

Transcript: Fiasp-NovoLog, November 3, 2023 Medicare Drug Price Negotiation Program Patient-Focused Listening Session



CENTERS FOR MEDICARE & MEDICAID SERVICES

Introductory Remarks

Meena Seshamani, MD, PhD, CMS Deputy Administrator and Director of the Center for Medicare

Greetings everyone. I'm Dr. Meena Seshamani, the Director of the Center for Medicare at the Centers for Medicare & Medicaid Services, or CMS. CMS administers Medicare, our country's federal insurance program for more than 65 million older Americans and people with disabilities. I deeply appreciate each one of you for taking the time to join us today. For the first time, Medicare is able to directly negotiate the prices of prescription drugs thanks to President Biden's lower cost prescription drug law, the Inflation Reduction Act. The benefits to consumers and patients from Medicare's new ability to directly negotiate drug prices are enormous. And alongside other provisions in the law that make healthcare and prescription drugs more affordable, negotiation strengthens Medicare's ability to serve people with Medicare now and for generations to come.

In August 2023, CMS announced the first ten drugs covered under Medicare Part D selected for negotiation, a significant and historic moment. Medicare's ability to negotiate directly with drug companies will improve access to some of the costliest drugs while driving market competition and fostering innovation. Our priority in negotiating with participating drug companies is to come to an agreement on a fair price for Medicare. Promoting transparency and engagement continues to be at the core of how we are implementing the new drug law and the Medicare Drug Price Negotiation Program. And that is why we set out a process for the first round of negotiation that engages you, the public. This patient-focused listening session is part of our effort to hear directly from patients and others and receive input relevant to the drugs selected for the first round of negotiations. But let me also remind you the law is about more than negotiation. Other provisions, including the \$35 insulin copay cap and \$0 out-of-pocket for certain recommended vaccines, are life changing and they are already impacting millions of people with Medicare across this country. Starting in 2024, the law expands the Extra Help program, which makes premiums and copays more affordable for people with limited resources with Medicare prescription drug coverage. And in 2025, the new \$2,000 maximum out-of-pocket cap will provide additional help to those enrolled in a Medicare Part D plan.

Thank you again for joining us. Your input matters and we are here to listen. Next, stay tuned to hear from a senior CMS official to give you more details on what to expect during this patient-focused listening session.

00:03:32

Disclaimer

This patient-focused listening session is being live streamed. The session is listen-only and CMS will not respond to feedback during the session. Participation is voluntary and speakers acknowledged and agreed by participating in the listening session that any information provided, including individually identifiable

health information and personally identifiable information, will be made public during the listening session through a live stream broadcast. Clinicians should be mindful of their obligations under HIPAA and other privacy laws. CMS intends to make a redacted version of the transcript for the listening session available at a later date.

00:04:14

Welcome

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you so much, Dr. Seshamani, and welcome to those joining us to share their input as well as people who are watching the live stream. I'm Dr. Doug Jacobs, the Medicare Chief Transformation Officer with the Centers for Medicare & Medicaid Services. This is a virtual public listening session for the drug Fiasp, Fiasp FlexTouch, Fiasp Penfill, NovoLog, NovoLog FlexPen, NovoLog PenFill, which was selected for the first cycle of negotiations with Medicare. I will refer to this selected drug as Fiasp-NovoLog going forward in this session for the sake of brevity. We'll give more detail on this session and get going shortly.

First, I'd like to quickly provide context. We at CMS fall under the greater umbrella of the U.S. Department of Health and Human Services. CMS is tasked with implementing the new prescription drug law that helps save money for people with Medicare, improves access to affordable treatments, and strengthens the Medicare program. The law gives Medicare the ability to directly negotiate the prices of prescription drugs for the first time, as Dr. Seshamani mentioned.

In August, we announced the list of ten drugs covered under Medicare Part D selected for first-round negotiations. This public listening session is one of a number of steps CMS is taking as part of the process for the first cycle of negotiation. The drug companies that manufacture all ten drugs selected for the first round of the Medicare Drug Price Negotiation Program signed agreements to participate in the negotiation program by October 1st. CMS will negotiate with these participating drug companies during 2023 and 2024 in an effort to reach agreement on maximum fair prices for the selected drugs that will be effective beginning in 2026.

This virtual, patient-focused listening session is an opportunity for the public to weigh in on the first round of the negotiation process. There are ten patient-focused listening sessions, one for each drug selected for Medicare negotiation. The goal of the listening sessions is to provide an opportunity for patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties to share input relevant to the drugs selected for the first cycle of negotiations and their therapeutic alternatives.

Another recent example of an opportunity for the public to share input on the selected drugs and their therapeutic alternatives was the data submission process, which invited manufacturers with the drugs selected for the first round of negotiations and other interested parties to submit data to inform the negotiation process.

In today's session, we are taking input from the community of people who utilize Fiasp-NovoLog in their own lives or the lives of those they serve and care for. Speakers who are joining via Zoom registered for a chance to speak and underwent a random selection process. They've been asked to bring forward information related to the clinical benefit of the selected drug as compared to its therapeutic alternatives, how the selected drug addresses unmet need, and how the selected drug impacts specific populations.

Next, a few programming notes and reminders. For me and all of us at CMS, the purpose of today's session is simple: it is to listen. I want to remind callers to stay on the topic at hand during the patient-focused listening session. On timing, every participant has a three-minute window. Other than to help keep time and stay on the topic at hand and to help transition from speaker to speaker, you will not hear from me.

Now, on to the participants. Please welcome our first speaker, **[INFORMATION HAS BEEN REDACTED]**, who registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:08:13

Speaker Remarks

Speaker 1

Hi, my name is **[INFORMATION HAS BEEN REDACTED]**. I'm T1International **[INFORMATION HAS BEEN REDACTED]**. We're a global, independent, pharma free, diabetes nonprofit working on insulin access and affordability. I was diagnosed with type 1 diabetes in 2012 and was first put on insulin pens. And having access to this easier to use insulin was really critical for me to be able to get back to my regular life. I went on an insulin pump and transitioned to using vials of insulin, so keeping pens of long- and short-acting insulin on hand in case of emergencies. Short-acting insulin NovoLog products were exactly the same type and filled the exact same need for my health but was really necessary that I had both dosage forms to be able to stay healthy. If I had to buy these at list price, it would cost me about \$289 a vial and \$530 for a box of five pens, just over \$2,000 a month just for short-acting insulin. Insulin aspart is readily available under several different dosage types and name brands. As mentioned just a moment ago, NovoLog and Fiasp and the Walmart ReliOn brands and dosage forms, including the vials and pens like FlexPens and Echoes and FlexTouch. Short-acting analog insulins like these are some of the most effective ways of managing diabetes and to control blood sugar levels, especially after meals. While insulin aspart has been off patent for years and there's no real unbranded insulin aspart readily available. All Medicare beneficiaries have been promised insulin for \$35 a month, under the Inflation Reduction Act, but we've been seeing formularies change mid-plan year, forcing patients to pay list price. Those out-of-pocket cost caps, if implemented effectively and equitably to the 3.3 million Part D enrollees using insulin should save lives. And because of the high list price of insulin that Medicare has formerly been unable to negotiate, they're estimated to cost the government billions of dollars over the next ten years, which is intended to lower the copays for patients. We know that insulin does not cost this much to manufacture. Negotiating the list price of these drugs will save the government money and will save lives. My insurance does cover my prescription for less than the manufacturer's promise of \$35 a month for the copay. And this is not because it has this low list price, but because it's so heavily rebated through formulary negotiations by my PBM. And there are many in our community who do not have good insurance, who are experiencing a lapse of insurance coverage, whose insurance does not negotiate the price of Novo products in this way, or don't have insurance at all. There's been so much fanfare about the insulin manufacturers, including Novo Nordisk promising insulin for \$35 a month copay cap, for all patients, regardless of insurance. We know that many in our community have been unable to access these promised price cuts, and there's no transparency or accountability to appeal these denials of these promised coupons. Novo Nordisk and other insulin manufacturers promised to lower the list price of insulin products at the end of this year, but the promised price cuts don't cover all aspart products notably for this conversation, Fiasp. The promised price cuts reduce the price of NovoLog down to

about Walmart's ReliOn. And for me as a case study, without my insurance, that would still cost me about \$500 a month after these promised price reductions are with the Walmart brands. This is down from \$2,000 a month that I was saying before, but that would still only fill my prescription for just my short-acting NovoLog prescriptions. Again, I cannot get unbranded insulin aspart the same product that research shows that these products only cost a few dollars to manufacture these vials and pens. And we need to make sure that we have access to insulin, because any small accident could kill me if I can't access –

00:11:42

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

I'm sorry to interrupt, **[INFORMATION HAS BEEN REDACTED]**. The three minutes are up. If you don't mind just taking a moment to finish up.

00:11:47

Speaker 1

That was it. Wanting to make sure that insulin is affordable and accessible for all.

00:11:51

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drugs or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:12:06

Speaker 2

Thank you. Thank you for the opportunity to speak today. I was diagnosed with type 1 diabetes at a time when only human insulin was available. When analog insulins like NovoLog came out, they made life easier, giving me much better control of a difficult to manage chronic illness. I've taken NovoLog on and off throughout the last 30 years and depend upon insulin to stay alive. There are definitely challenges to accessing prescription drugs, like NovoLog. This is mostly due to the exorbitant costs that's a result of pharmaceutical monopolies, patent tickets, pay to delay schemes, lobbying and more. Having been diagnosed with diabetes in childhood, I have not experienced adult life without the ever-present worry of whether or not I can afford to stay alive due to the high cost and difficulty of accessing insulin and diabetes supplies. I've had to have health insurance and have been lucky to be able to do so to help assuage the costs of insulin and related supplies, even though insurance is also very expensive and has varying degrees of coverage, depending upon a whole host of variables. Having to maintain insurance coverage via employment has kept me from pursuing professional opportunities because they didn't offer healthcare. When I've been in between jobs due to moving or taking a new position, I've had the impossible task of deciding what to do when it comes to insurance and hence access to medications like NovoLog. Do I risk going without it? Do I pay the absurd cost, usually triple or more of one's regular premium with COBRA, if I could even afford that? And because our healthcare is tied to employment in the United States, until you

qualify for something like Medicare, there's always the risk of losing access to insulin due to no fault of your own, if your employer downsizes. Even with insurance, however, I have never been able to choose my insulin and/or exactly what my doctor would prefer me to use. This has always been dictated by insurance formularies. Earlier, I noted I've taken NovoLog on and off for 30 years, this is why. Formularies can change mid-year, which then causes a patient to need an appointment with the doctor, which comes with a fee. You have to require a new prescription for the covered insulin all in order to get your next refill. For these and so many other reasons I don't have time to discuss in the slot today, I want to reiterate how critical it is that prescription drugs in the U.S. are made affordable and accessible to everyone, regardless of one's age, insurance, or income status. I know firsthand that insulin is still not accessible. Right now, in the U.S., one in four insulin dependent diabetics are rationing, many die. And while many, the vast majority of insulin users, are not eligible for Medicare, I am not a Medicare patient yet, for example, I know the value of having Novo Nordisk short-acting insulin products finally going through a price negotiation process where ultimately, more patients will benefit as a result. Thank you for your time.

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Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

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00:15:04

Speaker 3

Thank you. Good afternoon, my name is **[INFORMATION HAS BEEN REDACTED]**. I'm an advocate and a patient living with chronic conditions, one of which is type 2 diabetes. **[INFORMATION HAS BEEN REDACTED]** the Chronic Care Policy Alliance. The Chronic Care Policy Alliance brings together advocacy groups (excuse me) to make our collective voices louder as we work to improve the lives and health of those living with chronic disease. I became a health advocate because of my own struggle to get my health condition taken seriously by my health insurance plan, my doctors, and to find treatments that allowed me to resume my daily activities. If there's one thing I want you to take away from my comments, is that every patient is unique and depends on medical miracles that continue to be developed in this country every day. Access to the full breadth of life changing medications is critical to a patient's ability to function, contribute to society, and even how long they may live. Patients want to ensure they have access to affordable medication, but also that the development of life changing medications continues and that patients have access to them. 37.3 million Americans, about one in ten, have diabetes. About one in five with diabetes don't know they have it. 1.5 million of those Americans have type 1 diabetes, and that number is rising. People with type 1 diabetes cannot make insulin and need to use insulin to replace what they can't make. They are tied every day of their lives to monitoring their intake and accurately compensating what the correct amount of insulin. Yet every patient is different, and some will respond better to one insulin than another. That's why there are many different types of insulins and mixes, including fast- and slow-acting and regular insulin. As the negotiation progresses, we urge CMS to preserve access to alternatives for those who are dependent on insulin to live. Those with diabetes are also subject to related physical and emotional

issues. Diabetes can lead to vision and limb loss, heart disease, chronic kidney disease, nerve damage, and other problems with oral health, hearing, and mental health. The CDC says there's 244,000 children and adolescents with type 1 diabetes. Over the course of their entire life, they will use insulin and face the onset of further pain and disease caused by diabetes. We want to ensure that when we continue to seek, encourage, and provide innovation that will improve the life and health for those currently diagnosed with diabetes and for those who will be diagnosed. We ask CMS to take care to preserve innovation and seek to make medications more affordable. We believe in making patients the center of the conversation during these negotiations is critical and ask CMS to keep in mind that what works for many, may not work for everyone. Thank you again for this opportunity to present these comments.

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Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

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Speaker 4

Hi, my name is **[INFORMATION HAS BEEN REDACTED]**, and I live with type 1 diabetes. I'm **[INFORMATION HAS BEEN REDACTED]** T1International **[INFORMATION HAS BEEN REDACTED]**. I was diagnosed with type 1 diabetes at the age of 15. I remember being ensured that I could live a long, normal life if I took care of my blood sugars. That this disease needn't be a death sentence. What my doctors failed to prepare me for was how hard I would need to fight for affordable access to insulin. At the age of 26, I started rationing NovoLog. Even with a platinum insurance plan, my insulin was going to cost me \$2,400. When I got down to the last drops of my last vial of insulin. I remember digging through trash cans for any leftover vials that might have even a few drops left that I could inject. No one warned me of the exorbitant price. No one told me it would cost more than my entire monthly paycheck. I thought surely there were safety nets to help people in my situation. I checked with insurance and the pharmacy. I called Novo Nordisk, begging for help, but I didn't qualify for their patient assistance program. When I asked, in tears, how I was supposed to live without my insulin, the employee could only offer me the ER as a resource. My story, sadly, isn't unique. Twenty five percent of type 1 diabetics have reported rationing their insulin, and that includes NovoLog and Fiasp. Despite strides in reigning in cost, there are still people being turned away from Novo's patient assistance program. Today, someone is going to leave the pharmacy counter without their insulin because they can't afford it. Patients cannot adhere to a medication if it is not affordable. These medications should be affordable to all, not just those with platinum health insurance, a low deductible, or those with the privilege of steady health insurance. In order for negotiations to be truly effective for patients, CMS cannot look at net or average sale price as a key factor. The price of insulin is already excessively inflated. We also can't look to therapeutic alternatives. A lack of competition has artificially inflated those prices. Instead, we need to look and prioritize the cost of manufacturing, which studies show is only \$3 to \$6 for a single vial of insulin. It is my hope that one day I will grow old enough to be on Medicare, but that's only ever going to happen if insulin is kept accessible and affordable for all. And Medicare negotiations is a great place to start. Thank

you.

00:20:46

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

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Speaker 5

Thank you for giving me this opportunity to speak about Fiasp and what it means to me and my ability to control my blood sugar. Fiasp is an improved formulation of insulin, which provides quicker onsets, allowing me greater flexibility to administer insulin before, during, or even after meals. I'm no longer timed to schedules. My A1C has improved, while my episodes of hypoglycemia have decreased significantly. Depending on my blood sugar, I can take my Fiasp before my meal or within 20 minutes after starting my meal. So, I have options now. While on human insulin, I was subjected to many hypoglycemic episodes. I had to take the insulin, this insulin, before my meals and while eating out sometimes, my meals would not always arrive as expected, which often resulted in hypoglycemia. Fiasp has made diabetes management so much easier for me. It's important that those of us living with diabetes have access to the latest innovations so insulin continues to improve. I really appreciate you giving me this opportunity to speak today. Thank you.

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Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

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Speaker 6

Hi. My name is **[INFORMATION HAS BEEN REDACTED]**, and I've been insulin dependent since I was seven years old. That's when I was diagnosed with autoimmune type 1 diabetes. For the rest of my life, I will require a constant infusion of insulin through a pump. Without it, I would be dead in a matter of days. I'm incredibly fortunate that when I was growing up, my family had excellent health insurance through my father's job. This isn't to say my condition wasn't a financial burden. Even with great coverage, my parents had to shoulder the high copays of not just two kinds of insulin, but syringes, sterilizing alcohol, glucose monitors, test strips, emergency glucagon, and the added burden of frequent doctor's appointments. Despite all of that, they did their best to shelter me from the impact my condition had on our entire family. When I was first diagnosed, our insurance covered Humalog, one type of fast-acting insulin. Over the

following years, we were switched multiple times between Humalog and NovoLog, two types of insulin that are meant to be the same but affect my body very differently. I learned that I loved the way NovoLog worked for me, how it curbed my high blood sugars without dropping me into debilitating hypoglycemia. I was frustrated by the whims of our insurance and the frequent changes that forced me to readjust my insulin doses every time our coverage switched. But I didn't realize at the time that I was lucky to have access to any type of insulin at all. Our good fortune changed when I was 16, just as I was transitioning into managing more of my own medical care. The company my father had worked at for as long as I could remember, facing budget cuts, informed him that he was being laid off. No family ever plans for losing their primary source of income overnight. But for us, this shock came with an extra layer of panic. Not only were we losing our income, but also our health insurance. It was at this point, for the first time in nine years living with type 1, that I understood the magnitude of the burden my family had been carrying all this time. My father's search for a new job was fueled by the knowledge that without insurance, my vials of insulin, which I needed several of each month, cost over \$300 apiece. This was the first time I'd heard the word, rationing, applied to my life saving medication. The first time I'd comprehended the gravity of what could happen to me if we couldn't come up with the thousands of dollars it would cost to pay for all of my monthly supplies. As type 1s, we're taught to view every meal based on the number of carbohydrates it contains. That's how we calculate our insulin doses. But now, at age 16, I started viewing my meals based on another number: cost. This meal costs \$40 worth of insulin. If I skip this snack, I'm saving my family \$15. I was so grateful when my father found a new job with good insurance, one that covers NovoLog. Though I will add that we, like most type 1s, have never felt the effects of the supposed \$35 price cap. I'm so lucky that I didn't face any serious health consequences during those months of worry, but that mindset has never fully left me. The feeling of being a burden on my loved ones will likely never leave either. I've met countless others who carry the same trauma, and you've heard from some of them today. Our stories are different, but our question is the same, how many more of us will face this struggle? Access to insulin is our right. Thank you.

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[Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare](#)

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:26:07

[Speaker 7](#)

Hello, my name is **[INFORMATION HAS BEEN REDACTED]**. I live in **[INFORMATION HAS BEEN REDACTED]**, Oregon, and was diagnosed with type 1 diabetes at the age of ten. At the time of my diagnosis, human insulin was the insulin most widely available, and NovoLog wasn't yet covered by my insurance. For the first several years following my diagnosis, I took human insulin both regular and NPH. During that time, I had to adhere to a strict insulin and food schedule, and this had a huge impact on my success at school. And when NovoLog became more widely available, and I was able to use it, I was so relieved because it empowered me to be able to live a more normal life and return to focusing on school rather than staying alive. Today, I use an insulin pump that is filled with Humalog, Eli Lilly's NovoLog equivalent, which is what my insurance will

cover, and I have continued to benefit from the access to analog insulin. However, while the story should end here with a tone of relief, I have spent my adult life with the fear that my insurance would change and force me to return to using human insulin because of the high list price of analog insulins like NovoLog and Fiasp, reducing my ability to have the best control of my diabetes and live a full, healthy life. This fear has fueled my career path, and **[INFORMATION HAS BEEN REDACTED]** T1International, an organization of people with diabetes working for people with diabetes. Our constituency is made up of people who have experience with both the high price of insulin as well as rationing due to cost. I think it is really important to note that people of color are much more likely to experience lapses in insurance and to ration insulin due to cost. Recent studies have found that though the use of insulin pumps, which require analog insulin to operate, have grown in the past two decades, there were no improvements in racial gaps. Racial healthcare disparities continue to persist in diabetes care, and while I can't speak personally to the experience of a BIPOC patient, many advocates and 40% of our leadership team at T1International, including myself, identify as part of the Queer community, a group that also faces additional barriers to healthcare. I am testifying today because drug prices are too high, and I believe that no one should sacrifice their dreams, well-being, or risk their lives due to pricing on an essential medicine. I don't get to choose what kind of insulin I use, and the fact that I am at the mercy of the insurance company, manufacturers, and wholesalers, who decide what insulin they will cover, is a frightening reality. Patients should be able to clearly access the insulin they need to live, without trying to navigate muddy waters of rebate or coupon programs that so often fail. The pricing of NovoLog, Fiasp and all insulin needs to be affordable. Full stop. Thank you.

00:28:59

[Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare](#)

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

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[Speaker 8](#)

Thank you. My name is **[INFORMATION HAS BEEN REDACTED]**, and I was diagnosed with type 1 diabetes at the age of five. Being almost misdiagnosed, I was rushed to the hospital, and my carefree life as a child would never be the same. My blood sugar was over 800. I weighed less than or around 30 pounds, and like most type 1 diabetics, I had no family history of the disease. After spending a week at the hospital learning my new reality, I was sent home with my new lifeline, NovoLog insulin. I am now 22 years old, and I have lived with diabetes for over 17 years. In March of this year, my insurance company switched. My new insurer decided that they weren't going to cover my short-acting insulin of choice, NovoLog. I have been on NovoLog for 17 years. Ever since I was diagnosed. NovoLog has always worked for my body, but in order for me to receive it, I needed to pay over \$3,000 out-of-pocket. I was stunned. I had a choice to make. I had to decide to either pay over \$3,000 for the insulin of my choice or let my insurance choose for me. For that period of time, I borrowed additional vials of insulin, of NovoLog insulin, from fellow type 1 diabetics as I begged my insurance to cover NovoLog. As mentioned, insulin is manufactured for approximately \$3 to \$6 a vial. It has been 17 years since my diagnosis, and I have continued to watch the price of my insulin rise.

Absent of it ever changing effectiveness, molecular composition, or even delivery method. While I was nervous about switching my life sustaining medication, from NovoLog to a different insulin, I eventually was left to switch. I couldn't afford \$3,000. In the diabetes community, it is common practice for us to rely on one another when the healthcare system fails us. Whether our insurance doesn't approve a prescription in time, or our insulin is too expensive to afford, we come together to deliver each other insulin vials, so we can just live to see another day. In the last few years, in my experience, this has happened way too many times to count. We are left with no choice but to be the emergency insulin relief fund for one another. As I look forward, in just four years, I will age out of my parents' insurance. At this age, young adults like me should be focused on pursuing careers, finishing their higher education, paying off student loans. Instead, we as patients living with diabetes, are often forced to ration insulin due to its price tag and then yet are expected to meet all other expectations in society. Living with type 1 diabetes is difficult as it is, and affording my life sustaining drug shouldn't be. Thank you.

00:31:41

[Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare](#)

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

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[Speaker 9](#)

Thank you and good afternoon. Good morning to those out west. My name is **[INFORMATION HAS BEEN REDACTED]**. **[INFORMATION HAS BEEN REDACTED]** JDRF. JDRF is the leading global type 1 diabetes research and advocacy organization. Our mission is to accelerate life changing breakthroughs, to cure, prevent, and treat type 1 diabetes and its complications. Type 1 diabetes, as you've heard, is an insidious autoimmune disease that strikes children and adults and can be fatal without lifelong insulin therapy. Insulin affordability, particularly the cost of the person with diabetes, is a priority for our community because consistent access to affordable insulin means life and death. JDRF is committed to a future where everyone, regardless of insurance status, has the choice of their insulin products that work best for them and can access those products at an affordable cost. A continued focus by CMS on insulin affordability is critical to ensure this future happens. While inclusion of the two insulin products in the negotiation process may lower out-of-pocket costs for those using these products, we are concerned that the way insulin was included will create confusion among people with diabetes and potentially result in access challenges. The coupling of Fiasp and NovoLog insulins, in the negotiation process, may negatively impact access and coverage. These products have separate FDA approvals, are considered separate products by patients and healthcare providers, in part because people with diabetes, as we've heard today, have different experiences and outcomes with these insulin products. It's important that people with diabetes, and their healthcare teams, be able to choose the insulin and diabetes devices that work best for them. The evidence on this is clear, that choice leads to better glycemic control, which reduces the incidence of short- and long-term diabetes complications. But given the importance of choice, it's essential that CMS ensure the coupling of these distinct products for purposes of negotiation, does not reduce access to either of these insulin

products or to other insulin products that are so important to Medicare enrollees. We encourage CMS to further clarify how Part D sponsors are to cover these insulin products, while ensuring neither product is inappropriately excluded from a formulary. In this year, as we celebrate the 100th anniversary of the discovery of life saving insulin and its award as a Nobel Prize, we again want to thank CMS for its continued focus on the vital issue of insulin affordability. And we stand ready, as always, to continue our work with CMS to ensure that people with type 1 diabetes have affordable access to all FDA approved insulin. Thank you.

00:34:31

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:34:45

Speaker 10

Good afternoon. I'm **[INFORMATION HAS BEEN REDACTED]** the Partnership to Fight Chronic Disease, and we thank you for hosting these sessions. The copay cap on insulin in Medicare was a welcome change in coverage for the millions of Medicare beneficiaries who depend on insulins. The benefits of tight glucose control are well known and significantly reduce complications. The innovations in insulins, including the fast-acting and ultra-fast-acting products discussed today, are providing people with diabetes greater control while minimizing the impact of diabetes on daily life. Ultra-rapid-acting and rapid-acting insulins were developed in response to unmet needs to more closely mimic the mealtime insulin levels of people without diabetes. The predictable timing of response of the fast-acting and ultra-fast-acting insulins give people more flexibility before, during, and after meals, and reduce the risk of hypoglycemia. As a colleague of mine described it in the past, her insulin dictated what she ate and when. Now, she decides what and when, and adjusts her insulin accordingly. The faster-acting insulin analogs provide highly accurate, predictable responses and greater flexibility. The faster absorption, the closer to eating the person can take a dose and adjust to what they want to eat. That control is empowering and important. Three in four Medicare beneficiaries with diabetes live with at least two other chronic conditions they are managing. The importance of insulin availability and timing highlights the critical differences in Fiasp and NovoLog and how those relate to other insulins. CMS's decision to group these products together may perpetuate misunderstandings that the products, and potentially others, are interchangeable and lead to access restrictions. First, Fiasp and NovoLog are different drugs with separate FDA approvals. They're prescribed and used for different reasons. Second, grouping NovoLog and Fiasp together raises concerns about what CMS will consider as therapeutic alternatives. Clinical guidelines from both the American Diabetes Association and the American Association of Clinical Endocrinology distinguish between rapid-acting and ultra-rapid-acting insulins to reach glycemic targets. They also distinguish between human insulins and insulin analogs, like Fiasp and NovoLog. Speed and reliability matter. All would agree that dial up and broadband are not interchangeable, though they both provide internet access. So, today's key unanswered question is how CMS will select therapeutic alternatives? The vast majority of Part D plans cover ultra-rapid-

acting, rapid-acting and longer-acting insulins. Recognizing these classes are unique, used to address different medical needs, and lack interchangeability. We urge CMS to recognize these differences and adjust considerations accordingly. Thank you.

00:37:40

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move on to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:37:55

Speaker 11

Hi. My name is **[INFORMATION HAS BEEN REDACTED]**, and I was diagnosed with type 1 diabetes at 17. Adjusting to my new normal was even more difficult when I learned how expensive it was. The hospital nurse told me I couldn't leave until my NovoLog and Lantus insulins were paid for. I told her that was no problem. My parents, who had no health insurance, would of course, pay. She told me, "I don't think you realize how expensive they are." The entire 13 years that I've had with diabetes has been overshadowed by how difficult it has been to afford it. Despite constant blood sugar monitoring, fatigue, sick days, and my fear of needles, most days, affording my illness has been harder than living with the illness itself. I was 21 and in graduate school when I aged out of the Medicaid program. I'd spent years stockpiling supplies, as my endocrinologist warned me that this day would come. I rationed the expired insulin I did have, would get insulin from people whose grandparents passed away, found Facebook groups peddling black market insulin, met up with people in parking lots, and paid strangers to have insulin mailed to me. A nursing school friend snuck used vials from the hospitals. This insulin was not always insulin aspart and was many times less effective for my body, leading to poorly controlled sugar. But I used what I could, restricted carbohydrates, and in my last year of graduate school would skip daily doses entirely, choosing to forego testing my blood sugar because I didn't want to know what I was doing to my body. With the high deductible plan my school made me enroll in, it covered no more than \$500 in prescription costs per semester. I was disqualified from enrolling in any patient drug assistance programs because I had this insurance plan, and I couldn't afford the \$450 copay to see an endocrinologist anyways. When I didn't have insurance, I still couldn't afford to see a doctor to enroll in these programs. I didn't qualify as a student for Marketplace programs, nor did they cover the medications I needed. There are only so many times that a person can go to the pharmacy with a new coupon or savings card, hoping their insulin will be affordable, just to be told, "It's really expensive, are you sure you still want it?" And shaking your head, crying, and knowing that you can't afford it as you tell the pharmacist, "I don't want it, I need it" and then still leaving without it. Years later, even with good insurance and with a doctoral level education in healthcare, when I asked my doctor if I could try a faster-acting insulin, called Fiasp, which would better help me control my blood sugar, the copay was \$190 a month, on top of my \$500 a month in premiums and other copays. I stayed on the insulin, Humalog, that I could afford, a 27-year-old insulin that still retails for \$274 a vial. Since no true generic for insulin exists, many insurance plans ask us to pay 50% of the drug list price. The reality is that my care has always been dictated by the insurance I have or haven't had, and never by what I actually

needed to succeed as a diabetic. For all of this, I've been judged and labeled as non-compliant in the past, even when the only thing I have ever wanted is affordable and adequate care to manage my illness without fear of being able to afford a drug I will die in three days without. My experience is not isolated. Even though I'm not a Medicare patient, I know that subjecting insulin to price negotiations will impact millions. I never want people to go through what I faced as a young woman, which is why I'm speaking today. Thank you.

00:41:10

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:41:37

Speaker 12

Hello? Can you hear me?

00:41:40

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

We can hear you.

00:41:45

Speaker 12

Okay, thank you. My name is **[INFORMATION HAS BEEN REDACTED]**, a patient living with insulin dependent diabetes since 1990, currently using Fiasp in my insulin pump and sometimes using NovoLog and Lantus vials for backup when I am injecting. I would like to thank CMS and HHS for the opportunity to speak to this life-or-death issue. I would also like to thank each of the insulin manufacturers who are currently investing in serving the huge unmet needs for insulin in the U.S. market. I'm here today to share my experience, to explain why access to all brands and types of insulin need to be protected by federal law and available at \$0 or low cost to everyone who requires it. Diabetes is a disability at any age. When I was diagnosed, I was 24, doing work I loved and trained to do, a high school language teacher. But that diagnosis brought a new financial reality. On a teacher's salary, even with private commercial health insurance, I was unable to pay my out-of-pocket costs of NovoLog insulin, as well as my syringes, glucagon and blood glucose testing equipment and supplies. My parents started giving me insulin for my birthday and holiday gifts. As a result of my salary deficit, compared with my new cost of care for diabetes, I sought work with a higher compensation as a healthcare product salesperson. Not everyone is as fortunate as I was to be in a position to make such a career transition to be able to afford insulin before it's too late. That out-of-pocket cost of insulin can be \$1,600 a month or more, depending on the type of insulin a person needs. If you do not take the right dose at the right time, your body goes into a state of hyperglycemia, damaging your eyes, nerves, kidneys, and affecting every bodily function. That's why all types of insulins need to be included in price negotiations, including Lyumjev, one of the new fast-acting insulins. Patients can develop autoantibodies

and become allergic to some types of insulin and need to switch for medical reasons. Non-medical switching should be forbidden by a payer. Only a prescriber should be able to make a change in insulin based on their patient's medical need. The out-of-pocket costs of insulin leads many patients to engage in dangerous, self-destructive behaviors by rationing insulin to make it last longer or using expired insulin. Doing so is a dance with death. A person running hemoglobin A1C of 9% or higher has the same life expectancy as a person with stage three colon cancer. Think about that. When people with diabetes do not have access to insulin at any price, they die within a short period. Without the right dose of insulin, patients end up going to the emergency room for a much more expensive trip than a trip to the pharmacy. In my local town, the director of emergency department told me that 50% of his patients in his emergency room have diabetes and are in a state of hyperglycemia when they arrive. When asked why they did not take their insulin, the most common answer is that they could not afford it, or they say they forgot to take it –

00:45:14

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

I'm sorry to interrupt **[INFORMATION HAS BEEN REDACTED]**, your three minutes are up. Please take a moment to finish up.

00:45:19

Speaker 12

It is a well-known fact that going to the hospital is one way to get a little bit of insulin for free, but at what cost to our collective healthcare delivery system when this could easily be avoided. This is no way for the U.S. to treat its most vulnerable citizens, the elderly and disabled. Thank you.

00:45:34

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now I'll move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:45:48

Speaker 13

My name is **[INFORMATION HAS BEEN REDACTED]**. I'm turning 23 this month and I live in Michigan. I was diagnosed with diabetes at age three. When I was diagnosed, I had lost a third of my body weight and would only move my eyes while in the hospital. My mom had just given birth to my sister. My parents had just bought a house and a new car. I had just had my third birthday at Chuck E. Cheese. After my diagnosis, my mom returned the Easy Bake Oven, she'd bought me for Christmas. My parents sold the car and considered getting a divorce so I would receive Medicaid. And my mom ate a single McDonald's cheeseburger a day so we could afford my insulin and supplies, for over a year. My dad stayed at a job for years that required 60 hours a week at minimum, just so that I would have some sort of health insurance. He had plenty of job opportunities but refused them so I wouldn't lose coverage at a time before the Affordable Care Act. When I

was sent home from the hospital, I received two human insulins called NPH and Regular. Today it is prescribed to diabetic animals. I was on a very strict diet, and my parents were worried that I would grow up with a bad relationship with food. They were initially taught how to keep me alive, but not how to manage my diabetes. NPH and Regular kept me alive, but it came at a huge cost. These peak times would send me crashing and my parents had to feed the lows, meaning I had to keep eating and drinking juice until I finally became stable again. I had to be under 24-hour surveillance, so I didn't have a seizure, get brain damage, or die. My parents were burnt out but kept going anyway. We were poor. I was constantly swinging between high and low blood sugars, but I was alive. In 2005, I was the first child at my endocrinologist hospital system to go on analog insulins. I was no longer feeding the insulin. It made my blood sugars more stable, and I was no longer on a strict diet. I could eat what I wanted when I wanted, but it cost a lot more than the analog insulins in the U.S., even though analog insulins in the U.S. were already almost ten years old. In 2007, they refused to put me on an insulin pump, so my parents found a doctor at the **[INFORMATION HAS BEEN REDACTED]**. Now we only had to worry about one insulin and the supplies, but it was **[INFORMATION HAS BEEN REDACTED]** drive each way every three months. I'm lucky to have parents who, when need be, will make unthinkable sacrifices for my insulin and supplies. We've created our own safety nets, helped other diabetics, and I wouldn't be alive if they hadn't starved themselves and worked themselves to the bone. But not everybody has parents, family, and friends willing to drop everything and drive to Canada for insulin or starve themselves to afford it. And they shouldn't need to. Thank you.

00:48:24

[Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare](#)

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** declined to report whether they have a conflict of interest. Let's welcome **[INFORMATION HAS BEEN REDACTED]**.

00:48:38

[Speaker 14](#)

Hello. I'm **[INFORMATION HAS BEEN REDACTED]**, **[INFORMATION HAS BEEN REDACTED]** Survivors for Solutions. I want to thank CMS for engaging with patients who have to survive the policies we're discussing here today. I believe our experiences here provide the missing perspective about the real risk that this is putting on real patients. Readily, this effort delivers blunt force trauma to finally balance medical discovery ecosystem. This policy knowingly risks how Fiasp, and countless other innovations are discovered at all. Most troubling is it endangers the hope of people who most need it. When I was diagnosed with an incurable chronic autoimmune disease, there were zero disease modifying treatments, or DMTs, to slow my path to complete disability. That soon changed thanks to public policy that encouraged both cutting edge treatments and low-cost generics. Research could rationally take risks based on a predictable public policy. At age 28, MS basically fried my central nervous system. The first DMT, which worked for many, wasn't working for me. Out of options, my father checked me out of the nursing home I now required and into my parents' basement. Thankfully, around this time, a second DMT premise was developed and approved by the FDA. I had hope and a plan B, and I can say, without exaggeration, it saved my life. Within five years of this date, I went from being unable to work, walk, or swallow, to rejoining a career meaningful career I

thought was over, meeting my future wife and starting a family. I'm here today so you can look a patient in the eye, who's needed four different breakthrough drugs over 35 years. Various patients can't afford for that pipeline to end. No one knows better than me that these treatments don't grow on trees. I know cost can be a problem, but it's not the problem. Our illness is the problem. And the last thing we need are fewer options to fight disease. Had the IRA slowed innovation for me then the way it's doing now, I would have spent my life as a burden, as a ward of the state. We're discussing today one of ten different drugs that all have one thing in common, they help a lot of people. Contrary to popular belief, this exercise is not an attempt to lower patient cost, but to target successful therapies the government doesn't want to pay for. When a solution goes undiscovered, it doesn't just harm people most in need, it hurts people, hurts the whole country. Lost productivity, reduced revenue, increased suffering, and despair. Thanks for your time, and I look forward to sharing more of my patient experience during future sessions.

00:51:35

[Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare](#)

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now move to our final speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Let's welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:51:49

[Speaker 15](#)

Thank you. My grandmother lived for over 50 years with diabetes. Diagnosed as a teenager in 1949, she predates NovoLog, but felt blessed witnessing strides in developing better medicine during her lifetime. The priest at her funeral called her a brittle diabetic, and I couldn't disagree more. She was a hero and a resilient person that succeeded when I think I would have faltered. My father was diagnosed at 40 with diabetes in 2000, a year before my diagnosis at the age of 15. He is a miracle, surviving premature birth and cerebral palsy. He is on Medicaid now. He's on Medicare now. Unlike me, he uses NovoLog in addition to Lantus insulin, which is a long-lasting insulin. We consume about \$4,000 worth of insulin between the two of us every month, what would cost only \$80 to produce. We lived with diabetes for over 20 years each. Over 100 years between my grandma, me, and my father. Billions upon billions of profit for companies like Novo Nordisk, who price gouge these necessary medicines. While we ration and die, morbidities compound our suffering. We are made to pay or die. Our lives and health are leveraged for the greed of pharmaceutical manufacturers. I rationed in 2009, while underinsured, pre-ACA, could still be denied coverage for a preexisting condition like diabetes. Insulin was about \$100 a vial, and I was rationing everything. Insulin, medicine, test strips, food, juice, sugar, anything to prevent diabetic ketoacidosis or hypoglycemia. Two sides of the same deadly coin. I survived, though many had not. I now suffer complications, amputations, neuropathy, infections, macular degeneration, infertility, anxiety, depression, debt, blackouts, and seizures. All preventable if the quality of my life was protected over profits. I am too near to death to stay silent. **[INFORMATION HAS BEEN REDACTED]**, who just spoke about rationing, is a story that is neither new or unique. At least once a month, I meet someone in a parking lot to give them crowdsourced insulin or testing supplies, because they cannot afford it. My older brother was just diagnosed six years ago, in a similar form to my father. My family tree would have withered without access to insulin. Lost like the countless before us.

In 1922, when it was given as a gift to the world for \$1. We need to honor that commitment and make it accessible for everyone. This is a step and hopefully a snowballing avalanche –

00:55:17

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

I'm sorry to interrupt. **[INFORMATION HAS BEEN REDACTED]**, the three minutes are up. Please just take a moment to finish up.

00:55:22

Speaker 15

I'm almost done. Hear us. Listen. Our need is intensely great and ever present. While pharma greed is pervasively extortionate and acutely gross. Exploiting chronic illness is evil, is vile. Do more to protect us. Thank you.

00:55:46

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**.

Thank you all so much for taking the time to participate in this listening session. Your input will be discussed internally as we continue to thoughtfully implement the new law in our efforts to lower prescription drug prices. Thank you and have a great day.

For a list of the drugs selected for the first cycle of the Medicare Drug Price Negotiation Program, click [here](#).

For more information on the Medicare Drug Price Negotiation Program, please click [here](#).