S. HRG. 118–211

WHAT IS FUELING THE DIABETES EPIDEMIC?

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE DIABETES EPIDEMIC

DECEMBER 14, 2023

Printed for the use of the Committee on Health, Education, Labor, and Pensions

Available via the World Wide Web: *http://www.govinfo.gov*

U.S. GOVERNMENT PUBLISHING OFFICE
54–524 PDF WASHINGTON : 2024

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C O N T E N T S

STATEMENTS

THURSDAY, DECEMBER 14, 2023

WHAT IS FUELING THE DIABETES EPIDEMIC?

Thursday, December 14, 2023

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10:02 a.m., in room 430, Dirksen Senate Office Building, Hon. Bernard Sanders, Chairman of the Committee, presiding.

Present: Senators Sanders [presiding], Casey, Baldwin, Kaine, Hassan, Smith, Hickenlooper, Cassidy, Collins, Braun, Marshall, and Budd.

OPENING STATEMENT OF SENATOR SANDERS

The CHAIR. Senate Committee on Health, Education, Labor, and Pensions will come to order. Today, we are going to be discussing one of the major health crises in America, and that is the diabetes epidemic that is having a huge impact on our Country and an issue that must be addressed.

Diabetes, as I think we all know, is not only a serious illness unto itself, but it is a contributing factor to heart disease, stroke, amputations, blindness, and kidney failure. Type 1 diabetes is a major problem that impacts over 1.4 million Americans, and we are going to be discussing that issue today.

My understanding is that Senator Cassidy has brought two witnesses who are extremely knowledgeable about type 1 diabetes, and we look forward to hearing what they have to say. My focus is going to be on type 2 diabetes, which impacts about 95 percent of Americans who have diabetes.

There is obviously a whole lot that can be said about diabetes, but here are just a few of the questions that I hope we will dive into this morning. First, and maybe most importantly, why have we seen a huge increase in the number of people in America who have developed diabetes over the last 50 years? What is going on? What has changed?

I think that may be the most important question. Second, how is diabetes impacting our healthcare system? And I think we know some of those answers. Thirdly, given the huge number of people who are struggling with diabetes, how can we make the treatments, and there are some very effective treatments out there how do we make them available to everyone who needs them regardless of their income?

Further, when we talk about the cost of treatments and diabetes, we are cognizant of the fact that Medicaid and Medicare and other public health programs spend huge amounts of money for those treatments, as do private health insurance companies. So how do we make sure that we don't bankrupt Medicare and Medicaid in the process of treating diabetes? First, the problem.

Today in America, rather remarkably, we have over 35 million Americans, that is over 10 percent of our population, who have type 2 diabetes. And the cost of treating that disease is absolutely staggering. According to the American Diabetes Association, the total cost of diabetes in the United States was nearly $413 billion last year, $413 billion, and that is up 27 percent over the past 6 years.

That amounts to about 10 percent of our overall health care costs. So, $1 out of every $10 spent on health care is dealing with diabetes. And when we talk about the type 2 diabetes epidemic and the huge increase in new cases, we must also talk about another epidemic, and that is the epidemic of obesity in America.

Some 90 percent of people with type 2 diabetes are overweight or obese. These two epidemics go hand in hand. A key question that we must discuss. How did it happen, according to the CDC, that the rate of childhood obesity in America has tripled since the 1970's, tripled since the 1970's, and has gotten so bad that one out of every five children, and over 40 percent of adults in our Country, today are now obese.

Why is it that, according to the CDC, the number of children in America with type 2 diabetes is estimated to skyrocket by nearly 700 percent over the next 40 years unless we get a handle on that issue. Isn't that just an extraordinary number? The answers to those questions are not complicated. Difficult, but not complicated.

For decades, in my view, we have allowed large corporations in the food and beverage industry to entice children to eat foods and beverages loaded up with sugar, salt, and saturated fat purposely designed to be overeaten. The situation has gotten so bad that most of what children in America eat today consist of unhealthy, ultra processed foods that doctors have told us lead to a higher risk of type 2 diabetes.

Alarmingly, according to a recent study that will be discussed this morning, ultra-processed foods, which make up an incredible 73 percent of our Nation's food supply, can be as addicted—addictive, can be as addictive as alcohol and nearly as addictive as cigarettes.

While diabetes and obesity rates in America soar, while we spend hundreds of billions of dollars to treat diabetes, the food and beverage industry spent $14 billion last year on advertising to make many of their unhealthy products appealing to the American consumer.

Even worse, and I think really what gets to me, $2 billion of their advertising budget is used to directly market food predominantly high in sugar, salt, and saturated fat to our children in order to get them hooked on these products at an early age.

How is that? According to the Rudd Center for Food Policy and Obesity, children and teens view about 4,000 food and beverage ads on television every year, an average of 10 advertisements each day. Another study found that children who watch Nickelodeon and Nicktoons are exposed to over 10 unhealthy food and beverage ads every hour, they're going after the children. Let me give you just one example.

Last year, for example, Coca Cola spent $327 million on advertising in the United States alone. Not one of those ads will tell you that drinking one or two cans of Coke a day will increase your chances of getting type 2 diabetes by 26 percent. I didn't quite see that in those lovely ads that they do.

Nor will their TV ads tell you that one 20 ounce bottle of Coke contains over 15 teaspoons of sugar, more than twice the recommended daily limit for kids under the age of 18. Nearly 30 years ago, as I think we all know and the American people know, Congress had the extraordinary courage and it was not easy to take on the tobacco industry, whose products killed over 400,000 Americans every year, including my father.

Congress had the courage to do that then. Now is the time for us to seriously combat the type 2 diabetes and obesity epidemics in America. In order to do that, we must have the courage to take on the greed of the food and beverage industry, which every day is undermining the health and well-being of our children.

As adults, as responsible people, as representatives of the American people, we have got to do that. And in my view, a good place to start would be to ban junk food ads targeted to children. Now, this is not a radical idea.

The NIH has estimated that if the United States banned fast food advertising marketed to children, talking about kids, we could cut the childhood obesity rate in our Country by up to 18 percent.

In the 1980's, Quebec banned junk food advertising to children. Today, Quebec has the lowest childhood obesity rate in Canada and the highest consumption of fruits and vegetables of any province in their nation.

Ireland, Sweden, South Korea, Taiwan, Spain, Portugal, and several other major countries throughout the world have either seriously restricted or banned junk food ads targeted to children.

In addition to addressing the causes of type 2 diabetes, there is another important issue that we have got to address. We have got to make certain that the treatments available to people with diabetes are affordable for all Americans and are not bankrupting Federal health insurance programs or raising the cost of private insurance.

The very good news is that a new class of treatments for diabetes and obesity like Ozempic and Mounjaro have the potential to be a game changer with respect to these major epidemics. According to clinical trials, these drugs, which suppress appetite, have been estimated to help people lose 15 to 20 percent of their weight.

That is the good news, and it is importantly good news. The bad news is that these drugs also have the potential to bankrupt Medicare and the American people. According to research published in

the New England Journal of Medicine, if just 10 percent of people with obesity on Medicare took these drugs, it could cost Medicare up to $27 billion a year, driving Medicare premiums way, way up.

Further, incredibly, these drugs, Ozempic and Mounjaro are up to 15 times more expensive in the United States than they are in other major countries. Let me repeat, these two important drugs, up to 15 times more expensive in the United States than in other countries. Ozempic, manufactured by Novo Nordisk, cost $12,000 a year in the United States. Do you know what it costs in Germany? $750 a year.

Mounjaro, manufactured by Eli Lilly, costs $13,000 in the United States, costs $2,000 a year in the United Kingdom. Incredibly, it has been estimated that Eli Lilly, Novo Nordisk, and others in the pharmaceutical industry stand to make as much as $150 billion off of these drugs each and every year by charging us by far the highest prices in the world for their products.

This is, to my mind, unacceptable for so many reasons, and that is why I am going to be introducing legislation which is very simple. It is legislation that says that here in the United States, we cannot continue to pay the highest prices in the world for prescription drugs. We should not be paying more than other major countries.

If that bill were to be signed into law, we would lower the cost of prescription drugs in this country by 50 percent. So, that is where we are today. We have two issues. What is the cause of the epidemic, and how do we make sure that we have treatments available to all?

I very much thank all of the panelists for being here. This is a very important issue and I look forward to this discussion.

Senator Cassidy, the mic is yours.

OPENING STATEMENT OF SENATOR CASSIDY

Senator CASSIDY. Thank you, Chairman Sanders. The obesity epidemic is quite remarkable. And type 1 diabetes obviously not related to obesity, but nonetheless, part of that which we are addressing today.

If you look at a kind of a map of the United States over the last three decades and the prevalence and incidence of diabetes, it just lights up. Goes bigger and more intense, etcetera, however you look at the map. So, it is a bipartisan issue. I am glad the Committee is addressing it.

I will say, however, that the focus of the hearing has changed from our original agreement to explore the prevention, treatment, and management of diabetes from a clinical and public health perspective.

Diet and access to healthy foods are important, but I will point out that corporate marketing practices to consumers and human nutrition are not the jurisdiction of this Committee. Those are on the Commerce and Agriculture.

Food marketing is what this Committee will focus on today, but ideally, the Committee's time would be addressing issues over

which we have legislative authority. If we have legislative authority, we can do something. If we have a hearing on something over which we have no legislative authority, we have a hearing.

I will also point out, though, that our colleagues, Senator Susan Collins and Jeanne Shaheen have led the Special Diabetes Program Reauthorization, which the Committee did successfully vote out in June. When enacted, it will provide additional mandatory resources for diabetes research at NIH.

I would also like, and that would be a good thing to have discuss today, how the NIH is using its discretionary funding, because that is something over which we do actually have jurisdiction. We should look at why NIH habitually under funds obesity research, despite it being the kind of foundation of why the rate of type 2 diabetes has gone up so dramatically, as well as, by the way, its impact upon many other medical conditions.

It is important to explore the impact of recent medical advances upon the lives of diabetics. American medical innovation is saving countless lives. Diabetes is no different. Groundbreaking developments in diabetes management like the continuous glucose monitor, or CGM, increases patient adherence to treatment while improving quality of life for patients and peace of mind for parents and caretakers.

We could familiarize ourselves more with that. I am a doc, but I wasn't aware of it. And then somebody says, oh, you look on your phone and you see what your diabetes is. It kind of really brings it home to the folks.

It was quite remarkable. My internist friends explaining to me how this has been so positive of a change in terms of the management of diabetes. We can point out that even 10 years ago, parents were worried about their children developing diabetic shock.

But now, with affordable CGMs and other innovative devices, blood glucose levels are monitored in real time, and these devastating occurrences, such as diabetic shock, are prevented.

We need to continue to foster innovation and the solutions it creates. CGM are miracles to many now, but at some point it will become yesterday's news. We need the next miracles. Cellular treatments are on the horizon, and we have the potential to again revolutionize how Americans live with diabetes.

I visited an outfit in Massachusetts, and they showed me this kind of twirling bath, and they said those are islet cells that can be gathered up and injected under someone's arm, and this is a technology that will be implemented. Quite remarkable. Again, we could have been discussing that today.

The task of this Committee is to balance affordability with innovation. I accept the Chair's point. If there is an innovation that someone cannot afford, it is as if that innovation doesn't occur.

I am with you on that. But we should again be discussing topics within the Committee's jurisdiction. That is what we have the responsibility to do. And if there is something that we can actually address, then consider legislation.

I look forward to exploring the issues that we can address with our witnesses. With that, I yield.

The CHAIR. Thank you very much, Senator Cassidy. Now we are going to hear from our very distinguished and knowledgeable witnesses, and we are delighted they are with us today. Our first witness will be Dr. Ashley Gearhardt, who is a Professor of Psychology and Clinical Science at the University of Michigan.

Dr. Gearhardt's research focuses on the effects of poor nutrition on diabetes and obesity, and factors driving excessive consumption of unhealthy foods. Notably, she has published a recent study on how ultra-processed foods can be as addictive as nicotine and alcohol. Dr. Gearhardt, thanks so much for being with us.

STATEMENT OF ASHLEY GEARHARDT, PH.D., PROFESSOR OF PSYCHOLOGY, UNIVERSITY OF MICHIGAN, ANN ARBOR, MI

Dr. GEARHARDT. Chairman Sanders, Ranking Member Cassidy, and distinguished Members of the Committee, thank you for the opportunity to participate in today's meeting.

To begin, I will briefly review my qualifications to speak as an expert at this hearing. I received my Ph.D. in Clinical Psychology at Yale University with a focus on addictive disorders, obesity, and disordered eating.

I am currently a Professor of Psychology and the Director of the Food and Addiction Science and Treatment Lab at the University of Michigan. I am also a licensed clinical psychologist. Through my clinical experiences, I have gained a firsthand understanding of how hard people are working to try and get control over their eating.

I saw that even when people were faced with life threatening health conditions like diabetes and were very motivated to change, they still failed to do so. My research has been built on the parallels between what I observed in the clinic and my scientific training on how certain substances can trigger addictive processes.

In my research I use multi-method approaches to explore the neuro-biological, psychological, and behavioral factors that contribute to compulsive overeating and its negative consequences like obesity and diabetes. The American food supply has changed dramatically over the last 40 years.

The American diet is now composed mostly of ultra-processed foods. Ultra-processed foods are industrially manufactured products created by deconstructing foods from their component parts, modifying them, and combining them with a myriad of additives.

The resulting ultra-processed foods contain little, if any, whole foods, and they are a major source of added sugars and saturated fats in our diets. The average American adult and child gets the majority of their calories from ultra-processed foods.

Ultra-processed foods have been implicated in health conditions like depression and obesity across numerous studies. Based on analysis of 400,000 people, every 10 percent increase in ultra-processed food intake is associated with a 12 percent higher risk of type 2 diabetes.

There are strong parallels between addictive substances and ultra-processed foods. Addictive substances are created through processing natural substances like fruits or leaves into new prod-

ucts that rapidly deliver a naturally high doses of reinforcing ingredients into the body like nicotine and cigarettes.

Ultra-processed foods are similarly created by altering natural substances like fruits and grains into products that deliver a naturally high doses and combinations of carbohydrates and fats, which are then rapidly digested by our bodies.

Additives further enhance the flavor and texture of these ultra-processed foods and make them shelf stable, accessible, and convenient. Basic neuroscience finds that ultra-processed foods high in carbohydrates and fats activate reward systems in the brain in an analogous manner to addictive substances like nicotine.

Key signs of addiction occur in our intake of ultra-processed foods. Systematic reviews of over 280 studies estimate that 14 percent of adults and 12 percent of children meet the criteria for an addictive disorder in their intake of ultra-processed foods.

This includes losing control over intake, intense, almost irresistible cravings, and an inability to reduce intake despite serious negative consequences. This addictive pattern of ultra-processed food intake is associated with a more than five times greater occurrence of type 2 diabetes. I want to provide a representative quote from a research participant from my lab.

She said, I can't even be in the same vicinity as a donut store or any type of donuts because I will finish a dozen all by myself, and I am a type 2 diabetic so that could kill me. I know that, and I know that I shouldn't be eating all of those. I shouldn't be eating one, let alone a whole dozen, but for some reason I just can't stop eating them.

If addictive mechanisms are being triggered by ultra-processed foods, this may be an overlooked reason why it can be challenging to reduce intake even in the face of health conditions like diabetes. There are also strong connections between the tobacco and processed food industries.

From the 1980's to the late 2000, tobacco companies like R.J. Reynolds and Philip Morris became the biggest producers of processed food in the world. Internal tobacco industry documents demonstrate strategies designed to develop and sell cigarettes were applied to their processed food and beverage holdings, such as adding flavor enhancers developed for cigarettes into children's sugar sweetened beverages and increasing targeted marketing to children and racial ethnic minorities.

Lessons learned from the tobacco epidemic can help guide solutions here. Investing in science to understand how ultra-processed foods activate mechanisms of addiction and contribute to excessive intake is important.

Multi-pronged approaches and a focus on prevention, particularly for youth, will be important for improving Americans' health. Thank you for your time.

[The prepared statement of Dr. Gearhardt follows:]

PREPARED STATEMENT OF ASHLEY GEARHARDT

Introduction

Chairman Sanders, Ranking Member Cassidy, and Distinguished Members of the Committee: thank you for the opportunity to participate in today's hearing. To begin, I will briefly review my qualifications to speak as an expert at today's hearing. I received my PhD in clinical psychology at Yale University with a focus on addictive disorders, obesity, and disordered eating. I have spent 11 years on the faculty at the University of Michigan. I am currently a professor of psychology and the director of the Food and Addiction Science Treatment laboratory at that institution. I am also a licensed clinical psychologist who has provided treatment to individuals with substance use disorders, obesity, and compulsive overeating.

Through my clinical experiences, I have gained a firsthand understanding of how hard people are working to try and get control over their eating behavior. I saw that even when people were faced with life threatening health conditions, they often still failed to reduce their intake of highly palatable foods despite being motivated to change. My research has been built on the parallels between what I observed in the clinic and my scientific training on how certain substances can trigger addictive processes that keep people stuck in compulsive and destructive patterns of consumption. In my program of research, I use multi-method approaches to explore the neurobiological, psychological, and behavioral factors that contribute to compulsive overeating across the lifespan. I have published over 175 peer-reviewed articles, including in prestigious outlets like the JAMA Psychiatry and British Medical Journal.

Ultra-Processed Foods Dominate the American Diet

The modern American diet is now composed mostly of ultra-processed foods (1, 2), which are industrial formulations manufactured by deconstructing foods into their component parts, modifying them and recombining them with a myriad of additives (3–5). Common examples of ultra-processed foods are industrially created candy, sugar-sweetened carbonated beverages, instant noodles, frozen pizza, and salty snacks (4). Ultra-processed foods are a distinct category from minimally processed foods (e.g., fruit, vegetables) that have been washed, chopped, frozen, dried or fermented and processed culinary ingredients used for home cooking (e.g., butter, flour).

Ultra-processed foods are a major source of added sugar and saturated fats in the American diet (6, 7). Most ultra-processed foods are considered hyper-palatable due to their unnaturally high level of palatability-inducing nutrients (fats, sugars, carbohydrates and/or sodium), which trigger reward signals and reduce sensitivity to satiety signals (1, 8). Ultra-processed foods also often contain flavor additives and texturizers that enhance taste and the feel of the product in the mouth (3–5). The preservatives in many ultra-processed foods allow them to stay shelf-stable and come in convenient ready-to-heat or ready-to-eat packages (3–5). Epidemiological research estimates that the average American adult now gets the majority of their calories (57 percent) from ultra-processed foods while intake of nutrient-rich minimally processed foods like fruits, vegetables, and legumes is decreasing (2). This estimate is even higher for youth. From 1999 to 2018, a global team of epidemiologists found that the percentage of energy consumed from ultra-processed foods increased from 61.4 percent to 67.0 percent in children 2 to 19 years old (9).

A converging body of research highlights the potential ramifications of diets composed of high levels of ultra-processed foods (10). High levels of ultra-processed food intake have been implicated in an increased prevalence of health conditions like depression, heart disease, and obesity (10). In a controlled randomized crossover trial, a team of researchers at the National Institute of Health found that being given a diet high in ultra-processed foods relative to minimally processed foods over a 2-week period was associated with an increased daily intake of 500 calories and a two-pound weight gain (11). This occurred despite the ultra-processed and minimally processed meals being matched on the overall calories available to participants (11). Furthermore, a meta-analysis of over 400,000 participants found that every 10 percent increase in ultra-processed food intake was associated with a 12 percent higher risk of Type 2 diabetes (12). Thus, the high levels of ultra-processed food in the American diet are a major cause for concern and may be contributing to the obesity and diabetes epidemics.

There are Strong Parallels between Addictive Substances and Ultra-Processed Foods

Most addictive substances are created by processing natural substances (e.g., fruit, leaves) into a new product that delivers a heighted dose of a reinforcing ingredient (e.g., ethanol, nicotine) into the body (13). Speed of absorption is also important and the more rapidly the reinforcing ingredient is absorbed the more likely the substance is to be addictive (14, 15). All addictive substances activate the mesolimbic dopamine system, which is key to the reward and motivational mechanisms that go awry in addiction (16, 17). For example, cigarettes are created by processing naturally occurring tobacco leaves through drying and curing into products that can be smoked to rapidly deliver high doses of nicotine into the body. The nicotine in cigarettes is further amplified by flavor enhancers, such as sugar, cocoa, and menthol, which create brand-specific taste and flavor profiles (18, 19). These tastes and flavors become repeatedly paired with the delivery of nicotine and become salient drivers of smoking behavior in their own right (18, 19). The cigarettes that result from this processing are highly addictive and can lead people to continue smoking even when facing life-threatening health conditions, like heart disease and lung cancer (20).

Similarly, many ultra-processed foods are created by processing naturally occurring substances (e.g., fruits, grains, vegetables) into products that deliver unnaturally high doses of rapidly absorbed carbohydrates and/or fats. Refined carbohydrates, like sugar, and fat are highly reinforcing ingredients and they are effective at activating reward mechanisms in the brain (13, 21–23). While many minimally processed foods contain either carbohydrate (e.g., fruit) or fat (e.g., nuts, meat), the combination of both is rare in nature (21). In contrast, ultra-processed foods often deliver high levels of both refined carbohydrates and fats. This combination has a supra-additive effect in activating neural reward systems (22). Evidence exists that sugar, fat, and ultra-processed foods can activate mesolimbic dopamine in the brain at similar magnitudes as nicotine and ethanol (24–29). Additives further amplify ultra-processed foods by coupling industry created flavors and textures with the delivery of refined carbohydrates and added fats (4, 5). Thus, these ultra-processed foods with high levels of refined carbohydrates and fats are highly rewarding processed substances that share many commonalities with addictive substances like cigarettes (13).

Ultra-Processed Food Addiction

A common set of diagnostic criteria are used to identify individuals who are experiencing clinically significant problems with addictive substances (see Table 1), including a loss of control over intake, intense cravings, and continue consumption despite physical or emotional problems (30). In 2008, my colleagues and I developed the Yale Food Addiction Scale, which applies these same criteria to the intake of ultra-processed foods (e.g., chocolate, soda, French fries, pizza) (31). The Yale Food Addiction Scale has been extensively validated and is a widely used measure in the field with over 1000 citations and translations available in over a dozen languages (32). When we first began this research, the concept of ultra-processed foods was just emerging and investigations into what types of foods were consumed addictively was limited. Given the dearth of research at that time, we used the term "food addiction" to reflect meeting the diagnostic criteria for a substance use disorder in the realm of food intake. Since that time, it has become clear that not all foods are consumed addictively. Multiple studies have identified that people report consuming ultra-processed foods high in refined carbohydrates and/or fats in an addictive manner, but not minimally processed foods like fruits, vegetables, and legumes (33–35). Dietary intake studies confirm that individuals who meet "food addiction" consume higher levels of ultra-processed foods, but lower levels of minimally processed foods (36, 37). Thus, I will refer to the construct measured by the Yale Food Addiction Scale as ultra-processed food addiction in the remainder of my testimony.

Although ultra-processed food addiction is not currently an officially recognized diagnosis by the American Psychiatric Association, the science on this topic has grown quickly. Systematic reviews of over 280 studies from 36 different countries estimate the prevalence of ultra-processed food addiction to be 14 percent in adults (38), which is similar to the prevalence of alcohol and tobacco use disorder (e.g., 14 percent for alcohol and 18 percent for tobacco) (39, 40). The estimated prevalence of ultra-processed food addiction is twice as high (28 percent) in adults with obesity (38). Particularly relevant to the current hearing, ultra-processed food addiction has been associated with a more than five times greater likelihood of Type 2 diabetes even when adjusting for sex and age (41).

Below is a quote from a participant who was interviewed for a research study in my lab about their experience with ultra-processed food addiction.

"I can't even be in the same vicinity as [donut store] or any type of donuts, 'cause I will finish a dozen all by myself and I'm type 2 diabetic. So, that could kill me, and I know that and I know that I shouldn't be eating all those. I shouldn't be eating one, let alone a whole dozen. But for some reason I just can't stop eating them."

In children, the estimated prevalence for ultra-processed food addiction based on a systematic review of the literature is 12 percent, which surpasses the prevalence of other substance addictions at this stage of development (42). Children are typically protected against exposure to addictive substances through policy initiatives (e.g., marketing restrictions, age limits on purchases), but exposure to ultra-processed foods for children in America is a daily occurrence (9). There is also evidence that ultra-processed food addiction is important for older Americans. In collaboration with Michigan Medicine, my lab recently conducted a study on ultra-processed food addiction in the National Poll of Healthy Aging. This is a nationally representative poll of over 2000 older adults between the ages of 50 and 80. In this poll, 13 percent of participants met the criteria for a clinically significant ultra-processed food addiction, which was associated with a greater likelihood of reporting being overweight and in poorer physical and mental health (43). Finally, individuals with food insecurity that lack adequate access to nutritious food are more than three times more likely to meet the criteria for ultra-processed food addiction with chips, soda, chocolate, pizza, and ice cream being identified as the most addictive foods (35).

Taken together, this scientific body of evidence suggests that addictive processes play an important role in contributing to patterns of ultra-processed food intake implicated in poor health obesity, and diabetes (21, 44). If addictive mechanisms are being triggered by ultra-processed foods, this may be an overlooked reason why it can be challenging to reduce intake of ultra-processed foods even in the face of health conditions like diabetes.

Connections between the Tobacco and Processed Food/Beverage Industries

The industries that profit from tobacco and ultra-processed foods are inter-connected. In the 1970's and 1980's, the tobacco companies RJ Reynolds and Philip Morris bought processed food and beverage companies, including Kraft and General Foods (45, 46). When Philip Morris merged Kraft and General Foods in 1987, it became the largest processed food corporation in the world (45, 46). Although the tobacco industry sold off many of their holdings in this arena by the late 2000's (45, 46), they had already impacted the nature of the American food supply. Internal tobacco industry documents demonstrate they took strategies designed to develop and sell cigarettes and applied them to their processed food and beverage products (45, 46). This includes putting flavor additives developed to enhance the palatability of cigarettes in their leading children's sugar-sweetened drinks and increasing marketing strategies that targeted children and racial/ethnic minorities (45, 46). A recent study published in the journal Addiction found that between 1988 to 2001 products from tobacco-owned food companies were significantly more likely to have foods with hyper-palatable combinations of carbohydrates, fat, and salt compared to foods from non-tobacco owned companies (47). However, by 2018, non-tobacco owned food companies had increased their level of hyper-palatable foods to levels that compared with tobacco-owned companies (47). This contributed to a modern food supply composed largely of ultra-processed, hyper-palatable foods (1). During this same time period, the amount of diabetes doubled (48) and the presence of moderate-to-high risk obesity tripled in America (49).

What Can Be Done to Address this Problem?

Tobacco also provides a point of reference on how we might reduce the costs associated with excessive intake of ultra-processed foods. Even when the health consequences of smoking became more evident, it took decades for their addictive nature to be acknowledged. Tobacco can look different than other addictive substances, as it does not induce a clear intoxication syndrome and is legal and accessible. In part, because of these differences, the addictive nature of tobacco products was hotly debated for decades despite thousands of tobacco-related deaths occurring each year (20, 50). Eventually, consensus was reached that tobacco products were addictive based in large part on scientific evidence on their highly reinforcing nature and their ability to trigger compulsive patterns of use (20). A similar debate now exists about the addictive nature of ultra-processed foods (13).

Cigarettes are complex substances with up to 4000 different chemicals and even now the exact dose at which nicotine can trigger addiction in unknown (13). However, research has investigated how different aspects of cigarettes interact to increase their addictiveness. In addition to the dose of nicotine, additives and delivery mechanisms that speed up the absorption of nicotine appear to increase the addictiveness of cigarettes (18, 19, 51). Processes that enhance the taste and flavor of tobacco products (e.g., sugar, menthol, cocoa) have also been identified as important contributors to their addictive nature (18, 19). Investing in similar research to unpack how different aspects of ultra-processed foods interact to activate mechanisms of addiction and contribute to excessive patterns of intake will be important. This science could provide guidance to inform consumers about the risks associated with different types of ultra-processed foods and could guide targets for different policy approaches.

A wide range of potential approaches are available for consideration to reduce excessive intake of ultra-processed foods to improve the health of Americans. The history of addressing addiction epidemics also suggest that no singular approach will be sufficient to address complex public health like the obesity and diabetes epidemic. However, multi-pronged strategies have been effective in reducing the costs associated with addictive substances. In the context of tobacco, combining approaches like educational programs, labeling, economic incentives, age restrictions and marketing limitations helped drastically lower smoking rates in America (52–54). Countries, such as Chile and the United Kingdom, are instituting similar approaches to address the epidemic of diet-related disease, such as limiting marketing for less healthy foods to children. It is also not just people who experience clinically impairing levels of ultra-processed food addiction who would likely benefit. When addictive substances are inexpensive, easily accessible, and heavily marketed, many people without a clinical level of addiction are still prone to consume these substances excessively and experience problems in their mental or physical health. Thus, widespread use of addictive substances that stay below the clinical threshold for diagnosis can still pose a significant public health burden (55). On average, Americans experience between one to two symptoms of addiction in their intake of ultra-processed food, including intense cravings and an inability to cut down on intake despite a desire to do so (43, 56). Thus, many Americans would likely benefit from approaches to reduce the dominance of ultra-processed foods in the American food supply. Finally, another key point learned from the tobacco addiction epidemic is that prevention efforts can be far more cost effective than relying solely on treatment (57). Targeting prevention efforts on youth, especially, can be particularly helpful to shape lifelong health promoting behaviors (57).

Eating is necessary for survival. We each make numerous food-related decisions every day all while surrounded by grocery stores, restaurants, gas stations, convenience stores and marketing that promote ultra-processed foods. It is essential that we address the factors that contribute to obesity and diabetes and encourage an American food supply that promotes health, particularly for our children.

TABLE 1. Diagnostic Criteria for Substance Use Disorders

DSM–5 Diagnostic Criteria for Substance Use Disorders(30)
Consumption of larger amounts and/or over longer time than intended
Persistent, unsuccessful attempts to cut down
Significant time spent obtaining, using, or recovering from effects
Cravings (i.e., intense almost irresistible urges for the substance)
Interference with role obligations at work, school, or home
Use despite social or interpersonal problems
Important activities given up or reduced
Use in physically hazardous situations
Continued use despite physical and/or psychological consequences
Tolerance (i.e., needing more and more of the substance to get the desired effect)
Withdrawal (i.e., experiencing psychological and/or physiological symptoms when reducing intake)

Individuals meet the diagnostic threshold for a substance use disorder in the Substance-Related and Addictive Disorders section of the Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition (DSM 5) by endorsing at least 2 of the symptoms above plus clinically significant functional impairment or distress(30). Severity of substance use disorders determined by the number of symptoms endorsed (mild 2–3 symptoms; moderate 4–5 symptoms; severe 6–11 symptoms).

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[SUMMARY STATEMENT OF ASHLEY GEARHARDT]

Ultra-Processed Foods Dominate the American Diet: The American diet is now composed mostly of ultra-processed foods, which are industrial formulations manufactured by deconstructing foods into their component parts, modifying them and recombining them with a myriad of additives. The average American now gets most of their calories from ultra-processed foods and they are major sources of added sugar and saturated fats. Ultra-processed foods are implicated in health conditions like depression and obesity. Every 10 percent increase in ultra-processed food intake is associated with a 12 percent higher risk of Type 2 diabetes.

There are Strong Parallels between Addictive Substances and Ultra-Processed Foods: Addictive substances are created through processing natural substances to rapidly deliver unnaturally high doses of reinforcing ingredients to the body. Ultra-processed foods are created by altering natural substances into products that deliver unnaturally high doses of carbohydrates and fat, which are rapidly absorbed. This activates the reward systems implicated in addiction. Additives further enhance the flavor and texture of these products.

Key Signs of Addiction Occur in the Intake of Ultra-Processed Food: Systematic reviews of over 280 studies estimate that 14 percent of adults and 12 percent of children meet the criteria for an addictive disorder in their intake of ultra-processed foods. This prevalence is doubled in individuals with obesity. This addictive pattern of ultra-processed food intake is associated with a more than five times greater likelihood of Type 2 diabetes. If addictive mechanisms are being triggered by ultra-processed foods, this may be an overlooked reason why it can be challenging to reduce their intake even in the face of health conditions like diabetes.

There are Strong Connections between the Tobacco and Processed Food Industries: From the 1980's to the late 2000's, tobacco companies like RJ Reynolds and Philip Morris became the biggest producers of processed food in the world. Internal tobacco industry documents demonstrate strategies designed to develop and sell cigarettes were applied to processed food products, such as adding flavor additives developed for cigarettes into children's sugar-sweetened beverages and targeting children and racial/ethnic minorities in marketing.

Lessons Learned from the Tobacco Epidemic Can Guide Solutions: Investing in science to understand how ultra-processed food activate mechanisms of addiction and contribute to excessive intake is important. Multi-pronged approaches and a focus on prevention, particularly for youth, will be important for improving American's health.

The CHAIR. Thank you very much, Dr. Gearhardt. Our next witness will be Dr. Lindsey Smith Taillie, Associate Professor in the Department of Nutrition at the University of North Carolina at Chapel Hill.

Dr. Taillie is a nutrition epidemiologist who evaluates food policies and the industry's influence on consumer choices. Dr. Taillie, thanks so much for being with us.

STATEMENT OF LINDSEY SMITH TAILLIE, PH.D., ASSOCIATE PROFESSOR, DEPARTMENT OF NUTRITION, UNIVERSITY OF NORTH CAROLINA, CHAPEL HILL, NC

Dr. TAILLIE. Chairman Sanders, Ranking Member Cassidy, and distinguished Members of the Committee, thank you for the opportunity to speak with you.

My name is Lindsey Smith Taillie, and I am in nutrition epidemiologist who works in the U.S. and globally. My research focuses on understanding how the food industry and the food environment influences nutrition, particularly among kids, as well as what policies work to create healthier diets.

In every country where I work, one thing is true, parents want to make healthy choices for their kids. However, the current food environment makes it nearly impossible. Diets are a major driver

of obesity and type 2 diabetes, and this problem is especially alarming for kids. In the U.S., pediatric type 2 diabetes has doubled over the last two decades.

Healthier diets prevent diabetes and are more cost effective than medication. So why don't we change our diet? First, our food supply. Most of our packaged foods are ultra-processed and nearly half are too high in added sugar, sodium, and saturated fat.

Our food contains more sugar and sweeteners than other high income countries. We can't make healthy choices if healthy food is unavailable. Second, these products are aggressively marketed to children and disproportionately targeted to black and Hispanic youth. Food companies spend $14 billion a year on food advertising in the U.S., of which 80 percent is for unhealthy foods.

Marketing is powerful. It makes kids want unhealthy foods, and it makes them consume more of them. Third, kids will get mostly ultra-processed foods at school. Unhealthy food marketing inside schools is also very common. This serves to hook kids on unhealthy foods at a very early age. It is also very hard for parents to know what is healthy versus unhealthy. Nutrition claims like 100 percent all natural are very common in our food supply and lend an aura of helpfulness even to unhealthy foods.

Meanwhile, the Nutrition Facts panel provides useful information but can be hard to understand. Parents can't make informed choices without accessible information. Another major factor is price. Ultra-processed foods tend to be cheaper than healthy foods.

Even though parents want to buy healthy foods, they buy ultra-processed because it is cheaper. Right now, the price of these unhealthy products does not reflect the health cost of consuming them. Last, the food industry has interfered with science and policy. Companies that pay to play by funding professional societies and research scientists to change the narrative about what causes obesity and diabetes.

They also position themselves as part of the solution through voluntary initiatives, despite overwhelming scientific evidence that these programs are ineffective. So how can we fix this? We already have good data on what works. First, the U.S. should require clear nutrition labels on the front of food packages, a policy that the majority of Americans support across political parties.

The FDA is currently researching front of package labels for the U.S. However, many of the designs that the FDA is focusing on are not based on the scientific evidence from the 10 countries that have implemented these labels, nor the many experiments we have conducted in the U.S.

For example, several of the proposed FDA labels include numbers or color schemes that research shows consumers do not understand. In contrast, simple nutrient warnings like those in Mexico and most of South America are well understood even by children. In addition, in countries with these labels, the food industry has cut sugar, sodium, and saturated fat with no adverse effect on the economy.

The FDA needs to work closely with scientists to develop evidence backed labels that are easy to understand and clearly signal

to consumers when products are unhealthy. Second, the U.S. should limit unhealthy food marketing to kids, much as it has for tobacco. Restricting where ads appear and the use of techniques like cartoons cut kids exposure and helps them develop healthy preferences.

Also, companies should not be allowed to take tax deductions on what they spend on food advertising. Third, our kids deserve classrooms that are free from corporate food. We should restrict the marketing, promotion, and sale of ultra-processed foods in schools, which global data show reduces their availability and improves children's diets.

We also should use economic pressure to shift the food supply. Just like in tobacco, poor diets create massive health care burden and health costs in the U.S. And as in tobacco, taxes on the production of sugary drinks and ultra-processed foods would make food companies pay the true cost of these products.

Global data show that these taxes spur companies to create healthier products and reduce the consumption of unhealthy foods. To further support diabetes prevention, revenue from these taxes could be used to fund fruits and vegetables subsidies for low income families. Last, we need more funding for nutrition research.

Even though nutrition is the leading cause of obesity and diabetes, only a tiny fraction of the NIH budget goes toward nutrition. Additional research funding is critical to improving diets and preventing obesity and diabetes.

In conclusion, kids should not be sick because of our food environment. Federal policy action is urgently needed to make the healthy choice the easy choice. Thank you.

[The prepared statement of Dr. Taillie follows:]

PREPARED STATEMENT OF LINDSEY SMITH TAILLIE

Chairman Sanders, Ranking Member Cassidy, and Members of the Committee:

My name is Lindsey Smith Taillie, and I am an associate professor of nutrition and nutrition epidemiologist. I appreciate the opportunity to speak with you today about my research on how the food industry and food environments influence nutrition, obesity, and type 2 diabetes, as well as policy actions that other countries are using to address these issues.

For the last decade, I have worked in the United States and many countries in Latin America, Africa, and Asia to research the design and test the effectiveness of food policies. Our goal has been to create a toolkit for what works to prevent the continued increase in diet-related chronic diseases. Our premise, backed by scientific evidence, is that consumers want to make healthier choices, but that the current food environment makes it nearly impossible for them to do so.

First, obesity and diabetes are pressing public health concerns. Twenty percent of our children have obesity, as do 42 percent of American adults (Hu & Staiano 2022; Li 2022). Obesity is linked to a plethora of adverse health effects, including sleep apnea, joint pain, cardiovascular disease, cancer, and type 2 diabetes (Wang 2019; Raud 2020; Larsson 2019; Pati 2023; Klein 2022). Even more concerning, the incidence of type 2 diabetes among children has nearly doubled over the last 20 years (Wagenknecht 2023). These problems do not impact all Americans equally—Black and Hispanic children have been disproportionately affected, with steeper increases in both obesity and diabetes (Katz, Rodriguez & Knowles 2021). These health consequences are also very costly: Over $300 billion dollars is spent annually in the U.S. to treat diabetes, with an additional $100 billion spent on indirect costs like lower work productivity, unemployment due to chronic disability, and premature death (Parker 2023). About 67 percent of diabetes costs are paid by Medicare and Medicaid (U.S. Department of Health and Human Services 2021).

Poor diets are the culprit of the obesity and type 2 diabetes epidemics. Americans are the world's leading consumers of sugary drinks and ultraprocessed foods. Put simply, ultraprocessed foods are what you might know as "junk food:" food that is industrially produced and often contains high levels of added sugar, sodium, and saturated fat, as well as additives, colorants, and preservatives. Currently, approximately half of American children and adults consume sugary drinks on a given day (Marriott 2019). Drinking sugary beverages promotes excess calorie intake, which leads to weight gain (Nguyen 2023). Over time, the accumulation of fat can turn into non-alcoholic fatty liver disease, increase risk of diabetes, and raise the risk of heart disease (Qin 2020; Chen 2019; Yang 2022). Relevant to this hearing, obesity contributes to the development of type 2 diabetes by promoting insulin resistance, inflammation, and dysfunction of insulin-producing cells (Kahn 2016; Luca & Olefsky 2008). In other words, excess fat disrupts our bodies' ability to produce and use insulin. Research also suggests that unhealthy diets can increase cardiometabolic risk through other mechanisms like altering the gut microbiome, disrupting hormonal signaling pathways, and affecting the brain's reward responses (Stanhope 2018).

Ultraprocessed foods also pose a major threat to our health. A century ago, ultraprocessed foods did not exist. Now, 57 percent of calories consumed by U.S. adults and 67 percent of calories consumed by kids come from ultraprocessed foods (Juul 2022; Wang 2021), with consumption rising most rapidly among Black and Mexican youths (Wang 2021). High consumption of ultraprocessed foods substantially increases risk of obesity (Moradi 2023; Lane 2020), metabolic syndrome (Lane 2020), and cardiovascular disease (Suksatan 2022). The most compelling evidence to date comes from a rigorous randomized crossover trial conducted by Kevin Hall at the NIH (Hall 2021). In the study, participants were allowed to eat freely from nutrient-matched ultraprocessed vs. minimally processed menus for 2 weeks. The study found that during the ultraprocessed weeks, participants consumed roughly 500 more calories/day and gained 2.2 lbs (of mostly fat mass).

Sugary drinks and ultraprocessed foods are designed for overconsumption, leading people to take in more calories than they want or realize. It is very easy to overconsume ultraprocessed foods because they are "hyperpalatable," meaning they combine salty, sweet, and fat flavors in irresistible combinations not found in nature. They do not require much time or effort to prepare and are often eaten on the go or in front of a computer or TV, making it easy to eat or drink more than we realize. On a chemical level, ultraprocessed food ingredients are degraded to the point that they no longer give us feelings of fullness during digestion and send sugar and fat into our bloodstream more quickly.

Improving diets could prevent and delay the onset of type 2 diabetes in a way that is more effective and cheaper than medication (Lee 2019; CHOICES). The Diabetes Prevention Program clinical trial found better diets and physical activity reduced incidence of diabetes by 58 percent compared with a placebo, while metformin reduced incidence by 31 percent (Diab Prev Program Research Group 2002).

Consumers want to make healthy choices. However, it is very difficult to eat healthy diets in the current American food environment for the following reasons:

- **Food supply**: The U.S. food supply is rife with unhealthy foods: 50 percent of U.S. packaged foods in 2020 were ultraprocessed, while 43 percent were high in sugar, sodium, or saturated fat (under review). The U.S. has more sugar and non-caloric sweeteners in its packaged food supply compared to other high-income, English-speaking countries (Dunford 2018), and we consume on average 73 pounds of sugar, corn syrup, and other sweeteners per year (USDA 2023). Product-for-product, our food supply is sweeter: for example, the sugar content in children's breakfast cereals is 10–20 percent higher than in comparable countries (Chepulis 2019). The U.S. food supply is also full of industrial food additives (e.g., colors, flavors, flavor enhancers, emulsifiers, thickeners, and artificial sweeteners)—ingredients which are added to make the products more palatable and increase consumption. As of 2019, nearly 60 percent of U.S. consumer food purchases—and alarmingly, 73 percent of baby food purchases—contained additives (Dunford 2023).
- **Food marketing**: Sugary drinks and ultraprocessed foods are aggressively marketed to children. Food companies spend roughly $14 billion per year on food advertising in the U.S., of which 80 percent is for unhealthy foods (Rudd Center Food Marketing 2023). Companies target children with marketing for unhealthy foods everywhere they live, learn,

and play, including on TV, social media, in product placement, at school, and on their toys and clothing, and by using tactics like licensed characters, A green and black television celebrities, games, spokespeople, contests, and kids' clubs to attract their attention. Targeted marketing to children is very common: every day, U.S. children see an estimated 10 ads for unhealthy foods on TV alone (Fleming-Milici 2017). Advertising to youth is shifting from television to digital and mobile platforms, including ads on social media, branded games and ordering apps, and paid promotions from bloggers, influencers, and brand Ambassadors—marketing that is often disguised as entertainment. For example, teenagers see food marketing 189 times per week on social media apps—most for unhealthy foods (Potvin Kent 2019). Children are uniquely vulnerable to the impact of food marketing because of their inability to recognize its persuasive intent (Harris 2009). This exposure to unhealthy food and beverage advertisements increases youth's preference, selection, and consumption of unhealthy foods (Tsochantaridou 2023; Norman 2016).

It is also very concerning that food companies target unhealthy food marketing specifically to youth of color, who are most at risk for diabetes. For example, fast food and sugary drink ads appear at a higher rate on Spanish-language TV than English language TV; schools with >60 percent Hispanic populations have more outdoor food and beverage ads within a half a mile of the school (CSPI 2023). Food companies target children of color by designing specific products for them, adapting pricing, advertising on specific channels or in places in the community, using their own language and cultural references, and personalizing digital advertisements. Companies do this because children of color represent a rapidly growing market with significant economic impact, have high levels of media use, and are trend-setters for the general public. For example, marketing campaigns targeting youth of color use cause-related marketing like donations or collaborations with non-profits. Coca Cola and Pepsi are responsible for the majority of these marketing campaigns and they almost exclusively promote unhealthy foods (Rudd Center Targeted Marketing).

- **Food prices**: Cost drives food purchasing decisions, and unhealthy foods tend to be cheaper than healthy foods. For example, in New York City, the price per liter of sugary drinks is higher than low-calorie drinks (Bragg 2022). In many parts of the world, sugary drinks are cheaper than water (Blecher 2017); ultraprocessed foods also have lower per-calorie cost and have faced slower price increases in recent years (Gupta 2019). Low-income people are more affected and report having to purchase ultraprocessed foods and snacks vs. fruits and vegetables due to price (Ravikumar 2022).
- **Labeling**: The current food labeling environment is very confusing to consumers. Nutrition-related claims on food packages are very common (Taillie 2018; USDA 2023); yet their presence does not reliably indicate that a product is actually healthy. For example, 97 percent of fruit drinks, the top-consumed sugary drink among kids, carry some type of claim like "100 percent Vitamin C" or "Natural" (Duffy 2021). These claims lead to the "health halo" effect, in which claims give unhealthy products an aura of healthfulness, leading parents to make less healthy choices (Hall 2023; Hall 2020). The Nutrition Facts Panel got important updates in 2020, including the requirement to disclose added sugar content. However, few consumers consistently use these back-of-the package labels, with low-income and low-educated populations less likely to use them (Storz 2023). Moreover, people spend only seconds selecting a food item, making it difficult to understand complex, numeric information and make educated decisions.
- **School foods**: Kids consume about a third of their daily calories at school; foods served and sold to children in schools also affect lifetime food preferences. The Healthy, Hunger Free Kids Act improved the nutritional quality of school foods and helped prevent obesity among children in poverty, with no difference in school meal participation (Johnson 2016; Kenney 2020). However, our team's analyses of National Health and Nutrition Survey data found that in 2015–2018, the majority of calories kids consume at school comes from ultraprocessed foods (Vatavuk, unpublished). Moreover, unhealthy food marketing is highly prevalent in schools, with companies providing school sports sponsorships, student in-

centives (e.g., Pizza Hut's Book It program), branded fundraising and reward programs (e.g., General Mill's Box Tops for Education; fast food proceed donations), digital and physical advertisements, and the sales of branded fast-food products (Harris 2014). In addition, "Smart Snacks," or packaged snacks that have been reformulated to meet USDA school foods standards, are virtually indistinguishable from the less healthy versions sold outside of schools (Harris 2016). Thus, even these "healthier" snacks serve as another form of marketing to get kids hooked on specific brands, increasing their preferences and purchases.

- **Food retail environment**: Sugary drinks and ultraprocessed foods are ubiquitous in all retail settings and are often at checkouts, at endcaps of stores and are often placed in locations and heights that children are more likely to see and pester their parents to get. For example, a national study found 91 percent of supermarkets carry candy at checkout and 85 percent carry sugary drinks (Barker 2015).
- **Corporate interference**: To circumvent regulation, the food industry has followed the tobacco industry playbook: blaming personal responsibility, casting doubt on unfavorable research, funding favorable research, coopting professional organizations, lobbying, and arguing for self-regulation (Stuckler & Nestle 2012). For example, the sugar and sugary drinks industry has sought to shift the blame from sugar to fat (Kearns 2016); created a shadow group to create allies in academia and governments for pro-sugar policies, funded physical activity research to change the narrative about what causes obesity (Serodio 2018), and funded major nutrition and health societies in exchange for influence over proceedings (e.g., the American Academy of Nutrition and Dietetics) (Gunnarsson 2022).

The packaged food industry has proposed voluntary labeling and marketing self-regulations in an attempt to circumvent regulation. However, these initiatives have failed: they are slow, ineffective, and contain many loopholes while allowing companies to claim to be part of the solution (Boyland 2022). Federal regulation is needed to create healthier food environments. Many countries, particularly in Latin America, have already begun taking action. Below, I outline evidence-based policy recommendations to promote healthier diets and prevent diet-related diseases.

Key recommendations

1. Require front-of-package labels on unhealthy foods.

Since 2016, 10 countries have mandated front-of-package nutrition labels on foods high in sugar, sodium, and saturated fat, which includes all sugary drinks and most ultraprocessed foods. Compared to other labeling systems, "high-in" labels that signal when a product is high in unhealthy nutrients more effectively empower consumers to avoid nutrients of concern (Croker 2020). A simple black-and-white design grabs consumers' attention and is easily understood, even by children and those with limited English proficiency (Correa 2019; Hall 2021). Chile was the first country to implement high-in labels, leading to a 24 percent drop in sugary drink purchases and a 24 percent drop in purchases of foods carrying the labels (Taillie 2020, 2021). Chile's policy also incentivized the food industry to cut sugar and sodium in the food supply (Reyes 2020), with no adverse impacts on wages and employment (Paraje 2023). Many countries have followed Chile's lead and implemented similar warning label regulations—covering much of South America as well as Mexico and Canada. The FDA is currently researching front-of-package labeling options for the U.S. and plans to issue a proposed regulation requiring new labels in June 2024. FDA should consider that single-nutrient octagonal labels maximize consumers' ability to quickly and accurately identify unhealthy products, more so than labels with numerical information requiring numeracy skills (Grummon 2019). Ample experimental research in the U.S. already shows that warning labels help consumers quickly identify unhealthy foods and make healthier, informed choices (Musicus 2023; Taillie 2022). Using evidence-supported visuals like icons or symbols further increases comprehension (Hall 2021; Bopape 2021). Most importantly, the FDA must ensure that progress toward clear, informative labeling is led by governments and public health experts, not commercial interests.

1a. FOP labels should include visuals to increase comprehension, use single-nutrient octagonal labels to maximize consumers' ability to quickly and accurately identify products high in nutrients of concern (including sugar), and avoid including information about the percent of the daily value (percent DV).

1b. Restaurants should require similar labels. In November 2023, New York City passed the "Sweet Truth Act" that will require chains with 15 or more restaurants to use an added sugar icon on their menus and menu boards to indicate a food or drink item contains more than 50g of added sugar.

2. Restrict food marketing to children

Policies to reduce children's exposure to harmful food marketing should protect children of all ages (up to age 18 years); use a strong, government-led nutrient profiling to classify foods for restriction; be comprehensive enough to minimize the risk of migration of marketing to other media or to other age groups; and restrict the persuasive power of food marketing (World Health Organization, 2023). Chile provides the most compelling example of the impacts a strong marketing policy. In 2016, Chile restricted the use of child-directed appeals on products exceeding set nutrient thresholds, restricted placement of ads in media with high child viewership, and prohibited the sales and promotion of these products in school. In 2018, they extended this regulation by banning television advertisements on unhealthy food advertisement between 6am-10pm. Together, these regulations have worked in a relatively short amount of time to dramatically reduce children's exposure to unhealthy food marketing and lessen its persuasive appeal and power:

- In the first (and most lenient) year of the law, the percentage of TV ads for foods and drinks high in energy, saturated fats, sugars, or sodium dropped from 42 percent to 15 percent (Correa 2020).
- By 2019, Chile's marketing restrictions led to a total drop of 73 percent in children's daily exposure to TV ads for products high in calories, sugar, salt or saturated fat on all TV and a 90 percent drop during children's programming (Dillman Carpentier 2023). What's more, 67 percent fewer unhealthy food ads on TV used child-directed creative content such as cartoons, characters, toys, or contests, which are also prohibited under the country's laws.
- The percentage of regulated cereals (typically high in calories and/or sugar) with child-directed strategies featured on their packages dropped from 43 percent to 15 percent in the first year of regulation (Mediano Stolze et al. 2019).

3. Amend the tax code to remove the deductibility of expenses associated with advertising and marketing foods and beverages of poor nutritional quality to children.

Food companies can deduct expenditures related to advertising and marketing from their taxes. Through this process, the U.S. government provides a subsidy for marketing unhealthy food and drinks to children (Center for Science in the Public Interest [CSPI] 2023). Removing the deductibility of advertising expenses on sugary drinks and ultraprocessed foods would incentivize companies to decrease unhealthy food marketing to children and could raise $80 million in Federal revenue annually (CSPI 2023).

4. Implement taxes on sugary drinks and ultraprocessed foods and subsidies on healthier foods.

Tax policies would require legislative action and there have been several bills introduced to the U.S. Congress in recent years. We strongly recommend that a Federal tax on sugary drinks as proposed in the 2021 "SWEET Act" Bill, which sets a 2-cents/ounce tax on ready-to-drink lower-sugar SSBs and a 3-cents/ounce tax on ready-to-drink high-sugar SSBs. Importantly, it also proposes directing the resultant revenue toward public health and health promotion objectives. Uses of the revenue could include: improving school feeding programs and/or funding expansion of healthy incentive programs to support low-income families afford healthy foods as proposed in 2023 "GusNIP Expansion Act" and the "Opt for Health with SNAP (OH SNAP) Close the Fruit and Vegetable Gap Act" that were concurrently introduced into the U.S. House of Representatives and Senate, respectively. Dedicating the tax revenues toward lower-income communities

and families would enhance the equity potential, with multiplier effects for the local economies of these families, and address concerns around the income regressivity of the tax. In a new modeling study, our team found that a tax on sugary drinks following the SWEET Act would lower calories purchased, while targeted subsidies would increase fruit, vegetable, and healthier drink purchases without substantially increasing calories (Pourya under review). A broader tax that also includes ultra-processed foods along with targeted subsidies for minimally processed foods could promote healthier food choices among low-income households and could be budget neutral for the Federal Government.

U.S. and global data show that sugary drink taxes reduce consumption (Andreyeva 2022; Teng 2019; Powell 2021), reduce sugar content in the food supply (Dickson 2023), and result in health benefits, including reduced pediatric hospital admissions from dental caries (Rogers 2023), and decreased prevalence of overweight and obesity, particularly where price increases are steeper (Gracner 2022). Modeling studies have predicted that in Mexico, where the first sugary drinks tax was implemented, the tax will lead to a 2.5 percent reduction in obesity prevalence and prevent 86 to 134 thousand cases of diabetes a decade after the tax (Barrientos 2017). Fewer data are available on foods taxes, but our research in Mexico found that a modest 8 percent junk food tax reduced taxed food purchases by ?5 percent (Batis 2016).

- **5. Incorporate guidance on ultraprocessed foods into dietary guidelines**.

Increasingly, other countries (most recently, Mexico) include specific dietary guidance around the consumption of ultraprocessed foods. The 2025 U.S. Dietary Guidelines Advisory Committee is currently reviewing evidence on ultraprocessed foods for the 2025 Dietary Guidelines. Inclusion of guidance on ultraprocessed foods could help guide consumers and underpin other policies, including school foods.

6. Create healthier school environments.

Schools should be a place where children can eat healthy foods and learn good nutrition, free from the influence of corporate marketing. Creating this environment will promote healthier diets that track into adulthood.

6a. Ideally, schools should not sell any foods that are high in added sugar or any nutrient of concern (as identified by the FOP warning labels in Recommendation 1). At a minimum, school lunch standards should follow the Dietary Guidelines and ensure that added sugars are limited to 10 percent of calories per week. Schools should have product-based limits for high-sugar foods, including grain-based desserts, breakfast cereals, yogurts, and flavored milks, as well as other products like condiments, toppings, and dressings. Schools should not offer flavored sweetened milk, particularly among young children (under grade 9). We applaud many of the USDA's proposed updates to school nutrition standards which would address several of these concerns. The USDA could go even further by considering a policy like Brazil's, which requires that 75 percent of school food procurement expenditures be used on fresh or minimally processed foods, with only 20 percent allowed for purchasing processed and ultraprocessed foods.

6b. School food environments should be free from advertising, promotions, and marketing of products high in nutrients of concern. Again, Chile serves as an example: after banning the sales and promotion of unhealthy foods in schools, availability of unhealthy foods dropped from 97 percent of foods and 76 percent of beverages to only 14 percent, with concurrent reductions in calories, saturated fats, sodium, and sugar available to purchase (Massri 2019). After the policies, Chilean children consumed significantly less total sugar at school (Fretes 2021).

7. Increase nutrition funding.

A major barrier to progress in using nutrition to prevent diabetes is lack of scientific funding, which has remained flat over decades (Fleischhacker 2020). The National Institutes of Health only spends ?5 percent of its annual budget on nutrition, with only 1.3 percent dedicated to understanding the role of diet in preventing or treating disease. Increased funding for nutrition science is critical for preventing obesity, diabetes, and other diet-related chronic diseases.

Ideally, multiple of these policies would be implemented together as a policy package. Our experiences with food policies implemented in many countries suggest an interactive and reinforcing effect. For example, front-of-package nutrition labels can be used to guide what is permissible to market and sell in schools, where children can further learn how to use the labels to tell what is healthy vs. not healthy. Together, these policies can create healthier food environments for children, promoting healthier dietary behaviors that track into adulthood and help prevent obesity, type 2 diabetes, and other diet-related chronic diseases across the lifecycle.

[SUMMARY STATEMENT OF LINDSEY SMITH TAILLIE]

Why diet matters for type 2 diabetes prevention:

- The U.S. has an alarmingly high prevalence of obesity and type 2 diabetes. The incidence of type 2 diabetes among children has doubled over the last 20 years, with Black and Hispanic children experiencing the fastest increases.
- Americans consume too much sugary drinks and ultraprocessed foods. Often known as "junk food," ultraprocessed foods are industrially produced foods that typically contain additives and high levels of added sugar, sodium, saturated fat, and excessive calories. Nearly 2/3 of kids' daily calories come from ultraprocessed foods, and the steepest increases have occurred among Black and Hispanic youth.
- Sugary drinks and ultraprocessed foods lead to weight gain, which promotes diabetes. In an NIH trial, just 2 weeks on an ultraprocessed food diet led people to consume ?500 more calories per day and gain weight.
- Sugary drinks and ultraprocessed foods are designed for overconsumption because they combine flavors, sugar, salt, and fat in ways not found in nature; they are cheap; they are convenient; and we digest them more quickly.
- Improving diet quality would prevent and delay onset of type 2 diabetes and is more cost-effective than medication.

The U.S. food environment makes it very difficult for Americans to make healthy choices.

- Food supply: The U.S. food supply contains more sugar and sweeteners than other high-income countries. Fifty percent of U.S. packaged foods are ultraprocessed and 43 percent are high in sugar, sodium, or saturated fat.
- Food marketing: Unhealthy foods are widely and aggressively marketed to kids, particularly youth of color. Companies use tactics like licensed characters to appeal to kids, and strategies like specialized product design, language and cultural references, cause-related marketing, and personalized digital advertisements to target youth of color. Food marketing increases kids' desire for, purchases of, and intake of unhealthy foods.
- Food labeling: The high prevalence of nutrition claims in the U.S. packaged food supply makes it difficult for consumers to tell when a product is unhealthy. For example, claims like "Natural" on sugary fruit drinks mislead parents into thinking that drinks don't contain added sugar when they do. Although recent updates to the Nutrition Facts Panel, like requiring information about added sugar, are applaudable, most consumers do not always use the information and it is hard to understand for consumers with low education levels.
- Food pricing: Sugary drinks and ultraprocessed foods tend to be cheaper than minimally processed or whole foods. Parents report wanting to buy healthy foods but being unable to afford to.
- Retail environment: Sugary drinks and ultraprocessed foods are ubiquitous in food stores and are often placed in the checkout, end caps, and at locations and heights that kids are more likely to see and pester their parents to get.
- School foods: The Healthy Hunger-Free Kids Act improved school nutrition. However, most of the calories kids consume at schools still come from ultraprocessed foods, and unhealthy food marketing in schools is very common.

- Industry interference: The food industry has funded professional societies and research scientists to change the narrative on what causes obesity and type 2 diabetes, preventing policy progress.

What policies are needed based on global evidence.

- Front-of-package labels: Front-of-package nutrition labels that are clear, grab attention, and are easy to understand can help consumers make informed, healthier choices. In 2016, Chile was the first of now 10 countries to implement mandatory front-of-package nutrient warnings on unhealthy foods. The policy incentivized the food industry to cut sugar, sodium, and saturated fat in the food supply with no adverse impact on wages or employment. The policy also reduced unhealthy food purchases. The FDA is currently researching front-of-package labels and should consider a design like Chile's, which has been demonstrated in U.S. experimental research to outperform other label types.
- Food marketing restrictions: Voluntary corporate initiatives to restrict marketing are ineffective. Mandatory restrictions on unhealthy food marketing to children—for example, by limiting where ads appear or by reducing the use of techniques like cartoons—would help children develop preferences for healthy foods. In Chile, strong food marketing restrictions cut children's exposure to unhealthy food advertisements by 73 percent.

  An additional policy is the removal of tax deductions on companies' advertising expenditures, which would make it more expensive to advertise unhealthy foods to children, cut kids' exposure, and also generate tax revenue for the government.
- Taxes: Global evidence from 50+ countries shows that sugary drink and ultraprocessed food taxes incentivize reformulation and reduce consumption. Revenue from taxes can be used to fund public health programs to further type 2 diabetes prevention, such as for fruit and vegetable subsidies for low-income families.
- Healthier school food environments: Schools should be free from the marketing, promotion, and sales of sugary drinks and ultraprocessed foods. Global evidence shows that restricting the marketing, promotion, and sales of unhealthy foods in schools reduces their availability and improves children's diets.
- Increase funding for nutrition research: With only 1.3 percent of the NIH budget, more funding for nutrition science is needed to improve diets and prevent obesity, type 2 diabetes, and other diet-related chronic diseases.

The CHAIR. Thank you very much. Our next witness is Dr. Kasia Lipska, Associate Professor of Medicine at the Yale School of Medicine, and we thank her very much for being with us.

STATEMENT OF KASIA LIPSKA, M.D., M.H.S, ASSOCIATE PROFESSOR OF MEDICINE, YALE SCHOOL OF MEDICINE, NEW HAVEN, CT

Dr. LIPSKA. Thank you. Chairman Sanders and Ranking Member Cassidy, I am Dr. Kasia Lipska, Physician Scientist at the Yale School of Medicine. Thank you for the opportunity to present my testimony.

As a clinician, I take care of patients who have—who already have developed diabetes. There are now over 35 million people with type 2 diabetes in our Country. Nearly one in every third older adults has diabetes.

My focus with patients is to reduce the risk of complications of diabetes, such as heart attacks, strokes, amputations, kidney failure, and blindness. One of the biggest challenges in my clinical practice, including this past year, is still figuring out how to get my patients access to affordable treatment.

Even the best medications cannot help patients if they cannot afford them. According to a national survey, in 2021, 16 and a half percent of people with diabetes rationed their insulin because of cost.

This is not just due to lack of insurance coverage. Among Medicare beneficiaries with diabetes, 1 in 10 reported skipping, delaying, or taking less medication to save money. There has been so much excitement about the new medications and type 2 diabetes and obesity.

That is because some of the medications, including semaglutide or Ozempic, really seem to work. They not only help people lose weight, but also importantly reduce the risk of complications related to diabetes and obesity. But the price tags for these new medications are simply outrageous.

Ozempic, the brand name for semaglutide approved for type 2 diabetes and marketed by Novo Nordisk, has a U.S. list price of over $900 per month. Wegovy, the brand name for the same drug approved for obesity is $1,300 per month. If Medicare were to fully cover Wegovy for all of its beneficiaries with obesity for 1 year, we as American taxpayers would end up with a $268 billion invoice.

To give you some perspective, that is 70 percent of all the money that was spent on prescription drugs in the U.S. in 2021. And could we stop at 1 year? Probably not. What we know about semaglutide, and the related medications is that they work while people take them. However, as soon as they stop, their weight comes back.

Patients are looking at a potentially lifelong treatment, and we could be facing the most expensive subscription service in the history of medicine. What can Congress do to fix this? Ozempic is priced at roughly $100 per month in Sweden and just $80 in Australia and France.

That is 10 percent of what we are being asked to pay. One explanation is that those governments are negotiating prices directly with the pharmaceutical companies. That is not socialized medicine. That is smart negotiating. Price negotiation is critical, but I believe we must do more.

Pharmaceutical companies have absolutely no restrictions on the launch prices of their products, nor is there any evidence that these prices are reflective of research and development costs. No amount of expert negotiation can bring down drug prices years later, when the launch price is sky high to begin with.

We have to align the launch price with the drug's value, the cost to develop and manufacture the drug, and what patients can afford. This is a rational approach that is in place in many other developed countries. But I want to be clear here, medications alone cannot be the solution to the diabetes and obesity epidemics.

We need to be more farsighted and strategic than that. Neither diabetes and obesity is a moral failure or a personal choice. Just telling people to eat less, exercise more is not going to solve the problem.

Instead, we must address the upstream causes of obesity, like holding the food industry accountable, as my fellow experts have already made clear. The reality is that the drug industry is really

good at pushing its solutions and its products. Drug companies are powerful, sometimes more powerful than governments.

Novo Nordisk, which is based in Denmark, now has a market value that is bigger than its host nation's GDP. So, we must remember that drugs alone can't save us. They are only part of the solution.

We can't simply prescribe our way out of this problem. And before we sign up for that never ending subscription service and spend trillions of dollars, let's be smart consumers and have the Government at the negotiating table right from the start.

In closing, the bottom line is this, we have a food industry that profits from making people sick and a drug industry that profits from treating them. We must break that cycle. Thank you.

[The prepared statement of Dr. Lipska follows:]

PREPARED STATEMENT OF KASIA LIPSKA

Chairman Sanders and Ranking Member Cassidy, I am Dr. Kasia Lipska, a physician scientist at the Yale School of Medicine in the Section of Endocrinology and Metabolism. Thank you for the opportunity to present my testimony. I am here in my personal capacity as an expert in endocrinology and practicing clinician, and I am not representing the Yale School of Medicine.

My research has focused on the safety and effectiveness of medications to treat type 2 diabetes. I have evaluated trends in utilization of these medications over time and examined associated health outcomes. My overarching goal has been to generate evidence that patients and doctors can use to make decisions about what treatment is best for each individual. However, I realized that in my own practice, I was often forced to make decisions with my patients about medications—not based on scientific evidence about their safety and effectiveness—but rather on what options were affordable, even if those options were far from ideal. As a result, I expanded my research to consider cost-related barriers to treatment. In 2017, we conducted a survey in our Yale Diabetes Center and showed that 1 in 4 patients with diabetes, who were prescribed insulin, rationed this medication due to cost.[1] I became involved in advocacy efforts for affordable insulin. In addition to writing editorial pieces in national media outlets such as the New York Times,[2] and testifying before the House Energy & Commerce Committee on the human impact of rising insulin costs,[3] I have worked closely with T1International, an advocacy organization that does not accept any money from the pharmaceutical industry or any other entity that might influence their ability to speak out freely.

As a clinician, I take care of patients who have already developed diabetes. There are now over 38 million people with diabetes in our Country. Nearly 1 in every 3d older adults has diabetes.[4]

My focus with patients is to reduce the risk of complications of diabetes, such as heart attacks, strokes, amputations, kidney failure, and blindness. My clinic is in the Yale Diabetes Center in New Haven, CT where we serve over 3,000 patients with both type 1 and type 2 diabetes. About a third of our patients are insured by Medicaid, a third by Medicare, and a third have commercial insurance. New Haven's age, education, and race/ethnicity demographics reflect those of our Nation.[5] One

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[5] 'Normal America' Is Not A Small Town of White People. April 28, 2016 available at: *https://fivethirtyeight.com/features/normal-america-is-not-a-small-town-of-white-people/*. "The metropolitan area that looks most like the U.S. is New Haven, Connecticut" based on age, educational attainment, race, and ethnicity metrics.

of the biggest challenges in my clinical practice—including this past year—is still figuring out how to get my patients access to affordable treatment. This is what it's like in my clinic. I saw a 71-year-old man who is a retired auto body mechanic for follow-up the other day. He has type 2 diabetes, obesity, fatty liver disease, and coronary heart disease. He was taking metformin for his diabetes, but his blood sugars were uncontrolled. I prescribed Ozempic (semaglutide) but he was not able to fill this due to cost. We tried the other medications in the same class, but those were also expensive. I switched to Jardiance (empagliflozin), a pill for type 2 diabetes that reduces the risk of cardiovascular complications, but he had to stop this as well because our 340B program no longer offers it at a discount. He ended up on glipizide, probably the worst possible choice for his type 2 diabetes. Glipizide is associated with a risk of low blood sugar reactions and tends to result in weight gain.

Even the best medications cannot help patients if they cannot afford them. According to a national survey, in 2021, 16.5 percent of people with diabetes rationed their insulin because of cost.[6] This is not just due to lack of insurance coverage. Among Medicare beneficiaries with diabetes, 1 in 10 reported skipping, delaying, or taking less medication to save money.[7] What's more, when patients fill their perscriptions and purchase the insulin that they need, this is often extremely costly for them. Using nationally representative data from 2017 and 2018, we found that 14.1 percent of Americans reached catastrophic levels of out-of-pocket spending on insulin, defined as spending more than 40 percent of their disposable family income on insulin alone.[8]

There has been progress in making insulin affordable—in large part due to tireless advocacy efforts by many people living with the disease, including organizations like T1International, fighting for access to insulin for all. And progress has been made thanks to the many policies that you have proposed or passed into law to improve insulin affordability. But on the whole, insulin is still way too expensive. My patients continue to struggle to pay for this drug. Over a century ago, inventors of insulin gave their patent to the University of Toronto, for $1, so that humankind would have affordable access to the drug forever.[9] Instead, drug companies have been very resourceful at controlling the market, gaming the patent system to block more affordable competitors, inflating their product prices ever since. And now that there are many new medications for diabetes, we must apply the lessons we learned from insulin to not make the same mistakes again.

There has been so much excitement about the new medications in type 2 diabetes and obesity. That's because some of the medications, including semaglutide (marketed by Novo Nordisk as Ozempic for type 2 diabetes and as Wegovy for obesity), really seem to work. They not only help people lose weight but also reduce the risk of complications related to diabetes and obesity.10,11 In recent trials, these medications reduced the risk of cardiovascular complications by 20–25 percent.[10, 11]

But the price tags for these new medications are outrageous. Ozempic, the brand name for semaglutide approved for type 2 diabetes, has a U.S. list price of over $900 per month. Wegovy, the brand name for the same drug approved for obesity, is $1,300 per month.12 If Medicare were to fully cover Wegovy for all of its beneficiaries with obesity, we as American taxpayers would end up with a $268 billion invoice.[12] To give you some perspective, that's 70 percent of all the money that was spent on prescription drugs in the U.S. in 2021.[13] And could we stop at 1 year? Probably not. What we know about semaglutide, and the related medications, is that they work while people take them. However, as soon as they stop, their weight

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comes back.[14] So patients are looking at a potentially lifelong treatment and we could be facing the most expensive subscription service in the history of medicine.

How do we find a way to make these drugs affordable? We can't assume that this will simply get better with time, as patents expire after several years. There is just too much money on the table and the pharmaceutical industry is not about to walk away.

What can Congress do to help patients like mine? Ozempic is priced at roughly $100 per month in Sweden and just $80 in Australia and France.[15] That's 10 percent of what we are being asked to pay. One explanation is that those governments are negotiating prices directly with the pharmaceutical companies.[16] That's not socialized medicine. That's smart negotiating. That's a group of people leveraging their buying power to get a good deal.

The Inflation Reduction Act already authorizes the Secretary of the Department of Health and Human Services (HHS) to negotiate prices with pharmaceutical companies under specific provisions, and for a limited set of drugs. Notably, 4 out of the 10 initial medications selected for negotiation are medications for type 2 diabetes. But neither semaglutide nor the related medications in the same class are currently on the list of these drugs. As a result, millions of Americans are being asked to pay an impossible price—almost $900 a month—to get treatment that has the potential to change their lives. Many simply can't. That money is needed to pay rent, buy groceries, or make a car payment. So they go without. I see these patients every week in my clinic.

Price negotiation is critical, but I believe we must do more. Pharmaceutical companies have absolutely no restrictions on the "launch prices" of their products, nor is there any evidence that these prices are reflective of research and development costs.[17] No amount of expert negotiation can bring down drug prices years later when the launch price is anchored to be sky-high. We have to align the launch price with the drug's value, the costs to develop and manufacture the drug, and what patients can afford. This is a rational approach that is in place in many other developed countries.

But I want to be clear here: medications alone cannot be the solution to the diabetes and obesity epidemics. We need to be more far sighted and strategic than that. Neither diabetes nor obesity is a moral failure or a personal choice. Just telling people to eat less and exercise more is not going to solve the problem—that strategy has failed thus far. Instead, we must address the upstream causes of obesity on the systemic level, such as reducing food deserts and improving built environments.[18] (As my fellow experts have already made clear.)

The reality is that the drug industry is really good at pushing its solutions and its products. Drug companies are powerful, sometimes more powerful than governments. Novo Nordisk, which is based in Denmark, now has a market value that is bigger than its host nation's GDP.[19] And so, perhaps inevitably, the path of least resistance will be for us to prescribe our way out of this problem. So I leave with you two thoughts:

[1] drugs alone can't save us, they're only part of the solution; and

[2] before we sign up for that never-ending "subscription service," and spend trillions of dollars, let's be smart consumers and have the government at the negotiating table, right from the start. Every extra dollar spent on these exorbitantly priced drugs is another dollar not available to address the systemic issues contributing to diabetes and obesity in the first place.

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[SUMMARY STATEMENT OF KASIA LIPSKA]

Even the best medications cannot help patients if they cannot afford them. According to a national survey, in 2021, 16.5 percent of people with diabetes rationed their insulin because of cost. This is not just due to lack of insurance coverage. Among Medicare beneficiaries with diabetes, 1 in 10 reported skipping, delaying, or taking less medication to save money.

There has been so much excitement about the new medications in type 2 diabetes and obesity. That's because some of the medications, including semaglutide, really seem to work. They not only help people lose weight but also reduce the risk of complications related to diabetes and obesity.

But the price tags for these new medications are outrageous. Ozempic, the brand name for semaglutide approved for type 2 diabetes, has a U.S. list price of over $900 per month. Wegovy, the brand name for the same drug approved for obesity is $1,300 per month. If Medicare were to fully cover Wegovy for all of its beneficiaries with obesity, we as American taxpayers would end up with a $268 billion invoice. To give you some perspective, that's 70 percent of all the money that was spent on prescription drugs in the U.S. in 2021. And could we stop at 1 year? Probably not. What we know about semaglutide, and the related medications, is that they work while people take them. However, as soon as they stop, their weight comes back. So we could be looking at lifelong treatment here and then we're potentially talking about the most expensive subscription service in the history of medicine.

How do we find a way to make these drugs affordable? Ozempic is priced at roughly $100 per month in Sweden and just $80 in Australia and France. That's 10 percent of what we are being asked to pay. One explanation is that those governments are negotiating prices directly with the pharmaceutical companies. That's not socialized medicine. That's smart negotiating. That's a group of people leveraging their buying power to get a good deal.

Price negotiation is critical, but I believe we must do more. Pharmaceutical companies have absolutely no restrictions on the "launch prices" of their products. No amount of expert negotiation can bring down drug prices when the launch price is sky-high. **We have to align the launch price with the drug's value, the costs to develop and manufacture the drug, and what patients can afford**. This is a rational approach that is in place in many other developed countries.

But I want to be clear here: **medications alone cannot be the solution** to the diabetes and obesity twin epidemics. We need to be more far sighted and strategic than that. Neither diabetes nor obesity is a moral failure or a personal choice. Just telling people to eat less and exercise more is not going to solve the problem—that strategy has failed thus far. Instead, **we must address the upstream causes of obesity on the systemic level**, such as reducing food deserts and improving built environments.

The reality is that the drug industry is really good at pushing its solutions and its products. And so, perhaps inevitably, the path of least resistance will be for us to prescribe our way out of this problem. So I leave with you two thoughts: [1] drugs alone can't save us, they're only part of the solution; and [2] before we sign up for that never-ending "subscription service," and spend trillions of dollars, let's be smart consumers and have the government at the negotiating table, right from the start. **Every extra dollar spent on these exorbitantly priced drugs is another dollar not available to address the systemic issues contributing to diabetes and obesity in the first place**.

The CHAIR. Thank you very much.

Senator Cassidy, want to introduce your witnesses?

Senator CASSIDY. Yes, thank you, Mr. Chairman. Pleased to first introduce Mrs. Natalie Stanback, a mother to a type 1 diabetes patient. Mrs. Stanback provides an insightful, personal perspective on the issues of children with type 1 diabetes and their parents' encounter.

In 2015, Mrs. Stanback's daughter Nadia was diagnosed with type 1 diabetes, and apparently her family has a strong family history of type 1 diabetes, unrelated to obesity. Natalie volunteers

with JDRF, the Juvenile Diabetes Research Foundation, to advocate for type 1 diabetes research. Earlier this year, she served as chair of the JDRF's children's Congress.

She lives in Texas with her husband and three kids. Thank you for joining us. I look forward to your testimony.

STATEMENT OF NATALIE STANBACK, VOLUNTEER, JDRF, LEWISVILLE, TX

Mrs. STANBACK. Chairman Sanders, Ranking Member Dr. Cassidy, Members of the Committee, thank you for inviting me to testify today. I am here because unfortunately, I am deeply familiar with the many challenges presented by type 1 diabetes, or T1D.

I do not have this disease, but my 11 year old daughter Nadia does, and she lives with it. My brother died from complications of T1D when he was only 38 years old, so you can imagine the fear that I felt when Nadia was diagnosed at the age of three. It was overwhelming, to say the least.

Nadia does not know life without diabetes. We are blessed to have access to the best medical care, which helps her live the life she wants to live. She has an insulin pump and a continuous glucose monitor. She plays soccer and runs track. She looks like a normal kid, and in most ways she is.

But diabetes is always there, 365 days a year, 24/7. This disease is hard, and it is cumbersome. We are an emotionally positive family, glass half full, but this disease is still hard on all of us, but especially it is hard on Nadia. She can't eat without calculating how many carbohydrates are in the food so that she can dose the correct amount of insulin.

Her blood sugar levels can go low during soccer games, which forces her to sit out, and then treat it, and then get back in the game if there is still time. She has to deal with the needles necessary to change insulin pump infusionsites and glucose monitoring sensors in a way that many adults would and still do struggle with.

Then prescriptions and doctor's appointments must be diligently managed. My daughter is brave. She is responsible and she is miraculous, but it is still so very hard every day, not just for her, but for all those around her.

Her siblings, extended family members, teachers, coaches, friends, friends' parents, everyone needs to understand Nadia's needs and how they can help, especially in the case of an emergency. It takes a village to raise a child. It takes a city to raise a child with diabetes. I know that the Members of this Committee are aware of the realities of diabetes and have championed this cause for years.

I am grateful. I was honored to chair JDRF's children's Congress this past summer, and I know the amazing delegates and guardians you all met are so grateful too. Having you as champions has helped us get to where we are today.

In fact, SPD supported research directly contributed to the development of the incredible devices that Nadia relies on every day. They could still be—they could still be years in the future, if not for the support of the SPD.

What my daughter and what every parent of a child with diabetes needs, and what every person affected with diabetes needs is a cure. Something that removes the thousands of medical decisions we must make every day so that we can focus on everything else in life.

For my daughter, that would mean focusing on scoring goals on the soccer field and doing well in school, not whether she will go dangerously low or high in blood sugar in the process. Research can make that happen.

The STP has been foundational to nearly every advance in pursuit of that ultimate goal, which is cures. I am excited about the progress in therapies to delay T1D onset and those at risk of developing the disease.

Anyone who is able to take advantage of delaying T1D onset is receiving an incredible gift, time without T1D. I wish that Nadia could have had that opportunity. I do believe that someday Nadia will receive that ultimate gift, life without T1D. We have made incredible progress toward curing T1D through cell therapies.

This research is happening right now. I do not know when she will receive that gift. No one does. But I do know the best way to bring that day closer is long term, sustained funding for the special diabetes program. This research must continue. As a mom, I do not want my daughter to face a lifetime with diabetes.

With STP funded research, I no cures are possible. I know a life free of insulin pumps and monitors and the looming threat of complications is on the horizon, but only if the brilliant minds who have gotten us this far have the resources they need to get us across that finish line. And until then, we need affordable insulin.

The Insulin Act would help us make that more of a reality, so I urge you for your support. Thank you so very much for your time, and I look forward to your questions.

[The prepared statement of Mrs. Stanback follows:]

PREPARED STATEMENT OF NATALIE STANBACK

Chairman Sanders, Ranking Member Dr. Cassidy, Members of the Committee—thank you for inviting me to testify today. I'm here because, unfortunately, I'm deeply familiar with the many challenges presented by type 1 diabetes—T1D. I don't have this disease, but my eleven-year-old daughter, Nadia, lives with it.

My brother died from complications from T1D when he was only 24 years old so you can imagine the fear I felt when Nadia was diagnosed at the age of 3. It was overwhelming.

Nadia doesn't know life without diabetes. We are blessed to have access to the best medical care, which helps her live the life she wants to live. She has an insulin pump and a continuous glucose monitor. She plays soccer and runs track. She looks like a normal kid, and, in most ways, she is.

But diabetes is always there 365 days a year 24/7. This disease is hard. We're a very emotionally positive family—definitely glass half full. But this disease is hard. On all of us, but especially Natalie. She can't eat without calculating how many carbohydrates are in the food to dose the correct amount of insulin. Her blood sugar level can get low during soccer games, which forces her to sit out, treat it, and then get back in the game if there's still time. She has to deal with the needles necessary to change insulin pump infusionsites and glucose monitoring sensors in a way many adults would struggle with. And prescriptions and doctor appointments must be diligently managed.

My daughter is brave, responsible—she is miraculous. But it is still so very hard, every day. And not just for her, but for all those around her.

Her siblings, extended family members, teachers, coaches, friends, friends' parents—everyone needs to understand Nadia's needs and how they can help, especially in case of an emergency.

If it takes a village to raise a child, it takes a city to raise a child with diabetes.

I know that the Members of this Committee are aware of the realities of diabetes and have championed this cause for years. I am grateful. I was honored to chair JDRF's Children's Congress this past summer and I know the amazing delegates and guardians you met are grateful, too.

Having you as champions has helped us get to where we are today. In fact, SPD-supported research directly contributed to the development of the incredible devices that Nadia relies on every day. They could still be years in the future if not for the support of the SDP.

What my daughter, what every parent of a child with diabetes needs, and every person affected by diabetes needs is a cure. Something that removes the thousands of medical decisions we must make every day so that we can focus on everything else in life. For my daughter, that would mean focusing on scoring goals on the soccer field and doing well in school, not whether she will get dangerously low or high blood sugar in the process.

Research can make that happen. The SDP has been foundational to nearly every advance in pursuit of that ultimate goal: cures.

I am excited about the progress in therapies to delay T1D onset in those at risk of developing the disease. Anyone who is able to take advantage of delaying T1D onset is receiving an incredible gift—time without T1D. I wish that Nadia could have had that opportunity.

I do believe that, someday, Nadia will receive the ultimate gift—life without T1D. We have made incredible progress toward curing T1D through cell therapies. This research is happening right now. I don't know when she will get that gift—no one does—but I do know the best way to bring that day closer is long-term, sustained funding of the Special Diabetes Program. This research must continue.

As a mom, I don't want my daughter to face a lifetime with diabetes. With SDP-funded research, I know cures are possible. I know a life free of insulin pumps and monitors and the looming threat of complications is on the horizon—but only if the brilliant minds who have gotten us this far have the resources, they need to get us across the finish line.

Until then, we need affordable insulin. The INSULIN Act would help make that more of a reality. I urge your support.

Thank you very much for your time and I look forward to your questions.

[SUMMARY STATEMENT OF NATALIE STANBACK]

Chairman Sanders, Ranking Member Dr. Cassidy, Members of the Committee—thank you for inviting me to testify today. I am here because, unfortunately, I am deeply familiar with the many challenges presented by type 1 diabetes—T1D. I do not have this disease, but my eleven-year-old daughter, Nadia, lives with it.

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Until then, we need affordable insulin. The INSULIN Act would help make that more of a reality. I urge your support.

Thank you very much for your time and I look forward to your questions.

Senator CASSIDY. And now I have the privilege of introducing the next witness, Dr. Aaron Kowalski, the Chief Executive Officer and President of JDRF. In his role as CEO and President of JDRF, Dr. Kowalski is responsible for advancing and funding type 1 diabetes research by working closely with academics and the type 1 diabetes community.

He is also a scientist, and I am told, and this is apparently not HIPPA protected, you also have type 1 diabetes. I always got to throw that in there, Dr. Kowalski, and make sure I don't get busted.

Dr. Kowalski has authored a number of type 1 diabetes research articles focusing upon diabetes standards of care and the artificial pancreas. He has a doctorate in microbiology and molecular genetics from Rutgers. I look forward to your testimony, sir. Thank you for joining us.

STATEMENT OF AARON J. KOWALSKI, PH.D., CHIEF EXECUTIVE OFFICER, JDRF, NEW YORK, NY

Dr. KOWALSKI. Thank you. Chairman Sanders, Ranking Member Dr. Cassidy, Members of the Committee, thank you so much for inviting me to testify and your interest in diabetes. I am Dr. Aaron Kowalski, CEO of JDRF, the leading global not for profit focused on type 1 diabetes.

As a scientist by training, and Dr. Cassidy, as a person living with type 1 diabetes, I am honored to work for JDRF for the past 19 years, 4 of which in my current role. I would like to start with a thank you.

Because of your incredible bipartisan support and leadership, and the steadfast leadership of the Senate Diabetes Caucus Co-Chair Senator Collins, who just had to leave, unfortunately, and Senator Shaheen, the Special Diabetes Program, the STP, and the Special Diabetes Program for Indians, the STPI, are making a tremendous difference in the lives of people with diabetes and for their, our hope for the future.

These programs have helped fundamentally change what it means to live with type 1 diabetes and have put new life changing therapies in our hands and have brought us closer to cures.

JDRF and our countless volunteers are so grateful for the Committee—that the Committee recognizes the importance of building on this progress with the approval of S. 1855, the Special Diabetes Program Reauthorization Act.

We thank you, and we continue to work with your colleagues to ensure the 2-year $170 million per year for each program is enacted. Let me highlight for you a few of the many exciting breakthroughs that have resulted in the investment in the STP that gives us so much hope for a brighter future.

Because of STP funding, we have a new therapy approved, the first ever what we would call disease modifying therapy, it is called Tzield, that delays the onset of type 1 diabetes and the need for insulin for nearly 3 years.

This is a landmark, first time in 100 years we have ever changed the course of type 1. Other such therapies are advancing in the research pipeline. This is huge progress. Delaying the onset has a tremendous impact on the daily lives of people at risk for type 1, their families, and the overall health care system.

To take full advantage of Tzield and therapies on the horizon, we need to ensure widespread screening for the risk factors that trigger type 1. In June, the FDA approved the first ever cell therapy for adults with type 1, those who are unable to maintain average blood glucose levels due to severe episodes of hypoglycemia.

This therapy will allow some patients to live without external insulin for several years. This therapy could also have promise for the estimated 8 million people T2D, type 2, who also rely on insulin administration every single day. This would not have happened without STP funding.

Another game changer for people with diabetes is technology to better manage blood sugar levels. I and many others with type 1 wear an artificial pancreas system or AP systems. It consists of an insulin pump, a continuous glucose monitor, and a computer program called an algorithm that allows the pump and the CGM to communicate with each other and give the right amount of insulin at the right time.

AP systems aren't perfect. They don't replace what you lost when you developed type 1 diabetes, but they do make life better. Better blood sugar control and easier diabetes management. Several systems are on the market now and next gen systems are in the research pipeline.

Individuals with type 2 are also benefiting from these technologies. Many now use CGM to gain valuable information about how their food, exercise, stress, and other factors impact their lives, and help them better manage their blood sugar levels to improve their health. Just this last week, the ADA standards of care were updated to reflect the importance of diabetes devices and recommended them to patients right away when they are diagnosed.

Continued support of the STP will enable several long term T1D oriented research programs and clinical trial networks to continue their important work. It will enable researchers to explore new opportunities.

For example, highly beneficial SGLT inhibitors, drugs that lower blood sugar by preventing kidneys from re-absorbing glucose are approved type 2, but not for people with type 1.

We need to develop strategies to ensure these drugs can be safely used by type 1 people, which could reduce the costly and devastating impact of heart and kidney disease. Research for both type 1 and type 2 is critical to gain further understanding, advanced therapies, find cures, and JDRF and others are significantly investing in this research.

But absent Government support and investment, these advancements will slow. The cost of diabetes will rise. We need Congress to move swiftly and enact the STP and STPI funding contained in S. 1855.

Until cures, we need affordable insulin for all those who need it to live. JDRF supports the bipartisan Insulin Act of 2023, led by Senators Collins and Shaheen, and calls on Congress to support its enactment.

Thank you again for this opportunity to testify and I look forward to your questions.

[The prepared statement of Dr. Kowalski follows:]

PREPARED STATEMENT OF AARON J. KOWALSKI

Chairman Sanders, Ranking Member Dr. Cassidy, and Members of the Committee, I am Dr. Aaron J. Kowalski, Chief Executive Officer for JDRF, the leading global organization harnessing the power of research, advocacy, and community engagement to advance life-changing breakthroughs for type 1 diabetes—T1D. As a scientist by training, a person living with T1D, and someone with a brother with T1D, I have been honored to work for JDRF and to represent individuals and families impacted by T1D for the past 19 years, four of which have been in my current role.

I am also honored to testify and appreciate the Committee's focus on diabetes. I would like to start with a thank you. Because of your bipartisan leadership and support, and the steadfast leadership of Senate Diabetes Caucus Co-Chairs, Senators Susan Collins and Jeanne Shaheen, the Special Diabetes Program and the Special Diabetes Program for Indians (SDPI) are making a tremendous difference in the lives of people with diabetes and their hope for the future. These programs have helped to fundamentally change what it means to live with diabetes, have put new life-changing therapies in our hands, and have brought us closer to cures.

JDRF and our countless volunteers are grateful the Committee recognizes the importance of maintaining this momentum and building upon this progress with the approval of S. 1855, the Special Diabetes Program Reauthorization Act of 2023. We thank you and continue to work with your colleagues to ensure the 2-year, $170 million per year for each program, is enacted.

Diabetes—A Costly and Burdensome Disease

Far too many people are aware of "diabetes" but do not know the difference between type 1 diabetes (T1D) and type 2 diabetes (T2D). T1D is an autoimmune disease in which a person's pancreas stops producing insulin, a hormone that enables a person to utilize energy from food. The condition lasts a lifetime, and people with T1D must take insulin to live. T2D is a metabolic disease. With T2D, the body still produces insulin but cannot use it effectively.

Today, more than 37 million Americans have diabetes and 96 million have prediabetes. [1] Of those with diabetes, JDRF estimates that 1.4 million people have T1D. Diabetes affects people of all ages and races across the country. The complications that result from the condition are significant—ranging from heart disease and strokes to lower-limb amputations—and reduce life expectancy by at least 10 years

[1] Centers for Disease Control and Prevention. National Diabetes Statistics Report website. *https://www.cdc.gov/diabetes/data/statistics-report/index.html*. Accessed July 6, 2023.

in people with diabetes compared to people without diabetes. As a result of the breadth and impact, the total annual cost for diabetes in 2022 was $412.9B, including $306.6B in direct medical costs and $106.3B in indirect costs.[2]

Research for both T1D and T2D is critical to gain further understanding, advance therapies, and find cures for both conditions. JDRF and others are investing significantly in research, but absent additional investments the advances will slow significantly, while the costs of diabetes continue to rise exponentially.

JDRF—Partnering with the Federal Government

Before I share some of the exciting breakthroughs resulting from the SDP, I want Congress to know that JDRF's private funding works hand in hand with SDP funding to ensure that the most important and promising research projects have the support they need. JDRF accelerates the path to cures by raising funds and allocating them to T1D research and therapy development, as well as by leveraging our expertise and leadership to bring in additional funding and supporters.

I am proud to say that JDRF has invested more than $2.5 billion in research funding since our founding in 1970. And through direct research investments and partnerships within the public and private sectors, including through the SDP, we helped raise $473 million for T1D research and therapy development in JDRF's 2022 fiscal year. Investments from the JDRF T1D Fund, which is a separate mission-driven venture philanthropy fund focused on equity investments in companies developing life-changing T1D products, is a part of this total. This partnership between the public and private sectors is what it takes to deliver major advances for T1D research.

The Special Diabetes Program—Accelerating Breakthroughs

There has been tremendous progress that gives us hope for a brighter future. Here are some examples of the advancements that are exciting to the T1D community where the SDP played a role.

- **First Disease-Modifying Therapy Brought to Market**

  The SDP enabled the creation of TrialNet, the largest clinical network for T1D. TrialNet conducted the clinical trials that led to the November 2022 U.S. Food and Drug Administration (FDA) approval of Tzield, the first disease-modifying therapy for individuals at-risk for developing T1D. This therapy can delay T1D onset for almost 3 years; other therapies to delay and prevent onset are advancing in the research pipeline.

  A delay in the onset of T1D has a tremendous impact on the daily lives of people at risk for T1D, their families, and the overall healthcare system. It frees them from the constant burden and stress of blood glucose monitoring and insulin administration. It frees them from the worry and fear of short-and long-term complications, while giving them the opportunity to learn more about disease management. And it enables one to avoid the medical emergency that often accompanies a T1D diagnosis. This is both clinically and emotionally meaningful.

  With a therapy to delayT1D onset and others on the horizon, screening for the risk factors that trigger T1D is even more important. TrialNet has a screening program for those with a direct relative who has T1D; however, anyone who tests positive for risk factors may be eligible to enroll in a clinical trial. JDRF launched T1Detect, a community-based education and awareness program to expand screening to the general population. JDRF is also studying the age or ages when screening should be done. We know the need to focus on screening is great and look forward to talking with you further about it.

- **Advances in Cell Therapies**

  Another recent exciting development in diabetes research is the June 2023 FDA approval of the first cell therapy for adults with T1D. The approval is specifically for adults unable to maintain average blood glucose levels due to repeated severe episodes of low blood glucose levels or hypoglycemia. This therapy, with the use of immunosuppression, takes deceased donor islets and places them into people with T1D. This is an important first for

[2] American Diabetes Association. New American Diabetes Association Report Finds Annual Costs of Diabetes to be $412.9 Billion. *https://diabetes.org/newsroom/press-releases/new-american-diabetes-association-report-finds-annual-costs-diabetes-be* (2023)

the diabetes community, as it is a therapy that allows some patients to go without any injected or infused insulin for several years. This therapy could also have promise for the estimated eight million Americans with T2D who rely on insulin administration every day. Clinical trial data resulting from the SDP-supported Clinical Islet Transplantation Consortium contributed to this pivotal step toward identifying cures.

- **Artificial Pancreas Systems**

Yet another area of progress that is a real game changer for people with T1D is technology to better manage blood glucose levels. An artificial pancreas (AP) system consists of an insulin pump, a continuous glucose monitor (CGM), and a computer program called an algorithm that allows the pump and CGM to communicate with each other to give the right amount of insulin at the right time—much like the pancreas does in people without T1D. AP systems are not perfect, but they allow people to think about their diabetes a little less and have better blood glucose control, which improves the quality of life of those impacted by T1D and helps to mitigate costly and burdensome long-term diabetes-related complications. I was very involved in the development of AP systems and the approval process, and I'm thrilled to see the benefits that have resulted for myself, my brother who also lives with T1D, and the entire diabetes community.

SDP-funded research laid the early groundwork for developing AP systems. In fact, SDP funds contributed to the first fully automated insulin-dosing system being made available to patients in 2017, five to 7 years earlier than expected. Positive results from SDP-supported clinical trials since then have led to other FDA-approved systems and next-generation AP devices that have outperformed first-generation devices in children, adolescents, and young adults.

Individuals with T2D and athletes are also benefiting from some of this research. Many are now using CGMs to better monitor their blood glucose levels; gain valuable information about how food, exercise, stress, and other factors impact their levels; and better manage their levels for improved health or peak performance.

The Special Diabetes Program for Indians (SDPI)—Making a Difference

The SDP's sister program, the SDPI, is also demonstrating significant progress toward the prevention and treatment of T2D in American Indian and Alaska Native communities, which are impacted disproportionally by the disease. The SDPI serves 780,000 American Indians and Alaska Natives across 302 programs in 35 states. The program focuses on community-directed approaches that are culturally based.

Since the beginning of the SDPI, blood glucose levels have decreased by 11 percent, average LDL cholesterol risk factors have reduced by 25 percent, diabetes-related kidney disease has been cut by more than half, fewer people are developing diabetes, and primary prevention and weight management programs for Native youth have increased. That's amazing. These successes will continue, and even greater progress will be made with the continued Federal investment contained in S. 1855.

Future Opportunities—Building on the Momentum

While the opportunities before us are abundant, here are a few examples in need of funding with the next SDP renewal.

- **Fund Long-Term Research Programs and Clinical Trials**

Continued support of the SDP would keep several long-term T1D-oriented research programs and clinical trial networks running strong, enabling them to continue their work which has yielded so many exciting and promising discoveries. For example, The Environmental Determinants of Diabetes in the Young (TEDDY) study of 8,600 children, enrolled at birth and being followed until they are 15 years old, seeks to understand which environmental factors trigger or protect against T1D onset. Information on diet, infections, and other exposures is being analyzed from children who are progressing toward—or now have—full T1D onset. Results to date indicate that there are multiple pathways leading to T1D. Further investigation is needed to develop strategies to prevent the onset of the disease, ranging from a vaccine to specific dietary changes. The data collected from this study could also benefit other autoimmune diseases, such as celiac disease.

- **Protect Heart and Kidney Health for Those with T1D**

SGLT inhibitors, such as Invokana, Farxiga and Jardiance, protect heart and kidney health for people with type 2 diabetes but are not yet FDA approved for people with T1D. There is an immediate need to develop evidence-based strategies to ensure these drugs can be used safely by people with T1D, which could significantly reduce costly and devastating impacts of heart and kidney disease.

A recent study shows that for the current population living with T1D, lowering End Stage Renal Disease rates by 50 percent is expected to generate Medicare savings that build over time. At the 10-year mark, the cumulative savings to Medicare are $5.1 billion. By the 25-year mark, Medicare savings reach $13.6 billion [3]. These savings estimates do not incorporate individuals who will be diagnosed in the future and therefore are conservative.

- **Investigate Cardiovascular Disease in People with T1D**

Cardiovascular disease (CVD) in people with T1D is not as well studied as in people with T2D, even though it is a major cause of death in people with T1D. There is a major unmet need to identify the mechanisms that promote earlier development of CVD in people with T1D, to learn and develop new interventions to prevent and treat it.

Long-term, Uninterrupted SDP Support—A Critical Need

The critical research supported by the SDP requires lengthy periods to achieve optimal results. A long-term reauthorization would allow the National Institute of Diabetes and Digestive and Kidney Diseases to carefully plan the use of funds, which are directed toward new and ongoing clinical trials that take multiple years to complete.

Technology development also takes time. The noteworthy progress in developing artificial pancreas and other glucose management technologies has been spurred by long-term SDP support, as I noted earlier. For the scientists who conduct the research, long-term, sustained funding is incredibly important. With the uncertainty of sustained funding, they may pursue other research opportunities elsewhere. The assurance of long-term funding is also important to attract new talent to this field and to maintain a pipeline of future generations of scientists to conduct T1D research.

Again, I thank you Chairman Sanders, Ranking Member Dr. Cassidy, and Members of this Committee for advancing S. 1855—bipartisan legislation led by Senators Susan Collins and Jeanne Shaheen to renew the SDP and SDPI. I urge Congress to move swiftly and enact the 2-year, $170 million per year reauthorization for both programs so we can keep this exciting and life-changing momentum going.

Insulin Affordability—Also a Critical Need

While the focus of my remarks is on the SDP and SDPI, it is important to note that people with diabetes need access to affordable insulin until we have cures. I appreciate the Committee's interest in addressing this issue, as we all know the current drug pricing system does not work for countless people who need insulin to survive. Progress has been made but we need to take the next step. JDRF urges Congress to pass the bipartisan INSULIN Act of 2023, led by Senators Susan Collins and Jeanne Shaheen, which establishes a $35 per month insulin copay cap for people with commercial insurance and includes other provisions that would make insulin more affordable for everyone, regardless of insurance status.

Thank you again for the opportunity to testify. I look forward to answering your questions.

[SUMMARY STATEMENT OF AARON J. KOWALSKI]

Thank you. Because of your bipartisan leadership and support, and the steadfast leadership of Senate Diabetes Caucus Co-Chairs, Senators Collins and Shaheen, the Special Diabetes Program—SDP—and the Special Diabetes Program for Indians—SDPI—are making a tremendous difference in the lives of people with diabetes and their hope for the future. These programs have helped to fundamentally change

[3] Winn, A, Skandari, R, O'Grady, M, and Huang, E. "Potential Medicare Savings of Reduced End Stage Renal Disease in Patients with Diabetes," May 2023. Unpublished white paper.

what it means to live with diabetes, have put new life-changing therapies in our hands, and have brought us closer to cures.

JDRF and our countless volunteers are grateful the Committee recognizes the importance of building on this progress with the approval of S. 1855, the Special Diabetes Program Reauthorization Act. We thank you and continue to work with your colleagues to ensure the 2-year, $170 million per year for each program, is enacted.

Here are a few of the many exciting breakthroughs resulting from the SDP:

A new FDA approved therapy—Tzield can delay T1D onset—and the need for insulin—for nearly 3 years. Other such therapies are in the pipeline. This has a huge impact on the lives of people at risk for T1D and the overall healthcare system. To take advantage such therapies, we must ensure widespread screening for risk factors that trigger T1D.

In June, the FDA approved the first cell therapy for adults with T1D who are unable to maintain average blood glucose levels due to severe hypoglycemia. This therapy allows some patients to live without external insulin for several years and could have promise for the estimated eight million Americans with T2D who rely on insulin administration every day.

Several artificial pancreas (AP) systems are on the market and next generation systems are in the pipeline. They're not perfect, but they typically result in better blood glucose control. Individuals with T2D are also benefiting—many now use CGMs to gain valuable information about how food, exercise, and other factors impact their levels; and better manage their blood glucose levels.

Continued SDP support will enable several long-term T1D-oriented research programs and clinical trial networks to continue their important work. And it will enable researchers to explore new opportunities. For example, highly beneficial SGLT inhibitors—drugs that lower blood sugar by preventing the kidneys from reabsorbing glucose—are approved for T2D are not yet approved for people with T1D. We need to develop strategies to ensure these drugs can safely be used by people with T1D, which could reduce the costly and devastating impacts of heart and kidney disease.

Research for both T1D and T2D is critical to gain further understanding, advance therapies, and find cures for both conditions. JDRF and others are investing significantly in research, but absent additional government investments the advances will slow significantly, while the costs of diabetes continue to rise exponentially.

We need Congress to move swiftly to enact the SDP and SDPI funding, as contained in S. 1855. And until there are cures, we need affordable insulin for all who need it to live. JDRF supports the bipartisan INSULIN Act of 2023, led by Senators Collins and Shaheen, and calls on Congress to support its enactment.

Thank you.

The CHAIR. Thank you very much, Dr. Kowalski. This familiar product is a 20 ounce bottle of Coke. Contains over 15 teaspoons of sugar, more than twice the recommended daily limit for kids under the age of 18.

This is a 12 ounce can of Coke, and according to the Center for Science in the Public Interest, people who drink one or two cans of Coke a day, "have a 26 percent greater risk of developing type 2 diabetes than people who rarely consume such drinks. And the risks are even greater for young adults.?

Dr. Taillie, do you believe that Coca Cola and companies that make similar products should be marketing these products to children? Should there be labels on products like Coke warning people that regularly consuming sugary drinks substantially increases their chances of getting type 2 diabetes? Dr. Taillie.

Dr. TAILLIE. We know that food marketing is very effective for kids, and over 50 percent of our kids are still drinking products like Coke on a daily basis. That consumption has gone down over recent years, but still remains far too high.

These kids are being marketed products like Coke in many different ways. Increasingly, this is proliferating on social media and online, where kids aren't even able to identify it as advertising.

Kids are seeing nearly 200 ads a week for products like Coke. And so, this is really getting into their heads and creating these strong preferences for these products at a very early age.

In terms of clear labeling, we have a lot of data, both from experiments that we have done here in the U.S. and from global evidence from countries that have implemented these labels that these labels help people really clearly see when they are looking at the package that this is unhealthy.

Coke is a product that is more clear. More consumers know that sodas are unhealthy. But when we think about fruit drinks, those are the products that kids consume the most. Those are products that parents think are healthy. Those are confusing products, and they still contain a lot of sugar.

Warnings—warning labels would really help parents understand that better.

The CHAIR. Apologize for cutting you off. We don't have a lot of time. I want to go to Dr. Gearhardt.

According to your testimony, the food and beverage industry has used some of the same tactics as the tobacco industry to get our kids addicted to ultra-processed foods that are high in sugar, salt, and saturated fat.

Is that correct? Are we seeing products sold to kids similar to the style used by the tobacco companies?

Dr. GEARHARDT. Yes. So, there is documented evidence, given the intertwined histories between the tobacco industries and the processed food industries that these strategies used to sell, create market cigarettes were applied very intentionally to improve the profit margins of especially children's sugar sweetened beverages.

We know that our brains were never developed to handle this level of food reward, the amounts of sugar, how rapidly they are being delivered into the body. That these are really effective at engaging the core nerve circuitry of addiction.

The CHAIR. Thank you. Dr. Lipska, Ozempic costs about $12,000 per year in the United States, but just $2,000 here in Canada and $750 in Germany. What do these very high prices mean for your patients? Do you think your patients would be living healthier lives if we can make these drugs more affordable?

Dr. LIPSKA. Mr. Chairman, absolutely. These prices are, as I said, outrageous. And what happens is that patients cannot afford those medications and so they go without. And we know these medications have effects in terms of reducing the risk of heart disease. When people go without, they are at risk for these complications. They would be healthier if they were able to afford them.

The CHAIR. Would I be correct in saying not only do people suffer and die unnecessarily, but the cost to the health care system increases? If I can't give you a drug, you end up in the hospital. Am I correct in that?

Dr. LIPSKA. Absolutely. Absolutely correct.

The CHAIR. Okay.

Senator Cassidy.

Senator CASSIDY. I am going to defer to Senator Marshall. But before I do so, I would like to have unanimous consent—Senator Collins had to leave for a just called Committee hearing. She asked that I submit for the record testimony from the Endocrine Society. I ask for unanimous consent to do so.

The CHAIR. Without objection.

[The following information can be found on page 57 in Additional Material:]

Senator CASSIDY. With that, I defer to Senator Marshall.

Senator MARSHALL. Yes. Thank you. Ranking Member and thank you, Chairman. I sit here in this Committee hearing in my head is just spinning. Been on this Committee for 3 years and I am not sure we have made any meaningful impact yet on diabetes.

A huge epidemic, as we already know this. Through these opportunities to attack the nutrition standpoint, the education standpoint, it is time to stop studying it and forming committees.

It is time to move forward with action. I think we all understand the cost of prescription drugs is part of the challenge here. It is interesting to me that in 2022, Americans spent $633 billion on prescriptions, $633 billion. Almost $500 billion of that went through the hands of our pharmacy benefit managers.

$5 out of $6 that Americans spend on prescription drugs go through the hands of pharmacy benefit managers. And of course, there is kickbacks. They give some of that money back to Medicare and insurance providers, and we have no idea who and how much those are going to.

But in case you are feeling sorry for the PBMs, they had a profits of $27 billion in 2022. $27 billion was their profit margin. Three PBMs are now ranked 4, 5, and 12 on the Fortune 500 list. So, as I look to solving this problem of prescription drugs to treat diabetes, I tried to figure out where is the biggest bang for the buck without destroying innovation.

I keep coming back to these pharmacy benefit managers. We have done incredible work so far to address this problem, but our work is not finished. We have sponsored the Drug Act, which is a bipartisan, bicameral legislation that would delink administrative fees paid to PBMs from the price of prescription drugs.

Rather than paying a percentage of the drug, that there would be a flat fee. Obviously, the PBMs are motivated to the higher the drug costs, the more they are going to benefit when they get a percentage of that. We have had great colleagues here with Senators Kaine and Braun, and we withdrew our amendment because it didn't have a CBO score at the time.

But this remains my top priority. We had the CBO estimate. Guess what? This is going to save the Federal deficit by $654 million if it is fitted into the PBM Reform Act. Senator Collins said this legislation is literally right on the money, and certainly Senator Collins has been my mentor in trying to figure out what to do with diabetes here in many ways.

The underlying issue is that PBMs favor higher priced brand insulin over insulin biosimilars. We had hoped the biosimilars coming to market would help drive this down, but it remains a challenge.

This legislation eliminates the perverse incentives of PBMs to block access to affordable insulin, biosimilars, and generic drugs. Is there anybody on the panel that would disagree that by limit—by delinking this would help drive down the price. Does anyone disagree with that? Okay.

I just hope to have a commitment from our folks, from this Committee that we have continued to work on this and that somehow we could add this delinking amendment and get it as part of the package to move forward to actually impact the challenges that we have here already. I guess I got a minute and a half left.

Let's talk about education and nutrition. I will defend Coke and Pepsi for a second. They are going a lot to other more healthy drinks. I see them out there. And more and more, I see young people probably better so than people my age group making healthier choices. Does anybody have any comments on how we can promote that education in a better way?

Dr. TAILLIE. Sure. I mean, I think education is really important and we could do better in our schools by requiring nutrition education, which I believe is not currently required. But we also know that education isn't enough because there are all of these other forces around marketing and pricing, and really the confusing food labeling that makes it complicated.

When you are looking at that product, that sugary drink, and it tells you that it has got 100 percent vitamin C, it can still be hard to understand just how much sugar it has. So, there are other things that we could be doing besides education that would help people make healthier choices. Because we know people want to do that. It is just currently hard to do that even when they have education.

Senator MARSHALL. Okay, thank you so much. I yield back.

The CHAIR. Let me just briefly respond to Senator Marshall. I think you are aware that I consider the high cost of prescription drugs to be one of the great crises facing our healthcare system.

We are going to have to take on 1,800 well-paid lobbyists from the pharmaceutical industry here and all of the campaign contributions that they make. This ain't easy. But I think for the sake of diabetes and so many other illnesses, it should be a major priority of this Committee, and I look forward to working with you to make that happen.

Senator Hassan, I believe, is next.

Senator HASSAN. Thank you, Mr. Chair and Ranking Member Cassidy for this hearing. Thank you to our witnesses for being here today. Really helpful testimony. I want to start with a question to you, Dr. Lipska.

Last year, three major insulin companies announced that they would limit the cost of insulin to $35 a month for all patients. However, we have heard that patients may not actually be getting that discount at the pharmacy counter. In August, Senator Smith and

I wrote a letter to Eli Lilly, Novo Nordisk, and Sanofi asking how their companies will ensure that patients can get insulin at this lower price.

The responses from the companies confirm that many patients have to navigate a complex system of manufacturer coupons and online applications in order to access low cost insulin. While these programs allow drug makers to say that their insulin is low cost, it can be really nearly impossible for patients to navigate.

What are you hearing from your patients about the affordability of insulin and other diabetes medications?

Dr. LIPSKA. Thank you for this question. It is so important, and this is why I am here. I heard that the companies announced their cuts. I heard them give you their word, right, and my patients are not getting $35 insulin.

I thought initially, maybe they are doing something wrong. Let me try it. Let me try to print out the coupon. I asked my nurses in the Yale Diabetes Center, are you paying $35? Are you commercially insured? Are you getting this deal?

No, they are not either. So, I don't know. The system is really—it is really difficult to navigate, that is true. But we are savvy at the Yale Diabetes Center, and we can't get that deal.

Senator HASSAN. Well, that is very helpful and something that we all need to follow-up on, obviously. And I appreciate your work in this area. Dr. Kowalski, I wanted to turn to you and thank you and the JDRF for the important work you are doing to advance breakthrough treatments, and 1 day, a cure for type 1 diabetes.

In particular, you mentioned some of these clinical trials on one type of cell therapy, and Dr. Cassidy did too, called islet therapy, has been really promising. This therapy, along with bio-fabrication, is being researched and developed in New Hampshire.

I would invite the Chair and Ranking Member to New Hampshire to see our bio-fabrication center and could remove the need for insulin injections for some patients. Dr. Kowalski, I would like you to speak to the impact that this breakthrough therapy could have on patients with diabetes.

I would also like the Chair and Ranking Member to consider follow-up hearings or work on making sure that the FDA has the approval pathways they need for some of this groundbreaking research.

Dr. KOWALSKI. Excellent. Thank you for the question, Senator Hassan. And I was fortunate to be in Portsmouth at a groundbreaking for a cell manufacturing facility that Vertex is building. Cell therapies have the potential for me to take off my pump, and it gives me incredible excitement.

For years I mentioned cell therapies have provided a pathway to the cures, but they have required somebody to donate a pancreas upon death. We now have the ability to make insulin producing cells from stem cells.

The 8 million people in the United States on insulin could benefit from these tremendous advancements. And Senator Marshall said the Committee hasn't made an impact. They have, you have. The

advancements funded by STP to have brought us to the cusp. We are in human trials right now. People are coming off insulin.

The first patient has been off insulin for 2 years now. It is absolutely amazing. So, the continued support here is to drive this toward what we are calling it, an immunosuppression free version, and that is where further research is needed.

But the potential is massive. I truly believe I will be cured in my lifetime, as well my brother, who lives with type 1 diabetes, and this funding is critical to get us there.

Senator HASSAN. Thank you. One more question for you, Dr. Lipska, before my time is up. As we have heard today, new evidence shows that some diabetes drugs such as Ozempic appear to improve other conditions, such as obesity and heart disease.

However, with higher demand for these medications, I am hearing from constituents with diabetes who are experiencing really long delays to get their prescriptions filled. So, how can Congress ensure that all populations that can benefit from this medication have access to it?

Dr. LIPSKA. That is a very important question. Yes, I am seeing patients, my patients who come in previously well-controlled, uncontrolled diabetes because they are not able to access their medication. So, the supply issue is important, but there is also really important shortages because of the price.

Senator HASSAN. Right.

Dr. LIPSKA. And I think that is where this Committee can really help to ensure that patients can afford these drugs, which are transformative, but not if you cannot take it.

Senator HASSAN. Thank you very much. I yield, Mr. Chair.

The CHAIR. Senator Cassidy.

Senator CASSIDY. I will defer to Senator Budd.

Senator BUDD. Thank the Ranking Member. Thank the Chair, and the witnesses for being here today, including, I think, one from North Carolina.

Glad to have you all here. So, back in November, so not too long ago, The Wall Street Journal reported on a phenomenon where pharmacy benefit managers, PBMs, they favor drugs with higher list prices.

I think Senator Marshall mentioned this phenomenon. For example, one particular brand of insulin sells at $274 per vial, while an unbranded counterpart sells at only $25 per vial. Now, according to the Wall Street Journal, half as many Americans have insurance coverage for the less expensive product, as for the higher priced brand, which accounts for about 61 percent of the prescriptions.

Now, this is important because the PBMs that are in there, they preferred coverage for the higher priced medications because they are reimbursed on percentage of the list price. So, the proposal that Senator Marshall discussed on delinking PBM reimbursement from the list price, I think that would go a long way in realigning incentives to best serve the interest of the patients.

Now, a paper published by the American Enterprise Institute makes clear that the list price, and I believe the Chair mentioned

list prices when he was referring to some anti-obesity drugs that were $12,000 or so, but I don't think the list price is really the best way to look at that, and that is not the best indicator of their true cost.

Specifically, the study reveals that the rebates that manufacturers pay to those PBMs on anti-obesity medication can be as high as 80 percent of the list price. So, I ask unanimous consent to submit the paper for record.

The CHAIR. Without objection.

[The following information can be found on page 59 in Additional Material:]

Senator BUDD. Thank you, Chairman. Thank you. So, the question. Dr. Kowalski—again, thank you for being here. And again, I appreciate your presence in my State of North Carolina. You are making an impact there and a lot of friends affected by this in similar situation to you.

Natalie, thank you for sharing the story of your daughter, Nadia. So, the insulin of 100 years ago, they are not the same insulin that patients are utilizing today, as I understand. There have been countless innovations with insulin, auto injectors, longer lasting insulin, and some of the references you mentioned.

Dr. Kowalski, could you speak to how public, private partnerships have contributed to some of these advancements?

Dr. KOWALSKI. No, this has been an incredibly important field. When my brother was diagnosed in 1977 and I was diagnosed in 1984, we used to count pig insulin. It was really, really difficult to manage, incredibly unpredictable.

We have seen advancement over advancements in insulin, making insulin easier to use, more effective, and driving better outcomes. Today's insulins are not good enough, and I think this is the balance between innovation and access. JDRF believes we need to continue to innovate in better and better insulins.

For example, we have funded what are called glucose responsive insulins that would only work when your body needs them. These would be transformative. That said, an insulin that is generic and off the patent for many years needs to be accessible.

No one with type 1 diabetes should go without insulin. You die. If you took away my insulin pump, I would die within a week. So, this rationing of insulin is an unacceptable outcome in the United States of America.

This is a balance that we need to strike. But the advancements that continue are critically important. We know the average person with diabetes right now in the United States is not achieving their goals. We need to do better.

Senator BUDD. Appreciate you being here. I yield the floor.

The CHAIR. Thank you, Senator Budd.

Senator Smith.

Senator SMITH. Thank you, Chair. Thanks very much for this hearing, and thanks to all of you for being here. I want to just put a note on what Senator Hassan was asking about related to how people can get access to this, what seems like mythical $35 insulin.

I hear from Minnesotans every single day who tell me that they are rationing this medicine that keeps them alive. And then we have these big companies come in and tell us, oh, it's not us. We are doing everything that we possibly can. We are trying to—we are making our products available. And I don't believe it. I don't think that is what is happening.

Mr. Chair, I think that this is completely unacceptable and obviously it just pisses me off. I really appreciate your testimony about how food is being engineered by these big food companies to be addictive and the impact that has on people's health, their physical health, their mental health. It is pervasive.

I also have been really encouraged by some of the preliminary results that we are seeing for around enrolling diabetic or pre-diabetic patients in food as medicine initiatives. On the other hand, when you actually are consuming real food, it has a big impact on the quality of your health.

These studies, as I understand it, are showing decreases in A1C levels, increases in food security, and improvements in self-management of diabetes. So, Dr. Taillie and Dr. Gearhardt, could you talk a little bit about this? What is the potential of this?

What is the correlation between access to healthy foods and the risk of diabetes, and what should we be doing to take down some of the barriers that make it difficult for providers to support that kind of therapy?

Dr. GEARHARDT. Thank you so much for this really important question. We are actually doing work in my lab right now taking our food as medicine perspective. We have funding from the Eisenberg Family Depression Center at the University of Michigan.

Again, I am seeing as a clinical psychologist just this huge mental health epidemic in adolescents and teens. And we know that the majority of teens, teens are maybe getting more calories from ultra-processed foods than any other developmental stage young children or adults.

Yet we are seeing that when you can move people to real, nourishing whole foods, that it doesn't just help improve their physical health, but their mental well-being. And so, we are actually doing a trial to work with a company Fresh and Lean, to deliver affordable, convenient, minimally processed, ready to go meal packages for people as a potential treatment for depression.

I think we need to think not just about cost and protecting against marketing, but part of what ultra-processed foods do is they are super convenient. They have been designed so you can just pour in your mouth while you are driving your car—and cheap. And so, thinking about ways to make nutritious nourishing food convenient, accessible, and affordable so it can compete with these hyper palatable foods is key.

Senator SMITH. Thank you.

Dr. TAILLIE. The food is medicine data so far are very promising. It shows that it reduces food insecurity, increases intake of fruits and vegetables, and reduces A1C, so that is great. From a prevention perspective though, it means that somebody still has to get sick and access the health care system in order to get those pre-

scriptions. And in an ideal world, we would see that people had access to those foods as part of their daily lives before they develop obesity or diabetes.

Senator SMITH. I really appreciate that. And it gets to a whole other realm of questions that we could be asking if we were on the Ag Committee around challenges with concentration in the food sector, what that means for how people can get food, food deserts in rural communities and urban communities, particularly black and brown communities. There is a lot of work to be done there.

I want to just follow-up on this for a minute more. We know that American Indian and Alaska Native adults are much more likely than white adults to be diagnosed with diabetes. And we also know that the Special Diabetes Program for Native People, which funds community based initiatives, provides access to people to traditional food, native food is really effective because it incorporates traditional practices and traditional foods in combination with clinical interventions.

It seems like there is a correlation between what we are talking about here. Maybe, I just have a few seconds more, Dr. Lipska. Would you like to talk a bit about why this kind of program can be so effective?

Dr. LIPSKA. Absolutely. I actually spent some time working on the Navajo reservation, so I am very familiar with the setting and the rates of diabetes. You know, we have to tailor the foods, so they are culturally appropriate for our patients, and we have to—but I just want to say, I think we have to go really way upstream—I know we are out of time—with these interventions because it is much harder to intervene, as you said, once people already have prediabetes or obesity.

Senator SMITH. Thank you very much. Thanks, Mr. Chair.

The CHAIR. Thank you.

Senator Cassidy.

Senator CASSIDY. Senator Braun, would you like to go?

Senator BRAUN. Thank you. I am ready. This has been a subject of interest for me way before I got to the U.S. Senate. When you are talking about diabetes, drugs, prevention, and remediation, I wrestled with it to where I was at the point of frustration.

There was nothing that you couldn't generally solve in running a business other than health care, which generally ended up how lucky you were that it was only going up 5 to 10 percent each year.

When we were at the point where I could really do something about it large enough to self-insure, did three simple things. No. 1, I realized none of my employees were health care consumers.

They were the inelastic demands of remediation, generally wanting the plan to pay for everything. And in the same way, if your private plan doesn't pay for it, people look to Government to do it. It has created a system that has given us a bizarre kind of cross purpose where it doesn't jibe with what works in most other markets. What I did, they became health care consumers.

I gave them every wellness tool, including a free biometric screening. I didn't coddle them. You were going to pay more if you

wouldn't take that. And you know what it has done? It has lowered health care costs. Not—we have been doing that 15 years and have not had a premium increase.

I would like Dr. Lipska and maybe Dr. Kowalski, how much of what we are talking about here is part of a broken system that is now driven mostly by huge hospitals that love opaqueness, no transparency, and insurance companies that have gone way beyond indemnification to where they are in on everything, and they grab roughly 15 percent of the health care dollar that is purely administrative.

We are talking about things, I think, on the side of how you fix diabetes and other chronic ailments. What about fixing the system itself? I would love for you, Dr. Lipska, to weigh in, and then Dr. Kowalski.

Dr. LIPSKA. Thank you for that question. I agree with you that our system is broken.

In terms of how do we fix this for diabetes in particular, to prevent diabetes, to prevent obesity, I think we—the health care system needs to serve the needs of the patients who develop these conditions, but I think we have to, again, go upstream from the health care system in order to prevent people from getting sick in the first place.

I think that is critical. That is going to save us money and in the long run to keep people healthy. And I think that is upstream from the health care system.

Dr. KOWALSKI. So, I will just make a quick statement because I am going to come in with a research perspective. But start by saying we are talking a lot about obesity and diet, that being obese does not mean you are going to get diabetes.

Sometimes I worry we stigmatize people with type 2 diabetes by saying, and some of our colleagues said this, but you just stop eating and you will get diabetes. This is a genetically inherited disease, so——

Senator BRAUN. And I know that. I am asking about the framework within which you would like to see that we address it and many other things.

Dr. KOWALSKI. Absolutely. So, when we think at JDRF, our mission statement is accelerating life changing breakthroughs to cure, prevent better treat T1D and its complications.

I always take those words very literally and significantly, meaning your life has not changed if you don't have access to better care. And if the system provides barriers, as Senator Sanders said, to drugs that could improve your care and your life and your health, then we haven't succeeded in our mission.

Senator BRAUN. And I agree with that. And I think that is a particularity that will weigh in to be helpful. Let me tell you what I think is a solution to this and the extremely high cost of health care, access and all of it. And proud to say that later today, Senator Sanders and I will be introducing a bill called the Healthcare Price Transparency Act.

I have been working on this for the 5-years I have been in the Senate, and I think it is the umbrella that finally takes us to solu-

tions for this and many other things. Briefly, let me tell you what some of the things it is going to do. It is going to require machine readable files of all negotiated rates and cash prices between plans and providers, not estimates.

It is going to require pricing data standards, including all billing codes for services. It is going to require actual prices for 300 shoppable services, with all services by 2025. It is going to require a testing by executives that all prices are accurate and complete.

It is going to prevent preemption of state price transparency rules, codify the transparency coverage rule, and it is going to provide group health plans the right to access, audit, and review claims and counter data.

Thank you, Senator Sanders and Senator Smith for being on it. I hope to get all Republicans and Democrats on a bill that will fix many aspects of health care.

The CHAIR. Thank you, Senator Braun.

Senator Hickenlooper.

Senator HICKENLOOPER. Thank you, Mr. Chair. I thank all of you for being here. I have got a few questions, so I am going to hope you can be very concise. This morning, we have discussed what more we need to do to address upstream causes of obesity that are leading to higher rates of diabetes in our Country.

It is particularly important that we think about what we can do early on to ensure a fewer of our kids end up with type 2 diabetes. In addition to nutrition, one major tool, which has been talked about somewhat, to improve overall health and wellness is access to green spaces and outdoor activity.

Green spaces and getting kids into outdoor recreation can help promote the kind of lifestyle that keeps kids healthy. One in three Americans, including 28 million children, don't have access to green space within a half a mile. We are working on legislation to create a Federal Office of Outdoor Recreation, which will help ensure equitable access to recreation in all communities.

Let's start with Dr. Gearhardt and Dr. Taillie. Can you discuss the benefit that physical activity with healthy eating, along with healthy eating, can have in delaying or preventing the onset of type 2 diabetes?

Dr. GEARHARDT. So, we see that physical activity and nature can play a big role in our overall mental health and well-being. We do see that the role of nutrition and diet can kind of swamp some of those effects.

But I think you are right that it has really got to be multipronged and multifaceted, and we need to take holistic views, but also invest our energy and resources where it is going to make the biggest bang for our buck.

Dr. TAILLIE. Yes, to build on that. The diabetes prevention program showed that the combination of physical activity and diet changes were tremendously effective at preventing type 2 diabetes.

But at the same time, going back to Senator Sanders showing us that can of Coke, we know that it is really, really easy to drink a

can of Coke, and that would require exercising, running a mile and a half to offset that can of Coke.

It is really important to, in my view, really prioritize nutrition coupled, of course, with physical activity to promote overall fitness.

Senator HICKENLOOPER. Great. Thank you so much. Community health centers place an emphasis on integrated care models, take a comprehensive approach to patient care, focusing not only on treatment but prevention, nutrition, exercise, other social determinants of health.

We have seen some compelling data on this Committee that shows community health centers are more successful at helping patients with hypertension and diabetes control these issues, which really is remarkable because community health centers are more and more dealing with complex chronic conditions.

Dr. Lipska, what can other health care providers learn from community health centers and their approach to caring for a diabetes patients?

Dr. LIPSKA. Thank you. And I think it has to do a lot with the fact that community health centers take that holistic population view as opposed to the rest of health care, which often takes care of the patient in front of you, bill for the service, and then that is it, right.

I think that if we have these systems where you are responsible for the care of the population of patients, you are going to put more emphasis on prevention of disease rather than just treatment of complications when they occur. So, I think we can all learn a lot from that. I think that they are doing a great job.

Senator HICKENLOOPER. I agree. Just one other point on that, or separate from that, is consuming these ultra-processed foods like sugary drinks and all these things you have been—we have been talking about are also connected with higher rates of dementia in later in life. I didn't know whether you or any of the others would like to comment on that.

Dr. GEARHARDT. Yes, there has been some people have even started to think a little bit of Alzheimer's and dementia as type 3 diabetes. It has been discussed a bit.

I could say we have done research with the National Poll and Healthy Aging at the University of Michigan that found in older adults, 13 percent endorsed clinically significant signs of addiction in their intake of ultra-processed foods, and that was associated with higher mental health, physical difficulties, and overall tendency to have a lower quality of life.

I think older adults are a really key population whose increase of ultra-processed foods has been increasing remarkably over the last couple of decades.

Senator HICKENLOOPER. Got it. Great. Thank you. And just very quickly, Ms. Stanback, the National Institute of Diabetes and Digestive and Kidney Diseases at NIH funds this critical research across the country.

University of Colorado, a Denver diabetes research center with this important support, is spearheading research into type 1 and

type 2 diabetes. They also run a program to recruit young faculty into diabetes related research.

Your experience, first with your brother and then with your daughter Nadia, highlights the importance of prioritizing research and making sure future scientists are focusing on treatment. How have the recent medical breakthroughs, even over the course of Nadya's life, changed her experience of living with type 1?

Mrs. STANBACK. Peace of mind. A lot of us are talking about the pharmacy, pharmaceuticals and the medicines that help people with type 1 diabetes, but it also presents a very mental—a serious mental burden that presents in the form of burnout and other things that are detrimental to the health of people living with type 1 diabetes.

Her insulin pump and the CGM gives not only her but me also peace of mind and being able to manage the cumbersome disease.

Senator HICKENLOOPER. All right. Thank you. Thank you all. Appreciate you spending time to be here. I yield back to the Chair.

The CHAIR. Thank you.

Senator Cassidy.

Senator CASSIDY. We have 5 minutes, so if I interrupt you, I am not being rude—or maybe I am being rude, but that is the reason.

[Laughter.]

Senator CASSIDY. Dr. Kowalski, you mentioned risk factors for type 1 diabetes, but what is there besides genetics? What are the risk factors? Are there other risk factors that we don't know about?

Dr. KOWALSKI. Well, I think you are—so you are hearing that in both forms of diabetes, there is——

Senator CASSIDY. Just type 1.

Dr. KOWALSKI. Okay, but it is genetics and an environmental factor. And if we could find that environmental factor, we could stop this disease.

Senator CASSIDY. So, when you mentioned that we need to focus upon the research, it is just that this has to be developed. It is not that we know it now. You said that we need to study those who have the risk factors, but the principal risk factor would be like Ms. Stanback's family. My gosh, maybe yours because you mentioned your brother having it.

Dr. KOWALSKI. Yes. No, no, there is definitely a genetic component to type 1 diabetes. We know that well. But if you have an identical twin, it is not 100 percent that the second twin, if the first one develops it, will get it.

We have, for example, the STP funding a very, very important study called Teddy that tracks from in utero to adulthood children at high risk. And we are looking at environmental factors that could be triggering the disease. That will stop——

Senator CASSIDY. Let me interrupt you. I graduated from med school in 1983, and they have been talking about it since '83. So, obviously it is pretty difficult to tease out what those environmental factors are.

Dr. KOWALSKI. Very difficult, but we do have a number of candidates that are moving into human clinical trials, and we believe that we will get there.

Senator CASSIDY. That is fantastic. Ms. Stanback, Dr. Lipska mentioned that in her clinic, the workers there have a hard time getting $35 insulin. We know, we are told up here, but we often don't know what we know.

You are the person who has been kind of living with this. So, what is your experience in terms of—and I ask this not knowing the answer, what is your experience in terms of getting affordable insulin?

Mrs. STANBACK. Our insulin is only affordable because we are paying top tier for our private insurance. But I have also not seen it——

Senator CASSIDY. Let me ask you, do you have any insight into what your pharmacy benefit manager—because we have been told pharmacy benefit managers deliberately do not take the low cost insulin but rather get the higher cost insulin because frankly, the PBMs allegedly make more money by costing you more money. Do you have any insight into that?

Mrs. STANBACK. I don't I just know that we selected the highest tier of the insurance provided by my employer to make sure that we cannot have any ambitions when it comes to choice or selection of insulin.

Senator CASSIDY. That is great. And Dr. Lipska, do y'all have any insight into what Yale does for its PBMs? Because again, this does come up continuously and this is the big rub. Eli Lilly says, hey, listen, we are given it for $35. Yes, there is a tax, there is a dispensing fee, but our cost is $35.

The PBMs allegedly are saying, no, we are going to give you the top dollar and we are not going to take this one. Do you have any—when you inquire about this, do you know whether that extra cost being paid is due to the PBM or to the drug company?

Dr. LIPSKA. That is a great question. I don't know. I honestly haven't been able to get to the bottom of why this happens because it is so difficult.

Senator CASSIDY. So, let me ask then, and this may come to you, it is my understanding that on some of these processed foods, it is fructose more than glucose or sucrose, which is the problem.

That fructose is more quickly absorbed and causes a greater sugar high and kind of the greater sugar low, so therefore you want another hit. Now, again, I haven't looked at this for some time, but is that still kind of the thought?

Dr. LIPSKA. Yes, I think—I don't know if the other panelists want to answer that as well since, again, I treat diabetes, but I am familiar with some of that research and I understand that is true, that fructose does activate those rewards systems.

Senator CASSIDY. Could one of you all answer that quickly, please?

Dr. TAILLIE. That is true. But the high fructose corn syrup that we are consuming is actually very similar to sugar, from a chemical composition perspective.

Senator CASSIDY. The fructose?

Dr. TAILLIE. The main—yes.

Senator CASSIDY. Yes, but the fructose is more quickly absorbed.

Dr. TAILLIE. The main issue is also that we are consuming it via liquid forms, which means that it is much more rapidly digested. And that is true for ultra-processed foods as well. The way that those foods are made means that they are metabolized much more rapidly.

Senator CASSIDY. I get that, yes—the more fiber, the apple juice is absorbed more rapidly than applesauce, which is more rapidly than an apple.

Dr. TAILLIE. Exactly.

Senator CASSIDY. More fiber is slower absorption. But fructose is the independent factor, and it does seem like fructose is a particular issue here, I will just point that out. Ms. Stanback, coming back to you.

Again, we have had these kind of conversations as regards PBMs. When you change insurance companies, because periodically employers do, are they making you go through a prior authorization process for whatever your daughter's currently on?

The brand new one, no, this didn't work before, but you got to go through it once more just to satisfy our requirements?

Mrs. STANBACK. No, not with our private insurance. It is through my employer.

Senator CASSIDY. Do you have a big employer or a small employer?

Mrs. STANBACK. It is fairly large.

Senator CASSIDY. Do you mind telling us?

Mrs. STANBACK. I work for AMN Healthcare, medical staffing.

Senator CASSIDY. Yes. That is a pretty big company. Okay, well, I am almost out of time, but I thank you all.

The CHAIR. Thank you.

Senator Kaine.

Senator KAINE. Thank you, Chair Sanders. And great hearing, great witnesses. I would like to put an unusual document into the record. It is a JDRF 2023 children's Congress scrapbook.

A bunch of students in Virginia who have diabetes told their stories and they are Emory Ellis, Maddie Hawkins, Riley Kitts, Karson Owen, Jack Samples, Jane Vanden Eykel. I think these are worthy testimony.

I just want to read one that was interesting from Maddie Hawkins. She is in a family where mom, dad and her brother, the mother doesn't have diabetes, all the others have type 1 diabetes.

Listen to this. My dad was diagnosed with diabetes before I was even born and my brother diagnosed in 2020, so it is always crazy at my house. There is always some alarm going off, always someone who needs to treat their blood sugar. My mom's goal in life is

for all of us to have the same blood sugar at the same time, but that hasn't happened yet. Still, at the end of the day, sharing diabetes creates a sense of camaraderie.

Then there is a picture of the dad and the two kids who share this camaraderie because they have diabetes. I would just like to put that into the record.

The CHAIR. Without objection.

[The following information can be found on page 60 in Additional Material:]

Senator KAINE. And focusing on young people, during the height of the pandemic, Congress provided schools with a lot of flexibilities around meals.

One in five kids in the U.S. live without constant access to adequate food, and this temporary expansion during COVID allowed students, especially those in high need areas, to have much more access to meals that were nutritious.

Now, the pandemic era policies in several states have enacted legislation allowing for universal free school meals. In Virginia, there are currently about 511 schools that have adopted the community eligibility provision where eligible schools can offer meals at no cost to all students.

I am heartened to see this uptick in the CEP in my home state. Dr. Taillie, what impact does the nutritional value of school lunches have on students health, and what can Congress do to improve health outcomes for kids?

Dr. TAILLIE. School foods are probably the No. 1 way that we could promote healthier diets among kids and ultimately prevent diabetes. Kids consume a third of their daily calories in school, so this is incredibly important.

Universal school meals are critical because it ensures that all kids have access to food. We know that adequate nutrition is not only important for health and growth, but it promotes learning outcomes.

It also means that kids are stigmatized for receiving when only some kids get this benefit. So, in addition to universal school meals, as I said in my testimony, really making sure that our schools are free from corporate food marketing, ultra-processed foods, sugary drinks.

The marketing and advertisement and sales of those products to our kids is currently a major problem, and so reducing or eliminating that would make huge progress.

Senator KAINE. Let me ask another question. I have heard an interesting policy debate, and the question is should SNAP benefits be usable to purchase unhealthy and ultra-processed foods? Those who say yes say you shouldn't have a separate standard for people using a SNAP benefit—pardon, person using dollars and cents.

Those who say that SNAP benefits shouldn't be used, say why would we want to pay tax dollars to enable people to purchase foods that make them sick or kill them? And if SNAP benefits weren't usable for unhealthy foods, the food retailers and grocery stores that are in neighborhoods where there is a high percentage

of SNAP recipients would have more of a motive to offer more healthy food options. What do you all think about that debate?

Dr. TAILLIE. Yes, I can weigh in on this. I have tried to do research in the past on this and wasn't able to receive funding. I think it is really important to make sure that people who are using SNAP have dignity and choice.

At the same time, when we think about restricting, I think the clear place where we would start with that is around sugary drinks. I think there is an argument to be made that those may not even be considered as foods.

They provide no nutritional value. And the health harms are so very clear that SNAP is currently not allowed to use for like hot meals or alcohol or things like that, and I could see putting sugary drinks into that category.

Senator KAINE. Are thoughts from other panelists?

Dr. GEARHARDT. I think the problem is that those foods are also—the unhealthy foods are also cheaper, right. So, then your SNAP benefit is going to go potentially a longer way—if you can make those foods, the healthy foods, more affordable, that would make it easier.

Dr. TAILLIE. And beyond restricting, the double up box program is a really effective strategy to instead of saying, well, you can't buy this, to incentivize people to buy fruits and vegetables by giving them more money to do that.

Senator KAINE. Thank you. Mr. Chairman, last I will mention, which isn't really a question, is I know we are talking about doing work on the Older Americans Act next year, and I think there is a lot in this space that really we could do as part of a reauthorization of the Older Americans Act that has been touched on in the testimony earlier and look forward to working with you on that.

The CHAIR. I agree. Okay, Senator Casey.

Senator CASEY. Thank you, Mr. Chairman. I want to thank the panel. And sorry I wasn't here earlier. We had an Aging Committee hearing that I was Chairing that overlapped. So, we have your testimony, and I am—I know that Sara and my team has been here for the whole hearing.

I wanted to thank the witnesses for your testimony, bringing both experience and expertise to these issues. And I know the hearing touched on a number of critical issues relating to diabetes and including the high cost of insulin.

I was one of the, many were co-sponsors of Senator Warnock's bill that proposed a cap on co-payments for insulin in the commercial market at $35 bucks a month. That was similar to what we passed and the Inflation Reduction Act for Medicare Part D beneficiaries. So, I just have two questions, Dr. Kowalski, and I will start with you.

Type 1 diabetes is often perceived as a disease of children and young adults, but as health care for people living with diabetes has improved, it is truly a disease that can affect people a much longer time period throughout their lives, as you know. Are there specific challenges or factors we should consider with respect to older adults with type 1 diabetes? That is the first part of the question.

Then second, are there medical issues that need more research or policy changes specific to the needs of older adults that you would recommend?

Dr. KOWALSKI. Well, the great news is people with Type 1 diabetes are living longer. When I was diagnosed, we were told we were to have significant reduction in lifespan. And my brother and I fortunately are doing well, and many people.

That said, we know that older adults are particularly susceptible to severe hypoglycemia, hypoglycemia unawareness, which kind of called for because falls and broken bones.

Unfortunately, broken bones are another issue in older adults with diabetes. So, that is an area. Reducing hypoglycemia is a big, big priority. As we drive better glucose control, we know that complications of diabetes that have been mentioned by a number of panelists, heart and kidney in particularly, are forestalled but don't go away.

The risk of long term kidney disease, which is a major driver of CMF's cost, is another area where we are making progress. We have mentioned the benefits of these new drugs. GLP, SGLP inhibitors can reduce diabetic kidney disease and cardiovascular disease, a particular problem in older adults for type 1 and type 2 diabetes. So, this is an opportunity to reduce costs and improve care.

Senator CASEY. Thanks very much, Dr. Taillie—did I pronounce it right? Nutrition for children is obviously fundamental, as so many have made reference to. I introduced a bill that focused on what I believe are what should be the five freedoms for children.

One of them is a freedom from hunger, in addition to health care and education, and so much else that we want to provide our kids.

At the end of your written testimony, I think it is on page six, you mention the need for more research into nutrition science. What are some of the current gaps in our knowledge about nutrition, especially as it relates to kids?

Dr. TAILLIE. One of the gaps that we have been talking a lot about is the fact that we still don't have a really good understanding for the biological mechanisms of how ultra-processed foods work. They are such complex substances.

Kevin Hall at DNH did a wonderful trial that was the first step in showing this, but there have been no additional studies to replicate that, to look at this issue in kids, and to really go further—to really isolate what those effects are.

I think that would be the first piece of this. And then the second piece is understanding from a population level perspective, we are not thinking about how to treat these kids, we are trying to think about what policies work more broadly to prevent hunger and also promote healthy diets, because those things often kind of go hand-in-hand.

We have a lot of kids who are hungry and also consuming diets that are really high in sugary drinks and ultra-processed foods.

Senator CASEY. Thanks very much. Thanks, Mr. Chairman.

The CHAIR. Senator Cassidy, you want a brief closing remark?

Senator CASSIDY. Yes. Dr. Kowalski, I know you would agree with me totally, but just for the record, you mentioned that obesity does not necessarily lead to type 2 diabetes, but let's not imply that obesity does not have other problems associated with it.

Hip replacements, joint replacements, heart disease, hypertension, gallstones, what was mentioned earlier about Alzheimer's, on and on and on. And so, I am a big proponent for obesity research.

If the metabolic syndrome is almost always triggered by obesity, and I used to tell my medical students it is a hydra headed monster, and diabetes is one of those but there is many others as well.

I think we need to be asking the NIH and CDC to focus more attention upon obesity in of itself. And I know you agree with that, but just for the record.

Dr. KOWALSKI. I agree.

The CHAIR. That was a brief remark. Good. Let me thank all of our witnesses. I thought a very informative hearing, and I thank all of you for being here.

We have touched on a lot of issues the need for more research in type 1 diabetes and the need to address the crisis, and our kids becoming too heavy and the foods that they are eating, what they are drinking, and the need for affordable treatments.

We covered a lot of territory that I hope this Committee will effectively deal with but thank you all very much for being here. And with that, this is the end of our hearing today, and I—for any Senators who wish to ask additional questions, questions for the record will be due in 10 business days, December 29th at 5.00 p.m.

The Committee stands adjourned. Thank you all.

ADDITIONAL MATERIAL

ENDOCRINE SOCIETY

The Endocrine Society thanks the Senate Health, Education, Labor, and Pensions (HELP) Committee for conducting this hearing on the diabetes epidemic. We appreciate that the Committee is examining this critical issue, which impacts millions of people across the country. The Endocrine Society is the world's largest and oldest Society representing clinicians and scientists working to treat and research endocrine diseases and disorders. Founded in 1916, the Society represents approximately 18,000 physicians and scientists engaged in the management and research of endocrine disorders. Our membership includes over 11,000 clinicians who are on the front lines in treating diabetes and obesity, which are two of the most common chronic illnesses in the United States. Our member researchers are making significant contributions to the advancement of knowledge in diabetes research, prevention, and treatment and we have prioritized these issues in our policy work.

There is a diabetes crisis in America requiring immediate attention by Congress. Diabetes affects over 38 million people in the United States, which represents 11.6 percent of the U.S. population, and this number continues to increase at an alarming rate. The prevalence rate is even more alarming when broken down by race, ethnicity, and age. Approximately 29.2 percent of people over the age of 65 have diabetes; 16 percent of American Indian and Alaska Natives; 12.5 percent of African Americans; and 10.3 percent of Hispanic Americans have diabetes. No part of the country is immune from diabetes and many of the states represented by Members of this Committee are significantly impacted by this disease. Despite the fact that we know how to effectively treat and manage diabetes, prevent type 2 diabetes, and delay the onset of type 1 diabetes the number of people with diabetes continues to rise and people living with diabetes continue to experience barriers to access to care and affordability of the medicines they require. The Endocrine Society urges the

Senate HELP Committee to support and advance the following **bipartisan** legislation to address the diabetes crisis in our Country today: Reauthorization of the Special Diabetes Program, passage of the INSULIN Act, and passage of the Treat & Reduce Obesity Act.

Special Diabetes Program

The Special Diabetes Program (SDP) is a Federal program comprised of two components: the Special Diabetes Program for Type 1 Diabetes and the Special Diabetes Program for Indians (SDPI). Congress created these programs in 1997 to advance research for type 1 diabetes at the National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK) and to provide type 2 treatment and education programs for American Indians and Alaska Natives (AI/AN). SDP continues to receive strong bipartisan support because of the program's many successes. It has delivered groundbreaking research on the artificial pancreas, which has led to the development of commercial devices; research that has resulted in the FDA approval of the first drug that can delay the onset of type 1 diabetes; and the first cellular therapy to treat adults with type 1 diabetes who have reoccurring episodes of dangerously low blood glucose levels. SDP is currently operating on a short-term extension which expires on January 19th. Short-term extensions are extremely harmful to the Program and make it difficult for researchers to map out long-term plans for their research. It also puts the important education and treatment programs for AI/AN communities in jeopardy. **We urge Congress to reauthorize SDP through the end of 2025 at $170 million per-program, per-year, which is a 13 percent increase in current funding**. We were glad to see that the HELP Committee approved S. 1855, the Special Diabetes Program Reauthorization Act in a bipartisan fashion and we urge the Senate to reauthorize SDP before the program expires on January 19, 2024.

Insulin Affordability

As you know, insulin is a life-saving medication for many people living with diabetes. Unfortunately, despite being over 100 years old, insulin is a medication that continues to be unaffordable for many who rely on it. While the Endocrine Society hears from our members about many different clinical and research issues, the rising out-of-pocket cost of insulin is one causing the greatest concern for our patients. **We urge the Senate to pass S. 1269, the INSULIN Act of 2023, which is bipartisan legislation that would improve insulin affordability and access for the more than 7 million people nationwide who rely on this medication to manage their diabetes**. This legislation, introduced by Senators Jeanne Shaheen (D-NH) and Susan Collins (R-ME), the co-Chairs of the Senate Diabetes Caucus, includes several policies to make insulin more affordable. It would expand the $35 insulin co-pay cap, currently available for people on Medicare, to the private insurance market which would ensure that people on private health plans would pay no more than $35 per month for their insulin. The legislation would also ensure that people who rely on insulin are able to share in insulin rebates and discounts which often go to pharmacy benefit managers and private insurers. Finally, the legislation would promote competition by encouraging the approval of more generic and biosimilar insulins.

Obesity

While the primary focus of this briefing is on diabetes, it is also important for the Committee to recognize obesity, which is related to diabetes and another costly chronic disease impacting millions of Americans. As you know, people living with obesity are at increased risk of developing type 2 diabetes and many other complications. We are alarmed by the increased prevalence of obesity across the country. Over 42 percent of all U.S. adults and over 19 percent of children are estimated to have obesity in the United States. Obesity has a significant impact on economic costs accounting for $170 billion in higher medical costs each year. It has also impacted our Nation's military readiness and national security. Just over 1 in 3 young adults between the ages of 17 and 24 are too heavy to serve in our military. The management of obesity includes a range of options including lifestyle intervention and pharmacotherapy. Unfortunately, there are restrictions currently in place which prevent millions of Americans from accessing obesity treatment and care. Most notably, Medicare is currently prohibited by statute from covering FDA approved anti-obesity medications. Research shows that adding pharmacotherapy for weight management results in increased weight loss and overall improved health. Because Medicare is unable to cover these medications, which are scientifically proven to be

effective, many private insurers also do not cover them because Medicare often sets the standard on what is covered. **We urge the Senate to pass S. 2407, the Treat and Reduce Obesity Act (TROA), which would allow Medicare to cover FDA approved anti-obesity medications and also make it easier for Medicare beneficiaries to access Intensive Behavioral Therapy (IBT), which is an effective lifestyle intervention for obesity**. We encourage you to work with your colleagues on the Finance Committee to advance this important legislation.

We commend the Committee for taking time to discuss this critically important issue of diabetes and the impact it has on millions of Americans. We urge you to work swiftly to pass bipartisan legislation that prioritizes the groundbreaking research that continues to be done and ensures access and affordability for people living with diabetes and obesity. Our patients living with diabetes cannot wait longer. The Endocrine Society would like to work with you by providing information, having our member diabetes experts be a resource to you, and sharing our recommendations as you consider how to address this important public health issue. Please do not hesitate to contact Rob Goldsmith, Director of Advocacy and Policy, at *rgoldsmith@endocrine.org* for more details.

ESTIMATING THE COST OF NEW TREATMENTS FOR DIABETES AND OBESITY

The rising popularity of drugs to treat obesity and diabetes, including Ozempic, has focused attention on their costs. However, existing research has incompletely characterized prices by focusing on only discounted list prices. We estimate that net prices received by drugmakers are 48–78 percent lower than list prices. In effect, we document a large difference between net payments to manufacturers and the prices faced by some consumers who pay list prices, even after we adjust for currently available coupons from manufacturers. We conclude by highlighting uncertainty surrounding future prices of drugs in this class and policy implications.

The introduction of glucagon-like pcptide–1 agonists (CLP–1s), which include drugs such as Ozempic, represents a milestone in the treatment of diabetes and obesity. Clinical evidence suggests that diabetes products can help control blood sugar among diabetics, lower weight, reduce cardiovascular events and ease symptoms of heart failure. [1]

With mounting evidence of clinical benefit, these drugs have attracted understandable levels of policy attention, much of it focused on their cost. Recent projections suggest revenue for GLP-1s could reach $100 billion annually over the next decade (Erman 2023).

The majority of news coverage and research on these drugs has focused on their publicly available list price. [2] While list prices arc relevant for some patients, prior research has shown that this is often a highly incomplete summary of typical transaction prices in the U.S. This reflects the relatively opaque use of "rebates" and other discounts, which alter the prices paid for branded drug products.

In this report, we aim to characterize the prices of these drugs more completely. In doing so, we hope to give researchers, policymakers, and journalists a fuller and more accurate understanding of these products' current costs.

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[1] For a discussion of evidence on glucagon-like peptide-1 agonists (GLP-1s), see Herman (2023). For recent evidence on semaglutide's effect on major adverse cardiovascular events, see Novo Nordisk (2023). For recent evidence on semaglutide's effect on heart failure, see Kosiborod et al. (2023).

[2] For example, see Amin et al. (2023) and Cirruzzo and Leonard (2023).

Children's Congress
JDRF

SENATOR

TIM KAINE

Meet your JDRF 2023 Children's Congress Delegates

VIRGINIA

Emory Ellis

Maddie Hawkins

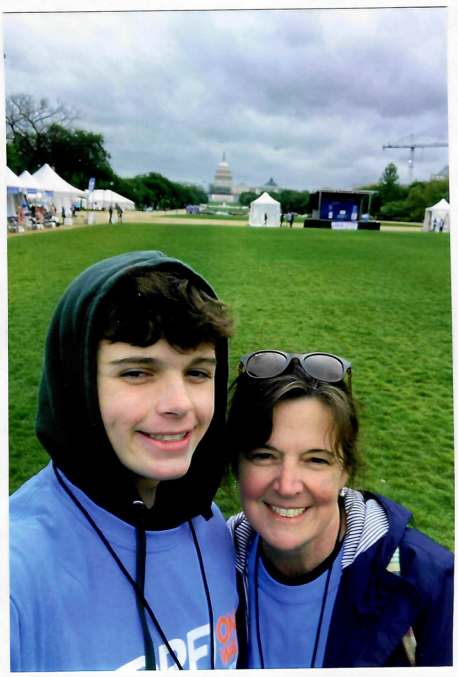
Riley Kitts

Karson Owen

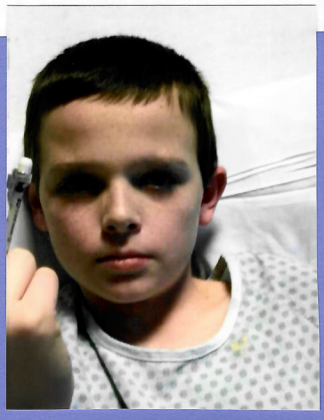
Jack Samples

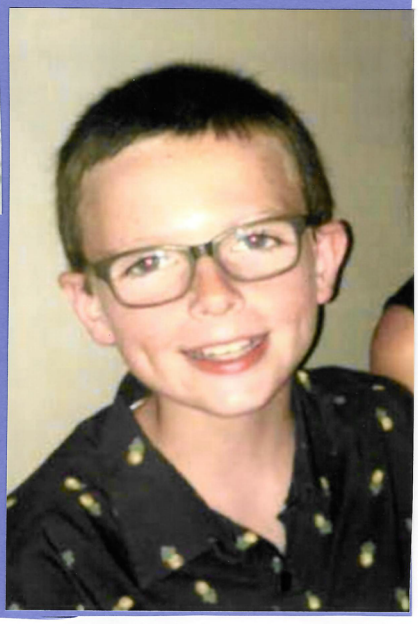
Jane Vanden Eykel

My name is Emory Ellis, and I am excited to be a delegate from Virginia at the 2023 JDRF Children's Congress! I live in Ashburn, VA and am a rising senior at Stone Bridge High School.



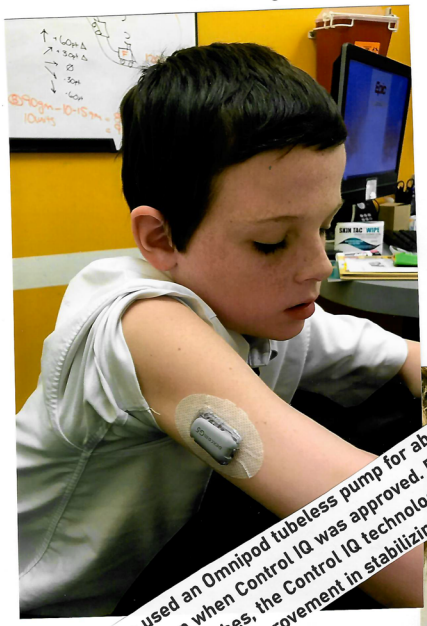
I was diagnosed with Type 1 Diabetes on March 5, 2018 when I was 12 years old. My diagnosis came a year after my older brother, Declan, was diagnosed and a year before my older sister, Annie, was diagnosed. Since my brother had been living with T1D for a year, we were able to recognize the symptoms early enough to keep me from going into DKA at diagnosis.



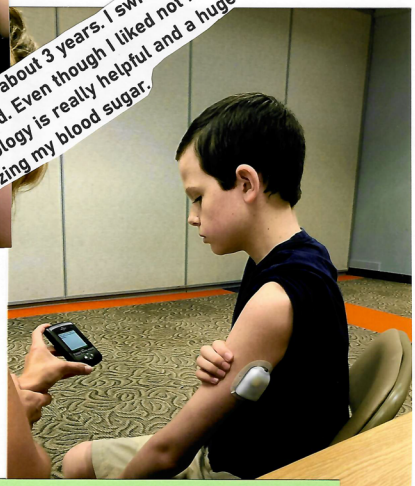


3/5/18

I knew I wanted to use a continuous glucose monitor. I saw how much easier it was for Declan to manage his highs and lows when he got his CGM, and our Dexcoms come with an app that lets my mom know if we have an urgent low or if our blood sugars go too high.



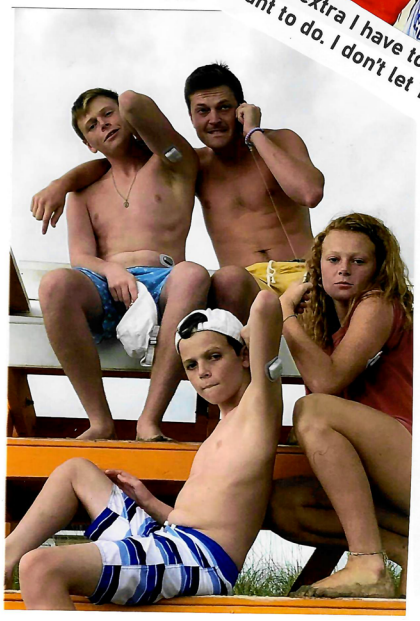
I also used an Omnipod tubeless pump for about 3 years. I switched to a tSlim pump when Control IQ was approved. Even though I liked not having wires and tubes, the Control IQ technology is really helpful and a huge improvement in stabilizing my blood sugar.

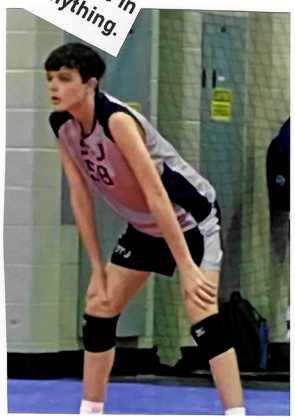


Every new advancement in technology means a healthier, safer life for people with T1D. I hope that one day soon the technologies that keep us safe will be accessible to everyone living with T1D.

I am thankful to have siblings who understand what it is to live with T1D. We support each other and help each other through the challenges that come with living with T1D.

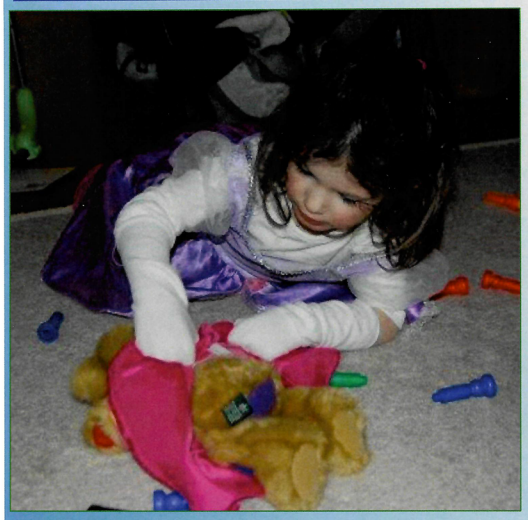
In spite of everything extra I have to manage, I still participate in all the things I want to do. I don't let T1D keep me from anything.



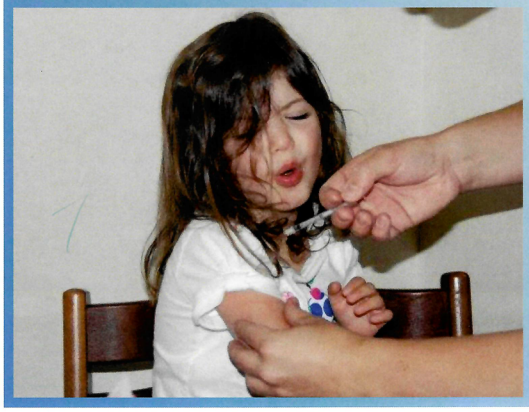


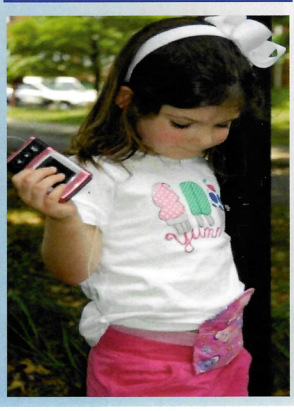

MADISON
Hawkins
Delegate from
Arlington
Virginia
17 Years Old

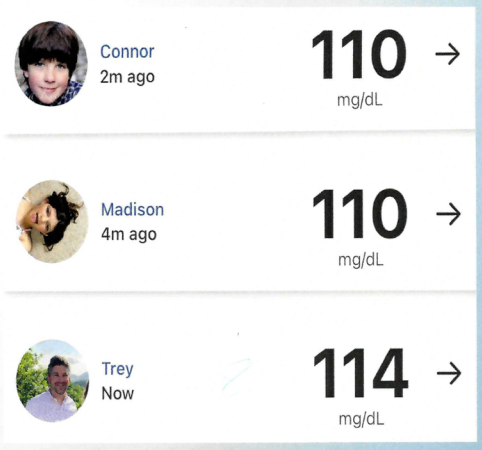
On February 19th, 2009, a month after my 3rd birthday, I got diagnosed with Type 1 Diabetes. I don't remember much about that day, nor the following months, but I do remember my dad sitting with me in my hospital bed. My dad had diabetes as well, and he told me that everything would be alright, words which have stuck with me forever.



At the hospital, I got a JDRF bear, named Madison Bear. She went through all the same trials as me, from receiving shots (shown in the picture) to getting a new pump.







My dad was diagnosed with diabetes before I was even born, and my brother was diagnosed in 2020, so it's always crazy at my house. There's always some alarm going off, always someone who needs to treat their blood sugar. My mom's goal in life is for all of us to have the same blood sugar at the same time, but that hasn't happened yet. Still, at the end of the day, sharing diabetes creates a sense of comradery.

I've participated in many clinical trials over the years, from week long summer camps to many months of wearing the same version of a new insulin pump. I know I can make a difference when I participate.

In fact, I'm currently in a trial right now at UVA!. This is a picture of me and my brother with a new version of the a Tandem pump. We are testing out new features that will come out in a few years.

About me

RILEY

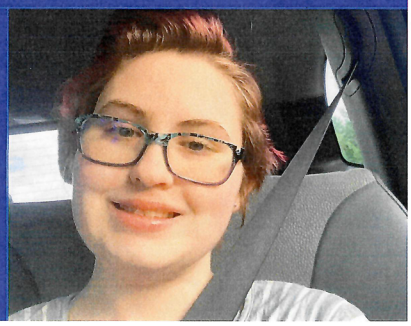
Hi, my name is Riley I'm 15 years old and live in Culpeper Virginia.

My diagnosis

Before Diagnosis.

After diagnosis

I don't remember my diagnosis, since I was 21 months. Ive been told that I was constantly thirsty and wetting through my diapers. I was also extremely grumpy and was usually a happy toddler. My parents took me to the doctor, and my blood sugar was too high to read on the meter. I then spent several days in ICU.



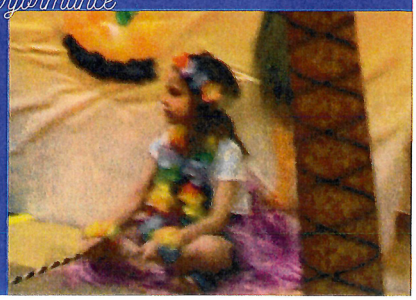
Theatre

Annie JR: Sandy

Moana Jr. Ensemble

I enjoy participating in theatre. I like to take theatre classes at my school and I have done 2 musicals. I also enjoy participating in my schools improv troop.

Preschool Performance

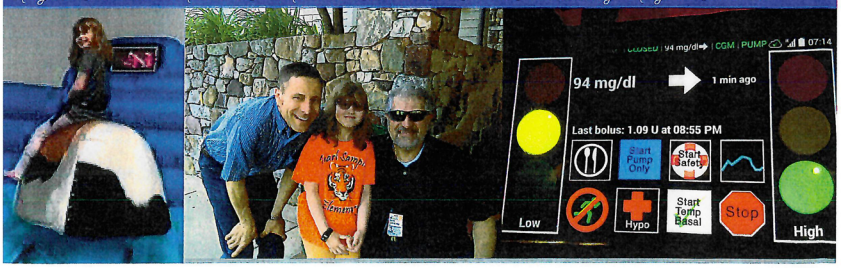


Advocacy work

JDRF Walks

For advocacy work, I have done 3 clinical trials. One of the first artificial pancreas trials and two Tandem T-slim Control IQ trials. My family and I have done about two walks for JDRF and look forward to doing more.

Artificial Pancreas Me with Dr Mark de Boer & Dr Daniel Chernawosky Artificial Pancreas

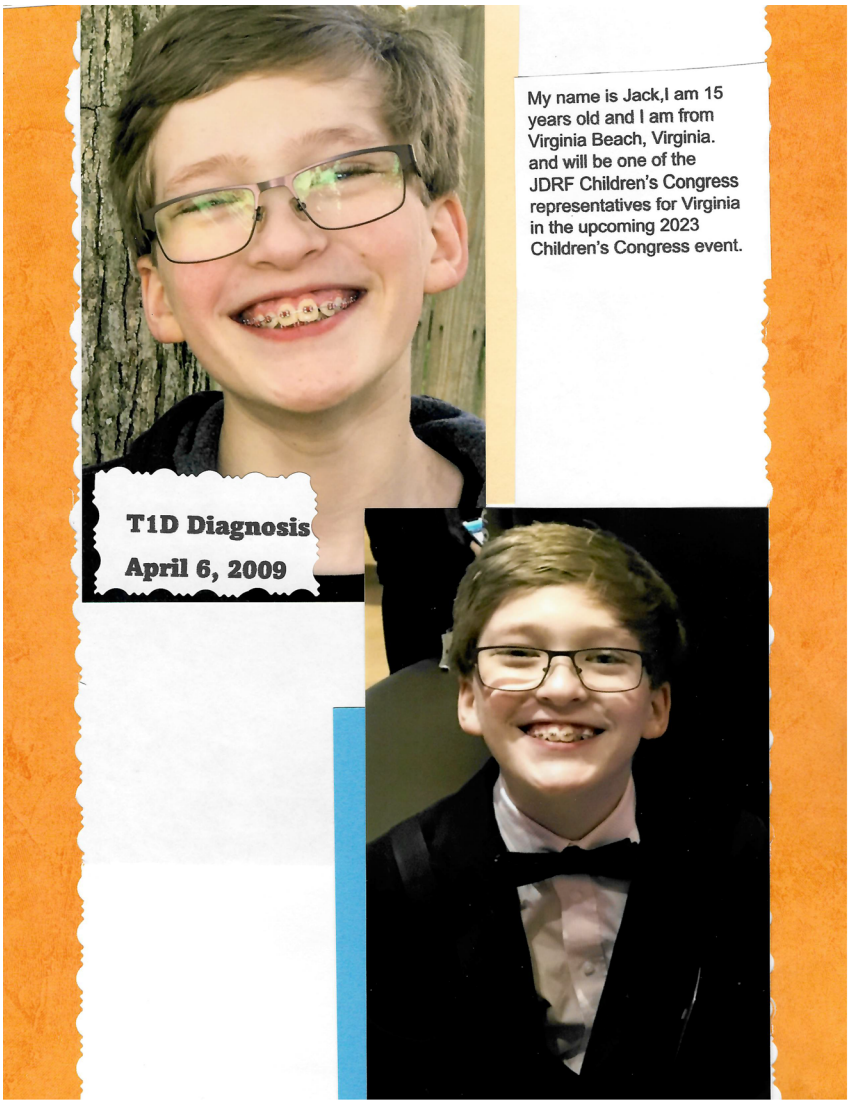



Karson
Age 11
(12 on 7/8)
T1D
Warrior
Born
and
Raised
in
Richmond, VA
JDRF
YOUTH AMBASSADOR
2020-Present
When I grow up
I want to be
a Scientist!
VIRGINIA
IS FOR
LOVERS
T1D
K.O. a Kure for T1D
JDRF Walk Team
#KoaKurefort1d
JDRF Children's Congress
2023

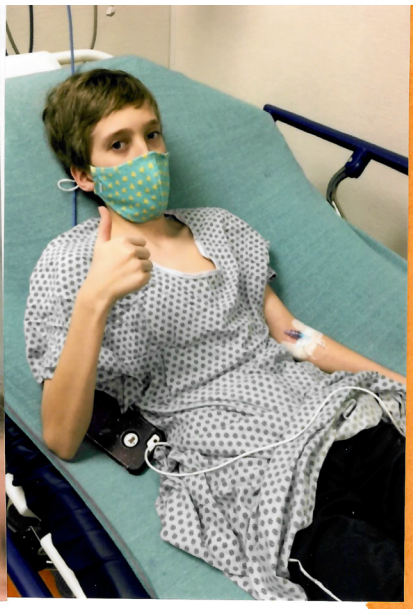

There are 3 of us with Type1 Diabetes:
My Sister Kamryn: Children's Congress 2013
Age 22 Diagnosed 7/9/2008
ATS
Me: Children's Congress 2023
Age diagnosed 8. Date 2/27/2020
My mom Treina – T1D for over 30 years
Just born! Picking up my sister from diabetes camp Wanna Cure, I weighed 6 lbs, 1 oz I still love Spongebob to this day!
Diagnosed 2/27/2020, my 1st visit to the Endocrinologist was 2 hours after 4:00 am. I got my JDRF bag & hope!
Crying happy tears when I found out I was chosen as a JDRF Ca2023 Delegate!
JDRF 2023 Children's Congress
JULY 9-11
page 2


GO BLUE
FOR DIABETES AWARENESS
TUES NOV 1ST
#KOAKURE
Greatest Leader
Nominated in 11th grade.
HAMILTON
APRIL 11 - 23
BROADWAYINRICHMOND.COM
Met Sponge Bob this Spring Break!
I love, love, love Hamil. I sing all the songs! I went to the play!
Started my middle school's 1st Go Blue Day 11/1/22
I love music! I play many instruments, including drums.
Page 3

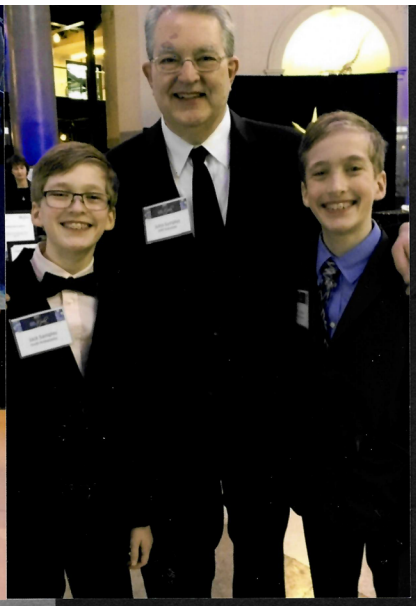

My Family! Volunteers 2023 Gala Fund A Cure
MILE OF HOPE
Karson, Kamryn, and Treina Owen
Ages 10, 21, and 42
K.O. A CURE FOR T1D
JDRF ONE WALK
K.O. a Kure for T1D 2022 Walk Team
K.O. A KURE FOR T1D
IN THIS FAMILY, NO ONE FIGHTS ALONE!
#KOAKUREFORT1D
Honored to meet President Joe Biden at Bermana Community College 2021. I didn't want to wash my hand he shook!
Invited to meet the POTUS by Congresswoman Abigail Spanberger!

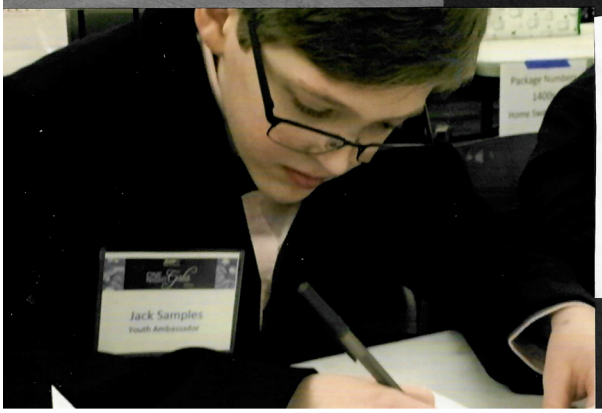

My name is Jack,I am 15 years old and I am from Virginia Beach, Virginia. and will be one of the JDRF Children's Congress representatives for Virginia in the upcoming 2023 Children's Congress event.
T1D Diagnosis
April 6, 2009


Although T1D comes with its complications I try to not let it get the best of me and I still do the things I love.

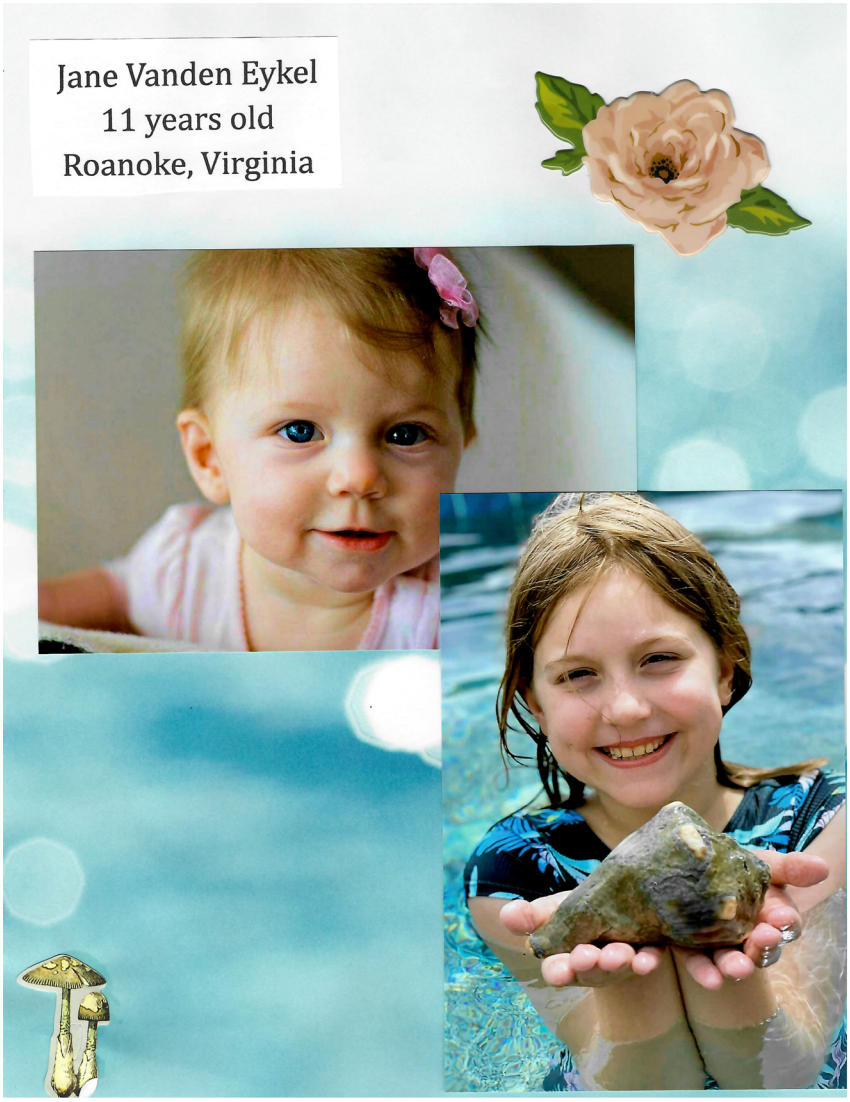


Our JDRF team was named Team Jackman because at that time I was the only member of myfamily with diabetes but as of recently we've changed the name to Team Betes Brothers due to my brothers diagnosis





Since I was young I've been involved with JDRF starting the year after I was diagnosed. In that time I've done a fair bit of of advocacy which include fundraising and saying the pledge of allegiance during the One Walk attending multiple fundraising galas and being a Youth Ambassador for nearly 3 years.


Jane Vanden Eykel
11 years old
Roanoke, Virginia


DOCUMENT THIS
My Diagnosis
when I was Diagnosted with type one diabetes on febuary 18, 2017 I was scared of needles, but I was mostly just hungry! soon I started using a continues blood glucose monitor and a pump, both of which helped me do what I did best while staying safe


I have walked in JDRF ONE WALKS, helped with our local JDRF Gala, Served as a JDRF youth Ambassador, and organized Fundrasors at home and School.
JDRF
TEAM JJF
I am participating in th
JDRF Roanoke One Walk
Support me by visiting
alk.jdrf.org/GBR
Advocacy


I love to play basketball, Hike, play Pokem, and read histord fictoin, I am also starting to baby sit. Someday I would love to become an entomologist
Insectes. Pl. 6.
1. Du Fenouil.
2. Du Ricin.
3. Apollon.
4. Sa Chenille.

[Whereupon, at 11:39 a.m., the hearing was adjourned.]

○