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THE ECONOMIC IMPACT OF DIABETES

HEARING

BEFORE THE

JOINT ECONOMIC COMMITTEE

OF THE

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FIRST SESSION

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CONTENTS

THE ECONOMIC IMPACT OF DIABETES

THURSDAY, JULY 27, 2023

UNITED STATES CONGRESS,
JOINT ECONOMIC COMMITTEE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:04 a.m., in Room 192 of the Dirksen Senate Building before the Joint Economic Committee Chairman, Martin Heinrich.

Senators: Hassan, Heinrich, Kelly, Welch, and Lee.

Representatives: Schweikert, Ferguson, Smucker, Malliotakis, Beyer, and Moore.

Staff: Nicholas Aquelakakis, Christina Carr, Tess Carter, Hannah Ceja, Sebi Devlin-Foltz, Ron Donado, Michael Farren, Tomas Gallegos, Owen Haaga, Colleen Healy, Jeremy Johnson, Brooke LePage, Mirella Manilla, Jessica Martinez, Michael Pearson, Elisabeth Raczek, Alfredo Romero, Christopher Russo, Jeff Schlagenhauf, Alexander Schunk, Douglas Simons, Lia Stefanovich, and Garrett Wilbanks.

OPENING STATEMENT OF HON. DAVID SCHWEIKERT, A U.S. REPRESENTATIVE FROM ARIZONA, VICE CHAIRMAN, JOINT ECONOMIC COMMITTEE

Vice Chairman Schweikert. All right. Shall we give this hearing a start? Welcome to the JEC. I actually have to give Senator Heinrich and the entire team, both the Democrat and Republican staff.

This is one, I am not even going to do this from some sort of script, has been in sort of discussion for quite a while. As we look at the health statistics of our nation, particularly diabetes, its cost to society not only just in health care cost but in so many of our brothers and sisters that just have misery.

And where this partially came from is about two-three years ago, we were actually doing a weird experiment. What is the real cause of income inequality in America? And yes, we saw education, we saw other things, but the one thing we were not prepared to see was health.

The numbers of folks in, I hate to use the economic term, in some of the quartiles that had real health issues and a number of it was diabetes. And so we have spent almost two years sort of digging around in the literature, trying to understand what is going on in society, particularly the growth of our population that are suffering, but also now we are seeing juvenile, our young people.

A chart came out about three weeks ago that basically said at the end of this decade, almost half of our kids will technically be obese, and then the cascade effect of potential diabetes with that.

Maybe there is a moment here where this is not Republican or Democrat, right or left. It is actually focusing on what is going on in our society and our moral obligation to find a way to end this misery, bring back productivity and there is a punchline for those of us who often sound like accountants on steroids. It is actually really good economics.

So I am—for our two witnesses, and then I will hand it over to the good Senator, Dr. Mark Herman serves of the Chief of the Section of—I always get the word wrong—Endocrinology. All right, thank you for bailing me out, diabetes and Metabolic at Baylor College of Medicine.

Dr. Herman is both a practicing doctor and leading medical researcher. His primary focus is on diabetes treatment and care. As an expert in metabolic diseases, Dr. Herman's research has improved our understanding of diabetes itself, as well as made advancements in diabetes treatment.

Doctor, and we did our best on this, Lullipo?

Dr. Ippolito. Ippolito.

Vice Chairman Schweikert. Not even close. He is a Senior Fellow of Economics and Policy Studies at the American Enterprise Institute. His research focuses on public finance and health economics. He has written on health care finance, competition and pharmaceutical markets, and the economics of value of medicine innovation.

He has earned his Ph.D. in Economics from the University of Wisconsin-Madison. Senator Heinrich.

OPENING STATEMENT FROM THE HON. MARTIN HENRICH, A U.S. SENATOR FROM NEW MEXICO, CHAIRMAN, JOINT ECONOMIC COMMITTEE

Senator Henrich. Thank you, and I want to start just by thanking Vice Chairman Schweikert for his passion in this area, and it is something that touches all of us. It certainly touches our two states, and when you look at just the raw numbers, the economic impacts of diabetes on our economy and our nation, are really astounding.

More than 37 million Americans, about one in ten, have diabetes, and another 96 million adults have pre-diabetes. Diabetes is growing more prevalent, with an estimated one in three Americans expected to develop the disease at some point in their lifetime, and that is just an astounding figure that drives so much of our health care costs.

The rising costs of diabetes are due to the high price of medications and treatments in the doctor's office, and also lost earnings due to sickness, lower employment rates and the cost of early retirement. These costs are borne by the patient, by our health systems, by employers and really by entire communities as we will hear about today.

That is where we focus in this hearing today I think, identifying the direct and indirect costs of diabetes on our economy, finding bipartisan solutions that ensure that we have a healthy population

who really can fully contribute to their economies. Part of tackling this is making sure that all Americans have access to quality, affordable health care, no matter their means or where they live geographically.

When patients lack access to health care, minor challenges can quickly become major challenges, with a lack of proper diagnosis and treatment, and that is especially true in rural and tribal communities, where diabetes is increasingly prevalent.

Too many Americans are living with undiagnosed to untreated diabetes, because they cannot afford to see a doctor, to pay for prescribed medications, or travel the long distances required to get to a provider. Living with undiagnosed diabetes can delay more effective treatments that prevent more extreme complications, and impact people's ability to provide for their families.

Like most diseases, we know that Type 2 diabetes prevention, early intervention and health education are both cost effective and lead to better health outcomes. Beyond that, we must understand and address the upstream causes of the disease, including factors like socioeconomic status and access to quality nutrition.

Food insecurity is closely associated with Type 2 diabetes. When families have access to nutrition programs like SNAP and WIC, they are able to more consistently access healthy food, and we have seen associated reductions in both poverty and health care expenditures. Fortunately, medical science has also had recent breakthroughs on pharmaceutical treatment options for diabetes, and I am looking forward to hearing more about how recent breakthrough treatments have had positive outcomes for patients, and have helped to change their lives for the better.

Unfortunately however, many of those treatment options remain unaffordable for many patients. The Inflation Reduction Act was an important step in controlling drug costs. The law established several cost control measures like limiting insulin co-pays for Medicare beneficiaries to $35 a month, and capping annual out of pocket prescription drug costs at $2,000 starting in 2025.

The Act also gives Medicare the ability to negotiate the price of some high cost prescription drugs, and forces drug companies to pay a penalty when the prices that they charge Medicare rise faster than inflation. These actions will all put downward pressure on drug costs, while having little impact on innovation.

It is clear that the most—the most effective treatment for diabetes requires a comprehensive and holistic approach addressing diet, lifestyle, mental health and other societal factors alongside medical treatments. We have had some successes on this front, such as with the Special Diabetes Program for Indians, which Congress established in 1997. This program provides funding for diabetes prevention and treatment services to over 300 Indian health programs across the United States, and provides grantees with flexibility to design and implement diabetes interventions that address locally identified community priorities.

Through this program, we have seen youth-based outreach, the planting of community gardens, running and fitness events and partnership programs for pharmacies that help patients manage their prescriptions.

The Special Diabetes Program for Indians has been extremely effective. Since it started, the prevalence of diabetes, end stage renal disease and diabetes-related eye disease among American Indians and Alaska Natives have all declined.

We need to increase the funding for this program to allow it to keep up with costs and better serve all tribes. And looking beyond tribal communities, we should look to this program as a model for how we can design and implement comprehensive disease treatment and management nationwide.

I am pleased to join my colleagues from both sides of the aisle to further explore these issues, and more today in this bipartisan hearing, and I am looking forward to hearing more today on the impacts of diabetes on our communities from the ways we can address the upstream causes, to the role of health and nutrition programs and prevention, treatment and the role of pharmaceutical interventions.

It is my pleasure to also introduce our two other distinguished witnesses. We have President Buu Nygren, who was elected as the 10th President of the Navajo Nation, an office he assumed in January of this year. He also serves as the Navajo Area Representative to the National Indian Health Board.

President Nygren previously served as the chief commercial officer for the Navajo Engineering and Construction Authority—we need more engineers around here, by the way president—a quasi-independent tribal enterprise headquartered in Shiprock, New Mexico from 2010 to 2018.

President Nygren was a national operation trainer and a project manager at a multi-billion dollar construction company that built schools, senior living homes and public safety facilities from Nevada to Florida. President Nygren also served as the first president of the Change Labs' board of directors, a non-profit that continues to support Navajo and Hopi entrepreneurs, with basic tribal-specific technical assistance.

President Nygren has a B.S. in Construction Management and an MBA from Arizona State University. You have heard of that, right?

[The opening statement of Chairman Heinrich appears in the Submissions for the Record on page 36.]

Vice Chairman Schweikert. I have the same MBA.

Chairman Heinrich. And a Doctor of Education in Organized Change, or sorry, Organizational Change and Leadership from the University of Southern California.

Mrs. Janet Brown-Friday is the president of Health Care and Education at the American Diabetes Association. Mrs. Brown-Friday has been a registered nurse for more than 40 years, and most recently serves as the clinical trial manager at the Albert Einstein College of Medicine's Diabetes Clinical Trials Unit.

Mrs. Brown-Friday serves on the National Board of the American Diabetes Association, and she remains a current member of the NYC Community Leadership Board for the ADA. Mrs. Brown-Friday also previously served as a committee member for the National Diabetes Education Program and as a special government employee and a council member for the National Institute of Diabetes and Digestive and Kidney Diseases Advisory Council.

Mrs. Brown-Friday holds an MPH in Community Health Education, and an M.S. in Community Health Nursing from Hunter College in New York City, New York.

President Nygren, we are going to begin with you and your testimony, and then we will go left to right or right to left. Okay, right to left down the dais today. So welcome President, and we look forward to hearing your testimony.

STATEMENT OF BUU NYGREN, PRESIDENT, NAVAJO NATION, WINDOW ROCK, ARIZONA

President Nygren. Good morning Chairman Heinrich and Vice Chairman Schweikert, and esteemed Members of the Joint Economic Committee. I am Dr. Buu Nygren, president of the Navajo Nation. I serve as also the Navajo Area Representative to the National Indian Health Board. I come before you to speak about a matter that not only affects the welfare of our nation, but also a significant issue for all indigenous people across the United States.

We are here to discuss the importance of the special diabetes program for Indians. Today, the Navajo Nation provides governmental services to over 400,000 members, and our on-reservation population is about 200,000, which accounts for one-third of all Natives living in Indian country.

Like many other American Indian tribes, Navajo people experience higher rates of preventable nutrition-related diseases such as obesity, diabetes, heart disease and cancer than the general U.S. population. These health issues are not part of our heritage, but the consequences of painful history marked by colonization, forced assimilation, displacement from our tribal homelands and relocated to reservation lands.

Historically, our communities thrived on farming, herding and hunting and gathering. These traditional practices provided us with nutritious foods that sustained us for generations. However, this way of life has been systematically eroded over time, as processed foods high in fat, sugar and salt have replaced all our traditional food sources.

This compounded by poverty, unemployment and the lack of transportation has amplified the health disparities we face today. In 1997, Congress established the SDPI, a critical response to the escalating diabetes epidemic in Indian country.

This program, as mentioned earlier, has a budget of 150 million funds, over 300 community-based intervention programs to prevent Type 2 diabetes. Despite these efforts, diabetes remains a persistent public health problem among our people.

In 2011, the Navajo Nation, in collaboration with HIS, changed their approach. We began to engage local community input and implement interventions that are culturally relevant and sensitive to our unique circumstances. Recognizing our inherent sovereignty, we have initiated our own disease prevention activities, data collection, policy development and evaluation initiatives.

In 2014, the Navajo Nation enacted the Healthy Action Act, that introduced a two percent tax on unhealthy foods. This Act has generated 10 million, funding over—funding vital local community wellness projects. This approach has provided much-needed funding and promoted healthier eating habits within our community.

However, these efforts alone are not enough. The special diabetes program for Indians is critical in providing quality diabetes care and prevention practices, resulting in lower incidence in end stage renal disease and lower prevalence of Type 2 diabetes among Native Americans.

All these things save taxpayer dollars in medical costs. From 1996 to 2013, incident rates of end stage renal disease among Native Americans of diabetes declined by 54 percent. This reduction along is estimated to have a value of 520 million over nine years.

These programs have had a tangible impact on our communities. The Navajo Wellness Centers funded by SDPI have already shown promising results, providing health screenings and conducting wellness activities. These centers help detect and manage diabetes, and have also been successful in promoting overall health and well-being within our communities.

However, the current funding levels for SDPI are barely enough to maintain existing initiatives. We need to ensure that every Navajo individual who is fighting this disease has access to the resources and care they need. Our ask today is for the reauthorization of the SDPI and for an increase in funding that will enable us to expand our programs, reach more people, ultimately turn the tide in this fight against diabetes.

We support legislation passed by committees in each chamber that would renew the SDPI for two years at a funding level of 170 million per year to serve more Native Americans effectively. The special diabetes program for Indians is the gold standard when it comes to diabetes treatment, and probably considered one of the most effective public health programs ever created.

We urge you to consider human faces behind the statistics. Our elders, our children and our family, they all look to you and hope that their government will continue to support them in their fight against this devastating disease. You have the power to turn this hope into reality. Thank you for your time, your consideration and your continued support. (Speaks in Navajo language) Thank you.

[The statement of President Nygren appears in the Submissions for the Record on page 39.]

STATEMENT OF JANET BROWN-FRIDAY, RN, MSN, MPH, PRESIDENT, HEALTH CARE AND EDUCATION, AMERICAN DIABETES ASSOCIATION, WASHINGTON, DC

Mrs. Brown-Friday. Thank you. Thank you Chairman Heinrich and Vice Chairman Schweikert, and distinguished Members of the Joint Economic Committee, for inviting me to testify on behalf of the American Diabetes Association, regarding cost of living with diabetes. We appreciate you considering this important topic at this critical time.

The ADA is the nation's leading voluntary health organization, fighting to bend the curve on the diabetes epidemic and help people living with diabetes thrive. For more than 80 years, the ADA has been driving discovery and research to treat, manage and prevent diabetes, while working relentlessly for a cure.

Today, I would like to take this opportunity to describe and offer context for some of the most significant drivers of cost increases for people living with diabetes, and the work ADA is doing to make

managing diabetes more affordable and prevent costly adverse outcomes.

According to the CDC, more than 37 million Americans live with diabetes and nearly 100 million Americans have pre-diabetes. Diabetes is the most expensive chronic condition in the United States. People with diabetes account for one of every four dollars spent on health care and nearly one-third of Medicare drug spending. People of color and other under-served populations, those who lack access to adequate health insurance coverage, health care services and the tools they need to manage bear a disproportionate share of the costs.

That is because 18 percent of black Americans, 17 percent of Latino Americans and nearly 15 percent of Native Americans have diabetes, compared to seven percent of white Americans. Because diabetes diagnoses are less likely when people have access to resources, diabetes prevalence is inversely related to household income.

Individuals who earn less than $30,000 per year are three times more likely to have diabetes than those who make more than $80,000. Lower income Americans in rural, in both rural and urban areas are also likely to develop diabetes, experience complications from poorly-managed diabetes and die younger than higher income Americans.

These costs and disparities become even more acute during the recent pandemic, and consequent economic impact. Americans with diabetes and other related underlying health conditions were hospitalized with COVID–19 six times as often and died of COVID–19 12 times as often as those who did not have diabetes.

One in ten coronavirus patients with diabetes died within one week of hospital admission. Americans with diabetes accounted for 40 percent of COVID–19 fatalities nationwide, despite making up just ten percent of the U.S. population at the time.

Some of the major drivers of these high costs are care of people with—for care of people with diabetes, high rates of hospitalizations. Having health insurance is the strongest single predicter of whether adults with diabetes will receive high quality health care services.

More than 27 million uninsured Americans have a higher likelihood of having undiagnosed diabetes because they are 60 percent less likely than insured individuals to have regular office visits with a physician, and have 168 percent more emergency room visits.

Comorbidities. People with undiagnosed diabetes are more likely to develop comorbidities, from kidney failure to coronary artery disease, increasing costs and severely limiting their ability to get healthy.

Costs of prescription drugs. Americans spend more treating diabetes than any other chronic condition. People with diabetes in the U.S. spend two and a half times more on health care than those who do not have diabetes, and one in four insulin-independent Americans report rationing their insulin supply.

The lack of access to diabetes technology. 31 percent of individuals with diagnosed diabetes or ten million Americans are treated with insulin and stand to benefit from a continuous glucose moni-

toring insulin pump, and yet we know that people who lack adequate access to health care providers and rely on Medicaid for health insurance coverage are least likely to be prescribed an CGM and other diabetes management technology.

Lack of access to healthier foods can lead to being overweight and obesity, both of which are proven risk factors driving as many as 53 percent of new cases of Type 2 diabetes each year. And we now know that rates of both Type 1 and Type 2 diabetes have increased and may be linked to COVID–19 infections, as has been seen in some studies.

I thank you for the opportunity to testify before the Joint Economic Committee on the cost of diabetes. The ADA looks forward to continuing the work with Congress to address health inequities, reduce cost to patients, and help Americans with diabetes access the tools, medications and services they need to stay safe and healthy.

[The statement of Mrs. Brown-Friday appears in the Submissions for the Record on page 44.]

Chairman Heinrich. Thank you, Mrs. Brown-Friday.

Vice Chairman Schweikert. And Mrs. Brown-Friday, some of that was wonderfully helpful, because you were—actually he and I are going to—Wow, did you hear what she said?

Doctor.

STATEMENT OF BENEDIC N. IPPOLITO, PH.D., SENIOR FELLOW, AMERICAN ENTERPRISE INSTITUTE

Dr. Ippolito. Well, Chairman Heinrich, Vice Chairman Schweikert and Members of the Committee, my name is Ben Ippolito. I am an economist at the American Enterprise Institute, where a lot of my work focuses on the issue of high health care cost, broadly speaking. So thank you very much for having me today.

And you know, when you think about diabetes, as the incidence of diabetes has grown, so too have its costs, both to individuals and, as was mentioned earlier, the country more broadly. I think a lot of us focus on the heath cost, the direct health cost and that is for good reason.

Higher health care utilization contributes nearly $300 billion a year in health care spending, and that is just adjusting prior estimates for inflation over the last five years or so. Individuals with diabetes, of course, pay some portion of that through higher out of pocket spending, but they do not pay all of it, right?

The rest of those costs fall on other people, including those paying premiums, particularly in the commercial market, but also on taxpayers and the federal government. And when you think about the incidence of the cost of diabetes it was just mentioned. Actually one-third, I think it was, of Medicare's drug spending is on diabetics. A very large share of this is borne through the Medicare program, which falls on taxpayers of course and the federal government.

But beyond just the direct health costs, there are indirect costs, and we see this with other conditions, but diabetes certainly. The condition affects labor market outcomes by increasing absenteeism,

lower productivity of workers and ends up resulting in lost work years and other outcomes.

That adds up to another $100 billion a year in the cost of the disease. So that is really, really significant, even above and beyond the direct health costs.

So as a result, treatments for diabetes can convey significant value, a point that I think is particularly notable given recent advancements in drugs like GLP–1 and please do not ask them to say their full name.

So I am going to highlight a few issues related to those treatments that I think are relevant for folks considering policy in this space. All right. The first is that it is not obvious how new therapies are going to affect the overall cost of diabetes, and that is because you have counteracting forces.

On one hand new treatments come with their own costs. They have prices. But on the other hand, they offset some costs. So either they replace existing therapies, they lower the use of other health care services, or they affect labor market outcomes. They might increase productivity, right.

How those things balance out is not obvious, and I will say in this particular case it is particularly not obvious because this drug market itself is very much in flux. We are seeing new treatments come to market, and as that happens, there is more competition to get on formularies, to get on insurance plans, and I included some data in my written testimony that shows that even in the last couple of years, some of the GLP-1s that were at $6,650 net price for the year are now around 4,000.

That is a really big chance over the course of a couple of years, and so thinking about how that is going to evolve across this whole market in the next, two, three, four, five years is hard to do.

That said, I will say it is still best to consider more than just budgetary effects for new therapies. If we are buying health, if we are effectively making people healthier, we should be willing to pay something for that. Not indefinite amounts of course, but something for that.

The second thing is going to echo earlier comments, is that new therapies raise questions about affordability and access, and I will make a simple point here, which is to encourage you to consider those questions holistically, rather than addressing affordability for specific drugs or conditions individually.

The reason I say that is for twofold. The first is that the health care system is very, very complicated as it is. When we have one-off approaches to different diseases or different types of conditions, it makes it all the more complicated to keep track of everything.

The second thing is that I think it raises legitimate equity questions. Should you preference Disease X over Disease Y? If so, why and how much? I think those are legitimately challenging questions. And so I would encourage you think about approaches like what we have seen with Medicare Part D.

There were bipartisan efforts to try and impose an out of pocket limit for folks in that program. That tries to address affordability, the high end of financial exposure in a broad way that affects everybody, regardless of condition.

And then finally I focus a lot on drugs in my own work, but while new drugs can improve the toolkit available to address health conditions, there are many non-pharmaceutical interventions that can remain highly cost effective.

And so in the case of diabetes, we have heard people talk about it, things like self-monitoring of blood sugar, lifestyle changes are sort of chief among those. So to the extent that those inventions provide good value for money, we want to make sure not to preference pharmaceuticals to the exclusion of those other interventions.

That is hard to sort of nail down in a specific policy, but as a conceptual approach I think that is important to keep in mind.

So all told, diabetes is a very costly disease along with a host of dimensions, and that is true for people with the disease and it is true for people who do not have the disease. And so I thank you very much for inviting me, and I look forward to your questions.

[The statement of Dr. Ippolito appears in the Submissions for the Record on page 51.]

Vice Chairman Schweikert. Doctor, thank you. Dr. Herman.

STATEMENT OF MARK A. HERMAN, M.D., CHIEF, SECTION OF ENDOCRINOLOGY, DIABETES AND METABOLISM, BAYLOR COLLEGE OF MEDICINE, HOUSTON, TEXAS

Dr. Herman. Thank you for the opportunity to discuss the impact of diabetes and some of the emerging technologies and therapeutics to address the ongoing epidemics of diabetes and obesity. Currently I serve as the chief of the Section of Endocrinology, Diabetes and Metabolism at Baylor College of Medicine.

My work as a physician and researcher is focused on caring for individuals with obesity, diabetes and other endocrine diseases. My scientific laboratory is committed to deciphering the molecular mechanisms responsible for these conditions, so that we can identify effective ways to treat these diseases.

Over the past decade, we have made significant strides in understanding how obesity, diabetes and associated cardiometabolic diseases develop in people. We have also made remarkable progress in developing medications and technologies for people with these diseases.

Today, I would like to highlight three areas of progress for you. One, the vital and revolutionary role of GLP–1 receptor agonists and related medications in treating diabetes and obesity. Two, the rapid advances in medical devices and technologies for diabetes, and three, our growing knowledge of the complex nature of diabetes and its complications, and what it means for the future of diabetes care.

I am sure you are aware of the news around GLP–1 receptor agonists. This class of medication, which mimics a natural hormone, has proven vital in improving glycemic control and promoting weight loss. GLP–1 receptor agonists were initially developed to reduce blood glucose levels.

This is of course a major goal in the treatment of diabetes.

However, these medications are remarkably effective in helping patients feel full, reduce their caloric intake and subsequently lose weight. Moreover, clinical trials are showing the GLP-1 receptor

agonists reduce the risks of cardiovascular events and death in high risk patients with Type 2 diabetes.

With obesity being a primary risk factor for diabetes and cardiovascular diseases, the potential of GLP–1 receptor agonists to induce meaningful and sustained weight loss may represent a significant advancement in preventative care.

In sum, GLP–1 receptor agonists have ushered in a new era in the management of diabetes and obesity. They are the latest evidence that a growing understanding of endocrine physiology can lead to therapies for pressing public health challenges.

Next, I would like to address how new medical devices and technologies are transforming diabetes management. You are no doubt aware of continuous glucose monitors, which are replacing the painful and inconvenient method of multiple daily finger sticks.

Real-time continuous glucose tracking offered by CGMs helps to prevent severe hypoglycemic episodes, a source of morbidity and fear, particularly in children with Type 1 diabetes. Similarly, insulin pumps have revolutionized the delivery of insulin, providing a more flexible approach compared to daily, multiple daily injections.

The pump delivers a continuous infusion of rapid-acting insulin, that can be adjusted with a click of a button to mimic the insulin production of a health pancreas.

The next steps in diabetes technology are artificial pancreas devices. These devices combine continuous glucose monitors and insulin pumps with an advance control algorithm to automate insulin delivery and reduce the burden of diabetes management. The ongoing integration of these technologies into patient care emphasizes the transformative power of digital health in managing chronic diseases like diabetes.

Finally, I would like to discuss the considerable progress we are making into coding varieties of diabetes. Research is showing us that diabetes is not a single disease rather a group of disorders with common traits. By analyzing common genetic variation, we have realized that different subtypes of diabetes may be driven by different genetic factors, and can lead to different adverse outcomes.

In parallel, examination of a rare genetic variation has allowed us to identify unusual forms of diabetes that point to underlying mechanisms that participate in development of more common forms of diabetes. By understanding the different genetic contributions to diabetes, we can move towards a more promising frontier of personalized and precise approaches to treatment.

Without a doubt, we stand on the cusp of revolution in diabetes and obesity management, powered by scientific breakthroughs and technological advancements. So thank you for allowing me to share my perspective with you, and I look forward to your questions.

[The statement of Dr. Herman appears in the Submissions for the Record on page 61.]

Vice Chairman Schweikert. Thank you, Doctor. Your questions.

Chairman Heinrich. I want to thank Vice Chairman Schweikert for allowing me to go first this morning. I am going to have to hop over to Appropriations here in just a few minutes. But I want to start with President Nygren. You know, Congress estab-

lished the Special Diabetes Program for Indians in 1997, in response to the growing prevalence of the disease among American Indian and Alaska Native populations.

It provides funding for diabetes prevention and treatment services to over 300 Indian Heath programs across the nation. I think the strength of SDPI is that it provides grantees with a great deal of flexibility, and we have heard a little bit about that on the Navajo Nation today, to design and implement interventions that are culturally competent and directly meet the needs of those individual communities.

President Nygren, how have you been able to tailor health programs on the Nation, and do you think that—this kind of approach can be successful at a wider scale in non-Native communities as well?

President Nygren. Good morning, good morning Senator Heinrich. Thank you so much for that question. One of the things that I want to mention too is I recently went to an event out in Crystal, New Mexico, which is south of—north of Window Rock, Arizona, and there was a couple of hundred walkers.

So people came out to walk either half a mile, one mile, two miles or three miles, and they were provided with bananas, good foods to eat and education. So we had the whole Navajo Department of Health was out there. So it was a very community approach. This is an opportunity for people to come out.

Not only one of the things that people take a lot of pride in too is the tee shirts that are being provided at those events, and a lot of those tee shirts encompass culture, encompass health, and this is something that they like to wear out in the community, and just—and it also brings them a lot of sense of pride.

This might be their first tee shirt that is brand new for the year, and they look forward to these events. So I think that the custom approach to the community is a very critical approach, because not every tribal community is the same across the country.

I know there is 574 communities across the country. Navajo is one of them, but I know that land-wise, population-wise, we are very unique. But I know that if by allowing every individual tribe to have their own unique approach, it is setting them up for success, because there is things in Navajo culture that are not the same with Hopi or not the same with Laguna, or different tribes across the country.

So I think having that tailored approach is a good way to utilize resources, and I think that just seemed to decrease not only in diabetes on Navajo, because of SDPI it is something that is related to having a tailored approach, just again just kind of like everybody's tailored suit today.

So we want to be walking. It is a little easier to walk around with something that is a little tailored. So again, just thank you so much to the Committee, to the programs for allowing us to be successful since 1997. But obviously the funding has also been the same since 1997.

So I know there is people that need to be hired and staff and to actually expand, and then Indian country is very rural and remote as Navajo. So again, thank you so much Senator.

Chairman Heinrich. Thank you President, and that is a great point. We have had flat funding for so many years in this program. As a result of inflation over those years, we have really lost a lot of buy-in power, and that is something that all of us need to look at.

Dr. Ippolito, President Nygren touched a little bit on nutrition, but I want to ask you, given that this Congress is one where in theory at least we are going to pass a new Farm bill, and if we look back in time to when diabetes really took off, in the 1970's we kind of re—we changed our agricultural policies and we focused more on commodities over horticulture, over nutrition.

And we saw these incredible increases from the 1970's to today in the prevalence of diabetes. So do you have thoughts on how we should be approaching the Farm bill in light of our challenges with diabetes?

Dr. Ippolito. Well, I guess I will answer that by focusing on the sort of underlying point, which is that, you know, we are accustomed to thinking about new pharmaceuticals, for example, as being cost effective or not. Do they deliver value for the money?

But when you look at things like diabetes and other conditions, there is ample evidence that suggests there is all sorts of other things that are cost effective if you look at them through the similar framing.

Chairman Heinrich. Right.

Dr. Ippolito. And so I think nutrition, eating habits, sort of lifestyle changes, it seems like there is fairly strong evidence for that. And so to the extent that that is something that fits within the purview of the Farm bill, it seems like it is something worth considering.

Chairman Heinrich. Great. Mrs. Brown-Friday, diabetes should be managed through a whole combination of prevention and treatment, and we have heard that here today. For most patients, this involves first being able to be diagnosed and treated with a combination of lifestyle changes related to nutrition, physical exercise, alongside the advances in medical interventions that we have heard about.

Many Americans simply do not have access to adequate health care that can prevent or delay the onset of diabetes, and prevent some of the more extreme complications of the disease. How do issues with accessing health care, such as being uninsured or under-insured, having trouble affording medication, create disparities in diabetes outcomes for different populations in the United States?

Mrs. Brown-Friday. I think that—sorry. I think that being under-insured or uninsured creates a problem for the population across the United States, across the board, across ethnicities, across cultures. I think that when you are under or, or not insured, you do not have access to the health care providers, or you have less access to the health care providers that can actually provide the information that you need, so that you can take better care of yourself.

You go and see a physician or a nurse practitioner or a diabetes educator for maybe 15–20 minutes, and the rest of the time you have to do it yourself. So it is—those visits are extremely impor-

tant and valuable, because during—if you have access to health care because you are well-insured, you have those visits in order to get those diamonds, those jewels that will be able to take you when you leave here to take better care of yourself, to know how to take your medications.

Not just to take them, but how to take them and also to choose, have better choices. Under-insured does not—does kind of correlate also with food insecurity. Frequently people who are under and are uninsured are in areas or food deserts where healthier foods are just not available, where their supermarkets are just not available or not close to them, even in both urban and rural areas.

Chairman Heinrich. Thank you. I want to thank you all for your testimony today. This is a topic of incredible interest to both the Vice Chairman and myself. I am going to have to go over to Approps, and I am going to leave it in his capable hands.

But I really want to thank all of you for your input. This is, this has huge budget ramifications, but it also has huge ramifications for every individual constituent of ours.

Vice Chairman Schweikert. Thank you, Senator Heinrich. I am going to try to be respectful for everyone's schedule, because you are here during sort of the screwy time of year. Senator Lee, you're up.

Senator Lee. Thank you so much, Mr. Chairman. It is great to have all of you here, and it is good to see my friend President Nygren again. He and I hold the alliance between Utah and Arizona in check. I was born in Arizona and moved to Utah as an infant. He was born in Utah, moved to Arizona young in life, and so it is good to see you sir.

I am grateful, Mr. Chairman and Mr. Vice Chairman, for the fact that you have scheduled this hearing. This is a really important topic. As of 2018, there were about 185,000 people living with diabetes in the state of Utah alone, and this is a significant disease.

It is a significant disease that presents all kinds of challenges. It manifests itself 24 hours a day. It never sleeps, and in the case of Type 1 diabetics, there is no reasonable prospect of living without it. There is no reasonable prospect, with the technology in existence today, of becoming no longer insulin-dependent. It is essentially with you for the rest of your life.

And so as a result of that, this causes all kinds of headaches, financially, emotionally in every aspect of your life. At every moment of your day it can step in and cause problems.

While the subject of today's hearing focuses on one disease, I believe my comments in some instances may be relevant to multiple conditions. I believe the federal government has itself been one of the main driving obstacles to increased innovation and we know, of course, that increased innovation brings about higher quality, better prospects for treatment of the disease, and ultimately brings down the cost. It produces cost savings with additional competition.

Sometimes when confronted with issues such as drug shortages and high costs, the government seeks impulsively to intervene through increased spending, and even more regulation. But this strategy ignores the fact that such shortages and those high prices are often the results of excessive and unwise government action in the first place.

It shows up all the time in the case of over-regulation. It is so difficult to get approve, sometimes needlessly so that there are fewer and fewer competitors. It is a natural barrier to entry. Sometimes it comes about in the form of price controls.

Take the Inflation Reduction Act, for example, which seeks to impose price controls on certain pharmaceuticals. Now the Congressional Budget Office, the nonpartisan entity that we hire to perform analyses like this, predicted that this would result in 15 fewer new drugs being launched over the next 30 years. Experts are increasingly warning that this policy will exacerbate shortages.

Instead of increasing spending and imposing mandates and engaging in even more aggressive regulatory action, in many instances Congress just needs to buckle down and focus on addressing the excessive government intervention problem, dealing with the regulatory stranglehold that exists.

If I could talk about two pieces of legislation that I have introduced to address those regulations, that prevent some of these innovative new treatments from coming forward and lower cost drugs from coming to market.

Recently, I introduced S.2305, the Biosimilar Red Tape Elimination Act. This is a bipartisan bill that I filed alongside my colleagues Senators Luján, Braun and Vance. The bill would align the U.S.'s biosimilar program along with the rest of the developed world, by getting rid of the arbitrary, unwise and unnecessary distinction between approved biosimilars and interchangeable biosimilars.

Biosimilars, you see, that is a word we use that is essentially the functional equivalent of generics for complex biological drugs. The U.S. is the only country that has these two tiers of approval, approval and interchangeability.

Congress created the interchangeability designation, and I have concern that there might be a risk of switching from one biologic to its biosimilar, and that they might not function the same way and that might cause problems. However, those concerns simply have not been borne out empirically. The science does not back them up.

What we gain from the distinction is next to nothing, and what we lose is significant. A lot of voices in the scientific community that the FDA's initial approval of a biosimilar is sufficient to establish that the biosimilar is in fact interchangeable to its—to and with its reference product.

Moreover, the interchangeability designation has confused states, patients, doctors and those who work with them by signaling that biosimilars are significantly different from their reference products. This in turn makes it less likely that they will be available for use, that they will be used as substitutes and the availability and use of substitutes brings down costs.

And so interchangeability thus raises cost, because biosimilars would otherwise provide much-needed competition for biologics. Biologic drugs make up approximately 46 percent of U.S. prescription drug spending despite making up less than one-half of one percent of all prescriptions, just 0.4 percent.

So when we talk about the high cost of drugs, we are often really talking about biologics, even though they are a tiny, tiny share of

the overall picture. My bill would help increase biosimilar competition by declaring that all biosimilars, upon initial approval, shall be deemed interchangeable.

Now the FDA's subject matter experts have communicated to my office that the bill would align our biosimilar program with current scientific understanding and improve biosimilar approval and uptake. This bipartisan legislation would help usher in greater biosimilar competition, thus reducing prices and benefiting all patients, including and especially those with Type 1 diabetes, who are for the rest of their lives dependent on insulin.

Another way that I have sought to support Type 1 diabetes is by exploring ways in which the current regulations simply do not make sense for innovative treatments, treatments of the sort that could actually bring about a functional cure for the disease, or something approaching that.

When we just throw money at government programs, sometimes we incentivize the status quo. We lock in on existing technology. To use an analogy, if we had done that in our music listening devices, we might still be stuck in the eight track tape world, something most people in this room do not even remember.

We do not want to do that with health care, especially in an area like the treatment of Type 1 diabetes, where technological advances are so important. For example, this year I was joined by Senators Braun and Blackburn in introducing S. 2205, the Increased Support for Life-Saving Endocrine Treatment Act or the Islet Act. Islets are these micro-organs inside the pancreas that produce insulin.

Now patients who have Type 1 diabetes do not have normally functioning pancreatic islet cells. We are not sure why but they stop working. The theory is that there is an autoimmune condition that attacks the healthy pancreatic islet cells and kills them or causes them to be non-functional. So they routinely require these insulin injections.

These treatment options are important, but they can become burdensome and expensive and cause the patient constantly to have to chase between highs and lows, which is its own form of hell. Thankfully we do have other options and possibilities.

Scientists have found ways to take pancreatic islet cells from deceased donors and transplant them into the bodies of patients with Type 1 diabetes. Some patients who have received these procedures have been able to go years without either any insulin injections or any type of continuous glucose monitoring.

But regulations have squashed the procedure. They have made it almost impossible. Rather than regulating islets as organs, HHS and FDA have regulated islets as drugs since 1993, despite the fact that other countries appropriately regulate islets as organs and not as drugs.

We have to take care of this. We have to fix this problem, and I have serious concerns about the FDA's recent action on this. The FDA recently approved a drug for this treatment, rather than going the route proposed by the Islet Act.

I am out of time. I wish I could have had more time to do this, but I do want to know eventually from the FDA how they decided to approve this product's biological licensing application as a drug,

especially since one of their previous reports had said that the agency could not assure the product's attributes correlate with clinical outcomes.

And how will the FDA's decision impact access to allogenic islet transplantation? Would such procedures be more affordable and accessible if islets were regulated as organs? The answer is almost certainly yes. The FDA has a lot to answer for. In this and in countless other areas, they are needlessly making this disease more expensive, more deadly, more long-lasting simply because of their own regulatory malfeasance. Thank you.

Representative Beyer. First of all Vice Chairman Schweikert, thank you for convening this. I greatly appreciate it. I thank all of you for being here. I thought I knew a lot about diabetes. I have learned so much this morning.

I want to add one factoid that came from our last Joint Economic Committee meeting, when Mick Mulvaney, who used to chair the Office of Management and Budget at OMB, was talking about how much of the Medicare budget is spent on end stage renal disease and dialysis, and the number he came up with was 31 percent. There is roughly $250 billion a year of taxpayer money just spent on dialysis.

You know, Senator Lee just talked about not incentivizing the status quo. A perfect comment, because we are marking up the Agriculture, the five-year Farm bill right now. And this is very relevant, because the Farm bill entrenches food policy in a way that supports our current food behaviors.

By subsidizing commodity crops, our current food—and rather than working on ensuring that specialty crops can be produced, we are sort of denying the nutritious greens that we need to do. We are really good at making corn cheap and sugar cheap, and that then of course gives us a food industry that specializes in making highly processed foods, without the education and intervention that will keep us from just continuing to promote Type 2 diabetes.

So we need to be concerned about unintentionally structuring a farm system at the federal level that supports the trend of obesity. But if you look at the rest of the Farm bill, you have SNAP and WIC. We know that Supplemental Nutrition Assistance Program reduces severe food insecurity between 12 and 19 percent. It is food insecurity and inadequate nutrition that Mrs. Brown-Friday pointed out.

You know, the lower the income, the more likely you are to get diabetes, and the higher the income, the better the food, the less likely. We are struggling with a budget right now where they are talking about fiscal year funding for 2024 for the SNAP program at a level of 2007. We are rolling it back decades.

Same with the WIC program, Women, Infants and Children's Program. They are going to cut it by $800 million, which is five million women and children losing fruit and vegetable vouchers. So we have really got to look hard at the Farm bill, and in the light of the diabetes challenge that we are facing right now.

Mrs. Brown-Friday talked about food deserts. President Nygren, can you specifically talk about food deserts in the Navajo Nation?

President Nygren. Congressman, thank you. When it comes to food deserts could you——

Representative Beyer. How big a challenge is it for you, with the Navajos who live both on the reservation and off, in terms of the ability to get the healthy food that will give them the lifestyle they need?

President Nygren. Okay, okay. Thank you,

Congressman. When it comes to food and having grown up myself, the nearest grocery was 75 miles, which is Farmington, New Mexico. So in order to get to a Walmart, you have to go 75 miles where I grew up from, and most of the time the nearest grocery store is the local trading post or the local gas station.

So all of us have been in a gas station. If you go to a Speedway or Sinclair, whatever the gas station is, most of the time it is candy, food, chips, things that are normally for people that are just on the road and headed to a certain direction. So I know that one of the things that—that is why we imposed that tax on junk food, to try to hopefully encourage our grocery stores and gas stations to at least carry some fresh fruits, some fresh vegetables and things like that.

But it is just when you are in really remote locations like Navajo, it is difficult to get access to quality foods. That is kind of the landscape of the Navajo Nation is you can go one hour or two hours and the only thing you will find is gas stations.

So I think the location of more stores that offer farm goods would be great, because I know on Navajo, we are really trying to encourage a lot more of our people to be farmers, to utilize some of the water, to go back to traditional practices, because overall I think that when it comes to being able to be able to farm and sell foods and groceries, I think that is a way.

As President, I am trying to encourage our people to do that. But regular grocery stores, they are hard to find.

Representative Beyer. Thank you very much. Mrs. Brown-Friday, as you know so much of the debate on the Hill the last 20 years has been about health insurance and access to health insurance for the American people.

Can you talk from your perspective at ADA and others about why health insurance is critical for people with diabetes, especially we talked about CGMs, the continuous glucose monitors? How do you get a CGM if you do not have health insurance?

Mrs. Brown-Friday. I would say it is basically impossible. Thank you so much for reminding me. I would say it is basically impossible to get a CGM without health insurance, because most people who are under or uninsured do not, cannot afford the cost of a CGM and all the supplies that go with it.

And so therefore the American Diabetes Association is really supporting people having better access to health insurance, easier access to health insurance, so that they can have—they can afford the medications and the instruments, and the technology that could actually help them have a better life with relation to their diabetes.

Representative Beyer. Thank you very much. And Dr. Herman, I am very excited about the agonists and the impact that they are having. But I agree with you that we cannot just think about taking a pill to solve all these problems.

Are you at all concerned about the down sides, the latest reports about stomach paralysis or gastroparesis? How are we, how are we balancing the negative side effects on these agonists?

Dr. Herman. So that is a really important question, and it is quite clear the GLP–1 receptor agonist, many patients that take them experience some sort of gastrointestinal side effect including gastroparesis, so slowing of the transit of food through the GI tract and some combination of constipation, diarrhea or abdominal distension.

And we have, we have put together kind of algorithms for titrating these medications, to try to avoid some of those side effects. Most people, if they continue those medications, they tolerate them. Even with some of the side effects, the side effects tend to go away with time.

So those gastrointestinal side effects do not seem to be permanent or persistent. Some people cannot tolerate the medications because of these side effects, and they choose not to continue them and then we move to other options. But the majority of patients can tolerate those medications and those side effects tend to wane.

Now the other aspect of your question is what are the long-term potential adverse effects, and to date we have not identified any significant long-term adverse events or effects related to GLP–1 receptor agonists. They are clearly in large clinical studies reducing the use of insulin while also reducing glycemia. So they are, they are saving lives, and we have not identified any long-term adverse consequences at this point.

Vice Chairman Schweikert. Thank you Mr. Beyer. Ms. Malliotakis.

Representative Malliotakis. Thank you Mr. Chairman, and appreciate you all participating in this important hearing. Obviously, we want to be proactive to help Americans stay healthy, to improve their quality of life, to lower their medical costs, and to also save taxpayers money.

It is no secret that Medicare has a solvency problem and diabetes and obesity are some of the main drivers. Nearly one-third of Medicare spend is attributable to diabetes population and as the obesity rate in the U.S. continues to rise, so will the rate of diabetes.

Of nearly $300 billion, diabetes currently accounts for one-fourth of all U.S. health care spending. The Congressional Budget Office has identified several options to rein in costs. However, many of these could be harmful to our seniors already suffering from inflation.

Promising new drugs and medical devices such as GLP–1, Ozempic and continuous glucose monitoring certainly should play a role in reducing the risks diabetics face and lowering costs to both individual finances and the federal government.

However, other innovations are happening in the health are space to treat diabetes, obesity and other diet-related diseases, so again people can live longer, healthier and happy lives. One of these innovations is medical nutrition therapy. MNT is provided by a nutritionist with the goal of assisting a patient choose and buy foods that are healthier, manage complex medical issues like diabetes by creating sustainable, behavioral changes.

In a nationwide representative study, a large health care provider showed that $130 per member per month savings or nearly $1,600 per year from giving members over 65 access to this type of nutrition guidance. But today in Medicare, only diabetes and renal disease are covered, while obesity, pre-diabetes and other chronic illnesses which lead to diabetes related to poor nutrition is not.

Yet if we look at the private payor space and then Medicaid, we are seeing with MNT coupled with tools to stretch people's food dollars in ways that allow them to meet their diet, cultural and religious needs, saving costs to patients, saving costs to the system and improving health outcomes.

My staff recently met with a company that works with private payors, Medicare Advantage plans and Medicaid MCOs to deliver telenutrition services to patients, and they have data right now that shows MNT patients lose an average between four to 6.5 percent of their weight, and continue losing weight after Year 2, due to behavioral changes.

Mr. Ippolito, should Congress press entities like the Congressional Budget Office to review this data, to help us understand how we can leverage nutritional programs as a strategy to provide relief to those at risk of diabetes, as well as to taxpayers continually paying for it?

Dr. Ippolito. Well, I guess my short answer is that I think Medicare could use any budget help they can get. So if you have got a proposal that could save money, then it certainly seems like something CBO should look at.

Representative Malliotakis. Anyone else want to chime in before I move to my next point? All right. Well during my time in Congress, I have been advocating and pushing to require at least in part or incentivize SNAP recipients to purchase healthy foods. I am joining Congressman Garbarino, also of New York, on an effort to end a ban on purchasing prepared and hot foods with SNAP, which would be I think a big step.

Dr. Herman, how would these reforms in the SNAP program affect the rates of obesity and diabetes among recipients, and do you believe that this would play a role in reducing government spending on obesity-related chronic conditions?

Dr. Herman. So it is an excellent question. I have to say I am not an economist or an epidemiologist, so the impact of changing policy on spending is really outside of my expertise. What I would say is that lifestyle management is always a part of diabetes and obesity care, and its demonstrated benefits.

Representative Malliotakis. Yes, I guess that really is at the end of the day the real question, is will it help people improve their health? Will it lead to healthier options for Americans who are SNAP recipients, so they can make, make these choices, I mean to not allow for prepared for hot food I think is a mistake that probably pushes people into a different direction or some of these, you know, preserved foods and stuff like that. Anybody else would like to respond?

Mrs. Brown-Friday. Yes, Representative Malliotakis. I would say that any time anyone has an opportunity to have an healthier

diet, I think that they would be able to take advantage of it, and I think it——

With the programs that you are proposing, that even starting at younger ages, the younger you start in these programs, the younger you are exposed to healthier foods, the more likely you are to continue that into adulthood and prevention, I think, is really the key. I think that prevention of obesity is definitely something that can be beneficial from these programs.

Representative Malliotakis. Great. Thank you both.

Vice Chairman Schweikert. Thank you. Ms. Moore.

Representative Moore. Thank you so much, and I want to thank the panel for being here today. I was caught up on other duties, so I was late. But I was listening to a lot of your testimony before I arrived, and I was intrigued, Dr. Brown-Friday, by some of your testimony that talked about diabetes, the onset of diabetes starting at younger. Not juvenile diabetes, but Type 2 diabetes.

And do you attribute that to the junk foods and stuff that President Nygren, for example, has talked about? To what do we attribute that?

Mrs. Brown-Friday. Well first I want to make a correction. I am not a doctor.

Representative Moore. Okay.

Mrs. Brown-Friday. I am a registered nurse by profession.

Representative Moore. That is good.

Mrs. Brown-Friday. I am very proud to be one. So in terms of Type 2 diabetes, starting at younger ages, this is something that has been a concern for the medical community and the American Diabetes Association for quite a while.

And I definitely agree with Dr. Nygren, that the availability of healthy foods and having it closer to your availability fast foods, not just for Dr. Nygren it is the gas stations, and for me, who works in the Bronx, it is access to McDonald's and I am sorry, and other fast food companies, where it is just high fat in the foods and younger people are not——

Like I said, once you are introduced at a younger age to healthier foods, then the more likely you are to have those foods when you are older.

Representative Moore. So Mrs. Brown, it is sort of counter-intuitive for us to be cutting fruits and vegetables from the WIC formulary, as an example, and upping things like cheese as part of the formulary for WIC. It just does not make any sense if we are trying to curb the cost of diabetes, to be cutting fruits and vegetables out of WIC.

That is my statement. I will not make you say it. I am intrigued by the disproportionate presence of diabetes in black and Native Americans and Latino communities. And so I guess Dr. Herman, there is no sort of genetic proof that these folks are disproportionately susceptible to enduring diabetes. So what would you say would—or why do you, how do you explain the disproportionate onset of diabetes in these populations?

Dr. Herman. I think that is really an excellent question, and I do not know the answer to that question. I will say there are, there are many investigators out there looking at that question specifically.

What we do know is that, is that obesity and diabetes in all populations is an interaction between genetic background and environmental exposure, and that includes diet and exercise and all sorts of things. And so if there is an increase in prevalence of obesity and diabetes in one population, it is some combination of a change in their environment, interacting with a change—with their genetics, which is not changed over decades that is producing that outcome.

It takes intensive research to identify within specific populations what those specific factors are, but there are many scientists and physicians out there searching for those answers within specific populations at this point.

Representative Moore. Well thank you so much. Your testimony, I think Mrs. Brown-Friday, made the testimony that 85 percent of people who have diabetes are obese, are overweight. This is one of the reasons that I am so happy that I have reintroduced a bill called the Treatment to Reduce Obesity Act. I think that it will give us some great results with regard to stemming one of the causes or one of the present features of diabetes.

I want to ask President Nygren, the Menomonee and Oneida Nations in my state of Wisconsin have taken on a culturally relevant project to use sort of Native foods to stem the tide of diabetes. Can you describe what you all are doing in the Navajo Nation to include culturally relevant foods?

President Nygren. Congresswoman, thank you for that question. I am very happy to hear that our other tribal communities are doing that, and on behalf of the Navajo Nation one of the things we are doing is walking and running. That has been very a part of our culture, and at the same time introducing them to foods such as fruits and vegetables at all of our events, along with like almonds and nuts and things like that that really help and promote a healthy lifestyle.

Because one of the things we have always done is we take the IHS, the best practices, and we try to focus on one of them for the year so that we can implement and educate our people on that. So we really have taken an approach where we invite the people out to the events, and then they do a walk, a run or we educate them on foods. But as far as farming, we are really trying to reintroduce farming, because Navajo people have been farmers for a very long time.

It is just that it is a lot easier to drive a couple of hundred miles and get a bag of groceries than to actually do the work and to produce healthy foods. But that is something that we are really working on, Congresswoman. Thank you.

Representative Moore. My time is waning, so I just want to get another question in with Dr. Brown-Friday. I did not understand why the continuous glucose monitor is not available to more low income people. Is that something that is not authorized by Medicare, or what are the dynamics in terms of getting these continuous glucose monitors available to low income people?

Mrs. Brown-Friday. Unfortunately, I am not an expert in Medicare, and so what I would have to say that in general, what I have heard from patients is that their insurance will not cover the cost of utilizing the continuous glucose monitor if their blood sugars are

not at a certain range, or if they are not taking a certain number of injectable medications.

And so therefore those are the things that are regulating the availability——

Representative Moore. Bureaucracy is stopping us from saving money. Okay. I will yield back to you, Mr. Chairman.

Vice Chairman Schweikert. Thank you Ms. Moore, and we are going to talk about that, because there has been a crash in the price of those units and some new products that just came in the market within the last six weeks. Mr. Ferguson or Dr. Ferguson.

Representative Ferguson. Thank you, Vice Chairman. I want to thank y'all for hosting this and to the witnesses, thank you for your time and your presence here. It matters and we have learned a lot. So thank you for taking time out of your schedules to help educate us.

I want to start my comments by saying that I truly believe that diabetes is probably the cruelest and most underrated disease in America. There are a lot of other things that get a lot of attention, and I am glad to see that this body is stepping up and focusing on this, because it is such a long, debilitating process.

Many times, you know, we tend to ignore because we do not see the rapid decline of someone. So this is important, so thank you for being here. I was a practicing dentist for 25 years. I saw the oral effects of this week-in and week-out in my practice.

But I also saw the systemic effects, and my ability to treat patients was, if they had diabetes, was greatly restricted. How they responded to care, how they responded to infections, how their body responded to antibiotics all played a role in their overall health.

I want to focus on something that this Committee, that some of the questions have already started to go to, because President Nygren, your comments about what you are doing in terms of food is really important. But I want to start with Dr. Herman.

If you go back and look at the last, I do not know, 40, 50, 60, 80 years, when did we really see the explosion or the exponential growth in diabetes within various populations? What is sort of the time line and how has that accelerated?

Dr. Herman. I think the dramatic increase in prevalence began largely in the 70's, of both obesity and paralleled by diabetes. Those both dramatically increased at that point, and I think the increase has been pretty consistent since the 70's.

Representative Ferguson. Okay. When we look at—when we look at things that have changed from a policy standpoint, and this may be a question for anybody on this panel as well that may have a better history on this than I do, what—what in the early 70's changed our food supply? What did we begin to prioritize and what was the—and what was the biggest part of that? It was calories, right?

So when we started to value calories over quality nutrition, then we set this thing in motion. When I first started my dental practice in 1992, I could tell the difference in kids that grew up in the country on well water and kids that grew up in the city limits, that grew up on fluoridated water, because the quality—their oral health was dramatically affected because the kids that grew up on

well water had, you know, just—they were ravished by cavities. Income did not matter, okay.

Kids that grew up in the city on fluoridated water, again because without regard to income, they had much better oral health outcomes. As I went through 20 years of practice, I could no longer distinguish between the two of them, and the common link that I saw in this was the food supply and the increase in sugar in our food supply in every form of refined carbohydrates.

I think we have got to take a—I think we have got to be very focused on our food supply. We can talk about spending more money on SNAP, listen. Again, I think cutting fruits and vegetables out of nutrition programs is absolutely, is absolute lunacy.

But I also think that funding, you know, allowing folks to buy high sugar content foods is like us saying we are going to pay somebody to keep smoking while they have got lung cancer. I do not mean to equate the two, but again, let us be smart about what we are doing here.

President Nygren, when y'all have done the work and you have talked about the success that you have had, what—other than money, what is the most important thing you think of or do you think we should be doing as a government in terms of the nutritional aspect of what your program is—your programs are focusing on?

President Nygren. Thank you Congressman. I think one of the most important things, as you mentioned, being able to tailor the nutrition and the programs to Navajo people and in the different tribes across the country, which is important because every tribal nation is different.

There are different foods and exercises and ceremonies that they use throughout their history. But if we can continue to tailor that, because I know over the past 20 years or the past decade when we have actually been able to tailor it more geared towards more Navajo, more Navajo foods, more Navajo types of exercises, the actual statistics have gone down because it was—we were able to tailor it to work with the existing dollars that we have been getting.

It has been very helpful. So I think that when we continue to think about the group specifically to their needs, then it is a lot easier, because I know up on Navajo, as I mentioned earlier, it is very remote and rural. But there is just so much access to processed foods that there is not enough options that people can have more access to. So I think education is very critical in that part too, so thank you.

Representative Ferguson. Yes, thank you. And look, I do not—there is—I think we do not, we should not try to make this a one, make a false choice here of either addressing the food supply or continuing to innovate, because it is going to take both of these things in my humble opinion.

Ms. Brown-Friday, just a comment, and again I practiced in a rural area. My hometown was about 64 percent African-American. It was, and again I saw this on a very regular basis. You talk about access to health care and access to health insurance.

I want us to move, because I truly believe that Americans have access to some type of health care, whether it is Medicaid, whether it is private insurance, whether it is care on the Exchange. I want

us to really focus on utilization, and because I can tell you in my practice, patients had access to care.

It was the utilization of the system, and all too often and to be candid with you what we saw is that too many of our fellow Americans live in poverty, and they live in the crisis of the moment. And the preventive aspect of health care and the early access many times takes a back seat to a plethora of other emergencies that are going on in somebody's week and a given time.

And Ms. Brown-Friday, I am not—I do not mean to lecture you on this; please do not take it like that. But help us talk more about the utilization of the system, in addition to making sure that the people have access to care? With that Mr. Vice Chairman, I yield back. Thank you again for hosting this.

Vice Chairman Schweikert. And Senator Kelly.

Senator Kelly. Thank you Mr. Chairman, and thank you all for being here today to discuss this critical issue that faces too many Americans, that carry not only physical but also, you know, medical effects for families, but also you know, the high cost for folks that live with diabetes.

President Nygren, great to see you here. Good to see you again, and thanks for being such an important voice on this issue. I, you know, spent a good amount of time on the Navajo Nation, and I know well the impact that diabetes has on our tribal communities.

We have got 22 tribes in this state, and this disease has dire consequences. There are a lot of individuals that are suffering from this and many are members of your tribe and the other tribes. I know you have worked very hard to impress upon the federal government the importance of the special diabetes program for Indians. Could you talk a little bit more indepth about that, the impact it has had on the Navajo Nation and tell us why it is so important that Congress reauthorize this program before it expires at the end of September, and what are the consequences if we do not reauthorize it?

President Nygren. Thank you, thank you Senator Kelly. I appreciate. I am always happy when you spend some time out in our communities and all the communities across the state of Arizona. Well one of the effects that it has had is just kind of—just to kind of read some statistics here, is for the first time diabetes prevalence in American Indian and Alaska Native adults has decreased and has done so consistently for four years, dropping 15.4 percent from 2013 to—from 2013 to 2017.

So I think just the decrease in diabetes prevalence was great through the SDPI program. Also diabetes-related mortality has decreased from about 37 percent during those times. Again, these are just some of the stats. The key thing there is it is decreasing. One of the percentages is that this program is working, and we are really trying to——

It is very unique. There is over 300 communities that it is serving across the country. I know there is I think about a dozen that is tailored to the Navajo Nation. But overall, I think it is critical because we are trying to make sure that we can continue to have healthy people in our communities, so that they can thrive and for it to be renewed, which is coming up very soon, and I think that

the—both houses, both the Senate and the House has approved it for about 170 million through their committees.

Really, that is 20 million more than the 150 that we were initially getting, and that 150 has been consistent for 20 years. So this 20 million is a good amount of increase to really help us get some of those programs out there implemented right away.

Because it is critical in terms of not every Indian country is the same, but the tailored approach and the partnership that we have been able to develop through this program has really helped us. Because I always see pictures of our elders. They were slim, they were fast, they looked very healthy a lot of the time.

So when you look through histories of—because as the president I have access to historical photos and things like that that I look at that is within our communities. There were farmers, there were ranchers, there were gardeners and you just look at how healthy some of these people look through history.

And then you look at the people now. It is very sad to see that we have come from very self-determined, self-resilient people to people that are just really trying to fight for their lives on a daily basis. So again, I think that this program is critical, and I definitely would continue to urge both the House and the Senate to approve this. So thank you Senator.

Senator Kelly. What would happen if we did not reauthorize it?

President Nygren. We would—for the Navajo, all of Indian country would lose about—they would lose staff, they would lose the program, they would lose the people.

Senator Kelly. But tell me what the consequences of that would be. I mean I think we know what the consequences are.

President Nygren. Yeah. I think you would lose a lot more people to diabetes.

Senator Kelly. Yeah, people would die.

President Nygren. Yes.

Senator Kelly. And probably in significant numbers.

President Nygren. Significant numbers, and you would also—a lot of people would lose hope and faith, and they would just be very, I think it would just break a lot of hearts, because not only are you looking at communities that are already in dire poverty levels, but you would put them in even tougher situations.

Senator Kelly. And folks even, you know, some cannot even—you know for seniors, you know, insulin is now capped at $35 a month and you know for some other individuals, the pharmaceutical companies have provided insulin at $35 a month. But that could still be very hard to afford for members of the Navajo Nation, which is one of the poorest areas of the country.

And that is true for the other tribal communities in the state of Arizona and across the nation. So it is critical that we reauthorize this program in September. Thank you.

Representative Smucker. Thank you, Mr. Chairman. This has been a fascinating discussion, and I think very important that we hold this hearing. Obviously yes, the Chairman has said previously this is a driver of our health care costs, that will impact our future expenditures, our future debt.

But it is also, and as he is fully aware, it affects so many other areas. It affects the ability for individuals to lift themselves out of

poverty by taking a great job. It affects that workforce participation rate that is critical for us to grow an economy, and it affects the everyday ability of individuals to live their lives to the fullest.

And I think if there is—there is a lot of things we could do for our constituents, but if somehow diabetes could be solved, it would have a dramatic impact, perhaps more impact on our constituents than anything else that we could possibly do.

And by the way, the same thing could be said for heart disease, for cancer and for Alzheimer's. All of these are drivers of all of these conditions, including our expenditures and including the impact on people's lives. It has been a great discussion. I agree with so much of what has been said here.

I agree with Senator Lee, that we should—we should create a system that promotes additional private investment, private innovation to help come—to help to develop new solutions for treatment. But I also agree with others who have talked about the government role in this.

You know, I have always supported investment in NIH funding, which is very, very important to drive, to drive the underlying research and development that leads to some of those innovations. And then like it or not, I think the government has for a long time been engaged, through the choices that or the incentives maybe is a better way to put it, the incentives that we have had in the system regarding nutrition, regarding the food that people eat.

You know, we have done food pyramids, we have done recommendations, we have done school lunches, recommendations there, and then we have done the SNAP program, the Farm bill. All of these help to lead to decisions that folks are making about their own lifestyle, about their own nutrition exercise and so on.

And so we are in this like it or not, and so we ought to be looking not only at the opportunities for additional new treatments that we could help to ensure that the right conditions are there for those to develop, but we ought to be incentivizing the right human behaviors to prevent the disease to the extent that we can, that individuals can prevent it in the first place.

So I guess the first question I have, Dr. Herman, I would like to—I would like to get your thoughts. We have talked about the link between obesity and diabetes. We have talked about the link from the early 70's of the commodization of food, so what we have promoted.

How much of diabetes is related to these lifestyle choices that individuals make? If you had—just imagine for a minute that people are eating healthily, they are exercising, they are doing the things that we know are good lifestyle choices. How much of diabetes would we do away with if that were the case?

Dr. Herman. So thank you for the question. It is really an excellent question. It is quite clear that, you know, a significant, a significant proportion of Type 2 diabetes is the direct result of obesity, and it is also clear that some lifestyle choices play into the development of obesity and diabetes in that path.

It is hard to quantify how much is, you know, how much of the lifestyle, which components of lifestyle or other environmental factors are the specific factors that have led to this epidemic. And so there is a tremendous amount of controversy around what are the

specific nutritional components or combination of nutrients, or how—or in what fashion are they presented that leads to obesity per se and diabetes.

And yet it is clear that that is a major component. It is hard to nail down an amount.

Representative Smucker. Sure. Anybody else want to take a stab at that? I know President Nygren, you have talked about the importance of programs that encourage good nutritional choices and exercise and so on. Does anybody else, you know, want to take a stab at how much we could resolve if people were making the right choices and had access to the right nutrition?

President Nygren. Again as president, one of the things of the Navajo Nation I have noticed is that—thank you Congressman—is that when people get out there, I think they are really enjoying these walks and their runs and opportunity to educate themselves on healthy foods, healthy diets, healthy lifestyles. I have seen a lot of people change, come turn around, and they tell me President, this is what I looked like a couple of years ago and now I have been attending these events that are being hosted and sponsored by this program that we are trying to get reauthorized.

Really to me it is—it helps. It helps dramatically. I do not know the percentage or the numbers, but I think that it is better, it would definitely decrease and it is just—I think overall mental health, depression, diabetes. I think it really just helps the person overall if they can eat healthier and participate in exercise.

So I think that in my community, it has really been working so——

Representative Smucker. Yeah, and I do not know. Go ahead.

Mrs. Brown-Friday. I think that you said a very key thing. I think the availability of healthy foods is really a very big key access. You said that let us imagine that everybody is eating healthily, but that is not the case.

Representative Smucker. Right.

Mrs. Brown-Friday. Everyone does not have the healthful foods available to them, and/or they cannot afford the healthful foods that are out there. I think that that is one of—that is the key that we have to think about. I think that definitely, as President Nygren was saying, when people are introduced to things and they are introduced to healthier lifestyles and healthier ways, they really do want to take advantage of it.

I am not saying it is 100 percent obviously, but I think that for the most part, and those who I have worked with, who I have introduced healthier lifestyles through a lifestyle change programs, have embraced it and have made significant changes. But again it is access.

Representative Smucker. If I could just follow up on that, I could not agree more with that, by the way, and we do not maybe know the exact amount. But you know, a dramatic impact. We, I think all would agree with that, and so I think this is a wonderful discussion to have in regards to how we can ensure that new treatments are being developed.

But I think we need to spend a lot of time figuring out how government programs today are incentivizing bad nutritional choices, and I am talking about the SNAP program. I am talking about the

Farm bill. You know, we subsidize a lot of agricultural development as well, a lot of farming.

We ought to be thinking about how we can ensure that we are educating, we are encouraging people to make the right choices, and then access is so critical. I completely agree. These are discussions that we really should be having to, you know, help to ensure that people have access to being able to make the right choices, and know what those choices should be.

So thank you so much for holding this hearing. It has been a great discussion.

Vice Chairman Schweikert. Thank you Mr. Smucker. To my good friend Peter.

Senator Welch. Thank you. It is very good to be with my colleagues from the House. You know, the two issues that we have been talking about, everyone seems to be focusing on are nutrition and exercise, right, because it is after the fact. If you get diabetes, then you get into the incredible medical challenges that folks face.

So I am interested in what are the policies, but it is tough to get good food. Dr. Ferguson left, and he was talking about how being poor is a hard job. It is a full-time occupation, just to try to figure out how to get from here to there, you know. You might have to take three buses as opposed to just get in your car and go.

You have to really try to figure out where you can get something that is affordable for you, which is not necessarily the most nutritious. So I am just interested in maybe hearing from each of you, what are like the two things that could be done to try to help folks who are really low income and struggling with a lot of the everyday challenges, of trying to make things work. What could be two policies that would help both with nutrition and making exercise available? Dr. Herman, start with you.

Dr. Herman. So in terms of, in terms of exercise, I mean the things we do with every patient we see is start with simple things, which is suggest try to get 10,000 steps a day. These are things that cut across socioeconomic status, that are shown to be beneficial and——

Senator Welch. So 10,000 steps.

Dr. Herman. Yes.

Senator Welch. All right. How are you doing today on that?

Dr. Herman. I am probably about a quarter of the way there today.

Senator Welch. Dr. Ippolito.

Dr. Ippolito. Yeah. The rest of the folks on the panel are better experts on the specific policies.

I will just raise one thing that is important for all of these policies, which is if they function through insurance, we always have to be very careful that we do not allow insurance companies to use policies that really are sort of nominally designed to be, you know, helping people be healthier, but instead really just risk-select.

They try and attract healthy people onto their insurance, right? So whatever the specific policies, I will just flag that as one consideration to keep in mind.

Senator Welch. Thank you. Ms. Brown-Friday, you deal on the ground with lots of folks.

Mrs. Brown-Friday. I do deal with a lot of folks and I think access, as I have been mentioning multiple times, to more nutrition, more nutritious foods, more vegetables in both rural and urban areas, as well as safe areas for people to exercise, because that is also—building infrastructure. Having either a park or even assisting people who might want to go to a gym, to pay for that, so that they can exercise in a safe environment.

Senator Welch. You know, the thing that I find about exercise is the more easy it is to do, that is integrated in whatever your day is, your day is different than my day. So how do you find a way within your day, in anybody's day for them to get the exercise. If they have to go to a gym, that is a project.

Mrs. Brown-Friday. Well again, it does not have to be going to a gym. Having a safe place in your neighborhood to walk, and do I have these conversations with some of my patients. Do you have a safe place to walk, you know, or can you just walk up and down your stairs?

If you are talking about me personally, I get up at 5:30 in the morning. But I cannot talk for everyone else.

Senator Welch. Thank you.

Representative Moore. Will the gentleman yield?

Senator Welch. Yes, sure.

Representative Moore. Will the gentleman yield? What about these medications and behavior modification to medications like Ozempic I think is the name of one of them. What about that as an intervention? Dr. Herman, anybody?

Dr. Herman. Sure. So it is clear that medications like Ozempic and in that class of medication, they are very effective in helping people suppress their appetite and reduce their caloric intake and lose weight. They have not been approached as kind of a, you know, what would their impact be if used widely as a preventative measure.

But I think it is probably a matter of time before—just a matter of time before folks like yourselves begin to think about utilizing interventions like that in that way from a public policy perspective.

Representative Moore. I yield back to the gentleman.

Senator Welch. President Nygren.

President Nygren. Thank you, Congressman. One of the things that I think about is trying to start early for our young kids, because on Navajo and a lot of reservations, there is not a lot of parks, not a lot of playgrounds, and not a lot of places to play basketball or any sports activities.

So I think that one way for us to do it is probably to create those parks and facilities, so that kids while they are younger they can learn how to exercise, and then as adults to have these facilities open to them, because they are—on a lot of reservations, a lot of these things are funded by the government, but they are closed off from 8:00 to—after, they are only open from 8:00 to 5:00 and then they are closed, and then after school and people that have left high school do not have access to go and exercise.

Senator Welch. Thank you very much. I yield back.

Vice Chairman Schweikert. Thank you, Senator Welch. I do not think I actually got around to saying congratulations. We are going to actually try to do—we are trying to do the Canyon.

Senator Welch. I know a House-coded insult when I hear it.

Vice Chairman Schweikert. Oh yeah, I was heading in that direction, yeah. All right. I have saved myself for last because as for some of my colleagues here, this is a fixation for me. And for me it started on the economics.

I have had—a number of you say 25 percent. I can actually show you really well peer-reviewed numbers that it is 33 percent of all health care spending, 31 percent of Medicare spending is functionally related to diabetes.

I hope everyone will get a chance to read the Republican Joint Economic Report, Chapter 3. We went to places, very uncomfortable for some, but we actually looked at diabetes and obesity in society, and it is both its cost, its moral cost, its potential effects on income inequality. Care a lot about this.

So let me, instead of proving what an idiot I am by just talking, we over and over and over and over have this discussion, changes in the Farm bill. Access to the technology, the new over the skin blood glucose. A new one actually got released a couple of days ago. It is just a wristband that works.

Number three, the adoption of some the GLP–1s for those who are particularly in the morbid categories, or those who have Type 2 diabetes, particularly now that we may have the oral, the single shot which is fascinating, which may be making it through FDA.

And number four, maybe by the end of the decade for our brothers and sisters who have succeeded in getting their weight down, but I have seen some data sets that say about 30 percent of that population which had Type 2 diabetes, their body will not start to produce islet cells that produce insulin again.

There is actually new, some of the new stem cells. Not just the cadaver bleaching model, but actually some of the ones that are in Type 1 that look like they already have high efficacy. There may be this path over the ten years of a radical change in diabetes in our society, and our math is that is five or six trillion dollars of spend in the ten years.

It is real money, and it may be the one path we have where our brothers and sisters on the left and those of us on the right actually might agree on something. Dr. Herman, start there and let us go down. Tell me where I am right, tell me where I am wrong.

Senator Welch. Uh-oh.

Vice Chairman Schweikert. Yeah. I am willing to take the beatings.

Dr. Herman. I think you are right.

(Simultaneous speaking.)

Dr. Herman. So I mean I will just say this from, you know, the perspective of a physician who has been treating these conditions for a couple of decades, the last decade has been a revelation with the new technology and these new medications.

We have things to offer patients for the first time that are incredibly effective for conditions that were previously very difficult to treat, and the options seem to be improving. And so I am very optimistic about the possibilities over the next ten years in applying these medications and technologies more widely.

Dr. Ippolito. I will highlight perhaps a piece of optimism on the cost side too. We often see sort of transformational developments

in the pharmaceutical market or devices that are sort of one shot. But we do not have that here. We have classes with lots of different products coming to market that have different benefits and costs, of course.

But that is beneficial in the short term because it means you have competition to get the formularies, you have price competition in the short term that you do not always get, and beyond that you as a patient now has four—it is like with statins. You have four options to choose from. You can choose what is best for you.

But I will also highlight, you know, ten year budget windows, I understand the focus for you guys. But when you think about the cost of drugs and technologies, I think you have got to think longer term. You had huge savings when things come off patents which happens, you know, in the case——

Vice Chairman Schweikert. And there are some GLP–1s that are almost at the end of their patent cycle.

Dr. Ippolito. Right, right. And so as that starts happening, it is not just that those prices go down; is that it puts more pressure on the remaining on brand products to compete with those off brand products. And so I will sort of signal a hopeful point on the cost side, that I think it may not be quite as devastating as some other projections are.

Vice Chairman Schweikert. Ms. Brown-Friday.

Mrs. Brown-Friday. Well, from my perspective I would say that I am very thankful and hopeful that all the innovations do come to pass, and that it is available to everyday. I would say also that in terms of cost, insulin was not always extremely expensive. It became expensive due to whatever it, the situation came to. Yes.

Vice Chairman Schweikert. No, no, no, you are absolutely—and look, we have had a fixation on the co-op that is about 70 miles from here. Medeford's is not too far from where you are, that actually is also producing even lower than the subsidized price. But the revolution is here. I do have an intense concern though that it be available for all populations.

Mrs. Brown-Friday. I agree with you, if indeed it is.

Vice Chairman Schweikert. And Navajo Nation. Look, you know, I have been blessed. As a young man, I spent lots of time in the community and most folks who have never been there do not understand. There is rural and then there is the Navajo Nation.

President Nygren. Uh-huh.

Vice Chairman Schweikert. And you actually have a really tricky job, because you know, let us be honest. Living in Window Rock is a lot different than some of the chapter houses, you know, up near the border. But I am incredibly hopeful with your leadership.

What can we do if my fantasy is change the Farm bill, access to the blood glucose type of management so you can actually see your macros—to understand your diet. That maybe living on fried bread, even though it is delicious, is difficult. Forgive me for the cultural reference.

What else can I do other than just funding another program? Is that revolution something we can actually deliver to the Navajo people?

President Nygren. I think one of the things, I am glad that you have brought that up, because even like with broadband, I am trying to bring it up at that level.

Vice Chairman Schweikert. Starlink.

President Nygren. Starlink.

Vice Chairman Schweikert. Satellites. No more waiting another 25 years for wire to go out to that chapter house. Put up the damn satellite, sorry.

President Nygren. Yeah. So if we go down that route, some form of some of the latest technology that is coming out, it would be great to implement it within the IHS program so that it is being staged instead of later down the road.

So I think that just having that better coordination with IHS so we can get it out to those main facilities out there, that would—I think that would be a key thing, is just communicating with the federal partners and then the Nation, and then being able to have our people have access to the latest and greatest.

Vice Chairman Schweikert. Thank you, and in some ways this is a derivative of even where Mr. Beyer had asked a question. I am blessed to represent Salt River—Pima and Maricopa. I have lived my whole life next to that community and Fort McDowell. And you know, it is a—it is an economically stable community, you know, being that close. It is an urban tribe.

And yet I have seen some data that says that maybe the second highest per capita diabetic population in the world, and their sister tribe Gila may be number one. So and sometimes it is more complex than just saying it is poverty. It turns out time, as some said, sometimes it is our need for convenience and those things.

And that is why for those of you who actually also have the microphone and the credibility for what you all do, help those of us who care passionately tell the story. Maybe it is time for revolution in what we do in the Farm bill. Maybe just growing the same five commodity crops when North America used to grow 3,300 types of grain. Optionality, so you do not have to process a process to make a profit.

Number two, the new technology. I am dying for the Apple watch that actually will have blood glucose in it, though I am told it might be two generations away so I am going to just buy the Samsung. Glad someone got that joke. But the GLP-1s. Every day I am reading an article about someone that is coming out with new products. So your point that prices are crashing. The availability here, and there may be some that are almost out of patent expiration.

Maybe the crazy thing is we buy the damn patent. We buy its last 18 months and use that for Medicare and Medicaid, Indian Health Services, VA populations, because the savings is remarkable.

I mean sometimes those of us who are on the right sound cruel because we are talking about the dollars and cents and do not talk enough about the morality of people's lives and their ability to participate in society, and the income inequality that health differential causes.

But the four of you are actually on the cusp of the thing, that maybe the one point we can—if we can build a unified theory here

that could have amazing impact on the U.S. solving debt and economic growth. But it cannot be what a lot of us here do, which is we talk about the one thing we know of eating onion rings or, you know, sorry about that.

Have you ever had a Navajo taco? I will explain it later. It is—so in the last part here, I need to give myself, and this is the danger of being unscripted. I owe a thank you to the Democrat staff and the Republican staff. Thank you for actually communicating with each other on this. This is one where the solutions great economics and wonderful morality help us tell the story.

The last bit I will give you is if any of you have things you want us to read, we are not walking away from this. This is almost the only path I have to dramatically change the direction of this society right now. Send it to us and we will continue to evangelize it.

And then for all of you, you have—I think it is another how many days to be able to submit additional for the record?

Speaker. Three.

Vice Chairman Schweikert. How many?

Speaker. Three.

Vice Chairman Schweikert. Three days. In the House we do a lot more. If you have other documents that you would like us to put into the public record, please send it our way. Please do it within three days, but if you send it on the fourth day, I will still put it in. And with that, we call this hearing adjourned. Thank you for participating.

[Whereupon, at 11:53 a.m., the hearing was adjourned.]

SUBMISSIONS FOR THE RECORD

Joint Economic Committee

Chairman Martin Heinrich
Opening Remarks for Hearing, "The Economic Impact of Diabetes"
July 27, 2023

Thank you, Vice Chairman Schweikert, for working with me to put together this bipartisan hearing today.

The economic impacts of diabetes on our economy and our country are significant. More than 37 million Americans—or about 1 in 10—have diabetes, while another 96 million adults have prediabetes. Diabetes is growing more prevalent with an estimated 1 in 3 Americans expected to develop the disease sometime in their lifetime.

The rising costs of diabetes are due to the high price of medications and treatments in the doctor's office, and also lost earnings due to sickness, lower employment rates, and the cost of early retirement.

These costs are borne by the patient, by our health systems, by employers, and by entire communities.

That is where we can focus in this hearing today: identifying the direct and indirect costs of diabetes on our economy and finding bipartisan solutions that ensure we have a healthy population who can fully contribute to their communities.

Part of tackling this is making sure that all Americans have access to quality, affordable health care, no matter their means or where they live. When patients lack access to health care, minor challenges can quickly become major ones with a lack of proper diagnosis and treatment. That's especially true in rural and Tribal communities, where diabetes is increasingly prevalent.

Too many Americans are living with undiagnosed or untreated diabetes because they can't afford to see a doctor, to pay for prescribed medications, or to travel the long distances required to get to a provider. Living with undiagnosed diabetes can delay more effective treatments that prevent more extreme complications, and impact people's ability to provide for their families.

Like most diseases, we know that Type 2 diabetes prevention, early intervention, and health education are both cost effective and lead to better health outcomes.

Beyond that, we must understand and address the upstream causes of the disease, including factors like socioeconomic status and access to nutrition.

Food insecurity is closely associated with Type 2 diabetes. When families have access to nutrition programs like SNAP and WIC, they are able to more consistently access healthy food, and we've seen associated reductions in poverty and health care expenditures.

Fortunately, medical science has also had recent breakthroughs on pharmaceutical treatment options for diabetes. I'm looking forward to hearing more about how recent breakthrough treatments have had positive outcomes for patients and have helped to change their lives for the better.

Unfortunately, however, many of those treatment options remain unaffordable for most patients.

The Inflation Reduction Act was an important step in controlling drug costs. The law established several cost-control measures like limiting insulin co-pays for Medicare beneficiaries to $35 a month and capping annual out of pocket prescription drug costs at $2,000 starting in 2025.

The Act also gives Medicare the ability to negotiate the price of some high-cost prescription drugs, and forces drug companies to pay a penalty when the prices they charge Medicare rise faster than inflation. These actions will all put downward pressure on drug costs while having little impact on innovation.

It is clear that the most effective treatments for diabetes require a comprehensive and holistic approach, addressing diet, lifestyle, mental health, and other societal factors alongside medical treatments.

And we've had some successes on this front, such as with the Special Diabetes Program for Indians, which Congress established in 1997.

This program provides funding for diabetes prevention and treatment services to over 300 Indian health programs across the United States and provides grantees with flexibility to design and implement diabetes interventions that address locally identified community priorities.

Through this program, we've seen youth-based outreach, the planting of community gardens, running and fitness events, and partnership programs with pharmacies that help patients manage their prescriptions.

The Special Diabetes Program for Indians has been extremely effective. Since it started, the prevalence of diabetes, end-stage renal disease, and diabetes-related eye disease among American Indians and Alaska Natives have all declined.

We need to increase the funding for this program to allow it to keep up with costs and better serve all Tribes.

And looking beyond Tribal communities, we should look to this program as a model for how we can design and implement comprehensive disease treatment and management nationwide.

I'm pleased to join my colleagues from both sides of the aisle to further explore these issues and more today in this bipartisan hearing.

I'm looking forward to hearing more today on the impacts diabetes has on our communities—from the ways we can address the upstream causes, to the role of health and nutrition programs in prevention and treatment, to the role of pharmaceutical interventions.

Testimony of the Honorable Dr. Buu V. Nygren, President of the Navajo Nation
Before the Joint Economic Committee Regarding "The Economic Impacts of Diabetes"
July 27, 2023

Chairman Heinrich, Vice Chairman Schweikert, and Members of the Committee, the Navajo Nation appreciates the opportunity to provide oral and written testimony to the Joint Economic Committee on the Economic Impact of Diabetes. My name is Buu Nygren and I am President of the Navajo Nation. I also serve as the Navajo Area representative to the National Indian Health Board (NIHB). Thank you for the opportunity to highlight the important work of the Special Diabetes Program for Indians which has made measurable impacts in type 2 diabetes treatment and prevention for American Indians and Alaska Natives (AI/ANs) nationally, and on the Navajo Nation.

Background

The Navajo (Diné) people live in the largest American Indian reservation in the US. The reservation covers more than 27,000 square miles, extending into Arizona, Colorado, New Mexico, and Utah. The Navajo Nation consists of 110 small communities (also known as chapters) that have an average population size of approximately 1,700 residents. Chapters function as the smallest level of government, where governance and planning are conducted by local elected officials. By population, Navajo is now estimated to be the largest American Indian tribe in the US with nearly 400,000 enrolled tribal members, of whom nearly half live on the Navajo reservation.[1]

Like many American Indian tribes, the Navajo people experience higher rates of preventable nutrition-related diseases such as obesity, diabetes, heart disease, and cancer than the general US population. These disparities stem from the negative impacts of colonization; the Navajo has been forced to endure threats to our existence because of federal policies, forced assimilation, removal from tribal homelands in 1864 and eventual return to our homelands. Altogether, this history has been detrimental to traditional lifeways. Access to nutritious foods that were once produced by subsistence activities of farming, herding, hunting, and gathering have given way to greater reliance on processed foods high in fat, sugar, and salt. Poverty, unemployment, lack of transportation, and remote, rural geography with few grocery stores amplify the challenges to healthy food access.

Established by Congress in 1997, the Indian Health Service's Special Diabetes Program (SDPI) for Indians has funded community-based interventions to treat and prevent type 2 diabetes on the Navajo Nation. Despite these efforts, type 2 diabetes is a persistent public health problem. In 2011, the Navajo Nation and Navajo Area Indian Health Service (IHS) shifted our approach to engage local community input to develop and implement community-based interventions. There remains a great need to expand and adopt evidence-based practices to prevent and treat diabetes among American Indians and Alaska Natives. The annual discretionary appropriated budget for IHS in FY 2023 is just under $7 billion, which is far below need. For example, in FY 2021, spending at $4,140 per patient, when the national average was $10,680.[2] In addition, SDPI is funded through

[1] Curley C. The Navajo Nation Healthy Dine Nation Act: Community Support of a 2% Tax on Unhealthy Foods. Journal of Public Health Management and Practice; 2023; 1-11.
[2] "Advancing Health Equity Through the Federal Trust Responsibility: Full Mandatory Funding for the Indian Health Service and Strengthening Nation-to-Nation Relationships The National Budget Formulation Workgroup's Recommendations on the Indian Health Service Fiscal Year 2024 Budget." May 2022. P. 17. Accessed on July 25,

mandatory appropriations at $150 million per year. This funding has remained flat for two decades. SDPI currently supports over 300 diabetes treatment and prevention programs[3] intended to implement key elements of quality diabetes care and prevention practices using traditional and culturally relevant approaches, as well as to participate in annual evaluations to monitor the quality-of-service delivery. For example, the SDPI currently funds 38 initiatives to evaluate the feasibility of providing evidence-based diabetes prevention programs modeled after the national Diabetes Prevention Program.

SDPI Works

Despite SDPI's flat funding since FY 2004, it is making measurable impacts nationwide. Communities with SDPI-funded programs have seen substantial growth in diabetes prevention resources, including more than doubling the number of on-site nutrition services, and physical activity and weight management specialists for adults, and an exponential increase of sites with physical activity services for youth. For the first time, from 2013 to 2017 diabetes incidence in AI/ANs decreased each year. Between 1996 and 2013, incidence rates of end-stage renal disease (ESRD) in AI/AN individuals with diabetes declined by 54 percent. This reduction alone is estimated to have already saved $520 million between 2006-2015. In short, by allowing Tribes to determine their own approach, SDPI has become the nation's most effective federal initiative to combat diabetes and serves as a useful model both for diabetes programs nationwide and public health programs in Indian Country.

In addition, we have taken steps to assert our tribal sovereignty and self-determination to address health outcomes (i.e., diabetes) and restore *hózhó*, a holistic health and wellness for our people, through our own disease prevention activities, data collection, policy development, and evaluation initiatives. Along with building our tribal data capacity, the Navajo Nation is the only location in the US to use its authority to create a historic tax policy, the Healthy Diné Nation Act (HDNA) of 2014, which introduced a 2% tax on unhealthy foods and waived a 6% sales tax on fruit, vegetables, and water. Unhealthy foods include sweetened beverages and prepackaged snacks that have been stripped of essential nutrients and are high in salt, saturated fat, and sugar. Some examples of tax-eligible items include sugar sweetened beverages, candy, chips, and sweetened baked goods. From 2015 through 2019, total revenue was $7.58 million. Disbursements occurred each year after collection for a total of $6,062,335 for local community wellness projects over the 4 years (2015-2019). Our Navajo SDPI program continues to operate the Wellness Centers across the Navajo Nation conducting health and wellness activities including health screenings.

The Navajo Nation appreciates the work you have provided to support SDPI reauthorization over the years. Your leadership in supporting this critical program has been essential in ensuring that we can sustain the major accomplishments of this life-saving program. Thank you again for your strong support of this program, Navajo Nation looks forward to working with you to renew SDPI at a funding level that will enable the program to serve more American Indians and Alaska Natives. SDPI expires on September 30, 2023. We are encouraged by both House (H.R. 3561) and Senate

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2023 at:
https://www.nihb.org/docs/09072022/FY%202024%20Tribal%20Budget%20Formulation%20Workgroup%20Recommendations.pdf

[3] For a full list of SDPI grantees see:
https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/2023_Letters/Enclosure-DTLL_DUIOLL-012523.pdf

(S. 1855) which would renew SDPI for 2 years at a level of $170 million per year. While this is less than the $250 million per year requested by Tribal Nations and in the President's FY 2024 budget request, we appreciate Congress' attention to the need for a funding increase for SDPI. We respectfully ask that the Committee work with leadership in both chambers to pass this legislation by September 30.

Overview

Navajo Special Diabetes Program focuses on community-directed approaches to treat and prevent Type 2 diabetes in Tribal communities that are culturally formed. AI/ANs suffer disproportionately from Type 2 diabetes, but appreciations to the success of Special Diabetes Program for Indians (SDPI) the numbers reflect a positive improvement. AI/AN people have a higher burden of many chronic diseases including Type 2 diabetes, hypertension, cardiovascular diseases, cancers, and mental illnesses.

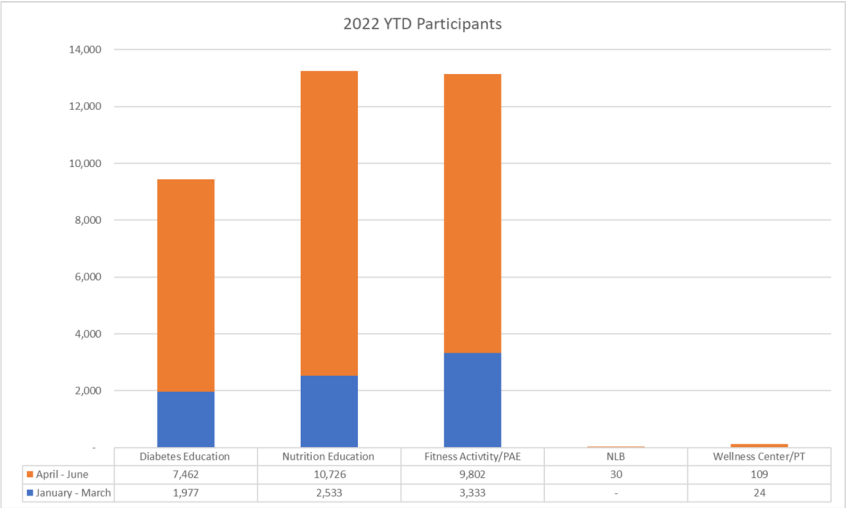
Special Diabetes Prevention Initiative on Navajo Nation

As a diabetes prevention program, services are directed toward the communities on the Navajo Reservation through community diabetes education, nutrition education, and physical activity and education. The service areas for the Navajo Special Diabetes Program are Chinle, AZ, Dilkon, AZ, Window Rock, AZ, Tuba City, AZ, Kayenta, AZ, and Crownpoint, NM. In June 2023, all Wellness Centers were reopened and reestablished group fitness classes and one-on-one personal training with participants at risk for Type 2 diabetes.

In 2023, NSDP would like to highlight the following numbers reflected in our year-to-date data collection with reflection of reestablishing the Wellness Centers in June 2023.

2023 Year-to-date

- Diabetes Education – 9,439 people reached.
- Nutrition Education – 13,259 people reached.
- Fitness Activity with Education – 13,135 people reached.
- Group Fitness Classes and Personal Training – 139 people reached.
- Total of 35,996 participants utilizing NSDP services



NSDP partners with Indian Health Services (IHS), Tribes, Tribal organizations, Urban Indian health organizations (I/T/Us), local governing committees, and educational institutions to implement evidence-based, practice-based, and culturally based activities, to share knowledge and build capacity in Indian Country.

Upstream Causes of Diabetes

According to the 2021 Annual Summary issued by IHS, there were more women (59%) than men (41%) diagnosed with Type 2 diabetes with a prevalent age range of 45-64 years. Participants with a Body Mass Index (BMI) of Obese: 30+% was calculated at 50%, Overweight: 25-29.9 % at 29%, and Severely Obese: 40+% at 10%. As obesity is a known risk factor for many leading causes of death in AI/ANs, including cardiovascular disease, cancer, type 2 diabetes, stroke, and kidney disease, the population burden of obesity may contribute to the observed disparities in mortality[4]. Improving lifestyle behaviors plays an important role in the prevention and control of these diseases[5].

The mission of the Navajo Special Diabetes program is to "Illustrate lifestyle changes to prevent or delay the onset of diabetes." It is our duty to provide community-based education to prevent the upstream causes of diabetes and most importantly prevent the onset of Type 2 diabetes.

Nutrition Programs

AI/ANs have traditional food and nutrition practices that support holistic health. However, these traditional practices have been interrupted by Western food systems, which has led to

disproportionate rates of type 2 diabetes (T2D) among AI/AN communities. Nutrition education interventions are particularly effective when developed to meet the needs of specific communities and when they emphasize strengths-based, culturally relevant healthy dietary practices[3].

NSDP has hosted virtual and in-person grocery tours, food demonstrations, hands-on guidance, and gardening to educate the community about the impact of nutrition on diabetes.

Pharmaceutical Interventions

According to the 2021 Annual Summary issued by IHS, Diabetes Management Therapy provides pharmaceutical interventions. Of the Type 2 diagnosed patients, 34% are taking one (1) medication and 20% not taking any medication. 65% of the diagnosed Type 2 patients were prescribed Metformin. Pharmaceutical intervention is in collaboration with IHS due to their clinical approach.

Conclusion

Thank you again for the opportunity to share about the impact of diabetes and the SDPI program on the Navajo Nation. While type 2 diabetes continues to impact our people at alarming rates, there is hope. Thanks to the impact of SDPI, we have increased nutrition counseling and patient interventions to help them treat or even reverse type 2 diabetes. We urge Congress to renew this critical program by September 30, 2023. Ahéhee' (Thank you)

[3]A culturally adapted online experience improves type 2 diabetes nutrition education for American Indians and Alaska Natives. (2023, February 26). NewsRx Health, 36. https://link.gale.com/apps/doc/A737805739/CSIC?u=uphoenix&sid=ebsco&xid=36674c68

[4]Zamora-Kapoor, A., Sinclair, K., Nelson, L., Lee, H., & Buchwald, D. (2019). Obesity risk factors in American Indians and Alaska Natives: a systematic review. Public Health, 174, 85–96. https://doi.org/10.1016/j.puhe.2019.05.021

[5]Zhao, G., Hsia, J., Vigo-Valentin, A., Garvin, W. S., & Town, M. (2022). Health-Related Behavioral Risk Factors and Obesity Among American Indians and Alaska Natives of the United States: Assessing Variations by Indian Health Service Region. Preventing Chronic Disease, 19, E05. https://doi.org/10.5888/pcd19.210298

American Diabetes Association®
Connected for Life

Written Testimony of Janet Brown-Friday, RN, MSN, MPH
President of Health Care and Education, American Diabetes Association
Clinical Trials Manager, Albert Einstein College of Medicine's Diabetes Clinical Trials Unit

Joint Economic Committee Hearing
"The Economic Impact of Diabetes"
July 27, 2023

Thank you, Chairman Heinrich, Vice Chairman Schweikert and distinguished members of the Joint Economic Committee for inviting me to testify on behalf of the American Diabetes Association (ADA) regarding the cost of living with diabetes. We appreciate you considering this important topic at this critical time.

The ADA is the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic and help people living with diabetes thrive. For 80 years the ADA has been driving discovery and research to treat, manage and prevent diabetes, while working relentlessly for a cure. We help people with diabetes thrive by fighting for their rights and developing programs, advocacy and education designed to improve their quality of life.

Today I would like to take this opportunity to describe and offer context for some of the most significant drivers of cost increases for people living with diabetes and the work ADA is doing to make managing diabetes more affordable and prevent costly adverse outcomes.

More than 37 million Americans live with diabetes, and nearly 100 million Americans have prediabetes, making diabetes is the most expensive chronic condition in the United States—people with diabetes account for $1 of every $4 spent on health care in the country and nearly one-third of Medicare drug spending. People of color and other underserved populations—those who lack access to adequate health insurance coverage, health care services and the tools they need to manage their diabetes—bear a disproportionate share of patient cost burdens. That's because 18 percent of Black Americans, 17 percent of Latino Americans and nearly 15 percent of Native Americans have diabetes, compared to seven percent of white Americans. Because diabetes diagnoses are less likely when people have access to resources, diabetes prevalence is inversely related to household income—individuals who earn less than $30,000 per year are three times more likely to have diabetes than those who make more than $80,000. Lower-income Americans in both rural and urban areas are also more likely to develop diabetes, experience complications from poorly managed diabetes and die younger than higher-income Americans.

To address these social and economic barriers to the appropriate providers, tools and services for diabetes management, the ADA launched our Health Equity Now in 2020. The ADA's Health Equity Bill of Rights guides our work to consider the social determinants of health that lead to a higher prevalence of diabetes and worse health outcomes. The pillars of our actions are built on this foundation.

The ADA has identified several major drivers of the high cost of care for people with diabetes and ways Congress can address them. Some of these include:

High Rates of Complications and Hospitalizations

Having health insurance is the strongest single predictor of whether adults with diabetes will receive high-quality health care services. The 27.5 million uninsured Americans have a higher likelihood of having undiagnosed diabetes because they are 60 percent less likely than insured individuals to have regular office visits with a physician, prescribed 52 percent fewer medications, and have 168 percent more emergency room visits. Diabetes-related amputations are a particularly expensive complication that requires significant health care resources and time in the hospital. A foot or leg amputation costs $30,000 to $60,000 in initial hospital costs, with an additional $40,000 to $60,000 in follow-up care in the three years post-surgery. These costs do not consider lost employment, or additional costs of mental health and other services commonly required by amputees.

These disparities became even more acute during the recent pandemic and consequent economic downturn. Americans with diabetes and other related underlying health conditions were hospitalized with COVID-19 six times as often and died of COVID-19 12 times as often as those who did not have diabetes. One in 10 coronavirus patients with diabetes died within one week of hospital admission. And Americans with diabetes accounted for 40 percent of COVID-19 fatalities nationwide, despite making up just 10 percent of the U.S. population at the time. While we are still learning about the relationship between COVID-19 and diabetes, we know that unmanaged diabetes—whether a lack of medication use or missing doses—is a key factor in COVID-19 severity and complications, and an important indicator of whether someone with diabetes and COVID-19 is likely to have a longer hospitalization.

Comorbidities, Including Obesity

People with undiagnosed diabetes are more likely to develop comorbidities—from kidney failure to coronary artery disease—increasing costs and severely limiting their ability to get healthy. More than 85 percent of people with type 2 diabetes have overweight or obesity. Similarly, research shows that people with type 1 diabetes are at a growing risk for obesity and related health conditions including heart disease, stroke, and 13 types of obesity-cancer. ADA understands the urgency of responding to the obesity epidemic to improve the health of millions of Americans particularly those with or at risk for diabetes. There is strong and consistent evidence that obesity management can delay the progression from prediabetes to

type 2 diabetes and is highly beneficial in treating type 2 diabetes. Effective weight management can lead to type 2 diabetes remission.

Obesity exacerbates or causes over 200 medical disorders resulting in declining physical, mental and emotional health and physical mobility. The Centers of Disease Control and Prevention identified that obesity also increases the risk of severe illness from COVID-19 and triples the risk of hospitalization. Mirroring trends with diabetes, obesity has a greater impact on people of color, with lower incomes and education levels. Over 49 percent of Black adults and over 45 percent of Hispanic adults, compared to over 40 percent of white adults have obesity.

The ADA recognizes that obesity is a common, chronic, progressive and relapsing disease with many medical, physical, and psychosocial issues. People with obesity deserve the access to person-centered, effective interventions available to treat to their disease and support healthy weight management as detailed in our 2023 Standards of Care. In addition to supporting access to healthy food and nutrition outlined above, we encourage Congress to help prevent diabetes by addressing the obesity epidemic:

- Improve Medicare beneficiaries' access to effective weight management services by updating the intensive behavioral therapy (IBT) benefit and allowing access to anti-obesity medications currently prohibited. Medicare's position and coverage restrictions are an outlier among other federal health care programs. The Department of Defense, Veterans Health Administration and the Office of Personnel Management provide access to a comprehensive obesity benefit across the continuum of care for enrollees. Unfortunately, state health care programs including Medicaid and State Employee Health Plans indicate Medicare's restrictions as rationale for non-coverage.
- Support access to preventive services for recommended by the United States Preventive Task Services (USPSTF) for state Essential Health Benefit (EHB) benchmark plans. In 2018, USPSTF recommended that "clinicians offer or refer adults with a body mass index (BMI) of 30 or higher to intensive, multicomponent behavioral interventions." Ensuring that EHB plans not only offer by provide access to these preventive services can reduce disparities and lead to better health outcomes for people with diabetes, at risk for diabetes and with comorbidities including obesity.

The Cost of Prescription Drugs

The increasing cost of prescription drugs has created an outsized burden on the diabetes community and the U.S. health care system writ large. For people with diabetes, many of whom rely on insulin and other expensive medications to manage their condition, this financial barrier can mean the difference between life and death. The price of insulin has roughly tripled in the past decade, increasing from less than $100 for an average vial in 2009 to nearly $300 for the same vial today, even though today's insulin is nearly the exact same product as it was 10 years ago. Americans spend more treating diabetes than any other chronic condition; that people with diabetes in the U.S. spend two and a half times more on health care than those who do

not have diabetes; and that one in four insulin-dependent Americans report rationing their insulin supply due to the cost of the drug and financial difficulty.

Currently, pharmacy benefit managers (PBMs) and other drug middlemen function at the center of the pharmaceutical supply chain, acting as intermediaries between insurers, manufacturers, and pharmacies. Health insurers hire or own PBMs to handle benefits for their health plans, who then develop lists—or formularies—of the drugs and devices the health insurer will cover. PBMs negotiate prices with drug makers for the products covered on the formulary, and as part of this process, manufacturers offer rebates to PBMs in exchange for preferred formulary placement. As a result, the actual price the PBM pays is lower than the list price. Because what the consumer pays at the pharmacy counter is based on the list price, not negotiated price, it is not clear how, if at all, rebates negotiated by PBMs benefit patients. More fundamentally, there is troubling evidence that current incentives for PBM formularies to favor the most high- cost drugs and devices may encourage the exclusion of lower-cost drugs and devices, putting more affordable options out of reach for our community.

The system in place has created perverse incentives and led to increased costs to consumers, negotiated by PBMs for prescription drugs should be shared with consumers, and those with unusually high launch prices where other lower-cost options are available, should be subject to a full pass-through of rebates to consumers so that they are not given preferential treatment that limits or blocks access to lower-cost options.

Limiting cost-sharing is another important way Congress has and can continue to help people with diabetes who are insulin-dependent. As a result of the ADA's leadership in advocating for state and federal limits on cost-sharing for insulin, 25 states and the District of Columbia have already enacted co-pay caps. We know that limits on cost-sharing for insulin can provide immediate, noticeable financial relief to patients. California Senate Bill 90 would cap out-of-pocket costs for insulin at $35 per month for state regulated plans and offer patients currently paying above the cap a 67 percent reduction in cost-sharing, from an average of $88 per prescription to $20 per prescription. The analysis estimated a 10 percent decrease in diabetes-related emergency room visits, which could reduce emergency room costs by more than $2.4 million in the cap's first year should the state enact it.

Given that people with diabetes typically require more than one medication to manage their diabetes and other comorbidities, we hope to see Congress take additional steps this year to make prescription medication and supplies for people with diabetes more affordable, especially for those who lack health insurance coverage. Our priorities include:

- Building on the $35 monthly co-pay cap that began with the Senior Savings Model in 2021 and culminated in the permanent Medicare co-cap in the Inflation Reduction Act by enacting a national insulin co-pay cap for commercial insurance plans so more Americans with diabetes can benefit from reduced cost-sharing regardless of the type of insurance they have.

- Increasing transparency throughout the pharmaceutical supply chain, including efforts to shed light on pricing practices, improve accountability in the pharmacy benefit manager (PBM) market, and ensure that rebates are benefiting patients and not artificially inflating prices or limiting patient options.
- Speeding competitive generic drug and biosimilar alternatives to market by, among other things, addressing loopholes in our patent system that allow manufacturers to stave off competition.
- Cracking down on insurance practices that push patients to choose between quality and affordability, including prior authorization and step therapy (or "fail first") policies that force patients to try the least expensive drug in a class first, even if their prescribing physician believes a different therapy is in the patient's best clinical interest.
- Increasing oversight and regulation of specialty drug tiers used by insurers that shift the cost-sharing burden disproportionately onto patients with rare and/or chronic conditions who rely on these medications.

Limitations on Access to Diabetes Technology

Thirty-one percent of individuals with diagnosed diabetes—or more than 10 million Americans—are treated with insulin and stand to benefit from a continuous glucose monitor (CGM). We know that access to CGMs in this population means better glycemic control. And poor glycemic control can lead to dangerous health outcomes—including heart failure, myocardial infarction, and death—not to mention increased costs as a result of hospitalizations for and treatment of these cardiovascular complications.

For millions of people living with diabetes, CGMs provide significant, potentially life-changing benefits for diabetes management and in turn for avoidance or delay of serious co-morbidities, hospitalizations and even death. A CGM provides much greater detail to patients and their health care providers than traditional blood glucose meters do regarding an individual's blood glucose levels, offering opportunities to analyze patient data more granularly than was previously possible and providing additional information to aid in achieving glycemic targets. CGMs also provide biofeedback in real time, allowing individuals with diabetes to modify their diet and insulin dose as needed in consultation with their health care provider. As a result, individuals with Type 1 and Type 2 diabetes who get a CGM are shown to have less hypoglycemia, and they experience a reduction in their average blood glucose (A1C).

Given what we know about the benefits of CGM access and the deadly impact of poorly managed diabetes in communities with limited access to health insurance coverage and the health care system, the ADA commissioned a study on the relationship between insurance coverage, age, geography and race to identify where the greatest barriers to CGM access are. The data show that the people who are least likely to get a CGM are people of color, low-income individuals who rely on Medicaid, and people who live in states with some of the highest rates of diabetes. The study found that poorer, older Americans of color are the least likely group to get CGMs.

In particular, three troubling trends emerge from the data:

Individuals covered by Medicaid are the least likely to get a CGM, especially if they are people of color. Income is the first hurdle to getting a CGM. The greatest access barrier shows up when we combine income with race. Individuals enrolled in Medicaid who take insulin are two to five times less likely to get a CGM than those who have a commercial health insurance plan. And the CGM access gap between Medicaid and commercial insurance plans is bigger for people of color than it is for white Americans. States with higher rates of white Americans enrolled in Medicaid have better CGM access than states with higher rates of black Americans, where Medicaid coverage of CGMs is abysmally low. Hispanic individuals are also less likely to get a CGM if they are covered by Medicaid than a commercial health insurance plan.

Where people with diabetes live is a major factor in how likely they are to get a CGM. Data show that people with diabetes covered by Medicaid living in poorer states and in more rural areas are less likely to get a CGM. Medicaid utilization of CGMs is consistently lowest in the Southeast. Texas, Arkansas, Louisiana, Mississippi, Alabama and South Carolina all have state poverty rates higher than the national average of 11.4 percent, and all states in this region have a diabetes mortality rate greater than 20 percent. Arkansas and Louisiana have a diabetes mortality rate greater than 30 percent, and in Mississippi more than 40 percent of deaths in 2020 were attributable to diabetes.

Young people are more likely to get CGMs than older Americans with diabetes are. Insulin-dependent children younger than 18 who have diabetes are significantly more likely to get a CGM than people with diabetes between the ages of 45 and 64 with diabetes are. For example, people with diabetes aged 18 or younger are 3.5 times more likely to get a CGM if they have commercial insurance than if they are covered by Medicaid. Individuals with commercial insurance between the ages of 19 and 44 are 4.3 times more likely to get a CGM, and individuals between the ages of 45 and 64 are 2.5 more likely to get a CGM.

For low-income people with diabetes who rely on Medicaid, the diabetes management technology they need may not be covered adequately, or at all. Because Medicaid coverage is often determined on a state-by-state basis, there are wide discrepancies in diabetes technology access from one state to another. Given both the short- and long-term health benefits of using a CGM for those with poor glycemic control, federal and state government officials can and should take steps to drive improved and more uniform coverage policies for diabetes technology and supplies within Medicaid as a vital health equity measure. Given the significant variation in Medicaid coverage between states—and the correlation between states with low CGM utilization and high diabetes prevalence—the onus is really on states to do more to make sure their Medicaid programs are allowing enrollees to access diabetes management technology. For example, states can promote CGM access by making them available through as many channels as possible, including both mail-order and local pharmacies, to increase access for the diverse populations that can benefit from CGMs.

As with prescription drugs, manufacturers of CGMs, insulin pumps and supplies typically pay rebates to middlemen like PBMs to carry their products, and the rebates similarly have a market-distorting impact that inherently reduces access to lower-priced, more cost- effective devices. Individuals who access diabetes technology across insurance coverage types often pay more for their devices as a result of rebates negotiated by pharmacy benefit managers. Opportunities to expand PBM rebate reform in the diabetes technology and supplies categories are meaningful, in much the same way they offer the promise of less burdensome costs in the prescription drug market. Diabetes device focused PBM rebate reform can bring needed pricing transparency, reduce costs at the counter and improve patient access to this vital technology.

Increase in Diabetes Diagnoses

Several factors are contributing to the growth of the diabetes population in the United States. Overweight and obesity are proven risk factors driving as many as 53 percent of new cases of type 2 diabetes each year. Additionally, rates of both type 1 and type 2 diabetes have increased as a result of COVID-19 infections.

Over the next 40 years, we are expecting a dramatic increase in the number of young people under 20 who have type 2 diabetes in the U.S.—as much as a 70 percent increase by 2060 according to recent studies. The projected number of young people with both type 1 and type 2 diabetes is expected to surpass 500,000 by 2060, putting significantly more pressure on the health care system as corresponding rates of insulin dependence and hospitalizations increase the cost of managing diabetes and treating complications. Data show that these increase in diabetes prevalence is likely to place a much higher burden on Black, Latino, Asian, Pacific Islander and Native American youth. Globally, the situation is much worse. Researchers believe every country in the world will see rates of diabetes—predominantly type 2 diabetes—rise over the next three decades, potentially doubling from 529 million people to 1.3 billion people by 2050.

Conclusion

Thank you for the opportunity to testify before the Joint Economic Committee on the cost of diabetes. The ADA looks forward to continuing to work with Congress to enact the proposals outlined above to address health inequities, reduce costs to patients, and help Americans with diabetes access the tools, medications, and services they need to stay safe and healthy.

AMERICAN ENTERPRISE INSTITUTE

Statement before the Joint Economic Committee on "The Economic Costs of Diabetes."

The Costs of Diabetes and Considerations for Policy Responses

Benedic Ippolito, PhD
Senior Fellow

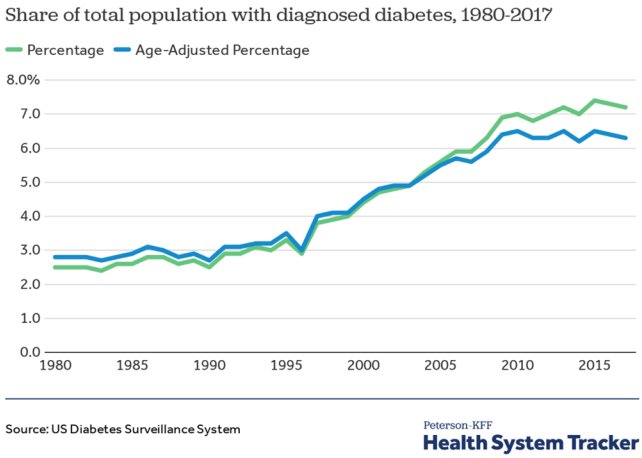
July 27, 2023

My name is Benedic Ippolito and I am a Senior Fellow in Economic Policy Studies at the American Enterprise Institute in Washington, DC. My research focuses on a number of topics within health policy including health care costs, drug markets, and how health care affects the personal finances of Americans. In my testimony, I will emphasize what we know about the costs of diabetes and, in turn, potential value stemming from relatively new therapies for the disease (and related conditions). I'll conclude by emphasizing principles that can help guide policy aimed at alleviating both the health and non-health costs associated with this condition.

The cost of diabetes

Over 37 million Americans currently have diabetes (including those who are undiagnosed) while nearly 100 million have prediabetes.[1] The condition is disproportionately common among groups with lower socioeconomic status, including those with incomes below the federal poverty level, those with less than a high school education, and certain racial and ethnic groups, like non-Hispanic black and American Indian populations.[2] As the prevalence of diabetes has risen, so too have its costs on individuals and the country. The burden of diabetes includes both the substantial direct health costs and those indirectly attributable to the condition.

[1] Centers for Disease Control and Prevention. By the Numbers: Diabetes in America. Oct. 2022.
[2] Centers for Disease Control and Prevention. By the Numbers: Diabetes in America. Oct. 2022.



Note: This figure illustrates diagnosed diabetes prevalence, while data quoted earlier in text includes those who are diagnosed and undiagnosed.

Most directly, the disease has first-order implications for health. Diabetes is associated with significant complications including heart disease, kidney disease, vision loss, and lower-limb amputation. It is among the top ten leading causes of death in the U.S.[3] The associated health care utilization, including over 8 million hospitalizations per year involving type 1 or 2 diabetes, results in substantial health care spending on those with the condition.[4] Estimates suggest that diabetes contributed to $237 billion in excess health care spending in 2017 (roughly $296 billion in 2023, adjusted for inflation).[5] As of 2013, diabetes was associated with the highest health care spending of a single condition.[6]

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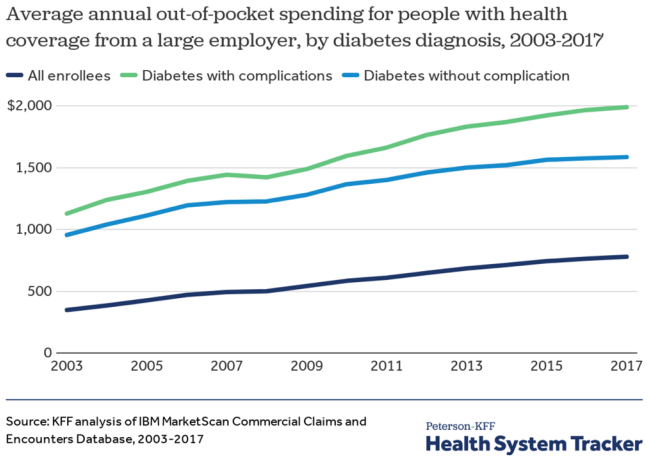
[3] Kamal, R., Kurani, N., Ramirez, M., & Gonzales, S. How have diabetes costs and outcomes changed over time in the U.S.? Nov. 2019. Peterson-KFF Health System Tracker.
[4] Fingar, K. & Reid, L. Diabetes-Related Inpatient Stays, 2018. HCUP Statistical Brief #279. July 2021. Agency for Healthcare Research and Quality, Rockville, MD.
[5] American Diabetes Association. Economic Costs of Diabetes in the U.S. in 2017. *Diabetes Care,* 2018; 41(5):917-928.
[6] Dieleman, J. L., Baral, R., Birger, M., Bui, A. L., Bulchis, A., Chapin, A., ... & Murray, C. J. (2016). US spending on personal health care and public health, 1996-2013. *JAMA*, *316*(24), 2627-2646.

The direct financial burdens of diabetes are borne by individuals with the condition and society more broadly. Unsurprisingly, those with diabetes tend to have higher out-of-pocket spending than those who do not. Data from the commercially insured market, for example, indicate high and rising out-of-pocket spending for diabetics compared to others.



The remaining excess health care spending among these patients is borne by those paying premiums or taxpayers. The balance between the two depends on the source of coverage. Roughly 60 percent of health costs attributed to diabetes are incurred by those over 65, meaning the Medicare program bears a significant portion of costs (largely financed by the federal government and taxpayers).[7]

[7] American Diabetes Association. (2018). Economic costs of diabetes in the US in 2017. *Diabetes care*, *41*(5), 917-928.

Diabetes has significant indirect costs beyond those captured by health care spending. Most notably, the condition can affect labor market outcomes. This reflects increased absenteeism, lower productivity, lost work years, and other factors.[8,9,10] Estimates suggest these factors add an additional $90 billion per year ($113 billion in 2023, adjusted for inflation) to the overall cost of diabetes.[11] Those costs are borne by individuals through foregone wages and the government through lower tax revenue.

All told, estimates suggest direct and indirect costs of diabetes total $327 billion annually (over $400 billion in 2023, adjusted for inflation).[12]

Policy considerations for efforts to alleviate the burden of diabetes

Given the significant costs of diabetes, treatments than combat the condition have the potential to convey significant value to society. Most directly, there is clear value in interventions that help avoid negative health outcomes like heart or kidney problems. The relatively-recent rise of Glucagon-like peptide-1 agonists (GLP-1s) has marked a notable development in the treatment of type-2 diabetes by improving blood sugar control and aiding in weight loss. Advancements in treatment offer a significant opportunity, but also raise a number of policy questions. I will emphasize a few questions that are worth considering for policymakers.

How will new treatments affect overall costs of diabetes?

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[8] Pedron, S., Emmert-Fees, K., Laxy, M., & Schwettmann, L. (2019). The impact of diabetes on labour market participation: a systematic review of results and methods. *BMC public health*, *19*(1), 25.
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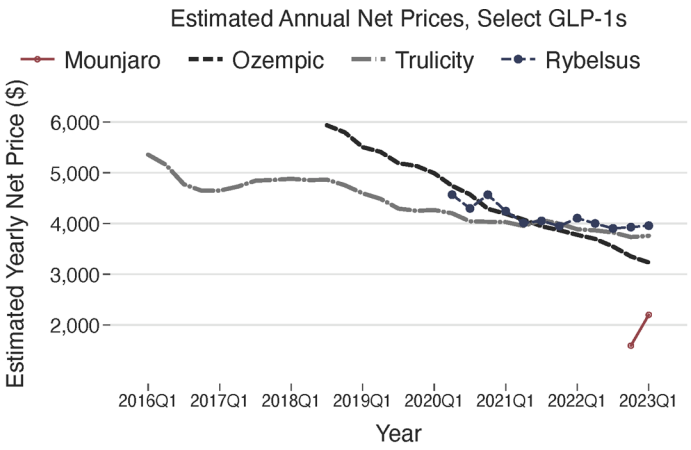
[10] Clark, M., Minier, J., Courtemanche, C., Paris, B., Childress, M. (2019). The Economic Impact of Diabetes in Kentucky. University of Kentucky Center for Business and Economic Research.
[11] American Diabetes Association. Economic Costs of Diabetes in the U.S. in 2017. *Diabetes care*, 2018; 41(5): 917-928.
[12] American Diabetes Association. Economic Costs of Diabetes in the U.S. in 2017. *Diabetes care*, 2018; 41(5): 917-928.

New treatments, like GLP-1s, have the potential to both increase some costs associated with a disease and decrease others. Most directly, new treatments have direct costs. In the case of GLP-1s, these costs are not trivial, as annual net prices (i.e., the price paid by insurers after rebates and other discounts) are often in the thousands of dollars per year. That said, the direct costs of these medications are subject to some uncertainty because this is an active area of drug development. As additional products enter the market, we should expect more competition over "preferred" coverage status on insurance plans, leading to lower prices (even absent generic or biosimilar entry). Below, I illustrate the estimated annual net prices of selected GLP-1s in recent years. Evidence is consistent with competition among these products moderating prices within the class.[13]

[13] Note that these estimates are consistent with select reporting from other sources. E.g., see the following ICER Report for pricing information on Ozempic.



Note: Data from SSR Health. Net prices reflect estimated payments to manufacturers after all rebates and discounts.[14] Figure is reproduced from in-progress research with Joseph Levy, Assistant Professor, Johns Hopkins Bloomberg School of Public Health. Estimates are similar to figures included in recent reports from the Institute for Clinical and Economic Review.[15] Annual net prices may vary by condition, particularly if dosing is higher or lower.

Looking forward, branded products will lose their patent protection and FDA exclusivity over time, significantly lowering their own price[16] and introducing more pricing pressure on remaining branded products. The aggregate costs of these medications will depend on how competition among branded products affect near-term prices and the effects of generic or biosimilar entry on medium-to-long run prices.

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[14] For a discussion of these data, see Ippolito, B., & Levy, J. (2022). Best practices using SSR Health net drug pricing data. *Health Affairs Forefront*.

[15] E.g., Lin, G., Brouwer, E., Nikitin, D., Moradi, A., Chen, Y., Herron-Smith, S., Hansen, R., Pearson, S., Campbell, J. Tirzepatide for Type 2 Diabetes; Final Report. Feb. 2022. Institute for Clinical and Economic Review; Rind, D., Guzauskas, G., Fazioli, K., Hansen, R., Kumar, V., Chapman, R., Borrelli, E., Bradt, P., Pearson, S. Oral Semaglutide for Type 2 Diabetes: Effectiveness and Value. Nov. 2019. Institute for Clinical and Economic Review.

[16] E.g., U.S. Food and Drug Administration, Generic Competition and Drug Prices, Center for Drug Evaluation and Research. Sep. 2022. Note that the effects of entry depend on whether products are biologic or small molecule products. The GLP-1 market has seen the entry of both injectable biologics and, more recently, oral tablets.

These products also have the potential to offset their direct costs to some degree. Perhaps most notably, better management of a condition can reduce health care spending in some settings. For example, research has shown that medications leading to better control of cardiovascular risk factors significantly slowed health care spending growth among older Americans.[17] Similarly, there is the potential for improved productivity among workers with diabetes. Empirical evidence analyzing the effect of treatments for conditions like chronic pain[18] or mental health[19] illustrate cases where therapies have had significant positive effects on labor market outcomes. The extent to which these factors offset the direct cost of the medications is subject to some uncertainty.

That said, new treatments should likely be evaluated on more than just their budgetary effects. All else equal, reducing health care spending is a high priority. However, if a drug is clinically effective and improves the health of diabetics, higher health care spending can be highly cost effective. Efforts to constrain health spending should prioritize settings where evidence suggests benefits are small relative to costs.

How should policymakers consider access to new therapies?

The advent of new pharmaceutical products regularly raises important questions about access. In the case of diabetes, these types of concerns may be particularly pronounced given the higher disease prevalence among those in lower socioeconomic groups. However, it is important to recognize that the health care system includes significant efforts to increase affordability of drugs for lower-income Americans. Medicaid and Low-Income Subsidies in Medicare Part D both significantly reduce or eliminate cost sharing for covered drugs. Those programs cover roughly 100

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[17] Cutler, D. M., Ghosh, K., Messer, K. L., Raghunathan, T. E., Stewart, S. T., & Rosen, A. B. (2019). Explaining the slowdown in medical spending growth among the elderly, 1999–2012. *Health Affairs*, *38*(2), 222-229.
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million Americans in total.[20,21] If policymakers remain concerned about affordability among these populations, it is important to consider how future policy efforts will interact with those that already exist.

Should policymakers want to provide greater access to new medications, there is merit to addressing such concerns in a comprehensive manner. That is, rather than addressing a specific medication or condition, policies are best designed to address costs in general. Policies that take a "one off" approach are likely to add to the complexity of health care markets and raise legitimate equity questions (e.g., should policy explicitly preference those with diabetes over those with cancer, or vice versa?). Some of the recent reforms to Medicare Part D provide a good example of embracing a wholistic approach to addressing these kinds of questions. Introducing an overall out-of-pocket cap provides all seniors with protection against large financial risks in a way that one would expect from a health insurance product. Similarly, reforms to the benefit design improve incentives facing insurers in a way that are likely to contain costs for all enrollees.[22]

Amidst any such effort, it is important to remember that long-run costs of pharmaceuticals are substantially lower than short run costs due to the eventual entry of low-cost copycat products. Thus, policymakers should be cognizant that efforts to improve affordability of branded products do not impede these long-run effects.[23]

How should access to novel therapies be treated relative to other interventions?

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[20] Medicaid.gov. March 2023 Medicaid & CHIP Enrollment Data Highlights. April 2023.
[21] Cubanski, J. & Damico, A. Key Facts about Medicare Part D Enrollment and Costs in 2022. Aug. 2022. Kaiser Family Foundation.
[22] For a summary of these features, see Cubanski, J., Newuman, T., & Freed, M. Explaining the Prescription Drug Provisions in the Inflation Reduction Act. Kaiser Family Foundation. Jan. 2023. Note that these reforms also share many of the same features as those included in other proposals (e.g., H.R. 19 Lower Costs, More Cures Act of 2021).
[23] Ippolito, B. & Levy, J. A New Fix for Insulin Prices Could Do More Harm than Good. *AEIdeas*. July 2022.

New drugs or biologics can meaningfully improve the toolkit available to address various conditions. That said, there are a host of non-pharmaceutical interventions that can play an equally important role in the incidence of diseases. Particularly in the case of diabetes, there are likely to be large benefits that stem from other interventions like screening for kidney disease,[24] self-monitoring of blood sugar,[25] and lifestyle modifications.[26] Measuring the cost effectiveness of new pharmaceutical products is commonplace and well-understood (these efforts benefit from the existence of relatively "clean" evidence from clinical trials). However, non-pharmaceutical interventions should be viewed through a similar lens. To the extent that these other interventions can provide good value for money, policymakers should be cognizant to not preference pharmaceuticals to the exclusion of other methods of addressing the burden of diabetes.

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[24] Hoerger T., Wittenborn J., Segel J., et al. (2010). A health policy model of CKD: 2. The cost-effectiveness of microalbuminuria screening. *American Journal of Kidney Disease.* 2010; 55(3): 463–473.
[25] Siegel KR, Ali MK, Zhou X, et al. Cost-effectiveness of interventions to manage diabetes: has the evidence changed since 2008? *Diabetes Care.* 2020; 43(7): 1557–1592.
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Testimony on **"The Economic Impact of Diabetes"**

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Before the Joint Economic Committee

of the United States Congress

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Good morning, Chairman Heinrich, Vice Chairman Schweikert, and esteemed Members of the Joint Economic Committee. I sincerely appreciate the opportunity to delve into the subject of emerging technologies and therapeutics available in our country, aimed at addressing the ongoing epidemics of diabetes and obesity.

Currently, I serve as the Chief of the Section of Endocrinology, Diabetes, and Metabolism at Baylor College of Medicine, where I oversee clinical and research enterprises that focus on care of individuals with obesity, diabetes, and other endocrine diseases. Prior to this, I had the privilege to work as a physician and

scientist at Duke University and Harvard Medical School. Alongside my administrative duties, I continue my hands-on role as a practicing physician, caring for patients affected by these conditions. I also direct a scientific laboratory committed to deciphering the molecular mechanisms responsible for these conditions, with the ultimate objective of identifying innovative and more effective ways to enhance the health of our citizens.

Over the past decade, we've made significant strides in understanding how obesity, diabetes, and associated cardiometabolic diseases develop in people. This understanding has been complemented by remarkable progress in the development of medications and technologies designed to treat affected individuals. Today, I'd like to spotlight three areas that showcase these advancements and their potential to improve human health:

1. The vital and revolutionary role of GLP1 Receptor Agonists (GLP1RA) and related medications in the treatment of diabetes, obesity, and associated morbidity and mortality.

2. The rapid progress in new devices and technologies, such as continuous glucose monitors and insulin pumps and advanced algorithms to integrate these technologies and facilitate diabetes treatment.

3. Our growing knowledge of the complex nature of diabetes and related complications, and what it means for the future of diabetes care. By analyzing genetic variations in large populations, we discovered that diabetes is a heterogeneous disease. The study of rare genetic variation revealed atypical types of diabetes, enriching our understanding of how diabetes develops and suggesting new avenues for treatments. These findings foresee a future of precise diagnosis and treatment of specific diabetes types and associated comorbidities.

GLP1 Receptor Agonists (GLP1RAs):

GLP1 Receptor Agonists (GLP1RAs) and related medications have emerged as a revolutionary force in the fight against diabetes, obesity, and their associated morbidity and mortality. This class of medication, which mimics the glucagon-like peptide-1 hormone (GLP-1) naturally found in our bodies, has proven vital in improving glycemic control and promoting weight loss, thereby playing an instrumental role in the management of these pervasive conditions.

GLP1RAs were initially developed based upon their ability to increase insulin secretion, thereby reducing blood glucose levels – a major goal in the treatment of diabetes[1]. However, their unexpected ability to promote satiety proved remarkably effective in helping patients reduce caloric intake and subsequently lose weight. Studies have consistently demonstrated the potency of GLP1RAs in lowering hemoglobin A1c levels, a key metric in managing diabetes, and promoting significant weight loss with recent regimens capable of producing 20% reductions in body weight [2,3]. This degree of weight loss had only previously been observed following surgical weight loss procedures.

The benefits of GLP1RAs extend beyond their ability to enhance glycemic control and promote weight loss. A growing body of evidence points to their substantial cardio-protective properties. In landmark randomized clinical trials multiple GLP1RAs have been shown to reduce the risk of major adverse cardiovascular events and cardiovascular death in patients with Type 2 diabetes at high risk for heart disease[4,5]. Furthermore, meta-analyses of these and other trials indicate that GLP1RAs reduce all-cause mortality, providing hope for enhanced life expectancy among patients with these conditions[6,7].

In the realm of obesity management, GLP1RAs offer a promising adjunct to traditional lifestyle modification and alternative to weight loss surgery. With obesity being a primary risk factor for the development of Type 2 diabetes, as well as a host of other metabolic and cardiovascular diseases, the potential of GLP1RAs to induce meaningful and sustained weight loss may represent a significant advancement in preventive care.

Until recently, it was not known whether achieving safe and significant weight loss could ever be achieved through medical intervention. In essence, GLP1 Receptor Agonists have provided proof of principle that this can be achieved. These medications have ushered in a new era in the management of diabetes and obesity, directly improving patient outcomes and extending lives. Their discovery underscores the potential of leveraging our growing understanding of endocrine physiology to create therapies that can address some of our most pressing public health challenges.

New devices and technologies to assist with diabetes treatment:

The advent of new devices and technologies, specifically continuous glucose monitors (CGMs) and insulin pumps, has transformed diabetes management, providing opportunities for a welcome shift from traditional methods. These advancements have particularly improved care for patients with diabetes by reducing hypoglycemia—a major concern, especially in children with Type 1 Diabetes[8].

CGMs represent a significant evolution in glucose monitoring. Traditional blood glucose monitoring required multiple daily fingersticks, which could be painful and inconvenient. However, CGMs provide real-time, dynamic glucose information, enabling more accurate insulin dosing decisions. They continually track glucose levels throughout the day and night, providing trends and alerts for potential hypoglycemia or hyperglycemia. This continuous tracking helps to prevent severe hypoglycemia episodes, a source of morbidity and fear in children with Type 1 Diabetes.

Similarly, insulin pumps have revolutionized the delivery of insulin, providing a more flexible approach compared to multiple daily injections. The pump delivers a continuous infusion of rapid-acting insulin, mimicking the normal background insulin production of a healthy pancreas. Additionally, patients can customize bolus doses for meals or to correct high blood sugar levels. Modern pumps can even interact with CGMs, adjusting insulin delivery in response to glucose trends, which may be especially useful in enhancing glycemic control without increasing hypoglycemic risk[9–12].

The introduction of closed-loop insulin delivery systems or "artificial pancreas" devices represents the next significant step in diabetes technology[13,14]. These systems combine CGM and insulin pump technology with a control algorithm to automate insulin delivery. Ultimately, this may further reduce the burden of disease management while improving glucose control. The cognitive demands to precisely match exogenous insulin treatment to varying levels of activity, food intake, and variable circulating glucose levels can be taxing. These novel technologies have the potential to markedly ease this burden.

Through these innovations, patients with diabetes, particularly children with Type 1 Diabetes, have seen improvements in their glycemic control and quality of life. They also experience fewer instances of hypoglycemia, improving their safety. The

integration of these technologies into patient care emphasizes the transformative power of digital health in managing chronic diseases like diabetes.

Decoding Varieties of Diabetes:

Over recent years, we've made considerable progress in understanding the complexity and heterogeneity of diabetes through advancements in genetic and other research modalities. Sophisticated studies of common genetic variation in large populations have shed light on the complex nature of this disease. We now recognize that diabetes is not a single disease but rather an umbrella term for a group of disorders with common phenotypic traits, such as hyperglycemia, but with varying underlying genetic and pathophysiological mechanisms.

By analyzing common genetic variation, scientists have identified numerous genetic loci associated with the risk of developing diabetes[15]. Analyzing these associations in conjunction with associated comorbidities and complications reveals that different subtypes of diabetes may be driven by different genetic factors and predispose to different adverse outcomes[16–19].

In parallel, examination of rare genetic variations has allowed scientists to identify unusual forms of diabetes, some of which are known as monogenic diabetes, such as Maturity-Onset Diabetes of the Young (MODY)[20]. Large scale efforts are underway to identify additional rare and atypical forms of diabetes[21]. These discoveries are essential because rare forms of diabetes, while individually infrequent, often point to underlying mechanisms that participate in the development of more common forms of diabetes. Again, defining these mechanisms can drive discovery with the potential for novel diagnostic and therapeutic strategies.

The dissection of both common and rare genetic variation has enormous implications for the future of diabetes care. By understanding the different genetic contributions to diabetes, we can move towards a more personalized and precise approach to treatment. This means we could potentially match the right treatment to the right patient based on their specific genetic profile, improving their outcomes, and reducing the risk of associated comorbidities. The investigation into the genetics of diabetes, therefore, opens a promising new frontier in our fight against this complex and heterogeneous disease.

Conclusion:

In summary, we stand on the cusp of a revolution in diabetes and obesity management, powered by scientific breakthroughs and technological advancements. The introduction of GLP1 Receptor Agonists has redefined treatment strategies, improving patient outcomes by effectively managing blood glucose levels, promoting weight loss, and reducing cardiovascular risks. Concurrently, the emergence of continuous glucose monitors and insulin pumps has significantly enhanced diabetes care, particularly in reducing the frequency of hypoglycemic events in patients, notably children with Type 1 Diabetes. Additionally, through the lens of genetic research, we are uncovering the complexities of diabetes as a heterogeneous disease with various genetic influences, paving the way for precision medicine that could lead to more effective, personalized treatment strategies. These pivotal developments inspire optimism for a future where we can more effectively combat the epidemics of obesity, diabetes, and associated cardiometabolic diseases, enhancing the health and well-being of our citizens.

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