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PRICED OUT OF A LIFESAVING DRUG:

THE HUMAN IMPACT OF RISING INSULIN COSTS

TUESDAY, APRIL 2, 2019

House of Representatives

Subcommittee on Oversight and Investigations

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:31 a.m., in Room 2322 Rayburn House Office Building, Hon. Diana DeGette [chairwoman of the subcommittee] presiding.

Members present: Representatives DeGette, Schakowsky, Kennedy, Ruiz, Kuster, Castor, Sarbanes, Peters, Pallone (ex officio), Guthrie, Burgess, Griffith, Brooks, and Walden (ex officio).

Also present: Representatives Rush, Welch, Barragan, Soto,

Bucshon, and Carter.

Staff present: Kevin Barstow, Chief Oversight Counsel; Jesseca Boyer, Professional Staff Member; Jeff Carroll, Staff Director; Tiffany Guarascio, Deputy Staff Director; Chris Knauer, Oversight Staff Director; Jourdan Lewis, Policy Analyst; Perry Lusk, GAO Detailee; Kevin McAloon, Professional Staff Member; Kaitlyn Peel, Digital Director; Tim Robinson, Chief Counsel; C.J. Young, Press Secretary; Jennifer Barblan, Minority Chief Counsel, O&I; Margaret Tucker Fogarty, Minority Staff Assistant; Brittany Havens, Minority Professional Staff, O&I; Ryan Long, Minority Deputy Staff Director; Zach Roday, Minority Communications Director; and Natalie Sohn, Minority Counsel, O&I.

Ms. DeGette. The Subcommittee on Oversight and Investigations will now come to order. Today, the Subcommittee on Oversight and Investigations is holding a hearing entitled, "Priced out of a Lifesaving Drug: The Human Impact of Rising Insulin Costs." The purpose of today's hearing is to examine insulin affordability challenges and the financial and health consequences on patients' lives. The chair now recognizes herself for the purposes of an opening statement.

Today, the subcommittee holds its first hearing in this Congress on the rising costs of prescription drugs which have devastating real-life consequences for families around the country. We are here this morning to examine the impacts of climbing insulin costs on the seven and a half million people in the United States who rely on insulin every day to manage their blood sugar levels and prevent debilitating complications.

Insulin insures the health and well-being of millions of people and for the 1.25 million people with type 1 diabetes it is a life-sustaining drug for which there is no substitute. The scientists who made the discovery of insulin knew of its lifesaving importance. Even nearly a hundred years ago, they were concerned that the discovery would be commercialized to the point of being put out of financial reach for those who needed it. To avoid this, they sold the insulin patent to the University

of Toronto for one single dollar. Yet, today, skyrocketing prices are making it unaffordable for millions of people in this country.

The price of insulin has doubled since 2012, after nearly tripling in the previous 10 years. We have been hearing stories and reading disturbing news reports for too long. People are skipping doses, failing to pay rent or buy groceries, and even resorting to an insulin black market to afford their insulin.

Just this past Friday, at home in Denver I had a listening session and I heard from some of my constituents as to just how real this crisis is. One of the people who came was a woman named Sierra. Sierra does not have insurance and she makes too much money to qualify for Medicaid. She has been struggling for the past year and a half to pay for her insulin. She took three jobs. She made other adjustments in her life in order to cut costs in her personal life, selling her car and living with relatives.

Even rationing her insulin, for example, not changing the reservoirs in her pump like she is supposed to, she is still paying out-of-pocket over $700 a month for her insulin. She is living day-to-day, bottle-to-bottle. She told me she was in the hospital. She went to the emergency room four times in past months, and, good news, they brought her blood sugar under control. And for her, better news, they gave her one bottle of

insulin. She said, "And that lasted me 2 weeks."

Now parents with children with diabetes are also living with this constant stress and worry. For example, last year, I heard from a parent in New York whose 23-year-old son was diagnosed as a type 1 diabetic at age 7 and needs insulin to survive. They said, quote, they worry that he won't be able to afford it once he is off our insurance.

Something must be done. Insulin doesn't make him better, it keeps him, literally, alive. No one should be forced to live under this strain or make incredibly difficult choices to afford insulin. But according to available data that we will learn more about this morning, about one in four people with diabetes are rationing their insulin due to costs. Not surprisingly, these patients were three times more likely than patients who weren't rationing their insulin to struggle to maintain healthy glycemic control and experience adverse health effects.

These stories and findings show just how urgent this issue is. Lives really are at stake, which is why last year Congressman Tom Reed and I, as co-chairs of the Congressional Diabetes Caucus, conducted an enquiry into the rising costs of insulin. The report ultimately depicts a system of perverse payment incentives and methodologies, a lack of transparency and pricing, and outdated patient regulations. These market failures have allowed a

handful of players along the insulin distribution pipeline, from manufacturers to health insurers, to capitalize on their strategic positions, driving up the price of insulin and minimizing competition. Now it is not my intention to blame these players, but to further examine where the pressure points are throughout the supply chain that are driving the increased costs of insulin to the patient.

And this discussion is critical in advance of next week's hearing when we will have several of the key players in front of this committee to discuss the drivers directly. I look forward to hearing from all of our witnesses today who collectively represent a range of key stakeholder associations and networks, clinicians and research perspectives, and also people with firsthand experiences with price challenges.

I want to thank each one of you for coming today and sharing your stories with us. Bringing this conversation to light is essential. Better understanding these factors will help us inform the policy decisions and actions. Millions of people who rely on insulin each day and sometimes many times a day are counting on that. Thank you.

And now I recognize the ranking member for 5 minutes.

[The prepared statement of Ms. DeGette follows:]

128 ********** COMMITTEE INSERT 1 **********

Mr. Guthrie. Thank you, Chair DeGette, for bringing this important hearing together. And we are working together to try to get to the bottom of what is happening in the insulin prices and hopefully use that as a case study for looking at others. The rebates are not only in the insulin space, but the Centers for Disease Control and Prevention estimates that more than 30 million individuals or 9.4 percent of the population in the United States have diabetes. A 2018 American Diabetes Association report found that diabetes is the most expensive chronic disease in the United States. According to this analysis, the economic cost of a diagnose of diabetes in the United States in 2017 was $327 billion. The CDC estimates in 2016 about 6.7 million Americans aged 18 and older used insulin.

The insulin prescribed in diabetics today is different than insulin discovered over a hundred years ago. Changes to this lifesaving drug over the years meant that according to the American Diabetes Association, almost everything has changed over the past 50 years for Americans with diabetes including how long a diabetic can expect to live. However, the list price of insulin has increased substantially over the past decade, putting this lifesaving drug out of reach for too many Americans.

According to a 2016 study, the average list price of insulin nearly tripled between 2002 and 2013. Many argue that while list

prices have been increasing, net prices have not grown as rapidly having stayed relatively the same or even gone down. For example, one popular insulin product had its list price increase from $391 in 2014 to $594 in 2018, a 51.9 percent increase. During the same time, however, the product's net price decreased by 8.1 percent, going from $147 to $135.

While no one is supposed to pay the list price for insulin, some patients end up paying the list price or close to it especially if they are uninsured or underinsured. An uninsured patient that purchases insulin at the pharmacy is likely to pay the list price for the medicine unless they have access to a Patient Assistance Program. Further, even if a patient has insurance, increasing list prices oftentimes directly harm patients by increasing their out-of-pocket costs. If they have a high deductible health plan as many Americans do today, they are likely to go pay the list price or close to it until they reach their deductible.

While Patient Assistance Programs can be a helpful resource to patients, we have heard from patients and patient advocacy groups that it can be difficult to qualify for a Patient Assistance Program. Patient Assistance Programs are viewed as a helpful resource, but only as a Band-Aid and short-term solution until we can find a permanent solution that improves access to and

affordability of medicine such as insulin. In addition, we have heard the formulary exclusions are helpful to drive down costs to the plans. We have also heard that they are having an impact on patients in the diabetic community.

We have heard stories that some patients have had their insurers change the insulin products covered by their plan year to year, or even in some cases in the middle of the year causing them to have to switch to a different insulin product or pay a higher price for the insulin that has been working best for them. Doctors and patients have shared that it can take days or weeks for someone to adjust to a new insulin if they adjust at all.

The prescription drug supply chain is complex and it lacks transparency. There is limited public information regarding changes in net prices due to a lack of transparency surrounding rebates and other price concessions. This makes it difficult to fully understand why prescription drug prices like insulin have continued to rise for patients, especially uninsured and underinsured patients. This lack of transparency makes it hard to determine who benefits from increases in list prices, but we know who loses: the patient. Prescription drug prices affects every American and that is why today's discussion using insulin as a case study is an important step to better understand the rising costs of prescription drugs in our country and how

we can work to make lifesaving prescription drugs more affordable for all patients again. I thank all of our witnesses for being here today and sharing your testimony and I look forward to this important discussion and I yield back.

[The prepared statement of Mr. Guthrie follows:]

********** COMMITTEE INSERT 2 **********

Ms. DeGette. The chair thanks the gentleman. The chair will now recognize the chairman of the full committee, Mr. Pallone, for 5 minutes for purposes of an opening statement.

The Chairman. Thank you, Madam Chair. Today's hearing continues our important effort to examine the high cost of prescription drugs. It is the first of a two-part hearing the subcommittee will hold on the urgent matter of skyrocketing insulin costs in the U.S.

American families are suffering from the ongoing and staggering price hikes of insulin. We have all heard the stories of people with diabetes who have gone to extreme measures to obtain the insulin they need as well as those who have died because they could not afford the lifesaving drug. Of the 30 million Americans living with diabetes, over seven million of them rely on one or more formulations of insulin and no one should suffer because the high price of insulin puts it out of reach. Yet that is exactly what is happening. Over the last 20 years, prices for the most commonly prescribed insulins have increased by more than 700 percent accounting for inflation. For instance, a vial that once cost $20, 2 decades ago, now costs over $250, and there are reports of patients paying more than $400 per month for their insulin. And this is particularly devastating for the uninsured, people who have high deductible insurance plans, and Medicare

Part D prescription drug beneficiaries who may be in the coverage gap.

We must find workable solutions to support the development of high quality drugs and insulin innovations while also ensuring that no one living with diabetes is ever forced to put their life at risk by rationing their insulin because they can't afford it. As the committee continues to explore this issue, it is important to hear today about the drivers of these steep prices and their consequences on the lives of people living with diabetes.

Multiple factors influence the price the patient pays for insulin at the pharmacy. The lack of transparency and financial agreements between stakeholders in the supply chain makes an already convoluted system even more complex, but at least some of the pressure points are clear. For instance, we know that insulin manufacturers set the list price of their drugs and may engage in practices that prevent the introduction of generics.

We also know that pharmacy benefit managers, PBMs, influence these prices within and throughout the supply chain through negotiated rebates. And we are going to have representatives of these companies before the committee next week and I look forward to asking them about the examples and issues we will hear about this morning.

Finally, as with other drugs, insulin pricing is a complex

issue that will require multiple policy solutions. However, I have concerns with the recent proposed rule that would eliminate rebates in Medicare Part D and Medicaid. There is nothing in this proposed rule that would actually require drug manufacturers to reduce their list prices and Health and Human Services' own actuary estimates that the proposal would increase government spending by nearly $200 billion while premiums and out-of-pocket costs would go up for the majority of Medicare beneficiaries.

So I strongly believe that the cost of prescription drugs including insulin must be addressed, but I am concerned that this is not the right approach what has been put in place by the Trump administration. So, finally, if I could just say, the health of millions of people living with diabetes depends on thoughtful policy solutions to address the high cost of insulin.

I thank our witnesses for joining us today. Your firsthand accounts, research, and recommendations will be invaluable contributions as we continue to examine this issue. I don't know if anybody wanted my time. And, if not, I will yield back. Thank you, Madam Chair.

[The prepared statement of The Chairman follows:]

********** COMMITTEE INSERT 3 **********

Ms. DeGette. The chair thanks the gentleman and now recognizes the ranking member of the full committee, Mr. Walden, for 5 minutes for purposes of an opening statement.

Mr. Walden. Thank you, Madam Chair, and I deeply appreciate you having this hearing. It is really important. My grandfather suffered from diabetes a long time ago and I can remember as a little kid he lost both legs to gangrene. And that was, you know, you just don't understand that stuff as a kid. My cousin has dealt with diabetes her entire life. So this is really important stuff. And I know your family has issues.

And we have to get to the bottom of this because this is a lifelong disease and it affects millions of Americans including more than 300,000 Oregonians. And due to the significant research and development efforts of biopharmaceutical companies, there are over 30 types of innovative insulin available in the U.S. and come in a variety of different formulations and different delivery mechanisms, and there are also obviously numerous oral medications available for type 2 diabetes to help manage the disease.

I am proud our committee has championed efforts to accelerate the discovery, development, and delivery of innovative drugs over the last 2 years under the bipartisan leadership of former chairman Fred Upton and of course Congresswoman DeGette.

Congress enacted the 21st century Cures Initiative and our work is not done. We need to continue to promote innovation, but we have got to balance it with affordability and that means competition. As we heard last Congress during our hearing examining the complexity of the prescription drug supply chain, that supply chain has evolved in a way that has ended up, in part, harming some patients at the pharmacy counter.

At that hearing I specifically asked the witnesses about the price of insulin and learned that the net price has not changed much over the last few years--the net price. But the list price or sticker price has increased and pharmaceutical manufacturers are providing larger rebates and discounts to their supply chain partners to lower that net price of the medicine.

While no one is supposed to pay the list price for insulin, some patients do. They do pay that list price or they pay something close to it when they go to get their drugs at the counter. One study found the average price of an insulin prescription in Oregon went from $322 in 2012 to $662 in 2016. That is a hundred percent increase, period. While these prices do not reflect all the discounts, rebates or coupons offered for a product, an insured individual who has not met their deductible or an uninsured person may be asked to pay this amount at the pharmacy counter. Moreover, the co-insurance paid by many

with insurance for their prescriptions is typically a percentage of that list price, not the negotiated net price. The higher the list price, the more these patients pay.

The three major manufacturers of insulin in the United States each offer Patient Assistance Programs and we are glad for that and other forms of assistance to help patients access their medicines. These programs are not a long-term solution though to the affordability and access issues, but they are an important effort in the interim to help patients access their lifesaving medicines.

I hope to learn more from the witnesses today about how these programs are working and I appreciate your testimony. Some providers also have certain patients pay for their medicines. For example, when we examined a 340B drug pricing program last Congress, we heard that some 340B-covered entities passed along all or part of their discounts to provide certain patients with reduced-price medicines including insulin. Since 340B entities can purchase some insulin products at a significant discount, diabetic patients could really benefit from having these savings pass through directly to them.

I also want to ask that we continue our work from last Congress with investigating these cost drivers, Madam Chair, in our healthcare system and that is from top to bottom. As I have

said on many occasions, healthcare costs continue to rise in the United States, and whether it is hospital care or physician and clinical services or prescription drugs, these expenditures are all interrelated as a consumer. So we need a holistic approach to examine the cost drivers in our healthcare system to identify long-term solutions to this complex problem.

I want to thank the chair for putting together this important hearing, this excellent panel. We will benefit from your views and your testimony today. And with that I would yield the balance of my time to Dr. Burgess.

[The prepared statement of Mr. Walden follows:]

********** COMMITTEE INSERT 4 **********

Ms. DeGette. The gentleman is recognized.

Mr. Burgess. Thank you, Ms. Chairman.

And just to point out, over the last 2 decades there have really been no major changes in the chemical makeup of insulin, no changes in the importance of insulin for insulin-dependent diabetics. So under normal circumstances, in the laws of economics you would expect these trends to decrease, not increase prices.

So certainly, I look forward to hearing what our panel today has to say about the massive price increases and perhaps some ideas of what Congress can do to ensure that nobody is forced to choose between insulin and the other necessities of life. And I yield back.

[The prepared statement of Mr. Burgess follows:]

********** COMMITTEE INSERT 5 **********

Ms. DeGette. The gentleman yields back. I ask unanimous consent that the members' written opening statements be made part of the record. Without objection, they will be entered into the record.

I ask unanimous consent for Mr. Rush, Mr. Welch, Ms. Barragan, Mr. Soto, Mr. Carter, and Mr. Bucshon to participate in today's subcommittee hearing, including the opportunity to ask questions of witnesses and submit a written opening statement into the record.

Without objection, so ordered.

I now want to introduce our panel of witnesses for today's hearing. First, we have Ms. Gail DeVore who is a patient advocate and Coloradoan living with type 1 diabetes for 47 years.

Gail, it is great having you here today.

Dr. William T. Cefalu who is the chief scientific medical and mission officer of the American Diabetes Association, welcome.

Dr. Alvin c. Powers, who is here representing the Endocrine Society and the director of both the Vanderbilt Diabetes Center and the Division of Diabetes, Endocrinology, and Metabolism at the Vanderbilt University Medical Center, welcome.

Dr. Kasia Lipska, Clinical Investigator at the Yale-New Haven Hospital Center for Outcomes Research and Evaluation, Yale

University School of Medicine; Ms. Christel Marchand Aprigliano, Chief Executive Officer, Diabetes Patient Advocacy Coalition, welcome to you.

And Dr. Aaron J. Kowalski who is the Chief Mission Officer of the Juvenile Diabetes Research Foundation, welcome. Welcome to all of you and thank you for appearing before the subcommittee today.

You are aware, I know, that the committee is holding an investigative hearing and so when doing so we have the practice of taking testimony under oath. Does anyone have an objection to testifying today under oath?

Let the record reflect that the witnesses have responded no.

The chair then advises that under the rules of the House and under the rules of the committee, you are entitled to be accompanied by counsel. Do you desire to be accompanied by counsel during your testimony today?

Let the record reflect that the witnesses have responded no.

So if you would, please rise and raise your right hand so you may be sworn in.

[Witnesses sworn.]

Ms. DeGette. Let the record reflect that the witnesses have

417 responded affirmatively and you now may be seated. Thank you.
418 You are now under oath and subject to the penalties set forth
419 in Title 18 Section 1001 of the U.S. Code.
420 The chair will now recognize our witnesses for a 5-minute
421 summary of their written statements. In front of each of you
422 there is a microphone and a series of lights. The light will
423 turn yellow when you have a minute left and it turns red to indicate
424 your time is coming to an end, and we appreciate you giving us
425 your opinions in that 5-minute period.
426 So, Ms. DeVore, I would like to recognize you first. You
427 are recognized for 5 minutes.

?TESTIMONY OF GAIL DEVORE, PATIENT ADVOCATE, COLORADOAN, LIVING WITH TYPE 1 DIABETES FOR 47 YEARS; WILLIAM T. CEFALU, M.D., CHIEF SCIENTIFIC, MEDICAL & MISSION OFFICER, THE AMERICAN DIABETES ASSOCIATION; ALVIN C. POWERS, M.D., ENDOCRINE SOCIETY REPRESENTATIVE, DIRECTOR OF VANDERBILT DIABETES CENTER, DIRECTOR OF DIVISION OF DIABETES, ENDOCRINOLOGY, AND METABOLISM, VANDERBILT UNIVERSITY MEDICAL CENTER; KASIA J. LIPSKA, M.D., CLINICAL INVESTIGATOR, YALE-NEW HAVEN HOSPITAL CENTER FOR OUTCOMES RESEARCH AND EVALUATION, YALE UNIVERSITY SCHOOL OF MEDICINE; CHRISTEL MARCHAND APRIGLIANO, M.S., CHIEF EXECUTIVE OFFICER, DIABETES PATIENT ADVOCACY COALITION; AND AARON J. KOWALSKI, PH.D., CHIEF MISSION OFFICER, JDRF

?TESTIMONY OF GAIL DEVORE, PATIENT ADVOCATE

Ms. deVore. Thank you, Madam Chair. Thank you, members of the committee, for allowing me to speak today. My name is Gail DeVore. I've lived in Denver for 36 years. My husband is a third-generation Denverite. I'm 58 years old and have had type 1 diabetes since Valentine's Day of 1972. That's 47 years, 1 month, and 19 days. My husband and I are members of the middle class. We do not live extravagantly. We are very careful with our budget. We have decent insurance, yet the cost of taking care of myself as a diabetic eats a significant hole in our budget

every month. I drive a 17-year-old car that's needed new struts for a few years. It's been a few years since we've had a real vacation, and it's seriously doubtful that either of us will ever have the opportunity to retire.

Just as we all need air to breathe, every person on this earth requires insulin to stay alive. Most people's bodies make their own insulin. However, in a type 1 diabetic, our autoimmune system has malfunctioned and killed off those cells that make insulin. We require injections of insulin to stay alive. Without insulin our blood glucose levels rise, our blood turns acidic, we fall into a horrible coma, and we will die without insulin.

A little more than a year after I was diagnosed, there came a time that I went without insulin for about 12 hours. Toward the end of that 12 hours I was in a coma. My parents drove me to the hospital an hour away from our home. I spent 2 days in a coma in the ICU and many more days recovering in the hospital. My parents were convinced I was not going to live. I will always need exogenous insulin. Every hour of every day of every week of every month of every year for the rest of my life I need insulin.

These four bottles are 1 months' prescription worth $1,400. In 1972, four bottles of insulin cost my family about five dollars. With an adjustment for cost of living, that would be

no more than a hundred dollars today. Every bottle, each bottle is about $350 in a cash price at my pharmacy at the full price. For diabetics without insurance coverage or diabetics who have a high deductible plan or when insurance doesn't cover the kind of insulin our doctor wants us to take, that's what we pay out of our own pockets and out of our own budgets to survive. My current insurance actually covers this kind of insulin at a reasonable copay.

I also have a prescription for a newer insulin called Fiasp. This is a faster acting insulin with no other alternatives on the market currently that compete with this formula. It's not on the formulary of my insurance. It's $346.99 at the Kroger Pharmacy near me. There's no way I can afford to use the prescription as it's written every month. To make it last longer, I ration it by diluting with Novolog, which is against the advice of both Novo Nordisk and my doctor.

I am personal friends with many other diabetics who must come up with 800, 1,200 and more at the pharmacy window before they meet their deductibles or an insurance does not cover their type of insulin. We all find creative ways to afford insulin. Some insurance plans require us to purchase 60 and 90 days of insulin at one time. That makes the immediate price tag double or triple. It has to be paid in full upon delivery.

Even though I've had type 1 diabetes for most of 5 decades, I'm healthy. Medical research shows that it's highly unlikely that I will ever suffer from complications from diabetes as long as I maintain the current level of control that I have now. But the price of insulin directly impacts how well I can take care of myself. I'm not your typical diabetic. I know my way around government. I know who to call and I have access to some high-level administrators.

I sit on the board of directors or committees of the Nightscout Foundation, the JDRF, and the Colorado Consumer Health Initiative. I recently helped get a piece of legislation passed in Colorado that assists all people with chronic illness. It passed unanimously through both Houses and signed by our Governor just 10 days ago. I'm an advocate and I am a problem solver.

However, the reality is there are no solutions for affording insulin. There are coupons and there are assistance programs, but they are not available nor do they work for every diabetic. My friend, Clayton McCook, who lives in Oklahoma City has a coupon that knocks $50 off of every bottle of insulin for his 10-year-old daughter Lily. Last week that brought the cost down to $1,398 for the month. The relief we need is right now. Not next week. Not next year. Before the discovery of insulin, every child that had diabetes died. There are no alternatives to

insulin. It's been almost 100 years since my heroes, Dr. Banting and Dr. Best, figured out that insulin would save our lives. When they sold their patents for one dollar each to the Eli Lilly Corporation, they intended it would always be affordable and accessible. Children and adults are still dying and suffering from disabling complications only because insulin is no longer affordable.

Thank you, Committee, for allowing me to testify today.

[The prepared statement of Ms. deVore follows:]

********** INSERT 6 **********

Ms. DeGette. Thank you so much, Ms. deVore.

The chair now recognizes Dr. Cefalu for 5 minutes.

Doctor?

?TESTIMONY OF WILLIAM CEFALU, M.D., CHIEF SCIENTIFIC, MEDICAL & MISSION OFFICER, THE AMERICAN DIABETES ASSOCIATION

Dr. Cefalu. Thank you, Chair DeGette, Ranking Member Guthrie, and all members of this subcommittee for the opportunity to discuss insulin affordability. Over 30 million Americans have diabetes and about 7.4 million of them rely on insulin. For millions of people with diabetes, including all those with type 2 diabetes, access to insulin is literally a matter of life and death. There is no medication that can be substituted for insulin.

As the leading organization whose mission is to prevent and cure diabetes and improve the lives of all people affected by diabetes, the American Diabetes Association believes that no individual in need of insulin should go without it due to prohibitive costs. In 1921, Canadian scientists, Frederick Banting and Charles Best, discovered insulin, revolutionizing diabetes care and making it possible for patients to live with the disease.

Banting and Best sold the patent to the University of Toronto for three dollars to ensure affordable insulin for all who need it. Since that discovery, further innovations have resulted in new formulations of insulin, from the animal insulin to the human insulin to the 1990s, the analog insulins. In recent years, there have been fewer advancements, yet prices continue to rise. Between 2002 and 2013, the average price of insulin nearly tripled, causing patients' out-of-pocket costs to rise and creating a tremendous financial burden for many who need insulin to survive.

Dangerously, more than a quarter of individuals report making changes to their purchase of insulin due to cost. When people cannot afford their insulin they skip doses or they take less than they need. This is called rationing. This puts them at risk for the devastating and sometimes deadly complications. If a person has type 1 diabetes and goes without insulin for as little as a day, they can develop diabetic ketoacidosis which can lead to death. Increasingly, ADA has heard stories of individuals forced to ration their insulin or forced to go without other important necessities so they can purchase the amount of insulin they need.

We needed to act on behalf of all those who struggle. In November of 2016, the ADA board of directors unanimously passed

a resolution on all entities in the insulin supply chain to substantially increase transparency and pricing and to ensure that no person with diabetes is denied affordable access to insulin. ADA's resolution also called upon Congress to hold hearings with all entities in the insulin supply chain to identify the reasons for the dramatic increases and to take action to ensure that all people who use insulin have affordable access to the insulin they need. In concert with the board resolution, ADA initiated a grassroots petition calling for the same actions.

Since launching this in 2016, over 480,000 people have signed this petition. We continue to hear from individuals who are impacted by the high cost of insulin. For example, Chair DeGette, we heard from Ann in Colorado. Ann has two young children who require insulin every day for life. At the beginning of the year, their monthly costs for insulin were $875. When the pharmacist asked Ann for this sum of money, she was shocked. She asked the pharmacy to run it through insurance. Unfortunately, he already had. Ann had to leave the medication at the pharmacy, go home and comb through her monthly budget to make sure they had enough money to pay for the medicine that would keep her two children alive.

As a physician, I've witnessed firsthand how the incredible research advances from biomedical research have dramatically

improved the lives of those with diabetes. However, this incredible innovation does not benefit those who can't afford their treatments. The ADA established an Insulin Access and Affordability Working Group to ascertain the full scope of the problem and advised the ADA on strategies to lower the cost of insulin. The Working Group held discussions with more than 20 stakeholders representing entities throughout the supply chain. The Working Group published a white paper in Diabetes Care in May of last year outlining what we learned. In follow up, the ADA published a set of public policy recommendations that we believe will help reduce the cost of insulin.

I look forward to working with you and others in Congress to develop strategies to lower the rising cost of insulin. And thank you, Chair Degette, Ranking Member Guthrie, and all members of this subcommittee for holding this very important hearing.

[The prepared statement of Dr. Cefalu follows:]

********** INSERT 7 **********

Ms. DeGette. Thank you so much, Doctor.

The chair now recognizes Dr. Powers for 5 minutes for an opening statement.

?TESTIMONY OF ALVIN POWERS, M.D., ENDOCRINE SOCIETY

Dr. Powers. Good morning. Thank you, Chair DeGette, Ranking Member Guthrie, and members of the subcommittee for the opportunity to provide a physician's perspective on the scope of the problem of insulin affordability. I'm Alvin Powers and I'm a physician scientist and I'm here representing the Endocrine Society. With over 18,000 members, the Endocrine Society is the world's oldest and largest organization of scientists and physicians devoted to hormone research and caring for patients who have hormone related conditions like diabetes.

One of the most frequent concerns we hear from our members is the rising cost of insulin. As the director of the Vanderbilt Diabetes Center, our healthcare providers and I have many patients who struggle to afford their insulin.

The need to address this growing problem is urgent. People are rationing their insulin and foregoing other necessities. This leads to serious health problems and hospitalizations. While I live in the diabetes belt in Tennessee, the story is no different

in Colorado, Kentucky, or elsewhere in the U.S. In this broad context of drug pricing debate, the problem of insulin affordability, I believe, is unique and merits special attention.

Here's a few reasons why I think it's unique. We've already heard that more than seven million people use insulin each day to manage their diabetes and that people who have type 1 diabetes must have insulin to survive. There is no other lifesaving drug used by so many people who would die in a matter of days if they didn't take it. We've also heard about the rising price of insulin over the past 15 years and it's difficult to understand how a drug that has not changed has skyrocketed in price. In 2017, expenditures for insulin in the United States reached $15 billion and three of the top ten medication costs were for a type of insulin.

We've also heard about how insulin has been around a long time. After scientists discovered it in 1921 and saw its miraculous effect on people with diabetes, Frederick Banting, one of the co-discoverers says, "Insulin belongs to the world, not to me." The discoverers as we've mentioned have sold the patent so that all patients would have access. However, it seems that exactly the opposite has happened, especially in the United States.

Let me illustrate the challenges that our patients face.

For example, if I'm at my office seeing a patient who has type 1 diabetes who requires injections of both the long-acting and a short-acting insulin each day, I prescribe both types of insulin. But while I'm sitting with the patient, I have no idea how much my patient will pay of that because the electronic health systems don't communicate patients' specific benefits.

When she goes to the pharmacy, she learns that she owes $1,200 for her four bottles of insulin that month, and why, it's because she has a high-deductible plan and it's January. This scenario could be true for many working Americans and many in this room who have high-deductible health plans. Our insulin supply chain is broken, unfair, and dangerous. Our patients deserve better.

Here are some observations and suggestions about the insulin supply chain. No one understands why insulin cost is rising. There's a lack of transparency and how drug prices are negotiated. Rebates between manufacturers, PBM, and health plans are not passed along to consumers. Patients have increasingly high-deductible health plans dramatically increasing their out-of-pocket costs for lifesaving medications like insulin.

Patient Assistance Programs are complicated, difficult to navigate, and overly restrictive. Because of lack of information, it's difficult for patients and their physicians

to have informed decisions about the cost of a patient's insulin. And finally, regulatory systems and patent extensions restrict the introduction of more generic or biosimilar insulins. Now there's plenty of blame to go around, but that doesn't solve the problem or help our patients.

Addressing the insulin cost problem is a priority for the Endocrine Society. We recently released a position statement outlining ways that stakeholders can improve insulin's affordability and we've submitted this for the record. I believe that we can make progress on insulin pricing and affordability. This can be a road map and can be extrapolated to other medications. I look forward to working with the subcommittee as it moves forward in addressing this important issue. Thank you very much.

[The prepared statement of Dr. Powers follows:]

********** INSERT 8 **********

Ms. DeGette. Thank you so much, Dr. Powers.

The chair now recognizes Dr. Lipska for her opening statement.

Doctor?

?TESTIMONY OF KASIA LIPSKA, M.D., CLINICAL INVESTIGATOR, YALE UNIVERSITY SCHOOL OF MEDICINE

Dr. Lipska. Thank you, Chair DeGette, Ranking Member Guthrie, and distinguished members of the Energy and Commerce Subcommittee on Oversight and Investigations. Good morning. My name is Kasia Lipska and I am an adult endocrinologist and a research scientist on the faculty at the Yale School of Medicine. I am really grateful for the opportunity to share with you my experiences as a clinician and scientist. And I'd like to state for the record I don't have any financial ties whatsoever to drug manufacturers and my views are my own.

First, I would like to tell you about a patient of mine. I'm going to call her Maria to protect her privacy. Maria is a 78-year-old woman who has type 2 diabetes, but relies on insulin injections several times a day to keep her blood sugars in check. When she saw me, Maria's blood sugars were running too high and this put her at risk for the complications of diabetes including

blindness, amputations, and kidney failure leading to dialysis. So I turned to Maria and I said, "Maria, it's time to increase the dose of your insulin." But she turned back to me and she said, "Doc, I really can't afford to."

Seeing patients like Maria led me to wonder just how common this was, so in the summer of 2017 we conducted a survey of patients at our Yale Diabetes Center to get a better picture. We found that one in four patients who are prescribed insulin reported using less than prescribed over the past year, specifically because of cost. And not surprisingly, these same patients had poor control over their blood sugar, so almost threefold higher chances of having poor blood sugars.

These findings were published in JAMA Internal Medicine and they have national implications. That's because our Center's diabetes patients are similar to diabetes patients in the U.S. and New Haven's demographics happen to be almost a perfect mirror of our nation. So the takeaway here is that one-quarter of our patients are rationing insulin and putting their health at serious risk.

Insulin is a lifesaving drug. It keeps patients with diabetes alive and out of the hospital. When patients use less insulin than is necessary, they risk the devastating complications we've already heard about. So let me give you a

sense of why so many patients ration insulin. One vial of Lantus insulin--that's the long-acting insulin--costs over $200 at a Connecticut pharmacy. That's the best price available when you go online and search. This can last for a week or a month depending on the dose needed. If a patient wants to take this insulin as a prefilled pen which is more convenient that will run them almost $300. And this price has skyrocketed over the past years.

Now Gail showed this to you earlier. What I'm holding here in this glass vial is insulin. This is Humalog insulin. It's quite small, right? This vial of insulin cost just $21 when it first came on the market in 1996. It now costs $275. There is nothing different about this Humalog. There is no innovation in this Humalog. It's the same, exact insulin hormone. The only thing that's changed is its price. Now Eli Lilly has made a big deal about its launch of an authorized generic for half the cost. But let's keep this in perspective: $137 is still seven times the original price. So what accounts for this? Drug makers and many organizations who are beholding to them make excuses for why prices have gone up. They say it's the fault of PBMs or the wholesalers, but the bottom line is that drug prices are set by drug makers. The list price of insulin has gone up and that's the price that many patients pay. This is what needs to

come down, it's as simple as that.

I'm here today because as a clinician I have very little to provide to my patients in the way of a solution. The Patient Assistance Programs offered by many drug makers aren't helping much. It's hard to find a patient who actually qualifies for their assistance. I can help my patients shop for the best price of insulin, connect them with a discount pharmacy, but these as was said before are Band-Aid solutions.

I think we have a moral obligation to address this problem. My patients like Maria are counting on you. Thank you.

[The prepared statement of Dr. Lipska follows:]

********** INSERT 9 **********

Ms. DeGette. Thanks so much, Doctor.

Now I am very pleased to recognize Ms. Aprigliano for 5 minutes.

?TESTIMONY OF CHRISTEL MARCHAND APRIGLIANO, CHIEF EXECUTIVE OFFICER, DIABETES PATIENT ADVOCACY COALITION

Ms. Marchand Aprigliano. Thank you, Chairwoman DeGette and Ranking Member Guthrie and members of the Oversight and Investigations Subcommittee. My name is Christel Marchand Aprigliano and I serve as the CEO of the Diabetes Patient Advocacy Coalition. DPAC is a nonpartisan nonprofit dedicated to promoting safety, quality, and access to diabetes medications, devices, and services.

I was diagnosed with type 1 diabetes in 1983 and like others here today have been personally impacted by the rising list prices of insulin analogs. My testimony I hope will provide a frank look at how our community is attempting to obtain insulin and potential solutions. People with diabetes who can least afford this life-essential drug are paying the most and some are paying with their lives. And it wasn't always this way, so let's take a look quickly about how we got here.

List prices are set by manufacturers and include rebates

to entice pharmacy benefit managers to place a drug on its formulary, and it's a vicious circle. To get preferred status on a formulary, manufacturers give higher rebates. The higher the rebate, the higher the list price. And more people are being subjected to list price than ever before as traditional insurance plans have been replaced by plans that include high deductibles and increased patient cost sharing based on a percentage of the list price rather than a flat copayment, and nobody as said before should ever pay list price.

In December of 2011, I paid $40 for a copay for insulin. 1 month later, in January of 2012 that same prescription cost me $1,269. My husband's employer had switched to a high-deductible health plan which placed the burden of full list price on us until we reached a $13,500 deductible. We had a new baby and one source of income and we had put money aside and it was meant for emergencies. Our emergency became insulin. For many of my friends, this emergency happens every single month and there is no more money to put aside. Now we can discuss what options are currently available to patients and even the financial help offered through copay cards and Patient Assistance Programs are not enough to make access affordable. For those with a commercial insurance, copay cards may help offset the high cost of insulin. Those who believe that copay cards pushes away

from generic options, please understand that for insulin analogs there are no generic substitutes. This is why policies that seek to address Patient Assistance Programs must be carefully nuanced to address potential abuses of the system and not punish the patients who depend upon them.

To circumvent the broken rebate system, nonprofit foundations created Patient Assistance Programs to help those who are uninsured, underinsured, or facing a financial crisis. However, these can fail. I can personally attest to this. DPAC and other patient organizations recently conducted a survey to learn how people with diabetes were using Patient Assistance Programs. We discovered that patients only had a 50 percent chance of being helped by these assistance programs, and approximately 44 percent of those who did receive help reported a delay in receiving medications.

With insulin, you cannot afford a delay. I have to note that 2.3 million Medicare Part D beneficiaries are often ineligible for help for these Patient Assistance Programs and copay cards. They have nowhere to turn. When these stop-gap measures fail, my community goes to desperate measures and desperate extremes to stay alive: online fundraisers, grey market sales or trades, and even shopping abroad. All of these avenues are a last-ditch response to our current broken insulin system

and all of them come with risks and none of them are permanent solutions. Our community is crying out for relief and the solution, we believe, involves dismantling the current system that promotes high prices in favor of discounts or true list pricing at the point of purchase where patients and not PBMs or any other portion of the supply chain profit.

DPAC supports the rebate proposal for Medicare Part D because of the two safe harbor protections that will transform the current system. One is to remove the rebates and instead create discounts at the point of sale directly to the patient, and the second is the creation of a fixed fee arrangement for PBMs rather than a percentage of the list price of the drug. We call on Congress to expand HHS's proposed rule to all insurance plans offered to Americans. This would help to destroy the perverse system of increasing list prices in order to increase the rebate amount given to PBMs.

If enacted in conjunction with an expansion of Patient Assistance Programs to help uninsured patients, all patients will benefit and we need solutions now. For medical professionals who feel helpless when their patients suffer, for family members who worry about us, and for patients like me who need insulin to live, every single person who takes insulin must be given the opportunity to raise their voice to help solve this issue.

878 And thank you for bringing DPAC to bring this patient's voice
879 into this life or death conversation. I appreciate your time.
880 [The prepared statement of Ms. Marchand Aprigliano follows:]
881
882 ********** INSERT 10 **********

Ms. DeGette. Thank you so much.

The chair now recognizes Dr. Kowalski.

Doctor, for 5 minutes.

?TESTIMONY OF AARON KOWALSKI, PH.D., CHIEF MISSION OFFICER, JDRF

Mr. Kowalski. Thank you. Chairwoman DeGette, Ranking Member Guthrie, thank you and members of the subcommittee for inviting me to speak today. What you're seeing is a united community here. We need to fix this problem. In 1977, my younger brother Stephen was diagnosed with type 1 diabetes, or T1D, at the little age of 3, and then it was a bolt out of the blue for our family. Then in 1984, I too was diagnosed with T1D. My career has been focused on the fight to cure this terrible disease and importantly help people stay healthy until that day.

As Chief Mission Officer at JDRF, the leading organization funding type 1 diabetes research, I'm very grateful for the opportunity to share our perspective and experiences of the many who are grappling day-to-day with--and you've heard this term many times--skyrocketing insulin costs. Type 1 diabetes is a fatal disease without insulin. Millions of Americans must take insulin many times a day, every day, just to survive. Yet as you know, the cost of insulin has soared. You've heard of Dr.

Lipska of the price. It's doubling, it's tripling, depending on the years--2012, 2016--it's out of control. Beyond the data are the lives of real people, your constituents.

As I travel the country the number one question I get asked, how can we make insulin more affordable? Even my own family's been affected. My brother has benefited tremendously from advances in modern insulins. They've significantly reduced life-threatening and costly, severe hypoglycemic episodes. But even as an owner of a small business in New Jersey, Steve was spending over $8,000 out-of-pocket for his insulin. His wife switched jobs just to obtain better insurance that would cover this cost.

When people with diabetes can't afford insulin, they resort to drastic and life-threatening measures to stay alive. Again, you heard Dr. Lipska talk about the number, 25 percent, of people taking less insulin than they need just to save on cost. At a time when new innovations can enable people with type 1 diabetes to live longer and healthier lives than ever before, the dramatic rise in the cost of insulin is undercutting this progress.

To get the best outcomes people with diabetes need access to affordable insulin and diabetes management tools year around. Without them people are not able to manage their blood sugar, threatening their health, driving up costs including doctors'

visits, hospitalizations, and ultimately terrible complications such as diabetic eye and kidney disease. At times, tragically, the results can be fatal.

No one should suffer or die because they can't afford insulin. No one should suffer or die because they can't afford insulin.

The time for action is now. We need systemic change, change that you all can make happen. On behalf of JDRF, I want to thank Congress for your commitment to solving this problem. Through our Coverage2Control campaign we've been rallying our community to call on companies to lower the price of insulin, and for health plans, employers, and the government to take steps to lower out-of-pocket costs. First, manufacturers need to lower the list price of insulin. To do this, rebates must be eliminated from the drug reimbursement system. We support the administration's proposed anti-rebate rule and urge Congress to end rebates in the commercial sector as well.

Second, insurers and employers must provide affordable coverage that reflects insulin's role as a lifesaving and sustaining drug. We support the policies that remove insulin from the deductible and provide it with a flat dollar copayment. At the same time, the public and private sector need to do more to help those who are uninsured obtain insulin they need to stay

alive and to thrive.

Third, we need to continue to invest in research. At JDRF we believe affordability and innovation go hand-in-hand to improve outcomes. Thanks to Congress's strong bipartisan commitment to the Special Diabetes Program and private investment from groups like JDRF, we are making progress on even better insulins, ones that are maybe glucose-responsive or faster-acting. On artificial pancreas systems, beta cell therapies and immunotherapies that will ultimately cure this disease.

While we work towards a brighter tomorrow, we need to ensure that today all who need insulin to stay alive can obtain it. Thank you, members, for your outstanding leadership on this issue. I ask you to continue the fight alongside us.

[The prepared statement of Mr. Kowalski follows:]

********** INSERT 11 **********

Ms. DeGette. Thank you so much, Doctor. And thank you to the entire panel for, really, what was compelling testimony and very informative for the committee.

It is now time for members to have the opportunity to ask questions and the chair recognizes herself for 5 minutes. We have heard unconscionable stories this morning about patients being forced to make sacrifices in their daily lives because they can't pay for insulin or even going without this lifesaving drug.

Ms. deVore, I want to start with you. You are a patient advocate, but you also live with type 1 diabetes, yourself, and so you are familiar with these types of tough choices due to insulin prices. I want to ask you, given your advocacy roles would you agree that there are still far too many diabetic patients or parents of diabetic children who are unable to access affordable insulin and then they are making these difficult choices?

Ms. deVore. Am I on now?

Ms. DeGette. Yes.

Ms. deVore. Every day I get emails from people asking how do I afford insulin? Every day. And every day I have to help them find a way to find insulin. These are families. These are adults. They're from every economic sector of our society. No one's exempt. Diabetes does not discriminate and the price

certainly doesn't. The price isn't dependent on your income.

Ms. DeGette. That is right.

Ms. deVore. It's always the expensive price that each of us has to pay if our insurance, or we don't have insurance, if it doesn't cover it.

Ms. DeGette. So, Dr. Lipska, we heard from the drug companies that the current--what they say is the current pricing system generally works for most people living with diabetes, but your study found 1 in 4 of your patients rationed their insulin at some point in the last year. So I would like you to comment about this and tell us what you think about the drug companies' argument that it is working for most people.

Dr. Lipska. Thank you for that question. It is clear that the system is broken. It is clear that this is not working for many people. So we've heard stories, some of them highly publicized, people have died because they were rationing insulin. But we know now with this research that we've done at the Yale Diabetes Center, but also the survey done by the American Diabetes Association and other surveys conducted by advocacy groups that this is widespread.

Ms. DeGette. It is not just a few people, it is like 1 in 4 people, right?

Dr. Lipska. It is not just--it is 1 in 4.

Ms. DeGette. Right.

Dr. Lipska. A quarter of people. This is a huge proportion.

Ms. DeGette. Thank you.

Dr. Cefalu, similar question, you testified that the ADA insulin affordability survey found in the last year over a quarter of those who responded had to make changes to their purchase of insulin due to cost. Based on these findings, what do you think the size of the population that the system is failing? How many people do you think this is?

Dr. Cefalu. Well, Chair DeGette, I'm not sure of the absolute numbers, but it's interesting that our survey at the American Diabetes Association actually agreed with the report from Dr. Lipska that 1 out of 4 reported that the cost of insulin either affected their--the cost either affected their purchase or use of insulin. What's disturbing is that of 1 out 4 either skipped doses, rationed doses, or more importantly they had a discussion with their physician and went to an insulin that may not have worked as well.

So this is more than an inconvenience for the patient. And the concern is that if you make it more difficult for the patient to get the care they need, they're not going to be adherent to medication strategy. And if you're not adherent to medication

strategy, that's going to relate to worse outcomes over time.

Ms. DeGette. Right. People could get the side effects that we are so--that Ms. DeVore said if you take--if you go by your regimen with the correct insulins then you don't get the side effects now, but if you are rationing, if you are not under control then you do.

Dr. Cefalu. Well, we actually found that if people actually had to make a choice with their insulin and because of the cost of insulin they either skip dose or rationed it, the outcomes are worse.

Ms. DeGette. Right.

Dr. Cefalu. And, actually, in the survey if you'll allow me--

Ms. DeGette. You know, we don't have a lot of time.

Dr. Cefalu. No, it's just that there was more emergency room visits, there's more hypoglycemia. There was worse control because of the costs in these patients, so it's clear that this is a problem to our patients and cost is indeed affecting outcome.

Ms. DeGette. Right, thank you.

Dr. Lipska, very briefly I wanted to ask you, so the manufacturers and the pharmaceutical companies say that if we lower price it is going to stifle innovation. Do you believe that is true?

Dr. Lipska. So I'll just go back to this vial of insulin. This is the same stuff, right. This is the same insulin that's been around since 1996. Nothing has changed except the price. I think drug makers can charge what they do because we continue to pay, and this has to stop. I think that you, as Congress, have an opportunity and we have an obligation to fix this.

Ms. DeGette. Thank you.

So I would just ask, as I mentioned in my opening statement Congressman Reed and I, as chairs of the Diabetes Caucus, did our own investigation last year and we issued a report in November of last year called "Insulin: A lifesaving drug too often out of reach." I would like to ask unanimous consent to put this in the record, so ordered.

[The information follows:]

********** COMMITTEE INSERT 12 **********

Ms. DeGette. And I also am going to give a copy of this to every member on the panel, because we researched. We talked to all of your organizations and we researched this over a year and we made policy recommendations in this report. I think it would be really useful for the members of this committee to read this report and to listen to your testimony before we come back next week for our hearing with some of the actors in the market.

And with that, thank you very much for your comity to the ranking member and I am now pleased to recognize Mr. Guthrie for 5 minutes.

Mr. Guthrie. Thank you very much.

And it is important to note there is a lot of innovation going on in the artificial pancreas, the trying to regenerate pancreatic function within diabetes, so that is stuff we don't want to stifle. Dr. Lipska hit it perfectly. We are looking at specifically at insulin, not all the other innovations going on because of little change, but little change in product, but big change in price. On the Republican side, we sent letters to both drug manufacturers and to the PBMs and we got a lot of different explanations on why the list price was going up while the net price stayed low. We posed similar questions to both sides and got a lot of different answers.

So I want to go to Dr. Cefalu. The Working Group convened

by the American Diabetes Association held discussions with more than 20 stakeholders representing entities throughout the insulin supply chain. After having these conversations, the Working Group concluded that current pricing and rebate system encourages high list prices.

Can you please elaborate on how we got to a pricing and rebate system that encourages high list prices and, in your opinion, why did the pricing and rebate system evolve this way?

Dr. Cefalu. Well, again, thank you. The question as far as the Working Group, we recognize that first and foremost the increase in transparency is the first step toward viable long-term solutions. The current rebate system as arranged in the list price, as the list price increases that our current drug price and rebate system encourages a high list price. So as the list price is increasing, intermediaries within the supply chain benefit.

The way this system is currently based fees, rebates, and discounts may be based on a percentage of that particular list price, so there are incentives throughout the supply chain that keep that list price high.

Mr. Guthrie. Okay. One thing we have heard from stakeholders is that the manufacturers set the list prices and they should just lower their list price. Manufacturers, however,

we learn there is always, this is very difficult in trying to find how it works. Manufacturers have told us that it is not as simple as that. They say if they lowered their list price, a PBM would be less likely to give them good formulary placement and therefore give patients more affordable access to their drugs because they couldn't offer as big of a rebate on the product.

What do you think would happen if a manufacturer just lowered the list price given how the current price system and rebate system works? I don't know if you want to say they just lower it and change the system, but under the current system can they just lower their price?

Dr. Cefalu. Well, based on what we found in the Working Group, there are issues at every level of the supply chain and it's a complex chain and there's no question that the manufacturers set the list price. But there's also no guarantee if that list price drops that there's going to be subsequent changes throughout the supply chain. We need to move away from a system that's based less on high list prices and rebates and make sure that discounts and rebates negotiated throughout the supply chain make it to the patient at the pharmacy counter. That's what's not happening now. So to your question, Congressman, simply lowering the list price unless you can control what happens downstream in the intermediaries and what happens

to the patient, there's no guarantee that just dropping the list price, in my opinion, and from the Working Group is going to get the job done. We need systematic change to make sure these discounts and rebates flow to the patient at the point of sale.

Mr. Guthrie. Thank you.

Ms. Marchand Aprigliano, in your testimony you highlight how we need systematic changes. The current complex pricing and rebate system, similar question, is harming many patients through the increased out-of-pocket costs. Given all the work you have done examining the insulin supply chain, what do you think would happen if a manufacturer just lowered their list price given how the current pricing and rebate system works?

Ms. Marchand Aprigliano. So the current contracts that are currently in place with the pharmacy benefit managers and the manufacturers are secret. We have no idea how much we're actually receiving in terms of that rebate, and we've been told that the rebates are then spread throughout those who have insurance and are used to lower premiums or to help in the possible cost sharings.

I don't know about anybody sitting here at the table, but my premium has never gone down. The cost of insulin keeps going up and I'm paying more and more in cost sharing. I'm not quite sure if magically the list price would suddenly drop down, I don't

believe that it would immediately. I believe that entire disruption of the rebating system needs to happen and it needs to happen now.

I do want to bring up one of the things that we talk about when we talk about rationing in 1 in 4. Part of that is, is it's a psychological torture that we all go through every month because we don't know if something is going to happen and we are going to lose access to our insurance or we are going to have to pay list price at that counter. And so every year when we see list prices rise and we wonder where exactly all that money is going to, we have no idea if it's going to rebates or to help lower the cost of an entire system in an insurance plan to help everybody else.

Are we subsidizing people who are healthy with the cost of insulin? And I think that that's the case right now.

Mr. Guthrie. Thank you for your testimony and I am out of time so I will yield back.

Ms. DeGette. The chair now recognizes the chairman of the full committee, Mr. Pallone, for 5 minutes for questioning.

The Chairman. Thank you, Madam Chair. We have heard today that the amount people ultimately pay for insulin can be significantly influenced by the manufacturers' list price even if they have insurance, and that price forces people to make

incredibly difficult decisions between the medicine that literally keeps them alive and all other aspects of their lives. So I will try to get a bunch of questions in here as quickly as possible.

Dr. Cefalu--I don't know if I am pronouncing it right. Your testimony stated and I quote, when people cannot afford the insulin they need, they may skip doses or take less than they need. This puts them at risk for devastating and sometimes deadly complications. So, Doctor, what do you know about the people who are burdened the most by rising list prices and therefore most at risk for these complications that you mention?

Dr. Cefalu. So the question is what is the most vulnerable population?

The Chairman. Well, I mean what--tell us, you know, a little more about, you know, the person who is impacted by this and, you know.

Dr. Cefalu. Sure, okay. So you've heard every--panelists have talked about cases where individuals cannot afford their insulin. And when you begin to ration insulin, two things happen. First and foremost, if you control the blood glucose, if between the provider and the patient that amount of insulin you give control the glucose and then you ration insulin and glucoses begin to rise, over the short term, uncontrolled dehydration. And

again, if there's less insulin in a type 1 will lead to the acute complication of diabetic ketoacidosis, which if not effectively treated does lead to death.

Over the long term, we've had studies for 20 years that show that adequate glucose control does prevent the blindness, the kidney disease, and the nerve disease. So the concern is now if someone takes less insulin to get by throughout the day and this is chronic uncontrolled glucoses, then over the long period they're going to give rise to more blindness and kidney disease and nerve disease. And we've spent 20 years as a medical community reversing these changes, and now if we can't afford the insulin to control glucose that will be a long-term control--

The Chairman. Okay. Well, that is very helpful. Thank you.

And, Dr. Kowalski, you are aware of individuals forced to take these risks, being forced to choose between filling their prescription and paying for essential household expenses. How common of a problem is this where people have to make those choices?

Mr. Kowalski. Yeah, I think it's really interesting we're talking about insulin rationing and a quarter of people are insulin rationing, but we aren't talking about this other part where people who aren't rationing are making decisions that is

either paying a mortgage, paying a car payment, college tuition, debt. And this is very common as we've seen an increase, a significant increase in people moving from traditional fixed copays to high-deductible plans. And people with diabetes who have high-deductible plans are hurt terribly by these rising costs.

The Chairman. All right, thank you.

Let me ask Dr. Lipska. Thanks for your research into insulin affordability and bringing to light the effects that high costs have on your patients' treatment. Just if you could, what additional research is needed in this regard, if you will?

Dr. Lipska. I've been asking myself that question. Thank you for this. I think that we already know. We already know everything we need to know about the impact on patients. We know it's a widespread problem. We've done research for many decades now showing that high blood sugars cause complications. We don't need to reinvent the wheel. I think we know this.

The Chairman. All right.

Dr. Lipska. I think we need to fix the problem which is why I'm here and not in my research lab.

The Chairman. All right, thank you so much.

Ms. deVore, you said in your testimony you continue to drive a 17-year-old car and believe that your husband will never be

able to retire due to the cost of managing your condition. You said that you are one of the relatively lucky ones who has good insurance to pay for your insulin.

So I wanted to ask Dr. Cefalu, now, the question, what parts of the system do you believe are responsible for driving up insulin prices?

Dr. Cefalu. So getting back to our Working Group, this was again by interviewing all stakeholders in the insulin supply chain. We don't think that there's one entity in which there's not accountability. It's clear that the manufacturers set the list price, but it's also clear that this list price incentivizes, the system encourages high list price. And a high list price, the intermediaries in the supply chain benefit from high list price.

So we feel that at every level of the supply chain, each entity has to hold some accountability in the pricing of insulin. And when we talk about solutions, when we talk about discounts and rebates flowing down, that happens at each level to get to the patient. So the system is dysfunctional and we need to ensure that we have a system that's not based on high list prices and rebates, and that if there are discounts and rebates they are seen at the pharmacy counter to lower the cost of insulin.

The Chairman. All right, thank you. And thank you to the

panel. I appreciate it.

Thank you, Madam Chair.

Ms. DeGette. Thank you so much, Mr. Pallone.

And the chair now recognizes Mr. Burgess for 5 minutes for purposes of questioning.

Mr. Burgess. Thank you and thanks to our panel for being here to a very informative discussion, a very thought-provoking discussion. Just to be clear, because this committee has done a lot of work on drug shortages over the years, at the present time there is no concern about any shortage of insulin; is that correct?

All witnesses said yes, no?

No concern, okay. I asked the question poorly. I asked for an affirmative to a negative, or a negative to an affirmative.

But as you all discussed, this, I mean this committee has done a lot of work on the opiate problem, but I mean insulin is something you don't have to worry about it being diverted. You don't really have to worry about someone overusing it because there is actually a biologic penalty for overusing it; is that not correct?

So I have had some questions about the rebate rule that the administration has proposed, but I promised Secretary Azar I would keep an open mind about that and I have. And several of you have

brought up about the rebate rule this morning and I hope that perhaps at some point in the future we can involve the agency either in this committee or the Health Subcommittee on their--to have them discuss the pros and cons of the rebate rule because rebates seem to be a recurring theme.

Now one of the things that strikes me when I look at the timeline for insulin increases, and I think, Dr. Cefalu, you have mentioned since 2002 there has been an increase and really it is dramatic after 2009-2010, and that is of course the point at which the Medicaid rebate was increased from 15 to 23 percent, but then a cap was placed on the rebate. And I don't know if that has had an effect, but you wonder because just again you superimpose the timeline of when that Medicaid rebate increase went into effect, which was in March of 2010.

So I am also struck--and I would never aspire to be a third-party payer, I have never wished that on anyone, actually. However, if I were a third-party payer or perhaps since we have Medicare and Medicaid under our jurisdiction perhaps something to be considered, why do we even charge for insulin? I mean if someone has got a diagnosis of diabetes, why not just treat it? So has there been any effort within, say, within Medicare?

And, Dr. Lipska, I think you mentioned the two patient studies that you outlined both of whom were in their 70s, which

is young I would hasten to add, but still in an age that is covered by Medicare, why would the Center for Medicare and Medicaid Services not just cover that?

Dr. Lipska. I'll try to answer that question. Life with diabetes is very hard to begin with. I think charging people, you know, exorbitant prices for insulin is backwards and unhelpful. And I think as was mentioned before, I think in the end it's going to cost us more, right?

Mr. Burgess. I don't disagree. The whole premise of copays several years ago, when someone is sick don't you want them to take their medicine? Why would you put a barrier there?

Dr. Lipska. It makes it harder for me to treat them. It makes it much harder for me as a clinician to help them.

Mr. Burgess. So have any of you as you interact with policymakers, have any of you had discussions along this line with the Center for Medicare and Medicaid Services?

Dr. Cefalu. The reduction in rebate, the ADA has been at the Secretary Azar when he discussed this and this is line with our Working Group's recommendation and our public policy. To your point as far as reducing the cost of insulin, that's in line with our recommendations to lower or remove cost sharing and to make sure any cost sharing is based on the lowest price that account for the negotiations throughout the supply chain. And

the amount of money a person pays for insulin is going to have a direct effect on their adherence of that strategy.

Mr. Burgess. Sure. I don't disagree.

Dr. Cefalu. And that is incredibly important. And again, we cannot go back to where we have more complications because of the cost of insulin.

Mr. Burgess. And again I don't disagree at all.

Dr. Cefalu. So to your point, lowering the cost of insulin, either cost sharing or rebates coming back to the point of sale, whatever we can do to lower the cost of insulin, I think, is going to increase adherence.

Mr. Burgess. But in a federal program why don't we just cover it? Why should there be any cost at all?

Dr. Cefalu. That's a question that I think this committee and Congress needs to ask.

Mr. Burgess. And my next question to Seema Verma next time I see her.

Thank you very much. I will yield back.

Ms. DeGette. Thank you, Dr. Burgess.

The chair now recognizes the vice chairman of the Oversight and Investigations Subcommittee, Mr. Kennedy, for 5 minutes.

Mr. Kennedy. Thank you, Madam Chair. I want to thank all my colleagues on the committee for being here for this important

hearing. Thank you to all the witnesses and your testimony. It is extremely compelling. I would also like to submit for the record a Boston Globe article that was published last November 16th that detailed the story of two moms that were protesting outside of a facility in Cambridge, Massachusetts with the ashes of their children who died because they did not get access to insulin. And we will pass that out for the committee. I would like to submit for the record again.

Ms. DeGette. Without objection.

[The information follows:]

********** COMMITTEE INSERT 13 **********

Mr. Kennedy. Thank you.

Drug companies are taking a lot of well-deserved criticism for the astronomical prices we are seeing and in response we have heard today about the free and reduced insulin, cost of insulin through Patient Assistance Programs or drug discount cards to provide some relief. These programs sound promising, but I am not sure it is quite that simple.

Ms. Marchand Aprigliano--did I come close?

Ms. Marchand Aprigliano. Close enough.

Mr. Kennedy. I am sorry. One more time for me?

Ms. Marchand Aprigliano. Marchand Aprigliano.

Mr. Kennedy. Marchand Aprigliano.

Ms. Marchand Aprigliano. The G is silent.

Mr. Kennedy. Thank you. I will do my best.

Ms. Marchand Aprigliano. North End.

Mr. Kennedy. There you go, thank you.

You testified about our recent survey on Patient Assistance Programs and noted that only about half of people who apply actually receive them. So, generally speaking, what can you tell me about the populations that use these programs to help pay for medication?

Ms. Marchand Aprigliano. So I will tell you that they come from all walks of life just like everybody who uses insulin.

Now that being said, part of the issue is that sometimes we don't meet the qualifications. The current qualifications can range from 250 percent to 400 percent of federal poverty level. So for a family of four that may be depending upon the type of insulin you take, you may be eligible for one program and not eligible for another one. One of the important things to note is that we said that 42 percent of the patients found that the qualifications to apply were difficult to find and understand. And out of that the 44 percent don't receive their medications in a timely manner.

Mr. Kennedy. So that is what I wanted to build on, Dr. Kowalski. So if you are in need of insulin in a timely manner how do these programs, how do they work?

Mr. Kowalski. Well, I think they're a barrier. I mean JDRF, we certainly are trying to do our best to disseminate that there are options out there for people. But as anybody who's sat on a phone, sat in front of the pharmacy, waited and struggled to figure these programs out, when you have a drug that your blood sugar is going up as you're sitting there, I mean these are barriers that we feel should not be in place. I mean relying upon Band-Aids when there's an overarching problem is something that JDRF, and I think we're all aligned at this table, needed to address.

Mr. Kennedy. So when drug manufacturers come in next week to testify I expect that they are going to tell us about the benefits that these programs are having.

But, Dr. Lipska, you say in your testimony and I quote, the Patient Assistance Programs do little more than provide a public relations benefit. It is hard to find a patient that meets the criteria. Doctor, from your experience, why are these programs failing to actually provide sufficient benefit to those looking for help and are there certain things drug companies should be doing that they are not?

Dr. Lipska. Right, great question. A lot of patients don't meet the criteria for, you know, because of income or they have commercial coverage or there are some other specific criteria that, you know, don't quite help them in those situations. That's one thing, so it is hard to find somebody who exactly qualifies.

But I also say that I don't think Patient Assistance Programs are a way to fix this. As was said, one, they cause delay, but two, they just, they require money--money. They require a time spent sort of, you know, applying and running through these hoops. People should not have to do this, it is just not right. Life with diabetes is hard enough as it is. I don't think we should be putting patients through this application process to get a drug they need.

Mr. Kennedy. And, Ms. Marchand Aprigliano, hopefully better, do you, building off of that do you have suggestions for how they can, the programs can be improved or do you think they should be essentially scrapped?

Ms. Marchand Aprigliano. Well, I think that they could definitely be improved by reducing the list price of insulin so that these Patient Assistance Programs don't need to exist at all. However, that being said, to be able to raise the eligibility requirements to 500 percent of FPL, we've discussed that in the paper that we published today, to make it easy for individuals to actually apply and then to educate individuals such as pharmacists as well as other healthcare professionals about these programs.

Only seven percent of individuals found out about these programs at the pharmacy counter, which is usually the first time that somebody who is obtaining the first notion that, oh my gosh, I can't pay for my prescription actually happens. That should be the first line of defense there.

And also, and I will say this, there needs to be help especially for those who are in crisis. I actually applied for a Patient Assistance Program when my husband unexpectedly was laid off from his job and I knew the system, I knew exactly what was supposed to be able to help me, and instead I was told that

I didn't qualify because the paperwork that I had to show only showed past income and that's all they would base their decision off of, not from the fact that we had zero income.

And I wasn't concerned about my husband, helping to find him find a new job, or concerned about how to put food on our table. I was concerned about how I was going to get insulin. And then to find out it would take 4 to 6 weeks before they made a decision about my application, that is unconscionable, unacceptable, and for Patient Assistance Programs we need to do better.

Mr. Kennedy. Thank you, yield back.

Ms. DeGette. Thank you.

The chair now recognizes Mr. Griffith for the purposes of questioning the witnesses.

Mr. Griffith. Madam Chair, thank you so much for holding this hearing.

You know, I really always learn things from these hearings and particularly today I have learned. And I just have to say that I hadn't thought about it, but Dr. Burgess's point is very appropriate and that is, is that with the high cost of the consequences of not providing the insulin or not being able to get the insulin, amputations are expensive, the physical therapy that follows an amputation is expensive. Loss of vision or even

a dimunition in your ability to see is expensive and all of the third-party payers are going to pay a lot more. It is fascinating.

Anyway, I have concerns about PBMs, pharmacy benefit managers, and the consolidation in that industry with three major PBMs controlling most of the market. Dr. Cefalu, in your testimony you discuss PBMs and how they have substantial market power and how the PBM's primary customers are health plans and employers and not patients. How has the substantial market power of PBMs changed, if at all, the list price and the net prices of insulin? And I know we have already touched on some of this, but let's get it on the record.

Dr. Cefalu. Well, the PBMs play a role in the insulin supply chain through their negotiations through manufacturers for the rebates, but their primary customers are the health plan and the insurers where they negotiate to lower total drug costs and they design formularies. What is not clear is whether those negotiations that take place, and I think some of the comments today were that they are opaque transactions, we don't know whether those transactions are actually benefiting the patient at the point of sale. There's information that we would need before we say how you would improve that system and that gets back to the transparency.

Mr. Griffith. And so, you know, when we have questions, Ms. Marchand Aprigliano said earlier she had speculations as to where the money was going and so forth. We just don't know when we are dealing with the manufacturers and the PBMs and the insurance companies, it is really hard to follow the bouncing ball and we had a hearing on that last year that dealt with how do we figure that all out. So I assume that everybody would be in favor of transparency so we can see what is going on and whether or not the rebates that are being offered to the PBMs are actually increased by a request by the PBMs to the manufacturers to increase their list price; is that correct?

Dr. Cefalu. One of the key things identified was the Working Group that increased transparency is key to understanding and designing long-term solutions. It's key. We do not understand the negotiations that occur with each entity in the supply chain and until we do we won't have the long-term solutions. And that was a key determination, a key finding from the Working Group. We just do not understand the flow of money through the supply chain.

Mr. Griffith. So at this point you don't know whether the PBM's use of their market power has benefited or hurt patients because you don't know what they are doing because it is all behind closed doors, so to speak?

Dr. Cefalu. The Working Group observation is that it was not clear that these negotiations actually benefit the patient at the point of sale.

Mr. Griffith. Ms. Marchand Aprigliano, in your opinion, why do you think the PBMs have so much power in the insulin supply chain?

Ms. Marchand Aprigliano. Well, I think that PBMs have power over the entire prescription drug supply chain. And PBMs started with the best of intentions just like much of anything else. This was supposed to help patients save on the cost of their prescription drugs. But over the course of several years this has changed to how much profit a PBM can make. And through the rebating system and a way to not share with the patient at the point of sale, we are subsidizing, those of with chronic illnesses are subsidizing the entire healthcare system.

Mr. Griffith. Including the net profits of the insurance companies, the PBMs, and the manufacturers?

Ms. Marchand Aprigliano. Everyone in the insulin supply chain. We realize that nobody's out to get us--

Mr. Griffith. Right.

Ms. Marchand Aprigliano. --and that no one, you know, wants to kill us, but there's no profit if no one can purchase a vial of insulin and broke patients can't buy insulin. So somebody

is making a profit and it's not the patients.

Mr. Griffith. Yes, ma'am.

Madam Chair, I appreciate you continuing our work into this and we will do this over the next year, I know, and I look forward to participating in that and thank you very much and yield back.

Ms. DeGette. Thank you so much. We are going to do it over the next week but, however, it is not going to take us a year to legislate.

Mr. Griffith. Well, that is good news.

Ms. DeGette. Okay, yeah.

Mr. Griffith. Thank you, Madam Chair.

Ms. DeGette. The chair is now pleased to recognize Ms. Kuster for 5 minutes.

Ms. Kuster. Thank you, Madam Chair. And thank you for coming together and for the bipartisan approach here today.

So I just want to emphasize the scope, you all have been very helpful. In New Hampshire, where I am from, approximately ten percent of the population, 1 in 10, is type 1 or type 2 diabetes, approximately 121,000. And physicians estimate that 34,000 people in my state have diabetes but do not yet know it. So it is a serious, serious health threat as you have laid out.

Thirty-six percent of our population, 370,000 Granite Staters have pre-diabetic symptoms including high blood glucose

levels. And just to give you a sense of the scope and we are a small state, the diagnosed diabetes costs in New Hampshire are an estimated $1.3 billion every single year including the direct medical expenses, 940 million, and then an additional 320 million spent on indirect costs including loss of productivity, so 2017 figures.

I want to try to get at the root causes of the rising insulin prices that we are here to discuss. Just to give an example, so the list price of Novolog, commonly used analog insulin, increased by 353 percent per vial and that was just from 2001 to 2016. During the same period, the list price of Humalog, another commonly used insulin, increased by 585 percent per vial. So it is little wonder that people can't keep up, as you have discussed.

I want to ask Dr. Lipska, you testified the cost of insulin today is now seven times more for the exact same product as 2 decades ago, and to quote you, recent research suggests that high prices primarily benefit the drug makers. Do you believe that the drug companies are the ones benefiting the most from the exorbitant price increases?

Dr. Lipska. Thank you for that question. Yes, I do. And this is based on research not performed by my group, by Dr. Peter Bach at the Sloan Kettering Memorial Hospital. They looked at

U.S. expenditures on prescription drugs in 2016 and estimated that those expenditures totaled 400 and billion dollars. Two-third--

Ms. Kuster. Four hundred billion, billion with a B?

Dr. Lipska. Four hundred and eighty billion dollars. Two-thirds of this total was captured by drug manufacturers in the form of net revenues. The remaining third was retained as gross profits in the supply chain. PBMs and wholesalers captured approximately 8.5 percent of that. So I think that helps keep this in perspective in terms of where the money is going. Now this is not insulin-specific data, these are prescription drugs-specific data. But I think it gives us a little bit of a perspective and a pause to pawn all of this just on PBMs and the inflating list price.

Ms. Kuster. Thank you. That is very helpful.

Dr. Cefalu, you discuss in your testimony the American Diabetes Association took a thorough look at the causes of rising insulin prices. And in summarizing the Working Group conclusion you stated, quote, as prices increase the profits of the intermediaries in the insulin supply chain-- wholesalers, PBM, pharmacies--increase since they may each receive a rebate discount or fee calculated as a percentage of that list fee.

So it sounds like everyone in the supply chain except the

person living with diabetes benefits from high list prices. What parts of the system do you believe are responsible for driving up insulin prices?

Dr. Cefalu. So, Congresswoman, again the Working Group looked at and talked to every stakeholder in the supply chain. It's clear that the price is set by the manufacturers, but as you stated a high list price benefits intermediaries. To Dr. Lipska's point, there are other studies that have looked at the flow of money through the supply chain. I can actually provide you information from the Schaeffer study from the University of Southern California that looked at the profit taken at each level.

But again, as the list price goes up, the intermediaries profit because of the percentage based on the list price. And this is where if we understood the negotiations, understood what is occurring between the manufacturer and PBM, the PBM and the health plan, the PBM and the pharmacy, understanding what is going on as far as negotiations, will we have a better idea as to your point as where the profits are taken. For now, it's based on data in the public domain and we'd be more than happy to give you information from the USC study which shed some light on where the profits are taken.

Ms. Kuster. That would be very helpful and we can get that into the record.

Dr. Powers, similar question, you state in your testimony, quote, it is difficult to understand how a drug that has remained unchanged for almost 2 decades continues to skyrocket in price. We all share your frustration with that. What do you believe are the fundamental causes of skyrocketing prices for these well-established drugs?

Dr. Powers. Yes, thank you for that question. I think that if this committee had members of each of the supply chain on a panel and you asked them who was the fault, they would do this.

Ms. Kuster. Well, we will get that opportunity next week.

Dr. Powers. Absolutely, right. They will do that, right. And so I think that we have--that each member of the supply chain have a responsibility to help solve this problem. That means the manufacturers, the PBM, the plans, the patients, the providers, and Congress all have a role in creating a new system for this. And I think that trying to single out one person or one entity, while satisfying, is not going to solve the global problem.

Ms. Kuster. I apologize for going over and I yield back.

Ms. DeGette. The chair now recognizes Congresswoman Brooks from Indiana for 5 minutes.

Mrs. Brooks. Thank you, Madam Chair, and thank you for holding this very important hearing. I am vice chair, one of

the vice chairs of the Diabetes Caucus. I want to thank the chairman of this subcommittee for her leadership, and Congressman Reed.

We know that CDC has issued a report, and part of the reason I am so involved is that over 586,000 adult Hoosiers suffer from diabetes and so it is a tremendous problem in our state. I think our state is one of the higher per capita, and so critically important problem.

I want to talk about a couple of things that I haven't really heard us talk about yet. I am going to start with you, Dr. Kowalski. I want to talk about the concept of non-medical switching and can you describe what that means and whether or not insulins are interchangeable? Can you just talk with me a little bit about non-medical switching?

Mr. Kowalski. Yeah, this is another issue that I think is very important here that we have multiple--it was mentioned on the committee, the panel here, that there are multiple forms of insulin and different people with diabetes benefit with different forms with different characteristics. For example, I use an insulin pump so I only use fast-acting insulin. Some people do shots and use fast and long-acting. What we're seeing in the community is people being switched by their insurance companies, not by the choice of their physician and the patient,

which is just not the right way to practice medicine.

Mrs. Brooks. Has that ever happened to you?

Mr. Kowalski. Oh, absolutely. And we work at JDRF--has a, I'm very happy to say, good coverage for diabetes of course.

Mrs. Brooks. I would hope so.

Mr. Kowalski. And we've been switched, and this is very frustrating because then you take a step back. For some people that's okay, but insurance companies shouldn't be making those decisions. The physician and the person with diabetes should be.

Mrs. Brooks. And did anything happen, so you were forced to switch insulins and were you required then to pay more or less for the insulin that you were instructed to switch to?

Mr. Kowalski. Fortunately I did not, but I can tell you just anecdotally a good friend, who again works in the diabetes business, his daughter and his foundation switched insulins and she had three incidents of severe hyper, high blood sugar glycemia. It took him 8 hours, and he is a professional who works in this field, on the phone plus the time of the physicians, so the physician calling a physician at the insurance company, to make a decision that his physician had ordered. So I mean this is a broken part of the system that JDRF is also committed to fixing.

Mrs. Brooks. Does anyone know, is there any data being kept about this switching issue and whether or not people are keeping track of these incidents or any organizations, just out of curiosity, keeping track of when the switches are being required to take place? Dr. Cefalu?

Dr. Cefalu. That is data--first of all, I agree with Dr. Kowalski. This is an issue in our survey that again 25 percent had problems with the cost of insulin and the use of insulin and one of those uses was being switched to another brand of insulin. And someone may be able to afford their insulin but then go to the pharmacy and find out that insulin is no longer available. So that is more, again it's more than an inconvenience. We need data, we need research, and really what the medical cost of the non-medical switching because once again making it more difficult for a patient who has controlled blood sugars is only going to result in poor outcomes over time.

Mrs. Brooks. Thank you.

Ms. Marchand--

Ms. Marchand Aprigliano. Aprigliano.

Mrs. Brooks. --Aprigliano, can you please share with us information that you are familiar with when doctors of patients must go through what is called "fail first" or step therapy and what the process what that means and what the implications of

that might be and that where a health insurance requires a patient to try other insulins first and prove they fail, which can you please explain how that works?

Ms. Marchand Aprigliano. So as insulins have become different we have insurers deciding that they want to pay for one type of drug, one type of insulin over another. I have a very good friend who works in the diabetes space, also is type 1, and he has been on a long-acting insulin for the last 2 years. He's great, no problem, A1Cs are terrific. Insurance decided that they wanted him on a different drug and in order for him--he could not even go through the prior authorization to get an override. He had to try one drug for 3 months. And then if he failed on that drug--

Mrs. Brooks. What does failure mean?

Ms. Marchand Aprigliano. Failure means a severe low--

Mrs. Brooks. And I have 13 seconds.

Ms. Marchand Aprigliano. --sorry--severe low or severe high. He failed, but yet had to go through another 3-month period of failure again. Meanwhile, he's having severe lows while he travels. I worry about him. I know his family worries about him. And this is through his insurance, it wasn't a choice. His medical provider has been fighting for him to change that.

Mrs. Brooks. And so it would be up to the patient to get

the insurance to change that coverage, or his physician.

Ms. Marchand Aprigliano. The insurance has denied twice because they believe that insulins are interchangeable, which they aren't.

Mrs. Brooks. Okay.

Ms. DeGette. And thank you.

Mrs. Brooks. I yield back.

Ms. DeGette. We have heard situations of patients who said you have to have a severe incident, so they actually tried to manufacture their own severe incident so they could get the insulin they need, which is crazy.

Dr. Ruiz is now recognized for 5 minutes.

Mr. Ruiz. Congressman Brooks, I have a bipartisan bill with Dr. Wenstrup that is the solution to this step therapy issue that gives it more of a patient and doctor voice in that decisionmaking process, so I look forward to sharing that with you and working with you on that.

I would like to thank the Chair DeGette for holding this important hearing and for her tireless work as chair of the Diabetes Caucus where I am honored to serve as a vice chair to work on policies that address issues like the affordability and access to diabetes medications and care.

I saw patients in the trailer parks in the Coachella Valley

where I grew up. I saw patients in the emergency department where I practice, and I see patients in the streets, mostly homeless, in street medicine who over and over have the signs and symptoms of the devastating health effects of not taking their insulin or rationing their insulin.

And as the prices of insulin have gone up, many patients have taken to cutting back on the amount of insulin that they take or even skipping doses entirely to stretch their insulin as long as possible. When I was leading a healthcare initiative, we had a community forum in the town of Mecca in my district, and afterwards I saw an elderly woman dig through the trash. And I went over and I was curious. I asked her what she was doing and she told me she was collecting aluminum cans because she can't afford her insulin and she was trying to collect cans for the rebates so she can pay for insulin. But she said, "But don't worry, Doctor." She told me, "Don't worry, I only take half a dose so it can last." Okay. So while this is a common reaction, rationing insulin carries enormous medical risks.

I have seen the patients, okay, I have treated the patients in diabetic ketoacidosis and hyperglycemic comas. I have seen the patients in pain because of their neuropathy. I have seen the patients who were rushing to the dialysis center because of nuance and renal failure and hyperkalemia.

I have seen the patients who come in with cardiac arrest because of that hyperkalemia and having to resuscitate them and send them to the ICU. So I have seen the emergencies that not taking insulin and not managing their glucose effectively can cause.

Dr. Lipska, you found that 1 in 4 patients who participated in your study said that they had used less insulin than was prescribed by their doctor which led to poor control of their blood sugar. Dr. Lipska, I want you to talk more about your experiences about the people in your study who underused or rationed their insulin and why did they do that.

Dr. Lipska. Right. So we've heard a lot of stories and I appreciate you sharing yours as well. I think that there are dramatic stories of people who underuse insulin such as diabetic ketoacidosis admissions, emergency room hospitalizations, but there are also a lot of stories of people using less than prescribed for prolonged periods of time and it takes a long time for some of these diabetic complications to then arise.

And so we're seeing this problem of rationing now. We're going to be seeing the complications down the road, some of these long-term complications that you mentioned, neuropathy, blindness, and, you know, more dialysis. These patients are suffering. So my Diabetes Center sees lots of patients with type 1 and type 2 diabetes. My niche is more people with type 2

diabetes who have had it for a long time, so that's why I presented my patient Maria to you. These patients have had diabetes. They've lived with the diabetes, they've lived with the diabetes for a long time. They have multiple other chronic conditions. They have other expenses. They have big expenditures and they're really suffering.

Mr. Ruiz. And so many times the patient feels that if they don't feel anything then they are not sick, so why do they have to take insulin. I have done talks about how this is this is the silent killer, right. You don't feel anything.

I have an uncle who says, "Ah," in Spanish, "Ah," you know, "it costs too much money. I would rather like put food on the table and use my car to go to work and pay the car bills, et cetera, than paying for insulin. I don't feel sick. I don't feel sick, so I am not sick." So there is a lot of miscommunications in that.

Dr. Cefalu, in your opinion, what can you inform patients about the adverse effects of not taking insulin appropriately given what Dr. Lipska just said?

Dr. Cefalu. Well, number one, if a patient can't afford the insulin the first thing we suggest is actually talk to their provider. Again, it may be that patient can take a least expensive form of insulin that may be appropriate. In the

majority of cases perhaps it's not, but you need to inform the patient what to expect.

Again, over the short term, a poor control of sugars, particularly in an elderly person, will lead to some mental status changes, dehydration, and that could lead to an emergency room visit in which there is tremendously high blood glucose, a hyperosmolar state, so this is not specifically just in type 1. But for type 1, poor control again may lead to increased urination, dehydration, nausea, vomiting, and again leading to ketoacidosis.

So educating the patient on what to expect so that if they are heading down this road that you can mitigate it is incredibly important, but the main issue, the bottom line is that insulin is a matter of life and death and nobody who needs insulin should ever go without it because of prohibitive costs and that's the issue we're trying to address here. We can put in mitigating circumstances to talk about patients and what they can do if they don't have the right insulin, but if they can't afford it that's the main problem we're here today to try to address.

Ms. DeGette. Thank you.

Mr. Ruiz. Thank you.

Ms. DeGette. Thank you very much.

The chair now recognizes Dr. Bucshon for 5 minutes.

Mr. Bucshon. Thank you, Madam Chairwoman. I was a cardiovascular surgeon before I was in Congress, so I changed professions a little bit. This is a very important topic. As a heart surgeon, a lot of my patients had diabetes, pretty substantial percentage. As you know, cardiovascular disease is one of the big things that happens.

I am going to ask something related to the 340B program. To remain eligible for participation in the Medicaid program, drug manufacturers must provide certain outpatient drugs to cover entities in the 340B program at significant discounts. And in certain circumstances, these manufacturers must sell their products to 340B-covered entities for a penny. Some, but not all, 340B-covered entities pass these savings on to patients. For example, during the committee's investigation of the 340B program during the 115th Congress, one 340B entity told the committee they offered insulin at $10 a vial to certain qualifying patients. So $10 costs them a penny. So, Ms. deVore, as a patient, do you have any experience with 340B drug pricing?

Ms. deVore. My husband actually works at a healthcare facility that has a 340B pharmacy and I have the availability of utilizing that pharmacy. But it doesn't, the cost difference--

Mr. Bucshon. Doesn't really make any difference?

Ms. deVore. No, it does not make any difference.

Mr. Bucshon. You haven't seen anything. So it hasn't affected you directly?

Ms. deVore. As far as the price is the same.

Mr. Bucshon. Yeah.

Ms. deVore. Whether or not I use a 340B pharmacy or outside, under our insurance plan.

Mr. Bucshon. Okay.

Ms. deVore. Because the way our insurance is structured that even with Fiasp that's not on the formulary because it's non-formulary I still pay the full retail price.

Mr. Bucshon. Okay. Does anyone else want to comment on 340B? Anybody have an comments on the 340B program?

Oh, too bad. I thought you were going to have a lot of comments on that.

And I won't take too much more time, Madam Chairwoman, because some of the concern that I have about 340B in a larger context is that because of the companies have to sell some of their products at such a low discounted price to 340B-covered entities, that on the backside of that to make up for that it is putting upward pressure on drug prices otherwise for non-340B-covered entities.

And so I think that I would encourage the subcommittee

to--this committee to also as part of our investigative look at pricing on insulin, also consider the ramifications of the dramatic exponential growth in the 340B program as a whole. And based on our previous subcommittee hearings in the last Congress, try to address some of the abuses that are occurring in 340B that may very well be putting an upward pressure on drug prices as a whole.

And with that I yield back.

Ms. DeGette. The gentleman yields back.

The chair now recognizes Ms. Schakowsky for 5 minutes.

Ms. Schakowsky. Thank you. Approximately 1,325,000 or 12.5 percent of the adult population in my home state of Illinois have diabetes. In 2017, Illinoisans diagnosed with diabetes were forced to spend $8.7 billion for direct medical expenses. I am talking about hospital inpatient days, emergency visits, ambulatory visits, but these costs don't even include the price of insulin itself.

The three pharmaceutical companies who dominate the global insulin market have raised their prices in lockstep over the past several years. When Eli Lilly introduced its Humalog brand of insulin in 1996, the list price of a 10-millimeter vial was $21 and it is $275 per vial, and diabetes patients as we heard can use four a month, sometimes even six a month for some individuals.

And when Sanofi insulin brand debuted in 2001 it was $35 a vial, now it is 250. And when Nova Nordisk insulin, Novolog, was introduced in 2001 it was $45, and now it is $289.

And I just want to note that these current prices are curiously similar how they have raised those prices. And though there is zero transparency into the business practices of these companies, I know none of them can logically attribute these price hikes to increases in manufacturing costs, for example, which we have heard, and not when insulin has been around since 1921 and improved human analog of insulin has been around since 1996.

So Ms.--I am going to try and get it right--Ms. Marchand Aprigliano, it seems to me that these pharmaceutical companies raise the price of insulin because they can. And am I wrong? Is there a better or more justifiable explanation for this?

Ms. Marchand Aprigliano. I don't work for the insulin manufacturers, so I can't say that--

Ms. Schakowsky. Okay, does anybody there want to give--yes, go ahead, Dr. Powers.

Dr. Powers. So I would just say that the price of the same drugs, those same insulins in Canada, Germany, France, England, very different. I have the story of one patient who paid $300 for her insulin in the country. She lost it when she was in London, had to purchase a replacement, $30.

Ms. Schakowsky. So this a decision that we don't have any transparency into how they do that, but I think this example tells us it doesn't need to be that expensive.

Dr. Cefalu, the American Diabetes Association white paper details the role of drug companies in this system. How do you account for an over 1,000 percent in the price of insulin since the 1990s?

Dr. Cefalu. Well, Congressman, as you've stated, the innovations since the 1990s, the price has tripled since 2002 as far as list price. And this is one of the concerns is that we don't know the factors behind how they set the list price. It's not in the public domain and this gets back to increase an in transparency, I can't speculate as to what those factors are.

In the Working Group, again getting back to the recommendations and conclusion of the Working Group, it's increased transparency that will get to the bottom of these price increases throughout the supply chain. So I don't know those factors that increase the list prices.

Ms. Schakowsky. I actually have legislation on a transparency bill. Let me just say that I want to associate myself with what Dr. Burgess said and I feel that this is considered a national, international health, lifesaving issue,

the issue of insulin and diabetes.

I think that we--and my time is up, but I would love to hear and maybe I will submit it for the record why you might think that we could save money, actually, if we would address diabetes and provide insulin to the people who need it. And I yield back.

Ms. DeGette. The chair now recognizes the ever-patient Mr. Sarbanes for 5 minutes.

Mr. Sarbanes. Thank you.

I just wanted you to speak to your confidence or lack of confidence on whether you think we can actually achieve some of these transparency measures that we have been talking about today. You have been around a long time, you know how the PBMs operate. And the manufacturers, you know that there is this kind of hocus-pocus exercise that has been going on for decades and the patients are left holding the bag on that.

So, you know, we are talking in a bipartisan way about the problem you all are pretty unified in your views that there is a problem, a structural problem that transparency would be a very good first step. So are we just going through an exercise here? What is your--I don't mean that you all are. But you are looking at us and you know that it is hard to break the stranglehold that the PBMs and the manufacturers have on how the system works and they have kind of reached--I mean in theory they are supposed

to be at arm's length, but they have managed to figure out a way to structure the system so they can be negotiating at a level that always protects, it appears to me, their profits at the expense of the patient.

So I just, I invite any of you to tell me maybe on a scale of 1 to 10 how optimistic you are that within the next 5 years we can achieve the transparency that would actually make a difference in terms of the impact on insulin pricing, but any other kind of pricing out there.

Dr. Cefalu. So there are a number of things that we can do and I think you've heard a lot of those recommendations today. Based on what we understand, I think it's clear the cost sharing for the patients is too much and whatever we can do to remove or lower the cost sharing would be important, removing insulin from the deductible, minimizing co-insurance, those are some things that we need to move forward, making sure that patients with diabetes continue to have the affordable health insurance so they can take care of their disease.

We haven't talked much about biosimilars, but there are steps moving to make more biosimilars available on the market. If biosimilars were more like traditional generics, we would have the lower price. And I know the FDA has taken some steps to increase efficiency in the biosimilar process, so those are some

of the things that were pointed out from the Working Group.

Mr. Sarbanes. By the way you just revealed yourself almost to be a plant on my part because I, and you are not, but I happened to introduce a biosimilars bill and have been working very hard to respond to these pay-for-delay schemes in that environment as well as with respect to prescription drugs. So you are absolutely right that is something that can be done.

Dr. Cefalu. And the fourth thing that you've heard today is that the patient with these negotiations are not benefiting and just ensuring that the results of these negotiations, the rebate and discounts, make it to the patient at the point of sale to reduce the costs. So those are, I think, some general principles that we should move toward to reduce the cost of insulin.

Mr. Sarbanes. So I agree with all of that. But just coming back to the question of how confident you are, what your level of optimism is, particularly now that we are hearing bipartisan criticism of the system, that we can actually get some of these basic transparency measures in place. But before you answer, I will just say that as far as I can tell there isn't any consumer in America who needs medicine at one time or another that is not impacted in that by the PBMs and how they operate.

And I am sitting here, every comment that you all have made

alludes to the profits that the PBMs are making and how they are looking to maximize their profits. They could probably do their job just as well if they were a nonprofit, I assume, right, and the fact that they touch every American certainly raises questions about whether they ought to be regulated more like a utility than to operate as a for-profit industry. There has got to be people in the room who just shuddered when I said that. So I would, frankly, start from that perspective given the impact that they have.

Any other comments? Yes, Ms. Marchand Aprigliano?

Ms. Marchand Aprigliano. See, you got it right.

I think the biggest issue is it's not just transparency. Transparency is one thing. If we find out what the cost of each section of the supply chain takes away from the patient it's the actual action that Congress will help us as protectors of the patients and citizens in the United States, whether it's fixed fee per transaction, whether it's designing to mandate that insulin is capped at a certain percentage, all of this has to be done.

We all know exactly what needs to be done. The end result is we need to have reasonable access and affordable access to insulin. Transparency is the first step, but we have got several other steps to go along with it. I am absolutely resolute that

we will find an answer and that Congress will help us with that.

Mr. Sarbanes. Thank you and I yield.

Ms. DeGette. Thank you.

The chair now recognizes Ms. Barragan for 5 minutes to question.

Ms. Barragan. Thank you.

I want to thank the panelists for being here today and for sharing your story. It is really heartbreaking when you hear about people who have to choose between medication like insulin and rent and other expenses.

Not long ago I was at the hospital with my mom who has diabetes and her blood sugar was pretty high. And I remember having a conversation about her needing insulin and the rising, really, the skyrocketing cost of insulin. And I thought to myself for a moment what would happen if we couldn't afford this, because we hear these stories day in and day out. We hear stories of people who ration, as you mention, the insulin and then die. And when that is happening in America, something is broken and people look to Congress. And so today when I see you, I thank you, and I speak on behalf of my mother and my sister-in-law and the millions of Americans that are living with diabetes.

I happen to represent a congressional district in California that has the highest rate of diabetes than any other congressional

district in the state of California. It happens to be a district that is about 88 percent Latino/African American, communities of color, communities that are suffering, and those who in my district have a very low household median income. One of my colleagues handed a list of about all the members and I think I was 350 of the household incomes.

Just to kind of show, I mean I represent areas like Compton and Watts in south Los Angeles, and it is just unconscionable that the price of insulin is unaffordable and it really breaks my heart. And one of the things I hear in my district, certainly when I have town halls, is what is Congress doing? What kind of oversight are we doing? I think this is a step.

But, frankly, I will tell you what I want to see, I want to see the drug manufacturers brought in. I want to see the PBMs brought in and I want us to ask the tough questions, because we have got to get down to why this is happening. Why is it that insulin has skyrocketed? What has happened? And let's hear from them to get to a solution. Frankly, the American people think that because they have a big lobby Congress is doing nothing, and there may be instances where that is happening. And we have to come together to show that we don't care about the lobby. We don't care about private industry in the sense that we are colluding with them, because sometimes the American people think

that. So I hope that we are going to have the oversight hearing.

Ms. DeGette. Would the gentlelady yield?

Ms. Barragan. Sure.

Ms. DeGette. We are bringing them in next week.

Ms. Barragan. Fantastic.

Ms. DeGette. You are welcome.

Ms. Barragan. And that is why I said this was a great start and I am really looking forward to having that conversation because this is what the feedback that I am hearing in my congressional district. And, frankly, we have been working for the people in trying to fix health care in this country. It hasn't been easy and it has been very frustrating.

I want to ask Dr. Kowalski, can you outline how the rising cost of insulin affects our minority communities and provide me with an estimate, if you have any idea, how many people of color die each year because they are unable to afford things like insulin, lifesaving medication?

Mr. Kowalski. I don't know that we have the best data on deaths due to lack of insulin, but we certainly know if you're socioeconomically disadvantaged this is a huge burden. And we heard across the income spectrum, but as you push lower it's worse. And JDRF funds research across the country including areas that are socioeconomically disadvantaged and often the choice that

are made are food on the table versus drugs. And again, I think this is--it's so, I would call it penny unwise-pound foolish, because we're cutting back and actually paying heavily on the back end whether it's diabetic ketoacidosis, diabetes complications, or, tragically, deaths. So this is a gross injustice that needs to be fixed.

Ms. Barragan. Thank you.

Ms. Marchand Aprigliano, the current Secretary of Health and Human Services, Alex Azar, was a former drug company executive. While president of Eli Lilly, Secretary Azar oversaw huge increases in the price of the company's insulin medications. The U.S. list price of Humalog insulin has more than doubled. How can we believe the current administration is serious about reducing the price of insulin when President Trump appoints the man who has contributed to the current drug pricing crisis?

Ms. Marchand Aprigliano. I don't have an answer for that. If anybody does have an answer for that I'm happy to listen. All I know is that the system that we are currently living in is unsustainable for individuals living with diabetes today. Solutions come from all different sources and I'm hoping that bipartisan support for individuals with diabetes to ensure that access to affordable insulin is available for everybody regardless of socioeconomic status, regardless of age, every

single person should not die or ration because of lack of access. This is just one step.

Ms. Barragan. Great, thank you. I yield back.

Ms. DeGette. Thank you.

The chair now recognizes Mr. Carter for 5 minutes.

Mr. Carter. Thank you very much, Madam Chair, for allowing me to sit in on this meeting, and thank all of you for being here. This is a very important hearing, I can attest. I practiced pharmacy for over 30 years and I have dispensed a lot of insulin over those years and I have seen what has happened with the price of that and it is concerning.

But before I begin just a couple of questions, let me say that I am proud to have Alex Azar as Secretary of Health and Human Services. I think he has done an excellent job. He is addressing a situation that the President has made one of his primary initiatives, that is, prescription drug pricing and specifically insulin drug pricing. Yes, Dr. Azar did serve as, or Secretary Azar served as CEO of Eli Lilly, and in many ways, I want someone, I want to know what is going on and I want someone helping me who does know and has the inside track.

So having said that I would like to start with Dr. Cefalu? I am sorry. I hope I got that right.

Dr. Cefalu. Cefalu.

Mr. Carter. Cefalu?

Dr. Cefalu. Cefalu.

Mr. Carter. Cefalu, excuse me. Well, thank you for being here. I wanted to ask you, what about transparency? Do you believe that transparency could help in the price of insulin or could play a role in the price of insulin?

One thing that has always concerned me has been the very opaque drug supply chain. I have dealt with this for many years. In fact, before I became a member of the Energy and Commerce Committee, I served on the Oversight Committee and we had a situation where Mylan Pharmaceuticals, it was about the price of the EpiPens.

And I had a chance to talk to the, or ask questions of the CEO of Mylan at that time about when it left the manufacturer, that is the beginning. I am the end. I am the pharmacist, I am dispensing it. When it left the manufacturer, it was $150 and that is what she told me and I believe her, and that is what she told me, okay. But when I dispensed it at $600, well, what happened in between? I am just trying to figure out can transparency help us in this situation?

Dr. Cefalu. Well, transparency in and of itself is not the answer. What transparency will do will help us understand the factors that go into the flow of dollars. Some of the things

that you mentioned is trying to understand what happens between each entity, and again we have to address this as a systemic problem. Going after one entity in the supply chain is not going to be the answer.

So understanding the negotiations between the manufacturer and the wholesaler, understanding the fees, the discounts, the rebates that occur between the manufacturer and the pharmacy benefit manager. The pharmacy benefit manager, how much rebate goes to the health plan, how much is--

Mr. Carter. But that is transparency. What you are describing is transparency.

Dr. Cefalu. That's transparency. Transparency--

Mr. Carter. So what you are saying is yes, we do need transparency to understand the drug supply chain.

Dr. Cefalu. Transparency's needed to understand the drug supply chain as to a long-term, coming up with a long-term, viable solution.

Mr. Carter. Great. Are you familiar, Doctor, or are any of you familiar with CMS's proposed rule changes as it goes to discounts being offered at the point of sale, as opposed to the way they are now where we don't even know where the discounts are going or who they are being applied to? Any of you familiar with that? I see you shaking your head. Any thoughts on that?

Dr. Cefalu. This aligns with some of the conclusions from our Working Group, again to make sure the rebate makes it to the patient at the point of sale.

Mr. Carter. Right. And do you believe that is happening now?

Dr. Cefalu. I can't say that's happening now.

Mr. Carter. Neither can I and neither can anyone. I mean if we don't have transparency we don't know. Anyone else care to comment on that?

I am sorry, I can't--

Mr. Kowalski. JDRF is supportive of this. It's one mechanism to remove rebates from the system and pass them along to consumers. We need to see this in the commercial sector as well. It's a step and I think we've heard there are systemic issues, but we see this is an important step.

Mr. Carter. Good. And yes, ma'am?

Ms. Marchand Aprigliano. So the fact is that the safe harbor protections, the two that have been recommended as part of the proposal, the second step in this is a fixed fee per transaction. And that is incredibly important when we're talking about transparency, because all of a sudden that is taken away, the rebates are taken away and what happens is that this goes to the patient, not lost in the system.

Mr. Carter. Good. Well, thank you for pointing that out because I would agree with you.

And, Dr. Cefalu, you are correct, we need transparency but that is not the only thing we need. But I would submit to you that that is an important part of what we are seeing right now. If you look at the mission of the pharmacy benefit managers, the PBMs, it will tell you their mission is to keep prescription drug prices low. Well, I would ask you, how is that working out? Obviously, it is not working out very well at all.

And when you have three PBMs that control almost 80 percent of the market, I don't think we have enough competition in that area. I want transparency and we need transparency. It is the only way we are ever going to see exactly how we can attack this problem that impacts everyone. It is a nonpartisan problem.

Thank you, Madam Chair, and I yield back.

Ms. DeGette. Thank you so much, Mr. Carter. The gentleman yields back.

The ranking member and I have a few more questions that I am going to ask and then he might have a few to follow up. But I do want to say, you know, Mr.Sarbanes was asking all of you how likely you felt it was that Congress would do anything, and I don't blame you for not wanting to answer. I will say this. I will say this though, you can see that the urgency that we

all feel about insulin pricing is bipartisan. I mean, Mr. Guthrie and I have worked hand-in-hand throughout this process. Usually the minority gets a witness and we agreed all the witnesses are the majority and the minority witnesses today. Ms. Brooks and Dr. Ruiz are both vice chairs of the Diabetes Caucus of which I am the chair. We are committed to fixing this. So I want to let all of you know this and everybody else who is listening, we are committed to a bipartisan solution and these questions I am asking are in that vein.

The first one is, Dr. Powers, this is something that I don't think has come out. People are asking about the list price and some people think it is the manufacturer, some people think it is the PBMs. But, in fact, virtually everybody in the system ties their pricing to the list price; isn't that correct?

Dr. Powers. That's my understanding.

Ms. DeGette. And so the higher the list price, everybody in the whole system gets a higher reimbursement; isn't that also correct?

Dr. Powers. Dr. Cefalu referred to the Working Group that the ADA had and that was their conclusion. I remember that Working Group and that was the conclusion of the Working Group.

Ms. DeGette. Right. So it is not just the manufacturers and the PBMs, it is endemic to the whole system which is why we

need to adopt a lot of these changes; is that right, Dr. Cefalu?

Dr. Cefalu. That is correct. Again, this is a systemic problem and it's a dysfunctional system and every level of the supply chain needs to have some accountability.

Ms. DeGette. That is right. And we are starting next week with the PBMs and the manufacturers, but as chair I am saying that I am not sure that we will be done with that after next week.

Dr. Lipska, I want to ask you. Mr. Sarbanes alluded to this issue of the biosimilars, but you held up your vial of insulin. That insulin has not changed in a number of years; is that right?

Dr. Lipska. That's correct.

Ms. DeGette. The only thing that's changed is the price.

Dr. Lipska. That's correct.

Ms. DeGette. But yet maybe, Dr. Cefalu, you can talk about this too, but yet because of patent evergreening we have had an inability to develop a range of generics; is that also correct?

Dr. Lipska. That's correct. And I think that was alluded to in the fact that these companies have increased their prices at, you know, at about the same time by the same amount suggesting there is very limited competition among them.

Ms. DeGette. Dr. Cefalu, do you have anything to add about that?

Dr. Cefalu. The newer formulations particularly in type

1, and I know that Dr. Kowalski can talk about this, have some added advantage over the old human insulins. I think that's clear. What I don't want to see is that actually, and there are a number of individuals on this panel that can talk to this point, I don't think we're there yet as far as innovation for the person with diabetes. We can say we have these wonderful analog insulins now, but we still have unacceptable rates of hypoglycemia which needs to be addressed.

So to Dr. Kowalski's point, we need to address the issue of affordability but we need to continue the innovation, because from our perspective we still need to advance newer and better insulins to address this issue.

Ms. DeGette. Dr. Cefalu, I totally agree with you. But we also need to find ways to get cheaper versions of the insulins that we have, right?

Dr. Kowalski, maybe you can comment on this.

Mr. Kowalski. Yeah, I think at JDRF we often say that we believe in competition. That competition drives innovation and affordability. And here we have a system where you have three similar insulins going up instead of down in price, which is confounding, and obviously we've heard that there are a lot of reasons that's happening. We aren't saying that the insulin companies shouldn't be profitable and invest in next generation

insulins.

Ms. DeGette. Right.

Mr. Kowalski. You heard from Dr. Powers that they're selling insulin abroad at a much lower price. So the question is, how can we make that happen in the United States of America and make sure insulins are affordable? That good insulins--my brother as I mentioned in my testimony has benefited from these advances in these insulins, but they need to be affordable. You do not achieve better outcomes. So having biosimilars or generics come to the market is another mechanism to drive affordability.

Ms. DeGette. Thank you.

Okay, I have one last question. I want everybody on the panel to briefly answer this question. Next week we are going to be having much of the supply chain here. We are going to have all three manufacturers and we are going to have the three largest PBMs. So I want to ask each of you to tell me and Mr. Guthrie, what is the one question next week you would ask of this panel?

Mr. Guthrie. That was my question. I was going to ask that.

Ms. DeGette. That was his--see, this is how bipartisan this is.

Mr. Guthrie. Don't make it shorter. Yeah, that was actually my--asked that question.

Ms. DeGette. Ms. deVore?

Ms. deVore. I would ask them why in their FDA filings and common talk amongst themselves at the time when they all, when Nova Nordisk and Eli Lilly both filed for Humalog and for Novolog that their statements included that insulin would become cheaper to manufacture and how has that--why has that turned out to not be the case.

Ms. DeGette. Thank you.

Dr. Cefalu?

Dr. Cefalu. I would ask them what is the hurdle from preventing the negotiations of the supply chain from making it down to the patient now.

Ms. DeGette. Okay.

Dr. Powers?

Dr. Powers. I'd ask them what is the best plan to get to affordable insulin, comma, and why aren't we arriving at that, comma, and what are you doing to help with that process.

Ms. DeGette. Thank you.

Dr. Lipska?

Dr. Lipska. I would ask how many more Americans will it take to die before prices come down.

Ms. DeGette. Thank you.

Ms. Marchand Aprigliano? We will have your name right by

the end, I think.

Ms. Marchand Aprigliano. Hopefully.

My question would be is what are you willing to give up in order to make sure that every single person with diabetes has access to affordable insulin.

Ms. DeGette. Thank you.

Dr. Kowalski?

Mr. Kowalski. I would ask how can we ensure that people with diabetes are paying the net price and why aren't we seeing that passed on to the consumer with diabetes.

Ms. DeGette. Thank you. Thank you.

Mr. Guthrie?

Mr. Guthrie. That was my exact question. I was going to say give me your elevator question that you would ask in 30 seconds from--but so we have put a lot of research into this. We really want to get this right because we have innovation coming and we want to make sure we have innovation in other areas of diabetes delivery.

And so when we met with--I know I have met with at least--specific manufacturers said that they don't believe anybody is paying more than $99. And so you guys are with all the pay, all the movement forward, you are saying that is just absolutely not--because I want to get to it next week. So you

are saying that because we may hear that, that through all the programs, whatever, people really aren't paying $1,400 a month. You are saying there are clear examples of people paying $1,400 a month that you know of. Not just anecdotal, people that you know of that are paying those full prices, all of you? That will be good to know.

Well, thank you--you wanted to--

Dr. Lipska. I can answer that question more specifically because we asked people in the survey, how much do you pay monthly or, sorry, annually for your insulin? And as you can expect it was difficult for people to estimate exactly, but the ranges, you know, were from zero to 5 to $600, on average, throughout the year.

Mr. Guthrie. Okay.

Mr. Kowalski. Ranking Member Guthrie, in my role at JDRF I travel to almost every state in our great country and it is, as I stated, the number one question I get with specific examples of paying exorbitant out-of-pocket costs. So it's absolutely still a prevalent problem.

Mr. Guthrie. Ms. deVore?

Ms. deVore. And I can leave this receipt for you. It is a copy from January 19th of 2019 for $728.49 from a friend of mine.

Mr. Guthrie. Thank you.

All right, I appreciate that. I just want to get that on the record as we go forward.

Ms. DeGette. Thank you so much.

I want to thank all the witnesses for coming today. And -- let me get to my conclusion here. And I want to thank all of the -- this way? There we go. I want to thank everybody for coming.

Pursuant to committee rules, members have 10 business days to submit additional questions for the record to be answered by witnesses who have appeared before the subcommittee. And I would ask all of you to respond promptly to any such questions that you should receive, in particular if they are relevant to next week's hearing that would help us in the hearing.

And with that -- and we also may invite some of you back at some point to brief us as to whether the companies are making any progress. We are serious about this. And my staff says that we might invite them back in September, but I think we might invite them back sooner because we are really committed to doing this. And with that the subcommittee is adjourned.

[Whereupon, at 12:54 p.m., the subcommittee was adjourned.]