

*This transcript was lightly edited for readability.*

## Introductory Remarks

### Moderator, RTI International

Hi, everyone good to see you today. I appreciate you joining me today. My name is **[MODERATOR]**. **[REDACTED]**, and I work for a company called RTI International. We're a nonprofit research organization in North Carolina, and I also want to introduce my colleague, **[SECONDARY MODERATOR]**, who's here with me today. **[SECONDARY MODERATOR]**, you want to wave so people can see you? There you go. Thanks, **[SECONDARY MODERATOR]**. You may hear from **[SECONDARY MODERATOR]** a couple of times a day with a couple of follow-up questions I may have missed.

The Centers for Medicare & Medicaid Services, also called CMS, is convening these patient-focused roundtable events as part of the Medicare Drug Price Negotiation Program.

The purpose of today's event is to hear from you all. And it's a group that includes patients, caregivers, and patient advocates, about your experiences with the conditions and diseases treated by Trelegy Ellipta, with Trelegy and other medications to treat the same conditions.

One thing I want to note is that today's discussion is more patient-focused, about the patient experiences with COPD [chronic obstructive pulmonary disease] and asthma. If you have more policy-level discussions or comments you want to make, we do have an email box that you can email comments to. We'll show you that at the end, but that email address is [IRARebateAndNegotiation@cms.hhs.gov](mailto:IRARebateAndNegotiation@cms.hhs.gov). Again, today is more focused on the patient experiences, so we can understand that better.

The information shared during our discussions will better help CMS understand patients' experiences with the conditions and diseases treated by Trelegy, patients' experiences with the selected drugs themselves, and patients' experience with other drugs that are used to treat asthma and COPD. CMS may use this information in negotiating Medicare pricing with the manufacturers of the selected drugs.

Your experience and perspectives are very important to us, and we genuinely appreciate your time today. Let's watch a brief video today from CMS leadership so that you can hear from them about how much they value your time and input today.

## CMS Remarks

00:02:16

Steph Carlton, Deputy Administrator and Chief of Staff, Centers for Medicare & Medicaid Services

Greetings, everyone. I'm Steph Carlton, the Deputy Administrator and Chief of Staff 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. Lowering the cost of prescription drugs for Americans is a top priority of President Trump and his administration. As the second cycle of negotiations begins under the Trump administration, CMS is committed to engaging with stakeholders for ideas to improve the Negotiation Program.

In January 2025, CMS announced the 15 Medicare Part D drugs selected for the second cycle of price negotiations. Medicare's ability to negotiate directly with drug companies will improve access to some of the costliest drugs while fostering market competition and continuing 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 Medicare Drug Price Negotiation Program. And that is why the process for negotiation engages you, the public.

This event is part of our effort to hear directly from a range of stakeholders and receive input that's relevant to the drugs selected for the second cycle of negotiations. Thank you again for joining us. Your input matters. And next, stay tuned to hear from the event moderator to give you more details on what to expect during this event.

00:04:15

Moderator, RTI International

I also want to make you aware that staff from CMS will be sitting in on this event, so they can hear from your experiences and opinions directly from you. Let me hand it over for a moment to **[CMS STAFF]**, so they can say hello. Hey, **[CMS STAFF]**.

00:04:28

CMS Staff

Hi **[MODERATOR]**. I want to welcome everyone on behalf of CMS. On the call today, we have staff from the Medicare Drug Price Negotiation Group, which manages the Negotiation Program. We want to thank you for participating. And we're looking forward to hearing about your experiences during this roundtable discussion. We're going to go off camera now, so you can focus on the discussion. But we'll be here in the background, and we'll be listening to the conversation. Thanks again.

## Housekeeping

00:04:52

Moderator, RTI International

Thanks, **[CMS STAFF]**. Before we begin. I do want to go over a couple of what we call housekeeping items and ground rules, so that everyone knows what to expect.

First, we want to hear from everyone and hear your opinions today, but if there's a question that you don't want to answer, that is totally okay. You don't have to answer any questions that you don't want to today. Please minimize background noise by silencing your cell phones and other devices. And please mute yourself when you're not speaking, if you can.

Just to let you know, today's discussion is not open to the press or to the public. I'm also going to be using first names only during the discussion to protect your privacy. Please don't share any unnecessary personally identifying information or personal health information during the discussion.

We are going to audio and video record today, which we are now. But these recordings will not be shared publicly. Following the event, CMS will prepare transcripts that have participant names and identifying information removed, and these transcripts will be made available publicly.

I also want to go over a couple of other things. One is for video. Thanks in advance for keeping your video on throughout the discussion. This session will last about an hour and a half total. And I have a lot to discuss today. There's a lot of questions I have of you all, and I might, during the session have to move things along. That's not me being rude. That's just acknowledging that I have so many questions, I may have to move on to another question.

If you get disconnected, please attempt to rejoin, and if you can't reach connect, please reach out to this email address, which is [IRADAPStechsupport@telligent.com](mailto:IRADAPStechsupport@telligent.com), and someone there can help you get reconnected.

If you need to step away or take a break from our discussion, that's totally okay. Just turn off your camera and your microphone and come back as soon as you can. You don't need to ask for permission to leave. You may leave at any time.

Please also try to speak one at a time. I may have to interrupt people if there's more than one person speaking. If you find you're having trouble getting a word in edgewise, there's also the raise hand feature. Hit that, and I'll know that you want to speak, and I will be sure to call on you.

Finally, your opinions and experiences will differ, and we want to know what each of you thinks honestly about the topics we're discussing today.

Okay, that was a lot of me talking. So, I'm going to pause for a moment to see if you have any questions for me before we begin our session.

Okay. Oh, yeah, **[Participant 1]**, go ahead.

## Discussion

00:07:29

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Before I forget, can you post where we're supposed to write any comments that don't get to be included?

00:07:37

**Moderator, RTI International**

Sure, I'm gonna ask **[TECH SUPPORT]** to put down the email address in the chat window.

00:07:43

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Yeah, please put it in the chat. Because otherwise I'm going to forget.

00:07:45

**Moderator, RTI International**

Yeah, no problem. And also, **[Participant 1]** at the very end, we're also going to show a slide with that email address, as well. So, we'll remind you of it. Don't worry.

00:07:53

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Thank you so much.

00:07:55

**Moderator, RTI International**

And I see that **[TECH SUPPORT]** is on top of it. Thank you, **[TECH SUPPORT]**.

I want to get to know you all first, so I understand a little bit about you and your perspectives, and where you're coming from. So, I'm going to go around the proverbial table here and ask you all to introduce yourselves. And, take about 30 seconds just for a quick introduction. Let me know your first name. Also, the condition or conditions that Trelegy treats that you have experience with, so either asthma or COPD. And also tell me whether you're going to be sharing your personal experiences or you're going to be sharing the experiences of a loved one, or you're sharing your experience as a patient advocate, and it might be more than one hat. That's totally okay. So again, first name, the condition or conditions you have experience with that Trelegy treats, and then if you're sharing it as a patient with personal experiences, you're sharing your experiences as a caregiver or as a patient advocate, and I will go in the order that they appear on my screen. And, **[Participant 2]**, you are first up. Hey, **[Participant 2]**.

And we'll need to get you off mute, **[Participant 2]** first.

I think that **[TECH SUPPORT]** can send you a prompt to help you out with unmuting.

00:09:10

**Participant 2 (registered as a patient)**

She did.

00:09:11

**Moderator, RTI International**

There we go.

00:09:12

**Participant 2 (registered as a patient)**

Can you hear me now?

00:09:12

**Moderator, RTI International**

I hear you. Hey, **[Participant 2]**.

00:09:14

**Participant 2 (registered as a patient)**

Excellent. Good morning. My name is **[Participant 2]**, and I was diagnosed with both COPD and asthma in 2019 and have been following this path long after that. I also happen to be involved in the Alpha-1 research, because I also am positive in Alpha-1, which is Alpha-1 antitrypsin, which also affects lung diseases.

00:09:45

**Moderator, RTI International**

**[Participant 2]**, glad to have you here. Thank you.

And next is **[Participant 3]**.

00:09:57

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

Hi, I'm **[Participant 3]**. I live in Wisconsin, diagnosed with COPD in late 2005, had to leave the workforce in late 2011. I'm currently Stage 4 COPD. And I'm also an advocate, and so I'll be happy to share both my personal experience with Trelegy, as well as what I've heard in all the various groups of patients that I'm involved with. It's a thrill to be here. Thank you.

00:10:33

**Moderator, RTI International**

Thank you, **[Participant 3]**. And next on my screen is **[Participant 4]**. Hey, **[Participant 4]**.

00:10:43

**Participant 4 (registered as a patient)**

Hello. My name is **[Participant 4]** from **[REDACTED]**, Texas, and I am coming in as a patient. Trelegy has really helped me because of my asthma. Really bad. Not only do I use Trelegy, but I have to use an albuterol inhaler, as well. So, this will be interesting to hear everybody's feedback during this session.

00:11:17

**Moderator, RTI International**

Great. Thank you, **[Participant 4]**, happy to have you here. Also, just a reminder, just be sure also not to mention where you live, just for privacy reasons. But you can say your state, but not city for sure. Okay, **[Participant 5]**? Hey, **[Participant 5]**.

00:11:31

**Participant 5 (registered as a patient)**

Hello! My name is **[Participant 5]**, and I have COPD, and I am also a patient advocate, so I'll be mainly telling my experience.

00:11:45

**Moderator, RTI International**

Wonderful. Thank you, **[Participant 5]**. **[Participant 1]**.

00:11:48

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Hey, I'm **[Participant 1]**. I have asthma and COPD. I've had asthma since I was a young child. I was diagnosed with COPD in 2000. I also was a caregiver for my father, who died of chronic bronchitis, and I've been a patient advocate since about 2007, so I will wear three hats.

00:12:11

**Moderator, RTI International**

That's good. Thank you, **[Participant 1]**. And **[Participant 6]**?

00:12:23

**Participant 6 (registered as a patient)**

Good morning, everybody. My name is **[Participant 6]**. I live in the great state of the Midwest. I was diagnosed with COPD about 12 years ago. Trelegy is my maintenance medication. I use it once, daily, every day. I notice the difference immediately if I stop using it. So, I'm here to share my personal experience as a patient. And also, if I have the opportunity to share perspectives as a patient advocate. Thank you.

00:12:55

**Moderator, RTI International**

Thank you, **[Participant 6]**. And last, but not least, is **[Participant 7]**. Good morning, **[Participant 7]**.

00:13:04

**Participant 7 (registered as a patient and representative of a patient advocacy organization)**

Hi, I'm **[Participant 7]**. I'm here as a patient and patient advocate. I use Trelegy to treat asthma, which I've had for 20 years.

00:13:13

**Moderator, RTI International**

Thanks, **[Participant 7]**. So, **[Participant 1]**, I think that addresses your question earlier, which is about seven people, all patients.

All right. So, my first question for you all is, and you can raise your physical hand. That might be easier. But I want to just by show of hands, have you or a loved one taken Trelegy either currently or in the past? So do you or a loved one currently take Trelegy, either currently or in the past, and you can just raise your hands, and I will do a count.

So, looks like five people currently are taking Trelegy. Wonderful. And six, okay, six are taking Trelegy currently. Great. Thank you so much.

So, in a moment, we're going to be talking about Trelegy a little bit more in depth. But I first really want to talk about COPD and asthma. And I think you all know this when I say COPD, I mean chronic obstructive pulmonary disease. And I just want to talk about those before we talk about Trelegy. So let's talk about asthma first. In general, how does asthma affect you, your loved ones, or patients' day-to-day lives? So again, how does asthma affect people's day-to-day lives? Who wants to go first? So, **[Participant 1]**, go ahead.

00:14:42

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

So much depends on the person and how good the control is. If their control is really good, most of the time they don't notice it unless it flares up, and then it can be a pretty big panic or excitement or problem for anybody around, especially if they don't happen to carry around the rescue inhaler.

I know I've scared a lot of people when I've had asthma attacks because they had sulfites in the salad bars in the seventies and eighties. And all of a sudden, I couldn't breathe at all, and no one knew what to do.

Yeah, it's very exciting. It's too dramatic.

00:15:40

**Moderator, RTI International**

And I think, **[Participant 2]**, you had your hand up, and then **[Participant 7]**. Go ahead, **[Participant 2]**.

00:15:50

**Participant 2 (registered as a patient)**

When I was working, I have recently retired, but when I was working especially, there are a lot of triggers for asthma and found some new ones every day. Probably the worst case was when somebody used one of those sprays to keep your clothes from sticking to you in a cubicle next to mine, and I went into a full-blown asthma attack and scared everybody.

And I had to stay out of the building for 30 minutes while I aired it out, because I couldn't be there at all. But the triggers of perfume, those kinds of sprays, anything like that, they can get you at any place at any time.

00:16:36

**Moderator, RTI International**

Actually so, **[Participant 2]** and **[Participant 1]**, you both talked about these episodes, which are scary for people. Tell me about that. And how does that affect people? And also, how does that affect you when that happens?

00:16:49

**Participant 2 (registered as a patient)**

Well for me, the very first experience that I had, and the reason I went in and got diagnosed, was in the middle of the night I woke up and I wasn't breathing, and I literally was like this. I couldn't get any air in and out, and I got to tell you, that's a pretty bad way to wake up. And I made it through that



attack, which I feel very lucky. And, I've had attacks since that have been bad, but nothing that has been that bad, and I've always had now a rescue inhaler to help deal with it.

And I am one of those people that has a rescue inhaler with them all the time. But for other people to watch when you are starting to have an asthma attack. They're like, what can I do? I mean, they lean in, and they're concerned, and they want to be helpful. But they don't know what to do. And so, it's from one perspective, it's kind of embarrassing, but at the same time it's like, hey, it is what it is. But it can be terror inducing, just saying.

00:18:02

**Moderator, RTI International**

I can imagine, yeah. **[Participant 7]**?

00:18:04

**Participant 7 (registered as a patient and representative of a patient advocacy organization)**

Yeah, I agree with everything they've said so far. I think asthma affects you differently throughout your life. For me, it started with trying to play soccer during allergy season and having to run to the sidelines multiple times a game to take a puff and then get back on the field.

As it got more controlled over the years, I was able to just take my inhaler before a game, and hopefully, I didn't have an attack during the game, but I've been to many urgent cares from a rec soccer game.

But, also, are you going somewhere that might be smoky? Are you going somewhere that maybe cold air triggers it? And you're going to walk to your car in the winter, and you have to remember to have your inhaler. Those are always things you don't worry about. And people make a point, some people are really good, and they'll be like I'm going to walk away from you and go smoke my cigarette, and sometimes they're there, and you're like, do I leave? Do I stay?

But over the years, it's changed. So now I can only worry about it mostly when I get sick, and it takes me months to recover from things like a common cold or the flu. And I bought a cool new keychain for my inhaler that I can clip to my belt loop, or on my purse. I look super cool at work, but you find ways to cope. But people are always wondering, why are you coughing? Are you coughing because you're sick? Are you coughing because you can't breathe? Are you going to die? What's happening? And so, you're dealing with not only your own anxiety, but other people's.

00:19:37

**Moderator, RTI International**

Now, when it comes to asthma, and I'll come back to COPD, don't worry. But when it comes to asthma, what aspects of asthma do you feel are the most important to you or people you love to have managed or treated? So, when it comes to asthma, what is most important to you to have managed or treated?

Yeah, **[Participant 1]**?



00:20:02

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

I think it's really important to try to get it so that it's under pretty good control, so that when you do have flare ups, it's not as scary for you or the people around you. I was with my sister-in-law, and we had samples at Costco, and all of a sudden she started wheezing because there was a little bit of mint in it, and I said, well, I happen to have my rescue inhaler. Why don't you take a puff because you're not breathing so well. And she doesn't carry a rescue inhaler because she normally doesn't wheeze. And I mean, it's just that dramatic for people if they're not used to having attacks, and because I do have attacks, I tend to think that way, and like, when I, my nephew was going to football camp. I said, do you have your rescue inhaler? He goes, no, I never need it. I said, you're going to football camp. You need it. Here, take this one because I can't let you go to a camp where you're going to be exercising and not know if you're going to be okay in case you do more than you expect.

00:21:22

**Moderator, RTI International**

The one important thing to have managed are those flare ups to make them less significant?

00:21:30

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Yes, kind of make it... Yeah.

00:21:34

**Participant 7 (registered as a patient and representative of a patient advocacy organization)**

I think the ability to recognize your triggers and know what they are, so that you know if it's asthma, if you're sick, if it's anxiety, because all those things can overlap in the moment. So, learning when you are triggered, and how your attacks start, and how to deal with it as soon as possible is super important.

00:21:53

**Moderator, RTI International**

**[Participant 2]?**

00:21:58

**Participant 2 (registered as a patient)**

Tracking is most important thing for me to learn. That's when I learned what it feels like every day to track my asthma, so that I know when I'm in a good zone or I'm in a more dangerous zone, and I had help in learning how to do that, and that has made a big difference for me.

00:22:17

**Moderator, RTI International**

All right, let's talk about COPD, so chronic obstructive pulmonary disease.

I want to again, before we talk about Trelegy, or any treatments, I really want to hear from you all about how COPD affects your daily lives, or people who have COPD, how it affects their daily lives. So how does COPD affect your day-to-day life? Yeah, **[Participant 3]**?

00:22:41

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

We need to all recognize that everyone is completely different. If you're say GOLD [Global Initiative for Chronic Obstructive Lung Disease] Stage 1 or 2, it's not going to have as much impact as if you're GOLD Stage 4, for example.

And it's critical that we keep moving, because we all say, the less we do the less we're able to do.

And it's also important, as was mentioned several times in the asthma conversation about knowing the triggers and reacting quickly. I'm sure we all remember the Andy Griffith show, and Barney's favorite phrase, we've gotta nip it in the bud. And that's critical, because if we react immediately and have an action plan, we're most likely not going to wind up being admitted to the hospital.

But as for me, how does it affect my daily life? I mean, currently, I've slipped a great deal, and my oxygen needs have really gone up, and I'm on palliative care right now, which is not a death sentence. I'm okay. But it's just, we're all different. And we all have different triggers. So, because I've got bronchiectasis as well, I just have a lot of mucus and phlegm. I'm not sure if that really addressed your question, but it's kind of an overall view.

00:24:12

**Moderator, RTI International**

Yeah. Well, so, **[Participant 3]**, I think you mentioned you said you're Stage 4 earlier, if I recall. Tell me, how your life has been affected by COPD? How's it impacted your day-to-day life?

00:24:24

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

Well, I for example, I love to cook, and I'm a very good cook. But recently I've not had the energy. I'm just not able to. And my wife, **[REDACTED]**, I never really considered her a caregiver, but now she most certainly is. I can't travel or go anywhere without her with me. Because I would go into a full-blown panic attack, so life has become in the last six months considerably different than it was before.

And I did, I think it's like maybe one of the first times that I've really felt helpless, where I really rely on her, and that's a tough thing to accept, because we all want to be independent and do what we can do. So did that maybe help answer it?

00:25:22

**Moderator, RTI International**

That does. I appreciate that, **[Participant 3]**

**[Participant 5]**, I see your hand is up. Let me give you a moment.

00:25:30

**Participant 5 (registered as a patient)**

Well, early on with my journey with COPD before it was well-controlled, I would have panic attacks. And most always, it happened in a parking lot. So, if I was coming from the grocery store and I knew to do pursed lip breathing, I knew all the diaphragmatic breathing. I knew all of that, but I would become panicked anyhow, because it didn't seem to be working fast enough, and it is a very, very scary thing not to be able to breathe as other people have mentioned. It's unbelievable. And I learned to overcome the panic by making my cognitive brain work which says, start naming all the cars in the parking lot very specifically, so that I'd get away from that fight or flight.

And now, mainly, I have to watch out for exacerbations, which I'm having one right now, and I'm on antibiotics and hopefully it won't go into pneumonia. But that's happened to me several times, too.

I also have had a problem with my lung collapsing, which is really a fun feeling. And actually, if we got right down to it and got honest, it's very, very hard to live with COPD. But, I think everyone here is someone who doesn't want to be that way. As **[Participant 3]** said, it's hard to admit that we can't do everything we used to do, so we keep on pushing as hard as we can, and I think, for the most part that's probably good.

00:27:36

**Moderator, RTI International**

So, **[Participant 5]**, both you and **[Participant 3]** mentioned panic attacks. Tell me a little bit more about panic attacks with the COPD. Like what triggers it? What's going on with the panic attacks?

00:27:51

**Participant 5 (registered as a patient)**

For me, it was a wheezing or not being able to get my breath, and then, like, I say, it's very scary not to be able to breathe, and so that would bring on the panic attack. I hope that answered your question.

00:28:09

**Moderator, RTI International**

And then, sorry. Go ahead, **[Participant 3]**.

00:28:11

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

Yeah, I just, I'll jump into it. I agree with **[Participant 5]**. A panic attack is air hunger. And it's really odd, because sometimes I'm sure we all have our pulse oximeters with us.

And I'll check it. And it's, say, 92, 93, which is fine, but you still have that air hunger, and you have to use self-calming techniques and tell yourself, hey, you're going to be okay. Just slow down and just pursed lip breathing. And you really have to tell yourself. But you know, I'm to the point where I'm also, if I get that air hunger, I'm on low doses of morphine sulfate, you know, under the tongue a sublingual. So yeah, it's anxiety and panic attacks. And it is scary. It's not a fun way to live.

00:29:10

**Moderator, RTI International**

I've heard you say that air hunger, and that makes a lot of sense.

**[Participant 1]**, let me give you about 30 seconds. And **[Participant 7]**, I need to move on to the next question, which I apologize for. But, **[Participant 1]**, go ahead.

00:29:23

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

For me, the worst thing is, you keep having these exacerbations, and they can last for one month, two months, or like half a year to get over.

And people don't understand, and they just say, well, I just have a slight cold. I'll be around you, and they will get sick for two days, and we will get sick for six months, and they don't understand that a cold is not a cold, and since I was diagnosed in 2000, I've had one to six exacerbations almost every year, except during COVID.

00:30:03

**Moderator, RTI International**

Makes sense.

00:30:04

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

That's the worst part.

00:30:06

**Moderator, RTI International**

Now, when it comes to COPD, what is most important to you all to have managed or treated when it comes to COPD? Okay, what's most important to be managed or treated for COPD?

Yeah, **[Participant 2]**.

00:30:27

**Participant 2 (registered as a patient)**

Well, I think for me, it's obviously being able to breathe. Well, that is absolutely the most important thing is having a medicine that you're using, that allows you to breathe well and makes a difference in your life.

That is the thing to me, the single most important thing. Understanding the disease is also a very good thing to do, but just simply being able to breathe because you're using a medication that helps open things up is the most important thing for me.

00:31:03

**Moderator, RTI International**

So, being able to breathe well. **[Participant 6]**?

00:31:07

**Participant 6 (registered as a patient)**

Yeah, I agree with **[Participant 2]** on being able to breathe well through the use of Trelegy is probably my primary concern. When you're air-starved, like **[Participant 3]** mentioned, you feel like you're suffocating. You feel like you're suddenly operating at 15,000 feet. And unfortunately, if you start panicking over that feeling, all it does, it gets worse. You try to catch your breath. It's an automatic reaction. You try to catch your breath, and the harder you try to catch your breath, the more restricted your lungs become. So Trelegy seems to be a good medication against that. I know Trelegy's got three separate medications in it, and I'm pretty sure the only other one on the market is Breo. But, I assume that I don't have a really good baseline to see how well it works, because I refuse to stop taking it. I missed it once a couple of months ago, and I felt the effects the same day, towards the end of the day.

So that's my maintenance medication. I'm assuming that as a maintenance medication, it works best after it builds up in your body a little bit. And I do have ProAir as a rescue inhaler that I use rarely when I feel as though I need it. But that's the reason why I like the Trelegy. Of course, I'd like it if it was a little cheaper, but you do what you have to do. So that's what I wanted to say.

00:32:58

**Moderator, RTI International**

I appreciate that. So, I appreciated hearing those experiences so far that you all have had. I want to talk a little bit about all the different medications that are available for asthma and for COPD, and I've heard a few mentioned, albuterol, I've heard Breo mentioned. Let's talk about asthma for a moment first and then we'll come back to COPD. When considering the different medications that are available for asthma, what matters most to patients in these medications? So, when it comes to medications for asthma, what matters most to patients? And **[Participant 7]**, go ahead.

00:33:39

**Participant 7 (registered as a patient and representative of a patient advocacy organization)**

For me, it's the side effects that come with it. And then the ease of access. The most effective drug, probably, for any of us is prednisone steroids, but they come with crazy side effects long term. And if you have multiple conditions, you probably, like I do, I need that to treat my arthritis too. So, I want something that is easy for me to afford, easy for me to get, and has the least amount of side effects, because I know I'm taking it forever.

00:34:08

**Moderator, RTI International**

And you mentioned ease of access. Can you talk more about that, **[Participant 7]**? What do you mean?

00:34:12

**Participant 7 (registered as a patient and representative of a patient advocacy organization)**

Yeah. So, some of the medications, you can go to your Walgreens and pick up pretty easily. Insurance doesn't fight you on it, like your rescue inhaler, never had a problem getting that. But when it comes to medications like Trelegy or higher level ones like biologics, you have to go through multiple authorizations, you have to enroll in multiple programs to afford it.

You have to sometimes convince insurance or your doctor or other doctors that you need it multiple times, even though you've already had that medication for years. So, there's those extra steps required every time that don't help you versus some of the cheaper ones like prednisone or albuterol that you can just get very easily.

00:34:56

**Moderator, RTI International**

And, **[Participant 1]**?

00:34:58

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Yeah, for **[REDACTED]** years I was taking two, and then, when Spiriva, the antimuscarinic antagonist Spiriva was approved in 2002, I was taking three medicines, all separately. Taking them all in one was much easier in terms of administration, but it took me a while to decide I was willing to go that way, because I always have side effects, like **[Participant 7]** said, and I wanted to make sure that the side effects wouldn't bother me, and I could identify which element might be causing side effects, if I do have side effects. Because I've had to take medicines to counteract side effects that I get from my drugs, like some of them cause really dry eyes, and I needed drops for my dry eyes, and some of them cause tachycardia, and we have to figure out whether to take a beta blocker for that. And it's like, you end up with polypharmacy without wanting to.

And like **[Participant 7]**, I've been taking my medicines for decades, and I'll probably take them until I die unless they come up with a new solution. They can't decide what stage I am, because they said, you really function well, but your lung function is terrible, so we don't know what stage you are, so we just keep going.

00:36:33

**Moderators, RTI International**

Okay. Now, for COPD, thinking about potential medications to treat COPD, what matters most to you or loved ones for COPD? And, **[Participant 2]**?

00:36:50

**Participant 2 (registered as a patient)**

I'm waiting for it to unmute.

00:36:51

**Moderator, RTI International**

You're unmuted now.

00:36:53

**Participant 2 (registered as a patient)**

Okay, great. Well, I'm going to give you just an example of one thing that happened to me, and that was early on after I was diagnosed, my physician was going to give me Stiolto because it was less expensive than Trelegy, and so, I took the prescription home, and, unlike some people, I actually usually go to the website to really review what it is that I'm taking.

And I've got the exact phrasing that's on their website says, important safety information for Stiolto Respimat. Do not use Stiolto if you have asthma, and I have COPD and asthma. And so, I freaked out. I'm like what? So, called my physician back. And he told me, well, really, it's just that it isn't FDA-approved yet. So I said, listen, if that's on their website, I'm not going to take it. That's too scary for me. That's like me saying this bridge is perfectly fine when it's got holes all through it. And so, I did find a way to stay on Trelegy, because, even though it was more expensive, it didn't have that web page that said, don't take this if you have asthma. So, having both, I found out that there are things that you have to consider that I considered that my doctor hadn't.

00:38:29

**Moderator, RTI International**

Thanks, **[Participant 2]**. **[Participant 4]** or **[Participant 3]**, sorry.

00:38:32

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

Yeah, I would just say that I agree with everything **[Participant 2]** said. And a lot of the comments in the asthma section apply to COPD as well. And just a quick clarification, I don't know who mentioned it, but someone had said Breo was the other drug on the market that's triple therapy or one. It's Breztri Aerosphere, not Breo. So, just a point of clarification I keep saying this, but it's true. We're all different. And what do I want and need? I want to lower the patient burden as much as I can for myself.

00:39:18

**Participant 2 (registered as a patient)**

Yes.

00:39:19

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

Having something like Trelegy, where it's one puff, one time a day, instead of two or three inhalers, some once a day, some twice a day. I mean, I've got my routine down where I really never miss, just because of the way I have everything set up. I never miss a dose, or rarely, maybe once every couple months.

I'm not currently using Trelegy. And I mean, I'll go into the reason now, I guess. I was given a one-month sample, because I was always on triple therapy. But I was using one drug that I took once a day and another drug, but both inhalers twice a day, two puffs in the morning and two puffs at night. And I was so used to it, I didn't really mind, but when I tried Trelegy, I thought, boy, this is so easy, easy peasy. That was the benefit, it lowered the patient burden.

But then, when the trial ran out or the sample ran out, at that time, my insurance was telling me it would be \$212 a month. And I thought, you know, for years and years and years I've been doing fine with two inhalers, which is far less expensive than \$212 a month. So next, I suppose the main reason I'm not currently using Trelegy, but since then I've switched insurance companies, and I need to check, because if it's affordable, I'll go right back to it. It's a great product, but the cost is very high.



00:41:23

**Moderator, RTI International**

Right.

So, one important thing for you, **[Participant 3]**, is lower patient burden, meaning, in your case, once a day treatment as compared to three or more treatments a day.

00:41:35

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

Yes and cost. Cost is also a burden, but as far as daily living, yes, just once in the morning, and you're done. Oh, that was so nice.

00:41:47

**Moderator, RTI International**

**[Participant 1]**, go ahead.

00:41:49

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Yeah, we've read online about other people that are paying up to \$900 a month. And that's why they can't take Trelegy, because it's so expensive. And the other thing about medicines, like **[Participant 3]** says, it gets really confusing when you have different medicines, you take different amounts, different times a day. Some are once a day, some are multiple times a day, and it's just, I had one medicine I was supposed to take four times a day. I think I only took it four times a day, maybe twice. It was just too hectic. I couldn't take it every four hours and having a medicine you take once a day is really much less complicated and a lot easier to get better compliance. And it's not because patients don't want to do it. It's just, we have busy lives. Some of us are caregivers and caretakers and patients, and some of us have jobs or other things. And then the other method of administration, if it's not an inhaler, sometimes people have nebulizers, and that takes a little more time and effort as well, and it's also a little bulkier if you're traveling with it, and it's just one more thing, and none of them alone are that difficult. It's just when you add them all up, and it's good that patients have a range of options, because for some patients like my father, he didn't have enough force to breathe in some of these medicines, and so he really needed the nebulizer, because it's more passive. And so, it would make a mist, and he could breathe the mist in without having to do much.

But for those of us that can breathe in and can have something that's once a day, one thing you just take it, and you're done for the day for all your inhalers. It's really a game changer. I didn't think I would love Trelegy, and I started it in November. I'm definitely sold.

00:43:56

**Moderator, RTI International**

All right, **[Participant 5]**, I need to move on to another question, but give me 30 seconds, or really quickly, then I'll move on.

00:44:03

**Participant 5 (registered as a patient)**

Okay. I just wanted to say that this hasn't been a problem for me, because I can drive, but I was speaking with someone the other day who said it was just really a burden for them to go to the drugstore three times to get their three inhalers, where, if they could have afforded Trelegy, they would only have to make one trip. And they have to pay somebody to take them. And so, the trips to the drugstore can be a major problem, too. And I think that the inhaler itself, the dry powder inhaler is the easiest one, or I found to be the easiest one, to physically take.

00:44:50

**Moderator, RTI International**

All right, we've been talking about treatments broadly. I want us now to focus specifically on Trelegy, and many of you have had experience with it already, which is great.

First, from the perspective of asthma. What are some of the main benefits that you got from Trelegy, and also what are some of the main challenges or drawbacks that you've experienced with Trelegy specifically? So again, benefits and challenges of Trelegy?

**[Participant 2]?**

00:45:26

**Participant 2 (registered as a patient)**

It's hard for me to separate what's it doing for asthma versus what's it doing for COPD?

00:45:32

**Moderator, RTI International**

That's fine.

00:45:33

**Participant 2 (registered as a patient)**

But from the perspective of I'm going to say both, what it does is I get up in the morning, and it's the first thing that I do, and I rinse my mouth out just like it says to and follow all the directions, and I breathe all day long. And it's wonderful. That's really it. The ease of use is fantastic. The one symptom that I had from it is now gone, and that symptom was, I would occasionally get a very hoarse throat throughout the day, and fortunately I have a fantastic friend that is a respiratory therapist, and she said, well, are you doing it like this or are you doing it like this? And I said, well, I'm more of a [inaudible] girl, and she goes, okay, don't do it that way. Do it slowly and evenly, coming in, because then it has less turbulence and less will land in your throat, and I did that, and tada.

00:46:38

**Moderator, RTI International**

It works.

00:46:39

**Participant 2 (registered as a patient)**

It works. So, I don't get the hoarseness in the middle of the day anymore. So, that's the only symptom I have had from it, and that's why I love it. It's great.

00:46:50

**Moderator, RTI International**

And **[Participant 2]**, at the beginning, you said you'd taken [inaudible]. I don't want to put words in your mouth, but do you feel like it's improved your quality of life?

00:46:59

**Participant 2 (registered as a patient)**

Oh, **[REDACTED]** yeah, I mean, excuse the French. But there were two things that happened once I was diagnosed. I went to pulmonary rehab, and that made a huge difference in my life. But Trelegy allowed me to go to pulmonary rehab to make that huge difference, because I could breathe better and more consistently. And I didn't have all this stuff during the day. And those two things, man, they're miracles, that's all there is to it.

00:47:30

**Moderator, RTI International**

Thanks, **[Participant 2]**. **[Participant 1]**?

00:47:35

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Yeah, I really like Trelegy, even though I was expecting not to, because I like to make sure that I don't have more medicines than I need, and I always want to titrate my doses and stuff, so I wasn't sure I would like it.

And in the beginning, I was doing what **[Participant 2]** was talking about, where you inhale rapidly, and it would always make me cough, and I was like, why am I doing this to myself? But once I learned how to inhale more gradually, I don't cough anymore, and I noticed, even when I did cough, it still gave me good control over my lung conditions, and so I knew I was getting the medicine anyway, but I thought I shouldn't be coughing it out, and now that I know how to inhale gradually, which they should teach us, it's much better. And, it is so much less confusing not to have the three inhalers where you have to worry about when they're gonna, how long you have left on each of them, and which one you're supposed to take multiple times a day, which one you're only supposed to take once a day, and sometimes I'd mess up, honestly, and I take the wrong one twice and the other one once, and it's like, this is ridiculous. So, it's much less to deal with right now.

00:49:07

**Moderator, RTI International**

And is it easier to know how much you have left because of the counter on it?

00:49:09

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Oh, yeah, the counter is good. The other ones had counters, too, but it was just confusing, because there were so many. There were three of them all the time, and then when I would travel, I'd use a fresh one, and then I'd use the old one when I came back, and it was like, it was just very confusing. It's much less confusing.

00:49:30

**Moderator, RTI International**

Yeah, **[Participant 7]**?

00:49:33

**Participant 7 (registered as a patient and representative of a patient advocacy organization)**

I haven't had any bad side effects from Trelegy, which is awesome. Some of the older inhalers used to give me heart palpitations, and so they were really scary, and I didn't want to take them. But Trelegy, have had nothing. So, it's been amazing. And after COVID and all the lung damage from that, Trelegy kind of saved my ability to recover from a sickness and prevent pneumonia and bronchitis.

You know, when I first started taking it, after getting sick, within 24 hours, I would feel so different. I would be able to walk around the house and not cough or talk without coughing. So, I think it's just kind of like a miracle kind of medicine, all in one great.

00:50:19

**Moderator, RTI International**

And then, **[Participant 3]**, are you speaking from COPD or asthma perspective? Because I'm going to come back to COPD.

00:50:24

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

Oh, well, I'll wait then.

00:50:28

**Moderator, RTI International**

**[Participant 4]**, I know you said you have asthma. Have you tried Trelegy? I wanted to make sure you had an opportunity to speak if you wanted to say something about your experiences.

00:50:58

**Participant 4 (registered as a patient)**

Yes, I just recently started Trelegy, and I wish I had discovered it a long time ago, because I hadn't discovered it until I went to a pulmonologist and told them how much I was using the albuterol inhaler. So now that I've been on it, it's been a lifesaver for me.

00:51:21

**Moderator, RTI International**

Okay. Great. Thanks, [Participant 4].

00:51:23

**Participant 4 (registered as a patient)**

No problem.

00:51:24

**Moderator, RTI International**

So, from a COPD perspective. Some of the benefits that you've experienced with Trelegy specifically, and some of the drawbacks? And, [Participant 3], I know you wanted to add something, so I'll start with you.

00:51:36

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

I almost forgot my train of thought, but I'll try to recover it. I think a lot of what was said on the asthma section also applies to the COPD section. But, everyone's singing the praises of Trelegy, but if you don't have therapies that work, it's going to increase the cost burden on CMS. So, I guess right now, these comments are directed to the CMS people lurking and listening in the background, the flies on the wall. It's going to benefit and help. And you're going to see better outcomes, lower readmissions. So, if something works, let people have better access to it. I think that's so critical.

And if I think of what else I was gonna say, I'll raise my hand again.

00:52:35

**Moderator, RTI International**

That's okay, or you can also put in the chat as well. Okay.

So, I want to talk, also, there is Trelegy, which we've been talking about. But there are also other medications to treat COPD and asthma and those drugs I'm going to call therapeutic alternatives.

First, what are some of the therapeutic alternatives that you've all taken for asthma?

I've heard albuterol. I heard Breo. What are some others that you've taken? We'll just do a quick list.

Yeah, [Participant 7]?

00:53:08

**Participant 7 (registered as a patient and representative of a patient advocacy organization)**

Yeah, all the albuterols, prednisone is the big one. I've tried Advair. I did Breo before I did Trelegy. I have a nebulizer. Airsupra is a newer one. That's a combination inhaler. But nothing works like Trelegy. But steroids is the big thing.

00:53:30

**Moderator, RTI International**

Steroids. Yeah.

00:53:31

**Participant 7 (registered as a patient and representative of a patient advocacy organization)**

Yeah.

00:53:32

**Moderator, RTI International**

And then for COPD, what are some medications that you all used other than Trelegy for COPD?

00:53:42

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

There's Spiriva, Symbicort. I don't use it, but there's Dulera, Breo. I mean there are multiple, but those are dual and single therapies that when you take two and put them together, you do get triple therapy. But, as mentioned earlier, Breztri is the only other one on the market for COPD that contains all three. But it's important to recognize that, GOLD a few years back, changed their position, and felt that you should not be on an inhaled corticosteroid unless you really needed it. And that's one reason that the dual therapies, the LABA [long-acting beta2-adrenergic agonist]/ICS [inhaled corticosteroid] are still doing well, because I'm sorry, the LABA/LAMAs [long-acting muscarinic antagonist] are doing well, because you don't need the ICS, if that makes any sense.

00:54:45

**Moderator, RTI International**

Yeah. And [Participant 5], so quickly, this is medications you've tried.

00:54:50

**Participant 5 (registered as a patient)**

First, I was on Advair, and I ended up being hospitalized in ICU [intensive care unit] at least once a year when I was on Advair. Then I went to Breo and Incruse, which, of course, is Trelegy. Once I went to Breo and Incruse, then I ended up not being in the hospital for two to four years, and so, of course, Trelegy is the same medication as Breo and Incruse. Just one advantage is that's one copay instead of two copays.

00:55:28

**Moderator, RTI International**

Makes sense. Okay.

I want to now compare these drugs, these therapeutic alternatives, and how well they work or don't work, and compare them to Trelegy specifically. So how do the benefits of these therapeutic alternatives compare to Trelegy? How do the therapy alternatives work better for you than Trelegy has?

00:56:05

**Participant 7 (registered as a patient and representative of a patient advocacy organization)**

Prednisone can work if you're in a flare that you can't get out of. It's the best emergency thing to take. It comes with a lot of side effects. You don't sleep well, you gain weight, you have a crazy appetite, it can cause anxiety. It causes bone loss, like there's all kinds of things that come with it,

but it's the number one best thing if I have pneumonia or bronchitis, and my asthma can't get under control. Trelegy doesn't help in the emergency, but it helps prevent future emergencies.

00:56:40

**Moderator, RTI International**

That makes sense.

00:56:41

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

It's a sledgehammer.

00:56:43

**Moderator, RTI International**

And then these therapeutic alternatives, what are some drawbacks of them as compared to Trelegy Ellipta?

00:56:56

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

I think a drawback is, in my case, using two inhalers, one once a day and the other one twice a day. I guess everyone else is mentioning brand names, you know, I'm currently on Symbicort and Spiriva. They do well for me, but when I had the sample pack of Trelegy, it did equally as well. But again, just one puff once a day. It was just such a godsend that way, so the alternative to Trelegy would be more medication, more copays and having to take some drugs once, some drugs twice. And I'm sure most all patients with COPD also have some comorbidities. I have some heart and artery issues. So, I'm on medications for that, and then on medications for anxiety. It all builds up, and pretty soon, people walk into your room, and they think you've opened a pharmacy.

00:58:08

**Moderator, RTI International**

**[Participant 1]?**

00:58:10

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Yeah, actually, I have become best friends with my pharmacist. I have his cell number. I have his email. And I give his kids presents because I see him so dang often. I mean, I never expected to be needing to see a pharmacist as often as I do. And now with Trelegy, I only have the one inhaler instead of the three inhalers. I already have three nasals, four nasal sprays. I have all these other things. I don't really need to have my inhaler routine to be complicated. It's, as **[Participant 3]** says, so many of us have comorbidities. We have other things going on. Many of us are over 40, and you know I have allergies. I have reflux. Now I have this postural orthostatic tachycardia thing going on, and it's like, you know, if we can keep one or more things simple, it really does change our lives, and especially if it keeps us from having exacerbations and needing to talk about going to the hospital or not going to the hospital and hopefully keeping us off of steroids. I mean, since I started Trelegy, even though some really bad things happened like my oxygen machines broke and I was on a trip



and I had no working machines. I was still able to avoid getting really sick, because I think I had the Trelegy, and so it gives you more headroom if it makes sense, so that you have a buffer. And normally, before I got to be with as low lung function as I have when things would come up you just kind of have a little bumpy day or two, and you wouldn't get really sick. But since my lung function has gone down as I've gotten older, I'm much more prone to getting really sick when bumps occur. And so, I think that's what I've explained to my doctors, and they agree that it seems to just give you just a little more headroom, so that the little things that happen in life don't throw you off into an exacerbation, and I love that.

01:00:34

**Moderator, RTI International**

Thank you. And I also just want to compare what the alternatives, and this could be for asthma or COPD, we'll open it up broadly here. So Trelegy is what's called DPI, dry powder inhaler, which you probably know. And there's also pressurized metered-dose inhalers, pMDIs. Tell me about how a DPI works better for you or works maybe less well for you as compared to the pMDI technology.

Yeah, **[Participant 6]**?

01:01:17

**Participant 6 (registered as a patient)**

Yeah, I have a ProAir inhaler that I use as a rescue inhaler. And I believe that's not DPI. The Trelegy is DPI, and I know that with the ProAir, the method of inhalation, from what I've been told, should be a lot more closely monitored than it typically is, because if you go to the hospital for an exacerbation, or whatever, and they give you a rescue inhaler to use like my ProAir, they always give you a fitting along with it. As a matter of fact, this is it.

01:02:02

**Moderator, RTI International**

It's a spacer.

01:02:04

**Participant 6 (registered as a patient)**

That keeps the actual inhaler away from your mouth, and it kind of meters how quickly you're inhaling. Because evidently a lot of people when they use that type of inhaler, they inhale too quickly. And the majority of the medication gets stuck in your throat. Well, actually, what never makes it to their lungs, I'm not sure where it gets stuck, but with a DPI, you don't have to worry about that. If you just give it a good strong inhale, hold your breath, rinse your mouth out when you're done, and that's it. And, I get the sense that accommodation means a lot more than I've actually considered it to mean, and it makes sense, though. The easier it is for you to take your medication, the more likely you are to use it like you're supposed to.

So that's my thought.

01:03:03

**Moderator, RTI International**

Do you find the dry powder inhaler easy to use, **[Participant 6]**?

01:03:06

**Participant 6 (registered as a patient)**

I do. I do. You use it once, I use it. You get a routine with it. That's pretty much the first thing I do when I get up in the morning. I'll use it, rinse my mouth off, and then start the day from there. And like I said, there was one time I did forget to use it. I did notice a difference in my breathing by the end of the day, nothing drastic but noticeable. So, evidently it's working. Well, it's been a good number of years since I was prescribed anything else in place of Trelegy, so I really can't remember how they all worked for me.

Now I'm assuming my condition is, over the course of the years, COPD doesn't improve, it deteriorates slowly. It's a progressive disease. So, I'm sure that when I was actually using medications other than Trelegy, my need for the medication probably wasn't as strong as it is now.

So, the Trelegy works good for me, and the convenience is there, and no, I don't have any trouble at all using the DPI inhaler.

01:04:25

**Moderator, RTI International**

Okay, **[Participant 3]**, did you also want to speak from the COPD perspective?

01:04:31

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

Yes, please. I agree with everything **[Participant 6]** said, and the other comments. There's so many different steps to using an inhaler that patients simply aren't aware of. For example, just tilting your head back a little to provide more of a direct flow to the lungs, etc. Every study has shown that well over two-thirds of patients using inhalers are using them wrong, so they're not getting a good delivery to their lungs, and this is a little off topic, but I think the clinicians, the providers need to use what's called teach back therapy, and have the patient demonstrate to them how they're using their inhaler.

And, you know, **[Participant 6]** mentioned you just take one quick inhale. But others had mentioned that, with Trelegy especially, it's more of a slower inhale like that. We need better training on how to use our inhalers. And you had mentioned pMDI. I've never heard that, it's just usually a DPI, a dry powder inhaler, and an MDI is a metered-dose inhaler. And then you have things like Spiriva, which is a slow mist release. But anyway, we aren't using our inhalers the way we should. So, we're getting a lot less bang for our buck.

01:06:06

**Moderator, RTI International**

And **[Participant 7]**, from the asthma perspective?

01:06:09

**Participant 7 (registered as a patient and representative of a patient advocacy organization)**

Yeah, I think the only thing additional is there are added steps when using the pMDI, like remembering to shake it so that the medication is mixing so that you're actually getting what you're looking for, and the fact that you have to do it multiple times, and you have to go to press the button and take the right inhale is also extra things to remember versus I opened the thing, and I inhale in.

01:06:38

**Moderator, RTI International**

Right. **[Participant 5]**, one last thought, and then I want to move to the next question.

01:06:43

**Participant 5 (registered as a patient)**

Well, I would say that those of us who are older and may have arthritis, sometimes it's hard to press that button.

And the coordination that it takes to press the button and inhale, that's a little more difficult.

01:06:59

**Moderator, RTI International**

I was going to ask about that, **[Participant 5]**. So Trelegy, do you find it difficult to use the mechanism where you have to slide it back and hit the button?

01:07:08

**Participant 5 (registered as a patient)**

No, I don't have any problem with it at all.

01:07:10

**Moderator, RTI International**

Okay. Oh, so with the MDI is where it can be problematic. Got it? Okay, thank you for clarifying. Okay.

So, let's talk about focusing just on the conditions for a moment again, and not the medications. What would it be like for someone who has asthma if there were no medications or treatments available to treat it?

What would life be like? **[Participant 2]**?

01:07:45

**Participant 2 (registered as a patient)**

Put it simply, I would be dead.

That's the bottom line. I came so close with my very first time that that happened, and they all told me, you're lucky to be alive. So, that's the bottom line.

01:08:01

**Moderator, RTI International**

**[Participant 1]**?

01:08:04

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

I think we'd have to live in a bubble and try to avoid everything and wear a mask everywhere, and try to figure out what all your triggers are, and just try not to go anywhere near any of them, but that just

makes you be a hermit like during COVID, where we were hermits, and some of us didn't have exacerbations just because we didn't go anywhere. Didn't talk to anyone, didn't do anything. We just Zoomed if we had to meet with people, and that was it. But that's really not the life most of us want to live.

01:08:42

**Moderator, RTI International**

No. And, **[Participant 6]**, you're speaking from the COPD perspective.

01:08:47

**Participant 6 (registered as a patient)**

Yeah. From the COPD perspective, I think that aside from potentially being a life-saving medication in the long run, it's how it affects your quality of life and how it lets you maintain it as long as you can. Again, everybody knows that COPD is a progressive disease. I feel as though I've been fairly lucky up to this point at **[REDACTED]** years old. I'm not bedridden. I'm not nearly as active as I'd like to be because of it. I was a tradesman all my life a carpenter, so there's been a major lifestyle change here for me. But the quality of life is still important. You want to be able to at least enjoy yourself if you're not tempting the gods and trying to do too much. If you know your limitations and you're taking your medication, then it makes a big difference, a big difference. And who would not want to take the medication if it's available.

01:09:55

**Moderator, RTI International**

Others with COPD, what would life be like if there were no treatments available for you?

Yeah, **[Participant 5]**?

01:10:08

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

I would be completely bedridden. I probably wouldn't be alive. Well, if I have an anxiety attack and my oxygen plummets to, say 77 or 78, and I'm not able to get air, well, we all need oxygen, and without my medications, and without other therapies like exercise and all of that, I want to, just to quote **[Participant 2]**, I'd be dead.

01:10:37

**Moderator, RTI International**

And, **[Participant 5]**?

01:10:41

**Participant 5 (registered as a patient)**

Well, I think like **[Participant 3]** said, I would be bedridden. Because you couldn't do anything, because as soon as you started doing something you got short of breath, and then, when the shortness of breath continued, you became panicked. Yeah, so eventually you would just say, well, I can't do anything, and so you probably wouldn't even get out of bed.

01:11:07

**Moderator, RTI International**

And, **[Participant 1]**?

01:11:08

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

I think your world just shrinks more and more, because there's more and more things you can't do because you don't want to set off a trigger, or an exacerbation, or a flare up, and you just know that if you do you have a little square, and you can't go beyond it. Because if you do, then you're taxing your body and you have no reserve, and you're just going to go straight down the tubes. And, I guess, the next step would be you'd be in the hospital, and they'd try to figure out how to get you healthier. But, it's much better if you can stave it off by having some effective treatment. Before I started getting any treatments for my asthma and COPD, I was waking every night because I couldn't breathe, and that's why they decided in 2000 I should get a better evaluation and find out why that was and what we could do about it. And that was not pleasant, waking up every night, unable to breathe.

01:12:18

**Moderator, RTI International**

Understandable. Thanks, **[Participant 1]**.

So, there are treatments available, but it doesn't help with everything. So, I want to talk about for folks with asthma first, what aspects of asthma do today's medications, what are they not able to address is what I'm trying to say? What do medications today for asthma, not address or help you with?

Or maybe also, what you wish it would do better? **[Participant 2]**, go ahead.

01:12:57

**Participant 2 (registered as a patient)**

The only thing that I can think of that it's not addressing and not dealing with, as far as my asthma is, you still have triggers, and I don't think we can expect it to anticipate triggers. I don't think there's a way to do that at this point, anyway. Maybe some medical futurist is going to invent that. But you're still going to have asthma triggers, no matter what it does do is, it makes you much more responsive to dealing with them, but it does not prevent the triggers to begin with, so that would be the only thing I can think of.

01:13:34

**Moderator, RTI International**

**[Participant 7]**?

01:13:35

**Participant 7 (registered as a patient and representative of a patient advocacy organization)**

Yeah, I was going to say the same thing. And there are treatments coming out that are getting better. You know, the biologic stomach treatments are going to change how the immune system works to hopefully make it so your body doesn't react to the triggers as much.

But that is the number one thing, like you can remove cats and allergens and all those things. But, we can't always change how your body works to react to them.

01:14:01

**Moderator, RTI International**

And then for COPD, what are today's treatments for COPD unable to address for you?

Yeah, **[Participant 1]**?

01:14:15

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Yeah, we still need oxygen. They haven't figured out how to improve our saturation rates. So, to do all the things we need to do, in addition to taking inhalers or whatever to open our airways, if our lungs can't give our bodies enough oxygen, we need supplemental oxygen and the delivery systems for supplemental oxygen are just inadequate. They keep saying they're making them better, but they're not making them better and lighter fast enough, and it's a real burden.

01:14:52

**Moderator, RTI International**

Yeah. **[Participant 6]**?

01:14:56

**Participant 6 (registered as a patient)**

I think that the one thing that the medications that I take for COPD don't do for me is they don't cure it. There are no medications I'm aware of that are actually an eventual cure for COPD.

Now, if that was part of a curative process, I think whatever the financial burden would be, would be a lot more justifiable than if you're just taking a medication as expensive as Trelegy, strictly for maintenance.

[Y]ou'd like to know that at some point, there'd be a light at the end of the tunnel. But I'm not sure that science is there yet for an illness like COPD.

01:15:45

**Moderator, RTI International**

Yeah. **[Participant 5]**?

01:15:56

**Participant 5 (registered as a patient)**

Okay, it doesn't take away the why I'm having an exacerbation right now is because it's allergy season. So, it doesn't take care of the effect that allergies have on my COPD, which is a lot, and so twice a year I still go through an exacerbation.

01:16:21

**Moderator, RTI International**

Yeah. **[Participant 3]**?

01:16:25

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

I just think we need to look at, because the question was, what do the medicines not do? They don't do, because there are other treatments that supplement that. There are endobronchial lung valves. There's a heat ablation. There's now freezing part of the airway, so it's a frozen type of ablation. There are, aside from transplant, because that's a completely different story, there are other things that are somewhat invasive, but the medications can't handle that.

But if, for example, lung valves can increase your lung capacity by five years, then you get five years more given to you with a relatively non-invasive product, so pharmaceutical is part of the answer. Then biologics, I think **[Participant 7]** mentioned biologics, and right now I think Dupixent is the only one approved for COPD, but we have to remember biologics are only applied to those that have eosinophil counts of 300 or more, so it's a subset or a subgroup that qualify for it.

But, there are a lot of avenues to go down, but I think that the overall, the overarching theme for this panel is, why do we need Trelegy? And why do we want it to be available to all at an affordable level? And I hope and I pray that we've done a good job of answering that.

01:18:27

**Moderator, RTI International**

Thank you, **[Participant 3]**.

So, we only have a few minutes left, and I've asked you a lot of questions, and I want to pause for a moment to hear from you all. Is there anything else that wasn't covered today in our discussion that you feel is important to share with CMS?

And, **[Participant 2]**?

01:18:53

**Participant 2 (registered as a patient)**

You have heard this, but I'm going to present it in a little different way.

When I came along, 2019, I don't know when Trelegy was introduced, but I know it was fairly recent, right in that timeframe, and so it was fairly new, and I got two months free of that, and I was on it, and it was wonderful. And then they were out, and I could not afford it. Point blank. Couldn't afford it. So, I went without it.

And I wouldn't take the other one because it didn't cover asthma, and that was, you know, stupidity on my part that I didn't do something different. But I didn't, and the degree of my COPD disease



progressed much more quickly because I wasn't taking something that kind of helped me every single day, and it wasn't until my hospital, who happens to be a non... what's the right word? They don't make money.

01:19:57

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Nonprofit.

01:19:57

**Participant 2 (registered as a patient)**

Nonprofit. Thank you very much.

Stepped in with me, and because they knew that I couldn't afford it, and helped me out, and that's the only reason I get it today, and I really feel like I'd be lost without it.

01:20:14

**Moderator, RTI International**

Thanks, [Participant 2]. [Participant 1]?

01:20:17

**Participant 1 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Yeah, I think that we need to remember that people are doing whatever they have to do in order to try to keep their lung condition under control, and so, if they can't afford whatever their doctor wants them to take, they will take whatever they can afford, whether that's oral prednisone, which has all the bad side effects that [Participant 7] already talked about, or they'll take a hodgepodge of whatever they can afford, and many of them are buying it from overseas because it's so much cheaper. It's cheaper than even their copay would be, or they stretch out their medicines, and then they end up in the hospital, and so if it's affordable, and it's what their doctors want, they'll take it if they can get it. But if it's not affordable, it doesn't make sense for them to even think about it, because it's just not in their ballpark. They just can't spend \$900 on one medicine every month.

01:21:26

**Moderator, RTI International**

And, [Participant 3]?

01:21:28

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

I think, for the most part, you could just put my voiceover to what [Participant 1] just said, because she mentioned everything I was going to mention, but, like the overseas. We all, I know that [Participant 1] and I both know, and [Participant 5] probably knows, many people that order medication from overseas.

And many of those medications, like the inhalers, are made by Cipla, which is FDA, I don't know what the right term is, they're not really certified because they're in India.

But it's the same drug, it's just generic which we don't have here in the U.S.

01:22:13

**Moderator, RTI International**

Okay, thanks, **[Participant 3]**. Anyone else? Some final thoughts.

Yeah, **[Participant 4]**?

01:22:23

**Participant 4 (registered as a patient)**

The last thing I'd like to add to it is that, if they could, I'll put this in the information I send in, but if they could also figure out some way else to have the counter, so you know what's left, because I myself am visually impaired. I know people that are losing their sight, so if they could figure out a way to make something tactile or have a button on it that you could press to say, you have X number left, that would be helpful.

01:23:02

**Moderator, RTI International**

That makes sense. It's hard to see the counter window. Yeah.

01:23:04

**Participant 4 (registered as a patient)**

Yes.

01:23:06

**Moderator, RTI International**

Okay, all right.

Well, thank you all for participating in today's group. And we really appreciate your time and talking about your experiences. Your input was really valuable and will help inform CMS' negotiations with these drugs. As I mentioned, CMS staff have been listening in to the roundtable and will be able to bring your perspective back to their teams. **[CMS STAFF]**, I just want to see if you want to add anything else.

01:23:32

**CMS Staff**

Yes, thank you. I just want to say, on behalf of CMS and my colleagues on this call, I want to thank you for your time and for sharing with us your experiences. Your openness and candor is really greatly appreciated. You've given us a lot of valuable information to consider, and we're deeply grateful to each of you for sharing. Thanks.

01:23:52

**Moderator, RTI International**

Great. Thank you, **[CMS STAFF]**.

And if you have any questions following today's session, you can submit them to this email address. And **[Participant 1]**, I promised you, it would be up on the screen here. And here it is. The email

address to submit any questions that you have after today's session is [IRARebateAndNegotiation@cms.hhs.gov](mailto:IRARebateAndNegotiation@cms.hhs.gov). Again, [IRARebateAndNegotiation@cms.hhs.gov](mailto:IRARebateAndNegotiation@cms.hhs.gov) and put the subject line, public engagement events.

Okay.

01:24:28

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

Can you guys send us a link to the open house discussion that's being held? I'm not even sure when. But there's something being held for the public pertaining to this?

01:24:41

**Moderator, RTI International**

It's going to be held on Wednesday. And I think if you, I'm going to try this to see if this works. Yes, if you Google "HHS TV," you'll come to a place on HHS's website, for HHS livestreaming. So just Google "HHS TV" and you'll come up to their site and you'll see that they have an event listed already. And actually, I'm going to put this in the chat window now, so you have it. Make it chat work.

Oh, sorry, **[CMS STAFF]** already did. Thank you. There it is. Thanks, **[CMS STAFF]**.

If you click on that link, it starts at 10 AM Eastern on the 30th and you can view there, and you don't have to register. You just click on that link and go there the day of, and you can listen to public feedback.

01:25:42

**Participant 3 (registered as a patient and representative of a patient advocacy organization)**

Perfect. Thank you.

01:25:44

**Moderator, RTI International**

Great. Thank you, **[Participant 3]**.

All right, thank you, everyone. You have a good rest of your Friday and enjoy your weekend.

Bye, everyone.

01:25:54

**Participant 6 (registered as a patient)**

Thank you.

=== END OF TRANSCRIPT ===

For a list of the drugs selected for the second cycle of the Medicare Drug Price Negotiation Program, click on the following link: <https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2027.pdf>

For more information on the Medicare Drug Price Negotiation Program, please click on the following link: <https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program>

## Appendix

Participant 1: Registered as a patient who has experience with the selected drug; a patient who has experience with the condition(s) treated by the selected drug; a patient with experience with other treatment(s) similar to the selected drug for those condition(s); a caregiver for an individual who has experience with the selected drug, the condition(s) treated by the selected drug, or other treatment(s) similar to the selected drug for those condition(s); a representative of a patient advocacy organization

| Declared Conflicts of Interest |   |
|--------------------------------|---|
| No                             | Receipt of financial payments (e.g., Gifts', funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of \$10,000 by you, your spouse, or an immediate family member |
| No                             | Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your healthcare provider  |
| No                             | You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of \$10,000 in a company or related association with direct or indirect interest in the Negotiation Program                     |
| No                             | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest  |

Participant 2: Registered as a patient who has experience with the selected drug; a patient who has experience with the condition(s) treated by the selected drug

| Declared Conflicts of Interest |   |
|--------------------------------|---|
| No                             | Receipt of financial payments (e.g., Gifts', funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of \$10,000 by you, your spouse, or an immediate family member |
| No                             | Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your healthcare provider  |
| No                             | You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of \$10,000 in a company or related association with direct or indirect interest in the Negotiation Program                     |
| No                             | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest  |

Participant 3: Registered as a patient who has experience with the selected drug; a patient who has experience with the condition(s) treated by the selected drug; a patient with experience with other treatment(s) similar to the selected drug for those condition(s); a representative of a patient advocacy organization

| Declared Conflicts of Interest |  |
|--------------------------------|--|
| No                             | Receipt of financial payments (e.g., Gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of \$10,000 by you, your spouse, or an immediate family member |
| No                             | Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your healthcare provider   |
| No                             | You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of \$10,000 in a company or related association with direct or indirect interest in the Negotiation Program                    |
| No                             | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest                                       |

Participant 4: Registered as a patient who has experience with the selected drug

| Declared Conflicts of Interest |  |
|--------------------------------|--|
| No                             | Receipt of financial payments (e.g., Gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of \$10,000 by you, your spouse, or an immediate family member |
| Yes                            | Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your healthcare provider   |
| No                             | You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of \$10,000 in a company or related association with direct or indirect interest in the Negotiation Program                    |
| No                             | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest                                       |

Participant 5: Registered as a patient who has experience with the selected drug

| Declared Conflicts of Interest |  |
|--------------------------------|--|
| No                             | Receipt of financial payments (e.g., Gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of \$10,000 by you, your spouse, or an immediate family member |
| No                             | Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your healthcare provider   |
| No                             | You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of \$10,000 in a company or related association with direct or indirect interest in the Negotiation Program                    |
| No                             | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest                                       |

Participant 6: Registered as a patient who has experience with the selected drug

| Declared Conflicts of Interest |  |
|--------------------------------|--|
| No                             | Receipt of financial payments (e.g., Gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of \$10,000 by you, your spouse, or an immediate family member |
| Yes                            | Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your healthcare provider   |
| No                             | You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of \$10,000 in a company or related association with direct or indirect interest in the Negotiation Program                    |
| No                             | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest                                       |



Participant 7: Registered as a patient who has experience with the selected drug; a patient who has experience with the condition(s) treated by the selected drug; a patient with experience with other treatment(s) similar to the selected drug for those condition(s); a representative of a patient advocacy organization

| Declared Conflicts of Interest |  |
|--------------------------------|--|
| No                             | Receipt of financial payments (e.g., Gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of \$10,000 by you, your spouse, or an immediate family member |
| No                             | Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your healthcare provider   |
| No                             | You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of \$10,000 in a company or related association with direct or indirect interest in the Negotiation Program                    |
| No                             | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest                                       |