UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, *et al.*,

Defendants.

Civil Action
No. 1:24-cv-810-NYW-SBP

PLAINTIFFS' NOTICE OF FILING OF EXHIBITS TO MOTION FOR SUMMARY JUDGMENT

Plaintiffs file this notice attaching the transcripts referenced as exhibits in Amgen's Motion for Summary Judgment, Doc. 24 at 13 n.8, which were inadvertently not included with the summary judgment filing.

Dated: July 1, 2024

Respectfully submitted,

/s/ Ashley C. Parrish

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EXHIBIT A

CORRECTED TRANSCRIPT

Colorado Prescription Drug Affordability Review Board - February 16, 2024 Meeting

BOARD STAFF LILA CUMMINGS: Callie, it looks like are we still waiting on Chair Mizner?
BOARD STAFF CALLIE ANN SHELTON: Thought I saw her.
BOARD STAFF LILA CUMMINGS: Thanks, everybody, for joining us this afternoon and thanks for your patience while we make sure we got all our Board members present.
BOARD STAFF CALLIE ANN SHELTON: I see her.
CHAIR GAIL MIZNER: Hello, I'm here.
BOARD STAFF LILA CUMMINGS: Hi, Dr. Mizner.
CHAIR GAIL MIZNER: Sorry about that.
BOARD STAFF LILA CUMMINGS: Absolutely fine.
CHAIR GAIL MIZNER: Good. So it is 1:01 p.m., and I would like to call this meeting of the PDAB to order on February 16th. Callie, would you please call the roll.
CALLIE ANN SHELTON: Of course. Dr. Sami Diab.
BOARDMEMBER SAMI DIAB: Present. Hello, everyone.
CALLIE ANN SHELTON: Dr. Amy Guttierez.

BOARDMEMBER AMY GUTIERREZ: Good afternoon. I'm here.
CALLIE ANN SHELTON: Cathy Harshbarger.
BOARDMEMBER CATHERINE HARSHBARGER: Present. Welcome, everyone.
CALLIE ANN SHELTON: Dr. Gail Mizner.
CHAIR GAIL MIZNER: Present.
CALLIE ANN SHELTON: And Dr. Justin VanderBerg.
BOARDMEMBER JAMES JUSTIN VANDENBERG: Present.
CALLIE ANN SHELTON: Madam Chair, we have a quorum.
CHAIR GAIL MIZNER: Thank you, Callie. Do any Board members want to disclose any stakeholder meetings?
BOARDMEMBER SAMI DIAB: Yes, Madam Chair. Sami Diab here. We had a meeting with Colorado Oncology Society and our executive director was present as well.
CHAIR GAIL MIZNER: Thank you, Sami.
LILA CUMMINGS: And then in turn, is there anyone else who would like to do that. Members of the Division of Insurance, so Chief Deputy Commission Kate Harris, as well as myself,

met with representatives from Gilead.
CHAIR GAIL MIZNER: Thank you, Lila. Anyone else? Okay. Do I have a motion to approve the December 8th minutes?
BOARDMEMBER JAMES JUSTIN VANDENBERG: This is Justin VandenBerg. Motion to approve.
CHAIR GAIL MIZNER: Thank you. Do I have a second?
BOARDMEMBER CATHERINE HARSHBARGER: This is Cathy Harshbarger. I second.
CHAIR GAIL MIZNER: Thank you, Cathy. So Dr. VandenBerg moved and Ms. Harshbarger seconded. All those in favor of approving the December 8th minutes, raise your hand and say aye. Aye.
BOARDMEMBER CATHERINE HARSHBARGER: Aye.
BOARDMEMBER SAMI DIAB: Aye.
BOARDMEMBER JAMES JUSTIN VANDENBERG: Aye.
BOARDMEMBER AMY GUTIERREZ: Commissioner, I just wanted to -- I know there was the meeting that I didn't attend in December. I just wanted to make sure I know my name is listed. I was just trying to look at my travel

records to make sure that wasn't the day, but if I could just get that clarification.
CHAIR GAIL MIZNER: Lila or Callie, are you able to clarify with whether Dr. Guttierez was at the December 8th.
BOARDMEMBER AMY GUTIERREZ: I believe I was there, but I just wanted to make sure that the record is clear.
CALLIE ANN SHELTON: Let me just double check.
BOARDMEMBER CATHERINE HARSHBARGER: Yeah, I think you came from -- didn't you participate from the airport on one of those days?
BOARDMEMBER AMY GUTIERREZ: Yeah, perhaps. Then I approve.
ATTORNEY ABBY CHESTNUT: Dr. Guttierez, I think you were present for the December 8th meeting, and I think you were not present on December 15th, so we'll have you abstain from the next vote.
BOARDMEMBER AMY GUTIERREZ: Thank you. I approve then, Chair Mizner.
CHAIR GAIL MIZNER: Thank you. Thank you, Abby, too for the clarification. So the

motion passes unanimously and the December 8th minutes are approved.

Do I have a motion to approve the December 15th minutes?

BOARDMEMBER SAMI DIAB: I will approve. Diab.

CHAIR GAIL MIZNER: Thank you. Do I have a second?

BOARDMEMBER JAMES JUSTIN VANDENBERG: Justin VandenBerg, I second.

CHAIR GAIL MIZNER: Thank you. Dr. Diab moved and Dr. VandenBerg seconded. All those in favor of approving the December 15th minutes, raise your hand and say aye with the exception of Amy who will abstain since she was not present. Aye.

BOARDMEMBER CATHERINE HARSHBARGER: Aye.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Aye.

BOARDMEMBER SAMI DIAB: Aye.

CHAIR GAIL MIZNER: Thank you. The motion passes. Commissioner Conway is here to provide opening remarks for todays meeting. Welcome, Commissioner.

COMMISSIONER MICHAEL CONWAY: Thank you, Madam Chair, and it's really not opening remarks; it's more a thank you. So it's been a while since I've come by to thank you all for all of your hard work. And obviously, in recent really kind of months, people have been paying a ton of attention to all of the work that you are doing that are very knowledgeable about PDABs just generally speaking throughout the country. And whenever they reach out to have a conversation, it's always the case that they are incredibly impressed about all of the great work that is being done and how far along the path that you all are.

And it's really a testament to all of the work that you're doing and all of the work that the team at the Division is doing, really the team just across the Board at the Division, the A.G.'s office, everybody. So it's a thank you to everybody, but most importantly, the Board members, and it really has been I think one of the amendments that went on to the legislation back a couple of years ago is to make sure that we appointed and the governor appointed experts on to the Board, and it's a testament to that

amendment that you all are here and that you're doing all the great work that you're doing.

We're incredibly thankful about the work that you're doing. The reason why I think we are moving as expeditiously and as, I think, concretely as you are is because you all are experts in the field and it's impressive every time that I get an update on the work that you're doing from the team, really how far you've gotten.

So really again, it's mostly just a thank you. I'm unfortunately not going to be able to hang out with you all day. I've got to hop off right after that. But like I said, it's been a while since I came and told you directly how thankful I am for all the work that you're doing. I know we don't pay you incredibly well and I know my thanks doesn't go too far, but it's good for me to come in and thank you personally every once in a while.

So again, thank you very much, folks.

BOARDMEMBER CATHERINE HARSHBARGER: Thank you, Commissioner, for allowing us to do the work.

COMMISSIONER MICHAEL CONWAY:

Absolutely.

CHAIR GAIL MIZNER: And thank you, Commissioner, for your support of our work.

BOARDMEMBER CATHERINE HARSHBARGER: And a special thank you to the executive team that we have. You really have some dynamic people working to help support us in our work, and I really can't thank you enough for the level of credibility they lend to this project.

COMMISSIONER MICHAEL CONWAY: Honestly, Cathy, thank you very much for saying that. They don't get to hear that. I tell them that all the time, I know you guys do too, but it's great for them to hear it publicly as well because they're awesome, they're rock stars.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, they are.

COMMISSIONER MICHAEL CONWAY: All right, folks, I'll let you get back to your meeting. But again, thank you. Have a good meeting. I will stop by again soon enough I'm sure.

CHAIR GAIL MIZNER: Thank you very much, Commissioner. We really appreciate your support.

COMMISSIONER MICHAEL CONWAY: Thank you, Madam Chair.
BOARDMEMBER CATHERINE HARSHBARGER: Chair Mizner?
CHAIR GAIL MIZNER: Yes.
BOARDMEMBER CATHERINE HARSHBARGER: I was wondering if we could, at some point, I would like to have an executive session to talk about -- talk with legal, get legal advice on recent correspondence.
CHAIR GAIL MIZNER: Okay. Lila, would you like us to do that now or would you prefer to give your director update first.
LILA CUMMINGS: I'd be happy to run through the director update first, so we can get that out of the way, and then maybe right after that if that sounds okay.
BOARDMEMBER CATHERINE HARSHBARGER: It's fine with me.
CHAIR GAIL MIZNER: Sounds great. Thank you.
LILA CUMMINGS: All right, well, thank you. So I just have two quick updates: 2024 legislative session and affordability review policy changes.

So just want to make you all situationally aware of some of the goings ons of the state legislature and the general assembly, so there's just two introduced bills that I would like to call to your attention: the first is Senate Bill 24-060, and that's a prescription drug affordability Board exempt orphan drugs. It details kind of exactly what the title says and does directly impact your statute. And then another one that is going through is Senate -- or that has been introduced is Senate Bill 24-077, and this is prescription drug manufacturer requirements, so it would require a level of registration for prescription drug manufacturers with the state.
If you have any kind of specific questions on these, be happy to connect you offline with our leg team, but these are two that have been introduced. There may be more this session. We got a couple of more months, so we'll just continue to kind of keep you situationally aware.
And then I will say that as of right now, I believe it's just Senate Bill 60 that has been calendared, so it's going to have its first

committee hearing next Thursday is what it's currently scheduled for.
BOARDMEMBER CATHERINE HARSHBARGER: Lila, who's carrying that bill, please, do you know?
LILA CUMMINGS: I do not know the sponsors offhand; our legislative team does. I should know the sponsors. I could look that up for you.
BOARDMEMBER CATHERINE HARSHBARGER: No problem. I just was curious. I can look it up too, so thank you.
LILA CUMMINGS: Okay, thank you. All right, and we can go to the next one.
Okay, so affordability review policy changes. At your last meeting, actually at the last few meetings, we have talked about potential changes and redlines to both the affordability review rule, as well as policy documents. And these potential changes have really been focused on feedback we've gotten from you all, as well as stakeholders, around the Board's ability to -- or potential ability to consider a prescription drugs orphan drug designation earlier in the process and specifically an ask of could you all

consider it during the selection stage.
Additionally, we've gotten some great feedback, constructive feedback from stakeholders on how we could engage patients and caregivers differently, as well as alternative ways to engage individual with scientific and medical training, so we've begun a redline. I think due to timing we didn't think today was the right meeting to bring that before you all to start looking at and discussing. I think the plan would be for us to do that at your next meeting. And then also note too that it wouldn't impact these affordability reviews; it would be for your next round of affordability reviews.
A question I have and would just like to get a temperature check from Board members is, would you all like to see redlines first and then we reach out to some of the stakeholders to kind of get their thoughts, or would you all like us to kind of present initial drafts of these redlines directly to stakeholders, start to gather their response, and then come to you with redlines. I was kind of curious which direction you'd like us to go.
BOARDMEMBER JAMES JUSTIN VANDENBERG:

Lila, who are the stakeholders that we're thinking of -- I guess it's to ask for their feedback before then it comes to us versus coming to us, possibly tweaking them before going out.

LILA CUMMINGS: Good question. I think so, for orphan drug designation, there are some specific groups, so I'm thinking of the Rare Disease Advisory Council over at CPHE, the National Organization of Rare Diseases. On the alternate ways to engage with patients and caregivers, I think we've just gotten some good feedback from specific conditions, specific consumer groups, so we'd reach out to them.

And then on scientific and medical training, I think we've kind of heard from you all that having a non-clinician in the middle of the conversation between clinicians maybe isn't the most efficient way, so that would probably -- I think will kind of engage in that.

I think with this, if you all -- and we would plan on this at some point. We'd also have just an open to any stakeholder to engage, so probably just a stakeholder meeting, but those are the groups that I think we're thinking about.

BOARDMEMBER AMY GUTIERREZ: Lila, what

would be the staff's recommendation in terms of what you believe would be most effective?

LILA CUMMINGS: I think it might be most efficient if we just go directly to stakeholders first with some of the redlines, and we can bring them to you all kind of after we've vetted them a little bit with stakeholders and kind of identified areas where we agree. And we can also, if we disagree with stakeholders, we can at least explain why we disagree.

So, yeah, I'd say allowing us to kind of go forth and share redlines earlier with stakeholders might be the most efficient.

BOARDMEMBER AMY GUTIERREZ: I don't know about the other Board members, but I'd recommend that we do have you work with the stakeholders first before we saw the redline. I don't know, fellow Board members, what do you think?

BOARDMEMBER JAMES JUSTIN VANDENBERG: I agree with you, Amy, yeah, to get that feedback and not have more of a back and forth, if it's coming to us, then going back out, and now the changes, and then to come back to us. I think you're on the right track.

CHAIR GAIL MIZNER: That sounds fine to me too. I apologize to everyone. I can't make my camera work. I'm working on it.

LILA CUMMINGS: Miss Harshbarger, Dr. Diab, any objections to kind of going out to stakeholders first?

BOARDMEMBER SAMI DIAB: No, I agree with that.

LILA CUMMINGS: Okay. Okay, then we will plan on doing that. And for the stakeholders that are listening in, we'll take a look at kind of calendars over the coming weeks and months and get some things on the website and on the LISTSERV for how we can engage.

And that concludes my updates.

I'll just make one last comment before we move on. Clearly, I think you can hear my voice is a little sore, not quite at 100 percent, so I may be going off camera and on mute more frequently this meeting. Please know I'm still listening, I might just be getting a hot cup of water, so thanks.

CHAIR GAIL MIZNER: Okay. Thank you, Lila. So it sounds like at this point, we should vote about whether we want to go into executive

session. Do I have a motion to meet in executive session to discuss legal questions that Ms. Harshbarger has.

ATTORNEY ABBY CHESTNUT: And actually, Dr. Mizner, if I can just interject.

CHAIR GAIL MIZNER: Yeah.

ATTORNEY ABBY CHESTNUT: So without waiving any privilege, Ms. Harshbarger, if you could just maybe specify with a little bit more detail what you want the topic on legal advice to be. We need to be a little bit more specific in the motion to go into executive session. And we also -- actually, let's just start there, Cathy, if you don't mind. Which correspondence were you wanting to get legal advice on?

I'm sorry, you're on mute.

BOARDMEMBER CATHERINE HARSHBARGER: Can you hear me now?

ATTORNEY ABBY CHESTNUT: Yes.

BOARDMEMBER CATHERINE HARSHBARGER: Okay. I just don't know where my camera went, but anyway...

I wanted to talk about the -- and that's what I had switched to, in specific, the letter received from Community Access National

Network.
ATTORNEY ABBY CHESTNUT: Okay. So I believe since that public comment letter was received for one of these affordability reviews, we're happy to provide legal advice on that, and I can help kind of formulate the motion. But since Dr. Diab has a conflict with that drug, I believe it's Genvoya, but please correct me if I'm mistaken. So since Dr. Diab has a conflict with that drug, we'll just ask that the remaining four Board members vote. Dr. Diab, you're welcome to vote us into executive session, but we won't have you join us.
So then I'll kind of phrase the motion, but Cathy, please correct me if this is not correct. So are you asking that the Board move into executive session to receive legal advice from its attorneys regarding the public comment letter received relating to Genvoya, pursuant to Section 24-6-402(3)(a)(II)?
BOARDMEMBER CATHERINE HARSHBARGER: Yes, I am. Thank you.
ATTORNEY ABBY CHESTNUT: Okay.
BOARDMEMBER AMY GUTIERREZ: I'll second Cathy's motion.

CHAIR GAIL MIZNER: So moved.
ATTORNEY ABBY CHESTNUT: Okay.
BOARDMEMBER AMY GUTIERREZ: And I'll second, Amy Gutierrez.
CHAIR GAIL MIZNER: Thank you. So sorry, who -- Ms. Harshbarger moved and Dr. Guttierez seconded to convene in executive session. We need to vote on that, so all in favor, please raise your hand and say aye.
BOARDMEMBER AMY GUTIERREZ: Aye.
BOARDMEMBER CATHERINE HARSHBARGER: Aye.
BOARDMEMBER JAMES JUSTIN VANDENBERG: Aye.
BOARDMEMBER CATHERINE HARSHBARGER: Aye.
CHAIR GAIL MIZNER: Thank you. The motion passes and the Board will now convene in executive session. The public is now excused.
LILA CUMMINGS: And just note for members of the public, the slide will be up and we will be back when this is done.
(00:19:09 Executive Session begins)
(00:33:36 Executive Session ends)
CHAIR GAIL MIZNER: Thank you everyone,

we're back. The Board has adjourned its executive session. The Board received legal advice regarding responding to public comment on Genvoya. The Board conducted no formal business within the meeting.
Next on the agenda is a discussion of Enbrel. Before we begin discussion of the affordability review data, Board members will need to disclose conflicts of interest related to the prescription drugs on today's agenda, Enbrel and Genvoya. Callie will do a roll call.
CALLIE ANN SHELTON: Dr. Sami Diab.
BOARDMEMBER SAMI DIAB: Yeah, I have conflict with both drugs.
CALLIE ANN SHELTON: Thank you, Sami. Dr. Amy Gutierrez.
BOARDMEMBER AMY GUTIERREZ: No conflicts.
CALLIE ANN SHELTON: Cathy Harshbarger.
BOARDMEMBER CATHERINE HARSHBARGER: No conflict.
CALLIE ANN SHELTON: Dr. Gail Mizner.
CHAIR GAIL MIZNER: No conflict.
CALLIE ANN SHELTON: And Dr. Justin VandenBerg.

BOARDMEMBER JAMES JUSTIN VANDENBERG: No conflict.
CHAIR GAIL MIZNER: Thank you. So we do have a quorum of four people to proceed. Before we begin deliberation, I'd like to note that all Board members were present at the December 8th meeting when staff presented draft evidence for the Enbrel affordability review. I'd like to also note that the Board members were provided with the entire unredacted draft report on February 9th. I'm sure everyone has read that, as have I.
To ensure that all Board members have had an opportunity to review the information in the draft report, I'd like to ask if any Board member feels we do not have sufficient information to deliberate regarding unaffordability for Enbrel today. Is there anybody who feels that we need further information before deliberating?
BOARDMEMBER CATHERINE HARSHBARGER: Nope.
CHAIR GAIL MIZNER: Okay. If there are no concerns, are there any objections to moving forward with deliberation?

BOARDMEMBER CATHERINE HARSHBARGER: No from Cathy.
CHAIR GAIL MIZNER: Okay, good. Lila, let's move forward with deliberation.
LILA CUMMINGS: All right. Thank you, Chair Mizner. We can go to the next slide.
So I will note that we have received several suggestions for redlines. Board members, that was those redlines were shared in your confidential protected folder, so you have the unredacted confidential version.
I also have on my desktop a redacted public version and was planning to open those documents up and we will go to them to walk through the changes as we go throughout the report but do let me know if you kind of would like the cadence to go any differently.
So we'll just start with therapeutic and utilization profile overview. I will say that, you know, the next I believe 40 slides are really just copy and paste or screenshots from the report itself, so we will defer to you on how much time you would like to spend discussing each slide. To save my voice, I'm not going to read each slide, but we'll leave it up on the screen

for a bit, and then you all can kind of discuss as you see fit.
I will note that when it comes to potential redlines to the report, the redlines that I'll share on my screen and that you all have in your folder, the redlines that we made were really around pulling up data sources. So we received some recommendations from Board members individually to kind of highlight things in appendices or to pull more data from source materials that were already footnoted and cited, so that's what today's redlines really focus on.
Before next Friday, if you all are in a space where you are ready to adopt the final report, I will note that there are a number of typos and grammatical errors that we do plan on fixing that we've not redlined for you today. But then also would encourage, if there are style or tone changes that you all would like to see in the final report, we will continue accepting edits there.
So these are for the therapeutic and utilization profile view includes information about Enbrel's clinical efficacy and the people who use it. Information is provided regarding

its indication, utilizer profile, health equity impact, and therapeutic alternatives, and these are the appendices with that information is pulled from. We can go to the next slide.
So Enbrel has six indications, six FDA approved indications: rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, psoriatic arthritis, juvenile idiopathic arthritis. And then October of 2023, an additional indication was FDA approved, and that's polyarticular juvenile idiopathic arthritis.
And actually, I'm going to pause here. This is actually -- apologies -- this is inaccurate. Juvenile idiopathic arthritis, and it's accurate in your report, juvenile idiopathic arthritis is not one of the indications; it's juvenile psoriatic arthritis. And so, we can get into that in future slides, but in your report, it is accurate. Apologies for this. Okay, next slide.
Orphan drug status. So Enbrel is classified by the World Health Organization Anatomical (ATC) as a tumor necrosis factor alpha (TNF) inhibitor. And the FDA granted orphan drug

designation in 1998 for polyarticular-course juvenile rheumatoid arthritis, which is now referred to as polyarticular juvenile idiopathic arthritis.
BOARDMEMBER AMY GUTIERREZ: So, Lili, just a comment. The orphan drug designation is only for one indication.
LILA CUMMINGS: Correct.
BOARDMEMBER AMY GUTIERREZ: Not for all of them.
LILA CUMMINGS: Correct. Next slide.
And then here is information on utilization of Enbrel according to the All Payer Claims Database from 2018 to 2022. And I will note Appendix D, we've talked about kind of considerations and limitations with APC data before and further details are outlined in Appendix B.
Next slide.
So we do have some utilization and All Payer Claims Database about payer type, so you'll see here information on utilization across commercial markets, Medicaid and Medicare Advantage, as reported in the APCD.
BOARDMEMBER CATHERINE HARSHBARGER: I

think the one thing that really does indicate too is that the out-of-pocket costs and copays are probably going to be, as we're going to see later, are going to show that that impacts people more than it usually does because it's more of the private commercial insurances are paying the majority of the claims, I guess is the way I want to say it.

CHAIR GAIL MIZNER: You mean with more associated copays and deductibles and like that.

BOARDMEMBER CATHERINE HARSHBARGER: Right, yeah.

LILA CUMMINGS: Okay. Any other comments on this slide? Okay, next slide.

And then here it's visualized a different way, the same information but a slightly different format. Okay, next slide.

So there was some research done and it's kind of much more comprehensive in the appendix, in the associated appendix, but we did summarize a bit of a health equity literature review in the body of the summary report, but I know Board members have looked at the full appendix as well.

I will note something that is noted in

the report, which is it is difficult to find drug-specific health equity data most times. And so, a lot of what this research focuses on and summarizes is the specific conditions and indications that Enbrel treats and is not necessarily specific to Enbrel itself.

BOARDMEMBER CATHERINE HARSHBARGER: I think that one thing that was interesting is finding out that the Hispanic and Black patients were usually undertreated and underdiagnosed as a beginning factor of that. I thought that was of interest and I thought that there's a map that shows that really, there's quite a bit of disparity within the different counties in the state as far as being able to access this medication.

CHAIR GAIL MIZNER: There are a paucity of rheumatologists in many rural areas.

BOARDMEMBER CATHERINE HARSHBARGER: Yes.

BOARDMEMBER AMY GUTIERREZ: We did, however, have the SVI score numbers and in 2022, almost 50 percent of the patients lived in a county with a higher SVI score than the statewide average.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah.

LILA CUMMINGS: Go to the next slide.

BOARDMEMBER CATHERINE HARSHBARGER: Really speaks volumes.

CHAIR GAIL MIZNER: Yeah. That would seem to indicate that there may be people in those purple counties, if I'm interpreting this correctly, that are either not diagnosed or diagnosed and unable to access certain medications.

LILA CUMMINGS: And also I apologize for not saying this earlier. We are joined today by a number of in-house and contract colleagues who are on hand to answer any questions you might have. I think they'll be kind of more in the coming slides, but we have Kate Davidson, our manager of insurance data science, as well as folks from the program on regulations, therapeutics, and law portal, specifically Dr. Ben Rome and Dr. Aaron Kesselheim are here today to answer any questions you might have. So welcome and apologies for not introducing you all earlier.

BOARDMEMBER CATHERINE HARSHBARGER: I

think these purple areas also -- I just read some of my notes. It said that the low-income people are also not as likely to have access to this drug as well.

LILA CUMMINGS: I don't know if we necessarily had information specific to Enbrel on access. I believe the research just pointed out that access generally to medications (sound glitch) across race and ethnicity.

BOARDMEMBER CATHERINE HARSHBARGER: Thank you.

LILA CUMMINGS: All right, so we'll get into therapeutic alternatives. So I will say you all made a decision with previous drugs to -- I guess I should just say this is the first time that kind of a deeper dive into therapeutic alternatives is before you all.

So here are the in-class therapeutic alternatives -- brand name therapeutic alternatives. You'll see them up there on the screen. I will not read through them.

I will note in the affordability review summary report, we did include additional information regarding Humira and Remicade having biosimilars. I'll let you all kind of have this

discussion a bit, then I'm going to show you my screen and pull up the redlined information that was added. But we just wanted to acknowledge that there is -- you know, that Humira and Remicade do have biosimilar products that have been introduced within the past five years.

But then I'll also note that the utilization of those biosimilars, because of the lag in claims data, was very, very small, so there was not an analysis done from the APCD data of biosimilars.

BOARDMEMBER AMY GUTIERREZ: I'd like to echo that. One of the things I noted, Humira was not available in biosimilar form when this analysis was done, but it was done for our neighbors fund release. And payers do have different -- from my experience, payers have different types of access depending on the drug.

The other thing that strikes me as I look at this is, most of these are probably pharmacy benefit drugs with the exception of Infliximab Remicade, which is an infusion. So as we start looking at copays and what the -- they're under a different benefit structure than the pharmacy benefit, the regional pharmacy

benefit. So I think we need to keep that in mind as we go down the road in looking at costs.

CHAIR GAIL MIZNER: So, Amy, you feel that Infliximab Remicade is sort of less comparable because it requires in-house infusion.

BOARDMEMBER AMY GUTIERREZ: It's usually typical -- and Justin chime in -- but usually medical benefits and pharmacy benefits have different copay structures, so it's kind of different. It's really hard to compare them as one-to-one when we start looking at copay and co-insurance.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Most of the thinking along -- absolutely right, Amy, but also thinking too of the access of even a location of an infusion center to where one could even be administered, especially in more of your rural areas; whereas, as a self-injection, subcutaneous has its own other access benefit. So just keeping that in mind too as we move down. But, yeah, as far as the pay structure, it's going to be very different.

LILA CUMMINGS: Okay. I think we can move on to the next slide. And then here is information on the utilization of both Enbrel and

its therapeutic targets over five years. So we'll just leave this up for a second.

BOARDMEMBER CATHERINE HARSHBARGER: I think noticing that Humira is by far twice the amount of people are utilizing that versus Enbrel. I don't know this, but probably as pharmacists you do, but is Humira maybe the first line or is there anything that's basically considered first line?

CHAIR GAIL MIZNER: There really isn't, Cathy, no. I mean, there's a huge armamentarium of rheumatoid arthritis and autoimmune drugs and there is no -- nothing that particularly says that you should use one over another.

BOARDMEMBER AMY GUTIERREZ: However, when we look at some of the patient comments and feedback we got in the report, there were some comments where we had to go back to step therapy. So my guess is given the fact that Humira is now biosimilar, at least in today's market, that that may be a workhorse for a lot of payers just because of the price comparison, and they may be using it as first line versus escalation.

I think Gail's right. There's a lot of inter-variability, but if you're newly diagnosed,

you got to stop somewhere, so I think they're probably utilizing the biosimilars more.

CHAIR GAIL MIZNER: I'm sure it depends in part on which drugs will be approved by their insurance. You know, there's a simple difference between Enbrel and Humira, which is that Humira is injected every two weeks normally and Enbrel injected every week normally, so few times having to inject yourself, you know. But there isn't a sort of this is what you start first, this is what -- unless you're looking at methotrexate, which has been traditionally what is often started first, but that's not actually necessarily current practice for I think many rheumatologists.

BOARDMEMBER CATHERINE HARSHBARGER: And I'm not sure totally on the cost, but I think in the graphs that we saw in our report, Humira cost-wise isn't cheaper, I guess is the way I'd put it; it's very expensive as well.

BOARDMEMBER AMY GUTIERREZ: Back in 2022, Cathy, yes. But after the -- it's kind of like whenever something goes biosimilar, it's kind of like a generic competition; you have multiple vendors that come up or pharmaceutical

manufacturers that come into the playing field. So just that competition lowers the price. That's kind of -- this is an unusual situation with this drug, given that the biosimilars didn't become available until 2023.

CHAIR GAIL MIZNER: And as you may recall, we actually decided not to do an affordability review on Humira because of those biosimilars that had become available.

BOARDMEMBER CATHERINE HARSHBARGER: Right, right, okay.

CHAIR GAIL MIZNER: It came out in the very expensive range as well, but that was the reason we did not decide -- we decided not to do an affordability review of it.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, that's for that review.

LILA CUMMINGS: And they're just echoing something that I believe Dr. Guttierez said. We, in talking with patients and caregivers and looking at the survey results, formulary placement seemed to -- that was something we heard from patients that impacted them across Enbrel and therapeutic alternatives was the different formulary placements.

BOARDMEMBER AMY GUTIERREZ: I think I read them saying that I was stabilized on Enbrel, but because the insurance wanted me to go try another agent again, I had to go do that before I could get access to it. I think I recall reading that.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, that happens unfortunately. You know, it's hard for patients and providers because they want to go with the drug they believe is going to be the best one, but that cost factor comes into play.

LILA CUMMINGS: We can keep moving along. So that kind of summarizes the therapeutic and utilization profile. There's more information in the report. And actually, I'm thinking that maybe one of the structures could be we'd go through all the slides for each drug, I will share my screen because I just want to make sure everybody specifically sees the redlines that we've proposed so far. So we'll get through all the slides and then I'll verbally mention them as we go. And we'll come, I'll share my screen and show you the redlines that we've made based on your input because you all

also have some good information for us.

So price and cost profile overview is next. This profile includes information on why different entities along the prescription drug supply chain or what do they charge for Enbrel, as well as what different entities pay. Information is also provided regarding Enbrel's financial effects on health, medical, and social services costs. You'll see there's a number of appendices that this relies on.

I will just call out in particular Appendix D, relative financial effects. Because Enbrel has, you know, six indications and five in particular that have had, you know, prior FDA approval prior to this past October, there is a lot of detailed information from across a number of national/international organizations, as well as from the manufacturer themselves regarding the relative financial effects of Enbrel. They are not summarized in a table in the summary report. Instead, we've encouraged Board members to go read Appendix D in full because there's a lot of great information there. So just noting that, that that's the kind of one time we said please go read this appendix. That's sounded a little

weird. I know you all read the appendices, but that one in particular has the information.

So next slide.

All right, so here is some summary statistics regarding both price and cost per person statistics, as well as statewide price and cost statistics as of January 1st, 2024. And then I'll just note since Enbrel's introduction, the WAC has increased over 1500 percent. So we'll leave this up for a bit, see if there's any questions, see if there's any clarifications that are needed.

BOARDMEMBER CATHERINE HARSHBARGER: I think the total -- yeah, I think the total out-of-pocket costs we showed was annually about 3,980, right, when you combined that with the copays.

LILA CUMMINGS: Yes. We do have, like, a deeper dive into out-of-pocket costs in a couple of slides. And you're correct, so there are times where -- and this is noted in the report -- there are times where Medicaid patients out-of-pocket costs are included in a statistic and there are times when it is not.

And we note that this is because

Medicaid patients typically pay zero to $3.00, so it could potentially, if you're trying to focus in on what the average commercially insured patient is paying, if you include Medicaid data, it's going to skew the results. And so, this average patient paid per person per year out of pocket of $2,295; that is including Medicaid patients. But then later in the report, we do specifically call out the average out-of-pocket for just commercially insured patients and that is that number you were mentioning, Cathy.

And then, Kate Davidson, correct me if I'm wrong on any of this.

KATE DAVIDSON: I do have a slight correction. This is still not including Medicaid for any average, we're not including Medicaid. This is including the Medicare Advantage folks, and so that's why this is different than that $3900 number that you referenced, Cathy, which is only commercially insured folks.

BOARDMEMBER CATHERINE HARSHBARGER: Okay. Still a significant number. When I looked at this, it said in the surveys that you did -- I believe it's the surveys, somebody can correct me -- that zero to $50 was paid by 57 percent of the

histogram, which is very, very skewed to a lower dollar amount, but swings all the way out to some small number of individuals who paid that much.

BOARDMEMBER AMY GUTIERREZ: The APCD database, if they were getting manufacturer patient assistance, would it show up still as a patient paid amount?

KATE DAVIDSON: It depends on how the assistance comes across, but it's very possible those individuals at the very high tail of that were receiving some sort of assistance and that's just not something that we're able to see in that database.

BOARDMEMBER AMY GUTIERREZ: So the survey information that Cathy referenced might be a better indicator of what's really happening with patients.

BOARDMEMBER CATHERINE HARSHBARGER: And I guess I see too that if 57 percent have a zero to $50, that's nice, but then there's still a huge amount of people that are paying more, you know, there's still a significant number there.

BOARDMEMBER AMY GUTIERREZ: Agreed.

CHAIR GAIL MIZNER: As I recall in the patient surveys, a significant number of patients

respondents, .3, and then the rest of it they paid between $9,8- -- some were as high as $9,850 to almost $10,000, 990, so those are significant variabilities in the cost to the patient that I just wanted to bring up. Because total patient paid out, it was, like, $9.8 million, significant number. Oh, it's right there on that page, total patient paid. I find that significant.

BOARDMEMBER JAMES JUSTIN VANDENBERG: What was the number of outliers again that had this severe -- or, like, the very, very high out-of-pocket costs, Cathy, like what you had mentioned?

BOARDMEMBER CATHERINE HARSHBARGER: Well, there was 57.3 percent that were zero to 50, and then those that paid the 9850 -- Lila, can you help me with that -- or is it the difference?

KATE DAVIDSON: So this is from the APCD claims and kind of just bucketing how many people paid within a $50 bucket. So it was 57 percent of people paid between zero and $50, and then a number of people that I can't tell you because it is 12 or fewer paid in that large chunk. And in the report, it shows kind of that

reported that the amount they had to pay was problematic for them.

BOARDMEMBER CATHERINE HARSHBARGER: Yes, they said that. And they also said that sometimes they were going without other things they needed in their lives to be able to afford that medication in those patient surveys. In fact, I actually put those numbers down: 52 percent of the people said they had to adjust for cost of medications in their budgets basically, and 21 percent said that they had medical debt as a result of that, and that was compared to nationally. Nationally, the 52 percent as compared to 27 percent nationally, and 21 percent medical debt in Colorado versus 13 nationally, so a higher amount of people are actually in medical debt as a result of this medication.

CHAIR GAIL MIZNER: You mean it seems worse in Colorado than it does nationally.

BOARDMEMBER CATHERINE HARSHBARGER: Correct.

CHAIR GAIL MIZNER: Because that was 21 out of 38, I believe.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah. I took the different percentages because

it speaks to it, yeah.
LILA CUMMINGS: We can actually keep moving along because I think these slides will get into some of the survey results and patient out-of-pocket response.
BOARDMEMBER CATHERINE HARSHBARGER: Sorry about that, Lila.
LILA CUMMINGS: Oh, no, please don't be sorry. Okay, so out-of-pocket estimates. So you know, we've got the All Payer Claims Database, as well as information from survey responses. Here is one way to visualize differences between Enbrel and its in-class therapeutic alternatives across the average copay, average deductible, and average total out-of-pocket cost.
So there's a lot on this slide, so I'm just going to give a moment and turn it over to you all.
BOARDMEMBER AMY GUTIERREZ: When I look at this slide, this is what made me make that comment about the Remicade being different because I think it's a different structure. When I look at the bottom, Enbrel, Humira, Cimzia, and Simponi, those are more the pharmacy benefit. I see them kind of in the same benefit structure

versus Remicade.
CHAIR GAIL MIZNER: So even if we take out Remicade, we still are seeing that Enbrel, in terms of out-of-pocket costs is second only to Humira, which of course, this is 2022, the most recent data may be -- is likely changing given the biosimilars at least that people are accessing biosimilars of Humira. And so, Enbrel does look relatively more expensive in terms of out-of-pocket costs for what patients in Colorado are paying.
BOARDMEMBER AMY GUTIERREZ: I agree with you, Gail.
CHAIR GAIL MIZNER: Any other comments on this before Lila moves on? Kate, anything to add?
BOARDMEMBER CATHERINE HARSHBARGER: There was, on one of those surveys, it did mention 10 patients, but, you know, we're talking about 22 or 23 people that were surveyed, that they still had trouble paying for their medication, so I thought that was pretty significant too out of the total number that we had -- well, almost half of the people were having trouble paying for it.

CHAIR GAIL MIZNER: I think you may have that slide coming up, right, Lila?
LILA CUMMINGS: All right, so here is information. This is just a better breakdown of the average month. And so, in the average month, what is someone paying across different types of out-of-pocket costs. Kate, before I speak, please remind me, is this commercial only or this got commercial and Medicare Advantage?
KATE DAVIDSON: I believe this is commercial only. Yes, this is commercial only.
LILA CUMMINGS: Okay.
BOARDMEMBER AMY GUTIERREZ: When we look at the out-of-pocket costs for Remicade, given that it is an infusion, is that just the drug or is it the drug with the IV solution and all of that, or do we know?
KATE DAVIDSON: I think it's everything. So the claim itself will include all of the costs associated with the infusion, so this is the copay associated with that medical distribution of the drug, if you will, so it does include that difference.
DR. BEN ROME: Dr. Guttierez, this is Dr. Rome from PORTAL. We've looked at this

separately as separate claims in prior studies and the cost of -- usually, you know, the out-of-pocket cost is mostly for the drug claim, the code that's for the drug; that includes the administration of the drug too. But there is a separate code, an administration code, that's like a sort of generic administration of an IV solution for cancer or for non-cancer, and it depends on the time and how long it takes. So those can generate additional out-of-pocket costs, but they tend to be small relative to the out-of-pocket costs of the drug itself.
BOARDMEMBER AMY GUTIERREZ: It does include the labor and everything for infusing; that's where I was kind of going with it.
DR. BEN ROME: Yeah. I mean, it includes the storage and delivery of the drug; there is a separate administration cost there that, you know, healthcare facilities can bill to insurance company. Obviously, that might vary by payer or how that's negotiated and whether they're allowed to bill that.
BOARDMEMBER AMY GUTIERREZ: Thanks.
BOARDMEMBER CATHERINE HARSHBARGER: The only comment I want to make on this is the

average total out-of-pocket per month is $373, and I always think that in relationship to what does it cost to have your house, what does it cost to buy groceries every week, especially right now. And so, $373 is a lot of out-of-pocket per month, it really is a lot, especially if you start talking about single-parent families or any of that going on as well.

CHAIR GAIL MIZNER: And in this review of just commercial insurance, Enbrel is the most expensive of the therapeutic alternatives.

BOARDMEMBER CATHERINE HARSHBARGER: Right.

CHAIR GAIL MIZNER: Any other comments on this before Lila moves on?

LILA CUMMINGS: Okay. And so, this is similar information shown in a different way, but I will note this is annual. So this table shows the annual change and the annual average out-of-pocket amounts comparing Enbrel, which is in dark purple, to its therapeutic alternatives. Each line is labeled with the name of the therapeutic alternative and then the percent change from 2018 to 2022, and Enbrel has the third highest increase in total out-of-pocket costs with a 77.8

percent increase.

BOARDMEMBER JAMES JUSTIN VANDENBERG: I mean, it doesn't seem like the story has really changed much on each slide that we've gone to. You know, I think any normal person, they're seeing Cimzia, like financial, you know, seem to be problematic to that level of having to pay an out-of-pocket cost there. I think that's where Amy was asking earlier about where does the copay cards come in or any kind of patient assistance. But even if it is adding in there, that's still - - well, I guess that's not reflective in this, so if it's showing that amount with that copay card, let's say if it was integrated, how much would that bring that 77.8 percent down.

I think that's kind of where it's that missing puzzle piece to see is that truly a large impact, a sufficient impact to say that it's making a change or making a dent for patient access or ability to pay. I don't know, that's kind of some of the pieces I'm trying to look for and tease out from the information here.

BOARDMEMBER AMY GUTIERREZ: I think Cathy said it earlier and I agree with you. Cathy said earlier that in the patient comments,

I think 30 percent of them said they still had trouble affording Enbrel, like paying their rent. And they would know about -- I mean, patient manufacturer programs are out there, so we still have -- and that's a big percentage. To have 30 percent have to decide between paying their rent or food or transportation versus their drug, it's a big chunk.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Absolutely.

CHAIR GAIL MIZNER: And I think, you know, there were also patient comments about the difficulty of having to be on the phone all day to access the patient assistance. It doesn't sound like the programs are particularly easy or that they always cover enough. I mean, just going back to one of the first slides, it's just impressive that the WAC would have increased 1500 percent; that is...

BOARDMEMBER JAMES JUSTIN VANDENBERG: Is that year over year or is that from when it first came to...

CHAIR GAIL MIZNER: When it first came out, which was a long time ago.

BOARDMEMBER JAMES JUSTIN VANDENBERG: I

just want to clarify on that one. I'm, like, did it go from (crosstalk) and then it went up to that? But still, long run, you know...

CHAIR GAIL MIZNER: Yeah.

BOARDMEMBER AMY GUTIERREZ: And, Lila, are we going to have a slide -- I'll hold my question then -- on rebates, because I know that's the next section on the report.

LILA CUMMINGS: We do have a slide with those confidential, so I'd be happy to kind of -- if you all would like to go into executive session. I will just reemphasize for folks. So we have rebate estimate data that we obtained through an organization called SSR Health. We are not allowed to share that information publicly. Board members cannot discuss if it is a high or a low rebate drug.

So Board members, you have access to that information, but you can't give specific percentages. Can't say if, in your opinion, it is high or low. You can say if a rebate has increased or decreased over time, so that can be said publicly. But, unfortunately, I would have to hop into executive session, which we absolutely can do if you all would like.

BOARDMEMBER AMY GUTIERREZ: Where I was going with this had nothing to do with the amount of the rebate. It had to do with the manufacturer, a letter that we received, where there was a contention that as the rebates go up, the drug price goes up. And I just wanted to see from Ben if there's any -- his thoughts on that. Because it was a pretty -- I mean, they even had diagrams in there about, well, when the rebate goes up, we have to increase our price to keep up or we're out of the market, so I just wanted to get the take, Ben, on what that comment was.

BOARDMEMBER CATHERINE HARSHBARGER: Is that the letter with the PBMs piece in it; are you talking about that one, Amy?

BOARDMEMBER AMY GUTIERREZ: Yeah, the payers. What they were alleging is the payers are getting or the PBMs are getting more of a rebate so they have to keep increasing the price. I just wanted to get some insight on that from our expert.

DR. BEN ROME: Sure. I mean, without talking specifically about Enbrel, in general what we've seen over the last decade or two has been that list prices for many brand-name drugs

have increased faster than inflation and rebates have gone up as well. There's been a widening gap, therefore, between sort of list and net prices. You know, it depends on the drug obviously in terms of what the net effect is on sort of net prices or after rebates and discounts. Although, you know, just to be clear, perhaps it's our health and all sorts of other estimates; this includes all sorts of discounts other than rebates as well and the supply chain.

So the net price is really the price that's received by the manufacturer but doesn't include sort of supply chain costs, of which there are always some supply chain costs to deliver a drug from the manufacturer to the patient, including the pharmacy fees and other sort of costs that, you know, everyone I think recognizes normal costs of doing business.

So that's just sort of some, like, general comments as you're sort of reviewing the rebate data. You know, there are many examples where the net prices have gone up despite increasing rebates, and, you know, just in other words, the increases and rebates did not fully offset the increases in list prices; that's just

sort of some general comments and for context.

BOARDMEMBER AMY GUTIERREZ: And I just brought it up just because we got it as a public comment and I wanted to understand that. Thank you.

CHAIR GAIL MIZNER: Do Board members feel the need to go into executive session to discuss confidential information?

BOARDMEMBER CATHERINE HARSHBARGER: No.

BOARDMEMBER AMY GUTIERREZ: No.

CHAIR GAIL MIZNER: Good.

LILA CUMMINGS: We can keep moving along, but if you change your mind, just let us know.

All right, so here is information on the relative financial effect. Not going to read the slide but will leave it up for a little bit. So there's really a couple of areas where we gather this input: input from patients and caregivers, input individuals with scientific and medical training, as well as review of different national and international health technology assessment organizations that do both clinical effectiveness research and summarization, as well as cost effectiveness, which we'll get to in a

second.

And then I'd also note too that we pulled information from the manufacturer, voluntarily submitted manufacturer documents with information they provided on the health effects of Enbrel.

I'll leave this up to just -- I was not going to read through but really want to leave time to highlight the input that was received from patients and caregivers on the health effects of Enbrel.

BOARDMEMBER AMY GUTIERREZ: Justin and Gail, since you're the other clinicians on here, what I recall reading is that Enbrel was the only one that worked in juvenile, is that right, or the others were actually more for the adult patients.

CHAIR GAIL MIZNER: I'm not sure it's the only one that works in juvenile. I think it's the only one approved.

BOARDMEMBER AMY GUTIERREZ: Approved, got it, okay.

CHAIR GAIL MIZNER: So it's not that other drugs aren't used.

BOARDMEMBER AMY GUTIERREZ: Are used

off label, yeah, got it.
CHAIR GAIL MIZNER: But I'm not a pediatrician, but that was my understanding.
LILA CUMMINGS: And I believe we can dive into appendices if we want. In Appendix I, input from individuals with scientific and medical training, we highlighted what was heard particularly around off-label usage.
BOARDMEMBER AMY GUTIERREZ: If you were going to use --
CHAIR GAIL MIZNER: That's what I think.
BOARDMEMBER AMY GUTIERREZ: If you had a patient with juvenile, the FDA approved indication would be use Enbrel.
LILA CUMMINGS: And I think a combination -- and be happy to pull these up -- a combination of the therapeutic alternatives appendix where it's listed which of the therapeutic alternatives are approved for specific indications, the six indications Enbrel is approved for, and then that Appendix I with input from individuals with scientific and medical training.
I will say staff did not conduct

research to identify -- you know, we really looked at each drug and its therapeutic alternative and what its FDA approved indications were. We did not do an indication-specific search where we looked at an indication and then looked at which prescription drugs were also approved.
BOARDMEMBER CATHERINE HARSHBARGER: I think you guys did a great job on that section, so thank you for that. I feel pretty good about it.
CHAIR GAIL MIZNER: I don't feel like we have to spend a lot of time on health effects. Enbrel is, it's clear Enbrel is an effective drug from a number of indications. There are a few patients who never find it effective, but there are other patients who find it extremely effective, and that's what the data shows. I mean, it's not news. It's a good drug. It's part of the armamentarium of rheumatologic agents.
DR. BEN ROME: This is Dr. Rome. Just on Table 4 of the report, it does list your therapeutic alternatives and the indications, as Lila was saying. So I think Golimumab or Simponi

received FDA approval for pediatric juvenile idiopathic arthritis in 2020.
LILA CUMMINGS: Thank you, Dr. Rome.
BOARDMEMBER CATHERINE HARSHBARGER: Thanks, Ben.
LILA CUMMINGS: Okay, we can move on to the next slide.
So here is a summary of the information gained from individuals with scientific and medical training, and we'll leave it up for a while as well.
BOARDMEMBER CATHERINE HARSHBARGER: The only thing is these are the same things we would see in the other drugs as well, right, because this is the indications that they have for any of them to be considered effective.
LILA CUMMINGS: Go ahead, Chair Mizner. Apologies.
CHAIR GAIL MIZNER: Detailing through the information, the appendices that have to do with this, I didn't feel we saw any evidence that Enbrel was less good or better than the therapeutic alternatives. Again, it's a good and effective drug.
BOARDMEMBER CATHERINE HARSHBARGER: I

think there was one report where it said Enbrel was inferior to Humira, but then there was another one that said it was superior to Remicade, but it was only a small amount of people, a small study, so there were still other alternatives basically.
CHAIR GAIL MIZNER: Yeah. I think that's clear, there are a variety of alternatives, both in just looking at TNF inhibitors and then looking at other kinds of (indiscernible) and biologics. But, you know, it's not a drug where I think we have to question that it's a worthwhile medication.
BOARDMEMBER CATHERINE HARSHBARGER: No, not at all.
CHAIR GAIL MIZNER: It's an effective medication.
BOARDMEMBER CATHERINE HARSHBARGER: Absolutely.
LILA CUMMINGS: I think we can move to the next slide because that...
And then this is what I was mentioning earlier. And Ms. Harshbarger, what you just mentioned is exactly from this appendix. If there's anything in the appendix you would like

us to touch on, happy to pull it up if you need, but we'll just leave this here for now.

We can keep moving on. I believe financial effects is next.

So here is one of the -- I think the full survey results from patients is found in Appendix H. It's coming in at 285 pages with kind of the full unedited answers. Something that we were really appreciative of is there were stakeholders that helped us get the word out when we reopened the survey in January, and so, I think we were pretty pleased with the response rate. But we did notice that there were, you know, a number -- there was a difference between national and Colorado, and so we've pulled that out here for a number of the questions.

I will say we got a suggestion to do exactly what you did on your own, Ms. Harshbarger, and put in percentages, so our plan would be to do that kind of through the appendices, as well as the report, to make it a little easier particularly when comparing national responses versus Colorado responses.

And when I pull up the edited version of the report, you'll see Table 12 around

percentage.

BOARDMEMBER CATHERINE HARSHBARGER: Right.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Speculation obviously. Do you think that has more to do with just the higher cost of living? Again, I mean, you know, like, the housing market, et cetera has gone up, I mean, exponentially to where you're comparing this market to homes in California. And I'm just -- again, now we're getting into a different area, but I'm just trying to think, like you said, having a higher percentage here from the responses to there, you know, what other factors are coming into play, and that one just pops into my mind immediately.

BOARDMEMBER CATHERINE HARSHBARGER: I think it's a good question. I think the biggest thing that I would remark is that we tend to do national markers against other metrics in healthcare, and so this is just one more that we take that national average basically and say here's what we think. So there's states that are higher and states that are lower, you know, because California is always one that you can

utilization management, we've put in percentages. And then we're going to go through and do that for a number of -- any time there's a comparison between national and Colorado, we'll put the percentages in.

BOARDMEMBER AMY GUTIERREZ: I was going to recommend that same thing, Lila, so good. I've had both at my calculator and started doing those.

BOARDMEMBER CATHERINE HARSHBARGER: But I have to tell you this information was very helpful in the format that you gave, so I mean, I just did a little math; that was all.

CHAIR GAIL MIZNER: And just to say what we already said, that 20 out of 38 felt that the cost of medication had caused them to have to cut costs in other areas of their life is significant I think.

BOARDMEMBER CATHERINE HARSHBARGER: I agree. And Coloradans struggle more so than even the national level, so that to me was also important to see.

CHAIR GAIL MIZNER: Right, even though the national level is still, you know, significant, but Colorado is even higher

look at, but there's other states that are high, New York and those kinds of areas as well, and yet we're still outpacing it in the wrong direction.

CHAIR GAIL MIZNER: And our basic charge is to decide whether this medication is unaffordable for Coloradans, so that Colorado data, I'm glad that you separated it out.

BOARDMEMBER CATHERINE HARSHBARGER: I like that we had a national one to look at as comparison, absolutely very important.

BOARDMEMBER AMY GUTIERREZ: Even the national one at 28 percent or 27 percent, it's still a lot. It's like 50 percent in Colorado, even though we are twice as high, it's still an issue across the country.

BOARDMEMBER CATHERINE HARSHBARGER: Right.

CHAIR GAIL MIZNER: Should we move on?

LILA CUMMINGS: Sorry, I was on mute. But, yes, happy to.

Okay, so then here is information from individuals with scientific and medical training. We'll leave it up for a moment for you all to take a look at, and then also survey responses

and summarize of meetings are in Appendix I as well.

BOARDMEMBER AMY GUTIERREZ: To me, looking at this kind of confirms what we were just talking about: there is affordability issues with this drug, given the amount of out-of-pocket expenses, the difficulty in getting it, patient assistance programs; it's kind of reiterating the same thing.

CHAIR GAIL MIZNER: That last comment is interesting to me. People who are undocumented can access financial assistance programs despite not being a U.S. citizen. There are -- certainly, there may be sometimes 340B programs that assist those patients, not all. And I really would be interested to know -- maybe that's confidential information, I don't know, for Enbrel; I don't think it should be confidential. Some assistance programs require a social security number and some do not, and that actually is a piece of information I would like to know.

BOARDMEMBER JAMES JUSTIN VANDENBERG: You're right, Gail. Every program is completely different. They can set whatever rules that they

want. I've seen it very specific, excludes a lot of areas; then I've seen some that are completely open. I mean, some of the easiest ones you just apply and essentially, you can get it, assuming you hit those little markers.

As far as what the requirements are, that is public knowledge to where we could ask staff to look that up as far as for Enbrel, if that's important in our review at this point, or would that be later on down the road.

CHAIR GAIL MIZNER: Well, I think it does -- would tell us something about affordability. If Enbrel is one of the programs that requires a social security number, therefore, requires you to be documented, that does exclude a significant number of people who might need it. So if that is information we can get from staff, that would be very useful I think. It's probably something somebody could look up very quickly just going on the Enbrel site actually.

LILA CUMMINGS: We pulled the information from Amgen's letter; they provided information tailored to us. We also looked at their website and what was publicly posted. That

is summarized, I believe, in Appendix K with rebate, discounts, and price concessions where we do a summary of manufacturer assistance programs.

BOARDMEMBER CATHERINE HARSHBARGER: I think for me, today anyway, I don't know that while that is important to note at some point, I don't know that it's going to get in the way of our decision today relative to Enbrel. And I say that because we still have statistics that show that people that are United States citizens and Coloradans are struggling. And so, for me, I see that as that's our core mission is to look at what is not affordable for people.

BOARDMEMBER AMY GUTIERREZ: And I agree with you, Cathy, especially if you look at that third bullet. Even if they aren't always aware and they have difficulty navigating the process, I would think that would be even more difficult for someone that's not a U.S. citizen to have to try figure all that out.

CHAIR GAIL MIZNER: Oh yeah, extraordinarily difficult.

And, Lila, this was an individual with scientific and medical training who said that the annual maximum copay amount that's awarded

decreased significantly in the last couple of years.

LILA CUMMINGS: My screen is a little...

CHAIR GAIL MIZNER: Looking at the fourth bullet there.

BOARDMEMBER CATHERINE HARSHBARGER: Annual maximum copay awarded.

CHAIR GAIL MIZNER: So I would summarize this input from individuals with scientific and medical training, essentially we're talking about rheumatologists and pharmacists who work with rheumatologic meds that this is proving to be pretty costly for people.

BOARDMEMBER CATHERINE HARSHBARGER: I'm guessing it's prohibited for some; some are even there that would like to be on Enbrel.

LILA CUMMINGS: Okay, we'll keep moving along. It's still financial effects. So this is a similar one around really taking a look at Appendix D for the specific cost effectiveness studies by indication. So if there's anything there that you would like to talk about?

I would say the summary of it was pretty similar to Chair Mizner, what you've

already said that some situations where folks have found it, where institutions have found it more or less, kind of right there in the middle. But if you have specific questions, I reference Appendix D.

We note this in the appendix. There's more research on cost effectiveness for the indications that utilize Enbrel more frequently, so rheumatoid arthritis and ankylosing spondylitis, those have kind of more research where some of the smaller utilization populations had less research.

CHAIR GAIL MIZNER: Anybody need more information there?

BOARDMEMBER CATHERINE HARSHBARGER: No.

LILA CUMMINGS: Next slide. So we've moving on to the third and final profile.

So this is the access to care profile, and it examines potential access concerns related to Enbrel and whether there's evidence that the causes of access to care concerns may be related to Enbrel's price or cost. This profile includes an examination of potential relationships with changes between utilization, price and costs, as well as information about safety net providers,

utilization management requirements, and health benefit plan design. And these are the appendices where that information is pulled from.

Okay, next slide.

All right, so we'll start here with price effect on access. So this is just simply showing the change in Enbrel's wholesale acquisition costs since its introduction, as well as the change, the percent change in inflation.

BOARDMEMBER JAMES JUSTIN VANDENBERG: I guess I'm curious. It's a very large number, but I'm curious to see what that compares to maybe the class of (indiscernible). But, like, are all of them doing that? Not saying it's right, but is this setting apart a higher rate than its competitors to where it seems -- I mean, just in general looking at it, it seems astronomical. But I don't know, just seeing it, like -- I don't know how to say the right word to it, but just trying to put it into a better context. Is every single drug out there going up at 1500 since it came out or that have been out on the market this long? My guess probably no, but I don't know, just wanted to...

CHAIR GAIL MIZNER: Looks like Dr. Rome

may have something to say.

DR. BEN ROME: I was going to add just one thing, which is that I know this graph only shows -- this is WAC data for Enbrel. Congress has released, you know, a public investigation comparing the WAC prices for Enbrel and Humira and shown that they increased sort of at the same rate, so this actually sort of stepwise increase with those two drugs. I don't think they looked at the other drugs, other therapeutic alternatives in the class. These are obviously the two most commonly used ones, but that gives you context within the class.

I think your other question (indiscernible) outside of the class is this abnormally high, and I think it is on the high end. There's, again, pretty good data that sort of looks at average price increases and it tends to be more in the, like, you know, 10 percent range per year on average for brand name drugs, so this is higher than average.

LILA CUMMINGS: I do want to highlight that in Appendix A for Enbrel, WAC, it's confidential, but there is information regarding the specific wholesale acquisition costs change

for Enbrel and all of its therapeutic alternatives, so you can access that information. It doesn't show percentage change; it just shows -- that's why it's confidential -- it shows the actual change in the wholesale acquisition cost.

BOARDMEMBER CATHERINE HARSHBARGER: My comment is it's high; that's what it is. It's high and even comparing with Humira, they both are high; that's my feedback from having read that appendix.

BOARDMEMBER AMY GUTIERREZ: Oh, go ahead, Cathy.

BOARDMEMBER CATHERINE HARSHBARGER: No, no. Ben's basically said that as well. I mean, the question with that always is what should it be, and the thing I keep saying to myself, it shouldn't be 1500 percent; that's what it shouldn't be. What it should be is up for debate, but it shouldn't be 1500 percent.

BOARDMEMBER AMY GUTIERREZ: I seem to recall reading somewhere they had something like 36 price hikes over this time period too, I mean, in terms of increases. I'm trying to find it on the report.

BOARDMEMBER JAMES JUSTIN VANDENBERG:

Amy, I'm trying to think, Amy, for some of the -- tying this into patients out-of-pocket, if it's a percentage. Oftentimes, on the commercial side, it's going off of AWP, not necessarily the WAC, and it's a percentage of that. And I'm just trying to think of -- but I assume you're not going to have an AWP that's below the WAC costs, so I guess you would see it in some degree fall in line with that. I'm just trying to match that up to then what's going to then translate to the patients either out-of-pocket.

BOARDMEMBER AMY GUTIERREZ: I'll bet if we graphed AWP, Justin, I'll bet we'd see the same type.

BOARDMEMBER JAMES JUSTIN VANDENBERG: I'll bet you're right. You're right, okay.

BOARDMEMBER AMY GUTIERREZ: Because (sound glitch) increase.

BOARDMEMBER CATHERINE HARSHBARGER: Is AWP, isn't it something that is considered after the price is set by the manufacturer or no? I don't...

BOARDMEMBER JAMES JUSTIN VANDENBERG: It's the average wholesale price, so I mean, it can certainly change depending on the product and

depending on how your charging is working, the charging model, that can certainly change everything. You go off of WAC or AWP, but typically AWP is more than your wholesale acquisition cost because you're buying it for the acquisition, so that's going to be lower and then the wholesale price is going to be closer to what you're going to be selling it at.

BOARDMEMBER AMY GUTIERREZ: It's also set, Cathy, AWP is how pharmacy reimbursements are set. It's AWP minus a certain percentage and that determines pharmacy reimbursement, which in turn goes to the patient.

BOARDMEMBER CATHERINE HARSHBARGER: Right, okay. I knew that. I just wasn't sure which one was the egg and the chicken, so to speak, on that.

CHAIR GAIL MIZNER: So I think this is, you know, a percent increase of 1500 is very impressive, but going back to what I think is most important is whether this is proving to be unaffordable for Coloradans. So I'd suggest we move on to the next slide.

BOARDMEMBER CATHERINE HARSHBARGER: Agreed.

LILA CUMMINGS: One thing I want to note too, and we can think about maybe at your future meetings changing this, there's a lot of context that's in the reports that we're not pulling out for these slides. So we can kind of see next meeting if you all would like us to just run through the report.

I'll note on the previous slide that a different 1500 number was listed in the text and in the graphic, and that's because, as is noted in the report, one is analysis of change in WAC to today, but then the figures are these five-year lookbacks, and so, the analysis stopped in December of 2022. And so that's why that number is 1502, it's slightly because in January of this year, there was an increase in the WAC, and so you'll see discrepancies like that. We footnote them in the report, but feel free to ask us if you've got any clarifications.

BOARDMEMBER CATHERINE HARSHBARGER: I'm okay with your PowerPoints the way they are, just for my feedback.

LILA CUMMINGS: Then we can move on to the next slide. All right, so here is information regarding the therapeutic

alternatives.

So Humira and Remicade, as we mentioned before, have recent FDA approval by similar products. So while this affordability review doesn't contain that information, we do have information for the four other therapeutic alternatives. So this figure shows the monthly number of utilizers for Enbrel and therapeutic alternatives. And you'll note that general utilization of Enbrel has stayed consistent from January 2018 to December 2022, and it's the second highest utilized drug after Humira, which has increased significantly within that timeframe, though you'll see what could be a slight dip towards the end and to the point that you all have made, the introduction of biosimilars.

BOARDMEMBER AMY GUTIERREZ: This makes a big deal of the formularies. Like in the news, I guess it's public information, but CVS Caremark has actually taken Humira off their formulary, so they're basically going to biosimilar only. So that is effective April 1st, 2024, they announced it.

LILA CUMMINGS: Okay. Any other

questions? We'll keep moving along.
All right, now here are some statistics that were pulled kind of in accordance with your rule on policy about the potential effects of price on access.
So you've got information here just summarized largely from other places in the report. They really look at patient count changes over five years, the total paid amount, the average paid per person, this includes both out-of-pocket costs, as well as the plan paid, and then that breakdown of total plan paid and average out-of-pocket costs.
And then WAC per unit, you all have access to but it's been redacted on this slide.
BOARDMEMBER AMY GUTIERREZ: So the average per person paid went up $13,000 in four years, $1,000 a month.
BOARDMEMBER CATHERINE HARSHBARGER: Thanks, Lila.
LILA CUMMINGS: Absolutely.
CHAIR GAIL MIZNER: The average out-of-pocket just is high. The average out-of-pocket is high. It did go down a little bit between '22 and '21, but for people to be having to pay over

$2,000 a year for one medication is a lot.
BOARDMEMBER CATHERINE HARSHBARGER: Yeah, and there are some that are paying $1,000 a month, so that's -- as their copay, it sounded like, from some of the professionals that we had give us feedback.
LILA CUMMINGS: Okay. I think we can move on to the next slide.
All right, so here's some information on safety net providers, utilization management, and health benefit plan design. So one thing, and I do want to share this. I believe this is maybe the last slide for Enbrel, so we'll switch to the redlines that we made and I'll run through.
So there's complications with the 340B program in terms of providers are not allowed to disclose the discount in their 340B price. So we did talk with some safety net providers, but no voluntarily submitted information around utilization was provided. Though we did -- and Dr. Guttierez, I'll turn it over to you - we did pull information on just not specific to Enbrel, but the number of 340B covered entities in Colorado and specifically by entity type.

We also pulled information on the number of distinct and unique addresses that are in Colorado. So that information, Board members, you have it, it's in your confidential folder. I'll share it. There's nothing actually confidential in that document itself. But just to paint a picture of the number of 340B providers in the state, and it's information that Dr. Guttierez put out is easily accessible. So not specific to Enbrel, but just that contextual understanding of 340B providers in Colorado.
Dr. Guttierez, anything you'd like to add?
BOARDMEMBER AMY GUTIERREZ: Yeah. First, I just maintained a database that you can actually query for the state by provider, by active participation. It even includes the authorizing official, the contact information, and it's updated every year usually through recertification, but there is a national database.
I just want to make sure the report outlined that that did exist and we could actually reach out to 340B if we desired to do so in the future. I think, Lila, you had found the

website and you were able to pull some data.
I think you're on mute, Lila.
LILA CUMMINGS: Thank you. So thank you for that, Dr. Guttierez. And so as an additional to research around 340B were staff access data around the benefit plan coverage design and formula structure. Data was pulled for carriers and the individual small group markets for which the division receives annual rate filings.
And so of note of the 10 carriers that submitted filings, eight carriers cover four or more dosage forms of Enbrel. All carriers that cover Enbrel require prior authorization, and in total, 576 plans provide coverage for Enbrel. And the majority of carriers place Enbrel on the highest two formulary tiers, meaning a higher portion of the drug is paid by patients than prescription drugs on lower tiers until the out-of-pocket maximum is met.
BOARDMEMBER JAMES JUSTIN VANDENBERG: As far as, I guess as far as safety net, you know, the medication is not on some sort of restricted formulary. It's going to be dictated by the payer on what's covered. So I don't know

how much you would really gather from a safety net component because they're not choosing it; the payer plan is. If it's step therapy, like we talked about before, you have to try X and fail before you can try Y.

But it would be going through the provider would write the prescription for the patient, it would go to the pharmacy, they would process, it would adjudicate, and either the claim would reject because it's not covered or prior auth needed to go through, you know, whatever the steps are, or it would go through per the contract and then that's what then the patient, if they had a copay, would have to pay to pick up the medication. Does that make sense? But it really is independent of what a safety net or 340B would even be; that's not going to drive it.

BOARDMEMBER AMY GUTIERREZ: I think Justin's right. In fact, the governor I think in 2022 signed a bill that really removes payers from paying 340B entities any differently than anybody else, so it's a law that's on the books right now.

BOARDMEMBER CATHERINE HARSHBARGER:

it and do it this way. That's not really what's going to be driving it. It's the payer plan on the prescription benefit.

CHAIR GAIL MIZNER: Oh, I see. So if it's a 340B entity, if the patient is insured at least, the fact that they may be getting that particular drug through a 340B with a 340B discount doesn't really affect what the patient pays.

BOARDMEMBER JAMES JUSTIN VANDENBERG: It's whatever is set with that contract or with the payer, your copay is going to be X amount of dollars, and that's what they're going to have to pay regardless of that additional discount potentially with 340B.

CHAIR GAIL MIZNER: And if the patient is uninsured, then what happens with most 340B providers, do you know?

BOARDMEMBER JAMES JUSTIN VANDENBERG: Now you're going a different process, but yes. So it's going to depend, but it could be -- oftentimes, it's looking which one has a patient assistance to where you could get it for free, and there may be a team within pharmacy maybe that works on that paperwork to help that

Yeah. I'm not surprised that came around.

BOARDMEMBER JAMES JUSTIN VANDENBERG: But that's probably why you didn't get anything from a safety net was they probably didn't feel like they had much to really offer, I guess.

CHAIR GAIL MIZNER: Can you go over that again, Justin? I'm not sure I'm following.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Yeah. So, I mean, if you're at a safety net versus a for-profit if you're looking at a pharmacy, you're going to have your provider, you're going to decide, okay, I want to start this drug for this patient, it's a pharmacy benefit. I'm going to send the prescription to the pharmacy. They're going to fill it and run it through the claims. It'll adjudicate, so it'll go through the contract with the payer and either the payer is going to reject it because maybe it's not first line and it'll usually say in the rejection, you know, patient needs to try this or to call the plan, or it'll go through and then the patient pays the specific copay.

But that's not going to drive a, you can't have this drug for this reason because we get a better price on it, we're going to change

patient; if they're not there, then it might be medical assistant or even the patient themselves that then completes that form to get approved from the manufacturer to where then they can get that for free or at a significant discount. That's going to drive that component.

I know that with pharma, they're changing the model a little bit to where if it's a prescription benefit, they almost have these cards, almost like an insurance card if you will and it changes, but it's for the patient assistance program. So even that is kind of changing right now of how some of these are covered, but that may drive.

So if you had three drugs, but one has the copay assistance, well that's the only way that the patient can pay for it, that's going to be driving -- for the provider is going to be driving not so much that, oh, well, this is the most expensive, this is the cheapest. You know, that could come down further down. But from a prescription benefit, that's typically what these newer and more expensive agents, the first direction that the pharmacy would go so that the patient could get it.

CHAIR GAIL MIZNER: So most 340B entities are not -- for example, if they're getting Enbrel for very -- obtaining Enbrel for very little money, they're not necessarily passing that savings on to an uninsured patient or an insured patient is what you're saying.
BOARDMEMBER AMY GUTIERREZ: I would imagine that there are some clinics, Gail, that maybe serve a lot of uninsured that probably drive your formulary around the 340B savings.
I think what Justin was referring to is more the insured status.
BOARDMEMBER JAMES JUSTIN VANDENBERG: Yes.
BOARDMEMBER AMY GUTIERREZ: For the uninsured, I think it's going to be really different.
CHAIR GAIL MIZNER: Yeah, got it.
BOARDMEMBER AMY GUTIERREZ: I know. I used to be with the County of Los Angeles. There's a lot of uninsured patients and our formulary was all centered around 340B low priced drugs.
CHAIR GAIL MIZNER: Yeah.
BOARDMEMBER JAMES JUSTIN VANDENBERG:

And that can change on a quarterly basis, which makes it tough. So within a quarter, that discount that could be pretty good could go away and then it goes up to a high -- and it might have a marginal discount, so you're kind of playing in that.
CHAIR GAIL MIZNER: Yeah, okay. Thank you both very much for that remedial lesson. In any case, it sounds like we're just not going to know a lot.
LILA CUMMINGS: Drug-specific information turns out to be a little tricky to get, not because of some confidentiality components. But I'm actually going to share my screen in a second. We've got one more slide on access to care and then I'll share my screen just to very publicly go over the redlines that were sent to you all.
So here was the results, very similar of questions around utilization management that we received from patients and caregivers. I know some of this had already been discussed too.
So with that, I am going to share my screen, and I will just show you things that we have already discussed. I just want to show you

what the changes were. Can you all see my screen?
Okay. So looking at the changes to just two portions of your report: one was the summary report, and one was Appendix F, which is input from safety net providers. And so, in the Enbrel report, summary report itself, so here is the information that was added about just acknowledging that there are biosimilar products available for both Humira and Remicade, and it includes the biosimilar's name, as well as the date that they began to be marketed. So we have information for another source around the date that they were, again, to be marketed. So that information you have, we will post as well.
And then I'm scrolling through. I will note you'll see some purple as I scroll, but we have taken out anything that needs to be redacted so there's no information that is being disclosed.
And then the only other change is towards the bottom of the report. Apologies for just the scrolling. And this is just we put in percentages, so we will go through. We put in percentages here and we're going to plan to go

through and do that for the remaining of the situations where we have both national response and Colorado response side by side, so we'll put in some percentages there.
Then the next change that was made was to Appendix F, impact on safety net providers. And so, here, you will see where we've pulled the information from HRSA's website. So we provide a little information about the database that exists, some summary statistics. And there are 108 unique active covered entity names in Colorado -- we did a filter by active -- with an associated 535 unique addresses. We also note that there are approximately 2,974 approved and participating contract pharmacies. I will note we did not do an assessment of if there were duplicates to addresses; that's just the number that was listed on HRSA's website.
And then here we provide information, again, not specific to Enbrel or dispensing Enbrel, but information around the number by entity type of 340B entities in Colorado, so you'll see the categories here.
We also make a note of the due to the differences in form and manner in which

information is submitted to HRSA versus All Payer Claims Database, we did not conduct an analysis of which of these. You know, it's nearly impossible to connect an analysis of which of these reported dispensing Enbrel in the APCD just because the data sources are so different.

We did note here that, in accordance with HHS's 340B drug pricing program ceiling price, prescription drug manufacturers are only allowed to charge a penny for prescription drugs when it's 340B ceiling price calculation results in an amount that is less than a penny. This penny pricing, as it is often referred to, occurs when a manufacturer raises the price of a drug substantially more quickly than the rate of inflation.

And so, we'll note here, this is not information that has been disclosed to us, so we just are calling out here the image that shows the change in inflation and the change in the WAC, and noting that Enbrel's WAC has risen significantly higher than inflation, though we have not done an analysis on the rate of change, just the fact that it has risen higher than inflation. So just kind of our two cents on the

penny policy. Apologies for that.

BOARDMEMBER AMY GUTIERREZ: Lila, I would just add if you're going to put that in there is put quarterly, 340B quarterly ceiling price calculation in that sentence. Because it is -- it's not like it's a penny forever, it's calculated every quarter. I think Justin mentioned that earlier.

LILA CUMMINGS: Absolutely. Okay, so those are the redlines that have been made. I will stop sharing my screen. And then I think we've got some, I believe public comment is up next.

CALLIE ANN SHELTON: We have three opportunities for public comment today: one for Enbrel, one for Genvoya, and then general public comment period at the end. So if you'd like to provide comment, please fill out the form in the chat, and I have a couple of people already lined up, so we'll get that started.

LILA CUMMINGS: And, Callie, will you remind us if there's a limit on the number of people, correct?

CALLIE ANN SHELTON: Yes, 10.

LILA CUMMINGS: Okay, thank you.

CALLIE ANN SHELTON: Thank you. First up, we have Bridget Serrett. Bridget, are you here?

BRIDGET SERRETT: Yes, I'm here. I would like to sign up at the end for general public comments.

CALLIE ANN SHELTON: Okay, thank you. And then, Jen (indiscernible), I have you signed up, but I'm assuming you want to go for Genvoya? That's before I put the other option.

JEN: Correct, thank you.

CALLIE ANN SHELTON: Tiffany Westrich-Robinson.

TIFFANY WESTRICH-ROBERTSON: Yes, hello. Robertson, I'm here.

CALLIE ANN SHELTON: You can go ahead, Tiffany.

TIFFANY WESTRICH-ROBERTSON: Okay, thank you. Hello, and I am representing the patient voice and also the International Foundation for Autoimmune & Autoinflammatory Arthritis, or AiArthritis for short. I'm also a person living with these diseases that can be treated by Enbrel.

I had a lot of planned comments, but

I'm frankly going to change all of them and talk about what I heard today because I am extremely, extremely concerned, more concerned than I was coming in, based on the conversation that I heard.

One of the things that I'm really concerned about is that the data that was presented was only based on a handful of people. And on October 3rd of last year, AiArthritis had submitted information that demonstrated that the survey that you're citing today was severely flawed, so the information that is being used is not even going to result in correct data.

For example, the question have you ever skipped a dose, stretched out a dose due to affordability, that question is severely flawed. I know because I was in the listening session for Cosentyx, and I said I can't answer this because it cost me zero dollars, but yes, I've skipped or stretched. The affordability comes with step therapy. The affordability comes with being switched by the insurance company, and then they tell you you can pay more for it because it's on a higher tier. None of that information was collected from patients, so I'm very, very

concerned that that's even being cited today.
The answer -- the other thing that I just really wanted to say is the conversations, there were a lot of questions that were asked that seemed to be conversations that should have been having months ago. I really encourage the Board, please pause, let's look back at these transcripts, publish them, give all of us an opportunity to clarify the conversations that you had and some of the points because they were not clarified. They were not. Please, I'm asking you, pause this decision until the transcripts can be out and we can come back and provide you with correct information and the potential to ask more patients why it is unaffordable. Thank you.
CALLIE ANN SHELTON: Thank you, Tiffany. Brett Johnson.
BRETT JOHNSON: Hi, thank you. Brett Johnson representing Amgen. Just to kick it off, I just want to call your attention to the process concerns that we've raised in our letters dated February 1st and December 4th, which include: first, public comments by a member of the Board in multiple meetings regarding off-the-record conversations with unnamed persons regarding

Enbrel's affordability; and second, the inconsistency in standards and procedures applied by the Board, including a lack of clarity about what those standards are and the inconsistent applications of what stated policies have been adopted.
To this second point, assessing the various reasons the Enbrel draft report posted over the past week, at least three of which we are aware, we're having trouble reconciling how some of the data points have been treated among the different medicines reviewed in just this first cohort.
For instance, can you help us understand why the percentage of patients paying $50 or less out-of-pocket per month feature so prominently in the Trikafta report at 51 percent but not in the Enbrel report at 57.3 percent, with the latter set focusing on the aforementioned results of the survey, about which we also have very serious real questions concerning the instrument used and the methodology. And even with those survey results, roughly half of the patients paying $100 or below out-of-pocket did not report trouble ever

affording their medicine, and it was ever affording their medicine.
Can the Board explain the standard it applied with respect to these data and, more broadly, how they factor into a decision about what constitutes affordability. For example, can you clarify what specific data has the Board reviewed and in what manner is that data being considered to support statements made today about formulary placement and its impact on patients.
And then finally with regards to the discussion today about patient assistance, which isn't reflected in the key claims data that's been discussed. It's important to distinguish between, one, copay card programs for which there's a streamlined access, it's online, it's very easy, and commercially insured patients with Enbrel are eligible, but generally not those covered by federal programs. For these programs, not a single Coloradan of the nearly 2,000 that applied last year were denied.
And then the need-based safety programs, which are different, which I assume is what was being referred to with some of the phone waiting and other complications. But due to

these in-common insurance verification requirements, which are required by rules that can be a challenge to some patients; they must be U.S. residents and either uninsured or have Medicare Part D with affordability gaps and household incomes up to three times the federal poverty line.
Even with this more thorough review process, the current average wait time for callers is 33 seconds. And through these programs, the Amgen Safety Net Foundation has provided approximately $2.5 billion in medicines just last year.
So if there are any questions or anything we can provide further information on, please do use us as a resource and, you know, we hope to be an aid to understanding some of these key points that appear to be a point of misunderstanding based on today's discussion, so thank you.
CALLIE ANN SHELTON: Thank you, Brett. Hope Stonner, please.
HOPE STONNER: Hello, my name is Hope Stonner. I'm the policy manager at the Colorado Consumer Health Initiative. Appreciate this

opportunity for public comment.
I also had some comments prepared, but also would just like to add. I think, as a local consumer advocacy organization who has a lot of experience engaging in sort of these, like, state regulatory processes, we have been very impressed with the way that the PDAB has been conducting this work, and I think there has been ample opportunity throughout this process for stakeholders kind of across the entire supply chain to engage in this work. And so, just wanted to raise that and reflect our gratitude for that.
I think some other things that the Board members have already called attention to that I just kind of wanted to reemphasize were the reports detailing of patients struggling to afford Enbrel even with access to financial assistance, which confirms concerns that CCHI had previously raised regarding the reliability and accessibility of manufacturer patient assistance programs for all patients across the board.
And I think that this is related to the report's findings that members also called out that Enbrel's prices have increased a whopping 36

times since its introduction, and we think that given this history and the fact that the last of Enbrel's patents are set to expire in 2039, the Board had a really important opportunity and authority to course correct today by deeming Enbrel unaffordable and initiating an upper payment limit process.
Thank you.
CALLIE ANN SHELTON: Thank you, Hope. Steven Newmark.
STEVEN NEWMARK: Hi, how are you. Sorry, give me a moment as I struggle with the unmute button.
Hello, I'm Steven Newmark and I'm the policy director for the Global Healthy Living Foundation, a patient organization, that works to help chronically ill patients around the 50 states, including Colorado. These patients are chronically ill, as I said, and many rely on the medication such as Enbrel to live their lives.
We have concerns over access issues to these medications that the Board is -- and some of the considerations that the Board is undertaking, and most notably, savings that will actually be realized by patients, but I'll let

our written comments stand on these points.
But for the oral comments, I just want to add that you raised some issues on copay cards and how it affects affordability, but there seemed to be a little bit of a trail off in the discussion. I don't know how deep you have spoken to patients directly about this issue. Further, I didn't understand the limited and partially non-public discussion on rebates. The slide itself said confidential. To not focus on rebates when dealing with drug cost issues is like trying to build muscles, but refusing to lift weights. I mean, that's a big part of dealing with the affordability issues.
But just for now, I just want to say that we at GHLF are eager to hear more about your plans for engagement with patients and caregivers mentioned at the top of this meeting. I hope it's not too little too late. As seen today, too often, the parent-caregiver voice is left out of these discussions, and we are hopeful that you will engage in robust discussions directly with these important stakeholders.
We look forward to hearing more about these engagement ideas and stand ready to share

them with our Colorado patients. Thank you for all that you do.
CALLIE ANN SHELTON: Thank you, Steven. I don't have anyone else signed up specifically for Enbrel, but I'll give you another moment. I'll put the link in the chat again, and again, if you'd like to provide comments specifically on Enbrel. I'm not seeing any more. We can close this public comment period.
LILA CUMMINGS: Then we probably need to go to the next slide.
CALLIE ANN SHELTON: Somebody just signed up for Enbrel.
LILA CUMMINGS: Oh, okay.
CALLIE ANN SHELTON: Jerry Cunningham. Jerry, are you there?
JERRY CUNNINGHAM: Okay. Can you hear me now?
CALLIE ANN SHELTON: I can hear you now.
JERRY CUNNINGHAM: Okay, great. My comment might be out of turn. Is Enbrel the potential replacement drug for Remicade, or was that conversation and Enbrel something else?
LILA CUMMINGS: Remicade is one of the

identified therapeutic alternatives for Enbrel in this affordability review.

JERRY CUNNINGHAM: Okay. So I suppose I could ask a question before I make public comment because I don't want to speak out of turn. So I have a family member, actually it's my brother, who uses Remicade. Is the Board considering Remicade as, you know, under its affordability -- you know, the umbrella or just Enbrel?

LILA CUMMINGS: This affordability review is specific to Enbrel.

JERRY CUNNINGHAM: Okay. Well, if you give me 30 seconds, I'll say what I was going to say, and then I will go ahead and just listen to the rest of the public comments.

I really have paused, someone just spoke earlier about how this meeting today has really set them back, and that goes for me as well, and I spoke on this before. I just want to reiterate that when public comment notifies you as professional individuals in the medical space, being doctors, also having an oath to not do any harm, I feel like there are smarter people than me that you all have access to that you can ask

that if a small pharmacy in Yuma, Colorado decides not to carry Enbrel or Remicade for my brother and that information leads to, you know, legal action, I can't see the Board not personally being liable because of the oath to do no harm.

So I just caution all of you to please speak to people that are way smarter than me because my brother already has a hard time getting Remicade because of the insurance loopholes and, you know, hoops that he has to jump through, and it is determined that someone is making it difficult for him to get medicine that he believes is lifesaving, that's harmful, and I can't see that not being something that people could come after everybody individually for.

That's all I will say. Thank you for giving me my time and I will go back on mute.

CALLIE ANN SHELTON: Thank you, Jerry. Bridget, have you changed your mind and you want to speak on Enbrel specifically? If so, you can.

BRIDGET SERRETT: Yes. Sorry, you'll have to forgive me. I'm fresh out of neurosurgery, so the brain is not quite checking

the way it should.

My concerns with this are going to be the stakeholder process clearly. I don't feel like we are doing our best to engage stakeholders to get as much information. I feel like the data process, the questions are very flawed and don't necessarily reflect why patients are having trouble accessing Enbrel, and I do also want to make sure that we make decisions that aren't going to hurt access for patients. There is still nothing in this process that I can see that is going to make these drugs more affordable for the end user, the patients, and I want to be sure that we keep that in mind as we go further into this.

Thank you.

CALLIE ANN SHELTON: Thank you, Bridget, and happy healing. Take care of yourself. Anyone else would like to speak specifically on Enbrel, maybe one more moment.

LILA CUMMINGS: And then we can move to the next slide.

CALLIE ANN SHELTON: Yeah, go ahead.

LILA CUMMINGS: Chair Mizner, we'll turn it back over to you.

CHAIR GAIL MIZNER: Thank you, Lila, and thank you everyone for your comments.

Is there any further deliberation about -- that the Board would like to undertake about Enbrel? Are you comfortable -- are Board members comfortable moving forward with determining whether Enbrel is unaffordable with the information presented?

BOARDMEMBER AMY GUTIERREZ: Yes.

BOARDMEMBER CATHERINE HARSHBARGER: Yes.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Yes.

CHAIR GAIL MIZNER: Any further deliberation? Lila, do you want to make any comment about some of the issues that were raised about our outreach to stakeholders?

LILA CUMMINGS: Yeah, I'd be happy to. I think, you know, there is a tension between needing to treat all drugs equally and then hearing from consumers that they would like tailored surveys. And so, that's something that I think, you know, we want to gather information as consistently as possible across drugs.

I will say for surveys, we always left

an option open for patients to kind of provide any information they would like, and we did get specific feedback from patient groups on the design of the survey, so our aim was to have a patient-friendly survey. That being said, we are -- you know, as we've talked about, we are open to continued improvement. I think we feel confident and we work to post the links so the Board members, I know you all have listened to the unedited audio from the public meeting with patients and caregivers for Enbrel.

And then we also posted unedited survey replies, so I think we feel that as staff that is accurate that you all have access to unedited information from us. I think we feel confident in it and to the degree that in the future, processes might change; that is always the conversation we're willing to have, but confident in what we've provided for Enbrel.

CHAIR GAIL MIZNER: Thank you, Lila.

BOARDMEMBER CATHERINE HARSHBARGER: One little comment. Even though we didn't talk about the confidential information, we had access to that and read that, and I just want to emphasize that to the public. There's some things that we

just knew what they had already said and so, therefore, we didn't need to deliberate further on it.

BOARDMEMBER AMY GUTIERREZ: I have something I want to add on to Cathy's comment. I think the staff did a great job at putting this report together. It was very comprehensive. There's a lot of information, a lot of work that was done on outreach, so I feel very confident in the work that they've done and I think we need to rely on that when we deliberate, make our decision.

BOARDMEMBER CATHERINE HARSHBARGER: Agreed.

CHAIR GAIL MIZNER: The staff did an enormous amount of outreach and was able to get a lot more input on their second attempt from patients and caregivers, as well as to my understanding some of the medical experts.

BOARDMEMBER CATHERINE HARSHBARGER: I'm comfortable with moving forward with a vote, Gail, when you're ready.

BOARDMEMBER AMY GUTIERREZ: So am I.

CHAIR GAIL MIZNER: Then I need a Board member to make a motion if there's no further

deliberation and having considered the evidence before us relating to each affordability review component. Do I have a motion regarding a vote on the unaffordability of Enbrel?

BOARDMEMBER CATHERINE HARSHBARGER: I'll make the motion. My motion is that the use of Enbrel is consistent with the labeling approved by the FDA or with standard medical practice and is deemed unaffordable for Colorado consumers.

BOARDMEMBER AMY GUTIERREZ: I will second Cathy's motion.

CHAIR GAIL MIZNER: Okay. Then Ms. Harshbarger moved and Dr. Guttierez seconded that we move that use of Enbrel consistent with the labeling approved by the FDA or with standard medical practice is unaffordable to Colorado consumers. Did I get that right, Cathy?

BOARDMEMBER CATHERINE HARSHBARGER: Yes, you did.

CHAIR GAIL MIZNER: Okay. Then I'm going to roll call a vote. Callie, are you going to call on people one by one?

CALLIE ANN SHELTON: Yeah, we can do that. Dr. Amy Gutierrez.

BOARDMEMBER AMY GUTIERREZ: Yes.

CALLIE ANN SHELTON: Cathy Harshbarger.

BOARDMEMBER CATHERINE HARSHBARGER: Yes.

CALLIE ANN SHELTON: Dr. Gail Mizner.

CHAIR GAIL MIZNER: Yes.

CALLIE ANN SHELTON: And Dr. Justin VandenBerg.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Yes.

CHAIR GAIL MIZNER: Okay. Then, Lila, please finalize the affordability review report for Enbrel by adding a high-level summary of our deliberations today, our determination that use of Enbrel is unaffordable for Colorado consumers, and correcting any clerical errors you all identify. We will vote to approve the final report at our next meeting.

LILA CUMMINGS: Absolutely. Thank you, Chair Mizner. And I'll just note for the public, the next meeting will be posted to the website. The next meeting of the Board will be next Friday, February 23rd at 10:00 a.m. So thank you, and we will do that.

CHAIR GAIL MIZNER: Thank you all. We

will now break. I'm thinking we need to make this 15 minutes, Lila.
LILA CUMMINGS: Okay, absolutely.
CHAIR GAIL MIZNER: We'll now break for 15 minutes, so be back at 2:39.
LILA CUMMINGS: Okay, great. Thank you.
(2:24:11 -- Break Begins)
(2:39:37 -- Break Ends)
CHAIR GAIL MIZNER: It's 3:39, but I'm not sure I see Dr. Guttierez and Ms. Harshbarger back with us yet.
BOARDMEMBER AMY GUTIERREZ: I'm here, Gail.
BOARDMEMBER CATHERINE HARSHBARGER: I'm here.
CHAIR GAIL MIZNER: Okay, great. Then let's get started. Welcome back, everyone.
We're now going to turn to consideration of Genvoya. Board members disclosed conflicts at the top of the meeting. Dr. Diab is the only Board member with conflicts and he will not participate in the deliberation.
Before we begin deliberation, I'd like to note that all Board members were present at

the December 8th meeting when staff presented draft evidence for the Genvoya affordability review. I'd like to also note that the Board members were provided with the entire unredacted draft report on February 9th.
To ensure that all Board members have had an opportunity to review the information in the draft report, I'd like to ask if any Board member feels we do not have sufficient information to deliberate regarding unaffordability for Genvoya today. Does anyone have concerns about that?
BOARDMEMBER JAMES JUSTIN VANDENBERG: I do not.
BOARDMEMBER CATHERINE HARSHBARGER: No.
BOARDMEMBER AMY GUTIERREZ: No.
CHAIR GAIL MIZNER: So if there are no concerns, are there any objections to moving forward with deliberation?
BOARDMEMBER JAMES JUSTIN VANDENBERG: Not from me.
BOARDMEMBER CATHERINE HARSHBARGER: No.
BOARDMEMBER AMY GUTIERREZ: No concerns.
CHAIR GAIL MIZNER: Lila, let's move

forward with deliberation.
LILA CUMMINGS: Okay. Thank you, Chair Mizner.
I think my first question would be, there were some more redline edits that were suggested, so both in the summary report for Genvoya, Appendix B, Appendix F, and Appendix M with HCFA, so I'd ask would you like to do the same thing where we showed them at the end or would you like me to show them at the top?
CHAIR GAIL MIZNER: You guys have any feelings about that?
BOARDMEMBER CATHERINE HARSHBARGER: I don't have strong feelings either way.
LILA CUMMINGS: Okay. Then I might just show them at the top because they're relatively small, but then that way -- so I'll plan on showing them, but the we can maybe save them for discussion at the appropriate point throughout. So I will share my screen first and then I will hop back to the PowerPoint slides.
So in the summary report itself, we did pull out some information, and this is under the indication that Genvoya treats. So we pulled out some information from the clinical guidelines

which are cited in Appendix D, so we pulled out information here.
And, Chair Mizner, this was kind of at your direction, so if you have any comments on this, we welcome that.
CHAIR GAIL MIZNER: Let me read it quickly. Thank you.
LILA CUMMINGS: And if you'd like to save your comments for the appropriate spot in the discussion, absolutely on that too.
CHAIR GAIL MIZNER: Yeah. I think what I was wanting to highlight is that Genvoya is not for patients who are na?ve to -- who have never been on any retroviral therapy before, that there are a couple of other regimens that are considered preferred, that Genvoya is included in the list of alternative regimens.
BOARDMEMBER CATHERINE HARSHBARGER: So it's not first line; it's kind of like a...
CHAIR GAIL MIZNER: Yeah, I mean, but there are only two that are listed as the preferred and then, you know, there are others that follow and Genvoya is among the others that follow, but I think that is important information. And the other little clinical piece

is that Genvoya does, because of the cobicistat in it, have more drug interactions, but those are just, you know, pieces of information that I think are relevant.

As we've seen with the information presented, Genvoya is an effective medication that is used by a number of patients still, even though it's not listed among the preferred agents.

BOARDMEMBER AMY GUTIERREZ: Gail, when you say preferred, it's by clinical evidence or resistance patterns or...

CHAIR GAIL MIZNER: It's largely based on the fact that the two preferred regimens contained integrase inhibitors that have higher barriers of resistance to viral mutation and, therefore, a development of drug resistance.

BOARDMEMBER AMY GUTIERREZ: I don't (sound glitch) with this drug class with this. They just keep changing; they keep adding those resistance to both. We add other drugs over time since HIV was first identified.

CHAIR GAIL MIZNER: And the integrase inhibitors are essentially the most recent widely used category and are very, very effective and

very beneficial for people, and Genvoya contains an integrase inhibitor.

LILA CUMMINGS: And then the only other change we made here, and we appreciate our partners at PORTAL, it was a tiny one -- you'll see it in the therapeutic alternatives appendix as well -- a tiny, but important.

So here just clarifying the mechanism of action for Dovato we had written to is, in fact, one, so that was the only other change.

CHAIR GAIL MIZNER: I thought it was one of the two drugs -- it's a two-drug regimen, as opposed to a three-drug regimen, so I was just wanting to make sure we were correct on that.

LILA CUMMINGS: So now I will minimize this. So in the therapeutic alternatives appendix, you'll see just the same -- that last change that we mentioned is also in there when you scroll down to Dovato. So the only change here is that corresponding change from two to one, so that's the only redline in this appendix.

Then impact on safety net providers. This is the same, very similar changes to what you've already reviewed, and I'd say there is more information here that we'll get into

regarding Ryan White. But we provided information from that HRSA database regarding covered entity types and number of unique addresses, again, not specific to Genvoya, but we have this information in here as well.

And, Lila, let's add that quarterly on there as well.

LILA CUMMINGS: Great.

BOARDMEMBER CATHERINE HARSHBARGER: That's 340B.

LILA CUMMINGS: There we go. Thank you. Fantastic.

And then the only other change here is in information from the Department of Health Care Policy and Financing. We have pulled out that there is a published report that mentions Genvoya. That is something we work with our partners at HCFA to identify, and it had to do with the fact that Genvoya is listed on potential drugs for importation for the HCFA's Canadian Drug Importation Program. I'll note that that is not approved yet by the FDA; it's an ongoing conversation.

So we had information on there on Genvoya, but then Chair Mizner said are there any

other HIV drugs that are also on that list. So we have pulled the information from the same source regarding the fact that there are other -- and it's on HCFA's website, it's drug category HIV. We did not do further analytics in terms of class or doses, but this is the information that was presented there, and then we've cited the source as well.

CHAIR GAIL MIZNER: Thank you, Lila.

LILA CUMMINGS: Yeah, absolutely. Okay, so those are the redlines, so I will stop sharing. Happy to come back to any of these if you would like. But with that, we can proceed back to the slides.

In the interest of time, I'm not going to reread some of these. We'll start with therapeutic and utilization profile, and I think you all are familiar with the appendices where we pull this information from. We can go to the next slide.

So indication, Genvoya has one indication, HIV-1, and so there's information up here from the FDA's website. I'll pause. Any questions on indication? We can go to the next slide.

So here is utilization data for Genvoya, and we've combined here two types of information. You've got the raw numbers, but then you also have information based off of utilization for just Genvoya; there is information on general utilization for Genvoya and its therapeutic alternatives. But for just Genvoya, here's how utilization has changed since 2018 across commercial, Medicaid, and Medicare Advantage plans, as reported in the APCD.

BOARDMEMBER CATHERINE HARSHBARGER: That's a significant reduction in utilization, isn't it? Is there -- we probably don't know why that is, or did somebody...

CHAIR GAIL MIZNER: I think we kind of do. It's that other medication combinations became available that were viewed as being either better tolerated or more effective, so it's basically that. As I mentioned before, Genvoya does have cobicistat, which makes it so that you cannot take a statin with it. And as HIV patients, age, cardiovascular disease becomes more and more of a concern, and so many people need to be on a statin, so that would be one potential reason that someone might switch away

from Genvoya.

So there are, you know -- I hate to be acting as the expert again, but that has been the tendency is with newer regimens coming out, people, for one reason or another, get switched.

BOARDMEMBER CATHERINE HARSHBARGER: Okay.

LILA CUMMINGS: And I would say note too that Chair Mizner, Dr. Mizner has been incredibly helpful. Because, you know, one of the sources that was used for this is the clinical guidelines, so she's been incredibly helpful in making sure that we appropriately translate some of the clinical guidelines.

Next slide.

All right, so again, same information just presented in a different way, in terms of utilization of Genvoya by payer type over five years.

Okay, next slide.

Health equity. So priority populations -- and this is just a note for folks that the Board has defined priority populations in your rules. So if folks are kind of wondering why we're using that term, it's just an all-

encompassing term where specifically priority populations are listed out; that's why we're using that language and would just encourage folks to look at the rule if they want to know specifically.

But HIV disproportionately impacts priority populations, particularly sexual minorities and communities of color. HIV disparities persist and the number of new HIV diagnosis linkage to care and treatment and retention and care, there's a pretty thorough overview of health equity literature related to HIV. We also heard from patients and caregivers that accessing HIV-related medications for people living with HIV, there's a historical context.

That is important that we heard that and patients submitted information to that context about particularly the disproportionate impact they felt in health equity and accessing prescription drugs in the past, and then kind of persisting potential health equities. So there's a lot more information in the health appendix as well, as well as input from patients and caregivers and individuals with scientific and medical training and voluntarily submitted

information.

And then another thing too that I'll note specific to Genvoya is that we heard a lot from patients and caregivers around stigma associated with HIV and how that might impact access to medications and access to care.

We can go on to the next slide.

So here is a map of utilizers of Genvoya in 2022. You've seen this map before, and so I'll just leave it here to pause to see if Board members have any kind of comments or thoughts or discussion.

CHAIR GAIL MIZNER: For the counties that are not counted ones where we don't have any patients as far as we know taking Genvoya?

LILA CUMMINGS: Correct. (Indiscernible) on here, they're in the claims database. There is no...

CHAIR GAIL MIZNER: Okay.

LILA CUMMINGS: Thank you.

CHAIR GAIL MIZNER: I think we can move on.

LILA CUMMINGS: All right. And then here are the therapeutic alternatives that were identified, so these are in-class single-dosage

form therapeutic alternatives. I'll leave it here for any discussion. I see on the slide it says two, not one, for Dovato. You've seen the change in the report.

BOARDMEMBER CATHERINE HARSHBARGER: Biktarvy, I guess I keep thinking that that one's kind of a preferred starting point. I think it said that in the report for new HIV patients, they tend to use that as their first choice.

CHAIR GAIL MIZNER: So the preferred agents listed by DHHS are Biktarvy or the combination of dolutegravir and tenofovir emtricitabine called Descovy. And so, that second combination is two pills taken just once a day, which for many people isn't a big problem. But that was not included in this just because it's two pills instead of one, so it wasn't felt to be quite comparable.

But, you're right, Biktarvy came out more recently in 2018 and has been very popular. It's a small pill that's easy to swallow, highly, highly effective, everything in one, and so it has been quite popular and it is listed as one of the first line.

BOARDMEMBER CATHERINE HARSHBARGER: It

of the patient out-of-pocket, it's about 2600 per year; is that how I'm interpreting this?

LILA CUMMINGS: Yes. Go ahead, sorry.

BOARDMEMBER AMY GUTIERREZ: That's over $200 a month, that's quite a bit.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, it quite a bit. Go ahead.

CHAIR GAIL MIZNER: Is this just commercial insurance or commercial plus Medicare?

KATE DAVIDSON: Yeah, it's commercial plus Medicare Advantage.

LILA CUMMINGS: And then something that I will note, like, I think we were going to get to it in a few slides, but since you all are discussing out-of-pocket costs. So in Appendix F, which is the impact on safety net providers, we spoke a couple of months ago with our peers at CDPHE who oversee the state drug assistance program, and they provided us with information on how the programs run, as well as what services and what kind of assistance is available.

So a summary -- and I said state drug assistance program, or SDAP, Ryan White, the federal Ryan White HIV/AIDS Program is kind of what that's referring to. Frequently, clinics

has lower side effects too; is that correct?

CHAIR GAIL MIZNER: What's that?

BOARDMEMBER CATHERINE HARSHBARGER: It has lower side effects.

CHAIR GAIL MIZNER: Probably it may cause a little more weight gain for some patients than, for example, Genvoya does. But generally, really most of these drugs are very well tolerated at this point.

BOARDMEMBER CATHERINE HARSHBARGER: Okay, thank you.

LILA CUMMINGS: I've actually just moved forward to the next slide where we have utilization data for Genvoya, Biktarvy, Dovato, Scribid, and Trimeq and total as well. Okay. Any questions on indication utilization or information about therapeutic alternatives and their utilization?

All right, so price and cost profile. I'll just leave this up here for a second, and we can go on to the next slide.

Here are the WAC and cost statistics that you've seen a similar version before. We'll leave it up for folks to discuss.

BOARDMEMBER AMY GUTIERREZ: So in terms

are referred to as Ryan White Clinics, but there's more information in Appendix F, and specifically, I want to highlight information about the state drug assistance program and the income eligibility chart that is there. And so, that is highlighting the certain kind of income eligibilities in which you can receive financial assistance to access drugs, including drugs like Genvoya.

And I'll just note that there is assistance that is available for up to 500 percent of the federal poverty line, and that is something -- so that access to that assistance is not reflected in claims data.

BOARDMEMBER AMY GUTIERREZ: Do we have any idea, Lila, how many of the commercially insured patients have access to that federal poverty level limit?

LILA CUMMINGS: That is --

BOARDMEMBER AMY GUTIERREZ: (Sound glitch) in this.

LILA CUMMINGS: Yeah, that is not something that we did an analysis of. Kate, correct me if I'm wrong, I do not believe there's any information in the APCD that could estimate

income levels.
KATE DAVIDSON: That's correct.
BOARDMEMBER CATHERINE HARSHBARGER: We probably wouldn't be able to get that because they probably do that on a one-on-one basis and keep it pretty confidential, so I would imagine that would be hard to get.
CHAIR GAIL MIZNER: So let me see if I can do a couple of clarifications. So that SDAP program or ADAP/SDAP program is available whether the patient -- as long as the patient is enrolled on the western slope, it's Western Colorado Health Network, so they can see a provider who's not a Ryan White provider and still be prescribed medications and receive them under SDAP. I know that because I'm not a Ryan White provider and most of my patients receive their medications under SDAP.
And that organization as well does an enormous amount to help get patients who can be on insurance on insurance and insurance that does cover the medication.
So I am, based on my experience, which is of approximately, must have taken care of at least 200 patients with HIV in the past three,

four, five years, I've never seen a patient have to pay $2,600, but I don't see wealthy patients either. So I'm a little surprised by that out-of-pocket number is what I'm saying.
I don't know, Kate, if you have commentary on that.
KATE DAVIDSON: Just reiterating what Lila said, that this is what the claims says, not necessarily what was experienced by the patient with all of the funding.
BOARDMEMBER AMY GUTIERREZ: The reason I asked the question, Gail, was out of that 2600 is the SDAP program available to them or are we really looking at patients that are insured, because there are quite a bit of insured commercial patients on here. Is that what their out-of-pocket is really 2600? That's why I asked that question.
CHAIR GAIL MIZNER: Yeah. And are they getting somehow other assistance.
DR. BEN ROME: Yeah. One point just about the 2600 is a mean, just to remind you all too, and I think we saw it with Enbrel and with this drug too. Like most drugs, these costs are not distributed such that -- you know, it's not

true that, like, half of patients are paying more than 2600, right. The mean tends to be driven by some skews on the very high cost, so, you know, there's going to be a range of patient out-of-pocket costs when you analyze these data.
LILA CUMMINGS: And I'd say we really appreciate the stakeholders that engaged in this process because, particularly in voluntarily submitted information, they pointed to very -- like, where assistance programs, you might not have full info- -- like, in manufacturer assistance program, you might not have full information on utilization. But in the case of Genvoya in particular, there are federal and state level policies around copays, and we'll get to that; that's in a few slides.
The patients survey results I think tell -- we will get to those in a few slides -- tell their experience, and then the Ryan White program. So there are a couple of very established, very transparent data in terms of what the rules and policies are that impact patient out-of-pocket costs is what we heard from stakeholders.
BOARDMEMBER JAMES JUSTIN VANDENBERG:

And I think that's really important. What you're noting, Lila, here is you have state, you have federal, you have patient assistance program. There's quite a few different pieces in there that are highlighting, as well as the stakeholders, of the ability to gain access to this medication.
BOARDMEMBER CATHERINE HARSHBARGER: You did have a pretty big WAC increase that it's noted on here.
BOARDMEMBER JAMES JUSTIN VANDENBERG: And I'm curious, looking at the graph that you had before and seeing that trend, the downward trend, I'm curious if we're almost catching this on the back end of it almost sunsetting itself, to some degree. As we were talking before, as new agents are coming out, as there is resistance and you're having to shift the medication, is it naturally kind of going to continue to go down and then probably, you know, bottom out to some degree a little bit.
But as far as our data collection, we're getting it on the tail end of this, so it encompasses here. But if were to, let's say, run this again in five years, my guess is Genvoya

wouldn't be coming up to this -- coming on to our radar as being one of the top medications would be my guess looking at the trajectory that it's going. Does that make sense?

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, it makes sense.

CHAIR GAIL MIZNER: Yeah. So I think what you're saying, Justin, is that it's likely that utilization is going to continue to decline as new medications come out, et cetera. So that total costs, you know, if we're looking at total costs for the state, those costs should probably go down for insurance carriers or whoever, just because of fewer numbers of patients.

I don't think we can predict that for sure. It might stabilize because there certainly are people who have been on Genvoya a long time and it works well for them and they like it and they want to stay on it. So I think it's hard to predict, but certainly, we do see a trend overall, but a tendency that as newer medications come out that have advantages, people get switched.

BOARDMEMBER CATHERINE HARSHBARGER: Would I be making a wrong assumption to ask

whether or not if people are on Genvoya, is it because they were potentially resistant to the other drugs available at the time and/or (sound glitch) side effects? I don't know.

CHAIR GAIL MIZNER: Not so much because it's not really, it's not a drug that you -- not one of the ones you turn first when you have a patient with drug resistance. When it first came out, it was very popular, which like I say, has worked well for some people, but other people had reasons to switch.

BOARDMEMBER CATHERINE HARSHBARGER: Okay, thank you.

BOARDMEMBER AMY GUTIERREZ: And, Lila, are you going to go after Table H1, which talks about out-of-pocket costs, because I was looking at because 90 percent of the out-of-pocket costs are under $50, at least from the survey of 22 patients you did. But you may already be presenting that later.

LILA CUMMINGS: I believe that's one of the slides or we can go to the report.

BOARDMEMBER CATHERINE HARSHBARGER: We can go to that part, yeah.

LILA CUMMINGS: Okay, we'll keep moving

along. Here is information in terms of a month, what was paid in a month. But again, note that this out-of-pocket costs for the month does not take into account SDAP funding.

Okay, we will keep moving on but can always come back.

So again, put a different way -- and we will get into this when we're getting into kind of patient and caregiver input, as well as individuals with scientific and medical training -- financial effects input. But again, this is information from the claims database around co-insurance deductible and copayment amounts and total out-of-pocket costs, but does not include SDAP or any other assistance program but specifically calling that one out.

BOARDMEMBER CATHERINE HARSHBARGER: That's where the patient data becomes so important to what they say is going on for them, meaning the patient's feedback. I'm sorry, I said that kind of wrong, patient's feedback.

CHAIR GAIL MIZNER: So the general gestalt of this for me is that there's not a big rise in out-of-pocket costs over the last few years.

BOARDMEMBER CATHERINE HARSHBARGER: Correct.

LILA CUMMINGS: Okay, next slide. So we've got here health effects, this is from Appendix D, so we have done some summarization here. There was one indication, so it was a little more concise, but also encourage you, Appendix D, H, I, and J are where the vast majority of these slides information come from. And again, we have linked to the Zoom for the public meeting for Genvoya with patients and caregivers, as well as their survey responses.

I'm noticing a typo on here, so apologies for that. I think the top line, apologies, that is Enbrel, but I think that was just something that wasn't deleted, that top area.

So moving on to health effects for patients and caregivers. The majority of patients aid their treatment goal was to remain undetectable and achieve overall physical health. They spoke to the importance of whole person wellness, in addition to medical outcomes. And they discussed the differences in Genvoya and other drugs under review, namely that Genvoya

treats a communicable disease and interruptions in treatment could lead to worries of a broader public health issue.

For health effects, I'm not going to read through this necessarily. I'll just leave it up there for folks to take a look at.

CHAIR GAIL MIZNER: Any questions on that, comments? I think we can move on.

LILA CUMMINGS: Okay. All right, so here is a summary of the health effects of Genvoya. It is both from -- we surveyed six different or reviewed six different health technology assessment organizations. We also noted if (sound glitch) was used in Appendix D, but here's the summary from both Canada and Germany.

I will note here that something we kind of consistently found in review was sometimes there are head-to-head studies with different drugs, but then kind of frequently, there were -- it was a comparison to a placebo. But those are cited, so you can investigate as you see fit.

CHAIR GAIL MIZNER: So really HIV drug studies are not done in comparison to placebo because that would be immoral; they're compared

to other drugs and that's just the way it has to be.

LILA CUMMINGS: And I think I just transcribed what I meant to say in my previous statement. Sorry, yes, apologies. Thank you.

BOARDMEMBER CATHERINE HARSHBARGER: The one thing to remember in all of this is the health effects, it seems like some of them are the norms for people if they're going to get it: diarrhea, nausea, things that you can get treated for, for the side effects if you wanted to. The one thing that's different about Genvoya is the effect it has on -- I don't know whether it's liver or just on the fact that you can't have a statin if you needed it.

CHAIR GAIL MIZNER: It's the drug interaction with the statin. It's complicated.

BOARDMEMBER CATHERINE HARSHBARGER: I'll trust you on that.

LILA CUMMINGS: I think Chair Mizner, correct me if I'm wrong, that is what we pulled up from the cited clinical guidelines into the body of the report.

BOARDMEMBER CATHERINE HARSHBARGER: Thank you.

LILA CUMMINGS: All right, so here's some information on financial effects. And again, all of this is in the appendices, so the information from surveys regarding the financial effects of the drug. Also, we've pulled some information from individuals with scientific and medical training appendix where they've provided information from their experiences on patient's ability to afford Genvoya.

BOARDMEMBER CATHERINE HARSHBARGER: I sit and ask myself the question about the 4 out of 22 or 18 percent, that the medication reduces the amount of time. Oh, wait, I'm talking about due to the cost of this medication, they cut costs in other areas.

And so, it makes me wonder if those are people that are on insurance, for one, and secondly, do they not know about other program because there's so many programs out there. I don't know that answer, or maybe they don't qualify for them. So even if they -- I don't know what that is, but at least 18 percent of the people have some impact relative to having to cut costs in their lives to afford the medication.

LILA CUMMINGS: And something I will

add to say here that feedback we received that we did discuss in December but we'll reiterate is, we received feedback from a number of organizations that are patient kind of focused organizations for people living with HIV. And we heard that because of the historical and current stigma associated with HIV, that there were some concerns about responding to surveys, and so that is something we've heard.

And I will note too that, you know, and we reopened the surveys at your direction in January, where we received a tremendous amount for other drugs. I will say for Genvoya, we did not receive any additional responses.

BOARDMEMBER CATHERINE HARSHBARGER: Which also makes me wonder how concerned they are about it. I don't know that answer exactly. I think the stigma definitely is part of the issue. People just don't want to be associated necessarily, have people associate them with their health issue in this case.

BOARDMEMBER AMY GUTIERREZ: For the second bullet under there, Lila, where it says some participants highlighted IQVIA lab data. I'm not sure IQVIA has lab data. It's probably

more -- they're looking at qualities and affordability. Do we validate that, that 85 percent of people have a copay of less than or equal to $5.00?

LILA CUMMINGS: We did not. So any voluntarily submitted information, we did not do an independent assessment of. And I will note that IQVIA is a clearinghouse that also does analytics, including claims-based analytics that, to our understanding, is based on claims data they receive from a number of organizations, but not state All Payer Claims Databases. So no, we did not; that's not something that we validated.

BOARDMEMBER CATHERINE HARSHBARGER: But this is from one of our scientific or medical trained people.

LILA CUMMINGS: Something that they provided, yup. And I believe this one in particular was the manufacturer who had individuals with scientific and medical training present at meetings.

BOARDMEMBER JAMES JUSTIN VANDENBERG: And didn't they just change this year. Sorry, this is bullet three, I'm jumping to the next one. I thought they got rid of copays for

Medicaid patients.

LILA CUMMINGS: Yes.

BOARDMEMBER JAMES JUSTIN VANDENBERG: So that line is probably outdated.

LILA CUMMINGS: So for particular, and we'll touch on that in a little -- I believe it's on this slide; if it's not, we'll touch on it. Yes, for individuals covered by -- who are insured through commercial insurances regulated by the State of Colorado, there is new legislation that prevents copays for any HIV medication.

BOARDMEMBER CATHERINE HARSHBARGER: Can anybody tell me, because I don't know what it is now, what's the federal poverty level this year; does anybody know?

LILA CUMMINGS: The information on who qualifies is in Appendix F for 2024.

BOARDMEMBER CATHERINE HARSHBARGER: Okay, thank you. I don't remember seeing it.

LILA CUMMINGS: I've got a lot of tabs open.

BOARDMEMBER CATHERINE HARSHBARGER: That's okay. I can look at it.

LILA CUMMINGS: I'd be happy to share

my screen if you would like.

CHAIR GAIL MIZNER: Just want to clarify for people too that the ADAP coverage includes undocumented, uninsured people, and this is very important from a public health standpoint. You don't want people uninsured because -- I mean, untreated because they can then transmit the virus; whereas, somebody who's well treated with an undetectable viral load will not transmit the virus.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, that's a social issue for sure.

CHAIR GAIL MIZNER: And I have no patients for whom I cannot get antiretroviral medication because of that excellent ADAP coverage and the excellent work of the Ryan White programs.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah.

LILA CUMMINGS: I think we can move on to the next slide. All right, so there was just one organization that had done kind of a summary of the financial effectiveness of Genvoya.

I will note, and we've noted this, that, you know, no assessment was done on

comparing the price Canada pays or the average reimbursement to Colorado-specific data. So for Canada, you'll see here that they said that Genvoya is similar in costs or less costly than other single tablet or commonly used treatment regiments for adolescents and adults in Canada.

Okay, we can keep moving.

All right, so moving on to the access to care profile. You've seen these appendices, you've seen the description, so we can keep moving.

All right, so here is the graphic that shows change in WAC versus change in annual inflation. And apologies, I think we've -- Google Drive shut down on us this morning, so we had some issues with saving some of the text properly. And so, you'll see there that is right, but on a previous slide, it was not, so this is good for Genvoya.

CHAIR GAIL MIZNER: Any comment on that?

BOARDMEMBER CATHERINE HARSHBARGER: No.

BOARDMEMBER JAMES JUSTIN VANDENBERG: No.

LILA CUMMINGS: The similar graphic to

what you've seen in the report. We have change in patient count, change in total paid, average paid for person, total patient, then average out-of-pocket costs.

Okay. Any discussion here?

BOARDMEMBER CATHERINE HARSHBARGER: Well, the graph does show us from 2018 to 2022, it's become I guess less costly for individuals, you know, the Colorado consumer, as well as just in general, the cost has gone down.

CHAIR GAIL MIZNER: Well, the total paid has gone down, but the number of patients using it has gone down.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, sorry. Yeah, there's a correlation, sorry.

CHAIR GAIL MIZNER: So I'm still sort of a little bit alarmed by that out-of-pocket cost, but I also think that with this particular medication, we know that, whereas unlike with some other medications where you simply -- it's hard to know if there are patients who need it and just simply aren't accessing it at all.

With this, because of the robustness of the ADAP program with possibly a few exceptions of patients who are afraid to -- have so much

stigma that they're afraid to approach the program or enter into care that people who need a drug are getting it.

Dr. Rome, what did you want to...

DR. BEN ROME: I was just going to add one more thing, Gail, just as you're thinking about that number. It includes copayments, coinsurance, and deductibles. So, you know, many patients do pay a deductible of a few hundred dollars at the beginning of the year. And if the person who has HIV but no other medical conditions, you know, the deductible will probably go towards Genvoya if that's the medicine they're using, and so, that also is counted here.

So just as you're sort of conceptualizing this number, that's another maybe reason why it might be a little higher than you were expecting because patients may not see that as a cost, you know, as a specific barrier to Genvoya. And obviously, the benefit design is such that it isn't, but if that's their only drug or their most expensive drug, it'll probably get applied.

CHAIR GAIL MIZNER: Right. Thank you.

BOARDMEMBER AMY GUTIERREZ: I think they key is too that 500 percent federal poverty level. Anyone above that will not apply.

CHAIR GAIL MIZNER: Right. That's a pretty generous amount, though, that it is 500 percent above federal poverty level is inclusive of quite a few people probably.

BOARDMEMBER AMY GUTIERREZ: I think I'm just looking it up, Cathy. I think it was 15,060 in 2023 FPL.

BOARDMEMBER CATHERINE HARSHBARGER: Right, thank you.

LILA CUMMINGS: And I would just note too that we don't have it on a slide, but in the summary report, particularly I believe it's Page -- or it begins on Page 25, there is information on monthly utilization for Genvoya's therapeutic alternatives. There's information for monthly total paid and average total paid.

And then there's also information from the survey responses, acknowledging that there were only 22 survey responses regarding patient self-reported out-of-pocket costs and any concerns with costs affecting access. And all patients reports that their out-of-pocket cost

per month was zero to 50 or 50 to 100.

And then there's also information on cost effectiveness on access where the majority said that cost did not affect access, and that's Table 12 in the summary report.

CHAIR GAIL MIZNER: I'm at the F-3, which is the Colorado State Drug Assistance Program income eligibility chart. So for a single person family size of one, 500 percent of federal poverty level is $75,300.

BOARDMEMBER CATHERINE HARSHBARGER: Oh, my math is right; that's what I calculated.

CHAIR GAIL MIZNER: And it goes up if you have more in your family. Can we move on?

LILA CUMMINGS: Yup, we sure can. So patients, caregivers, and clinicians provided input that treatment for HIV may be received at a clinical provider's office who receives funding from the Ryan White HIV/AIDS Program and that many, if not all, of these clinics are registered as covered entities.

I would say here that in the Appendix F where we list the different covered entity types, some of the clinics or one of the -- some of the covered entity types are specifically Ryan White

clinics or Ryan White adjacent. So that information, while we didn't do an assessment of was there utilization or couldn't do an assessment of was there utilization of Genvoya at those clinics, I think just due to the nature of there's a specific category for these providers under covered entities in the 340B programs is notable.

Individuals also provided input that these clinics receive funding in a number of programs, including SDAP, to lower the cost of prescription drugs. I won't read this. You've already talked about it and discussed the specific levels.

But then do also want to note, and Dr. VanderBerg, you mentioned this, so Colorado Senate Bill 23-189 requires Medicaid and state regulated commercial plans that cover health services related to STIs to include coverage for HIV prevention drugs or cover HIV treatment like Genvoya without step therapy or prior authorization requirements.

Additionally, at the federal level, Medicare requires Part D plan sponsors to include on their formulary all drugs in six categories,

including antiretrovirals like Genvoya, and they may not be subject to prior authorizations or step therapy requirements.

BOARDMEMBER CATHERINE HARSHBARGER: But probably would be subject to, like for Medicare, their copays and things like that -- not copays, their deductibles, right? Well, they can go to those programs as well, the Ryan White programs, state programs.

LILA CUMMINGS: And then here are the survey responses regarding utilization management and requirements from patients and caregivers.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Amy, do you think the second-to-last one is probably on there only offers 30-days. Was it my understanding a lot of that has to do with compliance and putting this into almost the specialty bucket because of the high cost? So they want to make sure there's adherence so they're not just going to give a three-month supply, and so they want to have a tighter check in, I think was my understanding on there. Not saying it's right. I'm just -- but I believe that's the rationale behind that.

CHAIR GAIL MIZNER: It's pretty common.

I'm almost surprised it's not higher than that.

BOARDMEMBER AMY GUTIERREZ: I agree. I think it's just -- that way, you at least don't wait three months to find out they're not taking their medication and you don't intervene, but I agree.

LILA CUMMINGS: I believe this is the last slide, so I'll pause here. And anything on the slides or in the report, right, the slides kind of touch on most areas. But if there's anything you'd like to discuss from the report through the appendices, I'm happy to do that.

BOARDMEMBER AMY GUTIERREZ: Lila, the report was well done.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah.

LILA CUMMINGS: Okay. Then with that, I believe we can move on.

CHAIR GAIL MIZNER: Okay. Any more comments before we move on then to public comment? Any more comments from the Board or deliberations from the Board?

BOARDMEMBER JAMES JUSTIN VANDENBERG: Can't think of...

CHAIR GAIL MIZNER: Great. Then we

will now take public comment regarding Board deliberations on Genvoya only. Callie will put the sign up form in the chat and we will take comments from up to 10 people today and each speaker will be given two minutes to speak. As a reminder, this period of public comment is limited only to comments related to the Board's deliberations on Genvoya. A time for general public comment will be available at the end of the meeting.

CALLIE ANN SHELTON: The link is in the chat. I have a few people signed up already, and we'll start with Jen Laws.

JEN LAWS: Thank you, dear. I hope your throat is doing all right. I'm going through the same thing.

I'm Jen Laws, President and CEO of Community and Access National Network. We participated in small group meetings and really tried to participate throughout this process. We're a 27-year-old national patient advocacy organization focused on HIV, Hepatitis C, and substance use disorder.

I, myself, am a transgender man living with HIV, so this particular issue was very, very

important as we engaged on this, including working with local partners over at CORA and a Colorado-based HIV patient advocacy organization as well.

I do want to clarify a point that might have been a little confusing for folks listening when Lila was going over the first part of this, saying that patients have sometimes run into issues around prescription medications for HIV. That is a historical health equity point because prior to the ACA, our drugs weren't covered, payers weren't required to do so, and we were adamantly discriminated against. It's the entire point of the AIDS Drug Assistance Program.

So that health equity and access piece around medication influences a lot of what you hear from patients around medication access and HIV. A lot of us have been dealing with this for a very, very long time before these protections were made available, and so we're facing what we're facing right now.

I do want to respond to what Dr. Rome had to say about not seeing it because of the deductible and everything else. I'm going to keep myself well behaved right now. The SDAP

actually helps with premiums and deductibles, not just as out-of-pocket costs, so that's a huge piece on this.

And I think this is the most important part of when we talk about system costs, not just that individual cost, because I'm going to tell you right now there are not patients in Colorado that meaningfully have an issue accessing Genvoya based on cost. We deal with those things, and we deal with those things nationally because HIV is a public health issue.

So to that end, with regard to 340B-based programs or 340B-covered entities, including Ryan White Clinics and the AIDS Drug Assistance Program itself and certain hospitals, what a UPL would do there is not reduce the ability for that entity to access the discounted cost, but will reduce the value of the rebates in which those entities are able to reinvest in their communities.

A UPL will dramatically increase issues of health disparities because it reduces those income availability, that program revenue availability to reinvest in communities. If UPL is instituted on any drug on an ADAP formulary,

what you are going to have as a result is a reduced ability for that program to serve people in need, and when that comes to the ADAP specifically, you are talking about your priority population too. You're talking about people living with HIV in marginalized communities, people who are impoverished. It is hard. This is a complicated process.

I believe in good faith that everyone here is trying to make sure that there is equitable access to care, not just poor people living with HIV, but across the spectrum and this is complicated. It is my sincere desire that as you approach legislative report back, that what you tell the legislature, so UPL is not the right tool for the job.

Thank you. Thank you, Callie. I know I went a little over.

CALLIE ANN SHELTON: Hey, Jen, I hope you get to feeling better. Natalie Rose. Natalie, you're muted.

NATALIE ROSE: Good gracious, that mute button. Thank you for letting me know.

My name is Natalie Rose. I am speaking as a medical value and evidence liaison with

Gilead Sciences. I respectfully ask that the committee protect all HIV medications, not deem them unaffordable, or place an upper payment limit on them, including Genvoya.

The draft report affirms that Coloradans with HIV have robust and affordable access to Genvoya. In its review of payer data and input from patients from stakeholders, the report included many examples of how Genvoya is affordable to Coloradans with HIV across all payer types with a significant portion of patients with low or even zero copays. We also appreciate that the report acknowledges the combined role of both federal and state safety net programs to assist with access to medications.

The affordability of Genvoya is further underscored by its low abandonment rates. Whereas, patient affordability or non-adherence may be an indication of patient affordability issues, the report found that three or fewer respondents to the patient survey indicated that the cost of Genvoya has ever affected adherence. This finding comports with our understanding that the abandonment rate for Genvoya is 50 percent

lower than rates seen across other specialty drug classes in 2022.

Furthermore, the further affirms Genvoya is accessible. The report found that of the 10 carriers in the market, all 10 carriers covered this medication with unrestricted access, and the majority of carriers placed Genvoya on the middle-to-lower tier, meaning a lower portion of the drug is paid by patients.

Lastly, the report includes many quotes from respondents who attest to the wide availability of assistance programs, and an overwhelming majority of patients surveyed reported using an assistance program. As affirmed here by the data presented in the Board's affordability report, Genvoya is affordable and accessible. Colorado can do its part to end the HIV epidemic.

I respectfully ask that the Board not find any HIV medication, specifically Genvoya, unaffordable and not set an upper payment limit within the HIV class. Thank you so much for your time today. I appreciate it.

CALLIE ANN SHELTON: Thank you, Natalie. Mark Thrun.

MARK THRUN: My name is Mark Thrun. I work with Natalie at Gilead Sciences. I direct HIV strategy at the present moment for the United States, but I'm a Coloradan. I am a public health infectious disease doc who's had 24 years of experience providing HIV care in Colorado. I used to direct the Sexual Health HIV Prevention Services at Denver Health, long time advisor to CDPHE, HCFA, and CDC mostly on matters related to sexual health and HIV.

And I wanted to touch on a couple of the things that you all have already brought up, and that is stigma and the importance of continuity of care. As was shown in the affordability reports, HIV is increasingly being diagnosed in persons who might also have challenges accessing and persisting in care, including disproportional new infections in Black, Latino, and MSM populations.

As you all noted, 60 percent of people on Genvoya are in counties that have an above average social vulnerability score. There remain significant challenges to accessing ongoing HIV care in a state in which most of the providers -- Dr. Mizner, you excepted -- are actually in the

front range.

Stigma is incredibly important as well, as you've just heard from Jen. HIV not only impacts those who are in marginalized communities, but HIV itself is a marginalizing disease. Many people living with HIV have not disclosed to their family and friends, they're reticent to seek care in HIV-specific settings, they're anxious as they go to Quest and LabCorp that somebody might mention it out loud, and they're reticent to go to a pharmacy to pick it up and to have the pharmacist mention the medication aloud. It's difficult for these folks to remain meaningfully engaged in care, and any potential disruption of care can be harmful.

The same stigma, as you've already talked about, likely played an impact in the number of respondents on the survey. On the website, it said that you all could not guarantee anonymity to the survey and certainly, I suspect that played a role in the few number of respondents.

Finally, as a public health doc, I really have to mention -- that I would be remiss in not mentioning, I should say, the need for

continuity of care. If someone stops their HIV medications, their viral load becomes detectable, then they can transmit virus; whereas, if they remain on their medications continuously and their virus is undetectable, there's zero likelihood of forward transmission to other Coloradans.

For all these reasons, we at Gilead support those in the community who have advocated for treatment choice, allowing a patient and provider to opt for the treatment regimen that works best for them and allows for them to remain on it without interruption. We at Gilead remain committed with all of you, based on your comments, to ending the epidemic for everyone everywhere, and we believe that access to appropriate tailored treatment regimens is central to that.

Thank you for the opportunity to speak. Thank you, Lila, for opportunities previously to share our insights with you.

CALLIE ANN SHELTON: Thank you, Mark. Christopher Zivalich, please.

CHRISTOPHER ZIVALICH: Hello there, hi. Thank you for letting me make comments today. My

name is Chris Zivalich, I use he and his pronouns, and I'm speaking to you today as a community member with extensive experience in HIV treatment and prevention, including my role as a volunteer co-chair for 5280 Fastrack Cities, a local HIV coalition.

I want to stress that placing an upper payment limit on Genvoya would render it less accessible, which puts a person living with HIV's ability to self-direct their own care at risk. As we've mentioned, 60 percent of people living with HIV taking Genvoya live in a county with high social vulnerability. My interpretation of that is that many people taking this drug are dealing with overlapping inequities and social determinants to health. So making something that is stable in their life like Genvoya less accessible could impact them more disproportionately than a person living with HIV in a less vulnerable county.

Also being on a medication that really works for someone living with HIV helps them maintain their adherence and ultimately achieve an undetectable viral load, which does eliminate the possibility of HIV transmission, so this

really is a public health matter.

And I want to emphasize that a person's HIV medication should always be the byproduct of a shared decision-making process between the provider and the patient.

I'd also like to emphasize, just as someone who's enrolled people in the past in a lot of these programs, that yes, Genvoya is eligible for copay support, usually with or without income limits; that will cover the entire cost of the drug, so it will not place an affordability burden on nearly all patients. However, the burden of being forced to a new drug, that could be a significant interruption. So while therapeutic alternatives exist, that switch really being forced on someone could be pretty distressing and destabilizing and it's very different when they choose to do that.

So I hope with this information you'll recognize how Genvoya access is critical and that decisions on this should really always center, first and foremost, the autonomy of the person living with HIV so they, you know, decide for themselves in consultation with their doctor or provider which drug is currently meeting their

care needs.

Thank you so much for the opportunity to speak today.

CALLIE ANN SHELTON: Thank you, Christopher. Sorry I did such a bad job pronouncing your last name.

CHRISTOPHER ZIVALICH: That's okay, I'm used to that.

CALLIE ANN SHELTON: Michael Deroche please.

MICHAEL DEROCHE: Thank you for letting me speak today. I'm a person who's living with HIV for 37 years, I believe. I can't most of the drugs because even though I'm always adherent with my medications, it's a smart little bugger virus.

I really think that HIV should not be one of the disease categories for this program. I think it's great what you're doing, but I just think that you need to be hands off of HIV. You know, a lot of drugs do help a lot of people in a lot of ways, but this drug is -- HIV drugs are essential to stay alive. If I stop taking my medication, it's just a matter of time until I'm going to get sick and die; it's as simple as

that.

I'm on this crazy regimen. By the way, I just want to correct you. You can take statins. I'm on a statin. I'm not on Genvoya and I'm not on cobicistat, but I'm on Ritonavir, which is the same thing; it's a sensory A inhibitor, which boosts levels of my (sound glitch) producing inhibitor. My prescription for Rosuvastatin is 10 milligrams instead of 20. If I ever go off that drug, I'm going to have to go back to 20 milligrams, so that just isn't really correct. And then I also take it in the middle of the day because I take my Ritonavir with breakfast and with dinner, so I take my (indiscernible) with lunch.

I just think it's really -- you know, first of all, Genvoya is on the way out, it really is; it's an older drug. And I'm a peer educator, I'm involved in the AIDS Treatment Activist Coalition and Treatment Education Net--which is a national organization, and Treatment Education Network, which is a local organization. I'm a peer educator. We provide programs with people with HIV.

You know, people will say, hey, what do

you think of blah, blah, blah, blah. They ask me for advice because they know I stay up on everything. And I say, well, why would you take a drug that has cobicistat in that, which has toxicities and it's not an antiretroviral, why would you take that if you don't have to. You know, I mean, Biktarvy, which is the same manufacturer, is a great option, and really Genvoya is on the way out.

It was interesting how well (indiscernible), which was (indiscernible), is an integrase inhibitor that wasn't even on your comparator list. I just think it's so important. If you need to have an HIV drug on your -- you know, if you need to target one -- you need one HIV drug to target, there's Crofelemer, which was developed for people with HIV that have diarrhea; it's a questionable drug, it's very expensive, but you're not going to die if you don't take it. There's also Egrifta, which is for sub-q hardened belly fat, which I think isn't diagnosed properly, but you know, it's really expensive but it doesn't keep you alive.

I think that's all I have to say. I know I was going to say other things, but you

know how your mind goes whatever. Thank you for this opportunity.

CALLIE ANN SHELTON: Thank you, Michael. Scott Bertani.

SCOTT BERTANI: Hey, thank you again. Hey, I am Scott Bertani and the director of advocacy for Health HIV. I'm the lead for the National Coalition for LGBTQ Health, and a former DG patient myself. And I mention the latter because I'm so glad that Dr. Mark Thrun was on there; in fact, he was my prescribing doc back in the day. And I can't ever remember him saying to my NP, Scott, oh yeah, switch his meds to meet my cost profile needs. It's just a communicable disease. Ignore that there are statutes on the doctors too. Shared clinical decision making just isn't that important.

So from that place, you know, facing challenges long before current protections, we've navigated the evolving landscape of healthcare and particularly in Colorado where HIV treatment access remains largely unimpeded by cost. It's thanks to vital national public health efforts and subsidies and patient programs that erase the premiums and the deductibles.

And the stigma likely contributed to the low response rate in the survey mentioned where anonymity really couldn't be guaranteed, and it highlights the challenges we have in engaging this population in care and research. And the ongoing dialogue, you know, it really underscores the importance of 340B programs and ADAP with a looming threat of UPLs potentially reducing rebate values that's essential for community reinvestment and it not exacerbating health disparities.

My personal journey as an HIV positive individual, it underscores the necessity of maintaining access to treatment so that I could be here today to help speak after Dr. Mark Thrun and emphasize that cost containment measures, they impact patient wellbeing and the healthcare ecosystem. And despite Colorado's healthcare legacy and the Denver principles that are patient centric where autonomy is a focus, the current strategies risk making crucial medications like this inaccessible and it undermines Medicare's protections and all the 340B programs benefits.

So I appreciate the conversations, and it really does call for a broader stakeholder

engagement and a reevaluation of data representation so that our healthcare decisions align with our needs and there are equitable access to treatments. So I appreciate the time, thank you.

CALLIE ANN SHELTON: Thank you, Scott. Dr. Mizner, that is everyone who signed up for Genvoya comments.

CHAIR GAIL MIZNER: Great. Thank you all. Are Board members comfortable moving forward with determining whether Genvoya is unaffordable with the information presented?

BOARDMEMBER CATHERINE HARSHBARGER: Yes.

BOARDMEMBER AMY GUTIERREZ: Yes.

BOARDMEMBER JAMES JUSTIN VANDENBERG: I am.

CHAIR GAIL MIZNER: Good. If there's no further deliberation and having considered the evidence before us relating to each affordability review component, do I have a motion regarding a vote on unaffordability of Genvoya?

BOARDMEMBER AMY GUTIERREZ: I'll make a motion. The use of Genvoya consistent with the labeling approved by the FDA or with standard

medical practice is not unaffordable for Colorado consumers.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Justin VandenBerg, I second that.

CHAIR GAIL MIZNER: Thank you. Dr. Guttierez moved and Dr. VandenBerg seconded that the use of Genvoya consistent with the labeling approved by the FDA or with standard medical practice is not unaffordable for Colorado consumers.

I am going to call for a roll call vote again. Callie, would you please call the names.

CALLIE ANN SHELTON: Of course. Dr. Amy Gutierrez.

BOARDMEMBER AMY GUTIERREZ: Yes.

CALLIE ANN SHELTON: Cathy Harshbarger.

BOARDMEMBER CATHERINE HARSHBARGER: Yes.

CALLIE ANN SHELTON: Dr. Gail Mizner.

CHAIR GAIL MIZNER: Yes.

CALLIE ANN SHELTON: And Dr. Justin VandenBerg.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Yes.

CHAIR GAIL MIZNER: Thank you. Lila,

please finalize the affordability review report for Genvoya by adding a high-level summary of our deliberations today, our determination that use of Genvoya is not unaffordable for Colorado consumers, and correcting any clinical errors you all identify. We will vote to approve the final report at our next meeting.

BOARDMEMBER AMY GUTIERREZ: Can I just say I want to thank all those that stood up and provided public testimony, including those who even disclosed personal details about their own illnesses and such and really thank you for taking the time to provide us with really valuable input from the public, so just a thank-you to you.

CHAIR GAIL MIZNER: So I want to second that.

LILA CUMMINGS: And just something I want to -- and I'll give my kind of closing comments about timing, and then we'll turn it over to public comment.

So the next Board meeting will be next Friday, February 23rd, from 10:00 to 11:00 a.m. is what is scheduled, and there will be kind of a couple of actions that could take place. We will

present kind of these final draft affordability reviews taking into account changes and a summary of your deliberations today and the vote, so for each of the drugs, there will be that.

For Enbrel, you all will also be taking a vote on Friday on whether or not you would like to initiate the rulemaking process for establishing an upper payment limit, so that is a decision that is before you next Friday. And then we will also come with a proposed timeline for what that could look should you all choose to move forward with that.

BOARDMEMBER CATHERINE HARSHBARGER: Lila, I will be -- as I mentioned to you I think before, I will be out of state and I was going to attend via Zoom like we do anyway. I will do my very best to be there at that time. I'll let you know if I have any problems with it, okay?

LILA CUMMINGS: Okay, we'll follow up. Thank you.

BOARDMEMBER CATHERINE HARSHBARGER: Thank you.

LILA CUMMINGS: Okay. So now we'll turn it over to general public comment.

CALLIE ANN SHELTON: A few folks signed

up already, but if anybody else wants to sign up, click the link in the chat. Amy Goodman.

AMY GOODMAN: Thank you. First, I want to say that as the PDAB decides whether to set an upper payment limit on Enbrel since it has deemed it unaffordable, Colorado Bioscience Association continues to stress that government and price controls and caps are the wrong solution for patients. Government price controls will not lower costs for patients and risk serious unintended consequences, including limiting patient and prescriber choice and reducing investments in new medicines.

Also, I would just like to ask a question to clarify the process regarding the small group meetings that have happened with scientific and medical experts. At this time, the current draft affordability review reports do not include links to recordings of staff meetings with scientific and medical experts, and the draft reports also do not include a list of scientific and medical experts with (indiscernible).

What is going to be publicly shared about those meetings, which inform the

affordability review reports. We think these meetings should be made visible to the public, so I hope that we can get more insight into that soon. Thank you.

CALLIE ANN SHELTON: Thank you. Mannat Singh. Mannat, are you still here?

MANNAT SINGH: Hello. Sorry, my microphone was being a little glitchy. Thank you.

My name is Mannat Singh, and I am the executive director of the Colorado Consumer Health Initiative. I use she/her pronouns. As a consumer advocacy organization, it's CCHI's priority to make sure that Coloradans can access the prescription drugs that they need.

The findings today illustrate that the Board's work is very useful and very necessary. We appreciate the Board's care in discussing the complex and nuanced nature of access to Genvoya in Colorado at this time.

We're also encouraged by the designation of Enbrel as unaffordable, particularly the acknowledgement of racial health disparities in discussing affordability. We hope to see an upper payment limit process initiated

for Enbrel so that patients can get the financial relief that they deserve from this high-cost drug.

Upper payment limits are the only tool that Colorado has to address the root causes of the high cost of prescription drugs. PDAB is a really important opportunity to make meaningful policy choices that promote health over profit. CCHI remains optimistic about the Board's potential to create long-overdue accountability as one overall goal, to increase access to the highest (sound drops) drugs in our state. Thank you.

CALLIE ANN SHELTON: Thank you. And lastly, Katelin Lucariello.

KATELIN LUCARIELLO: Good afternoon, now evening, everyone. This is Katelin Lucariello, deputy vice president of state policy with pharma. First of all, thank you, of course, for the opportunity to provide public comment. We really appreciate that at this meeting, you've made time for public comment following deliberations and before votes on affordability.

We'd like to ask that the general comment period be moved to the beginning of your

meetings so that those considerations raised in public comment or questions, like some of those that had been asked this afternoon, can be deliberated or discussed by the Board at the meeting.

We'd also like to ask that the Board include a comment period at every meeting, including their shorter meetings to finalize the affordability reviews. At the meeting on 12/15, the Board did not have public comment and under PDAB's policies and procedures, the Board has said that they'll provide an opportunity for public comment at every meeting. It is really one of the few ways I think that we've seen the impact that stakeholders can really communicate directly with the Board in real time and provide input on deliberations. And so, we would greatly appreciate your consideration of those two suggestions.

Thank you very much and have a great weekend.

CALLIE ANN SHELTON: Thank you, Katelin. And we have one more, Bridget Serrett.

BRIDGET SERRETT: Hello. First, I want to thank you guys for all the work that you are

putting into this. I definitely would not want to be in your situation right now because I know it's a very difficult task to balance affordability and everything that's coming at you.

First, I want to address maybe some problems or some issues that I see with the process. For instance, the upper payment limit doesn't necessarily describe what this is. The PDAB bill was sold and I quote, "This bill is projected to save Coloradans up to 75 percent on the most unaffordable drugs and will pave the way for a more equitable healthcare system that prioritizes the wellbeing of patients over profits for the pharmaceutical industry."

But the more that I am involved with this process, I realize that upper payment limits are reimbursement caps. We have not changed what the manufacturer can charge for the medication, and so that means our specialty pharmacies may not be able to stock it if they can't get reimbursed for what it costs for them to get it and stock it.

So this bill seems to be geared towards shifting the process, rather than giving them

back to actual Coloradans, and I feel like insurance companies and pharmacy benefit managers are going to be the biggest winners in this and that is concerning.

I do want to also bring awareness to the transparency of this. The process is incredibly rushed, and, while I absolutely appreciate you guys reopening the surveys for Enbrel, we weren't given very much notice. And we had two and a half -- you know, we had four or five days to kind of rally everybody in only two and a half weeks for the surveys to be open, and that ultimately is not a long period of time, especially when you're dealing with medically complex community members and this was over a holiday, which made it even more difficult to find people to take part in this.

The data collection, the surveys don't actually prompt the patients to -- they answer questions about affordability and the value of the medication, but it doesn't ask about did you have less hospitalizations, were you able to work more, were you able to get off disability.

LILA CUMMINGS: Bridget, I apologize. We're at the limit on the time.

BRIDGET SERRETT: Oh, okay. Well, thank you very much. You guys have a good weekend.

CALLIE ANN SHELTON: Thank you, Bridget.

CHAIR GAIL MIZNER: Okay. I want to thank everyone for their participation today, staff, my fellow Board members, members of the public, experts. It's been quite an afternoon.

The next PDAB meeting will be held at 10:00 a.m. next Friday, February 23rd. And so, unless there is any objection, the meeting is now adjourned. Thank you all very much.

LILA CUMMINGS: Thank you, Board members, and thank you to members of the public.

BOARDMEMBER CATHERINE HARSHBARGER: Thank you everyone.

CALLIE ANN SHELTON: Lila, you cool if I end it?

LILA CUMMINGS: Yup. Thank you.

CERTIFICATION

I, Sonya Ledanski Hyde, certify that the foregoing transcript is a true and accurate record of the proceedings.

Date: JUNE 1, 2024

Sonya Ledanski Hyde

EXHIBIT B

CORRECTED TRANSCRIPT

Colorado Prescription Drug Affordability Review Board - February 23, 2024 Meeting

BOARD STAFF LILA CUMMINGS: I'm going to shoot the other Board members a message just to see if they're having any tech troubles. One moment.

All right. Just heard from Dr. Diab. He should be able to get in soon. He's having some tech issues with his work computer, and then still working on Ms. Harshbarger. So, Dr. Diab should be here soon.

BOARDMEMBER DR. SAMI DIAB: Sorry I am late.

BOARD STAFF LILA CUMMINGS: Thanks for joining, Doctor.

CHAIR GAIL MIZNER: Lila, do you want -- should we wait for Ms. Harshbarger? Are we...

BOARD STAFF LILA CUMMINGS: I think we can go ahead.

CHAIR GAIL MIZNER: I haven't heard back from her.

BOARD STAFF LILA CUMMINGS: I think we might want to -- I'll keep reaching out to her. We could go out of order on the agenda if we want to try and see if we can get her. Let me keep calling. I'll give her a call again.

CHAIR GAIL MIZNER: Okay.

BOARD STAFF LILA CUMMINGS: So maybe we could wait just a moment. And also, there are some things on the agenda that could go first, if she needs a little bit more time, so let me see where she's at. One moment.

CHAIR GAIL MIZNER: Okay, thanks.

BOARDMEMBER DR. SAMI DIAB: And Madam Chair, I have a patient in the room, so, can I just -- I'm going to leave for five minutes. I'll be right back.

CHAIR GAIL MIZNER: Okay. Thank you, Sami.

BOARDMEMBER DR. SAMI DIAB: Madam Chair, I am back.

CHAIR GAIL MIZNER: Great. Thank you. Lila, should we proceed, and maybe change the order of our agenda? Or do you want to wait a few more minutes for Ms. Harshbarger?

BOARD STAFF LILA CUMMINGS: I was not able to get in touch with her. But I might propose we go a little out of order on the agenda. We can do some of the updates first. And then, Dr. Diab, we might be able to get you in a situation where you can help, potentially, vote where you can, and then you can leave a

little early on some of the things where there's a conflict, so we can work on that.

BOARDMEMBER DR. SAMI DIAB: Sounds good. Thank you.

BOARD STAFF LILA CUMMINGS: So, we will, I think what we can do is, we'll start out with the, actually, last agenda item. So, we'll do the Ad Hoc Work Group Meeting for General Assembly Report, so we can give some background on that and talk about a Board staff suggestion. And then, kind of be going reverse order and talk about the Cosentyx and Stelara and then, but back go Enbrel and Genvoya.

CHAIR GAIL MIZNER: Okay. So, I'm going to call the meeting to order. It is 10:10 AM. And the February 23, PDAB Meeting is called to order. Callie, would you please call the roll?

BOARD STAFF CALLIE ANN SHELTON: Of course. Dr. Sami Diab?

BOARDMEMBER DR. SAMI DIAB: Present.

BOARD STAFF CALLIE ANN SHELTON: Dr. Amy Gutierrez.

BOARDMEMBER AMY GUTIERREZ: Present.

BOARD STAFF CALLIE ANN SHELTON: We are

still waiting on Cathy Harshbarger. Dr. Gail Mizner?

CHAIR GAIL MIZNER: Present.

BOARD STAFF CALLIE ANN SHELTON: And Dr. Justin Vandenberg?

BOARDMEMBER JAMES JUSTIN VANDEBERG: Here.

BOARD STAFF CALLIE ANN SHELTON: Thank you. Madam Chair, we have a quorum.

CHAIR GAIL MIZNER: Thank you, Callie. Okay, Lila, you want to move first to discuss the Ad Hoc Work Group Meeting in preparation for General Assembly Report?

BOARD STAFF LILA CUMMINGS: Yeah, absolutely. And so, Sabrina, if you would scroll to the end of the PowerPoint. There we go. Go back one more. There we go.

So, it's kind of approaching time for the Board's annual General Assembly Report. So, you can see here on the screen that your statute outline said on or before July 1, 2023, and every July 1 thereafter, the Board shall submit a report summarizing the activities of the Board during the preceding calendar year to the Governor, House Health & Insurance Committee, and

Senate Health & Human Services Committee. And so, this report that is coming out July 1 of this year, will summarize your events from 2023, including any work that you all conducted on affordability reviews and upper payment limits.

We've outlined some potential goals here. And really, on the next slide, we'll talk about, I think, what we've heard from Board members as well as from Advisory Council members, of some extra thought that you might want to put into the report. And it wasn't so much around summarizing your activities; it was, there's a section in the statute that says you all can make policy recommendations.

And so, we've put together kind of a potential timeline goal. On the next slide, we'll revisit some of the policy recommendations that you all have brought up in the past, and then just want to open it up to discussion on what Board members think the right cadence is, between now and July 1, for drafting this report.

So, the staff proposal here is that sometime, kind of in early April, we could help facilitate an Ad Hoc Meeting, that would include Board members, Advisory Council members; could

also include members of the public, and a public comment period, to discuss the report contents. I will say we had three members from the Advisory Council volunteer for, if there was an Ad Hoc Work Group created, they volunteered to serve on that. And so, that was -- the Chair, Dr. Kimberly Jackson, Edward Dauer and Nathan Wilkes. So those three Advisory Council members volunteered to help support in this discussion.

Then, if we have that meeting, Ad Hoc meeting in early April, we could then bring to the Board a kind of final draft, still in draft form, of the report contents for your April 26 meeting. And then incorporate any changes you'd like to see for, hopefully, at your June 7 meeting, a kind of finalization of the report. And then we could send that off to the General Assembly.

So, that's the general timeline that we're looking at. And if we could go to the next slide. So, what we anticipate this report and this Ad Hoc Work Group, would really focus on the space. So, there's space in the report for recommendations the Board may have for the General Assembly, concerning legislative and

regulatory policy changes to increase the affordability of prescription drugs, and reduce the effects of excess costs on consumers and commercial health insurance premiums in the state.

The Board had brought up some topics last year that you said you might want to revisit and continue to think through. So, one of these was the role of group purchasing organizations and the supply chain; research into prescription drug costs and indications that may signal a prescription drug is unaffordable. And then potential ways to better understand topics that are typically hard to know. So, prescription drug challenges for the uninsured, impact of utilization management and prior auth on prescription drug access, and prescription drug manufacture assistance programs, advertisement discovered and utilization information.

So, those are some topics from last year. And we anticipate that these work group meetings would focus mainly on this component. Board staff can work to summarize your activities, and absolutely kind of clear that with Board members and make sure we're

summarizing it properly. But in our minds, this Ad Hoc Work Group could really focus on drafting these recommendations. And Board staff would work you all as well, before the April 26 and June 7 meetings, where we could bring kind of final recommendations for discussion. And so I think we can go to the next slide.

So, here we, I'd say, first, I would love to hear from Board members on kind of what, any questions about the General Assembly Report? Do you like this idea of an Ad Hoc Work Group? We've got this slide up here, if you'd like us to kind of go that direction, but we'll pause here for conversation.

CHAIR GAIL MIZNER: What does everyone think?

BOARDMEMBER AMY GUTIERREZ: I think it's a good idea to be able to provide some more directed (indiscernible) on potential areas that we could be looking into, to make sure that our decision is, decisions that we make are as tight as possible. So, I think it's a great idea.

BOARDMEMBER DR. SAMI DIAB: Yeah, Sami here. I second that. I think it's really great for discussion-generating ideas, you know, and

really moving forward. So, I totally support that.

CHAIR GAIL MIZNER: Justin?

BOARDMEMBER JAMES JUSTIN VANDEBERG: No, I like that. I think where I'm thinking is, and maybe I'm putting the cart before the horse as far as how often are they going to meet? Do we have a set number so that it gives them enough time to produce a quality report and not just, you know, we meet one afternoon and that's it. But no, I think it's a great idea to be able to put more time and not thoughtfulness, but I think that time of being able to, you know, create a more robust report on that. I certainly agree.

CHAIR GAIL MIZNER: I agree too. In fact, I think there may be ideas that arise from board members or from PDAAC members that are not even listed by Lila, and that maybe we actually would need more than one meeting to discuss those, Lila. Maybe we should even aim for the first meeting of an Ad Hoc Committee in March. What do you think about that?

BOARD STAFF LILA CUMMINGS: We can build time for that.

CHAIR GAIL MIZNER: Okay.

BOARD STAFF LILA CUMMINGS: And I'm also wondering, and we could check with Dr. Jackson. There is a PDAAC meeting scheduled for April 11. So, I'm also wondering if there might be some synergy, if we've got a March meeting of an Ad Hoc work group, if we kind of -- if there's some piggybacking we could do with the Advisory Council meeting. We can look into that.

CHAIR GAIL MIZNER: Okay. And Lila, do we need to decide now which Board members would be on the Ad Hoc Committee?

BOARD STAFF LILA CUMMINGS: I think that would be the hope, is which one of you would like to volunteer to put extra meetings, to be on the Ad Hoc Committee?

CHAIR GAIL MIZNER: So it can be only one person?

BOARD STAFF LILA CUMMINGS: No, it can be multiple.

CHAIR GAIL MIZNER: Okay. Okay.

BOARDMEMBER DR. SAMI DIAB: Sami here. I'm happy to volunteer, but if anybody else wants to do it or, you know, happy to do that as well.

CHAIR GAIL MIZNER: I'm also interested in being on the Ad Hoc Committee. Justin? Amy?

What are your thoughts?

BOARDMEMBER AMY GUTIERREZ: I'd volunteer too, but is it going to -- can all of us be on it or (indiscernible)?

BOARDMEMBER JAMES JUSTIN VANDEBERG: That's why I was just keeping my mouth shut for a second, because I'm like -- see where it went so that it wasn't, yeah, just turned into a full -- full blown meeting thing.

CHAIR GAIL MIZNER: Right, right.

BOARDMEMBER DR. SAMI DIAB: So, you know, if there's interest, I withdraw my name at this point, if somebody else wants to do it, since there's already a physician on it. That's totally fine.

CHAIR GAIL MIZNER: Okay. Thank you, Sami. All right. So, we need to formally delegate Board members to form an Ad Hoc Work Group to help prepare a draft for the General Assembly. Let me -- so, it's sounding like Dr. Gutierrez and I are the ones who would -- are most keen on being on this Ad Hoc Group. Do I have a motion to delegate Dr. Gutierrez and myself, Dr. Mizner, to form an Ad Hoc Work Group to help prepare a draft General Assembly Report?

BOARDMEMBER DR. SAMI DIAB: I so move.

CHAIR GAIL MIZNER: Thank you. Do I have a second?

BOARDMEMBER JAMES JUSTIN VANDEBERG: Justin Vanderberg, I second.

CHAIR GAIL MIZNER: Okay. Thank you. Dr. Diab move and Dr. Vandenberg seconded. All those in favor of forming an Ad Hoc Work Group to help prepare a draft General Assembly Report, raise your hand and say aye.

BOARDMEMBER DR. SAMI DIAB: Aye.

BOARDMEMBER AMY GUTIERREZ: Aye.

BOARDMEMBER JAMES JUSTIN VANDEBERG: Aye.

BOARD STAFF LILA CUMMINGS: Aye.

CHAIR GAIL MIZNER: Okay. I think that's unanimous, with the exception of Ms. Harshbarger, who's not here. Any opposed, say nay. Okay. The motion passes. So, we will be forming an Ad Hoc Work Group with some members of the PDAAC, and with myself and Dr. Gutierrez as the Board representatives, to help prepare a draft General Assembly Report. Great. Lila, where do we want to go next?

BOARD STAFF LILA CUMMINGS: I think

next we can go Cosentyx and Stelara, though I am, I think there might be kind of an emergency that has taken Ms. Harbarger away, so we'll talk about Cosentyx and Stelara, and then proceed, kind of at the top of the agenda. And it looks like Ms. Harshbarger might not be able to join.

So, (indiscernible), if you could go a couple of slides -- thank you.

Okay, and so here, I do know that we need the brief, Cosentyx and Stelara, the next slide, conflict of interest disclosure.

CHAIR GAIL MIZNER: Okay, so are there any Board members who have a conflict of interest with either Cosentyx or Stelara? Should we do a roll call on that?

BOARD STAFF CALLIE ANN SHELTON: Dr. Diab?

BOARDMEMBER DR. SAMI DIAB: I believe I have conflicts.

BOARD STAFF LILA CUMMINGS: And actually, counsel, would you be able to help Dr. Diab here with, I believe it's just one.

BOARD STAFF SARA STULTZ: Yes, no problem. Dr. Diab, we believe, based on your prior disclosures, you have a conflict of

interest with Cosentyx. Does that still sound...

BOARDMEMBER DR. SAMI DIAB: Yeah, nothing has changed. Thank you for the help.

BOARD STAFF SARA STULTZ: No problem.

BOARD STAFF CALLIE ANN SHELTON: Dr. Gutierrez?

BOARDMEMBER AMY GUTIERREZ: No conflicts.

BOARD STAFF CALLIE ANN SHELTON: Thank you. Dr. Mizner?

CHAIR GAIL MIZNER: No conflicts.

BOARD STAFF CALLIE ANN SHELTON: And Dr. Vandenberg?

BOARDMEMBER JAMES JUSTIN VANDEBERG: No conflicts.

BOARD STAFF LILA CUMMINGS: All right. We can go to the next slide. Okay, so here, and we just want to check with you all to see if there's any objections. I'm not necessarily asking for a formal vote. But we just want to see if there were any objections to us as staff, gathering additional information for Cosentyx and Stelara, in the same way you all directed us to, for Genvoya and Enbrel. And this was due to the kind of lower survey and stakeholder engagement

responses. So, in an effort to gather more input from, so two different groups.

So, first of all, input from individuals with scientific and medical training. So, staff plan to reopen the surveys for individuals with scientific and medical training for probably two to three weeks, as well as outreach to physicians and pharmacists who are actively prescribing and dispensing Cosentyx and Stelara, for additional information on the health and financial benefits of the drug. So, we'll plan on doing that, unless there's any concern. And then, for input from patients and caregivers, we do plan to reopen the survey for the same amount of time as the other surveys, to gather additional input.

BOARDMEMBER AMY GUTIERREZ: Can I ask a question? I know, in some of the comments, public comments that we got, there was a question about conflict of interest with professionals that are providing us survey responses. Are we planning on having individuals disclose those when they do provide us with responses?

BOARD STAFF LILA CUMMINGS: That's a -- we can look into that. It's something where, in

policy documents, we encourage people to disclose. But there's not a requirement that individuals disclose. And because we haven't required that disclosure previously, I think we might have some hesitancy to do it now. But there is this general, we encourage folks to disclose. But that is something we could talk about.

BOARDMEMBER AMY GUTIERREZ: Okay. Thank you.

CHAIR GAIL MIZNER: Yeah, I agree with you. Amy, I think that's important to know. And you know, this -- what we're doing here is a process, and we are trying to constantly improve it. So, I would encourage us to require disclosure on the part of medical professionals about any connection to the manufacturer.

I also realize that we have gotten some public comment and feedback regarding the surveys themselves. And I wonder whether we would want to -- I know we've had expertise already, in developing the surveys, but I wonder whether we should take a second look; maybe get an outside survey expert, if we can find the funds for that, to just review before we send out those surveys,

to make sure that they are as well developed as possible, given the feedback that we've gotten. I'm not saying the feedback is necessarily correct, but I do think we should get somebody with real expertise to take a second look at that.

BOARD STAFF LILA CUMMINGS: Okay, okay. Something we can do -- I think we're just mindful of wanting to have the surveys open for a number of weeks, with enough time to take the results to present. But I think that if we -- we can look into both the conflict-of-interest disclosure requirement, as well as kind of the -- somebody looking at the surveys for potential edits. And what we will do is we can get back to you with answer on that for your next meeting; which means that the surveys would not reopen till after March 15. But we can look at that in an effort to try and get answers to those questions. And then, when you all are ready, we might be able to kind of open the immediately after March 15, because we want to ensure we can leave the open while still having time to interpret the results. So, we'll plan on gathering some of that information for March 15.

CHAIR GAIL MIZNER: Great.

BOARD STAFF LILA CUMMINGS: Any other discussion about the surveys or gathering additional input? Great. Well, then I think -- Chair, I think we can probably move to the top of the agenda. It does look like Ms. Harshbarger will not be able to join us today.

CHAIR GAIL MIZNER: Okay. That's too bad. All right. Before we vote on the final versions of the affordability review reports for Enbrel and Genvoya -- actually, should we -- I know there's some -- I would like to hold an executive session for legal advice on public comments that we've received on Enbrel. Do we, should we do this conflicts of interest first, or should we go straight into voting about whether to do an executive session?

BOARD STAFF LILA CUMMINGS: Sara?

BOARD STAFF SARA STULTZ: Sure. We should just go ahead and do the conflicts, and then we can do executive session. Again, Dr. Diab can still vote us into executive session, but if he has a conflict with one of the drugs, Enbrel, then he won't be able to go into the session with us.

CHAIR GAIL MIZNER: Okay, great. Thank you, Sara. So, I would like to move to, that we move into executive session to receive legal advice on public comments received on Enbrel, pursuant to section 24-6-402(3)(a)(III), CRS. Do I have a second?

BOARDMEMBER AMY GUTIERREZ: I'll second, thank you.

CHAIR GAIL MIZNER: Thank you, Dr. Gutierrez. So, I, Dr. Mizer moved, and Dr. Gutierrez seconded, that we move into executive session to receive legal advice on public comments received on Enbrel. All those in favor, please raise your hand and say aye. Aye.

BOARDMEMBER AMY GUTIERREZ: Aye.

BOARDMEMBER JAMES JUSTIN VANDEBERG: Aye.

CHAIR GAIL MIZNER: I think I heard Dr. Gutierrez and Dr. Vandenberg. I'm not sure if Dr. Diab --

BOARDMEMBER DR. SAMI DIAB: Aye.

CHAIR GAIL MIZNER: Okay, thank you. The motion passes. The Board will convene in executive session. The public is now excused.

[EXECUTIVE SESSION / NOT RECORDED]

CHAIR GAIL MIZNER: Okay, the Board has adjourned its executive session. The Board received legal advice regarding public comments received relating to Enbrel. The Board conducted no formal business within the meeting.

And so, let's go back up our agenda. So, next on the agenda would be to adopt the affordability review report for Enbrel. Before we vote, I'd like to note that all Board members were present at the February 16 meeting, when the Board voted that use of Enbrel is unaffordable for Colorado consumers. To ensure that all Board members have had the opportunity to review the summary of deliberations and changes made by staff from the draft report, I'd like to ask if any Board member has objections to moving forward with approval of the final report? None. Okay. Do I have a motion to adopt the final Affordability Review Report for Enbrel, with the changes as discussed?

BOARDMEMBER AMY GUTIERREZ: So moved.

BOARDMEMBER JAMES JUSTIN VANDEBERG: This is Justin Vanderberg. I second.

CHAIR GAIL MIZNER: Thank you. Dr. Gutierrez moved and Dr. Vandenberg seconded. All

those in favor of adopting the final Affordability Review Report for Enbrel raise your hand and say aye.

BOARDMEMBER AMY GUTIERREZ: Aye.

CHAIR GAIL MIZNER: Aye.

BOARDMEMBER JAMES JUSTIN VANDEBERG: Aye.

CHAIR GAIL MIZNER: That was the three of us. All opposed say nay. The motion passes. Staff, please publish a clean version of the report.

We will now take public comment regarding whether to select Enbrel for establishment of an Upper Payment Limit. Callie will put the sign-up form in the chat. We will take comments from 10 people today. And each speaker will be given two minutes to speak, only two minutes please. So, say exactly what you need to say.

As a reminder, this period of public comment is limited only to comments related to whether Enbrel should be selected for establishment of (indiscernible). Okay, Callie, I'm going to let you call the roll. Or I mean, open the public discussion.

BOARD STAFF LILA CUMMINGS: Before Callie does that, I just want to check. I know we're approaching time, and I assume that Board members are okay if we run a little bit long, to allow for public comment in the remainder of your potential votes. Okay. Thank you. Okay, back to you, Callie.

BOARD STAFF CALLIE ANN SHELTON: First up we have Tiffany Westrich-Robertson.

TIFFANY WESTRICH-ROBERTSON: Hi. Can I go ahead and start?

BOARD STAFF CALLIE ANN SHELTON: Please.

TIFFANY WESTRICH-ROBERTSON: Okay. First of all, I just want to thank the Board and Callie and Lila, for this opportunity to give public comment. My name is Tiffany Westrich-Robertson. I am a patient living with autoimmune arthritis disease, and a person who couldn't use Enbrel. I'm also with the International Foundation for Autoimmune & Autoinflammatory Arthritis, or AiArthritis, representing the 3,400-plus patients in Colorado using Enbrel.

I just wanted to first mention that we are the organization that submitted several

reports. I have approximately 40 pages identifying flaws in the survey and listening session question design. And we do appreciate that that has been recognized. We did, some of the highlights of that is during the affordability deliberation that the Board did view total numbers of the respondents of the 38; actually 50 percent were on Medicare and Medicaid, which significantly impacted the results, because they were all analyzed together. I wanted to mention that nine of the 17, the 53 respondents who reported that zero of 50 of out of pocket was too expensive for Enbrel.

I want to make sure that it's clear that as far as the UPL, that it is known that the Colorado PDAB Upper Payment Limit Policy and Procedures, document section 10-16-1407 CRS, states that Medicare and Medicare programs are not subject to the policies of the Board, including a policy applying a UPL limit. Therefore, half of the data that was analyzed is being used to date to judge for that.

AiArthritis urgers the Board to vote against a UPL for Enbrel. We believe a restriction will only benefit payers and will not

address any of the affordability expressed by patients in Colorado. For those who Enbrel works for, they should not lose access to it. For those who are responding, it should be up to the patient and their rheumatologist to decide to switch or not to switch to a drug.

Again, I wanted to thank you for this opportunity, and in knowing that information needs to render the unaffordability decision is incorrect, or at least potentially incorrect, moving forward, voting in favor of our UPL would be premature.

Finally, I want to give public kudos to Callie and Lila who have been absolutely amazing in this process. Thank you.

BOARD STAFF CALLIE ANN SHELTON: Thank you, Tiffany. Brett Johnson, please.

BRETT JOHSNON: Thank you. Can you see and hear me?

BOARD STAFF CALLIE ANN SHELTON: We can, Brett.

BRETT JOHNSON: Okay. Yes, Brett Johnson with Amgen. And I'm here to say that we're here to urge your no vote on proceeding with the UPL. Considering the very real

potential consequences to patients and providers who are concerned with the notion that you must vote to pursue an Upper Payment Limit, in order for us to understand what that might actually look like in Colorado. For instance, there's been discussion of methodology on how a UPL will be developed, and no discussion of the scope of application to the supply chain, among many other fundamental aspects of a UPL policy. We should have answers to these fundamental questions before voting to move forward on such a policy. Again, the prospect of not doing so could be very real unintended consequences for patients and provides in Colorado. And this is not just a concern for Amgen. These concerns have been shared by others in the patient and provider communities.

Based on what little we do know about the intent for a UPL, we fail to see how this will actually improve out-of-pocket affordability for patients. And the focus really should be about what patients are paying out of pocket. For instance, we know those that pointed out and submitted comments that substantial issues with the patient survey process and the instrument

itself, and the cost-sharing figures discussed by the Board, and in the report, did not account for assistance being provided to patients to reduce out-of-pocket cost. As we've noted previously, every eligible Coloradan, nearly 2,000 of whom applied for copay card assistance last year were approved. And more broadly, the Amgen Patient Safety Net Foundation provided $2.5 billion in medicines last year, to the uninsured and those experiencing Part D affordability gaps; for roughly two-thirds of Enbrel prescriptions to those with commercial coverage, including those for whom a co-pay card was used, patients ultimately paid $10 or less per month, and only 14 percent of those prescriptions cost more than $100 per month.

Patients, instead, need reforms that help lower the price patients pay for medicines, such as making monthly costs more predictable, ensuring cost-sharing assistance is applied to a plan's out-of-pocket spending requirements, and sharing the negotiated savings on medicines with patients at the pharmacy counter. We're here to help you and other policymakers work through what these reforms might look like.

BOARD STAFF CALLIE ANN SHELTON: We're at two minutes. Apologies.

BRETT JOHNSON: Okay. And we believe that process starts here with a no vote. Thank you.

BOARD STAFF CALLIE ANN SHELTON: Thank you, Brett. Corey Greenblatt.

COREY GREENBLATT: Hello everyone. Can you hear me and see me today?

BOARD STAFF CALLIE ANN SHELTON: We can, Corey, go on.

COREY GREENBLATT: Great. Hello. My name is Corey Greenblatt. I'm speaking on behalf of, today, of the Global Healthy Living Foundation. We're a nonprofit patient organization advocating for patients with chronic pain and autoimmune disease. Many in our community rely on medications like Enbrel and are very worried that the decision to move forward with UPL today will risk their access to the medication that they rely on to live their lives as pain free as possible.

I'd like to start today by simply asking this Board to take a pause before making any further determinations. As you debate

whether to add an Upper Payment Limit to Enbrel, I'd like to remind you that your stated purpose, and the stated purpose of this Board, is to reduce the cost of prescription medications. We live in a world where there are many different costs related to the medication, but to us as a patient group, we believe the one that matters most is the price that the patient pays. And in this regard, Upper Payment Limits do nothing to reduce the out-of-pocket costs for patients. In fact, the term 'Upper Payment Limit,' is one of many misnomers in healthcare, that sound beneficial, but in reality, could really harm patients. In practice, these limits often act as a reimbursement cap. These caps will likely be significantly lower than the list price and will result in local pharmacies either stocking this medication at a loss, or not stocking it at all, which will drive patients to rely on national specialty pharmacies, many of which are owned by the insurance companies that use them, due to vertical integration, which will further reduce accessibility for patients.

While there may be many other medications that treat patients, similar to

Enbrel, it is not as easy for patients to switch between biologics, as it is to simply switch between a brand and a generic. Patients spend, on average, over a year, to find a medication that works for them. And if they suddenly lose access to that medication, it could lead to a windfall of unforeseen costs due to worsening health.

Short of outright voting no today, I am again asking this Board to take a pause and evaluate what the impact on accessibility will be on patients, should you continue to press forward. Thank you for the opportunity to comment today and have a good day.

BOARD STAFF CALLIE ANN SHELTON: Thank you, Corey. Brian Warren?

BRIAN WARREN: Hi. Good morning, Board members. Brian Warren with the Biotechnology Innovation Organization. I would like to reiterate our concern that rather than improving access to medicines for patients, implementation of an Upper Payment Limit will not save money, most patients money, and it will create supply chain problems that could impact all patients needing medicine, subject to the UPL. The UPL

will not improve affordability because it will not change the most important factor in determining what patients pay; their cost-sharing as determined by insurance benefit design. Instead, a UPL would likely have the biggest impact on the first in-state purchaser of a drug. In most cases, this would be a Colorado hospital, clinic, or pharmacy, purchasing from a national distributor or wholesaler. These entities would be prohibited from paying more than UPL for their product, even if their product is not available at that price.

We've seen what happens when, for example, pharmacies are required to purchase drugs subject to a maximum allowable cost, which is a maximum reimbursement amount. And oftentimes, providers lose money as a result. The UPL would theoretically function somewhat similarly, and it would have the force of law.

We know you did not design the law you are tasked with implementing, or the concept of a UPL. And perhaps you believe that other actions could be taken that would have a more significant impact on patient affordability. Now is your opportunity to say, that even though you have

determined a medicine to be unaffordable, the UPL is not the right tool at this time, because we still do not really know how it will be implemented, or how to prevent unintended consequences on patient access. Thank you.

BOARD STAFF CALLIE ANN SHELTON: Thank you, Brian. Emily Zadvorny.

EMILY ZADVORNY: Hi everyone. Thank you for the opportunity to weigh in. Thanks to the Board. I'm not here today to comment on whether or not there should be an Upper Payment Limit consideration for Enbrel specifically, but just echoing some of the concerns that we have to the Board for many years now. And I reference a letter sent to the Board in January of '23. As pharmacists, of course, we want nothing more than patients to have access to their medications, and as affordably as they can. But I do implore you to consider all the aspects of operationalizing any drug that you might consider selecting for an Upper Payment Limit. We don't need to look much further than what's going on with EpiPens right now, where, you know, the pharmacies are faced with either losing money or not providing access to a drug, and it's a real problem that we're

seeing actually happening right now in our state.

So, we simply just can't have a situation that puts our frontline providers, as pharmacists, or the pharmacies, at a disadvantage financially, where they have to lose money or, potentially, not have the financial support to provide access to these medications.

Thank you so much for letting me be the broken record on the record. Thanks so much.

BOARD STAFF CALLIE ANN SHELTON: Thank you, Emily. Hope Stonner.

HOPE STONNER: Hi. My name is Hope Stonner. I'm with the Colorado Consumer Health Initiative, appreciate this opportunity for public comment today. I would just like to say that the Colorado Consumer Health Initiative, which works to protect and promote access to affordable and equitable healthcare in the state, believes that the comprehensive process of the affordability review, and the process outlined in the statute for the UPL, has appropriate guardrails in place to protect patient access, because we believe, overall, that the goal of the PDAB is to encourage access to drugs in the state, that we know that folks may be struggling

to, or cannot access at this time.
We believe that the UPL process can work alongside other policies that folks have called out in public comment, that are already being implemented in the state, to meaningfully lower drug costs for patients in the system. And due to Enbrel's high cost to the to the healthcare system, particularly when the report stated that the drug remains out of reach or is unaffordable for so many Coloradans, we believe that Enbrel is a perfect example of the need for a PDAB in the first place, and an appropriate candidate for a UPL. Thank you.
BOARD STAFF CALLIE ANN SHELTON: Thank you, Hope. And I'll put the form in the chat, and this is the last call for public comment. Madam Chair, I'm not seeing any more public comments.
CHAIR GAIL MIZNER: Okay, thank you, Callie. And thank you to everyone who gave us public comment, both written and the recent couple of comments you just gave. Is there any deliberation on the part of the Board on whether to select Enbrel for establishment of an Upper Payment Limit?

BOARDMEMBER AMY GUTIERREZ: Can I ask for a clarification? Because I thought we already selected Enbrel. What is the action that we're doing?
CHAIR GAIL MIZNER: We already determined that Enbrel was unaffordable for Coloradans.
BOARDMEMBER AMY GUTIERREZ: Got it. Okay.
CHAIR GAIL MIZNER: Now what's before us is whether, is to determine whether to initiate the process of setting an Upper Payment Limit for Enbrel. And I think I'd like to remind the Board and the public that a vote to initiate the UPL process, does not mean that we are bound to complete the Upper Payment Limit process. So, we could, at any point, if we, if the data presented to us indicated to us that it wasn't appropriate, to move forward with setting a UPL, we could stop the process at any point in the future. I think the other thing to keep in mind that has been outlined by staff is that we're looking, we're not looking at making a decision about a UPL in a month. We're looking at probably a six-month process of data gathering

and discussion. So, that's kind of the -- that plan that's been outlined that I think is wise, that we would not proceed rapidly.
BOARDMEMBER AMY GUTIERREZ: Thanks Gail, for that clarification. Do you need a motion?
CHAIR GAIL MIZNER: Yes, I do, unless there's further deliberation.
BOARDMEMBER JAMES JUSTIN VANDEBERG: No, I think that clarification that you had set up was, I think, a good reminder as far as the process for, you know, everyone in the meeting. I'm good to let the motion to approve, to work on establishing a Upper Payment Limit for Enbrel.
CHAIR GAIL MIZNER: Okay.
BOARDMEMBER AMY GUTIERREZ: I'll second the motion, Chair Mizner.
CHAIR GAIL MIZNER: Thank you. So, Dr. Vandenberg moved and Dr. Gutierrez seconded. All those in favor of selecting Enbrel for establishment of an upper payment limit, raise your hand and say aye.
BOARDMEMBER AMY GUTIERREZ: Aye.
CHAIR GAIL MIZNER: Aye.
BOARDMEMBER JAMES JUSTIN VANDEBERG:

Aye.
CHAIR GAIL MIZNER: That's the three of us. Opposed, say nay. The motion passes. As a reminder, the Board establishes UPLs through a rulemaking proceeding. Our vote today to establish a UPL for Enbrel, initiates a rulemaking process that will involve multiple public hearings. Do I have a motion to direct staff to initiate rulemaking, to establish a UPL for Enbrel, with the Secretary of State, so that we can hold our first rulemaking hearing at a future meeting that accommodates the Board's overall schedule?
BOARDMEMBER AMY GUTIERREZ: I move that we direct staff to initiate rulemaking to establish an Upper Payment Limit for Enbrel, with the Secretary of State, so that we can hold our first rulemaking hearing at a future meeting that accommodates the Board's overall schedule.
BOARDMEMBER JAMES JUSTIN VANDEBERG: This is Justin Vandenberg, I second.
CHAIR GAIL MIZNER: Thank you. Dr. Gutierrez moved, and Dr. Vandenberg seconded. All those in favor of directing staff to initiate rulemaking to establish a UPL for Enbrel with the

Secretary of State, so that we can hold our first rulemaking hearing at a future meeting that accommodates the Board's overall schedule, raise your hand and say aye.

BOARDMEMBER AMY GUTIERREZ: Aye.

BOARDMEMBER JAMES JUSTIN VANDEBERG: Aye.

CHAIR GAIL MIZNER: Aye. The motion passes. Staff, please work with us in future meetings regarding timing of the UPL rulemaking hearings for Enbrel, and to initiate rulemaking to establish a UPL with the Secretary of State, in line with those discussions.

Okay. Now, we are scheduled to move onto Genvoya. Board members disclosed conflicts at the top of the meeting. Dr. Diab is the only Board member with a conflict of interest for Genvoya and will not participate in the deliberation.

Also, before we vote, I'd like to note that all Board members were present at the February 16 meeting, when the Board voted that use of Genvoya is not unaffordable for Colorado consumers. To ensure that all Board members have had the opportunity to review the summary of

round's affordability review process for Genvoya. Staff, please publish a clean version of the report. Lila, did you want to now go through a UPL rulemaking timeline with us?

BOARD STAFF LILA CUMMINGS: Yes. Yeah, absolutely. We can go to the next slide. So, here is what we are going to propose and how we'll propose to proceed unless we hear differently from you all in terms of kind of some of the next steps for Upper Payment Limit rulemaking.

So, at your next meeting, on March 15, we will save a portion of the time, probably not a large portion of the time, we're thinking maybe half an hour, to just revisit and reacquaint ourselves and everyone with the Upper Payment Limit rule and policy that already exists, that you all promulgated and adopted over a year ago.

So, we'll spend some time just reacquainting ourselves with the rule and policy, answering any questions that you all may have, and then continue to save some time at your April 26 meeting as well, for continued kind of conversation. So, not really looking at specific data for Enbrel, just really looking at the rule

deliberations and changes made by staff from the draft report, I'd like to ask if any Board member has objections to moving forward with approval of the final report.

BOARDMEMBER JAMES JUSTIN VANDEBERG: I do not.

CHAIR GAIL MIZNER: Do I have a motion to adopt the Final Affordability Review Report for Genvoya with the changes as discussed?

BOARDMEMBER JAMES JUSTIN VANDEBERG: This is Justin Vanderberg. I motion to adopt the Final Affordability Review Report for Genvoya with the changes as discussed.

BOARDMEMBER AMY GUTIERREZ: Amy Gutierrez, second.

CHAIR GAIL MIZNER: Thank you. Dr. Vandenberg moved and Dr. Guitierrez seconded. All those in favor of adopting the final affordability review report for Genvoya, raise your hand and say aye.

BOARDMEMBER AMY GUTIERREZ: Aye.

BOARDMEMBER JAMES JUSTIN VANDEBERG: Aye.

CHAIR GAIL MIZNER: Aye. Okay. The motion passes. The Board's vote concludes this

and policy, answering any questions that you might have, and just thinking about how you want some of the data gathered.

Then, you'll see on here, there is a potential hold here for a meeting on May 3, but we anticipate that would be, like today, really focusing, only if needed, on conversation about Cosentyx and Stelara.

Then, on June 7, would potentially be the first rulemaking hearing for Enbrel. And then, that would be kind of that formal process with testimony, both written and verbal testimony provided, and then moving on. And we would strongly recommend a second rule-making hearing, at a minimum, on July 19.

And so, if things are kind of moving this way, and we can start this way, but if there's a time as you all mentioned, where you'd like to slow down, or where you'd like to speed up, we can absolutely adjust as needed, but this is kind of how we propose at this point to proceed.

And then the only other thing I'll note is, in the past, any time you all have done rulemaking, we have held separate stakeholder

meetings to gather input and really talk with individuals and stakeholders directly to get their feedback, so we can converse with them before the rulemaking hearing. We would plan on doing the same thing.

So, we don't exactly have a date yet for when those stakeholder meetings would be, but we would anticipate sometime between April and June, and heading even into the summer, as your rulemaking continues, and your rulemaking hearing continues. The staff hosts meetings with stakeholders to answer questions. The Board members would not need to attend, but that will host those meetings so folks can ask questions.

Any kinds of concerns or thoughts or comments on this proposed timeline for now? We'll continue to check in at each meeting to make sure kind of this is the right cadence. Chair Mizner, you were on mute.

CHAIR GAIL MIZNER: My feeling is that as long as we're able to slow down at any point where we feel that we need to, to gather more information, more input, whatever, I think that makes sense. I want to be sure that both Board has enough time for every meeting to read and

incorporate all the information gathered into their thinking, and also that we have enough time for public comment and stakeholder meetings. I think those are just key. Amy and Justin, do you have other thoughts about this timeline?

BOARDMEMBER JAMES JUSTIN VANDEBERG: No. I think you state it very well, just as far as being able to -- I don't want to say flexibility, but maneuverability, based on the data as is presented.

BOARDMEMBER AMY GUTIERREZ: I agree as well, Gail, with your comments. And I think it's going to be important on the flexibility because it's the first time we've done this, so it will be important to be flexible on some of the timelines agreed.

CHAIR GAIL MIZNER: All right. Great.

BOARD STAFF LILA CUMMINGS: Great. Then we'll proceed with this, but we'll check in with you at every meeting, kind of, if this is the right timeline. I believe that's all I have and I think we did the next two agenda items at the top, so I believe you're done.

CHAIR GAIL MIZNER: Okay. And I think we are done with our work today. Thank you to

everyone. The next PDAB meeting will be held at 10:00 AM on Friday, March 15. And unless there's any objection, the meeting is now adjourned. Thank you all very much.

BOARDMEMBER DR. SAMI DIAB: Thank you Board members.

C E R T I F I C A T I O N

I, Sonya Ledanski Hyde, certify that the foregoing transcript is a true and accurate record of the proceedings.

Date: May 31, 2024

Sonya Ledanski Hyde