Washington State Health Care Authority
Prescription Drug Affordability Board
Meeting Transcription
January 31, 2024

Mike Neuenschwander: The recording is in progress. Thank you, Board Members for coming out. Sorry we are starting just a couple of minutes late, but we have a great agenda for today. So I think in terms of just general welcome and introductions. I think we know most of the people here now in terms of the Board members and our AG, who is with us. Our data team will be online today doing one of our presentations for us, and Simon will also be doing a presentation on the advisory Boards. Generally speaking, I think last time there was a question in terms of the coverage number of insured here. Simon, do you want to follow up with some of those numbers?

Simon Borumand: Yes. So I think the question was how many lives in Washington are covered -- would be covered under UPL? And so the number from the Office of Insurance Commissioner is that about 15% of Washingtonians are in a plan that is regulated by the Office of the Insurance Commissioner and would therefore be subject to a UPL as such around 1.1 million Washingtonians.

Mike Neuenschwander: Thank you, Simon. I just wanted to make sure we followed up on those questions that the Board members had. Additionally, we did receive a couple of comments from a couple of different groups over the past couple of weeks, and so we did send those out to the Board members to take a look at, and I believe both of those parties will be commenting during the public comment section a little bit later today. I just wanted to acknowledge that we received those comments and forwarded them onto the Board, and we look forward to hearing from them here a little bit later at the end of the meeting. So in terms of things that we are going to be doing and approving today, first will be looking for the election of the Board Chair and Vice Chair and then also voting on the policies that we were discussing to approve those. Again, our policies are a living document. We are going to be updating them very frequently as we build more methodologies, so there are lots of chances to get input and review on those. But let's start with our first item.

Eileen Cody: So I would make a motion, but I don't [indistinct] -- so are you technically the Chair?

Mike Neuenschwander: Um.

Eileen Cody: But make a motion that MaryAnne Lindeblad be elected Chair of the [cross-talk] Board. Can you second?

Hung Truong: Yeah, I second that.

Multiple Speakers: [Cross-talk] [laughter].

Hung Truong: There was no hesitation there. [cross-talk]

MaryAnne Lindeblad: See, you got to jump in quick [cross-talk] --

Mike Neuenschwander: Yeah.

Eileen Cody: So by acclamation we could.

Mike Neuenschwander: Okay. It comes to the Robert's [indistinct] to put that up for a vote then.

Multiple Speakers: [Cross-talk]

Eileen Cody: Well, yeah. Now, is Doug on?

Hung Truong: He is on.

Mike Neuenschwander: Doug, are you there?

Douglas Barthold: Yes, hi. Nice to -- well, actually, I can't see anybody. This video isn't on, but I would say, nice to see you. Um, yeah, I was just wondering if we -- it would be great if we turned the video on. It is currently disabled. I am trying to turn mine on and it says -- oh, wait. There you go. I think you got it fixed. Yes. [Indistinct].

Mike Neuenschwander: Can you see us in the room, Doug?

Douglas Barthold: I cannot see you, no.

Mike Neuenschwander: Maybe the start [cross-talk] --

Eileen Cody: All of it's moving.

Douglas Barthold: There we go. Now I see you, Mike.

Michael Tunick: I would just do the Robert's Rules of Order. There has been a motion, seconded, and I guess you would state the question, which then there would be an opportunity for discussion, and then after discussion or if there is no discussion, then you would put the question to a vote.

Mike Neuenschwander: Okay.

Michael Tunick: Yeah. Okay.

Mike Neuenschwander: Okay, so I would be [cross-talk] --

Multiple Speakers: Yeah, yeah.

Michael Tunick: So it has been moved and seconded that [cross-talk] --

Mike Neuenschwander: Okay. So, sorry, I am a little rusty with Robert's Rule of Order here.

Michael Tunick: And I forgot to bring today, knowing that this is [cross-talk] one of the more important [cross-talk] --

Mike Neuenschwander: So it's been moved and seconded to nominate MaryAnne for the Chair. Any opening the floor for any discussion?

Eileen Cody: I know she can do it, so would -- and she lost the coin toss.

Multiple Speakers: [Laughter].

Eileen Cody: We can go ahead with the vote.

Mike Neuenschwander: Okay. Any other discussion? Doug? Hung? Thoughts?

Hung Truong: No.

Douglas Barthold: No.

Mike Neuenschwander: Okay. So I will proceed to the vote. All in favor raise your hand or say Aye.

Multiple Speakers: Aye. Aye. Aye. Aye. Aye.

Mike Neuenschwander: All opposed?

Michael Tunick: Very good. Okay. You know, I am trying to hear that pursuant to Legacy International formally adopted policies and procedures, but those call for a role call vote.

Mike Neuenschwander: Ah.

Michael Tunick: So it will be [cross-talk] --

Mike Neuenschwander: Okay, so [cross-talk] --

Michael Tunick: -- along with your vote is [cross-talk] --

Mike Neuenschwander: [Cross-talk] Okay. So Hung, how do you vote? Yay or Nay?

Hung Truong: Yay.

Mike Neuenschwander: Eileen.

Eileen Cody: Yay.

Mike Neuenschwander: Okay. MaryAnne, can you vote for yourself?

MaryAnne Lindeblad: I have to abstain, I think.

Mike Neuenschwander: Okay. Doug?

Douglas Barthold: Yay.

Mike Neuenschwander: Okay.

MaryAnne Lindeblad: Thank you. I don't have to abstain.

Mike Neuenschwander: Okay. So the motion passes. MaryAnne, you are the new Chair of the Prescription Drug Affordability Board. Congratulations.

MaryAnne Lindeblad: Thank you.

Mike Neuenschwander: So as the Chair, will she be [cross-talk] running the votes now? [Cross-talk]

MaryAnne Lindeblad: Oh my gosh. Okay.

Mike Neuenschwander: Okay.

MaryAnne Lindeblad: All right. [Cross-talk] -- it can get worse [indistinct] [cross-talk] --

Mike Neuenschwander: Okay, we will have Simon get a gavel.

MaryAnne Lindeblad: [Indistinct]. All right.

Mike Neuenschwander: So do we need a Vice Chair as well, right? Okay.

MaryAnne Lindeblad: Because I would nominate Eileen Cody as the Vice Chair.

Hung Truong: I second that.

MaryAnne Lindeblad: It's been moved and seconded Eileen Cody is the Vice Chair. We will take a vote. [Cross-talk] voice vote.

Michael Tunick: Opportunity for a discussion [cross-talk].

MaryAnne Lindeblad: Yeah. Any comments, discussions? Doug, anything?

Douglas Barthold: No.

MaryAnne Lindeblad: Okay. Voice vote. [cross-talk] --

Eileen Cody: Yay.

MaryAnne Lindeblad: MaryAnne, Yay. And Doug.

Douglas Barthold: Yay.

MaryAnne Lindeblad: Okay. Eileen has been elected now as our Vice Chair.

Eileen Cody: Okay, just [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] --

Mike Neuenschwander: Wonderful. Okay.

MaryAnne Lindeblad: And that was probably the easiest ever to get a Chair and Vice Chair.

Mike Neuenschwander: Quick and efficient [cross-talk] --

MaryAnne Lindeblad: Mm-hmm.

Mike Neuenschwander: [Cross-talk] --

MaryAnne Lindeblad: Moving along. So we need to go ahead and move on to the Board policies vote. So Mike, that is yours.

Mike Neuenschwander: Okay. Uh, so yeah. We have reviewed the policies. Again, as I mentioned before, these are living documents that are going to be updated quite frequently. These are not rules which require the much more detailed feedback and had time to go through. So with the policies, I guess, proposed to approve them as they are and then again with the note and the caveat that we will be updating these regularly and continually adding to them as we develop our methodologies.

MaryAnne Lindeblad: I think the point of these are living documents [cross-talk] is truly there. I mean there are just things that as we learn, too, we will be making amendments and changes. So I think at this point is there a motion to go ahead and adopt the Board policies?

Eileen Cody: I would move that we adopt the policies as written at this point.

MaryAnne Lindeblad: Do we get a second? [cross-talk] --

Douglas Barthold: Second.

Eileen Cody: I think he said.

MaryAnne Lindeblad: Doug, thank you as the second. So it has been moved and seconded [cross-talk] that we go ahead and adopt these policies as written today. We take a vote on that? Do we need to put a voice vote on this?

Eileen Cody: A role -- yes, he said role call vote [cross-talk] --

Michael Tunick: Yeah [cross-talk], I also need to first give instructions.

MaryAnne Lindeblad: [Cross-talk] oh, for any [cross-talk] for any [cross-talk] --

Michael Tunick: [Cross-talk] Yeah, so I think that --

MaryAnne Lindeblad: [Cross-talk] Okay. [Cross-talk] So any discussion. I will get down [cross-talk] Any discussion? Doug, any comments, discussion? [cross-talk] --

Douglas Barthold: [Cross-talk] Yes. I will be right around here.]

MaryAnne Lindeblad: [Cross-talk] All right. Then I think [cross-talk] we will go ahead with the vote -- the voice vote. Doug?

Douglas Barthold: Yay.

Hung Truong: Yay.

Eileen Cody: Yay.

MaryAnne Lindeblad: Myself. So moved and seconded. [Cross-talk] --

Eileen Cody: [Cross-talk] --

MaryAnne Lindeblad: Like I said, you know this is still early. [laughter]

Eileen Cody: You got to get [cross-talk]--

MaryAnne Lindeblad: You got to get into the routine. Okay? Rhythm.[Cross-talk] It's been a while since I have Chaired a Board. So it's passed?

Mike Neuenschwander: Right.

MaryAnne Lindeblad: All in favor, so [cross-talk] --

Hung Truong: The policy and procedures [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] Yep, we have our policies and procedures, so that is great. Really, that has been amazing work. I mean there is a lot in those, and the staff who put those together did a really nice job.

Mike Neuenschwander: Good job, Simon.

Eileen Cody: So now we know who [cross-talk] --

MaryAnne Lindeblad: Well, I was going to say [cross-talk] --

Multiple Speakers: [Cross-talk] [indistinct].

MaryAnne Lindeblad: And now it says break. [cross-talk] --

Eileen Cody: I am not sure [cross-talk] --

Mike Neuenschwander: [Cross-talk] Okay.

Eileen Cody: -- but I don't think we need a break.

Mike Neuenschwander: Yeah, I was going to [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] I don't think we need a break.

Mike Neuenschwander: Yeah, I was going to say the Chair and Vice Chair wasn't very contentious. The policies were pretty easy, so I think we can go ahead and [cross-talk] with them. Our two big topics today are going to be the Advisory Board because that is outlined in the Legislation, and we need to start thinking about and looking at that. Simon will be presenting on that. Then after that, maybe we can do our break, and then we can go to our drug selection methodology that we [cross-talk] --

MaryAnne Lindeblad: I think will be a little more challenging. [Cross-talk] --

Mike Neuenschwander: Yes. [Cross-talk]

MaryAnne Lindeblad: Yeah.

Mike Neuenschwander: Yes. That one is going to be probably our meatiest discussion. So Simon

Simon Borumand: Great. So yeah, I agree. I think that the drug methodology is going to be the bulk of the conversation. This presentation, I think you might have previewed it. It's fairly short kind of high level, but just to get us to start thinking about how to set up advisory groups. And so for today, the objective, I discussed the overarching structure of what the Drug Affordability Review Advisory Group could look like, start to think through the size, the roles, the expertise that we want, and then start to map out an administrative structure. How would we communicate with them? What would we ask of them? And then looking ahead, we can solidify that into more formal operating policies and procedures. And one thing I will note, too, is both this and the methodology discussion, and these are initial informational pieces to start informing us on what our possibilities are and what could this look like. We are not making any decisions or final proclamations right now. So there is still time for feedback or for us to ask questions, go back and forth with the review, so this is just an introduction to both of these topics. So just to kind of orient to this presentation, the first few slides are around the legislative mandate and then what we have written into the WAC rules, just to give us an outline of what we are able to do. The broad comment is that the Legislation is not super specific in how we need to set up these Boards. They basically say that we should have advisory groups that will assist in putting together the Drug Affordability Review, and they say that the authority will provide the administrative support, much like we have done for the Board. And they have similar conflicts of interest language that we had for the Board with one exception. There can be a member of Industry as part of the advisory groups, whereas for the Board, we didn't have anyone from Industry. So in the WAC, we have laid out a little bit more specifics around who we would like to see on one of these Boards, but, as you can see, the languages may include but not limited to, and so this is a starting point, not a defined it has to be these folks. What we have at the top is patients and patient advocates and then a list of experts, experts in pharmaceutical business model, supply chain, practice of medicine, and healthcare research, healthcare marketplace. And later in the presentation, I have broken out how we can set up the Board to have some standing members and some rotating in members just to get different expertise and kind of take this list and set it up a little bit differently. More summary of what is in the WAC, just kind of the high-level points. The Members are chosen by HCA, so the staff will work with you all so you can who are the candidates, but I think that was just put there so you don't have to interview every single person who applies. They will also complete a conflict of interest check, much like you did. The WAC we wrote in that ideally members will have experience in developing policies for

underserved communities. And then, as I mentioned earlier, one member can be a representative from the prescription drug industry. And then finally, unlike the Board, this is voluntary, so it's uncompensated, not that you are super highly compensated for this work, but.

MaryAnne Lindeblad: Do they get travel reimbursement stipends?

Simon Borumand: I don't believe so. That is not written in the WAC. No.

MaryAnne Lindeblad: That might be something we want to look at [cross-talk] especially for someone who, perhaps, would not be able to attend because it would be [cross-talk] --

Eileen Cody: [Cross-talk] And to try and get people from eastern Washington [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] Exactly, over. Yeah.

Eileen Cody: Of course, we do so much by Zoom now, but still.

MaryAnne Lindeblad: Still, there would be times when [cross-talk] you want them here in person, sometimes.

Mike Neuenschwander: Yeah, that is a good thing to think about.

Simon Borumand: Yeah, I think that is a great idea, and that is something that we can flesh out when we draft out policies when we start looking at hiring. Ways to expand the net and make sure we get a lot of voices in. So a structure that we are proposing is to have a consistent core advisory group with two-year terms that are staggered and then to have supplemental experts added for each drug that we review. That way you have assistant knowledge but also expertise coming in. And the first bullet here is that there are other Boards that HCA manages, and they also have advisory groups, and so we have a lot of drafted policies, drafted applications that we can borrow and use as a model. Helpful to have those lessons learned.

Hung Truong: Thanks, Simon. Hi, it's Hung Truong. Is that a requirement for residency, or it could be anyone? Yeah? Okay.

Simon Borumand: There is no residency requirement, and the other Boards that we spoke to HCA mentioned that as they were recruiting, they even reached out to folks in other states just to say, hey, you may not be clued into the job postings in Washington, but we'd like your expertise.

Eileen Cody: And if you don't -- there is no compensation, I doubt you are going to get a lot of people.

Hung Truong: No, and you'd be surprised.

Eileen Cody: Uh.

Hung Truong: I mean if we want folks that understand this well, it needs to be national. I mean everything is through Zoom, [cross-talk] so you don't need to come here.

Simon Borumand: What we are thinking with these supplementary advisors is that as we select drugs, think through what sorts of expertise would be appropriate for that drug or that condition. And in addition to those, let's say, four to six supplementary advisors for a drug, we are thinking we would also invite guest speakers to the different meetings and have more specialized expertise. The theme here is just getting a lot of voices into the room and getting as much perspective as we can as we go down this path. I went through some of the advantages of having this kind of a core advisory group and then supplemental experts because we had tossed around the idea of, Would you have a separate advisory group for each drug under review? But that could be up to 24 a year, and you wouldn't have that knowledge retention.

Eileen Cody: Certain cats.

Simon Borumand: Exactly. Exactly. So you get to carry over the lessons from each affordability review to the next one. A lower administrative burden so we can focus on the actual work instead of earning caps, as we said. So here's the proposed model having up to seven members on a core advisory group, and on the left-hand side I just pulled in those categories that were in the WAC. So experts in the pharmaceutical business model, supply chain, a clinician or an expert in the practice of medicine, a general kind of healthcare consumer or patient-perspective voice, not necessarily specific to that drug. Someone with expertise in healthcare costs, trends, and drivers, and then someone who understands the healthcare marketplace and clinical and health services

research. And then we were thinking for each drug under review having up to six additional members, and that would include patients and/or patient advocates, a representative from that specific industry, with the caveat of being aware of any sort of conflicts of interest. So if we are reviewing one drug, we don't want their direct competitor to be on the advisory group. And then having healthcare providers as well that specialize in that condition. So you get the general perspective and the specific one. And here, just a quick note, we have put "up to," and so there's flexibility there. But ideally, we would want, I think, an odd number of folks just in case there is a vote, and we want to not have a tie. I see Doug raised his hand. Doug, do you have a comment?

Douglas Barthold: Yes. So for the core advisory group, is there an insurance representative on there? Or I mean does HCA have a representative on there?

Simon Borumand: Uh, we didn't put anyone from HCA, but we could. I mean this is open to change, and I think the insurance side is likely what they were thinking is the pharmaceutical business model. You might have someone who is familiar with insurance or PBM, but I think we can add that specifically as well.

Eileen Cody: Or the state's healthcare marketplace.

MaryAnne Lindeblad: Right.

Eileen Cody: That is another one that the insurance would probably fit. I guess, I would just caution that we don't get too many people because you don't want -- I mean just looking at this, that would be like we could go to 13 members on each drug, and that is a lot of people to be fighting about what is going on.

Douglas Barthold: We are never going to schedule a meeting.

Eileen Cody: Yeah. Yeah. [Cross-talk] .

Douglas Barthold: Besides, you could -- could we expand on the Representative of the state's healthcare marketplace? I don't understand who that would be. Like, , is that that they are representing?

Simon Borumand: That is like I think it could be either someone who is like a state representative from the state that is familiar with the marketplace or someone who is just an expert in how the healthcare marketplace works. And

I think the idea there -- and I will pass it to Ryan in a second -- my assumption is that was around if an affordability review were to have an impact on accessibility of the drug within this market, having an expert there to speak to that, but maybe, Ryan, you have a different perspective.

Ryan Pistoresi: Hi, good morning. I think one of the people who could maybe represent the states healthcare marketplace could be from the Health Benefit Exchange, which is another state agency that does help with the enrollment for people looking for health plans either into a qualifying health plan or into Apple health, if they meet those requirements. And so we could look at someone from that agency to be filling that role as the expert in the state's healthcare marketplace.

Douglas Barthold: I see. So it's more of the health insurance marketplace then, right? Is that how I should be thinking about it?

Ryan Pistoresi: That is at least how I think about it. You know, [cross-talk] I think given that it's written as broadly as it is, it could be someone from the Health Benefit Exchange or if there is someone else that is outside of the Health Benefit Exchange, but they meet that healthcare marketplace expertise, they could be that representative.

Douglas Barthold: Okay.

MaryAnne Lindeblad: The OIC would be another. Yeah.

Simon Borumand: Yeah, but -- so the fact that the lives that are covered under these regulations would be regulated by the OIC, having the OIC, respectively, would be great. The Office of the Insurance Commissioner.

Douglas Barthold: I agree.

Mike Neuenschwander: Any other thoughts or questions?

Hung Truong: I think the next question on the supplement group that looks like a representative of the prescription drug industry, so at least a PBM.

Eileen Cody: Or the company itself.

Douglas Barthold: I assume that would be manufacturer.

Mike Neuenschwander: There is -- I will go back a list in the Legislation, so a representative from prescription drug industry be an employee, consultant, or Board member of a drug manufacturer or trade association. And then we could have somebody from a PBM perspective or insurer perspective [indistinct] --

Hung Truong: I concur with that we need to go in the managed care folks or the health insurance folks.

Simon Borumand: So this Power point presentation is kind of nuts and bolts just how these groups would be administered. So they report to and be staffed by HCA in a similar way that we have worked with the Board, and then a Chair would be chosen as well, and they would help HCA with facilitating the meetings. The deliverables we were thinking of as a starting point, but this is something that we should really dive into down the road. So we are thinking one, there would be a comprehensive report, and you all would outline what you would want to see in that report. And then the job of the advisory groups put that together over the drug affordability review. And also the idea is that if there are questions that come up over the course of your work, you could send ad hoc questions over to them, where they would be tasked with responding. And yeah, we talked about the cadence. So we are thinking that they would meet in between your meetings and then not only have their meeting, but also have some time that we ask them to commit to do work outside of those meetings. And so that way if you are meeting in January, you have a few questions for them. By the time we come back in March, they will have had time to answer what those discussions may have been. We are going to try and structure the communication so it comes through HCA just so it follows all the public meeting requirements and record keeping requirements. And ideally, in speaking with other Boards at HCA, they said being really clear with the advisory groups of what you are asking of them and then what they're able to ask of you. Like they're not going to be asking the Board to go off and do work and then report to them. Right? So then the term duration, we were thinking for the core group having two-year terms and then staggering though so there is always some knowledge being retained. And then the supplementary advisory group would just serve the length of each drug affordability view.

MaryAnne Lindeblad: Not a term limit.

Simon Borumand: Yeah.

MaryAnne Lindeblad: [Indistinct].

Simon Borumand: We could change that if you want people to continually be, but at this point we are just [indistinct].

MaryAnne Lindeblad: It's something to think about and then somebody cycles off, could they cycle back in? That sort of thing. Got a little more specific. And it may be for the first go around you might want to think about having the first group kind of on a little bit longer because there is going to be a lot of education and learning.

Simon Borumand: Yeah.

MaryAnne Lindeblad: And by the time they really get effective, two years might be over.

Simon Borumand: True. Other thoughts? Then continuing with this sort of nuts and bolts. So recruiting, we have a number of different channels that we use to recruit with the agency. So we have the website. We have the state government job site. There is a listserv at GovDelivery, which is how folks get the meeting notifications for this as well. We will announce during the PDAB meetings. We also work with NASHP, and so we can have them help spread the word. And then one piece of advice we got was also to come up with lists of folks that maybe aren't monitoring our job Boards, but we want to get their perspective, and then we can reach out to them directly as well. We have some applications like draft applications from other Boards that we can use as a starting point by just basing information on who they are, their expertise and background, conflict of interest form, and why they want to participate. And we are thinking HCA will collect those, we will review them, we will share them all with the Board, but we will narrow down the list, and if we need to do interviews, do interviews before submitting a recommendation to the Board, further to a point. And then next steps. Oh, Doug, you want to chime in?

Douglas Barthold: Yeah, thanks. I am just wondering, for the Advisory Board, do they have the same conflict of interest requirements as our Board?

Simon Borumand: Yes. I think the language is nearly identical except for that exception that one person can be from industry.

Douglas Barthold: I see. But so for the rest of the people, they wouldn't be able to have any consulting positions or anything of that sort.

Simon Borumand: I don't believe so. I have to go back. Yeah. No, no. I think it's the same.

Douglas Barthold: Okay, thanks.

Simon Borumand: So next steps, if we are okay with moving forward with this structure of like a core and the supplementary group, then we can start developing the policies and developing the applications for the rule. And with the caveat that this is a slow process because we haven't even narrowed down the list of drugs to do an affordability review, but we would like to just get started on hiring that core group and getting them up to speed in the meantime.

MaryAnne Lindeblad: So will you be putting like the time, some timing so we have some understanding of what is going to come first, second, okay.

Simon Borumand: Yeah. Yeah. If this structure sounds good to the Board, then we can put together a timeline of what [cross-talk] --

MaryAnne Lindeblad: Okay. Any more questions?

Mike Neuenschwander: Well, one thing I would say, too, is I know in other states advisory groups have been getting that feedback. It's been really, really important, especially once a drug is picked. I know there is a lot of passion and, yes, sometimes people are worried, and people want to know what is going on. So getting this input from the various groups and being able to kind of hear what they're saying I think has influenced other Boards quite a bit being able to see patient advocates and whatnot. The big things that they're concerned about, especially from a very practical point of view of people who are directly affected by this type of stuff, so I think being able to get this feedback is going to be a key part as we move forward with these drug reviews because especially depending on the drug. Some of these things can be very sensitive or politically a little bit more [audio cuts out] as well. So I think being able to get as much feedback from different groups as we can will play a really important role in how we decide to move forward and look at certain drugs.

Eileen Cody: So I assume that you will start trying for the seven members, or at least the core group, immediately, and then the supplementals will have to wait until

we know what drugs we are doing, but trying to get the core group together as quickly as possible is probably.

Mike Neuenschwander: Yeah, just getting started on it, at least, just knowing how long these processes take, and we are still down one Board member [cross-talk] so it can take a while to find the right people. So yes.

Mike Neuenschwander: Yeah. And, too, I think being able to get that core group helps iron some of the kinks out so that hopefully finding the additional members for drug specific -- the administrative process will hopefully go a lot more quickly when we need it to once the drugs are selected.

Eileen Cody: Yeah. Well, I think once you have a specific drug, there's going to be so many people interested in the specifics. [Cross-talk] I think it's going to be harder to get the generic grouped together.

Mike Neuenschwander: Generic?

Eileen Cody: Much. Yeah. [laughter] much less.

Mike Neuenschwander: [Audio cuts out] no other questions and [audio cuts out] forward, maybe now we could take that break and then go back to Kelly's.

Ryan Pistoresi: Okay.

Multiple Speakers: [Cross-talk] --

Ryan Pistoresi: Five minutes?

Mike Neuenschwander: A 5-minute break.

Ryan Pistoresi: [Indistinct].

Mike Neuenschwander: Okay.

Douglas Barthold: So reconvene at 9:15, is that right?

Mike Neuenschwander: Yeah.

MaryAnne Lindeblad: Sounds good.

Douglas Barthold: Okay, thanks.

[break]

Mike Neuenschwander: Okay. So we're ready to rock.

Multiple Speakers: [Cross-talk].

Kelly Wu: All right. Can everybody hear me okay?

Mike Neuenschwander: Yeah. Thank you, Kelly.

Kelly Wu: [Cross-talk] Okay, great.

Mike Neuenschwander: [Cross-talk] before we were helping on the presentation, I just want to mention [cross-talk] again, that this is -- we are not making any final decisions on this methodology. It's still very much in the process. It's a draft that we are introducing for discussion as we are trying to put this together, so there will still be lots of time for us to talk about what we are doing. Both Kelly and Ryan can explain a little more in detail the mechanics behind all of this and also do a little bit of education as well. This is going to be a bit of a complex topic, and so if you have any questions, Board members, please feel free to ask, and we will do our best to address those. But again, not making any decisions. There is still lots of time for us to look at this. We are going to be talking about this over the next couple of meetings before we finalize this list and -- or finalize the methodology to create that drug list so. With that, Kelly, go ahead and take it away.

Kelly Wu: All right. So hi, everyone. I am Kelly Wu, and I am the PDAB Data Analyst. Today I am going to present an overview of the preliminary methodology that we have developed for identifying drugs for affordability review, and I am going to have Ryan, our Assistant Chief Pharmacy Officer at HCA and subject matter expert, help me with answering questions during this presentation. Are the slides advanced? Okay. So during my presentation, I am going to go over the thresholds for affordability reviews specified by the law. I am also going to go over the preliminary methodologies we have developed for identifying drugs subject to affordability review. We will also have some Q&A and discussion time, and then I will go over the next steps. So if during this presentation you have any questions or you need to go over something,

again, just feel free to interrupt. All right, so I will be presenting the methodology by each section of the bill, so I don't think it's necessary for us to read through at all since I am going to go over it, but I still want to acquaint everybody with it. So this is RCW 70.405.030, which establishes the criteria for drugs to be subject to affordability review by the PDAB. And so there are three main sections, and I am going to go over the methodology that we developed for the first two sections, and we are still working on the methodology for the third section, so I will present that at a future Board meeting. Okay. So most of us probably don't have a pharmacy background, so I first want to introduce some terms I will be using throughout this presentation starting with NDC. So what is an NDC? It stands for National Drug Code, and it's a unique 11-digit code that is maintained by the FDA to identify drug products, and NDC drug products can also be displayed as 10 digit digits, but in our data it's 11 digits and it contains the same information. So the NDC contains three segments of information, and so from the NDC you can determine the labeler, which is the manufacturer or distributor of the drug; the product code, which describes the specific strength, dosage form like capsule, tablet, liquid, and formulation of the drug, and the package code, which describes the package size and type. So an example on the right that I am showing here, if you were to look up the three segments of this NDC, you could identify it as a bottle of 100 Prozac 20 mg capsules distributed Dista Products, and a drug can also have more than one NDC if they were produced by different manufacturers like for some generics where it comes in different doses or dosage forms. Okay. So now I am going to go over some of the definitions of the different drug types that are mentioned in the bill. So first we have a brand name drug, and that is a drug which is marketed with a specific brand name by the company that manufacturers. So this is usually the same company that develops and patents it. Then when this patent runs out, then the generic versions of the drug can be produced and marketed at a lower price by other companies. And so the generic drug has the same ingredients as a brand name drug, and it has to go through clinical trials to prove that it is just as safe and effective as the brand name drug. And so a good example of brand name and generic is Advil, which is the brand name drug in ibuprofen, which is the generic. Another important drug type mentioned by the bill is biologics, so these are drugs that are made from natural living sources. So a good example of this are vaccines. So vaccines contain a small amount of virus, bacteria, or other pathogens, and a biosimilar is a drug that is very similar but not identical to an existing biologic, which I will call its reference biologic. And it also has to be shown that there are no differences in safety and effectiveness compared to the

reference biologic before a biosimilar gets FDA approval. So on the right here is an example of a reference biologic, Lantus, which is an insulin and its biosimilar is [indistinct]. Okay. And another important trend you will see in this presentation is the wholesale acquisition cost (WAC). So drug pricing can be really confusing because, as you can see on the thread on the left, there are several types of prices depending on who is buying and who is selling. But one of these is the WAC, which is the manufacturer's price for the drug. products to the wholesalers or direct purchasers, not including discounts or rebates. So basically, wholesalers purchase drugs from manufacturers at the WAC price, and then the wholesalers distribute the drugs to customers such as pharmacies, hospitals, or other medical facilities at a different price. All right. And so moving on there are other terms that I wanted to discuss in the bill. So for the term drug, we are defining each distinct NDC as a separate drug when we identify drugs that meet the criteria for review. But once we identify an NDC eligible for review, we are going to review all the other NDCs from the same manufacturer or distributor or brand of products that have the same drug ingredient as that NDC. And then for seven years on the market, which is specified in the bill, we are defining a drug as being on the market for seven years -- if it's been on the market since -- if the drug ingredient has been on the market since July 1, 2016. So by this I mean we can review a generic or a biosimilar that has been on the market for less than seven years, as long as its original drug ingredient has been on the market for at least seven years. So going back to that Advil and ibuprofen example, what this means is we can review like ibuprofen made by a new manufacturer that just came onto the market say yesterday because, Advil, which contains the original drug ingredient, ibuprofen, has been on the market for more than seven years. Yeah, Doug. If you are talking, I don't hear anything.

Doug Barthold: My bad. Sorry about that. Yeah. So yeah, diving deep on the ibuprofen example. So if, whatever, there's the CVS generic ibuprofen, and then there is the Amazon generic ibuprofen. Those are two separate affordability reviews.

Kelly Wu: [Cross-talk] Uh [cross-talk] --

Ryan Pistoresi: [Cross-talk] So this is Ryan. So in that example, yes, they would be because if we are looking at drugs that have a price above the threshold regardless of the manufacture, or we would look at them differently. So if we think of if one of those manufacturers had it at like $1 million, and the other one had it at $100,000, you know, they would both be eligible for an affordability review, and we would want to look at what the pricing is that the manufacturers are

using to justify those costs. So in that example, yes, those would be two separate ones because they are two different manufacturers and then have two different pricing rationale.

Doug Barthold: I see. Okay. Thanks. And then I know this is further down the road, but ultimately, would an upper payment limit apply to both or just one of those in that situation, assuming we decide we want to apply an upper payment limit say to ibuprofen, but would it be for ibuprofen in general, or would it be to one of those two specifically?

Ryan Pistoresi: That is a good question. I believe that if you were to be applying an upper payment limit, it would be on those drugs from that manufacturer, and I think a good example of that is if you were to find the, let's say, $1 million to be too high. You could put an upper payment limit on it, or if you thought both were too high, you could put an upper payment limit on both. And again, this is still in the early phases, and so I think if we need to look at the different versions of these different drugs, and there is a different rationale, that may lead to different upper payment limits that we apply on these drugs.

Doug Barthold: Okay. Thank you.

Mike Neuenschwander: Hung?

Hung Truong: Hey, Ryan, this is Hung. So how about indication if an NDC, same drug used differently -- example, GLP-1s for diabetes then also used for weight loss.

Ryan Pistoresi: That is a good question, and I think you could look at different indications because of the different value that they could be bringing to a patient. So, for example, as we are getting into the affordability review, you may be looking at a cost utility analysis of how one drug works on one disease state, and you may see that the utility that a GLP-1 provides in a diabetes patient is going to be different than the utility that it provides in a weight loss patient, and so from there you may want to use that as a factor in setting the upper payment limit. But I think when you get to the advisory group and they may talk about well, here are the downstream effects of how it impacts pharmacy reimbursement, the wholesalers, whether the health plans are going to now put a new PA on these drugs to look for those indications or require that physicians write a diagnosis on the drug. I think some of that will come out, but I think it's up to you, as the Board, to have that ability to choose if you

want to have a different upper payment limit for a drug based off of its indication.

Hung Truong: It's a quick follow-up question. So Mike and Simon, is that language we were just talking about, I remember we had this discussion. An NDC drug versus classification of the drug class. Are we -- I guess the question is, can we look at a class? Because going back to the same example, there are competitors, there are a few companies that make the same. They are all priced about the same just because of the competitive nature of it. So I don't remember the language in that we look at the whole class itself.

Mike Neuenschwander: So the WAC in the section that describes affordability reviews, so that is WAC 182-52-0040. It says, "Board may choose to conduct an affordability review of up to 24 legend drugs or biologics per year and consider the following: The first thing is the class of the prescription drug, whether any therapeutic equivalent prescription drugs are available for sale as part of the affordability review to consider that whole class.

Eileen Cody: Well, actually following up on his question that I don't know. Is it the same dosage or the indications are different, isn't it?

Hung Truong: It can be different.

Eileen Cody: Yeah. Oh, so when they are class -- you know, figuring out this as we get back in here, if we were looking at it for different classifications, will we do the different dosages, or would we lump it together? I guess that is another question.

Mike Neuenschwander: It's an open question, but I would say I would take therapeutically-equivalent prescription drugs and say that if it's a different dose, but it is the therapeutic equivalent maybe run in the same class.

Hung Truong: Yeah. You probably don't want to go with the dose because in each drug there is a different active ingredient, and one meets 50 mg, the other one meets 10 mg, but it costs the same. They don't dose by milligrams. They dose based on just what is the equivalent needed. Thank you.

Eileen Cody: Go ahead, Kelly.

Kelly Wu: Okay. Thanks, Ryan, for [cross-talk] -- oh, go ahead.

Doug Barthold: Yeah. I am sorry. Just one other comment on this, and I think I don't know if this is something we have resolved now, but it does seem like -- I am just thinking more about this granularity of the level at which we conduct the affordability review and ultimately the level at which we implement an upper payment limit, and the more granular we that we get, I think it in some ways would kind of it could lead to a perception of arbitrariness in terms of which -- where we implement an upper payment limit. I am just thinking about an example here. Let's just say that there is given that we can only implement so many -- we can only do so many affordability reviews and so many upper payment limits -- if we let's say that we have -- let's say there are five labelers making the same -- working on the same ingredient, and they are all pricing roughly around the same thing. That means that we are either going to do five affordability reviews and then use five upper payment limits on that. But if we have a limit on upper payment limits, then we have to choose just one. And then, I mean, ultimately, you would expect the other four to be impacted by the upper payment limit of the one that we implement. But I think the initial choice of which one we would put the payment limit on, I don't know how that could be not a non-arbitrary decision. So, I don't know. Does that make sense to you? You know, I guess the question of the [indistinct] the rest of the Board if you agreed to that, it seems like it could be an issue.

MaryAnne Lindeblad: [Cross-talk] I will say the truth, [cross-talk] --

Ryan Pistoresi: [Cross-talk] You know, Doug, I think that -- oh.

MaryAnne Lindeblad: [Cross-talk] can you maybe talk a little bit more or -- I don't know. It seems a little confusing.

Douglas Barthold: Yeah. So I guess, like, let's just say that there are five labelers making ibuprofen, and they priced at, like, $100, $101, $102, $103, $104, and we decide that we are going to implement an upper payment limit on the one who was charging $104, and we are going to say, "Okay, you can only charge $50.00." That seems like an arbitrary decision to put that upper payment limit on only that one labeler when the other four were basically charging the same thing.

Ryan Pistoresi: Yeah. And I think these are great points. I don't think that we really are ready to get to that today. I think that is going to be more at a future meeting when we are going to be talking about the affordability review. I think for the

purpose of today and this presentation, we are really going to be focusing on that drug list. But these are great things that I think we need to take back and consider and then get ready for one of the future PDAB meetings when we are going to be a bit more ready on the affordability review. But I think that is a great point that you bring up, and I think Mike and Simon and I and the rest of the PDAB data team are going to be looking at that and considering how do we want to acknowledge that in the affordability review phase before making the upper payment limit decisions.

Doug Barthold: Yeah, and I totally -- I definitely take that point, and I appreciate it. I guess I think the same point would apply to the selection of drugs for [indistinct]. I am sorry. Now, this is a question for Kelly. These criteria, we can -- the criteria that we are applying here, we can apply to essentially an infinite number of NDCs, right?

Kelly Wu: Yeah.

Douglas Barthold: Okay. So there is no constraint right now on this, but even when we choose 24 drugs for affordability review, since we are limited to 24, then that type of -- the same type of arbitrariness could apply at that stage, too, so I think we want to be conscious of that when we get to that stage.

Ryan Pistoresi: And this is Ryan again. I think that is a good point, and I think, again, we will get to that at the affordability review phase. When I think about Colorado, another PDAB state, they do have a system in which they are looking at the different ways in which they rank and value different drugs for their affordability reviews, and I think we would be happy to do some research and reach out to Colorado, learn a little bit more about how they take the initial drug list and try to make sense of how do they go from this initial drug list with you know. Hundreds or thousands of NDCs and hundreds and thousands of drug ingredients and into the affordability review phase. So again, more on that at a future meeting.

Douglas Barthold: Okay, great. Thank you.

Kelly Wu: Okay, great. All right. So moving on to the last two interpretations of the bill. So one of the terms in the bill is we are going to exclude drugs from review that are dispensed at our retail specialty or mail order pharmacy, and so we are going to exclude them based on data from the first data bank or FDB, which is one of the databases that we are using to pull our data, and I will

give some more background on it in the upcoming slides. But we are using two data fields from there to exclude institutional products and products that are likely to be used by home healthcare providers. And then also in the bill it mentions that we also are not going to review drugs that are designated by the FDA for treatment of a rare disease or condition, which are also known as orphan drugs, and so we are going to identify these drugs using the FDA website, which has a database where you can look up these drugs. But at the moment we haven't gone through this process yet, and we are in the stage of exploring if we can make this process more efficient rather than having to manually search for each drug in the website. Okay, so now I am going to jump into the methodologies we will be using to identify the drugs for review. And as Mike mentioned earlier, these methodologies are still preliminary and subject to change. Okay. So in terms of data sources, we are using two commercial databases to get our drug and pricing data, which are (FDB), which is where we are going to pull all the drug information, and then Medi-Span, which we are using to pull the WAC prices, and we chose to pull the pricing data from Medi-Span because it keeps a longer history of an NDC's pricing data compared to FDB, so FDB keeps up to seven price histories or price changes, and Medi-Span keeps [audio cuts out]. And we also have some further exclusion criteria from our affordability review. So we are basically going to exclude everything that is in a prescription drug because even some stuff like lancets or adhesive dressings or like a wrist brace may have NDCs, so we need this step to take them out of our review. And we are also excluding obsolete, withdrawn, or expired NDCs, except in the case of reference biologics, so we are still going to review the biosimilar if its reference biologic is expired or withdrawn. So after these exclusions, this is the number of distinct NDCs per category that are eligible for review. Keeping in mind that we haven't gone through and excluded the orphan drugs yet. All right. So going section by section of the bill, I will start with the methodology for a brand name or biologic products that have a WAC cost of $60,000 or more for a course of treatment lasting less than one year.

Mike Neuenschwander: Hold on, Kelly. We have a question.

Kelly Wu: [Cross-talk] Okay.

Hung Truong: [Cross-talk] Hey, Kelly, a quick question on the orphan drug. So are we talking about -- because an orphan drug can have different indication where other indications are not orphan status, so it doesn't mean that whole drug is excluded, right? It's just for that indication that is an orphan drug.

Ryan Pistoresi: So that is a great question. I think the way that we interpreted this language is that if a drug is solely approved for an orphan condition that it is not eligible for an affordability review. And I think a good example of that would be a cystic fibrosis drug like Trikafta because its only approved indication is for cystic fibrosis, we would exclude it. Whereas Humira -- you know Humira has a lot of different indications, and some of them like, I think, juvenile idiopathic arthritis is an orphan condition, but because it's not solely approved for it, we can review that drug, and as part of the affordability review, you can look at that orphan condition because the drug is not solely approved for that orphan condition.

Hung Truong: Right. Perfect. And then one more question. Kelly, can we think about adding data as pricing criteria? Look into that. I know we were looking at WAC, but I think NADAC could be an important data source for us.

Eileen Cody: What is NADAC?

Hung Truong: It is the National Drug Cost. It's fairly new.

Ryan Pistoresi: Yeah, yeah, that is a great point. I think the reason that we are using WAC right now is what is in the RCW for us to look at the price point. But I think as we are moving into the affordability review, we can certainly use NADAC and other pricing points that that we saw earlier on in the presentation. But I think for now we are required to use WAC because of the statue.

Kelly Wu: Okay. Yeah, I made a note of that, so we can look up if NADAC will be helpful for us. Okay, so moving on to the first section of the methodology. So I want to go into more detail about the FDB data that we are using for this section, so we are specifically using the FDB Dosing Module, so this contains dosing data for NDCs by age category, and I am going to show an example of how the data looks in the coming slides. And so the FDB gathered this dosing information by reviewing things like manufacturer documentation or clinical literature to identify the high and low dosage amounts for each NDC, and our goal for using this data source is to determine how much of a drug a person would use in a year if they were to take it by the book, so if they followed their prescribed regimen perfectly. And so in order to better understand that data, I need to introduce you to some of the terms that you will see in that data. So you will see the term high dose, and that is the high dose per day for that NDC, and it is specific to age, reason for use, dose type, and route route

of administration. And there is also the high duration of therapy, and that is the recommended amount of time and days that the drug should be used. So, for example, if the doctor gives you an antibiotic and tells you to use it for 10 days, then the duration of therapy would be 10 days, and the duration of theory would be 10 days. And we are using the high duration of therapy in our methodology, so this would be the high-end of the recommended amount of time to take the drug. There is also disease duration, which is the length of diagnosis, disease state, or health-related condition or procedure that someone would use this NDC for. So in the FDB data the disease duration could be acute, which are diseases which can develop suddenly and last for a short amount of time, like the flu or an injury. The disease duration could also be chronic, which are diseases that persist and last a long time, like heart disease. Or the disease duration could be classified as both, so the dose would be for both acute and chronic disease durations. And then I will also be referring to the term "maintenance dose. " That is the dose of the drug you need to take to get a steady concentration of the drug in your system, and then also single-dose, which is the amount of the drug taken at one time. Okay, after understanding the data better we had some additional exclusions from our review, so we are also going to exclude vaccines and non-drug products. Vaccines are biologics, so they wouldn't have been filtered out by our previous exclusion criteria. And also even though we tried to filter out all the non-drug products, some of them still have brand names, so they got included, and we need to take them out again in this [indistinct]. Okay, so in order to identify which drugs are brand name, we used a field in the FDB that is called the generic name indicator. So it basically uses the name of the NDC to identify whether it is brand, generic, or something like medical devices or healthcare products. We identified biologics using the FDA Purple Book. This is a database that is maintained by the FDA that contains information on all the FDA-licensed biological products. Okay, so there are three main steps that we plan on taking to calculate the cost of a course of treatment. So first, we need to deduplicate the data, which I will go into more detail in the next slide because an NDC can have dosing data for multiple age categories, disease durations, or dosing type. And then after we do that, we will multiply the NDC's high-dose by the high duration of therapy in days, and then that will get us how many NDC units would be used in a year, and then we would multiply that by the NDC's WAC unit price as of January 1, 2023, and then that would get us the cost of a course of treatment for one year. And so we are choosing to use the high dose and the high duration of therapy because we want to capture the high end of what people would pay for a course of treatment. Okay. So to better walk everyone through the deduplication

process, I have here a sample of what the FDB dosing data looks like. So in this case, I am showing data for Bactrim, which is an antibiotic. So just for this one -- and you see there are multiple rows of dosing data for different patient ages and dosing types, and our end goal of the deduplication process is to wind up with just one row of information for this NDC that we can use to calculate the cost of a course of treatment. Yeah, go ahead.

Douglas Barthold: Yeah, thanks. I was just wondering how much variation is there between, I guess, like the high dose and the low dose or average dose? I am just wondering if we are calculating the high end, how different is that going to be if we calculated it for for the average?

Ryan Pistoresi: [Cross-talk] You know that's a [cross-talk] --

Kelly Wu: [Cross-talk] I think [cross-talk] oh, go ahead.

Ryan Pistoresi: Yeah, I was going to say that that is an interesting question, and I think given that the range is pretty much every drug for every disease state, some disease states are going to be different, and the reason that we were selecting this high dose is that we wanted to capture the population for Washington, so not necessarily looking at an average dose in which we would potentially say that this drug doesn't meet the affordability review, but we have some people on the higher end who may be having some of the affordability issues that we could be ignoring. So we erred on the side of caution, and we are looking at the higher dose so that way we try to capture more of the complete population including those that were at the medium dose and even the low dose, and so that is why you know for this initial one we are selecting the high dose.

Doug Barthold: Okay. I agree with that. That makes sense. And then, yeah, maybe at the next stage, we will want to consider utilization as well, I mean, just to make sure that it is a medium to large population that uses that at whatever dose we are calculating for. But, yeah, that makes sense for this this selection phase. Thanks.

Ryan Pistoresi: Right. And on that note about the utilization, I think that is part of the affordability review, so we do have plans for how to look at how the state population are utilizing these drugs, but I think that is going to be more in the affordability review than here in the initial price list.

Douglas Barthold: Great. Thanks.

Kelly Wu: Yeah. And that is also like one of the limitations of our methodology, which I will talk about at the end of my presentation. Okay, so this is the deduplication algorithm that we developed to achieve the goal of narrowing down the data to just one row per NDC. So for the first step, we are going to keep the NDC's maintenance dose, and if an NDC doesn't have a maintenance dose, we will use the single dose. So going back to Bactrim, you can see that there is like a single dose and maintenance dose. So according to our algorithm, we would just keep the maintenance dose rows to look at and not look at the single or the loading doses. And then if the NDC doesn't have any maintenance dose there, then we would go with the single dose, and we aren't considering the loading dose because that only exists if there is a maintenance dose because you have to load up to get to the maintenance level. And so after step one where we keep only the maintenance dose, we would use only the chronic dose for our calculations. So if the NDC isn't used for any chronic conditions, then we would use the acute dose. So this is in line with our goal of wanting to calculate what is the highest that a person may spend on this NDC for their course of treatment. So going back to Bactrim, the disease duration is both acute and chronic, so we are not going to be able to eliminate anything in this step for Bactrim. And then, finally, for our algorithm, we are going to use the dose for the highest age category. So for the algorithm, if an NDC it can be used for both kids and adults, this algorithm would choose the dosing data for adults, and if, for example, there is dosing data for adults 18 and older, but one is for age ranges 18 to 65 and another is for 18 to 110, the algorithm would choose the data for ages 18 to 110. So this is not the case for Bactrim because the data is just for 18 to 110, so that is what the algorithm would choose. And so after running the deduplication algorithm, we would end up choosing the data from the row for Bactrim, which I highlighted here. So again, you didn't have to choose between using chronic and acute disease durations here since the disease duration for these doses are for both chronic and acute. So we would just end up choosing the maintenance dose and the highest age range of the data available. Which is 18 to 110 years old. Okay. So after deduplicating, we would just have one high dose associated with each NDC. So we will divide the high dose by the NDC strength because one high dose may not always be exactly one pill or one unit of NDC, and then we need to know how many units of the NDC was used for a high dose. And then once we calculate that, we multiply it by the high duration of therapy in days. So if it's used every day, for example, the high duration of therapy would be 365, and we would

multiply that number by 365 to get the total units of the NDC that a person would use in a year. And then once we get that, we will multiply it by the WAC unit price as of January 1, 2023 to get the cost of a course of treatment. So this is step three of the methodology, and the formula here just fills out all of what I just said, and I also have an example prepared in the next slide to show this formula. And so one extra step that might happen that is not shown in this formula is a unit conversion. So sometimes the units of the high dose are not in the same units of strength as the NDC. So, for example, the high dose could be in milligrams, but the NDC is in grams, so then we need to include a conversion factor to convert milligrams to grams to find out how much of the NDC is used for a high dose. So another complication with [cross-talk] --

Mike Neuenschwander: Okay. Hold on, Kelly. So we are going through a lot of material here real quick. Any questions about deduplication or conversions or the initial calculating cost of course of treatment. It's a lot, so please, if you have questions if you want to stop. I know Kelly spent a lot of time looking at this, but this is your first go around at it. Hung, did you have a question?

Hung Truong: Yeah, Kelly, did you look into like -- I know some of them is they look at the number of syringes, not necessarily the mg or mL. I don't know [cross-talk] if that [cross-talk] --

Kelly Wu: [Cross-talk] Sorry. Yeah. So some of the conversions are more complicated than just applying a conversion factor, so that is where I am roping in Ryan and the pharmacy team to look over some of the more complicated conversions to see like how we would calculate the unit price for those.

Ryan Pistoresi: Yeah, and that is a great question. So we did look at what types of units were used for that max dose or the high dose, and we tried to simplify it in either milligrams or tablets per day or milliliters. But for some of them the way that it was entered in this database is some of the more complex ones. So if you think about certain chemo drugs where they are looking at body surface area, we had to do some other calculations for that, and I think later on in this presentation, we will talk about some of the more complex ones.

Mike Neuenschwander: Any other questions? Okay. Sorry, Kelly. I just want to make sure we are addressing any questions if we have them.

Kelly Wu: Oh, no worries. Thanks, Mike. And yeah, feel free to interrupt me if you want me to go over something again. Okay. So let's go over an example of how we would calculate the course of treatment. So this is real data, and we are going to look at the data for Juxtapid. Sorry, I am going to be butchering these drug names all day. So Juxtapid is a brand name drug, and it helps lower cholesterol in adults who have a disorder where it is hard for the body to remove the bad cholesterol from their blood. And so after we run the deduplication algorithm, we are going to use data for Juxtapid for patients 18 to 110 years old. We'll be using the maintenance dose, and it's going to be for both acute and chronic disease durations, and the high duration of therapy in the data indicates that this is a chronic medication, so the person will be taking this medication every day of the year. So this is what Juxtapid's data looks like in our database. So the high dose of Juxtapid, which is in the leftmost column, is 60 mg a day. And this is a chronic dose, so you would take it every day, 365 days a year. The NDC strength on the second to right column is 30 mg, and it comes in 30 mg capsules. So applying our formula, the high dose is 60 mg a day, according to the data, and a capsule of this medication is 30 mg. So a person is going to end up taking two capsules a day every day for the high dose, and so that is two capsules x 365 = 730 capsules a year. And the WAC unit price for this NDC as of January 1, 2023 is $1710.61 per capsule, and this price came into effect on January 1, 2022, but that was the price as of January 1, 2023 because there are no other increases. And so, according to our formula, it would be 730 capsules at the cost of $1710.61 per capsule, so for a year that is $1.2 million per year for a course of treatment. That is definitely over our threshold of $60,000 for a course of treatment, and that would qualify this drug for review. So I am just going to stop here because that is the end of this section. If anybody has any questions or comments.

Eileen Cody: I would have to think about it a little bit.

Multiple Speakers: Yeah. Yeah. Yeah.

Eileen Cody: Yeah. It's the million dollars [cross-talk] --

Multiple Speakers: [Cross-talk] --

MaryAnne Lindeblad: Right? [cross-talk] --

Eileen Cody: Yeah.

Kelly Wu: Okay, great. [Cross-talk] All right, so. Oh.

Mike Neuenschwander: [Cross-talk] And we have spent weeks looking at this stuff. So again, we have been trying to ponder this and figure it out, so we are not expecting you guys to just look over this in five minutes and be, like, Oh, that looks good!

Kelly Wu: Okay, well, if you think of something later on and want to come back, we can always come back because there is going to be a discussion section at the end. Okay. Great. So now we will move on to the second part of the brand and biologic drugs for review, so hopefully this part is a little more simple to understand. So this part would be new reviewed drugs that have a 15% price increase in a 12-month period for a course of treatment lasting less than 12 months or a 50% increase over three years. Okay. So to calculate whether an NDC has a price increase of 15% or more in any 12-month period, we are defining the 12-month period as the 12-month period prior to the date that the NDC's current price as of January 1, 2023 was set. So I will be showing an example in the next slide. Let's say the drug has a price of $20 as of January 1, 2023, but this price actually came into effect on July 1, 2022, and there are no other price changes since then. So this $20 would be the price as of January 1, 2023. And then now the 12-month period that we look at for this drug would be 12 months back from July 1, 2022 when this $20 came into effect. So the 12-month period would be July 1, 2021 to July 1, 2022. So according to our methodology, if this drug had price increases in October 2021, January 2022, or March 2022, we would use the earliest price in the period, so we would use the price increase from October 2021 for our calculations. And if the drug had no increases in the past 12 months, we would use the drug price as of the start of the 12-month period. So back to our example, if the drug had no increases between July 1, 2021 and July 1, 2022, we would use whatever its price was as of July 1, 2021 for our calculations. Does that make sense? Because I just mentioned a lot of different years and dates.

Eileen Cody: Sort of [laugh].

Doug Barthold: Okay. So it's over the -- so on January 1st of '23, we are basically looking at all of '22 and calculating the percent change since 12 months ago for all of '22, and then if that ever is 15%, it qualifies.

Kelly Wu: So not from 2022 because a lot of drugs may not have had price increases in 2022, so we would just be leaving out a whole bunch of drugs from our

review, so we would be looking at what its price was as of January 1, 2023. So maybe its last price increase was from, like, 2020, so that would be the price we would look at for our review, and then for the 12-month period, it would be 12 months back from whenever they had that price increase. So if they had a price increase in 2020, then we will look at one year back from that 2020 date, if that makes sense.

Doug Barthold: I see. So basically your first selection is you look at the set of price increases, and then you calculate it, basically, if any of those were up 15% or more. Is that right?

Kelly Wu: So it would be like the -- so the most current price as of January 1, 2023, whenever that was set and then, like, the earliest price in the 12-month period, so if they did have an increase in that 12-month period, we would use, like, the earliest price increase, and if they [cross-talk] didn't, then we would use whatever the price was at the start of that 12-month period [cross-talk] because like not every drug always has a bunch of increases in a year.

Doug Barthold: It makes sense. And then the example you are giving here is for January 1st of '23. Do we also do it -- or do you also do it in prior years, too? Or does it has to be during that -- this most recent year.

Kelly Wu: No. So what we are saying is the NDC's most recent price as of January 1, 2023, so that is just what their price is so that is not like -- it doesn't -- like, their price doesn't have to be set right then. Like if a price increase happened in 2020, that would still be the price in 2023 because nothing else happened.

Doug Barthold: Got it. Okay. Great. Thank you.

Kelly Wu: Yeah.

Ryan Pistoresi: Yeah. And I think an important thing to note is that we are doing this price review every year, and so this time next year as we are getting towards the June 30, 2025 deadline, we will be looking at the previous year from that. So each year is going to be a new review over this 12-month period, so we should be able to catch every single price increase every single year.

Doug Barthold: Okay, thanks.

Hung Truong: Hey, Ryan, it's Hung. Are you looking at calendar year? Because there are occasions where prices go up two or three times a year.

Ryan Pistoresi: [Cross-talk] Yes, so [cross-talk] --

Kelly Wu: [Cross-talk] So we are looking [cross-talk] --

Ryan Pistoresi: Oh, go ahead, Kelly.

Kelly Wu: I was going to say that we are looking at 12 months back from the last price increase date, so whatever 12 months is so we are not saying, like, calendar year or fiscal year or anything.

Hung Truong: Okay. Okay. Whenever. If there is a price increase, then we look back.

Kelly Wu: Yeah. So I will show that in an example in the coming slides, so hopefully, that will illustrate that better.

Hung Truong: Thank you.

Kelly Wu: Ryan, did you want to say something?

Ryan Pistoresi: Nope. I think you covered it. Thank you.

Kelly Wu: Okay, great. So, just to go over the increased formulas, it's basically the new price minus old price, if you will, divided by the old price, and then I will show an example in the next slide that will hopefully help everybody understand this better. Okay. So the drug I am going to use for this example is Nalocet, which is a brand name painkiller. So if you look at the rightmost column, the current unit price or the most recent price we have as of January 1, 2023 is $31.73, and that came into effect for this drug on January 1, 2022. So according to our methodology, the 12-month period is 12 months back from January 1, 2022, so that would be January 1, 2021 to January 21, 2022, which is the period which we would look for an increase, and so for this particular drug, there was no price changes in that period, so we are going to use whatever its price was as of January 1, 2021. So the beginning of that 12-month period you want to look at, and so that price is $24.04, and that came into effect on July 1, 2020. So these are the two prices that we would use to calculate the price increase. Does that make sense?

Hung Truong: Yes.

Kelly Wu: Okay. All right, so now is the easier part where we just plug in the numbers to our formula. So we will do the current unit price, which is $31.73, minus the price as of January 1, 2021, which is $24.04, which came into effect on July 1, 2020, and then based on these prices, we get that balance to increase by roughly 32% in a 12-month period, which exceeds our review threshold of having a 15% or more increase. Is everybody following that?

Multiple Speakers: Yeah. Yeah.

Mike Neuenschwander: I think so.

Eileen Cody: Yeah.

Kelly Wu: This one is more straightforward. It is a little easier to get. All right, so there are no questions on that. The three-year, 50% increase is very similar, so we are just looking back three years instead of one year, and I also prepared another example for us to look at. So the drug, Mytesi, is used to treat non-infectious diarrhea in adults living with HIV and on antiretroviral therapy. So again, this is really similar to the previous example, except we are looking back three years from the most current price change. And so for this specific example, its current price as of January 1, 2023 is $39.58, so this is a price that still stands from the price change on December 1, 2022. So that means we are going to look back three years from December 1, 2022 and see what its price was, so the time period would be December 1, 2019 to December 1, 2022. And so, in this case, there was a price change in that period, so January 1, oh -- there was not a price change in that period. Sorry about that. Its most current price as of the beginning of the three-year period was a price change from January in 2019, and there are no other increases since then, so that price still stands as of the beginning of the three-year period we want to look at, and that price is $11.14. And then the easy part where we just plug the numbers into our formula. So after plugging in the numbers, we get that there is a roughly 255% increase for this drug over a three-year period, which is over the 50% threshold for review. So that would qualify this drug for review by the Board. So is everyone okay with this part?

Doug Barthold: I just have a question. I agree with how you are calculating the percent changes. I just have a question about what we are using as a unit price, and like what is a unit? You know? Like in the previous section, you gave us a

detailed description of how you are calculating the WAC for a course of treatment for a year. Right? For a course of treatment, and like that was kind of like our unit price, so what is our unit price for these percent changes?

Kelly Wu: So it's the same. It's the WAC unit price. Sorry, I should have mentioned that in those slides.

Douglas Barthold: Great.

Kelly Wu: But yeah, for the WAC unit price.

Doug Barthold: And that is for a course of treatment -- over a year a course of treatment.

Kelly Wu: Um, no. So it's for our price increase. So we are comparing like the WAC price to see if it increased.

Ryan Pistoresi: [Cross-talk] And so --

Doug Barthold: [Cross-talk] Okay. And so -- and because -- but so whatever the course of treatment is, it should be consistent between those two, so it shouldn't matter if that is like for a one-day supply or for a one-year supply?

Kelly Wu: [Cross-talk] So [cross-talk] --

Ryan Pistoresi: [Cross-talk] Yeah, so [cross-talk] yeah, I was just going to say, yeah. Yeah. So for this one, we are just looking at the price increase because it's going to be the same drug [cross-talk] the disease treatment or the duration of treatment we assume is going to be the same because it's the same drug. So that is why we reduce that in this step. Whereas when we are looking at the total course of treatment or the cost per year, we do have to factor in what that dosage strength is. But for this one, it makes it a lot easier because we are just looking at price A and price B.

Doug Barthold: Great. Got it. Thank you.

Kelly Wu: Yeah, so in, like, formula terms, if you were to consider the number of units used, it would just cancel out.

Douglas Barthold: Yeah.

Kelly Wu: Yeah.

Douglas Barthold: Okay, cool.

Kelly Wu: Okay. Great. So, lastly, we are going to go over the methodology for identifying biosimilars with an initial lot cost that is not at least 15% lower than its reference biological product. Okay. So the FDB maintains information on which NDCs are biosimilars and reference biologics and provides documentation on how to link the biosimilars with their reference biologics, so that is what we use to pull the biosimilars and their reference biologics. And we will calculate the increase using the price of the biosimilars earliest listed WAC price and comparing it to the price of the reference biologic at the time of the biosimilars' earliest listed price. Also using a really similar formula to what I just showed in the previous example, and I will show an example in the next slides. I want to mention that I say earliest listed WAC price, not the launch WAC price, which is what is in the bill because Medi-Span contains a history of 12 price changes, so if a drug has had more price changes than that, the earliest one may not be in Medi-Span. So this is also a limitation that I am going to talk about later in the presentation. I just want to put that out there. So any questions about this part so far? Okay. So in this example we are going to look at a biosimilar, Semglee, which is an insulin, and its reference biologic is Lantus. You may remember this from the example that I showed about what biosimilars and reference biologics are. So we can see that the initial WAC price of Semglee, the biosimilar, is $26.94 in October of 2021, and the price of Lantus as of October 20, 2021. The date of the initial price is $28.35, and this price has been effective for that since January 4, 2019, so these are the two prices that we would use for our calculations. Okay. So as a reminder, we want to review any biosimilars whose initial locked price is not at least 50% lower, which is different from the previous sections where we wanted to review the increase. So this is we want to see if it's lower. So after applying our formula to this example and plugging in those prices, we see that Semglee is only about 5% lower than Lantus, so this qualifies Semglee for review by the Board because it's not at least 15% lower. Sorry. I thought someone was talking. Yeah, so let me know if you have any questions because that is the end of this section of the methodology, and then next we are going to move on to discussions and questions.

Hung Truong: Ryan, Kelly, what do we do with same drug but high WAC and low WAC different NDC but same drug?

Ryan Pistoresi: So in that case -- as I think you are probably referencing some of the new Humira biosimilars that are coming to the market -- we would be capturing just the ones that have the high WAC, and the strategy with those is that they are offering rebates to offset that cost. But per the definition in the statue, we would capture those, but not the low WAC ones, unless the low WAC ones are not at least 15%, but in those cases, yeah, we would just be capturing the high WAC ones.

Eileen Cody: So have you -- do we have any preliminary idea of how many are going to fit these three different examples like that? I know that since we haven't really decided on the methodology yet that probably we don't have it for sure, but I just was wondering if you have looked at and have an idea of what a ballpark of how many different drugs fall under each one of the categories?

Kelly Wu: So we did run the data, but we haven't really reviewed it yet because we are still in the process of developing this methodology. But, yeah, I think we are going to share that in a future Board meeting, where we will share the number of drugs that we found, and maybe we will even have the list ready, so that is definitely something we are going to share with the Board.

Eileen Cody: Well, I just was curious as to which one of the formulas is going to drive the biggest amount -- number. I was trying to see if it was even between the three or if there is going to be a thousand drugs underneath the first one and only five drugs under the last one, and so like I just was curious as to which one of the formulas seems to drive the --

Ryan Pistoresi: And that is a great point. I think as we are getting this list ready for you to review, I think part of the presentation could be to say here is how we identify these drugs based off of these different criteria, and then that way you have a number of drugs that met those criteria, and I think we should also then look at how many were eligible within those criteria. Right? How many of these are the brand name drugs? How many of these are biologics or biosimilars? And then that way I think it gives you a better sense of how these different drugs meet those criteria.

MaryAnne Lindeblad: So Ryan or Kelly, is this a similar approach to what we are seeing is happening in Colorado?

Ryan Pistoresi: So this is Ryan again. Yes. I believe that some of the criteria are similar, but it's not the exact same. So I think in Colorado they have a lower price threshold for that cost per year or cost per course of treatment. I know in Colorado they can look at orphan drugs, so when I mentioned Trikafta earlier in the meeting, that was actually one of the drugs that Colorado did an affordability review on, and so they do have a lot of information that they have presented to their Board around that drug, whereas for us in Washington per our RCW, we are not allowed to look at that type of drug. So there are some differences, but the methodology is fairly similar between us and the other PDAB states.

MaryAnne Lindeblad: Thank you. Any other questions?

Douglas Barthold: I have a couple. Can you remind me what RCW is?

Eileen Cody: Revised Code of Washington.

Douglas Barthold: Right. Okay, thanks. And then I guess my other question is, should there be a third category for generics, or is that -- wait, is that just not -- have we not done that yet?

Kelly Wu: Yeah, so we are still working on that, and we are going to present it at a future meeting.

Doug Barthold: Okay, great. Awesome. Yeah, I wasn't sure if that was getting -- it looks like it should be relatively similar in terms of applying the rules that you have already told us about to just to generics. But okay, thanks. Yeah.

Eileen Cody: And actually, I guess I have a question. When we are doing -- when you are doing the work on this, whether you will be able to tell us or come up with the list where the drug might show up in three categories, I mean we would have the generics and would put it on these three, I would think it's possible that it is over $60,000 a year they have increased the price by over the three years over 50% and 50% one year. Like [cross-talk] mathematically impossible. Right?

Kelly Wu: Yeah. So we did find some NDCs that had increased 15% over a year and over 50% in three years. So, yeah, that is possible.

Eileen Cody: So those might be the ones we really want to focus on. It's kind of like the Trifecta.

Mike Neuenschwander: [Laughter] We and that --- once we get the list, that will be a whole other discussion is trying to figure out how to sort that list because, again, other states have had hundreds but then they whittled it down to five. And so part of that is that there could be a whole host of considerations. Do we want to look at a million dollar drug versus a drug that did have a 15% increase, but it's still only $30.00. Right? You know, does this -- how much of the population does this affect? Is this a drug that a lot of people are using? Or is it just a specialty that only a couple hundred, maybe. So there is going to be a -- that is going to be a whole other methodology in of itself of how many drugs do we want to look at, A.), and then B.), how do we choose those?

MaryAnne Lindeblad: Go ahead, next.

Kelly Wu: All right. So the next part of the presentation is almost the last part. So I am going to go over some limitations to our current methodologies, and then we can jump into any more discussion or questions if there are any. And so throughout the process of developing our methodologies, we identified some limitations. And so, first of all, we aren't making any adjustments for price inflation. So in terms of how this would affect our review is we may end up overestimating price increases because if we adjusted for inflation, then the older prices would be higher in today's dollars, so the increases wouldn't be as big. Another limitation is related to our data sources, which I mentioned before. So Medi-Span, which we are using to pull the price data, may not contain the complete price history for an NDC, so what this would affect would be the biosimilars because we need to pull their launch WAC price. So if the biosimilar have many price changes when it came out, the earliest listed price may not be its launch WAC price, and I don't think this would cause us to specifically under or overestimate anything, but because since we are comparing the earliest listed biosimilar price to the price of its reference biologic at the time, you would think they would both be increasing over time, so maybe their price gap is sort of constant, but just something to note because it may be possible for the older biosimilars that are like 10 years old or something that they may have had 12 price changes or more, and so we wouldn't be pulling their actual launch records. And then, finally, another limitation that we identified is that we are using the high dose and high duration of therapy to calculate how much of a drug that people are using in a year, and this might not reflect the amount that most people are prescribed.

So going back to Bactrim, the antibiotic that I used for my deduplication algorithm example, so I took this before for, like, 10 days for a skin infection, but when I looked up the dosage data, it can also be taken for three weeks for a type of pneumonia that affects people who are immunocompromised. So based on our methodology would be using that three weeks to use for the course of treatment, but probably most people are taking it for a shorter term to treat an infection. So this might cause us to overestimate the amount that most people would spend on a course of treatment. All right, so I am going to stop there and see if anybody has any questions or comments.

Eileen Cody: I have got a question about it. So when you are talking about looking at the history of the biosimilars, I guess I envisioned that maybe you were telling me something and I am not getting it. But the release of a new biosimilar, I think, was what we were discussing in the Legislature about. So are you talking about -- let's use some of the MS drugs, or we have got biosimilars since I know a little bit about those. Are you saying that you are going to go back and look at the released price of those biosimilars and compare them to the name brand? Because, I mean, some of them have been out for years.

Kelly Wu: Yeah. So at the moment, we want to try to review all the biosimilars, but we might modify that later. So, yes, we are at the moment we want to review all the biosimilars and look at what their launch price was compared to the lot price of their reference biologic at the time.

Eileen Cody: Well, they will get most of the biosimilars. Won't they also get caught in the dosage or, how much, $60,000 a year? I mean, I guess I am questioning whether it's worth -- The juice is worth the squeeze and going through and figuring all that out.

Kelly Wu: Yeah, but we are doing it by statistical programming, so there's no manual working vault, so might as well just run it on the whole data set, right?

Eileen Cody: Yeah. Okay.

MaryAnne Lindeblad: Anything else?

Mike Neuenschwander: Doug?

MaryAnne Lindeblad: Doug has got a quick question.

Mike Neuenschwander: Doug's got a question?

MaryAnne Lindeblad: Yeah.

Douglas Barthold: Yeah. I wanted to ask, did the Legislation provide any guidance on inflation?

Eileen Cody: No.

Ryan Pistoresi: So, yeah. So that is a great question. The Legislation does not talk about inflation or adjusting for inflation. So for this analysis we are not doing any adjustments.

Douglas Barthold: Okay. I mean, presumably it doesn't really matter that much at this stage where we can -- essentially, we are going to have a long list that we are going to whittle down. But ultimately, I mean, I think that does -- that will matter a lot because, I guess, if we are looking at you get a 15% price increase in 2022, that is very different than if you had one in 2020, so we want to consider that eventually.

Hung Truong: Quick comment. Are we looking at market condition as well, Ryan? Let's say a manufacturer -- you know, there are three or four and then one just stopped making it then, hence, supply demand and prices go up.

Ryan Pistoresi: So that is a good point. At this stage for this initial price list, we are not considering that. I think that will come into play during the affordability review phase, and I think, Mike and Simon, that is something that we will need to look at as we are putting together our methods for assessing the affordability review and what information we would want to put together because I think that is going to be an important point that tells the story of why its price might have changed during this review phase.

Mike Neuenschwander: Yeah, correct. Because this first part is just trying to get that list based on the price considerations that are outlined in the Legislation. But then, yeah, that drug review is going to go into a lot more of the details of the why. Why does it look like this? How does it look like this? That that will help us give the information. Considering all these other factors, is it supportable or not, right?

Eileen Cody: And give you the opportunity to ultimately whittle down the list.

Mike Neuenschwander: Yeah. Well, so yeah. We have the initial list, which is our our biggest. It is our first methodology, it's our biggest based solely on these price factors and then after that, yeah, then we have our methodology of how we are choosing that. What is it? How many people does it affect? And once we look at the drugs specifically, then we start taking in all these other things into account. Is this only drug to have a high cost to manufacture etc., etc.

MaryAnne Lindeblad: These are just the first sort of [cross-talk] --

Mike Neuenschwander: [Cross-talk] Yeah.

MaryAnne Lindeblad: Yeah, right.

Mike Neuenschwander: Yeah.

Eileen Cody: Well, and I will ask our AG this question. So because it's not in the Legislation, though, the Board can make further -- just like if we decided that we are going to figure out the inflation over the three years when we are looking at it through the three years, we could -- the Board could decide that we would include inflation and deduct it. Right? It doesn't -- that doesn't have to be in the [cross-talk] --

Michael Tunick: [Cross-talk] I don't think I am the only one to answer this, but yeah, I mean I kind of get the idea that there is sort of like the entire universe of [cross-talk] drugs, and then there's sort of a statutory criteria that is like, whittling it down to like 5000 drugs, and then you are going to have to somehow [cross-talk] --

Eileen Cody: [Cross-talk] Take it down to [cross-talk] --

Michael Tunick: -- nonarbitrary ways to get it down to something that is more manageable up to 24 per year.

Mike Neuenschwander: Yeah, and there are a lot of things that we shall, that we need [cross-talk] to look at, things we may look at, and then there is that kind of open-ended and other things [cross-talk] --

Eileen Cody: [Cross-talk] The Legislature likes to include a little flexibility [cross-talk] --

Mike Neuenschwander: Yeah, other things Board considers [cross-talk] important. So yeah, I feel like things like that could fall under [cross-talk] that other category.

Kelly Wu: All right. So now getting into the next steps. All right. So for the next steps, we are going to finalize the methodology for the third section, which I didn't show today, so calculating the amount of NDC units used for a 30-day supply, we are going to finalize our methodology for identifying orphan NDCs, and then we are going to produce preliminary lists for the Board to review. And that is the end of my presentation. So thank you for listening. Yeah. And hope it wasn't too much for everybody.

MaryAnne Lindeblad: Any other questions for Kelly?

Eileen Cody: Well, I guess the question I'm -- on calculating the amounts, what are you trying? Are you going to have maybe thinking about low and high, or what are you -- what are you -- what's in your bag of tricks now trying to figure? What are you figuring out for [indistinct]?

Kelly Wu: Um, are you talking about the amount for the third part of the [cross-talk] --

Eileen Cody: The NDC units. The first thing that your -- on your list of what you have to finalize.

Kelly Wu: Yeah. So we are actually kind of -- we are trying to develop how we are going to find out how many units somebody uses for a 30-day supply because the FDB data that we are using doesn't include days of supply, so we are wondering how we are going to divvy up the duration of therapy or how we are going to figure out what a 30-day supply is. So that is, yeah, what we are trying to develop. I hope that answered your question.

Eileen Cody: I guess, yeah.

MaryAnne Lindeblad: Any other questions? So we went through this pretty quickly.

Eileen Cody: Yeah, I know.

MaryAnne Lindeblad: It is now time for public comments, right?

Mike Neuenschwander: Yeah, we could do public comment, and then we will just kind of go over real quick our next meeting that is coming up and do that.

MaryAnne Lindeblad: Sounds good.

Mike Neuenschwander: So you want to take a short break before public comment?

MaryAnne Lindeblad: Yeah, let's do that.

Mike Neuenschwander: Okay.

MaryAnne Lindeblad: Let's take a little five-minute break [cross-talk] --

Mike Neuenschwander: [Cross-talk] Okay, great.

MaryAnne Lindeblad: -- because the public might not be.

Mike Neuenschwander: Okay. So let's come back here at 10:35, and then we can do the public comment.

MaryAnne Lindeblad: Thank you.

Mike Neuenschwander: Doug?

Eileen Cody: See, we could have started later.

Mike Neuenschwander: I know.

Eileen Cody: So I could have [indistinct].

[break]

Mike Neuenschwander: Welcome back, everyone. I will go into the public comment portion of our meeting here, and Simon will introduce the various commenters as they are signed up. Then after that we will wrap up and talk about our next meeting, and it should be good. Simon.

Simon Borumand: Cool. So as with prior meetings, each commentary there will be three minutes to speak, and we ask that you start with your name and your affiliation or who you are representing if anyone, and we can start with the folks in the room if anybody wants to make a public comment. A lot of shaking heads. So then we will go to the two names that had signed up in advance. So Daria

McGrew from Pharma and Tiffany Westridge Robertson from AI Arthritis. So maybe we could start with Daria, and I will go to the participant section and see if I can unmute you. One moment here. We just got to switch computers to access the right people. Okay, great. Daria, do you have access now to speak?

Daria McGrew: I think I do. Confirming you can hear me.

Mike Neuenschwander: Yep.

Daria McGrew: Okay. Thank you so much.

Mike Neuenschwander: Feel free to go ahead and start speaking, and I will start the timer in the background.

Daria McGrew: Okay. It's not giving me video. Oh, but that is fine. Thank you. Thank you, Board and staff for the conversation today. Daria McGrew, Policy Director for Pharma. I appreciate the recognition in your discussion early on in the meeting that there could be great interest in these proceedings from stakeholders. In that vein, I ask you to make changes to your processes, specifically around public notice and public comment. So far, the public notice of your meetings and meeting materials to date have not given stakeholders adequate time to evaluate comment. For the Board policies last month, no feedback was requested or noticed, and we did submit comments after the meeting but note that there was no additional discussion of the policies before a vote was taken today. And we ask you to please clarify inconsistencies in your public comments. For example, your website requests to written testimony one week prior to meetings, but the agenda and slides weren't shared before that deadline, so requesting revisions there. For today's meeting, thank you for walking us through the methodology in such detail and how much work you have already put into it. I note that we -- as I noted, we weren't able to comment -- review or comment on the slides ahead of the meeting, but we will provide comments later. As you move forward, encourage you to post not just your methodologies but also data in advance of the meetings as we have seen in other states going through this process. There are frequently errors or revisions needed of the data sets as you go through this process, and the public needs to be able to review and provide feedback in an adequate time before any voting decisions are made. Thank you for your time.

Mike Neuenschwander: Thank you very much.

MaryAnne Lindeblad: Thank you.

Mike Neuenschwander: Great. And next we can move to Tiffany. You are on. We have allowed you to talk [cross-talk] --

Tiffany Robertson: [Cross-talk] Okay.

Mike Neuenschwander: -- if that works.

Tiffany Robertson: Can you hear me?

Mike Neuenschwander: Yep.

Tiffany Robertson: Okay, great. May I go ahead and start?

Mike Neuenschwander: Yep, yeah, [cross-talk] [indistinct] time [cross-talk] --

Tiffany Robertson: Okay, great. Thank you. So I just wanted to thank the Board and staff for allowing us to participate today in your meeting, and I also wanted to thank your staff for having a meeting with me. I represent the International Foundation Autoimmune Autoinflammatory Arthritis. We just say AI Arthritis for short as you can see for obvious reasons, long name, and just appreciate having a prior meeting to better understand the processes and inclusions of patients and patients' organizations in the process, and saying that I just wanted to focus really on that as you are thinking about your process development and the importance of including patients and patient voices. I am really thrilled to see the opportunity for extended stakeholder opportunities for people who are on the drugs that end up being included on the lists to have those people as part of the extended stakeholder. Brilliant idea. I am definitely going to share that with other PDABs. And I just wanted to really encourage you to reach out to patient groups including AI Arthritis. We have done a lot of work with other PDABs as well as CMS, and as people living with the diseases because of that lived experience, we have identified some pretty serious flaws in the processes that they have utilized to include patients, for example, surveys with questions that the design has is going to render some incorrect data. For example, myself as a patient, I also have axial spondyloarthritis, participating in the Colorado PDAB I was asked the question, Have you ever skipped a dose? Have you ever extended a dose due

to affordability? And the honest answer is yes to both but nothing to do with affordability. It is because of prior authorizations and other utilization management. So in closing, as you are going through the process, I really do hope you also consider the fear that a lot of the people in your state who are living with these diseases have around losing access to the treatments that work best for them. Our diseases are heterogeneous, which means just because we have a diagnosis does not mean that one biologic will work for all of us. So I do so much appreciate your willingness to listen to patients and make sure that together we maintain access in the most affordable manner possible. Thank you, again. We are here for you for any questions you have and any inclusion of patients along the way. Thank you.

MaryAnne Lindeblad: And thank you. Thank you for your comments.

Mike Neuenschwander: Yes, thank you very much. And as you did previously, always feel free to reach out. We are we are happy to chat and listen to your points of view.

MaryAnne Lindeblad: Any anyone else?

Mike Neuenschwander: Any other attendees who want to speak can use the raise hand function on Zoom, and then I can unmute you. Not seeing any raised hands.

MaryAnne Lindeblad: Well, with that, Mike, anything else [cross-talk] with the meeting?

Eileen Cody: I think he was going next meeting [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] Oh, next meeting. [Cross-talk] That's right. Planning plan.

Mike Neuenschwander: Yeah, yeah. No, the party never ends here, so we still got more stuff to do.

MaryAnne Lindeblad: I was going right by the agenda. [laughter]

Mike Neuenschwander: So yeah, just kind of as a wrap up, thank you to everyone who commented, and I always appreciate hearing your insights, and we will keep striving to do better. This is a learning process, and we are definitely on our way here. So our next meeting, Simon, correct me if I am wrong, but it's going to be scheduled for March 20th. I know this year we are still trying to tweak some things as we were looking for room of availability, but March 20th, and then I think the topics -- main topics that we are going to be going on is a continuation of the advisory Boards discussing a little bit more. We are going

to try and start drafting some policies and getting some more of the details around that. And then, also, we will continue our talk about the drug list methodology with Kelly, so we can try and get those last pieces of the puzzle here and have a more complete view so we can get that drug list done. And then some other potential topics, maybe an introduction to a contractor who will be helping us as well with the methodologies, as well as maybe some initial discussions on the number of drugs we may want to review and some of the ways we may want to start thinking about choosing those drugs as well.

Eileen Cody: Can you remind me, since I don't forget when what the dates are like throughout the year when we were planning on sending the first ones -- for picking the first ones for review, when the review is supposed to be done?

Mike Neuenschwander: Yeah, so by June 30th of every year per the Legislation we are supposed to create that new list of drugs to review for that year. So our goal is to get this methodology done and create that list. Once the list is created, then we can choose from the list and then hopefully we will also be starting to work on our drug review methodologies as well over the spring and summer so then we can start trying to implement that into the fall and hopefully get those reviews going. So it'll be a big busy summer.

Eileen Cody: And when and how long do we think the reviews with take once they [cross-talk] --

Mike Neuenschwander: That is a fantastic question as we haven't done one before [cross-talk] that will be a to be determined, I think. The idea is -- you know, the hardest part is going to be getting the methodology done, and then once we have figured out, hey, this is the data we want, this is where we are going to pull it from, this is how we put it all together, I am hoping that should be relatively easy. Again, not having done it before -- knock on wood -- but that way, hopefully, we could do that once we start getting into the swing of things maybe look at a drug or two every Board meeting. So --

Eileen Cody: Okay.

Mike Neuenschwander: So, again, we haven't quite crossed that bridge, but we will know more here as we get a little further along. Okay?

MaryAnne Lindeblad: Sounds like a plan.

Mike Neuenschwander: Okay. Any other questions? Yes, Doug?

Doug Barthold: Yeah. Would you all just list the rest of the meetings we have for the rest of the year? I have got May 22nd, September 18th, and November 20th.

Mike Neuenschwander: Simon?

Simon Borumand: So May 22nd, July 16th, September 18th, and then November 13th.

Doug Barthold: November 13th. Got it.

Mike Neuenschwander: It's in a complex on the November one, so we had to move that to a different date.

Doug Barthold: Okay. Great. Um, and I think I told -- I mentioned this already, but I can't make the next one on March 20th. So hopefully, I will be able to review some of those materials beforehand and/or afterwards and provide what is necessary.

Mike Neuenschwander: Yeah, and I can meet with you individually to catch you up a little bit and answer any questions that you might have.

Douglas Barthold: Sounds good. So do you want to do that before or after that meeting?

Mike Neuenschwander: Uh, both.

Douglas Barthold: Works for me.

MaryAnne Lindeblad: Yeah.

Mike Neuenschwander: All of the above.

Douglas Barthold: Okay.

Hung Truong: Hey, Simon, if you are unsure of the dates, can you just send out a placeholder invite?

Simon Borumand: Oh yeah, yeah.

Hung Truong: It's for all those things. Then we can change it later.

Mike Neuenschwander: Yeah.

Hung Truong: Yeah.

Mike Neuenschwander: Okay?

MaryAnne Lindeblad: Okay.

Eileen Cody: Anything else?

Mike Neuenschwander: No, I think that's it.

MaryAnne Lindeblad: All right. Well, I think this meeting can be adjourned, then. Thank you. Thanks for everyone's participation.

Hung Truong: [Cross-talk].

MaryAnne Lindeblad: [Cross-talk] Appreciate it.

Hung Truong: Oh, yeah.

[end of audio]