

Expert Q&A

A one-on-one discussion with Michael Mawby, Chief Government Affairs Officer for Novo Nordisk, on the health reform legislation currently supported by Novo Nordisk.

Common Cents

The Investment in Preventive Health:
A closer look at how Congress evaluates the cost of legislation and the benefits of using diabetes as a model to better understand the value of the costs/savings associated with preventive health programs.

How Expensive is Diabetes?

A summary of the recent University of Chicago study, which projects future cost and spending associated with diabetes over the next 25 years.

Advocacy in Action

An overview on Novo Nordisk's advocacy efforts in the prevention, detection, treatment and care of diabetes.

Welcome to the inaugural issue of the Novo Nordisk BlueSheet, the industry's definitive resource for information on diabetes and chronic disease. Novo Nordisk is a healthcare company and world leader with an 87-year history of innovation and achievement in diabetes care. Each quarter, we will highlight key issues in diabetes prevention, detection, treatment and care and related topics from the legislative process to innovation in patient care to public education. In our first issue, we tackle a topic that has been at the forefront of Congress and every dinner table and water cooler across America – health reform. Clearly, we like a challenge.

Like many of those involved in the debate over health reform, we have an ambitious goal. We want to defeat diabetes. Whether it's collaborating with partners in the public and private sector, funding science and research or supporting education and humanitarian efforts, Novo Nordisk is 100% committed to finding better methods of diabetes prevention, detection and treatment.

Access to care, utilization and rising costs are fueling the current healthcare debate and one of the major drivers of utilization and costs today is diabetes. As the fifth deadliest disease in the U.S., diabetes affects almost 24 million

Americans. In fact, it costs the nation an astonishing \$218 billion each year in medical expenses and lost productivity. That amounts to 10 percent of all U.S. healthcare spending.

With such staggering numbers, we have to ask ourselves, why isn't there more funding and government support for diabetes *today*? Given what we know now, shouldn't diabetes have a substantial role in health reform? Something just doesn't add up here, particularly since the federal government has consistently dedicated significant funding and resources to diseases like cancer and HIV/AIDS over the years – an investment that has accelerated progress for those diseases. We need to fix this disparity – starting now.

Without improved access to affordable healthcare, and the jury is still out as to whether the recently enacted legislation will be affordable, the costs associated with diabetes and its related complications will continue to skyrocket. This is precisely why we also need to improve the way diabetes is funded and treated. This is a critical time. Just as our country has had a national response to cancer and HIV/AIDS, diabetes must have a national response focused on prevention and treatment.

As a global leader with more than

HEALTHCARE REFORM

The costs associated with diabetes and its related complications will continue to skyrocket without improved access to affordable healthcare. This first issue of the Novo Nordisk BlueSheet examines how legislation, advocacy and research can help to change the way diabetes is funded and treated in the U.S. today.



87 years in the prevention, detection, treatment and care of diabetes across 76 countries, we've seen the power of innovative thinking, perseverance and passion. From our work in developing nations to the invention of innovative products that enhance the lives of patients to our continuous lobbying efforts on Capitol Hill, Novo Nordisk is dedicated to changing how diabetes is treated, how it is viewed, and how the disease evolves in the future. But we cannot do it alone. By stimulating a public dialog, we hope to act as a catalyst for change by encouraging action, influencing legislative policy and building advocacy for the prevention, detection, treatment and care of diabetes around the world.

Jerzy Gruhn

President of Novo Nordisk Inc.

EXPERT Q&A

Changing Diabetes: One Bill at a Time

Diabetes is dramatically underfunded when it comes to government spending. At the Centers for Disease Control and Prevention (CDC), cancer and HIV/AIDS are funded at a rate five and 10 times higher, respectively, than diabetes, yet diabetes surpasses both diseases in prevalence. Legislation would help make diabetes a higher priority among federal agencies, increase the investment in research and prevention, improve access to care and resources for screening and diagnosis, reduce health disparities, and improve coverage and benefits for people with diabetes.

THE 4-1-1 ON DIABETES

Nearly 24 million Americans have diabetes and another 57 million have pre-diabetes and are at risk of developing the disease.

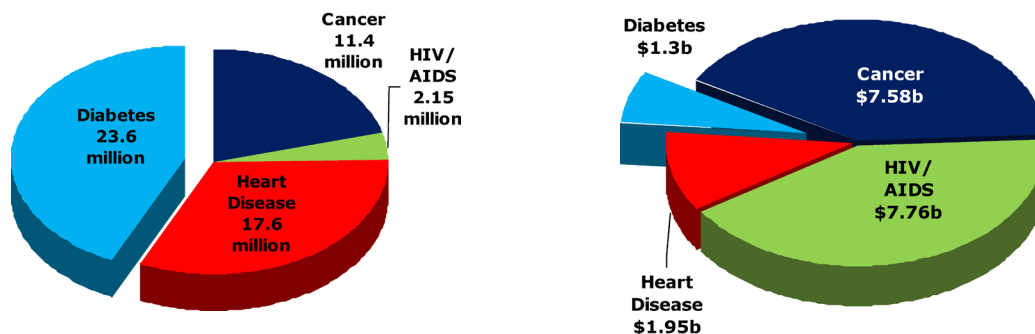
2007 National Diabetes Fact Sheet, CDC

The statistics around diabetes are staggering. While cancer and HIV may seem more prevalent due to the funding, resources and attention they receive, diabetes is actually the more common chronic disease in the U.S. with nearly 24 million Americans – 7.8 percent of the population – suffering from the disease. In the next 25 years, the number of Americans living with diabetes will nearly double, increasing from 23.7 million in 2009 to 44.1 million in 2034. It is predicted that about one in every three persons born in 2000 will develop diabetes in his or her lifetime.

So how can diabetes be stopped? Early detection and prevention are critical to reversing the trajectory of this epidemic. Studies have shown that people at risk for developing diabetes can in fact prevent or delay the onset of the disease. At the same time, new and better treatments are available that can help people with diabetes delay or avoid altogether the serious and deadly complications that can arise from diabetes.

With targeted and thoughtful diabetes-related policy and legislation, millions of Americans can benefit from increased diabetes research, appropriate screening, disease prevention, access to care, and appropriate treatment. Novo Nordisk is leading the effort to elevate diabetes on the national agenda and working with patient advocacy groups and diabetes healthcare providers to influence public policy to improve prevention, detection, treatment, and care for people living with diabetes. Michael Mawby, Chief Government Affairs Officer for Novo Nordisk, discusses Novo Nordisk's current work on Capitol Hill to improve the lives of people living with diabetes and the importance of these ongoing advocacy efforts.

Chronic Disease: A Comparison of Prevalence* and Estimated Spending* on Prevention and Research



* Prevalence and estimated spending analyzed for cancer, diabetes, heart disease and HIV/AIDS only. Heart disease is heart disease/stroke in breakout of funding for CDC. Identified spending includes NIH, CDC, IHS and Ryan White (for HIV/AIDS only) funding estimates. Diabetes spending includes \$300 million special diabetes funding through the Public Health Service Act for type 1 diabetes and Indians.

Sources: FY2011 Congressional Justification, Centers for Disease Control and Prevention and Indian Health Services; National Institute of Health <http://report.nih.gov/rdc/categories/>; Ryan White legislation

Q Why is legislation necessary to combat the growing diabetes epidemic in the U.S. today?

A Diabetes impacts millions of people annually, with 1.6 million new cases of the disease diagnosed each year—an incidence rate that outpaces other chronic diseases. Nonetheless, it is dramatically underfunded when it comes to government spending. The federal government has dedicated significant funding and resources to diseases like cancer and HIV/AIDS -- cancer receives five times more research dollars than diabetes and HIV/AIDS receives 2.7 times more research dollars than diabetes. Both diseases have seen drops in mortality rates. Diabetes, on the other hand, exceeds both of these diseases in terms of prevalence, and the diabetes mortality rate continues to climb. Yet it is significantly underfunded relative to this burden. Unfortunately, diabetes doesn't get the attention it deserves from our leaders. But we can work toward this through appropriate legislation. The development, passage and enactment of legislation can help make diabetes a higher priority among federal agencies; increase the investment in research and prevention; improve access to care and resources for screening and diagnosis; reduce health disparities; and improve coverage and benefits for people with diabetes. Simply put, it is our best chance at defeating diabetes.



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.

Q What measures of the Patient Protection and Affordable Care Act are related to the prevention, treatment and care for diabetes?

A There is language in the bill identical to the Diabetes Prevention Act of 2009 which would establish, run, monitor and evaluate 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. We will still need to secure the funding necessary to establish this program, which could be a groundbreaking achievement in the national efforts to prevent diabetes.

THE 4-1-1 ON DIABETES

One in every 10 healthcare dollars is spent on diabetes and its complications, and one in every three Medicare dollars is spent on people with diabetes.

Halvorsen, George, Healthcare Will Not Reform Itself, CRC Press, 2009, p. 131

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THE 4-1-1 ON DIABETES

If we are not successful in slowing the number of new cases of diabetes through prevention or delay of onset, by 2034 annual spending on diabetes will nearly triple to \$336 billion.

Huang et al (2009) Projecting the Future Diabetes Population Size and Related Costs for the U.S. Diabetes Care, December 2009, Vol. 32, No 12, 2225-2229



Improving the diabetes data sets we use to track the disease and its complications will serve to shine a light on the growing problem and keep the public – and policymakers – eyes on the prize.

Q What provisions of the Catalyst to Better Diabetes Act exist in the Patient Protection and Affordable Care Act?

A There are three (out of five) provisions from the Catalyst to Better Diabetes Act that are in the Patient Protection and Affordable Care Act. Specifically:

1. There is language directing the CDC to issue a biennial National Diabetes Report Card as a way to regularly report to the American people on progress being made in the fight against diabetes. We believe this will serve the purpose of improving the diabetes data sets we use to track the disease and its complications as well as serve to shine a light on the growing problem and keep the public – and policymakers – eyes on the prize.
2. There is language directing the CDC to assist states in improving statistical data tracking on death certificates to provide a clearer picture of the impact of diabetes. This is important because diabetes is perennially underreported as a cause of mortality.
3. There is language that directs the Institute of Medicine to issue a report within two years of enactment on the state of diabetes education in American medical schools. We hope this will bring attention to the fact that part of the reason that diabetes is so poorly controlled in the U.S. is that physicians get very little training on how to deal with the needs of these patients during medical school - and proceed to enter practices that are literally being overrun by patients with diabetes.

Finally, there is important language in Patient Protection and Affordable Care Act that would authorize the Centers for Medicare and Medicaid Services (CMS) to modify the current Medicare coverage for dietary counseling services such that the benefit could be offered for both beneficiaries with diabetes or renal disease and beneficiaries with pre-diabetes. This important provision may ultimately help reduce diabetes-related expenditures in Medicare by providing people with pre-diabetes the knowledge they need to prevent the progression to diabetes.

COMMON CENTS: THE INVESTMENT IN PREVENTIVE HEALTH

Securing adequate funding for preventive health services presents a significant challenge to the nation's budget. To evaluate this investment, today's policymakers need a long-term analysis of healthcare costs in order to make accurate decisions that reflect the true impact of prevention programs. Among all chronic diseases, diabetes offers the best data, modeling and studies to help government budget analysts better understand the value of the costs/savings associated with preventive health programs.

Skyrocketing healthcare costs are crippling the nation's budget and with the rise in chronic diseases among Americans, there is simply no end in sight to these costs. Chronic diseases like cancer, heart disease and diabetes are the leading causes of death and disability in the U.S. (Source: CDC) and account for 75 percent of current health costs. Total direct and indirect costs for diabetes and pre-diabetes were estimated at \$218 billion in 2007 – making it one of the most costly diseases in America. While chronic diseases are among the most common and costly today, it is important to note that they are the most preventable.

Securing adequate funding for preventive health services in today's healthcare reform environment presents a considerable challenge. Preventive care must first be recognized and evaluated as the investment that it is. Thus, legislators need to analyze the impact of preventive healthcare based on a long-term analysis of costs. This process is known as "scoring." Through scoring, legislators estimate the federal government spending of all proposed bills – in short, each bill is "priced." At the direction of Congress, The Congressional Budget Office (CBO) manages this scoring process and decides whether or not the proposed legislation would affect the federal budget. Currently, the CBO uses a 10-year scoring window to make these determinations, but with chronic diseases – particularly diabetes – this time span presents policymakers with an incomplete view of preventive health measures as an investment. Since chronic diseases develop over a longer period of time, the highest costs associated with their treatment and care come later in the life of the disease; therefore, the savings are far more apparent at 25 years than at 10 years. As a result, many organizations – including Novo Nordisk – are asking Congress to re-evaluate this scoring window to enable better-informed decisions when it comes to preventive care and funding for chronic diseases. To do this, policymakers need a long-term analysis of costs to make accurate decisions that reflect the true impact of prevention programs.

Preventive care must first be recognized and evaluated as the investment that it is.

THE 4-1-1 ON DIABETES

Currently, only 3.7 percent of the National Institute for Health budget goes to diabetes research, despite the fact that one-in-five healthcare dollars is spent caring for someone with diabetes and one-in-ten dollars spent on healthcare is attributable to diabetes and its complications.

National Institute of Health, FY 2008

THE 4-1-1 ON DIABETES

On its current course, the number of people with diabetes is projected to nearly double by 2034 to 44.1 million due in large part to the aging of the baby boom population and increased rates of overweight and obesity.

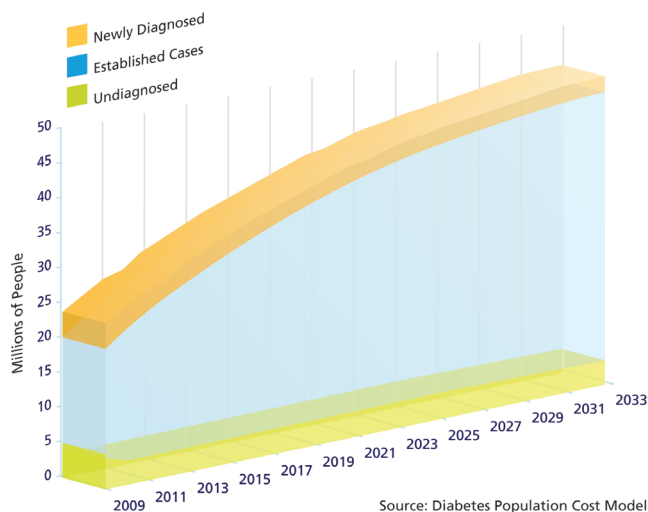
Huang et al (2009) Projecting the Future Diabetes Population Size and Related Costs for the U.S. Diabetes Care, December 2009, Vol. 32, No 12, 2225-2229

A recent study did just this. As one of the nation's greatest public health challenges, diabetes is an excellent spending projection model when it comes to making more informed budget decisions. Among all chronic diseases, diabetes offers the best data, modeling and studies to help policymakers better understand the value of the costs/savings associated with preventive health programs. In 2009, Novo Nordisk funded a study from a team of researchers at the University of Chicago to illustrate this. The study was published in the peer-reviewed journal *Health Affairs* and endorsed by key diabetes and medical associations. The study uses diabetes as a model to improve the budgetary and health outcome information available to Congress by projecting the future burden of diabetes and predicting the growth in diabetes costs over 25 years. Critical findings from landmark clinical trials were also incorporated into the research to demonstrate that an investment in early, aggressive prevention and treatment of diabetes yields payoffs that increase over time. According to this forecast, the number of Americans living with diabetes will rise from 23.7 million in 2009 to 44.1 million in 2034 – unless we see a significant investment in prevention now.

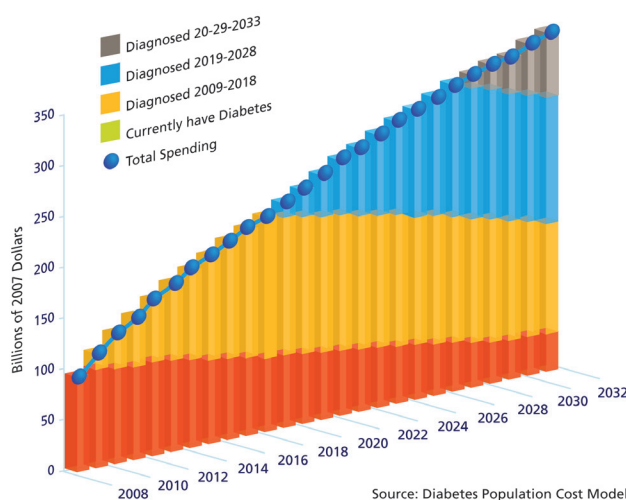
In 2009, legislation was introduced to lead to a more accurate assessment of the costs and benefits of preventive health, including preventing complications of chronic diseases such as diabetes. The bipartisan Preventive Health Savings Act of 2009 (HR 3148), which is supported by Novo Nordisk, calls on the CBO to weigh clinical or observational studies – like this diabetes study – when modeling projected costs and savings related to preventive health, and in certain circumstances, to look beyond the traditional 10-year budget window.

For a more in-depth look at the study, visit: www.ncdp.com

Projects Distribution of Newly Diagnosed, Undiagnosed and Established Cases of Diabetes, 2009-2034



Projects Direct Spending on Diabetes and its Complications for Different Cohorts, 2008-2033



HOW EXPENSIVE IS DIABETES?

In a recent study published in the peer-reviewed journal *Health Affairs*, researchers from the University of Chicago predict that the diabetes population in the U.S. will almost double over the next 25 years and annual medical spending on the disease is projected to nearly triple, hitting \$336 billion, up from \$113 billion today. The population and costs associated with diabetes are expected to add a significant strain to our overburdened healthcare system unless we make changes in our public or private strategies. Increased screening and better access to care may require additional funding now, but these measures will significantly reduce the costs associated with disease treatment and complications in the long run.

How much will diabetes cost the U.S. over the next 25 years? Will the prevalence of diabetes escalate or will we see a significant decline in the disease? In a recent study published in the peer-reviewed journal *Health Affairs*, researchers tackled the question of its future costs and prevalence using a diabetes-based economic decision-making model. The model presents a realistic way for policy-makers to understand the cost of diabetes by projecting future direct spending on diabetes. The “Diabetes Population Cost Model” is a computer simulation that integrates a diabetes progression model with publicly available data from a number of sources.

Created by Michael O’Grady, Senior Fellow at the National Opinion Research Center at the University of Chicago and his research team, this model shows annual expenses of a diabetes program at a cost of \$1,024 per patient are offset by 58% over 10 years, and when carried out to 25 years, are offset by 89%.

In a follow-up article published in the journal *Diabetes Care* in December 2009, the researchers show that the population and cost growth associated with diabetes are expected to add a significant strain to the already overburdened healthcare system in the U.S. unless we make changes in our public or private strategies. This news is not surprising when you compare the skyrocketing costs of healthcare against the growth of diabetes among Americans today.

The study further contends that:

The diabetes population in the U.S. will almost double over the next 25 years and annual medical spending on the disease is projected to hit \$336 billion, up from \$113 billion today.

The number of Americans living with diabetes will rise from 23.7 million in 2009 to 44.1 million in 2034. For the Medicare program, the increases over the next 25 years are even more dramatic.

The number of Americans living with diabetes and covered by Medicare will rise from 6.5 million to 14.1 million, and Medicare spending on diabetes will almost quadruple, skyrocketing from \$45 billion this year to \$171 billion in 2034.



THE 4-1-1 ON DIABETES

Diabetes is one of the most costly diseases in America, with total direct and indirect costs for diabetes and pre-diabetes estimated at \$218 billion in 2007.

Dall, T., et al. The Economic Burden Of Diabetes. Health Affairs. 29, NO. 2 (2010)



ADVOCACY IN ACTION

Healthy People 2020

The Healthy People Initiative, a program of the U.S. Department of Health and Human Services (HHS) provides science-based, 10-year national objectives for promoting health and preventing disease. Healthy People 2020 will reflect assessments of major risks to health and wellness, changing public health priorities, and emerging issues related to our nation's health preparedness and prevention.

Public input is playing a crucial role in the development of Healthy People 2020. In December 2009, the Medicare Diabetes Screening Project, funded by Novo Nordisk as a Changing Diabetes Leadership Initiative, led an effort to include important diabetes screening/detection measures in the objectives, resulting in dozens of organizational comments to the Healthy People effort.

The Healthy People 2020 objectives will be released along with guidance for achieving the new 10-year targets in 2010. For more information, visit www.healthypeople.gov/HP2020.

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Health/Wellness Fund

Increased funding for prevention and wellness is a key component of the current healthcare reform legislation. Indeed, the new law would provide \$15 billion over 10 years. This prevention/wellness trust would focus on a number of wellness initiatives, including: 1) a national strategy to improve the nation's health through evidence-based clinical and community-based prevention and wellness activities; 2) a grant program to support the delivery of evidence-based and community-based prevention and wellness services aimed at reducing health disparities; 3) promotion of positive health behaviors in medically underserved communities; and 4) grants to plan and implement programs to prevent obesity among children and their families.

At this point in time, there is no certainty as to which diseases/conditions will receive funding from the proposed trust. However, diabetes certainly merits significant attention. Every year, diabetes increases in prevalence, yet federal funding has not even come close to reaching a level that will enable us to address the growing, urgent need to stem the tide of diabetes through prevention, research and its translation, education and community outreach. Between FY 2008-09 and FY 2009-10, the CDC's funding allocated to states to address diabetes – already low due to a lack of funding attention – further decreased 4.3 percent while CDC's total budget increased by nearly 2.5% or over \$200 million in comparison. (Source: Fiscal Year 2009/2010 Diabetes Prevention and Control Program (DPCP) Funding Information, personal memorandum, Centers for Disease Control and Prevention). Adequate financial funding and government leadership has significantly reduced the impact of cancer and HIV/AIDS; however, the prevalence and death rate related to diabetes – which lacks the same funding or commitment – continues to climb.

Novo Nordisk works constantly to educate policy-makers about the need to increase funding for diabetes prevention, detection, treatment and care while raising awareness about this growing chronic disease worldwide. Recently, Novo Nordisk helped form a broad coalition of healthcare professional membership and patient advocacy organizations to advocate for significant diabetes funding from the proposed prevention/wellness trust fund.