacist-based intervention to improve diabetes risk factor control among hypertensive diabetes patients with poor control of blood pressure in two integrated delivery health systems: Kaiser Permanente and the Veterans Health Administration. This study is a component of our Translational Research for the Prevention and Control of Diabetes and Obesity program which tests cost effective approaches to diabetes improved care that can be widely disseminated.

Pharmacists play an important role in the NIDDK-CDC National Diabetes Education Program. The NDEP has developed an important resource called Working Together to Manage Diabetes: A Guide for Pharmacists, Podiatrists, Optometrists, and Dental Professionals (http://www.ndep.nih.gov/publications/PublicationDetail.aspx?PubId=26), which provides resources for key professionals, including pharmacists, in the diabetes care team.

The Honorable Michael C. Burgess

1. The CDC indicates that there are nearly 24 million Americans diagnosed with diabetes and as many as 57 million Americans with pre-diabetes. I know there are not nearly enough endocrinologists or other physicians who have received specialized training in diabetes to care for all of these patients. What is the federal government doing to ensure that primary care physicians and other professionals who may not have specialized training in diabetes have the resources and tools to provide quality care to diabetes patients?

FRADKIN: The NIH and the Centers for Disease Control and Prevention co-sponsor the National Diabetes Education Program (http://ndep.nih.gov/) in order to provide information and tools to primary care physicians and other health care providers to help them translate best practices for diabetes care and prevention of type 2 diabetes into their practices. Not only does the NDEP provide information on how best to treat and prevent diabetes, it also provides a valuable resource to help primary care providers assess and evaluate the diabetes care they deliver through the Better Diabetes Care website (http://www.betterdiabetescare.nih.gov/).

The NIH is also testing approaches to improve the quality of care by identifying aspects of health care that lead to better outcomes and improved risk factor control, and using that information to test strategies to improve health care delivery for the millions of people with or at risk for diabetes through its Translational Research for the Prevention and Control of Diabetes and Obesity program. Some studies look at how electronic health records can be used to guide treatment decisions and ensure that proven therapies are delivered. Other studies examine approaches to supplement the care that can be delivered by physicians through use of diabetes educators, pharmacists, or community health workers. Many physicians do not have the time or tools needed to help patients make lifestyle changes that can prevent or delay type 2 diabetes. Their patients might benefit from referral to programs that can deliver effective lifestyle change cost effectively in a community setting. Successful pilot studies funded through this program include research to use a group-based lifestyle intervention delivered by professional and lay health counselors in a community setting and research testing a similar group-based approach delivered in YMCAs. Already based on these exciting pilot results, the CDC and private insurers are moving to expand access to the YMCA program.

2. Healthy lifestyle intervention, according to the findings in the clinical trials, appears to one of the most successful methods of controlling diabetes. With a disproportionate impact on minority populations – many Medicare eligible – how do you propose encouraging these populations to change their eating habits/exercise habits, which may require the spending of additional money, when their resources are already strained?

FRADKIN: The NIH and NIDDK are committed to research aimed at helping to eliminate health disparities such as those associated with type 2 diabetes. The Diabetes Prevention Program, Look AHEAD, HEALTHY, and other major type 2 diabetes prevention and control trials at the NIH have recruited a large proportion of disproportionately affected minority participants, to help ensure that the results of those trials will be of broadly applicable. Moreover, these studies

developed culturally sensitive and validated programs to foster lifestyle change that are now being disseminated by government and private sector efforts.

The Translational Research for the Prevention and Control of Diabetes and Obesity program is an important approach to help make the lifesaving discoveries of that research program accessible and affordable to as many of those in need as possible. This initiative has funded exciting research to deliver proven diabetes prevention methods efficiently and at relatively low cost. For example, studies from this program have shown that the lifestyle intervention that was successful in the DPP can be delivered in group settings by fitness trainers or community health workers at much lower cost without loss of efficacy. In addition, a new program recently announced by the NIDDK is a funding opportunity for NIDDK Centers for Diabetes Translation Research. The program will emphasize bedside to practice and community translation and will be a nexus for research in such areas as effectiveness, dissemination, implementation, and cost effectiveness research, health disparities, health literacy and numeracy, diabetes self management, lifestyle change, and health communication.

3. As an Ob/GYN for over 25 years, GDM (Gestational Diabetes Mellitus) is an important issue to me. You mentioned that a recent panel of experts has recommended changing the diagnostic criteria for GDM to be less stringent. By lowering the criteria, could this have adverse effects of doctors misdiagnosing GDM and inadvertently over treating women?

FRADKIN: I appreciate your concerns. These recommendations are based on the results of the Hyperglycemia and Adverse Pregnancy Outcomes, or HAPO, study, supported by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and NIDDK. By examining blood glucose levels and pregnancy outcomes in over 23,000 women around the world, the HAPO study demonstrated that there is a continuum of risk according to glycemia at levels below those currently used to diagnose gestational diabetes. In the study, the higher a pregnant woman's blood glucose levels following an oral glucose tolerance test, the more likely she was to deliver a high birth weight baby, and the more likely the baby was to have signs of hyperinsulinemia. Elevated blood glucose also raised risk for problems such as preeclampsia and shoulder dystocia. Most significantly, there was no clear threshold level at which these outcomes began—that is, there is apparently no "safe" level of hyperglycemia. The increasing rates of GDM are driven in large part by increased rates of overweight and obesity in women of child bearing age. Thus, one approach to minimizing risk for these women and their babies would be to monitor and minimize excessive weight gain during pregnancy. NIDDK is also pursuing multiple efforts to address and prevent GDM. For example, in addition to ongoing research efforts to better understand causes of GDM, we are considering new clinical trials that would test lifestyle interventions to improve maternal metabolic status—for example, lipids, glycemia, and optimal weight gain—and examine impact on offspring using markers identified in the HAPO study. These trials could result in highly cost-effective, short-term interventions with a significant impact on future health of mothers and their offspring.

4. What is being done to research the correlation between gestational diabetes and the mother or child developing type 2 diabetes?

FRADKIN: We are very interested in understanding these correlations, as it could help our efforts to reduce the burden of diabetes in women and children. Important information on the relationship between diabetes during pregnancy and future type 2 diabetes risk in offspring emerged from a collaboration between NIDDK intramural researchers and the Pima Indians of the American Southwest. The Pima have an extremely high rate of type 2 diabetes, a fact that enabled NIDDK investigators to see the long-term effects of maternal diabetes in the same family, when one child was born before a mother had diabetes, and another was born after she had developed diabetes—thus helping to distinguish the effect of diabetic pregnancy from simple heredity. Other population studies have revealed that mothers with GDM have a greatly increased risk for developing diabetes within 10 years after pregnancy. Together, these findings have spurred a wealth of research in recent years on factors that influence maternal metabolism and fetal development during pregnancy and post-partum. For example, we are now supporting studies that are using primates and other animal models of pregnancy to study the effects of diet on outcomes for both mothers and offspring. We are also identifying appropriate human cohorts in which to study correlations and outcomes. For example, we are planning a follow up study in children from the HAPO study. This new project will help us to identify markers that link exposures in utero with the development during youth of known risk factors for chronic disease—for example, adolescent obesity. This effort may also help us to better understand how differing levels of maternal hyperglycemia influence long-term outcomes.

Encouragingly, the DPP found that lifestyle change aimed at modest weight loss reduced the risk of type 2 diabetes in women with a history of gestational diabetes. The NIDDK is partnering with the NIH Office of Research on Women's Health to disseminate the results of this important study to pediatricians and OB/GYNs who are likely to interact with women with a history of GDM.

5. In June, it was recently announced that HHS will spend $250M to increase the number of healthcare providers and strengthen the training of the primary care workforce. What steps are being taken to ensure appropriate diabetes-related education for these new providers?

FRADKIN: Most people with diabetes receive care from their primary care providers, rather than from endocrinologists. The current guidelines that these providers use to treat their diabetes patients derive from NIH-supported research, and the NIH plans to continue its vigorous support of research to inform prevention and treatment strategies for people with diabetes. Moreover, the NIDDK and CDC co-led National Diabetes Education Program has developed several resources for use by health care providers to promulgate these guidelines, including an at-a-glance pocket guide that provides a list of current recommendations to diagnose and manage pre-diabetes and diabetes. More detailed information is found in the NDEP's "Guiding Principles for Diabetes Care," which outlines important patient-centered principles of diabetes care, helping health care professionals identify people with pre-diabetes and undiagnosed diabetes for treatment aimed at preventing long-term complications. Another useful resource is the Better Diabetes Care website, which focuses on helping health care providers assess and evaluate systems of care, or how they deliver care to their patients with diabetes. Representatives from the American Academy of Family Physicians and the American College of Physicians, the leading professional associations for primary care physicians, participate in the NDEP and help to promulgate NDEP materials and messages to members of these associations.

Question by the Honorable Diana DeGette to Buford Rolin:

Thank you for your work combating diabetes in Native American communities, where the disease is all too prevalent. Advocates such as those from JDRF have consistently impressed upon me the need to reauthorize the Special Diabetes Programs in a timely manner because of the timing of the NIH grant cycles. Given that the Special Diabetes Program for Indians addresses treatment, education, and prevention—rather than bench-to-beside research—can you please elaborate on what it would mean for Indian populations were it not to be reauthorized this year?

Response:

Funds from the Special Diabetes Program for Indians (SDPI) support personnel and program costs through grants and sub-grants in over 450 Indian communities in 35 states. If the funding is discontinued, those 450 programs will mostly disappear. This will result in a loss of services, such as children's weight management programs, after school physical activity programs, community-based diabetes prevention programs, community nutrition counseling programs, group diabetes education sessions, community-based amputation prevention activities through home visits, and many more. This will result in a real loss of services in real people's lives, people who are at risk for the devastation that diabetes wreaks. It will result in a loss of hope for AIAN communities that the diabetes epidemic can be turned around. In some tribal communities, the programs supported by SDPI funds are the only diabetes education, treatment and prevention efforts underway. If these programs disappear, some communities will be left with no federal effort focused on diabetes. It addition, it is critical that Congress renew SDPI this year so that program staff can focus on continuing successful programs as opposed to how to begin to close them down.

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JDRF Juvenile Diabetes Research Foundation International

dedicated to finding a cure

August 4, 2010

The Honorable Diana DeGette
c/o Earley Green, Chief Clerk
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515-6115

Dear Representative DeGette:

On behalf of the Juvenile Diabetes Research Foundation (JDRF), I am deeply appreciative of your strong leadership and interest in type 1 diabetes research issues and am pleased to provide you with the attached answer to your follow-up question from the Subcommittee on Health's July 1, 2010 hearing entitled "The Battle Against Diabetes: Progress Made; Challenges Unmet.'

Thanks to the strong public-private partnership between the federal government and JDRF as I reference in my attached response, we are at a pivotal point in type 1 diabetes research. JDRF and our countless individuals and families who are affected by type 1 diabetes will continue to do our part. As you know, we need the renewal of the Special Diabetes Program (SDP) this year to ensure that the large-scale, multi-center clinical trials responsible for much of the advances to date can continue uninterrupted.

I look forward to working with you and your staff further to achieve our mutual goal of a cure. Please do not hesitate to contact me or Laura Whitton, JDRF's National Director of Government Relations at lwhitton@jdrf.org or 202-465-4103 if we can be of any assistance.

Sincerely,

Robert A. Goldstein, M.D., Ph.D.
Senior Vice President, Scientific Affairs

Attachment

JDRF Juvenile Diabetes Research Foundation International

dedicated to finding a cure

Dr. Robert Goldstein, M.D., Ph.D., Senior Vice President, Scientific Affairs
Response to the Honorable Diana DeGette' Question
from the July 1, 2010 Hearing entitled
"The Battle Against Diabetes: Progress Made; Challenges Unmet."

The Honorable Diana DeGette
"Dr. Goldstein, your testimony stressed the importance of the public-private partnership in accelerating research into type 1 diabetes, and I know that JDRF takes seriously its commitment to funding the most promising research toward a cure for type 1 diabetes. Can you describe for the committee how JDRF's research priorities compare to the research goals of the Special Diabetes Program and how the two research portfolios complement each other toward the mutual goal of a cure for diabetes?"

The Special Diabetes Program (SDP) has the following overarching goals:
- Identify the genetic and environmental causes of type 1 diabetes;
- Prevent or reverse type 1 diabetes;
- Develop cell replacement therapy;
- Prevent or reduce hypoglycemia in type 1 diabetes;
- Prevent or reduce the complications of type 1 diabetes; and
- Attract new talent and apply new technologies to research on type 1 diabetes

JDRF shares the same goals as the SDP. JDRF is pleased to work in close partnership with the National Institutes of Health to ensure we are doing all we can to efficiently and expeditiously reach our mutual goals. Two examples – there are many more – might serve to illuminate how the partnership accelerates the delivery of research results to people with type 1 diabetes:

- NIH funded the original research which led to the glucose sensing technology used in many continuous glucose monitors (CGMs). This technology was then licensed by companies and developed into the products available today. The Special Diabetes Program-supported DirecNet program sponsored studies of the use of CGM devices in children and found them to be effective. In 2006, JDRF conducted an additional study -- a large, national, 10-site clinical trial -- to assess the effectiveness of CGM use. The trial, results of which were published in *The New England Journal of Medicine* in 2008 and *Diabetes Care* in 2009, found that people with type 1 diabetes who used CGM devices to help manage their disease experienced significant improvements in blood sugar control. Based on these results, JDRF initiated a campaign to encourage health plans to provide coverage for CGMs. Today, all the national health plans – Aetna, CIGNA, Humana, United Healthcare, and WellPoint – cover CGMs, as do many regional plans. In addition, nationally recognized clinical guidelines recommend CGMs for people with type 1 diabetes.

- NIH-funded researchers first identified a drug – a monoclonal antibody named anti-CD3 – that can slow the progression of type 1 diabetes. Together, JDRF and NIH (with the SDP-funded Immune Tolerance Network and Type 1 Diabetes TrailNet) funded the proof-of-concept clinical trial that showed that a short 1-2 week treatment with anti-CD3 helps patients maintain or increase their ability to produce insulin naturally for several years after diagnosis compared to a placebo. These findings are significant because patients use less insulin and have more stable blood glucose levels for an extended period of time.

  Anti-CD3 is just the leading edge of a robust pipeline of potential therapies for reversing new onset type 1 diabetes. Promising other drug therapies, such as anti-CD20, are being tested currently in clinical trials funded by JDRF and NIH with the strong support of the Special Diabetes Program.

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August 4, 2010

The Honorable Gene Green
c/o Earley Green, Chief Clerk
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515-6115

Dear Representative Green:

On behalf of the Juvenile Diabetes Research Foundation (JDRF), I am deeply appreciative of your strong leadership and interest in type 1 diabetes research issues and am pleased to provide you with the attached answer to your follow-up question from the Subcommittee on Health's July 1, 2010 hearing entitled "The Battle Against Diabetes: Progress Made; Challenges Unmet."

We are at a pivotal point in type 1 diabetes research and the renewal of the Special Diabetes Program (SDP) this year will ensure that the large-scale, multi-center clinical trials responsible for much of the advances to date can continue uninterrupted. One such example is the remarkable progress we have seen related to diabetic eye disease thanks to the SDP- supported Diabetic Retinopathy Clinical Research Network (DRCRNet) as referenced in my attached response.

I look forward to working with you and your staff further to achieve our mutual goal of a cure. Please do not hesitate to contact me or Laura Whitton, JDRF's National Director of Government Relations at lwhitton@jdrf.org or 202-465-4103 if we can be of any assistance.

Sincerely,

Robert A. Goldstein, M.D., Ph.D.
Senior Vice President, Scientific Affairs

Attachment

JDRF Juvenile Diabetes Research Foundation International

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Dr. Robert Goldstein, M.D., Ph.D., Senior Vice President, Scientific Affairs
Response to the Honorable Gene Green's Question
from the July 1, 2010 Hearing entitled
"The Battle Against Diabetes: Progress Made; Challenges Unmet."

The Honorable Gene Green
"Earlier this year, the House passed a resolution I authored to recognize the need for type 1 diabetes research funding and the importance of the Special Diabetes Program at the NIH. This program is funding important research across all stages of the disease, including the complications of diabetes. As the founder of the Congressional Vision Caucus, I know that diabetic eye disease is the leading cause of blindness in working age adults. As such, research in this area will have tremendous implications for society. I read recently that researchers have found a way to not only halt the progression of diabetic eye disease but reverse the disease in patients enrolled in clinical trials supported by the Special Diabetes Program. Can you please comment on this research and what you see for the future for those affected by this complication of diabetes?"

The research cited was conducted throughout the United States by the Diabetic Retinopathy Clinical Research Network (DRCRNet), one of the clinical consortia established with the Special Diabetes Program (SDP) funds.

The DRCR Network tested 3 different treatments for macular edema, a severe form of diabetic eye disease. An innovation of the trial design was that each treatment was a combination of drug with the standard laser treatment.

Standard laser therapy leads to improved vision in only about 30% of treated eyes. In a previous trial, the DRCR found that steroid was also an effective treatment, but not as good as laser. One of the combinations for the new trial was steroid plus laser, testing whether the combination might give better results than either treatment alone. A newly developed drug, called anti-VEGF, was tested in the other combinations: a combination of anti-VEGF plus laser; or a combination of anti-VEGF and then later laser. **The results of the trial, reported in *Ophthalmology* in April 2010, showed that nearly half the people whose eyes were treated with the anti-VEGF combinations, had an improvement in vision of at least two lines on an eye chart after one year. And fewer people receiving treatment experienced big vision loss compared with those who got only standard laser.** These results have been sustained through 2 years of the 3-year trial. Dr. Frederick Ferris III, clinical director of the National Eye Institute, which sponsored the trial, was quoted in *The New York Times* saying, **"This is the first new treatment for people with diabetic macular edema in a quarter of a century."**

The DRCR Network is a collaborative network including over 320 physicians in 109 participating sites (offices) throughout the United States, dedicated to facilitating multicenter clinical research on diabetes-induced retinal disorders.

HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

JOE BARTON, TEXAS
RANKING MEMBER

ONE HUNDRED ELEVENTH CONGRESS

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July 21, 2010

Robert R. Henry, M.D.
Professor of Medicine
University of California Department of Medicine
Chief, Section of Endocrinology, Metabolism & Diabetes
VA Medical Center, San Diego
3350 La Jolla Village Drive (111G)
San Diego, CA 92161

Dear Dr. Henry:

Thank you for appearing before the Subcommittee on Health on July 1, 2010, at the hearing entitled "The Battle Against Diabetes: Progress Made; Challenges Unmet."

Pursuant to the Committee's Rules, attached are written questions for the record directed to you from certain Members of the Committee. In preparing your answers, please address your response to the Member who submitted the questions.

Please provide your responses by August 4, 2010, to Earley Green, Chief Clerk, via e-mail to Earley.Green@mail.house.gov. Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,

Henry A. Waxman
Chairman

Attachment

The Honorable Diana DeGette

Hemoglobin A1C Test

1. New research is showing the power of some very practical, evidence-based tools in meeting the challenges of diabetes. For example, changes in diet and exercise that have been shown to reduce the onset of diabetes by 58%. In addition, use of the hemoglobin A1C lab test to identify a person's blood glucose levels—and, thus, help detect diabetes.

   In fact, the American Diabetes Association recently recommended the hemoglobin A1C test as one of the tests that is appropriate for detecting diabetes. One of the reasons for recommending the test is that it is consumer friendly—patients no longer have to fast before taking it. What impact do you think this test might have in terms of consumer willingness to be tested and on overall diabetes detection and management?

   Since the test can be done without fasting, and isn't affected by short-term illness or stress, individuals can be tested at any time (if they go to a doctor in the afternoon, if they are admitted to a hospital, etc.). Many people affected by type 2 diabetes have no symptoms and require targeted testing in a health care setting to diagnose the disease. Type 2 also disproportionately affects populations with less access to healthcare, who may only see a physician if they have some other problem. Being able to take whatever opportunity to test high-risk individuals for diabetes (or prediabetes) using the hemoglobin A1C test is likely to reduce the number of people with the disease who are undiagnosed. In addition, it is essential that targeted diabetes testing, in accord with the American Diabetes Association's recommendations, be provided without cost sharing through implementation of the Affordable Care Act. A quarter of the nearly 24 million American with diabetes are currently undiagnosed. Reliance upon the A & B recommendations of the United States Preventative Services Task Force will thwart efforts to identify this population as well as the nearly 57 million people with pre-diabetes so that prevention and treatment efforts can be effectively implemented.

Pre-Diabetes

2. As legislators and as individuals, we often hear about the damages from diabetes—vision problems, nerve damage, kidney failure, and more. We also hear about its costs—some $174 billion annually. But these costs—both in human and dollar terms—may just be the beginning in light of the fact that an additional 57 million Americans have what is known as pre-diabetes.

   - Pre-diabetes is a condition in which patients experience elevated blood glucose levels that are close to full-force diabetes, but are just shy of the threshold.
   - Pre-diabetes patients stand a 50 percent greater chance of stroke and heart disease than patients with glucose in the normal range.
   - Some 40 percent of pre-diabetes patients will become fully diabetic in 3 – 8 years.

   I know that a Representative from the ADA will be present at a diabetes caucus briefing on July 12 about pre-diabetes and its costs, its impact, and practical solutions in dealing with it. Can you

comment about how we can best support efforts at combating pre-diabetes from becoming full-blown diabetes?

We know that type 2 diabetes can be prevented or delayed if people with pre-diabetes have education and ongoing support to lose 5-7% of their body weight and to exercise (such as walking) at least 150 minutes a week. The barriers to this evidence-based approach are two-fold: most people with prediabetes are not aware that they have it because they haven't been tested, and evidence-based prevention is only just beginning to be carried out in less costly community settings. The best way to support prevention efforts would be: 1) to support more screening (targeting testing of high-risk people) for diabetes and prediabetes (the same risk factors and tests apply); and 2) support the development and dissemination of community-based prevention, through the National Diabetes Prevention Program (NDPP).

The NDPP was authorized through the Affordable Care Act because it has proven its ability to dramatically – and affordably – reduce diabetes. It is based on the Diabetes Prevention Program (DPP), an NIH funded clinical trial that showed people with pre-diabetes can reduce their risk of developing type 2 diabetes by 58% with modest lifestyle changes. Through the CDC, this was translated into a community-based group intervention, where it has been shown through places like the YMCA that the same results can be achieved at a lower cost of around $300 per person. NDPP includes grants for model sites, and provides for training, quality assurance, outreach and further research. We know this works; we now need to develop the infrastructure to bring it to scale. However, although authorized in the Affordable Care Act, the NDPP has not yet been funded. We believe that in order to stem the diabetes epidemic, it is critical that the NDPP be implemented at $80 million dollars in FY 2011.

Comprehensive & Coordinated Federal Strategy

3. More than 24 million Americans have diabetes and almost 60 million are at great risk of developing it. This is an overwhelming public health problem that requires a comprehensive and coordinated response, similar to the Ryan White CARE Act of 1990. That landmark legislation launched a nationwide program to fight HIV/AIDS and has achieved great success in halting the growth in cases of HIV/AIDS and providing better treatment options for those with the disease. Do you think that similar legislation would help us fight diabetes?

Yes. Although the Association is grateful to Congress for providing vital resources to address the diabetes epidemic, it is painfully obvious that we as a country have not recognized the burden that diabetes has on our citizens and our fiscal health – or the juggernaut that awaits us if we don't take action to stop diabetes. Through the work of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health, the Division of Diabetes Translation (DDT) at the CDC, and the Indian Health Service, our collective knowledge of the disease has been elevated and expanded so the work towards ending the epidemic can continue. But the bottom line is more needs to be done if we want to change our future, one in which one out of every three American children faces a life with diabetes.

On several key occasions, including the passage of the National Diabetes Mellitus Research and Education Act in 1974, and the creation of the Special Diabetes Program, Congress has

expanded the federal response to the diabetes epidemic. With the prevalence of the disease on the rise and the human and economic toll escalating, the Association would welcome a federal effort of the magnitude of the Ryan White CARE Act in order to stop diabetes. We believe that such an effort should strengthen the hands of the NIDDK, DDT, IHS, other key agencies, providers, community-based organizations, academic institutions, and patients to more aggressively address diabetes. Such an effort should quicken the pace of research and speed up the translation of new discoveries into improved prevention, treatment and management tools; broaden and intensify community-based prevention strategies; ensure access to health care for individuals with and at risk for diabetes; ensure that all federal agencies support the most appropriate and effective methods for screening and detection; and eliminate health disparities in diabetes research, prevention, and care. The Association stands ready to assist Members of Congress in this needed commitment to stop diabetes.

4. In 1974, when there were only 4 million people diagnosed with diabetes, Congress established the foundation for our nation's diabetes research and public health activities by passing that National Diabetes Mellitus Research and Education Act. Despite advancements in research and improvements in the Medicare program, today there are 24 million people suffering from the disease and the death rate continues to climb. The 1974 Act was a landmark effort to put the federal spotlight on diabetes – likely for the first time; however, the bill only focused on the federal government's own approach and attitude towards diabetes. It seems to me that, today, that won't be enough – we need the public engaged. Modernizing the Act would be a good step, but in doing so, from a legislative perspective, what can Congress do today – working with the Administration– to give the public tools to combat this terrible disease?

We are thankful that Congress supports the DDT, NIDDK, IHS and other agencies to engage the public in diabetes awareness, prevention, care, and research, through NIDDK clinical trials, DDT prevention programs, the National Diabetes Education Program, and other efforts. However, as a voluntary health organization focused on individuals with and affected by diabetes, the Association believes that more should be done to further ensure public input and engagement in our national diabetes strategy. For example, Congress, working with the Administration, should ensure that individuals with expertise in diabetes are represented on federal advisory committees implementing the Affordable Care Act, such as the Health Promotion and Public Health Advisory Committee and the United States Preventive Services Task Force. A key link to public engagement from the federal government is the work of DDT. Sadly, DDT remains woefully underfunded, providing a mere 80 cents for each American with diabetes or pre-diabetes. We cannot hope to fully engage the public without the means to reach and teach them about this disease. In addition, for people to have the tools to combat diabetes they must have access to adequate and affordable health care. The Affordable Care Act is a milestone in making this a reality, but it is crucial that it be implemented in a way that makes its promise a reality for people with diabetes. This includes targeted testing for diabetes as discussed above and ensuring that the essential benefits package includes the tools needed for effective diabetes management. Absent these efforts, we will continue to pay for an amputation caused by diabetes but not provide the tools needed to prevent that amputation.

The Honorable Michael C. Burgess

1. How do we encourage payers to cover diabetes patient education and reimburse providers for time and resources need to properly guide patient self-management?

   The American Diabetes Association does not take positions on issues related to specific provider reimbursement legislation. However, the Association recognizes and supports the tremendous efforts that these provider organizations make to improve the lives of patients with diabetes and strongly supports reimbursement for the tools and services needed to effectively manage diabetes including diabetes self-management education (DSME).

   The Association is keenly aware of the problems many patients face in accessing the DSME they need to successfully manage their disease. Accordingly, we are firmly committed to promoting greater access to DSME and to supporting the crucial role of the diabetes educator. Over the past year, the Association has actively fought for a number of provisions in the federal health reform debate that would greatly improve access to DSME. These include ending the discrimination that permits insurance companies to refuse insurance to people with diabetes or to charge them significantly higher insurance rates because they have diabetes, ending lifetime and annual caps on benefits, capping annual out-of-pocket expenses, and increasing affordability of coverage through expanding Medicaid and implementing subsidies for those who cannot otherwise afford insurance.

   As the Affordable Care Act is implemented, it is essential that diabetes self- management education be included in the benefits package and all cost-sharing (i.e., co-pays and deductibles) be eliminated for DSME under Medicare. In addition, pilots for new care delivery systems and associated payment structures should be used to develop systems that recognize the essential role of DSME .

2. Specifically is the ADA watching the MLR definitions coming out of HHS?

The Association recognizes the importance of the HHS MLR definitions to health care organizations, providers, and patients and but is not taking a specific leadership role in reviewing the definitions.

   a. If they are too strict with their guidelines and management programs are excluded from MLR what do you think might happen?

   b. So it is essential that we keep a close eye on them because they could really hurt patients?

3. There is a common myth that starting insulin means you are failing to appropriately manage your disease and many patients see taking insulin as a defeat. However, the most important thing is to get glucose levels stabilized using appropriate insulin as soon as possible. How do we de-stigmatize insulin therapy, as well other therapies, and encourage patients to see

aggressively managing their blood glucose levels as a positive lifestyle choice, instead of a negative?

4. In your experience what is the best way to encourage patients to aggressively manage their blood glucose levels as a positive lifestyle choice, instead of a negative?

The Association believes that your questions are related, and will answer them together. Patients need accurate information about the benefits of taking care of their diabetes, the progressive nature of type 2 diabetes (which requires additional therapies over time), and realities (vs. myths) about therapies. Patients are more likely to accept insulin therapy if they know from the beginning that it is often needed to manage diabetes and not because of failure on their part. In order to ensure that patients have the ability to effectively manage their diabetes, they also need healthy environments and support for exercise and healthy eating (as do all Americans). One barrier to effective diabetes management is that it is expensive. People with diabetes are typically on multiple medications, and even with prescription drug coverage the co-pays are a problem for many. Many people with diabetes live in "food deserts" where fresh healthy food is not available or in areas where even simple exercise such as walking is not feasible. Given these challenges, healthier communities and improved access to affordable health care would benefit people with diabetes (and all Americans).

Another barrier is that the media have sensationalized any negative aspect of diabetes therapy without highlighting the many positives. Patients hear greatly exaggerated stories about oral medications and insulin, but do not hear the good news that complication rates are declining for people who appropriately manage their diabetes. The message people are getting may be that glucose control doesn't work or is even dangerous. Nothing could be farther from the truth, yet patients, and even many health care providers, are confused. That's why patients need accurate information about all aspects of their diabetes so that they can work with their providers to develop and implement an effective diabetes management plan.