Transcript: Januvia, November 7, 2023 Medicare Drug Price Negotiation Program Patient-Focused Listening Session

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
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.

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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

Kristi Martin, Senior Advisor, Center for Medicare

Thank you so much, Dr. Seshamani, and welcome to those joining us today to share their input as well as people who are watching the live stream. I'm Kristi Martin, a senior advisor with the Centers for Medicare & Medicaid Services. This is a virtual public listening session for the drug Januvia, which was selected for the first cycle of negotiations with Medicare. 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. This 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 the first round of 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 become effective beginning in 2026.

This virtual, patient-focused listening session is an opportunity for the public to weigh in on this 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 our data submission process, which invited manufacturers with 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 Januvia in their own lives or the lives of those they serve and care for. Speakers who are joining us 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 participants 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, Bich-May, who registered as a healthcare provider who has experience prescribing, dispensing, or administering the selected drug or its therapeutic alternatives. Bich-May reported no conflicts of interest. Welcome Bich-May .

00:08:40

Speaker Remarks

Speaker 1

Hello. I am a family physician with over ten years of clinical experience. Currently, I'm not listed in Open Payments because I have not received any industry funding. I do serve on the Board of Doctors for America. We are 27,000 physicians and medical students in all 50 states, representing all areas of specialization. We focus on access to affordable care, community health and prevention, and health justice and equity. We focus on what is best for patients not on the business side of medicine, and we don't accept any funding from pharmaceutical or medical device companies. Growing up, I watched my grandmother give herself insulin shots. She took her diabetes very seriously after having two strokes and developing partial paralysis of her left hand. She would meticulously drop her insulin and choose a different spot in her belly to inject herself. She has since passed away but would have appreciated having pills instead of insulin. Over the past decade, newer classes of diabetes medications have become available. As a conservative prescriber, I prefer to wait about seven years for a new medicine to be on the market before I start prescribing it, because that's about how long it takes to see adverse effects once it's widely available to the public. Just because something is approved by the FDA does not mean it will be affordable. Checking a price comparison website a couple of weeks ago, a 30-day supply of sitagliptin costs anywhere from $545 to $996. There are no generics available. Upon preparing for this listening session, I realized sitagliptin received FDA approval in 2006, about 17 years ago. Drug companies often try to suppress competition. Many will spend a significant portion of their research and development, or R&D, on finding ways to suppress generic and biosimilar competition instead of on innovative research. And according to the Kaiser Family Foundation, about six in ten adults say they are currently taking at least one prescription drug, and a quarter say they are taking four or more prescription drugs. About three in ten Americans don't take their medicines as prescribed due to the cost. And according to a 2021 RAND report, prescription drug prices are 256% higher in the U.S. than the other 32 comparison countries combined. Additionally, drug companies take in money from research and sales. The U.S. government funds significant innovative research via the National Institutes of Health, or NIH. Of the 356 new drugs approved from 2010 to 2019, they all received NIH funding totaling over $200 billion. Yet the drug companies charge Americans high prices. They spend more on shareholder profits than R&D. From 2016 to 2020, the top 14 companies spent $567 billion on stock buybacks and dividends. This is especially galling when you realize the value of sitagliptin is limited. It doesn't do very much in terms of patient-oriented outcomes that matter. It lowers the A1C 0.5% to 1%. It doesn't reduce someone's risk of heart disease or stroke, unlike other classes of diabetes drugs, and this is really similar to other new drugs, less than one in three newly approved drugs have significant therapeutic value. With its limited benefits and high costs, sitagliptin is not worth the price. The NIH subsidized R&D, and Americans pay high drug prices. Sitagliptin is expensive and does not impact patient-oriented outcomes that matter. Thank you very much

for letting me speak today.

00:11:39

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, Bich-May. 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 a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:11:56

Speaker 2

Welcome. My name is **[INFORMATION HAS BEEN REDACTED]**, and I'm from **[INFORMATION HAS BEEN REDACTED]**, North Carolina. I am 71 years old and living with a rare blood cancer and type 2 diabetes, two health conditions that require very expensive drugs. Every month, the treatment I need for both my blood cancer costs $16,000 plus a $200 copay for a 90-day supply for my Januvia. Januvia helps keeps my blood sugar in check. I have been a hard worker all my life, and I've always had to work multiple jobs simultaneously so I can afford my medications. My doctors have constantly warned me over the years of how the strain from all these jobs could seriously impact my health. Yet at age 71, I cannot retire because life is too expensive. My drugs are too expensive. For far too long, drug makers have made a fortune while patients like me live in constant fear, wondering how we can pay for our medicine. I am afraid if I retire, I won't be able to afford what I need to survive. At times I had to forego or ration some of my drugs in order to make ends meet and pay other necessary bills, expenses like food, rent, and utilities. I say this again and again, no one in America should have to live this way. I am personally grateful for the passage of the Inflation Reduction Act as it already had many positive benefits on my life and others around me. I'm also glad CMS has launched its efforts to negotiate for lower drug prices because many Americans like me need it more than ever. Instead of having to pay $400 per month for my insulin prescription, I now get it for $35 thanks to the IRA. And if it weren't for a grant that I received to pay for my cancer treatment and other medications, which would run me a total of $16,070 a month, I'd either be drowning in debt or frankly have succumbed to my disease. I know Medicare negotiations is a blessing and not a deterrent for patients like me as the decrease in price would allow working class Americans to feel some well needed financial relief and enjoy access to more affordable medications. Lower drug prices would firmly allow me to rest more often and hopefully help me transition from working full time to working part time. Without Januvia, my diabetes will get out of control. Lastly, drugs don't work if people can't afford them. I have an issue with neuropathy, and the diabetes is helping with… controlling my diabetes is helping keep the neuropathy getting worse. Thank you, CMS, for allowing me the opportunity to speak.

00:14:19

Kristi Martin, Senior Advisor, Center for Medicare, CMS

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

REDACTED].

00:14:36

Speaker 3

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 that our experiences will provide the missing perspective of the real risk this is putting on real patients. Regrettably, this effort delivers blunt force trauma to a finely balanced medical discovery ecosystem. This policy knowingly risks how Januvia and countless other innovations are discovered at all. When I was diagnosed with an incurable chronic progressive disease, there were zero DMTs to slow my path to complete disability. That soon changed thanks to a policy that encouraged both cutting edge treatments and low-cost generics. 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 in my parents' basement. Thankfully, around this time a second MS therapy was approved by the FDA. I had hope and a plan B. Within five years, I went from being unable to work, walk, or swallow to rejoining a meaningful career I thought was over, meeting my future wife, and starting a family. I'm here today as living proof of this fact that American patients can't afford for that pipeline to end. I know full well how 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 the way it's doing now, I would have spent my life as a ward of the state. We're discussing today one of the ten different drugs that often have one thing in common. They help a lot of people. Contrary to popular belief, this exercise is not to lower patients' cost, but target successful therapies that the government doesn't want to pay for. When a solution goes undiscovered, it doesn't just harm people most in need, it hurts the whole country. Thank you for your time. I look forward to sharing more of my patient experience next time.

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Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Please welcome our next speaker, **[INFORMATION HAS BEEN REDACTED]**, who registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome **[INFORMATION HAS BEEN REDACTED]**.

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Speaker 4

Thank you and good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm an advocate for over 30 years and a patient living with chronic conditions, one of which is type 2 diabetes. **[INFORMATION HAS BEEN REDACTED]** Chronic Care Policy Alliance. The CCPA brings together advocacy groups to make our voices louder as we work to improve the lives and health of those living with chronic diseases. 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. Once you have a health issue that doesn't resolve, and in other words, a chronic condition, the struggles do not stop. For the rest of your life, there may be series of barriers and battles as you work to get the correct tests,

treatments, and access to health care required to maintain and improve your health. We ask that CMS take care to preserve innovation and access to innovation as it seeks to make medications more affordable. Every patient is unique and depends on these medical miracles. Today and every day, millions of patients are fighting for the treatments that they need. Thirty-seven million Americans, about one in ten, have diabetes. Approximately 95% of them have type 2diabetes. Type 2 diabetes most often develops in people in age over 45, so fast approaching the Medicare age. But recently, more children and teens and young adults are also developing it. People with type 2 diabetes have cells that are insulin resistant. Older medications have more side effects, don't work, or continue to force the body to make more insulin for cells that may be resistant to it. New medications work more effectively and have different approaches to managing blood sugar. Access to new and better and more effective medications is important to the patient's ongoing health, as the patients require regular monitoring and ongoing treatment to maintain normal or near normal blood sugar levels so their disease does not progress. Maintaining blood sugar levels is critical to avoiding increased cost of outpatient care, emergency room visits, hospitalization, and controlling the complications of diabetes such as vision and limb loss, heart disease, chronic kidney disease, nerve damage, and other problems with oral health, hearing, and mental health. Access to the full breadth of life changing medications is critical to a patient's ability to function, contribute to society, and longevity. Patients want to ensure they have access to affordable medication, but also that development of life changing medications continue and that patients have access to them. We believe that making patients the center of the conversation during these negotiations is very critical. I want to thank CMS for these listening sessions and for giving me the opportunity to present these comments.

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Kristi Martin, Senior Advisor, Center for Medicare

Thank you, **[INFORMATION HAS BEEN REDACTED]**, for your comments. Moving on to our final speaker, please welcome **[INFORMATION HAS BEEN REDACTED]**. **[INFORMATION HAS BEEN REDACTED]** registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Let's welcome **[INFORMATION HAS BEEN REDACTED]**.

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Speaker 5

Hi, I'm **[INFORMATION HAS BEEN REDACTED]**. **[INFORMATION HAS BEEN REDACTED]** the Partnership to Fight Chronic Disease and so appreciate you hosting these listening sessions. Januvia is an FDA approved medicine that's prescribed, along with a healthy diet and exercise, to improve glycemic control for people with type 2 diabetes. Diabetes is prevalent within Medicare. One in three Medicare beneficiaries overall have been diagnosed with diabetes, and even more troubling, 43% of Black, non-Hispanic and 46% of Hispanic beneficiaries have diabetes. Despite innovations in diabetes treatments, many struggle to meet treatment goals and benefit from having a variety of treatment options available to try. Januvia is taken once daily with or without food, and medicines like Januvia that are easy to take, have few contraindications or drug interactions, and are well tolerated, are important in addressing the unmet needs of people with type 2 diabetes, particularly the majority who have other comorbidities. Four in ten beneficiaries with diabetes live with five or more chronic conditions. Controlling glycemic levels is key to managing diabetes and reducing complications, but unfortunately, disparities in disease incidents and complications are common.

Compared with White beneficiaries with diabetes, Black beneficiaries suffer twice the death rate, have almost four times higher risk of hospitalizations for uncontrolled diabetes, and have more than three times higher rate of end-stage renal disease. Barriers to access, including out-of-pocket costs, often fall hardest on underserved populations, emphasizing the need for care and caution and inadvertently creating additional access barriers. Januvia costs Medicare less than $400 a month per beneficiary taking it before rebates. According to the Government Accounting Office, Medicare benefits from substantial rebates on diabetes medicines. In fact, a GAO report released this September found that beneficiaries paid more than Part D plans did for 79 out of 100 drugs receiving the most rebates in Medicare. Diabetes medicines accounted for 42% of those rebates, but as the GAO noted, plans did not use the rebates to lower beneficiary out-of-pocket costs. Today, my key unanswered question is how will CMS weigh the potential effects of such a dominant focus on diabetes in the first round of ten drugs? Even small, well intentioned policy changes can have profound negative consequences. CMS' initial list of ten medicines for drug pricing includes three plus two insulins that directly treat diabetes and three additional medicines that involve common diabetes comorbidities. How will action on pricing for these medicines affect access to them? And how much will CMS consider these larger disease area impacts as they proceed? Access barriers are likely as plans gain revenue by continuing to favor more highly rebated products without passing those savings on to the people taking the medicines, as the GAO study found, those barriers will make managing diabetes and multiple comorbidities even more challenging for benefits –

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Kristi Martin, Senior Advisor, Center for Medicare

[INFORMATION HAS BEEN REDACTED], I'm sorry to interrupt. Your three minutes have expired. I'll give you a few moments to wrap up.

00:24:28

Speaker 5

I was done. Thank you.

00:24:30

Kristi Martin, Senior Advisor, Center for Medicare

All right, thank you, **[INFORMATION HAS BEEN REDACTED]**, for your comments, and thank you all so much for taking the time to participate in today's 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.