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Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce

Priced Out of a Lifesaving Drug: The Human Impact of Rising Insulin Costs

Tuesday, April 2, 2019
10:30 am; 2322 Rayburn

Purpose

Purpose of the hearing was to examine insulin affordability and the ensuing financial and health challenges and effects on patients' lives.

Members Present

Chairwoman DeGette; Ranking Member Guthrie; Rep. Pallone; Rep. Walden; Rep. Schakowsky; Rep. Kennedy; Rep. Ruiz; Rep. Kuster; Rep. Sarbanes; Rep. Burgess; Rep. Brooks; Rep. Bucshon; Rep. Barragan; Rep. Carter

Witnesses

Gail deVore
Patient Advocate
Coloradan living with Type 1 diabetes for 47 years

William T. Cefalu, M.D.
Chief Scientific, Medical & Mission Officer
American Diabetes Association (ADA)

Alvin C. Powers, M.D.
Endocrine Society Representative
Director, Vanderbilt Diabetes Center
Director, Division of Diabetes, Endocrinology, and Metabolism
Vanderbilt University Medical Center

Kasia J. Lipska, M.D.
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 (DPAC)

Aaron J. Kowalski, Ph.D.
Chief Mission Officer
JDRF

Opening Statements

Chairwoman DeGette stated that the purpose of today's hearing was to examine insulin affordability and the ensuing financial and health challenges and effects on patients' lives. The Chairwoman highlighted patient stories on the high costs of insulin and data relating to insulin prices. She noted insulin ensures the health and wellbeing for millions with diabetes. It is a lifesaving drug. The scientists that discovered insulin knew its importance and they were concerned about costs it those needing the drug. So they sold the patent for $1 to ensure access to insulin. But today, skyrocketing prices are making it unaffordable. We have been hearing stories for too long. She heard from constituents on the costs of their insulin and described those stories. People are living day-to-day, bottle-to-bottle. Parents with children with diabetes are also living with this stress. Parents worry about the costs when a child leaves parent insurance. One in four people with diabetes ration insulin, and these patients have increased negative health outcomes. She noted that next week the Committee will hear from key players in the supply chain on the costs of insulin.

Ranking Member Guthrie stated that list price of insulin tripled over the last few years. However, or the same time, net prices have decreased or remained flat. Some patients are paying the list price of insulin, especially if they are uninsured or underinsured, or if they have high deductible health plans (HDHP). Additionally, it is difficult to qualify for patient assistance programs. And the formulary exclusions are having an impact on patient costs. Prescription drug supply chain is complex and lacks transparency. It is difficult to understand my insulin prices have increase. There is a lack of transparency and the patient loses. This hearing is an important case study on the increasing costs of prescription drugs effecting patients.

Rep. Pallone stated that today's hearing is important in examining prescription drug costs. Families are suffering with the high costs of prescription drug costs. No one should suffer due to the high costs of insulin but unfortunately this is happening. This is devastating for the uninsured, underinsured, and those with HDHP. We need to find solutions while also ensuring no one rations insulin. It is important to talk about the drivers of these costs. Lack of transparency between stakeholders makes this more complex. Manufactures preventing generics, PBM influences. We are going have these representatives here next week. I also have concerns about the Administration's proposal rule. Costs of insulin must be address but this is not the right solution. The health of millions depend on insulin. I am looking forward to hearing the witnesses' testimony.

Rep. Walden stated that my grandfather suffered from diabetes and he lost both legs. This is really important stuff. And we are going get to the bottom of this. There are many types of innovative solutions for addressing the disease. We are proud of the development of innovative drugs. We need to continue innovation but need affordability. The supply chain has evolved to harm patients at the pharmacy counters. However, net price has not changed. Instead list price has increased and rebates have changed. No one is supposed to pay list price but they do, specifically the uninsured, underinsured and, those on HDHP. The 3 major insulin manufactures offer patient assistance program – but these are not a long term solution to access affordable drugs. I hope to learn more about the situation. Additionally, when we examined the 340B program last Congress, we learned that *some* covered entities passed the full savings/discounts on to patients, including for insulin. Since 340B entities can purchase drugs at a discount, diabetic patients can really benefit if the savings was passed on to them. I want to ask that we continue to investigate these cost drivers. We need to investigate health care drivers through a holistic approach.

Rep. Burgess noted that there are no major changes to the chemical structure of insulin, and there are changes in the importance of insulin to diabetics. So under normal circumstances so you expect prices would decrease. I look forward to the panel discussion and what Congress can do, so that no one is forced to choose insulin and the other necessities of life.

<u>Testimony</u>
Ms. deVore stated she is a Type I diabetic and relies on insulin. She has been a diabetic for 47 years. She and her husband are careful spenders and budget their money. However, she doubts that her or her husband will ever be able to retire due to her diabetes. She and other diabetics rely on insulin to stay alive. She previously was in coma due to rationing insulin. She needs insulin every day, every hour of her life. She rations her insulin against her doctor's advice and against the Novo Nordisk instructions. In her testimony she provide personal experience on the costs insulin and discussed how the increased costs affects her, her family, and others how have diabetes.

Dr. William T. Cefalu stated that there is no substitute for insulin. In 1920, insulin was discovered and the researchers sold the patent for $1 to ensure people could afford it. In recent years there have been few advancements but the prices are increasing, creating a burden for patients. When people can't afford insulin they skip or take less but this can create deadly situations. The ADA has heard increasing number of stories on patients rationing insulin. No person should be denied access to insulin. We called on Congress to examine all stakeholders in the supply chain. We continue to hear from people on rising costs of insulin but depend on it for life. ADA has created a workgroup to advise how to lower the costs on insulin and published a white paper including recommendations on how to lower the rising costs of insulin.

Dr. Alvin C. Powers stated he is a physician scientist. People are rationing insulin, which is increasing complications. Rationing is happening across the US. However, the insulin problem is unique. There is no other lifesaving drug that so many people would die without it. Additionally, there has been little change to the product but costs increase. The insulin discoveries sold their patent so all could have access, but exactly the opposite has happened. When I prescribe insulin, I do not know how much the insulin will cost a patient. HDHP patients, uninsured pay high costs for insulin. Our insulin supply chain is broken and needs changes. He noted that no one understands the rising cost of Insulin - there is a lack of transparency in how drug prices are negotiated. Rebates between manufacturers, pharmacy benefit managers, and health plans are not passed along to consumers. Regulatory systems and patent extensions restrict the introduction of more generics. Addressing the insulin costs is a priority for the Endocrine Society and they have published recommendations on opportunities to reduce patient costs. If we address these issues in insulin, the solutions also could be expanded to other drugs.

Dr. Kasia J. Lipska stated she is an endocrinologist and a research scientist on faculty at the Yale School of Medicine. She noted that she does not have financial ties to drug manufactures. Dr. Lipska discussed a diabetic patient stories. She also discussed a study she at the Yale Diabetes Center which found that 1 in 4 patients used less insulin than prescribed specifically due to costs. These patients also had worse health outcomes. These findings based on data from a single center likely apply to the U.S. as a whole. One quarter of patients are rationing and putting their lives at risk. She discussed the costs of insulin in her local area. One vial of Lantus insulin – which can last for a week or a month, depending on the dose needed – costs $200 at a Connecticut pharmacy. That's the best price available. Insulin has not change, the only that changed is its price. What accounts for this? Drug manufactures make excuses and blame PBMs, or wholesalers. But the list price are set by drug makers. And list prices have gone up and that is what many people pay. The patient assistance program are not helping much. It is hard to find a patient that qualifies. But these are band aide solutions. My patients need real solutions.

Ms. Christel Marchand Aprigliano stated she is the CEO of DPAC. DPAC is a nonpartisan, non-profit group working for diabetics. She is a diabetic and has been effected by the rising costs of insulin. People with diabetes are paying the most, and some are paying with their lives. List prices are set by manufacturers and include rebates to incentive PBMs to put a drug on their formulary. To get preferred status, manufacturers give rebates. The higher the rebate, the higher the list price. This is happening at the same time as more people are using HDHP. No one should pay list price. She discussed her own experience of costs of diabetes, and her experience with a HDHP. She noted that her emergency savings was used for insulin. Their emergency was insulin. For many friends this happens every month. Financial help with copay card and patient assistance programs are not enough. For some insulin services, there are no generics. Patient assistance programs can fail. DPAC and other patient association put out surveys on patient assistance programs. They found that patients only have 50% chance of being helped by these programs and 44% reported a delay in receiving insulin. Medicare Part D beneficiaries are often ineligible for help. They have nowhere to turn. When these stopgap measures fail – patients take drastic measures. Our community is crying out for relief, we believe the solution is to dismantle the current system. DPAC is supportive of the administration's proposed Part D rule that would create two safe harbors - the first protection being discounts that would be passed on to consumers at the point of sale for Medicare Part D beneficiaries. The second safe harbor protection would be the creation of a "fixed fee" arrangement for PBMs, rather than a percentage of the list price of a drug. We call on to expand HHS' proposal to expand this proposal to all insurance plans. This will help destroy the perverse system. We need solutions now.

Dr. Aaron J. Kowalski said you are seeing a united community. He noted that in 1977, my younger brother Stephen was diagnosed with type 1 diabetes. I was diagnosed with type 1 diabetes in 1984. My career has been focused on the fight to cure this terrible disease and to help people stay healthy until that day. As the Chief Mission Officer of JDRF, the leading organization funding type 1 diabetes research, I happy to share our experiences. Type I diabetes is a fatal disease without insulin. The costs of insulin have soured, it's out of control. Beyond the data is your constituents, with the question of how can we make insulin more affordable. When people can't afford insulin they take drastic measures. No one should suffer or die because they can't afford insulin. We need systematic change. We have called on companies to lower the price of insulin. First, manufactures need to lower list prices. Rebates need to be eliminated and we support the Administration's anti-rebate rule and we urge Congress to end rebates in commercial sector as well. Second, insurance companies need offer coverage that reflect insulin role as lifesaving product. Insulin should be removed from the deductible and instead be a flat copay. And third, we need to invest in research. Thank you for your attention and I ask you continue to fight on this issue.

Questions and Answers

Chairwoman DeGette said we have heard stories of patients making sacrifices in their daily lives to afford drugs. I want to ask you, **Ms. deVore**, do you agree that there are patients and parents who do not have access to affordable insulin and are making these difficult choices? **Ms. deVore** said I get emails everyday on how to afford insulin. These are families, adults, and from everyone economic part of society. The price is not dependent on income. Everyone has to pay an expensive price. **Chairwoman DeGette** said we have heard from drug companies that the current pricing system works for most, but you (Dr. Lipska) found 1 in 4 ration/can't afford insulin. She asked Dr. Lipska can you talk about the drug companies point that most people can afford insulin? **Dr. Lipska** said it is clear the system is broken, it is not working for many people. People have died because of rationing. Research has shown this is wide spread. One in 4 people can't afford insulin. It is a huge portion. Chairwoman DeGette then asked Dr. Cefalu how many people do think are effected by the failing system? **Dr. Cefalu** was not sure the exact numbers, but our study agreed with Dr. Lipska's study in that 1 out 4 patients reported that the cost of insulin effected their purchase of insulin, rationed insulin. The concern is if you make it difficult to afford insulin, the patient is not adhering to the medicine and costs is affecting outcomes. **Chairwoman Degette** stated that manufactures are saying that decreasing costs will decrease innovation. She asked Dr. Lipska is she believed that was true? **Dr. Lipska** stated that this is the same stuff, the same insulin that has been around since 1996. Nothing has changed but the price. Drug makers can charge what they do because we continue to pay. And Congress has a responsibility to address this.

Ranking Member Guthrie stated that on Republican we sent letters to manufactures and PBMs asking why costs are going up for insulin and we got a lot of different answers. He stated the ADA workgroup found that current rebate system encourages high list prices. He ask Dr. Cefalu to discuss how we got to a pricing and rebate system and how it encourages high prices and how it got this way. **Dr. Cefalu** said that the ADA workgroup also noted that lack of transparency lead to increased prices. Our rebate system encourages high list prices. As list prices increase, entities in the supply chain benefit. There are incentives across the supply chain that keep prices high. **Ranking Member Guthrie** also said that one thing he heard from stakeholders was that manufactures set list prices, and they should just lower the list prices. However, manufactures say it is not as simple as that. If they lower list prices PBM will be less likely to give them formulary placement. **Ranking Member Guthrie** asked what would happen if we lower the list price – what would happen to rebate and pricing system? Can they just lower their price? **Dr. Cefalu** said that we know that there are issues at every level of the supply chain. No question that manufactures set the price. But there is no guarantee the price drops if list price decreases. We need to move away from a system that relies of rebates, and move towards a system that ensures discounts make it to the pharmacy counter. There is no guarantee that lower list prices will decrease costs to patients. **Ranking Member Guthrie** you highlight the rebate system. What do you think would happen if we lowed list prices? **Ms. Marchand Aprigliano** the contracts between the manufactures and PBMs are secret. And we have no idea what we are receiving in terms of that rebate. We have been told rebates are spread out. My premium has never gone down and my OOP costs have gone up. I believe an entire disruption of the entire rebate system needs to happen and happen now. When list prices rise and we wonder where it is going.

Rep. Pallone stated that we heard that the amount people pay is influenced by list prices. He asked, Dr. Cefalu what to do you know about the people that is impacted by this? **Dr. Cefalu** said that when you ration insulin health outcomes decrease. This is shown across a number of studies. **Rep. Pallone** asked Dr. Kowalski how common a problem is this? Dr. **Kowalski** stated that I find it interesting that we are talking about rationing but there are a lot of other people going into debt. And we are seeing an increase in people moving to HDHP and people with diabetes in these plans are getting hit by these costs. **Rep. Pallone** asked Dr. Lipksa what additional research is needed? **Dr. Lipska** said we know about the impact on patients. We need to fix the problem not research it. **Rep. Pallone** asked Dr. Cefalu what parts of the system are responsible for driving up insulin prices? **Dr. Cefalu** stated that we there is not one single entity responsible. The system encourage high list price and entire system benefits from that. Each entity needs to be accountable. Discounts and rebates happen at each level.

Rep. Burgess first asked the panel to confirm that there is no concern on the shortage of insulin. All panelists agreed, no concern. Rep. Burgess said that he has questions about HHS's proposed rebate rule, but promised Secretary Azar to keep an open mind. He hopes that we can involve the agency on the rule and discuss the pros and cons on the rebate rule. He also noted that was curious if the Medicaid rebate had an effect on this. Burgess also asked why we even charge for insulin. **Rep. Burgess** asked Dr. Lipska why doesn't Medicare just cover it? **Dr. Lipska** stated that life with diabetes is very hard. Charging people high prices is backward and will cost us more. R**ep. Burgess** asked why in federal program, Medicare, why isn't it covered? **Dr. Cefalu** stated that that is a question this Congress needs to ask. **Rep. Burgess** said he would asked Seema Verma about this.

Rep. Kennedy asked Ms. Marchand Aprigliano to discuss what she knew about the patients using patient assistance programs. **Ms. Marchand Aprigliano** said that they come from all walks of life. Current qualification range from 200% to 500% of FPL. Many patients noted that patient assistance qualifications are difficult to find and difficult to understand. **Rep. Kennedy** asked Dr. Kowalski how these program work? **Dr. Kowalski** said they are a barrier. At JDRF we are trying to do our best to disseminate information on these programs. But relying on band aides when there is an overarching issue is a problem. **Rep. Kennedy** asked Dr. Lipska why patient assistance programs are failing. **Dr. Lipska** stated that a lot of patients do not meet the criteria. But also patient assistance programs are not a way to fix this. We should not put patients through this. **Rep. Kennedy** asked how these programs should be improved or should they be eliminated? **Ms. Marchand Aprigliano** said they can be improved by reducing the list price of insulin so these programs do not need to exist at all. But rising income qualifications, making it easier to apply, and educating health care professionals would be helpful. And there needs to help for patients in crisis.

Rep. Griffith said he had concerns on PBMs. He asked Dr. Cefalu how is the market power of PBMs effects list price? **Dr. Cefalu** said that PBMs primary customer is the health plan. What is not clear that the negotiation takes place, and how it benefits the patients. We need more information on how these systems work and that gets back to transparency. **Rep. Griffith** asked if they would agree for transparency for PBMs. **Dr. Cefalu** said transparency is key. Griffith asked Dr. Cefalu that based on his working group to confirm that they are not sure whether PBMs benefit the patients because the lack of transparency. Dr. Cefalu said that it was unclear. **Rep. Griffith** asked Ms. Marchand Aprigliano why PBMs are so powerful in the drug supply chain? **Ms. Marchand Aprigliano** said that PBMs have power over the entire drug supply chain, and they were supposed to help patients. But over years this has changed. No one in the supply chain can benefit if patients can’t afford insulin.

Rep. Kuster asked Dr. Lipska do you believe that drug companies are the ones benefitting the most from price increases? **Dr. Lipska** said yes. She noted additional research on drug manufactures profits, and that PBMs have a much smaller profit than manufactures. She noted that we should give pause to just blaming PBMs. Rep. Kuster asked Dr. Cefalu what parts of the system are driving up insulin prices? **Dr. Cefalu** said that is clear that list prices are set by the manufactures. There are other studies that look at the flow of money across the supply chain. But as list price goes up the supply chain benefits. We need to know about negotiations and increased transparency. **Rep. Kuster** asked Dr. Powers what he believes is the drivers in costs of insulin? **Dr. Powers** said that if the Committee had individuals from the supply chain on the panel they would all blame each other. Each member of the supply chain has responsibility to address this. Calling out one entity will not solve the problem.

Rep. Brooks asked Dr. Kowalski on non-medical switching and to describe what that means. **Dr. Kowalski** said this is very important. There are different forms of insulin and people use different types of insulin. But what we are seeing if that people are being switch on the type of insulin they are receiving by their health plan and not be the choice of their physician and the patient. And it has happened to me. Insurance companies should not make this decision. **Rep. Brooks** asked the panel if there are any data on this issue? **Dr.**

Cefalu said their working group found this switching issue as a problem. And this will increase the costs of outcomes overtime. **Rep. Brooks** asked Ms. Marchand Aprigliano to discuss what happens when patients go through step therapy and its implications. **Ms. Marchand Aprigliano** said that health plans what to pay for certain insulins over others. She discussed a story from a friend who went through step therapy, while his health decreased.

Rep Ruiz asked Dr. Lipska to discuss her experiences about the people in her studies that ration insulin. **Dr. Lipska** said we have heard a lot of stories and they are dramatic stories. But there are long term complications of rationing, so we will see more complications down the road. **Rep. Ruiz** asked Dr. Cefalu how and what can you inform patients on the adverse effects of not taking insulin? **Dr. Cefalu** we suggest that patients who can't afford to talk to their provider on different types of available insulin and the effects of not taking their medicine. Educating the patient on what to expect is important. Insulin is a matter of life or death. And no one should be without because of costs.

Rep Bucshon began his remarks on the 340B program. He stated that to remain eligible for participation in the Medicaid program drug manufactures must provide certain outpatient drugs at discounts to covered entities in the 340B program. In certain circumstances these manufactures provide discounts to 340B covered entities at the cost of a penny. Some, but not all, of these 340B entities pass savings onto patients. For example, during the Committee's examination of the 340B program during last Congress, one 340B covered entity told the Committee they offer insulin to certain qualifying patients for $10 a vile. So $10 for the cost of a penny. He asked Ms. deVore, as a patient, do you have experience with the 340B program? **Ms. deVore** stated her husband works a facility with a 340B pharmacy, so she uses that pharmacy but the cost difference doesn't make a difference. The price is the same if I use the 340B pharmacy or outside under our insurance. My drug is non-formulary I pay the full costs. **Rep. Bucshon** asked if anyone else on the panel had any other comments on the 340B program. No panelists had comments. **Rep Bucshon** said that was too bad, he thought there would a discussion on 340B. He said some of the concerns he has on 340B is that drug companies have to sell some of their products at such a low discount to 340B covered entities that on the backend to make up for it, it puts upward pressure on drug prices otherwise, for non-340B covered entities. He stated he encourages the subcommittee, as a part of investigation on insulin, to also consider the growth of the 340B program on a whole and try to address the abuses of 340B that the program that can create upward pressure on drug prices.

Rep. Schakowsky stated to Ms. Marchand Aprigliano that it seems drug companies raise the price of insulin because they can. Am I wrong? **Ms. Marchand Aprigliano** said she doesn't work for a manufacture so she can't say why. **Dr. Powers** said that the prices of insulin in Canada, England, and other countries is much different. She asked Dr. Cefalu who accounts for the over 1000% price increase in the cost of insulin compared to the 1990s? **Dr. Cefalu** stated that we don't know the factors on how they set list prices and this gets back to transparency. Transparency will get to the bottom of these increases across the supply chain.

Rep. Sarbanes asked the panelists on a scale of 1 to 10 do you think we can address the transparency issue? **Dr. Cefalu** said there is a lot of things we can do. Cost shifting to the patients is too much. Making sure patients with diabetes can take care of their disease. There should be more biosimilars available, and the FDA has taken steps to increase efficiencies. But the patients are not benefiting. **Ms. Marchand Aprigliano** stated it is not just transparency. But it is the actual action of Congress. We all know that has to happen, and we need to have reasonable access to insulin. Transparency is the first answer. I believe we have the answer and Congress can help with that.

Rep. Barragan noted she wanted to see manufacturers and PBMs brought in to hear why this increase in costs is happening. She noted that this is a great start and looks forward to next week's hearing. **Rep. Barragan** asked how the rising costs of insulin effects people of color? **Dr. Kowalski** said not he was not sure if we know the exact number of deaths. But we do know that if you are socio-disadvantage this is a huge burden. Choices are made between food on the table and prescription drugs. **Rep Barragan** noted Secretary Azar's former role at Eli Lilly and asked how we can be sure that the Administration will be serious about lowering drugs. **Ms. Marchand Aprigliano** said she didn't know the answer to that. But that no one should die because of lack of access to insulin.

Rep. Carter asked Dr. Cefalu on transparency. What happens in the supply chain? **Dr. Cefalu** said that transparency is not the answer, it will help us understand what happens between the entities. But we need to address this a systematic problem. We need to understand what is happening across the supply chain. Transparency is needed to come up with a long term solution. **Rep Carter** asked the panelists on knowledge on the Administration rebate rule. **Dr. Cefalu** believes this aligns with the workgroups. **Dr. Kowalski** is supportive and we need to see this in the commercial sector as well. **Ms. Marchand Aprigliano** said that the second step of this is a fixed fee transaction which is important. Because the rebates are taken away and are going to the patient. **Rep. Carter** said that with only 3 PBMs controlling everything there is not enough competition.

Chairwoman DeGette stated her committed to fixing this and finding a bipartisan solution. Chairwoman DeGette asked Dr. Powers to confirm that everyone in the system ties everything to the list price. **Dr. Powers** noted that was correct. **Chairwoman DeGette** stated that the higher the list price, the higher payment everyone gets. **Dr. Powers** noted that was the conclusion of the ADA working group. **Dr. Cefalu** stated that everyone on the supply chain needs to be accountable. **Chairwoman DeGette** then asked about patent ever-greening that there is a limited available in developing a range of generics. **Dr. Kowalski** noted that we have 3 similar insulins going up in price, this is the opposite of competition. The question is how can the US have affordable insulin? They need to be affordable. Having biosimilar or generics is another mechanism. **Chairwoman DeGette** asked the entire panel to tell the Members what is one question they would ask to the manufacturers or the PBMs that are testifying next week? **Ms. deLovre** – why in manufactures FDA filings includes a statement that manufacturing insulin would become cheaper and why that is not the case? **Dr. Cefalu** – what is the hurdle in the supply chain from allowing patients have savings? **Dr. Power** – what is the best plan for affordable insulin, why aren't we arrive at that, what are you doing to help that process? **Dr. Lispka** – how many more Americans will it take to die before prices come down? **Ms. Marchand Aprigliano** – what are you willing to give up to make sure people with diabetes have access to affordable insulin? **Dr. Kowaski** – how can we ensure that people with diabetes are paying net price, why aren't we seeing that passed onto consumer.

Rep. Guthrie stated that was going to be my question.