Transcript: Xarelto, November 15, 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.

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 Xarelto, 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. 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 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 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 Xarelto 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, John, who registered in the category of other. John reported a conflict of interest. Welcome, John.

00:07:36

Speaker Remarks

Speaker 1

Good afternoon. I'm the Executive Director of the National Forum for Heart Disease & Stroke Prevention: a nonprofit, nonpartisan organization dedicated to health equity and optimizing cardiovascular health and well-being throughout the lifespan. Through our Value and Access Collaboration, patient, provider, payer, purchaser, public health, and pharma organizations collaborate to enhance health and well-being by supporting people's access to evidence-based care that is appropriate for them. The National Forum appreciates the opportunity to provide feedback on the Medicare Drug Price Negotiation Program as it will have rippling effects on population health in the short and long term. We urge CMS to ensure its Drug Price Negotiation Program provides beneficiary access to the right treatment for the right patient at the right time. Given that stroke reduces mobility in more than half of survivors aged 65 plus, it's essential that this policy improves and not reduces access to rivaroxaban. The price negotiation program must not worsen access to rivaroxaban for populations with disproportionate prevalence of stroke caused by atrial fibrillation. For example, non-Hispanic Blacks have far higher rates of first stroke and death from stroke, an event that rivaroxaban helps prevent. We recommend CMS work with the Office of Minority Health to achieve this imperative. We urge CMS to guard against potential unintended consequences, such as utilization management, that could result in reduced access to appropriate treatment. Price ceilings intended to benefit consumers could have the unintended and opposite effect of reducing access if pharmacy benefit managers drop medications from formularies or move them to higher out-of-pocket cost tiers, because higher price drugs offer the PBMs bigger rebates. Anticoagulant therapies are not interchangeable. Multiple studies have found different event rates for people on different anticoagulants. Therefore, we support the implementation of evidence-based care that aligns incentives for patients, providers, pharma innovators, and purchasers. In summary, the National Forum, on behalf of its more than 100 nonprofit, for profit, and public sector member organizations, urges CMS to ensure the Medicare Drug Price Negotiation Program supports evidence-based strategies for appropriate care and protects beneficiary access, guards against potential unintended consequences such as utilization management that could result in reduced access to appropriate treatment, and aligns incentives for all stakeholders.

00:10:53

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

Thank you for your comments, John. 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**

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00:11:06

Speaker 2

Good afternoon. **[INFORMATION HAS BEEN REDACTED]** the Partnership to Fight Chronic Disease. Thank you so much for this opportunity. Since its first FDA approval in 2011, Xarelto has achieved eleven FDA approved indications, including five for which it is the only direct oral anticoagulant, or DOAC, with that approval. In addition to Afib, which affects more than five million people in the U.S., Xarelto is also approved to treat peripheral artery disease, or PAD, coronary artery disease, or CAD, and clot prevention for hospitalized patients with acute medical illness. The latter includes the majority of Medicare beneficiaries hospitalized at some time during their lifetimes. About 21% of beneficiaries have CAD and 13% have PAD. Xarelto and other DOACs marked revolutionary advances over warfarin by greatly reducing the serious safety risks reflected in warfarin's narrow therapeutic range and need for constant blood tests, dose adjustments, and dietary restrictions. Too little warfarin increases clot and stroke risk. Too much risks life threatening bleeds. The advancement Xarelto represents, and its multiple indications, has made it a go-to choice for medical professionals and patients. Because Medicare identified the initial ten drugs focusing on gross Part D drug spending, Xarelto is on this list despite it costing Medicare, before rebates, less than $400 a month per person using it. A recent GAO report found that the anticoagulants are among the highest rebated drugs within Medicare, yet beneficiaries do not see that savings at the pharmacy counter, and that contributes to disparities. Health disparities are widespread, as are multiple comorbidities for the conditions Xarelto treats. With PAD, for example, amputations are common, though half the people who undergo amputation die within a year. Amputation is four times more likely for Black patients with PAD compared with White patients. Despite the opportunity to prevent amputation with Xarelto and pursue other treatment. PAD is also tragically underdiagnosed and undertreated, leading to preventable amputations, disability, and deaths falling disproportionately on Black patients. Similar research shows that Black women and men are also 30% more likely to die of heart disease, including CAD and Afib, than White and Hispanic men and women. This poor outcome is despite research showing supplementing aspirin with Xarelto lowers the risk of heart attack, stroke, and death in people living with CAD. That leads me to today's unanswered question. How will CMS factor health disparities into consideration of unmet medical needs? Xarelto's multiple approved indications address the diseases for which significant health disparities exist. In its health equity framework, CMS promises to, quote, adjust our policies to optimize health equity. It's important that in drug pricing, CMS follows this promise and considers how Xarelto and other drugs address the unmet needs of underserved populations. 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 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]**.

00:14:41

Speaker 3

Good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]** and I'm representing the Mended Hearts, Inc., the world's largest peer-to-peer cardiovascular patient support network, hosting over 100,000 members across 20 countries. Personally, I live with a structural heart defect and have navigated three open heart surgeries, numerous medical interventions, and prescribed medication. We at Mended Hearts support the ideals of the Medicare Price Negotiation Program, designed to lessen the financial burden on Medicare beneficiaries. Key provisions like the Part D out-of-pocket maximum, the prescription payment plan, and expanded low-income subsidies all strive to make drugs more accessible and affordable. However, as the new law unfolds, there are pressing concerns that we urge you to address. Without safeguarding the preferential access or rectifying formulary tiering issues that may result from price negotiation for selected drugs, there is a risk that medications like Xarelto will be relegated to a non-preferred formulary. This jeopardizes access that countless cardiovascular patients depend on to mitigate the risk of heart attack and stroke. We're also apprehensive about the law's potential ripple effects in the cardiovascular sector. Five out of the ten drugs selected for price negotiation this year are used in treating heart patients. This new reality could hinder the development of novel treatments, especially given the inherent challenges in the cardiovascular drug development process, such as high clinical trial expenses and comparatively low success rates. My rare heart condition, known as single ventricle heart disease, and the palliative sub-Fontan circulation that accompanies the condition, often results in arrhythmias. In 2021, there was a randomized, multicenter clinical trial for Xarelto to determine the effectiveness of the anticoagulation therapy for Fontan patients. The FDA eventually approved Xarelto for the Fontan patient indication. The Medicare Price Negotiation Program may hinder sponsors from conducting a trial such as the Xarelto trial for additional indications, putting patients like myself in the dark about the potential benefits of the existing drugs for rare disease populations. Lastly, the introduction of Xarelto and other direct oral anticoagulants has revolutionized cardiovascular care. My personal care journey saw years on warfarin, demanding regular clinic visits and constant dose adjustments. A severe bleeding episode, which led to an emergency room visit and multiple follow ups, eventually drove, in my case, the decision to discontinue warfarin. Direct oral anticoagulants like Xarelto have undoubtedly spared countless hours in travel and medical monitoring and saved millions in healthcare costs associated with warfarin's unpredictable nature. We urge CMS to assuage our concerns that the new law may subject patients to unnecessary utilization management practices or limit Xarelto's access by categorizing them under non-preferred formularies, thus raising the price for Medicare beneficiaries. Thank you for your time and consideration.

00:17:46

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]**.

00:18:00

Speaker 4

Good afternoon. I'm an Afib patient and **[INFORMATION HAS BEEN REDACTED]** StopAfib.org, a nonprofit

for those with Afib. I'm also a patient who is on a direct acting oral anticoagulant, or DOAC. We reached out and asked Afib patients in our community about their experiences with Xarelto and other DOACs, and over a thousand responded saying that these DOACs have been a godsend for them, but cost is a challenge. Between Medicare disallowing coupons and vouchers and patients going into the donut hole earlier each year, many are forced to stretch or even forego their medications. We patients need lower cost overall, but that may not happen. As payers have said, they'll increase utilization management, such as prior authorization and non-medical switching, in order to compensate for the IRA. I deal with my Part D plan each year for a prior authorization for a brand cardiovascular medication after having an adverse event on the generic. My cardiologist recommended the brand and requested the brand because I'd been stable on it. After approvals of a prior authorization for several years, it was denied last year. And we took it all the way to the administrative law judge who found in our favor. Patients and clinicians should not be forced to invest weeks in dealing with tactics that deprive patients of life-saving medications. My doctor's office was shorthanded this year and unable to fight the denials, so I've had to forego my life-saving medication and pray that I survive to try again next year. Stable patients should not be forced off of their life-saving medications such as DOACs, where they risk a life-threatening stroke that can be costly to Medicare and to the family. U.S. direct stroke cost exceeded $71 billion in 2012 and that should triple by 2030. The CDC says that non-Hispanic Black adults have almost double the risk of a first stroke and the highest rates of stroke deaths, so this is a massive health equity issue, as the underserved are especially penalized. In the IRA negotiations, please don't let patient and clinical autonomy and shared decision-making be taken away from us. Thank you.

00:20:52

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 Dharmesh, who registered as a healthcare provider who has experience prescribing, dispensing, or administering the selected drug or its therapeutic alternatives. Dharmesh reported no conflicts of interest. Welcome, Dharmesh.

00:21:09

Speaker 5

Good afternoon. Thank you for allowing me to provide comments on Xarelto's impact in the cardiovascular community. My name is Dr. Dharmesh. I'm a practicing cardiologist in Mississippi and Tennessee. There are around 625,000 Medicare patients in Mississippi, representing over 20% of the state's population. It is important to note that about 8,000 Mississippians die from heart disease every single year, making it the second worst state in the country for death rate due to heart disease. During my career, I have witnessed the exciting introduction of innovative drugs and devices that have really saved and changed the lives of millions of patients. Meanwhile, however, I have also witnessed our country lose its battle against cardiovascular disease, particularly in underserved and underrepresented communities. And I'm concerned that CMS' actions do not fully address the access issues that plague my patients and could in fact, make them worse. Price is a critical access barrier for patients, but it does not equate to value. I fear the scope of the negotiation program is too narrow and does not adequately address the plethora of access and equity issues plaguing our healthcare system. This is clearly evidenced by Xarelto. Xarelto is unique because it's

one of the most recent and innovative therapies for peripheral vascular and chronic coronary heart disease. It affects eight to 12 million Americans, most of whom are over the age of 50. As with most cardiovascular disease states, underrepresented communities suffer from peripheral artery disease, or PAD, at a higher rate. Black men older than 50 have the highest rates of prevalent PAD, and Black women experience much higher rates than groups according to the 2023 American Heart Association. Higher rates are also observed in Hispanic and Indian groups compared to White adults. This is important because of the ten therapies chosen for negotiation, Xarelto is the only therapy that alleviates PAD. One in five individuals with PAD, either underdiagnosed or untreated, will suffer a heart attack, stroke, or death within five years. Patients are at risk of losing limbs, which is a devastating psychosocial and impact on life and increases health to the cost care. As you has been told earlier, 50% of patients die if they do have an amputation within one year. Under this negotiation process program, I fear that patients will experience a higher burden to access their medications because there's been no guarantee that CMS will address utilization management practices once the program is fully implemented. The people who will suffer are the patients. Imagine having to sacrifice a leg because you are not able to gain timely access to a therapy due to utilization management. If patients must endure step therapy, prior authorization, or nonmedical switching, they may as well be considered untreated. My job as the doctor is to provide patients the therapy that is known most effective for their condition. Please ensure that when this program is implemented, patients are not forced to step through more dangerous and less effective drugs. Please ensure stable patients are not switched from their therapies, and please ensure that prior authorizations do not delay necessary care. Millions of patients are relying on you. Thank you very much.

00:24:33

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

Thank you for your comments, Dharmesh. 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]**.

00:24:46

Speaker 6

All right, good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**, and **[INFORMATION HAS BEEN REDACTED]** the Alliance for Aging Research. On behalf of the older adults that we advocate for, we thank CMS for hosting these forums. While some stakeholders have been pointing to warfarin as an alternative to direct oral anticoagulants known as DOACs, this isn't an apples-to-apples situation, and the costs are not directly comparable. DOACs can easily be taken at home and have fewer harmful drug interactions and do not require dietary restrictions. In contrast, warfarin provides vigilant monitoring via Prothrombin Time Blood Test, and the drug interacts with many common OTC medications such as acetaminophen and ibuprofen, and some dietary supplements. For individuals that are unable to self-administer the test, they may incur additional clinical costs and effort to have INR monitoring done at a lab, testing center, or medical office. These costs are not nominal and illustrate how vital it is to consider the outcomes that are important to patients. In the Medicare population, beneficiaries are older and have a greater level of disability compared to other insured populations, which may limit their ability to both self-

administer as well as travel for testing. It is important to not only include the sticker price, but to consider the ancillary cost and outcomes that patients find important and improve their quality of life. It is also vital that care providers maintain autonomy over determining the therapy that is best for their patients. In a previous listening session, one participant noted that their insurer had used step therapy when they started DOAC therapy when their doctor felt that another DOAC would have been more appropriate for them. While there are more protections in Medicare than in private plans, it is vital that CMS establish additional protections to prevent inappropriate utilization management, such as non-medical switching, given the financial dynamics of Part D redesign. CMS should also use head-to-head studies whenever possible in comparing outcomes and negotiating prices and avoid using metrics such as the equal value of life-years gained methodology, which may discriminate against older adults and people with disabilities, the very populations that Medicare serves. Pricing should also acknowledge that ambiguity exists. For example, some studies show that Eliquis may have fewer side effects than Xarelto, while a 2018 study indicated that Xarelto has fewer serious side effects when used in medically frail populations for nonvalvular Afib. Pricing should support and incentivize the use of the drug that is best for specific patient populations. In addition to Afib, Xarelto is indicated for the treatment of deep vein thrombosis and in the pediatric population, among other indications. In short, CMS must consider relevant pricing and outcomes for secondary indications in establishing prices giving the agency's moiety policy. Today represents the final listening session for the ten drugs subject to price negotiation in 2026. In the future, we want to ensure that CMS receives feedback during these sessions as directly applicable to price negotiation discussions. We've heard a number of participants talk about guardrails to prevent UM abuse. Just as importantly, CMS needs to know not only about the outcomes, data, and endpoints that matter to patients, but be able to ask clarifying questions and open dialogue. The Alliance and other patient organizations look forward to working with the agency to create a two-way conversation. Thank you again.

00:28:02

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 Raj, who registered as a healthcare provider who has experience prescribing, dispensing, or administering the selected drug or its therapeutic alternatives. Raj reported no conflicts of interest. Welcome, Raj.

00:28:19

Speaker 7

Thank you for the opportunity to provide you comments today on rivaroxaban, generic name for Xarelto. My name is Raj R., speaking on behalf of Doctors for America, or DFA. I've completed my third year of medical school, including all my core clinical clerkships. I'm currently a Master's student in Health Policy, studying cost effectiveness analysis and econometrics, at the London School of Economics and the London School of Hygiene & Tropical Medicine. After I return to medical school, I will apply to neurology. DFA represents 27,000 physicians and students across all specialties and states. We do not accept any funding from pharmaceutical or medical device companies. I am Vice Chair for Access to Affordable Care for all members of DFA and also a member of DFA's FDA Task Force, which regularly appears before Congress members and FDA and CMS officials. DFA has also joined several amicus briefs on the side of HHS and the recent lawsuits

regarding the negotiation program. I also spoke in the apixaban session. DFA comes to you today with a simple message to CMS: to stand firm on your principles in negotiation and negotiate the best possible price for our patients for rivaroxaban. We also urge CMS to take advantage of the unique opportunity provided by two medications in the same therapeutic class, both rivaroxaban, which is one of the top five highest Medicare expenditure drugs, exceeding the next drug by $2 billion, and apixaban, the number one drug, exceeding the next by $9 billion. DOACs such as rivaroxaban hold great importance in management and prevention of thrombosis, pulmonary embolism, heart disease and stroke, with major improvements over the numerous inconveniences required with warfarin monitoring. Rivaroxaban was first approved in 2011, twelve years ago. But in 2018, Bayer and Janssen, two of the pharmaceutical companies involved in rivaroxaban, won a suit to prevent generic entry until Fall 2024. You might think, great, that's only ten more months. But Bayer and Janssen have been embroiled with disputes with multiple other generic drug makers since then, with a trial expected in Spring 2024, to proactively continue extending their patent. They are making it seem like an end is in sight while continuing to move the goalpost. And that's not even mentioned that Janssen and numerous other pharma groups have sued HHS to rule the entire negotiation program unconstitutional. We would also note and strongly urge CMS to look into the funding sources for various other testifiers in these listening sessions to ensure that they do not present a conflict of interest. Thank you very much again for the opportunity to present comments today.

00:30:45

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

Thank you for your comments, Raj. 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]** declined to report whether they have a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:30:59

Speaker 8

Hello, I'm **[INFORMATION HAS BEEN REDACTED]** Survivors for Solutions and advocate for all patients no matter what illness they suffer. I would like to thank CMS for allowing me to contribute at these public meetings. I hope CMS leadership learned as much as I have here. All patients have the same common story. Every patient said how vital their medication was to their well-being. Every single one. Yet this very negotiation program is already slowing innovation and only promises to get worse. Living with my disease, I, like millions of other patients, require a flowing pipeline of new treatments. While none of the ten drugs discussed are prescribed for multiple sclerosis, all are part of the same medical discovery ecosystem. I wanted to be here because ultimately, there is so much stake, there's so much being risked. The fact is, when you disrupt discovery in one place, you impact it all. Saying you're targeting a few drugs is like saying you want milk in only half of your cup of coffee. A nice idea, great. But in the real world, impossible. The cancer drug, for example, on your hit list, uses a mechanism of interest to many, including those fighting my disease, MS. The discouragement you're placing on one drug will harm countless others. So if you think you can isolate the damage you're doing, think again. CMS has been given an impossible task to enforce a law that will hurt patients that they are supposed to help. I hope that you're listening carefully. Listening to how vital innovative treatments are, how lives are saved and improved by their discovery, and how you are

distorting the medical research with regulatory overreach that is already choking the future…

00:33:19

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

Looks like we're having some technical difficulties. Okay, well, thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move to our final speaker. Please welcome **[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]**.

00:33:36

Speaker 9

Good afternoon and thank you. My name is **[INFORMATION HAS BEEN REDACTED]** I'm an advocate and patient living with chronic conditions. **[INFORMATION HAS BEEN REDACTED]** the Chronic Care Policy Alliance. The CCPA is a network of state and regional advocacy organizations working on public policy that improves the lives of those living with chronic conditions and diseases. I became a health advocate because of my own struggle to get my health condition taken seriously by my health insurance plan and to find treatments that allowed me to resume my daily activities. What I learned through that struggle, and what 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. We don't want patients just to survive. We want them to thrive. The development of life saving, changing medications must continue, and patients need access to them. My husband is among those with cardiovascular disease and Afib, so access to medications for related conditions is an issue dear to my heart. Xarelto is a blood thinner that treats and prevents blood clots. It can lower the risk of stroke, deep vein thrombosis, pulmonary embolisms, and similar conditions. The medication belongs to a new type of blood thinner called DOACs. They may be safer and more effective than older blood thinners. There is a large patient population affected by thromboembolic conditions because they are more common as we age, but also accidents or surgeries can bring on thrombosis. They are painful and can be deadly. I want to speak in these sessions because of patients affected by sudden onset disease and for long-term developing chronic conditions and diseases. While patients with chronic conditions have all varying needs, all chronic conditions can be life threatening. They may destroy our ability to work, to play, to move, to participate with our family. I am here because you are making meaningful, impactful decisions about our health and our lives. We need to lower out-of-pocket costs to better ensure access to medications without bankrupting or causing people to go without other life necessities. However, CMS sets the standards not just for Medicare, but standards that will flow through our healthcare system and directly affect my health benefit as a Medicare patient, but it also benefits people with health care coverage through employers and direct marketplace plans. We fear lowering prices is not as easy as let's drop that price, $10 or $100 a month. It's much more complicated. The role PBMs have in our healthcare system must also be addressed. Questions to keep in mind: Is one of these medications the most advanced medication available and serves patients much better than what came before? Will there be interest in pursuing continued research if you drop the price too far? Will the research into cures be inhibited? As this process is put in place, will formularies be disrupted and patients switched or access changed? Will patients using the product off label or in a different dose have their care interrupted? We ask

CMS to take great care to protect patients' access to current and future treatments and cures. We hope that your goal is to make patients the center of the conversation. Keep in mind, what works for many does not work for all. In my closing remarks, I would like to thank CMS for providing these listening sessions and taking time to listen. We are grateful for the opportunity to be heard and look forward to keeping the conversation going. Thank you.

00:37:27

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

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. And thank you all really 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.