Mike Neuenschwander: Good morning, everyone. Doug, Greg, or Hung, can you give me a thumbs up if you can hear me? Okay, great. So we're still waiting, I think, for Eileen, so we will, yeah, [indistinct] few more minutes, and then we can go ahead and get started so, all right.

[break]

Mike Neuenschwander: Okay. I think we're ready to rock [cross-talk] and roll.

Eileen Cody: [Cross-talk] Okay.

Mike Neuenschwander: Eileen, take it away.

Eileen Cody: All right. If we could get started here. Welcome everybody to our Prescription Drug Affordability Board Meeting, and I guess we should do -- start with roll call, right? Good. Well, let me see what we got. Do we have -- we don't really have any introductions, do we? New?

Mike Neuenschwander: I don't think there's anyone new, so --

Eileen Cody: Okay, so roll call. You want to --

Mike Neuenschwander: Uh, sure. Okay. I get to start, I guess. Yeah. Okay. So, Ryan, do you want to [audio cuts out] here?

Ryan Pistoresi: I'm Ryan Pistoresi. I'm the Assistant Chief Pharmacy Officer here at Health Care Authority.

Eileen Cody: And online? Doug, I see you.

Douglas Barthold: Hi. Doug Barthold, Board Member.

Eileen Cody: Okay. And Hung.

Hung Truong: Hung Truong, Board Member.

Eileen Cody: And Gregory.

Greg Gipson: Greg Gipson, Board Member.

Eileen Cody: And who else do we have there?

Mike Neuenschwander: And I'm pretty sure we got Kelly online.

Eileen Cody: Okay.

Mike Neuenschwander: And then, Marina, are you there?

Marina Suzuki: Ah, yes. Hello, good morning. This is Marina. I'm an HCA staff Health Economic Analyst.

Eileen Cody: Okay. Well then that probably -- did that take care of it?

Mike Neuenschwander: Yeah.

Eileen Cody: Well, we got everybody here this morning. That's good. Hopefully, someday Marianne will be back. I know she hopes so, too. So then we can move on to the director's report, Mike.

Mike Neuenschwander: Okay, great. So yeah, we are back after a little bit of a break, but great to be with everyone again. As you just mentioned, our fifth Board seat is still vacant as of right now, but I'm hearing they are in the works to get new HCA directors, so yeah. And our old Board Member back. We'll have to wait for budgets and appointments and a few other things to stabilize. So you know, we'll see what happens here in the next month or two. Some interesting updates. I know I've talked with most of the staff and the Board Members a little bit about this. But as most of us know, there was a lawsuit over in Colorado around some of their drug reviews that were done, and so just kind of an update. About a month ago, maybe a little more, the District Court dismissed the lawsuit because it said the Amgen did not have standing to sue. So that concluded the Amgen lack of standing because it was not directly regulated by the PDAB law, that it was challenging, and it could not show that it faced concrete and imminent future injury from the law as an unregulated party.

And then the court upheld that the UPL would not directly regulate the wholesale prices that manufacturers charge. This is intended to apply to downstream transactions in the pharmaceutical chain. Further, the court held that future hypothetical injury to Amgen was too speculative a basis for Amgen standing to sue at this point, since the PDAB has not established a UPL yet and, thus, it was not quite clear whether the UPL will be lower than Amgen's current wholesale price. So long story short, that doesn't solve all of the questions that surround UPL's, but it does clear the way for Colorado to continue with their drug reviews. Other interesting things that are happening. So over in Colorado, I believe it's this week there having a rulemaking hearing and creating some rules about upper payment limits for Enbrel. So they're going to be doing some introductions for the rules as well as the data presentation from the staff. So that's moving forward.

And then I found out Oregon are having a public comment period here. I believe they also having a PDAB meeting this week for the list of prescription drugs and insulin products that were selected for their affordability review. So just some of the other interesting things that are happening around in other states.

Eileen Cody: Everybody's ready to move on.

Mike Neuenschwander: Yep.

Eileen Cody: Okay then. Well, then I guess we move on to reviewing the drug selection policy. That's you, too.

Mike Neuenschwander: Yep. Yeah. So with the drug selection policy, we posted that to our website, and we sent that out to the Board Members. Not a whole lot of new and different stuff. It was just basically updating our policy since in the dashboard the Board Members wanted us to sort our list by ingredient, so just some updates to the policy to reflect how the changes were made in the dashboard, and then Kelly will be going over the dashboard here in just a little bit to show us what's been done, talk a little bit about the process, and then see if any Board Members have questions. So yeah, policy has been sent out and then just I think have a vote to see if everyone is okay with updating it as it stands, and then we can --

Eileen Cody: All right. Do any of the Board Members have any comments about the changes in the selection in the -- ah, can't even talk this morning -- selection policy? I don't see anybody. Can I get a motion to approve the changes then?

Greg Gipson: Move to approve.

Eileen Cody: Okay, and a second?

Mike Neuenschwander: Second.

Eileen Cody: Thank you. All those in favor, say aye. Aye.

Hung Truong: Aye. Aye.

Eileen Cody: Any opposed? Okay, then the changes have been adopted.

Mike Neuenschwander: Fantastic.

Eileen Cody: Okay. So now we can rev -- go to Kelly for the updates.

Mike Neuenschwander: Okay, Kelly, take it away. Kelly on the [cross-talk] -- I do see Kelly [cross-talk]. Yeah, okay. I just want to make sure she is a panelist so she can present.

Eileen Cody: There we go.

Mike Neuenschwander: [Audio cuts out] right now.

Eileen Cody: Kelly, if you're talking, we can't hear you.

Kelly Wu: All right. Can you hear me now?

Mike Neuenschwander: Oh, there we go.

Eileen Cody: There we go.

Kelly Wu: All right. So since the last Board meeting, which was I think six months ago, we made some changes to our short list. So in this presentation I'm going to go over how we went from short list at the NDC level to aggregating the NDCs by a labeler code and generic name to create our new aggregated shortlists. So since it's been six months, I will refresh everyone's memory of the PDAB bill language about affordability review. I'll go over some data revisions we did alongside our revision of the shortlists, and then I'll go over again the data measures that are going to be used for selecting prescription drugs for affordability review. I'll go over how we aggregated the NDCs that are eligible for affordability review at the labeler code and generic name level, and then we'll have time for a discussion and Q&A. But if you have any questions throughout the presentation, or if there's anything you want me to go over again, feel free to stop me. You don't have to hold your questions until the end.

And as a reminder of where we are in the affordability review process, we are at the selecting drugs stage. All right. So a refresher on the bill language concerning conducting affordability reviews. So the Board shall consider the class of subscription drugs and availability of therapeutic equivalents, input from relevant advisory groups, and the average patient's out-of-pocket costs for the drug, and then the Board can choose up to 24 drugs a year to review. So when we were aggregating the NDCs, we did drop a couple of NDCs from our list of eligible prescription drugs, and I'll explain why. So when we looked at the manufacturers for all of the prescription drugs eligible for affordability review, we noticed that four NDCs, which I will be showing in the next slide were distributed by repackagers, and according to the bill language, if they're distributed by a repackager, they are not considered a manufacturer, and so they're excluded from affordability review. And so if you don't know what a repackager is, they're like companies that buy

prescription drugs from the manufacture and bulk and repackage it into smaller containers for sale.

And then so after dropping the four NDCs, we now have 290 eligible drugs for affordability review instead of 294. And these are the four NDCs that we dropped from the list because they're from repackagers. And we also reviewed their manufacturers of the remaining 209 drugs just to make sure there are no more drugs that need to be dropped.

Okay, so before I get into how we aggregated the drugs for our new shortlists, I wanted to do a quick refresher on the data measures that we used since it has been a while. So when choosing prescription drugs for affordability review, the Board will look at the three required measures from the bill that I showed earlier, which is color-coded in blue here. And then the Board came up with the dark green measures that they wanted to look at. And then you'll also notice that there's a little graph icon for the measures, so those are the quantitative data measures or the measures that can be measured, counted, or expressed as a number, and these are the measures that are going to be used in our ranking and weighting methodology, which I'll also go over again.

All right. So I'm going to go over the steps that we use to aggregate our drugs. So there's actually only one new step in our methodology to create the shortlist, which is after we separated the drugs into specialty and non-specialty. We then aggregated the drugs by labeler code and generic name, and after that the rest of the steps are the same. They're just conducted at the labeler code and generic name level instead of at the NDC level, but I will still briefly go over each step.

So the first step we did was we separated the eligible indices into specialty and non-specialty drugs. So as a reminder, our pharmacy team defined specialty drugs as medications that require special storage, handling, administration, or monitoring, with the exception of drugs that were classified as bio -- reclassified as biologics under the Biologics Price, Competition, and Innovation Act. So for us, this means that. Some drugs that are biologics and biosimilars were considered specialty, and brand and generics were considered non-specialty.

And then after we did that we moved on to the new step in our methodology, which is aggregating the end used by labeler code and generic name. So I want to bring back a modified version of the slide that I showed in, I think, maybe one of our first Board meetings. So if we go back to the definition of what an NDC is, I mentioned that an NDC is made-up of three segments of code which identifies the labeler, the product code, and the package size of the NDC. So when I say we are aggregating by labeler code, that means we're aggregating an NDC that share the first same first five digits of the NDC, which means they share the same labeler.

What is a labeler? Well, a labeler code uniquely identifies the company, which is the labeler that manufacturers and/or distributes the drugs. So then using this makes sure we are aggregating the

drugs from the same manufacturer or distributor. And a generic name is on the list of drug ingredient names, so this makes sure we're aggregating the same drug ingredients together. So our goal is to aggregate drugs from the same ingredients from the same manufacturer or distributor. So when we did this aggregation, we also had to aggregate the selection criteria since they were calculated at that NDC level. So the selection criteria once again are those four quantitative data measures that the Board used to prioritize the drugs eligible for affordability review. So for some selection criteria like sums, like total paid amount, that just meant summing them up for each NDC. But then for some others we had to recalculate the selection criteria, and I'll have an example of that in the next slide.

All right. So here's an example of how we aggregated these NDCs, which are Orencia by labeler code in generic name. So I don't have the manufacturer shown here, but you can see that they both have the same first five digits of their NDC. So that indicates they're from the same manufacturer or distributor. And the last four columns in this example are the four quantitative selection criteria, and so I'm first going to point out the straightforward data measures that were combined. So total out-of-pocket cost, which is OOP abbreviated in the table, which is the third column from the right is simply summed, and so is the total paid amount, which is the first column from the right. So those were the straightforward ones, but then for a number of people using the drug, which is now called number of people using the labeler generic name, we had to re-pool that because we want a distinct account. So really, it's number of distinct people using the labeler code and generic name. So in other words, if a person uses like multiple NDCs that are in the same labeler code and generic name, we only want to count them once.

For example, in this example, if somebody used both the syringe and the ClickJet, we only want to count them as using this labeler code and generic name once. So if you didn't re-pool this at the labeler code and generic name measure, we would have been counting like people twice or maybe three times, and it would just artificially inflate the number of people using the labeler code and generic name. So we did have to re-pool that. So that's why if you're -- in a lot of cases, if you're comparing an aggregated list, if you just eyeball it, you'll think that the numbers are off, but really, we're recalculating some of the measures. And another thing -- another example of a measure that we're recalculating is the average out-of-pocket cost, and this is because this calculation is an average, so you can't just like sum that averages of all the NDCs when you aggregate them. So we actually had to recalculate the average at the labeler code and generic name level. So in this case, the average out-of-pocket cost is the total out-of-pocket cost divided by the number of people using the labeler code and generic name.

So we took the sum of the two out-of-pocket costs for the two Orencia, and then we divided it using the number of distinct people using the labeler code and generic name, which is 1585. And then you'll notice the new number for average out-of-pocket cost is $1017.18. That's different than if you just sum the average out-of-pocket cost for the two NDC level Orencia. And so after

doing the aggregation, my next step is to rank and weight the data to calculate a weighted rank for each labeler code and generic name. So nothing has -- nothing major has changed methodology wise, so we're still sorting each quantitative data measure in descending order. Only now they've been aggregated at the labeler code and generic name level, whereas, before they were being sorted at the NDC level.

So if this slide looks familiar, it's because I just changed the column on the very left to say labeler code and generic name instead of NDC because it's the exact same concept. So each quantitative data measure is sorted in descending order and assigned a rank. And then you'll see that the labeler code in generic name may not have the highest rankings across the Board for the four data measures, so they'll most likely have a mixture of rankings across the data measures. And then for tied rankings, we're still using the average ranking method to break the ties. For example, and again, I only changed NDC to labeler code and generic name here. Labeler code and generic name 0003C and 0004D both had a total paid amount of $12.00, and they are technically ranked in position 3 and 4 here, which is not correct because they both have the same total paid amount. So using the average ranking method, their final total paid amount rank is the average of their rankings, so that would be a sum of their rankings, 3 and 4, which is 7 divided by the number of tied labeler code and generic names, which in our case is 2, so 7 divided by 2 is 3.5, and then so their new rankings are both going to be 3.5.

And even though using the same exact methodology we're using for creating the short list at the NDC level that we did previously, I'm still going to go over the methodology again for calculating the weighted rank. And if you wanted like an even more detailed refresher on the methodology, you can go back to the slides that are presented last November. So I'm just going to go over this really briefly. As you remember, we had the Board Members assign points to help us rank and weight the quantitative data measures. So these are the weights that were created from that exercise. And this is a visualization of the formula used to calculate the weighted rank for each labeler code and generic name. And then, once again, the top 25 lowest weighted ranks for specialty and non-specialty labeler code and generic names would make up the two shortlists. And so the weighted rank is the sum of the rank of the data measures multiplied by their respective weights, which are those points that the Board assigned to each data measure. This is the same formula used at the NDC level so, again, nothing has changed except we're now applying our methodology to the aggregated data. Here is the formula with those points or weights plugged in.

All right. And then, yeah, let's go over an example of applying the formula to aggregated data. So this is labeler code 00078, and the generic name of this group of drugs is -- excuse my pronunciation -- fingolimod hydrochloride, and the brand name is Gilenya or Gilenya. I'm not sure, and these drugs are used to treat multiple sclerosis. So you can see that this labeler code and generic name has varied rankings across the four data measures, so it doesn't rank highly across all four data measures. Using our formula to calculate weighted rank, the weighted rank is the sum

of the average out-of-pocket cost rank, which is 14, multiplied by the weight of the average out-of-pocket cost, which is .19, plus the total out-of-pocket cost range, which is 7, multiplied by the weight of the total out-of-pocket cost, which is .35, and so on. And then when you plug all those numbers in, you'll get that the weighted rank for Gilenya is 7.17. And so once we calculate the weighted rank for every labeler code and generic name, we selected the top 25 specialty and non-specialty labeler code and generic names with the lowest weighted ranks, and those turned into our two shortlists.

So here are the two short lists that we ended up with, and after aggregation, we actually only had 17 total specialty labeler code and generic names, so all of them made the list. This list is copied from our PDAB dashboard, which is available online, which I will do a demo of after this presentation so you can look at the lists on the dashboard as well, and you don't have to go to this presentation to look at them. All right. So now that we have some new shortlists, the Board will look at the weighted rank and all of the data measures, both quantitative and non-quantitative to select drugs for affordability review.

And I showed this list last time of drugs that other state PDABs have selected for affordability review, and even though we do have some new drugs on our list after doing the aggregation, we still only have one drug, which is Enbrel, that is in common with another state that's doing affordability reviews, and that's with Colorado. This is just a continuation of the list because Oregon also had some insulins. All right. The next steps will be for the Board Members to review the new short lists and make selections for affordability review. That was my last slide, so I will open it up for general discussion or questions.

Eileen Cody: Doug, go ahead. I'll save mine.

Douglas Barthold: Thanks, Kelly. Great job and great presentation. That's a really good synopsis of the process, and I appreciate that. So I just was -- I wanted to go back to the -- on the aggregated prioritized list. So there's only -- there's 17 specialty drugs on that. Did you say that's because all 17 of the specialty drugs that were eligible? -- Does that exhaust all this such as drugs that were eligible?

Kelly Wu: Yeah, um, I don't know off the top of my head like how many specialty NDCs we had, but after we aggregated by labeler code and generic names, we ended up with these seventeen groups, so all that made the list.

Douglas Barthold: I see. Okay. And then? Yeah. It's like -- I guess it would be help -- I mean, well, it's not really critical, but I'm just kind of curious what the -- how many non-specialties there would have -- that there were, you know, that's the top 25. How many did we get? Then we went

from the 290, and then we aggregated how many, you know, generic name. I forget you had a good term for it, but how many aggregated units are there?

Kelly Wu: Yeah. I think that number is somewhere in the policy, or it's on the dashboard. I'll have to take a look. But yeah, for -- I should have had it prepared, but I forgot.

Douglas Barthold: Okay. No problem. Do you know where on the dashboard it would be? Let's see.

Kelly Wu: Um, I'm going to walk through the dashboard right after this, so I will take a look because I know we had some text issue -- text limit issue, so I don't know where I stuffed it in the dashboard [cross-talk].

Douglas Barthold: [Cross-talk] Okay, thanks.

Eileen Cody: So I don't -- Kelly, I don't know whether it's you or Mike that would know this the best. I'm just curious what the difference is between Washington and the other states and why we only ended up with one of the same. I mean, I'm sure some of it's got to be statute. But I'm just -- I just was curious as to how much different we ended up being.

Ryan Pistoresi: So I can help take a stab at that. So as you were correct, it is statute, and so the different cost thresholds in the different states really changes how the states are looking at these drugs. One other thing that Washington has, let's say Colorado does not have, is that we have to exclude drugs as they are only approved for an orphan indication. And so some of the, I believe cystic fibrosis or one of the other medications that Colorado selected was not eligible in Washington. Oregon selection is very different. I think it is tied into their Drug Price Transparency Program, and they also are required to have an insulin. So I think because the different state legislatures passed slightly different criteria is why our list is different than the other lists.

Eileen Cody: I think we were after Colorado, I know. I think after Oregon, too. Right?

Ryan Pistoresi: Yep, I think [cross-talk] --

Eileen Cody: [Cross-talk] Yeah.

Ryan Pistoresi: -- we were #4. So Maryland, Colorado, and Oregon are all there. [Cross-talk] --

Eileen Cody: [Cross-talk] other people [cross-talk] --

Ryan Pistoresi: And then all of the other PDABs since are following in our footsteps.

Eileen Cody: Yeah, okay. Just was curious. Thought that was it, but I wanted to -- just seems really odd when you look at it.

Kelly Wu: Yeah. And I know some other states don't -- like we have a restriction that our drugs must be on the market for seven years or more, and I know some other states don't have it, which is, I think, like when other states review Ozempic or something like that, so we wouldn't be able to review that yet for a couple of years. And then I know some of them also have some lower thresholds. Ours is like 60,000 or more for a course of treatment, and I saw some of them have like 30,000, so that might also be why we're selecting different drugs.

Eileen Cody: As if we need more. Any other questions for Kelly on this? Okay then [cross-talk] --

Hung Truong: I have a question.

Douglas Barthold: Yeah.

Eileen Cody: Okay.

Douglas Barthold: Go ahead, Hung.

Hung Truong: Sorry. Hey, Kelly, just on the slide that you have on right now, I think we need to clarify between non-specialty and specialty because on this non-specialty list, when you look at the top 15 drugs, the majority of those are considered specialty medication. And so we need to make sure we clarify that with just how we define it further because the Xtandi, Cabometyx are oncology drugs, right? And then Epclusa is hepatitis. And then Gilenya is what we went through. That's an MS, so those are really all specialty, so people don't get confused.

Ryan Pistoresi: And Hung, if I may say, so the reason why we have the two lists the way they are is the way that they were approved through the FDA. So the column on the left, the non-specialty were the NDAs, whereas the ones on the right are BLAs. And so another way that we could think about it are traditional versus biologic. So that's -- I agree with you. I think we could look at how we could rename these lists, but that was the basis for why we have these two separate lists.

Hung Truong: Okay. Which makes sense, Ryan, because the definition of specialty is very vague and broad, and it can be anything from the way you store it to even how much it cost, and it's defined the majority by the insurance companies. So I think just making clear what you just said, Ryan, between the two, that would be great.

Ryan Pistoresi: Yeah, we can make that update.

Hung Truong: Thank you.

Eileen Cody: Doug?

Douglas Barthold: Sorry, I got distracted. Uh. And I forgot I was going to say, but it will come back to me. Thanks.

Eileen Cody: Okay, well. And we -- uh, let's see. Kelly, do you want to go over the dashboard now or is that -- ?

Douglas Barthold: Oh. Now I remember, sorry.

Eileen Cody: Go ahead. Go ahead.

Doug Barthold: Okay. So when I look at when we were discussing the differences between -- in the results between us and the other states, um, you were saying how the statutes for the other states were basically more inclusive, would allow more drugs to get onto the eligible list. I'm just curious why -- if anyone has an idea why the other states didn't get Humira on their on their lists just because that was a real standout when I look at the data -- on our dashboard. You know, -- it was a standout high spending drug, and so that would think -- if they're more inclusive that -- they should have had that, and so I'm just wondering if anyone knows why they didn't choose that?

Mike Neuenschwander: I mean, I can't speak specifically to their exact reasoning why. I know they did their own selection criteria dashboard matrices, and their Board Members did kind of a similar thing where they were voting on the things that they wanted to prioritize, for example, over in Colorado of things that they thought were important. So I'm not -- I'd, you know, I'd have to go and speak to their director directly, but I do know that they did have other ways that they were wanting to sort and look at data, and their Board Members had their own priorities, so they weren't set up exactly how we were in terms of data that they wanted to see, the ways they weighted and ranked things. So yeah, I can't say exactly why, but they did have different selection criteria.

Douglas Barthold: Okay. Thanks.

Eileen Cody: Of course, from my perspective, I'd be curious to know whether they might be different prescribing practices, too, with the physicians. Like it may not be as popular with -- it seems odd, but I'm just saying it's possible, or the incidence of the disease, that type of thing. Is that Ronnie?

Ronnie Shure: Just one missing, one piece that I've noticed and looking at what's happening in Colorado and Maryland and other states is that part of the decision making was not to choose a drug that the -- Medicare had already done an evaluation of in order not to duplicate the work from them, but that was an internal decision and there were other factors involved, but I believe from what I've read, when the other Boards were looking at issues, that was a reason for not choosing Humira. Does that makes sense, Doug?

Eileen Cody: Yep.

Doug Barthold: Yes, thank you.

Eileen Cody: Yeah. Okay. So Kelly, do you want to go over the dashboard then? Yeah? Is that [cross-talk] --

Kelly Wu: Yeah, sounds good.

Eileen Cody: Okay.

Kelly Wu: All right. So our dashboard is on our website. If you're not sure where it is, if you go to our PDAB page and go to resources, you can click the PDAB data dashboard, and it'll take you to the dashboard. And so our dashboard is basically the same, but then we just added like two additional -- or three additional tabs to show our aggregated data. So I'll just go over the whole dashboard again in case you haven't looked at it in a while. So first we have this overview page, which describes the -- some background about our dashboard, and it's also updated with 290 drugs now instead of 294, and then it gives an overview of the data sources that we used for our dashboard. And then in this dashboard information tab, we have a list of all the dashboards in our dashboard and what they contain.

In this data dictionary tab, we have a data dictionary for all the data fields used in our dashboard. And while we are talking just now, I just went through it really quick and found that I stuffed the number of specialty and non-specialty NDCs into the definition of specialty here. So if you go to the definition of specialty, it's here that we had 58 NDCs classified as specialty and 232 classified as non-specialty. So once we like consolidated those 58 specialty drugs by labeler code and generic name, there are only like 17 labeler code and generic names.

And then this is a summary of the eligible drugs that we have, so a table of those 290 NDCs and which threshold they met in the legislation. And then we have a graph that shows the breakdown of the cost of the course of treatment by a drug type. And then down here are some interactive tables, where you can sort by a number of people using the drugs. So this is at the NDC level, and you can also sort the top drugs by total paid amount.

Next is our drug product lookup tool, so you can look up information for specific drugs at the NDC level. And I forgot to mention that there is this little dictionary icon on every dashboard, so if you forgot like -- or you want to look up a certain definition, you can just click on that icon, and it'll take you to the data dictionary tab. And then if you don't want to scroll through all the fields, you could just use this filter and search for the specific field that you want to look up.

Next is the drug products on multiple list tabs, so this just lists the NDCs that met multiple thresholds of the legislation and which ones they met. And I think all of these met like the 15% and 50%. And next was our NDC level list. So this was on here before, so this was just our short list but at the NDC level. And then these are the visualizations connected to the short list, and so if you filter something here like this drug, then it's also connected to the visualizations. So yeah, they're connected, and you can compare like multiple drugs at a time.

And then we're moving on to the new stuff added to our dashboard. So these are the short lists at the labeler code and generic name level, so it's in the same format as the NDC level list. Same concepts of the linked filters. You can filter by the labeler code and generic name. You can filter by brand name. You can filter by therapeutic class, and then you can filter by specialty. And then these are the same visualizations, except we took out the increase and course of treatment visualizations because we didn't calculate them at the labeler and code and generic name level.

And then, finally, we added this tab that's a cross log, so you can see like which NDCs are within each labeler code and generic name, and so I wasn't able to link this to the filters in the previous -- in the aggregated list, but I think there's not a lot, and they're also in order or you can use a filter so you can find like what you want to see? And yeah, that's it for the dashboard. So yeah, I don't know if we want to move- -- if you want to see anything again or -- yeah. I'll just keep this up and then we can scroll through it if we want for the next part of our discussion.

Eileen Cody: So Kelly, I just have to ask, did you have to design the website, too? Or -- I'm very impressed. Let's just put it that way.

Kelly Wu: Oh no, I can't take credit for this. All credit goes to Arsheena. She did like this design, and then I just updated it. But yeah, I think our design is kind of modeled after Colorado's because I think the Board mentioned that that was what they were looking for, so yeah.

Mike Neuenschwander: I was going to say this is pretty slick.

Eileen Cody: Yeah.

Mike Neuenschwander: It makes it really easy to see a whole lot of different stuff.

Eileen Cody: Right. So anybody have any questions for her on this dashboard?

Hung Truong: Hey, Kelly. It's weighted, right? Is that weighted, then the weight that you had described on the last presentation you had used that formulation?

Kelly Wu: Right. So these are the top 25 most weighted rank, wo there's the weighted rank in the [cross-talk] actually.

Hung Truong: [Cross-talk] Okay [cross-talk] --

Kelly Wu: Yeah.

Eileen Cody: Okay. Great. Well, then I guess we can move on.

Douglas Barthold: I'm sorry.

Eileen Cody: Okay. Sorry Doug.

Douglas Barthold: Yeah, that's okay. So I feel like we talked about this before, but I can't remember what we -- the answer was. So we have the -- there's the way that you can filter by specialty on this list, and it has to be Y or N, and I just -- is there any way to not have any filter by specialty so you can basically see both together? And actually -- let's just shoot for this list more, more on the prioritized list visualization, the next tab to the right on the dashboard. I think this one would be really helpful to see without the specialty filter, so you can see both of them together.

Kelly Wu: Yeah, I agree. I'll have to think about that because I linked them together. So maybe. Yeah, I'll have to figure out how to like manipulate the filters, but yeah, I agree.

Doug Barthold: Yeah, because I mean just like the way that I'm trying to make my choices. You know, like I -- so I opened up two tabs so I have the dashboard open on both, and I have one with a filter for specialty yes and one filter for specialty no, but I'm still toggling back and forth to see like okay, you know, the, uh, total out-of-pocket costs for Humira is, uh -- actually, I can't even see it here but it's something close to $10 million. And then for -- I have to go over to the other tab to see that Cabometyx is somewhere over 4 million. And it's like they're not -- it basically requires, you know, having multiple windows open and making these comparisons, so it's kind of hard. Is that -- I mean I'm wondering is there a reason -- is there any reason why we wouldn't want them together? At least on this prioritized list visualization tab.

Kelly Wu: Well, I honestly didn't think about that because -- for like this list, we're just comparing them like within specialty and non-specialty [cross-talk] but, yeah, I should have thought that you would have wanted to compare the visualizations for everybody. So yeah, I can try to add that in.

Hung Truong: Yeah, I think, Doug, I had questioned that like maybe six months ago or the meeting before that was, you know, when we put it all together, which even to make sense with putting -- being able to see it all together. But one piece was that when we added it, all the specialty drugs were on the top. Right? And we wanted to see are there any non-specialties that are worth for this Board to take a look at because it's going to affect many more people, and I think. And so the definition of the two is a little bit off is what we had discussed a little bit earlier. But yeah, -- that was my -- like, I had -- that was my question back then.

Douglas Barthold: Right. Actually, I remember that now. You're right. So it was that we were worried we were only seeing specialty.

Hung Truong: Yeah.

Doug Barthold: Yeah. I do think there's -- given, I -- given what you said about like the distinction between specialty and non is it's somewhat ambiguous, and so I guess it would be helpful to see it with both. I am surprised though, like if you look at the number of users, there's only -- and you toggle between the specialty and the non, on the non-specialty, there's only a couple of drugs that have more users than the specialty ones, and that's -- let's see. So it's Gavilyte and SPS. Otherwise, it is still -- you're still looking at Enbrel and Humira as the most used, I guess [cross-talk] --

Hung Truong: [Cross-talk] Yeah. And the two that you [cross-talk] mentioned are actually non-specialty drugs, truly [cross-talk] non-specialty that you can get it at a Safeway [cross-talk] --

Doug Barthold: [Cross-talk] Oh, so you put Gavilyte and SPS, they're not [cross-talk] specialty.

Hung Truong: [Cross-talk] Yeah, yeah, yeah. And so all the other ones are limited distribution, or it's -- [cross-talk] truly specialty. And I think that that's where the -- I think where it's costing. Like Xtandi, I mean, it's problematic since it's like a $20,000-$30,000 drug.

Doug Barthold: Okay. Let's see [indistinct] --

Mike Neuenschwander: And one thing I'll just mention is just kind of going back to the advisory group recommendations, too. I believe it was the top four of the ones we have on the specialty list and then the top three. You know, when we're coming out with this aggregate, aggregated list, the top four on the specialty and top three on the non-specialty are the ones that they had

recommended. So just kind of a throwback to that. You know, before we put everything together, those are the ones that they were actually choosing .

Eileen Cody: Any other comment? All right. Well, then I guess we move forward. Mike?

Mike Neuenschwander: Yeah. So really, at the end of the day, you know, we've created the dashboard. We've got a lot of good data to look at. I think there are some ways we can keep working and tweaking the dashboard, but really, we're getting down to the point where, you know, we -- in order to kind of move on to the next steps, we need to make a decision and go forward. So I think the two, the two things that we are needing to look at are, you know, A.) how many drugs are we wanting to try and do a review on here for this go around, and then B.) you know, which drugs do we want to shortlist? And so, you know, my thought or vision on this was, you know, let's create our short list of the drugs that we want to potentially review, give ourselves and, you know, the general public a couple of months to think about that, comment on it, and then we can actually vote and do the selection, and then start with the actual review process -- or start the first steps, rather, to kick off the review process in July. So, really, that's kind of where we're at, is how many do we want to do, and which ones do we want to do to move forward?

And as Kelly was mentioning, you know, there's some -- we have a list of where we saw the other drugs that the other state have chosen. Enbrel is the only one right now that's crossing over that, you know, other states have done already. And then one other thing I want to note is for the top drugs on the list, especially for the specialty. [Indistinct] also done some reviews on those as well, so they have data that could be useful for the Board to consider. So yeah, with that just kind of opening up here for the Board to discuss, and let's make a decision.

Eileen Cody: All right guys, you have some opinions?

Hung Truong: I can start for a little bit. I think it's obvious that we look at this list that like the top five or six for sure, but I think we need to consider the therapeutic class and not just pick one without looking at the competition. I'm worried about limiting looking at one and then not the others in the same class that are able to -- people are able to switch around. Like if we choose Enbrel or Humira, I think, Cimzia, Simponi, they need to be included when we review.

Doug Barthold: Can you say that again? Which ones?

Hung Truong: So -- if we intend to choose Enbrel and Humira, then we need to look at others that are in the same category or therapeutic class, Doug, like Cimzia. Because looking at one and not looking at a major competitor, I think, you know, are we limiting or ? I don't know. It just feels like we need to take a look at the class or at least the top drugs in that class.

Greg Gipson: Hung you're kind of thinking like, you know, they're all within the same class so all used for treating the same thing. They are all TNF-alpha inhibitors. You know, reducing the price of one really isn't quite equitable amongst the group. Is that kind of what you're thinking?

Hung Truong: Yeah, yeah, we're making it anti-competitive. I mean, just a whole host of issues that I can see.

Eileen Cody: Well, I guess I'm going to ask the question. Could the ones that -- the Humira and Emeril would be the more expensive. So right now, there's already, I mean, if the competition, the people will be switching to the lower price if they can't afford it. So I don't really -- I guess I'm questioning your -- I understand [indistinct] looking at the whole class, but in a lot of ways I don't know that it's really going to change things. That's -- I'm just pushing back a little bit.

Hung Truong: Yeah. It's not. It's not less money. It's a lot of times it's very close to each other because that's the competitiveness of it. It's because Humira and Enbrel are much more widely known, and they've been around for a while, and so you see them go to the top of the list. There isn't a cheaper alternative when you're talking about these drugs.

Eileen Cody: Right, right.

Hung Truong: Most of the time.

Eileen Cody: No. I'm very -- I'm familiar from the MS side. You know? People -- we've ended up switching people because of cost some of the time.

Hung Truong: Yeah.

Eileen Cody: But that's not usually the first thing that they think of.

Hung Truong: Yeah, unless there's a generic that's been out for a while [cross-talk] and you see it. But for a lot of these, the only thing that we might see anything that is less is the biosimilars that are coming out, and there are quite a few. I mean it's more than a handful. [Cross-talk] There's like 10 sold.

Doug Barthold: I think I -- actually, I agree a little more with Eileen here just because, you know, if there's -- you know, the reason those are at the top of the list, if it's because they have more people using them, then that means that they are more of an affordability problem in Washington, and so I think that merits. You know, just, you know, like I think, Hung, what you're saying about like, oh those are -- they don't, they don't really cost that much more, it's just that there are more people using them. Well I think that matters that there's more people using them. Like that merits their

affordability review, you know, more than -- more than the ones that are less used. So I think that's something to consider as we're -- making the decision.

Hung Truong: [Cross-talk] Sure -- [cross-talk]

Eileen Cody: [Cross-talk] Donna Sullivan has something to say.

Donna Sullivan: Yeah. I mean, specifically the Humira, there's been a flood of biosimilars come to market that are considerably cheaper than Humira, and the population is shifting to that biosimilar utilization. So I'm not sure if you review Humira you're going to get the impact that you anticipate.

Doug Barthold: A good point. Yeah. I mean -- and I think part of the review will include, you know, what are the therapeutic alternatives? And so, yeah, it's a good point.

Greg Gipson: You know, I was actually just looking at that yesterday, that like Humira used to have 96% of the market share like a couple of years ago, and all these biosimilars came in. I mean they still have 70%, I think, as of like January of 2025. But yeah, it's sliding, right? Where it may be -- I don't know. It may be a self-resolving problem.

Hung Truong: Yeah, it's going to slide quick because many of the PBMs or the benefit pharmacy managers, obviously, benefit managers, are adding biosimilars to their formulary, and many as a requirement.

Doug Barthold: I think that one of the other things that we have to be thinking about here is the number of affordability reviews that are feasible by the HCA in this first year. And in my -- in the conversations that I had with Mike about this, it sounded to me like -- sort of, like, two was that number. And so I think that's important for us to consider as well is like, you know, it would be great to do, whatever, ten of these or something. But if we like -- if we only have the capacity to do two affordability reviews, then we have to think about that as we're making this decision. Is that an -- I don't know, Mike, do you want to talk a little bit about what you actually think the -- what you think our true capacity is?

Mike Neuenschwander: So having never done this before, you know, it's hard to guesstimate. You know, there's going to be a number of steps in terms of -- and I'll kind of talk about this in a little bit, but, you know, engagement with advocacy groups and patients, collecting data from industry, which we will also be talking about. You know, figuring out -- as we go through the affordability review, you know, exactly what do we need and how can we present that data in the most useful way for the Board Members to make a decision? So this first go around, it's going to be working out a lot of kinks, and then once we have our pattern like, you know, for example, creating the

dashboard took a while, right? Because it's our first time doing it. What do we even want to see on the dashboard? You know, -- the technical piece behind it of putting it together.

Now that we've done it, you know, and we've created the drug list, in doing that, yes, it will take a little bit of time, but because we know what we're doing now, next year -- next time, it will go a lot faster. So with these drug reviews, I'm anticipating a similar thing. This first time is going to be a little, you know, a little bit rough as we figure it out, trying to, you know -- okay, how do we collect the data? You know, what data is used for all [indistinct]? We collected some of this, maybe that wasn't worth the squeeze of an effort of getting it. And so, so yeah, my preference is to start on the smaller end, and if we -- pound through it, and it's like, you know, Ryan's like, oh my gosh, you guys did this all in, you know, three months, and it was a piece of cake, and everyone cooperated and gave us all the data we asked for and then some, and, you know, then we can look back. Okay, sure, we'll -- let's do a couple more reviews. But yeah. So generally speaking, I won't tell the Board, you know, exactly, but, you know, starting on the lower end and working our way up, I think is a good strategy. But, of course, we can -- we can do -- if we want to choose more drugs and say, okay, these are the first two that we're going to start with, and if we get to the other two, great. If not, we can save them for next year. You know, that's something else we can do as well.

Doug Barthold: [Cross-talk] That's something that occurs to me because given that we don't know the capacity, I do think that some type of ranking or tiering of the priority -- well, we already have the priority list right front of us, but the -- yeah, using that priority -- prioritization to sort of, you know, fill in the capacity as much as it's available.

Mike Neuenschwander: Yeah. And one other thing I'll mention, too, is, I mean, I still don't even know exactly what our budget implications are. You know? Do we have any contracting money?

Eileen Cody: The measure was passed yesterday, signed yesterday. [Cross-talk] --

Mike Neuenschwander: See I still don't even know exactly what that means for us in terms of, you know, capacity to do, you know, you know, external work and get stuff. So we're still a little bit in a in a gray spot.

Eileen Cody: Well, I could have -- I was going to push because the fact that, you know, if you're going to have some money from the legislature, they expect some results. So I don't know that two, you know, actually needs -- I can tell you that Senator -- former Senator Kaiser actually saw me and wanted to know what the hell was going on, and so she's watching. And so I just -- I think that we probably need to at least come up with, I would say, four or five and then have priority, you know, have the priority where you start on it, but I want to put a little pressure on you to make sure that we're moving forward.

Mike Neuenschwander: Well, and I do, I do also want to say one of the things that I appreciate kind of our positioning and where we're at. You know the PDABs are a new program for all states. And so, you know, I will say other states have tried to push too fast, and then they've had to completely stop and start over from the beginning. It was, you know, I'm a slow and steady. Yeah, it takes a little longer to get going, but for me, you know, it's proven to usually win the race. So I totally get, yeah. And the idea, again, is once we have the kinks worked out, then our capacity can improve -- increase dramatically. But yeah, you know, I think there's a balance, so we [cross-talk] --

Eileen Cody: What is somebody that has to keep putting pressure [cross-talk] --

Mike Neuenschwander: No, no, and that's good. Someone, someone, someone's got to crack the whip and keep us moving.

Greg Gipson: What? Can we -- choose like -- choose five and then start with two as initially, and then jump on to phase two of the first round or something if that goes well?

Mike Neuenschwander: Yep, yep.

Douglas Barthold: I like that.

Greg Gipson: Okay. [cross-talk] --

Eileen Cody: [Cross-talk] So --

Douglas Barthold: [Cross-talk] Would it be okay if [cross-talk] I share a screen? Just because I think I'm looking at the two different visualizations here. I think it's helpful. Thank you. Okay. Is that working? There we go. Um, can you all see that?

Greg Gipson: Yeah.

Douglas Barthold: So basically on the left I have specialty, and on the right, I have non-specialty. So these are all the drugs that made it onto either of the two prioritized lists. And I think this is helpful just because it's telling us like, yeah, I mean like this issue of like how many users are there we can actually see? So for Enbrel, there are 6736. Um, so I think -- so when I look at this, specialty is actually pretty easy. So specialty on the left. Humira and Enbrel stand out so much that I think it could be very easy to start with those two if we only were looking at specialty. And I guess that's this Humira, all of these. Enbrel is all of these. But then it gets more complex when we bring in the non-specialty, just because Gavilyte and SPS have so many users. However, their costs are really low. This is the average out-of-pocket cost. So Gavilyte is the most used -- by far the most used drug on our -- on either list. But the average cost per user -- average out-of-pocket cost per user is

$6.35. So I don't know. Anyway, I just thought this would be helpful for us to kind of like frame the discussion around the prioritization.

Greg Gipson: But Doug, like this is where kind of like Board point weighting system will help us, right? Because we've already -- like some of us, like I said, I don't care how many people are using it. If it's cheap, then it's fine [cross-talk] --

Douglas Barthold: [Cross-talk] Yeah.

Greg Gipson: -- but we all feel differently. But we have like this so, right?

Douglas Barthold: I totally agree. It's just that when we -- um, and I hate to [indistinct] just like take us back to this, but if we look at this list, this list you have to select either non-specialty or specialty. And so how do I compare Taltz -- okay, how do I compare Taltz with Xtandi?

Greg Gipson: Right. Yeah. I see what you mean.

Mike Neuenschwander: Well, then one thing I'll say, you know, so on that one drug that does have the really high utilization, you know, it says for our review is prescription drugs chosen for affordability review. The Board must determine whether the drug will lead to, has lead, or will lead to excess cost. So you know, if we're seeing out-of-pocket cost is, you know, $6, you know, does that really meet our goal of, you know, excess costs, I think we can probably put that one lower on the list, right? Whereas [cross-talk] you know [cross-talk] --

Douglas Barthold: So to Greg's point, I could put it like -- to Greg's point, maybe it makes sense to look at the, you know, using these two lists, it's kind of the -- we'll put non-specialty on the left. Oops, I didn't actually. Okay, here we go. Yeah, non-specialty on the left, and then specialty on the right. If we need to choose five, should we consider the top five on both of these lists to be our candidates?

Mike Neuenschwander: That would be 10.

Douglas Barthold: I know, but if maybe [laughter] -- I know, but maybe it needs a different -- so like [cross-talk] if we have to choose five right now, I would consider the top five on the two lists to be at the 10 candidates for those five slots.

Hung Truong: [Cross-talk] I agree with that.

Eileen Cody: [Cross-talk] I agree with you, Doug.

Hung Truong: Yeah.

Douglas Barthold: Okay. I need two more tabs. I need another monitor. [laughter] Um, okay. Let's see here. So --

Greg Gipson: You can also scroll to the right and see the columns. I don't know if that's [audio cuts out]. You can't [cross-talk] --

Douglas Barthold: [Cross-talk] Oh yeah. Okay.

Mike Neuenschwander: Okay.

Greg Gipson: That's what I was doing.

Mike Neuenschwander: [Cross-talk] -- looking at out-of-pocket costs, you know, $4 million and change for the top there.

Greg Gipson: Because our highest weights were on total out-of-pocket cost and total amount -- total paid amount.

Douglas Barthold: Right. I just pull it right their weights here.

Greg Gipson: That's funny. I've got it up. [laughter]

Hung Truong: I mean, even if you look at it and just think about putting it together that the five on each would make sense. There would be a top 10 on a combined list.

Douglas Barthold: We still have to rank though because, uh, we have to give them the prioritization. So Enbrel seems like an obvious #1 to me.

Eileen Cody: Mm-hmm, yeah.

Douglas Barthold: A lot of users. It's -- basically every category except for average out-of-pocket costs. These top two non-specialty are higher.

Ronnie Shure: So Mike? This is Ronnie Shure. We had a discussion in the core advisory group. You asked members of that group to recommend drugs. Do you have those results? Can you share [cross-talk] --

Mike Neuenschwander: Yes. Yeah. So basically, like I mentioned, the top four on the specialty were selected, and then the top three on the non-specialty were the ones that the advisory group recommended.

Eileen Cody: So we're on the same track.

Mike Neuenschwander: Yeah. And that was recommended before we aggregated everything as well. So, you know, I think the advisory group was kind of reading between the lines pretty well of, you know, what things seemed like they were going to be the most towards the top of the list.

Eileen Cody: I agree with you, Doug, if we could like see those 10, -- it would be easier. It's hard to go back and forth.

Greg Gipson: But what if we do like the top three for non-specialty and top three specialty, and then we devise a sort of prioritization for how we go about them? I don't know. Or do we want to wait until we can like merge -- the data?

Eileen Cody: We're not voting today on this.

Mike Neuenschwander: No, no. So again, the idea is to create a short list here. So yeah, if we did top three, top three, and then maybe in that time, you know, Kelly could merge them -- merge the lists, [cross-talk], and then in July we could just [cross-talk] --

Eileen Cody: Well, I say keep the top five at T5 as Doug said and to merge. Right? Is that [cross-talk] --

Douglas Barthold: Yeah, sorry I didn't -- I thought we had to vote today. I was nervous.

Mike Neuenschwander: No, no. [laugh] No. Today, we're just trying to get that short list again, so that way, you know, we can think about it, the public, and, you know, our industry partners can think about it, [cross-talk] send in comments [cross-talk] and then -- and yeah, I know I can see they're really excited in the back.

Eileen Cody: I'm sure they'll have something to say.

Mike Neuenschwander: Um, and then -- and then, yeah, we can vote on that July, and then start working on next steps, basically, to begin the drug reviews.

Eileen Cody: And actually, I was going to like try and review. So what -- how -- when are you thinking with the review you would be done with, even the first one if you're just going to say?

Mike Neuenschwander: So yeah, I guess that can kind of take us a little bit into our next [cross-talk] next steps. And so, again, this all hasn't been done before, so, you know, data requests, you know, depending on, you know, if industry, we send it out like, oh my gosh, we can turn that around in a week, you know, easy peasy, you know, then that will obviously go faster [cross-talk]. If it takes a little longer, that could take longer, so. But so I'll just kind of hit that general point right now. So again, creating our short list here, voting on picking our drugs, and maybe prioritizing them like two at a time from there. And then so kind of the next thing is once we get our drugs is surveys and forms, so, you know, sending out data collection forms to the manufacturers, payers, PBMs, and wholesalers, creating patient advocate surveys. We already have some examples from other states that, you know, are our starting point and then gathering input from individuals with medical or scientific expertise. So this is some of the stuff that's, you know, per the legislation that we need to do.

Meetings also, you know, depending on how much or we need and how much we're able to do meetings with, you know, patient or patient advocates, industry members, the advisory group as well, and then once we select specific drugs, we might, you know, want to add, you know, drug-specific people to the advisory group to help with that. And then so gathering all of that information, imagine doing that from July into the fall, and then -- so hopefully, around during our September meeting, you know, we can have a good chunk of that information collected, and then, again, I'm just kind of ballparking having been synthesizing that data into like information you can use, maybe by like November, and then putting that into an actual report probably at the beginning of next year. So, you know, once we select a drug, I'm hoping six to eight months for this first review to get everything put together.

Eileen Cody: The reason I was -- because it's my recollection is that the Board would have to decide or recommend an upper payment level, but it can't go into effect until after the next Legislative Session.

Mike Neuenschwander: 2027 is the [cross-talk] --

Eileen Cody: [Cross-talk] 27, okay.

Mike Neuenschwander: [Cross-talk] Yeah, is upper payment limit.

Eileen Cody: [Cross-talk] So we can't even do that until [cross-talk] --

Mike Neuenschwander: Yeah, so that [cross-talk] --

Eileen Cody: Takes a little bit of pressure off of you.

Mike Neuenschwander: [Cross-talk] It's actually really nice because it gives us that time that we can create this process for the first time, come up with our first drug reviews, and then fine tune it for another round or two. Um, and then so then, yeah. Hopefully, in a year and a half from now when we have the authority to begin looking at upper payment limits, we have a few drug reviews under our belt. And then also, you know, again, other states like Colorado are just beginning to wade into, you know, creating rules and stuff for their upper payment limits so, hopefully, that will give us, you know, some good experience and best practices to share for us then to start moving into that. So that's still a [cross-talk] --

Eileen Cody: [Cross-talk] I was thinking April 26th, so [cross-talk] you're off the hook.

Mike Neuenschwander: Yeah. No, no, we're -- yeah, we got -- we're thinking ahead. Don't worry. So yeah, so that's kind of the tentative future timeline. And then, you know, if we can get two of those, you know, the first two drugs on that review pounded out here in that half year, then we can start on the next ones and then, again, once we got the process down, you know, hopefully we can start, you know, doing multiple more reviews at the same time and put those together a lot faster once where we've kind of got the templates to just fill in.

Eileen Cody: So then if we -- like, let's say we come up with when we get to four or five drugs at -- for your first list, and you get a couple done that we will get new lists next January, right?

Mike Neuenschwander: June.

Eileen Cody: Or June?

Mike Neuenschwander: Yes, June -- it' June of that following year.

Eileen Cody: So okay. So this is from the 20 -- the years. I'm just trying to figure out when the list that we have now is all the drugs through the end of '24?

Mike Neuenschwander: Kelly, when -- yeah '23 I want to say [cross-talk] --

Eileen Cody: '23.

Mike Neuenschwander: Yeah.

Eileen Cody: So, okay. So it's at -- there's like a two-year lag. Well, I get like one and a half years.

Mike Neuenschwander: Okay.

Eileen Cody: Just trying to think it out here.

Mike Neuenschwander: Yeah. Yeah, and so that would actually be nice because if, you know, if we can get these first two drug reviews done and then get the other two drug reviews started at least, if not done, then we'll have our new list next summer that comes out that then can create our list and say, "Okay. Here's our next --" [cross-talk] -- you know [cross-talk] --

Eileen Cody: Because there were some we may change -- some of the drugs that we have this year, we may decide that we don't want to move forward on it because it like belongs the point of people moving off or something like that.

Mike Neuenschwander: Yeah. Well, yeah. And then there is potentially new drugs that will be on the list [cross-talk] because of the seven-year market [cross-talk] --

Eileen Cody: [Cross-talk] Right.

Mike Neuenschwander: -- thing that we have to work with or price changes or whatever, and so then that will sort a little bit so we can say now these are going to be our new priority with our new list.

Eileen Cody: That's good. I just needed to get the timelines in my head again.

Mike Neuenschwander: Yeah.

Eileen Cody: [Indistinct] is that you guys got? Did you get that straight, or did I confuse you?

Greg Gipson: [Audio cuts out] it sounds like we have a lot of time.

Eileen Cody: Okay. So do we have a consensus here that we want to have the short list of the top five from each group for us to look at our next meeting?

Douglas Barthold: [Audio cuts out] Yes [audio cuts out] --

Eileen Cody: Okay.

Mike Neuenschwander: Okay.

Eileen Cody: [Audio cuts out] satisfy you guys?

Mike Neuenschwander: Yeah, that sounds good. And then [cross-talk] --

Ronnie Shure: [Cross-talk] I've got to say something. [cross-talk] --

Mike Neuenschwander: [Cross-talk] And then we can work on getting those combined, so then we can do apples-to-apples comparison on a single list.

Eileen Cody: Ronnie, you have a question?

Ronnie Shure: I do. It's just one of the factors I think we should keep in mind is choosing drugs from different indications. Pricing of drugs is not transparent, but it's obvious that if a company is marketing a drug, that's only used for six months for a specific cancer or infection, they're going to price it one way. If it's used for chronic use for rheumatoid arthritis, for instance, then it will be priced in a different way. So I think if we're going to start with a couple of drugs, we should keep that fact -- those clinical factors in mind. We don't know the pricing, and there are lots of variables in pricing, but I think that's one thing we should keep in mind as the Board makes a decision about which drugs to choose.

Eileen Cody: Well, yeah, I understand what your point is, but I think that somewhat gets affected by the number of people that would be using it. Because if it's a one-time short-term use, there's not going to be as many people as -- well I guess -- eh, never mind. After I said that, it doesn't add up.

Ronnie Shure: Well, certainly some of the drugs are used for cancer, and those are not necessarily small groups.

Eileen Cody: Right.

Ronnie Shure: So there are drugs near the top that fit that category. Excuse me.

Douglas Barthold: I agree with Ronnie that if we're doing an affordability review and we consider are there therapeutic alternatives [cross-talk] drug, which will matter if there are multiple indications.

Mike Neuenschwander: Yeah, yeah.

Eileen Cody: And, well, and of course, the real problem is off-label use, too.

Douglas Barthold: I'm going to trust Hung to tell us [laughter] the reason for it.

Eileen Cody: Yeah. Okay. Well, and next step. Now we did that. Is that -- did we finish next steps?

Mike Neuenschwander: Yeah. So that was kind of the next steps that I was going to run through of, you know, what our future is going to look like here for the next six months to a year-ish and, again, just the things we're going to have to put together and consider and do as we move into the actual drug review phase. Um. So yeah. So I think that kind of takes us over those both of those two items of we'll create that short list of top five from each, combine it. We'll do a couple of drugs at a time. Once we finish those, then we'll move on to the next. We just need to prioritize them. And then that's the next stuff that we're going to be setting up here, and we'll talk a lot more about in July as we put those different pieces together. So yeah, I think that kind of wraps that up. If there's any other questions on those two topics.

Eileen Cody: You guys are okay to move ahead? Yeah, it looks that way. Okay, then. The revisions to the affordability review data.

Mike Neuenschwander: Yeah. So yeah. So that takes us in, basically, we're trying to plan ahead for getting all of this data. We've talked about the forms before, and during our last meeting we had a public meeting where we got some feedback from a variety of industry partners on the forums and, you know, what data they thought, you know, was feasible and versus usable or not. And so then we've been chatting with the Board Members one-on-one about some of the data in the forms and things. Basically, what's the data that we think we really need? What's the data that could be optional or, you know, like nice to have? Then what's the other stuff that, you know, we think we don't need to include to reduce, basically, the amount of data processing that we need to do if it's not really relevant to determining, you know, does this cause excess costs? And also it could reduce the burden on the people providing the data.

So with that, Marina, we'll kind of take this away. And again, I think the idea is, Board Members, you know, really give us your feedback. What do you think you really need for us to collect? And what do you think we don't need? This is really what we're trying to hear, so that way we can make sure we're not wasting time trying to get information that, you know, really won't be helpful to you during these affordability reviews.

Eileen Cody: Marina.

Marina Suzuki: All right. Yeah. Thank you for the introduction, Mike. Yes. So we did one-on-one with each Board Member, and it's a bit split opinions what you're going to need and what you don't need. So this is just an opportunity for you to discuss among themselves and for us to hear your thoughts. I just have only three slides to give you some background, and then we can go from there. So just to give you a heads up so we did have a webinar on February 27th with stakeholders

to go over the original or draft forms or information collection sheets. And then we had a commenting period, which was closed for the first round of the affordability review. So we reviewed all the comments, and currently what is posted on the website is the original or the first draft, but we are now in the process of making our Division. And here the stakeholder means just manufacturers, payers, PBMs, and wholesalers, and each of them will have one Word document. It's going to be more descriptive information [cross-talk] --

Douglas Barthold: [Cross-talk] Sorry to interrupt. Where on the website is this form? I can't find it.

Marina Suzuki: If you go to just a PDAB main website and click the affordability review subsections, then it should be there.

Douglas Barthold: Okay.

Marina Suzuki: Let's see if I can. Let me see if I can pull it up here.

Douglas Barthold: The manufacturer [cross-talk] information submission form?

Marina Suzuki: Mm-hmm. Yeah. So yeah. This is the main website, and then if you go under affordability review here, you find the webinar recording, and also all of the forms for each stakeholder.

Douglas Barthold: Okay.

Marina Suzuki: And then also just to point out, so the patient and clinicians are subject matter experts. They will be surveyed separately, so it's going to get different strategy to collect their information. So it just the forms are intended to these four stakeholders. All right. So some of the updates following or reviewing the comments, one is to be adding more clarification. So some of the Excel templates have a bit confusing terminology on the column head, so more information or details were added to the data submission guide and some of the wording changed and want details on the Word document as well. So the details are added based on their request from the stakeholder, but two other major items, one is to ease some submission burden, especially on the manufacturer's form. So I think a common theme among the stakeholders, especially from manufacturer side, was that submission burden. And I kind of agree if we're trying to get a pretty comprehensive collection of data.

So one idea was to make some sections optional, especially for information that's available from the public placing platforms or any commercial database that we have access to, like the First Data Bank or medicine databases we can use to retrieve and interpret the data, then those sections will

be optional. So that's one approach we'd like to take. We were a bit hesitant to remove the sections completely because it's kind of taking the opportunity away from the manufacturer to submit their own side of the data. Some states, they did their own data analysis, and a few complaints from the stakeholder as they kind of disagree with the data published in the Medi-Span FDB. They wanted to submit their own data, so I just want to keep the sections available to the stakeholders so that they want -- if they want to submit their own data, there is a section or fields for them to do it, but if they can agree with whatever is available to the public and it's okay for us to retrieve those later, then they can just omit those submissions, so we're thinking of making some sections optional for them. Also there are few sections I want you to discuss today, so we'll go over that on the next slide. And just also a quick comment here regarding the concerns on the confidential and proprietary information. So the stakeholders addressed, expressed their concerns, also submitting their confidential and proprietary information, and I totally understand that.

The submission process will be secure. It's going to be actually a secure thing that they will submit their data or information, and the link is available, actually, just for a really small window of the time period. So that's why the data submission guide doesn't have the whole process of how to submit yet because a link needs to be created, and it's only active for, I think it was seven days for them to act on it and for us to retrieve the data. So again, that will be coming once the drug is selected and when we reach out to each stakeholder. And once the data is submitted, we'll apply strict data governance. So for the both [indistinct] and access of submitted information. So yes, we'll definitely keep all the confidential and proprietary information secure, and we'll discuss that information only in the closed session, so nobody in the public will have an access. So I just want to comment on it. And the last slide is to sort of direct you to what to discuss today.

Eileen Cody: We're not seeing the slides.

Marina Suzuki: Oh, can you -- you can't see the slide?

Eileen Cody: No, we're seeing you.

Marina Suzuki: Oh. I think it's -- I think it's shared. Hold on, let me see. Is it coming up on your end, or no?

Eileen Cody: It just -- yes, now we have it.

Marina Suzuki: Oh, okay. All right, sorry about that. [cross-talk] --

Eileen Cody: [Cross-talk] Do you -- do you want to back up just so we can see what we -- if there was anything?

Marina Suzuki: Yeah, yeah. So yeah. This was just the background [cross-talk] information. We are pointing out. Yeah, we had the webinar, the commenting period close, and here the stakeholder means just four entities. Yeah. [Cross-talk] And then this -- yeah, this was a general update on the forms and the process, so the data submission, the handling, access, it will be all secure, and we'll be doing the minor updates on the phones where they requested by the stakeholder. But the major discussion point today is here how to make the submission burden lighter for the manufacturers. And then so this is -- actually, this is the most important one. [laugh] Yeah, I want to think about it. And I cannot give you a head's up already during our one-on-one meetings, but four sections we want to focus on one [indistinct] pricing and also reviews conducted by the HTA agencies abroad and what type of research and development costs, and also marketing, advertising, and moving costs.

So these are the four sections I kind of wanted to discuss among yourselves to see if you want to keep these sections or you want to delete it or simply simplify somehow? Yeah. So these are the four sections I kind of want to hear your thoughts. And it was a straight split opinions when we did one-on-ones. So that's just a heads up.

Eileen Cody: Okay. So I guess we try and figure out how to -- do we want to do each section the foreign pricing goes line by line on this just to have discussion?

Greg Gipson: I think that [audio cuts out].

Eileen Cody: Okay. So opinions? I know you guys have opinions.

Greg Gipson: I mean, I think for foreign pricing, I think I brought that up as well, and I wasn't sure kind of like how that would play into our decision if we're going to use that in some way to kind of help us decide an upper payment limit. I think if we're not including that into that formula, then it may not be as useful as what I was thinking but love to hear whatever other people think.

Douglas Barthold: I agree. I didn't see how it was relevant.

Hung Truong: I concur. There is just a lot of noise around foreign pricing right now, and I don't think it has much to do with what we're doing here, and so I'd rather keep that noise away.

Eileen Cody: Yeah. I and -- it'll be interesting to see what the feds do on foreign pricing that. We'll let them have that argument. These are discussions that have been going on for 20 years, [cross-talk] so it's --

Eileen Cody: Yeah, for sure. Okay. So Ronnie, did you have a comment?

Ronnie Shure: Yes, just a comment on foreign pricing. I agree that it's not an issue to discuss at this point of time. If we were to talk about foreign pricing, it would be involving policies that the industry and the government have -- were able to develop together, which happens in most of the countries, and I don't think we're even close to that. I think our role is just looking at the existing situation. So I agree.

Eileen Cody: Okay. [Cross-talk] Okay then. [Cross-talk] --

Ronnie Shure: [Cross-talk] Don't include foreign pricing.

Eileen Cody: Review conducted by the ATA agencies abroad. Oh, that? This is the quality question?

Marina Suzuki: Uh, yes. So in the US, we have the ICER that's like a third-party organization looking at the clinical effectiveness and cost effectiveness of a drug, so that would be really helpful for us to look at. But the caveat is that the ICER doesn't do the reviews on every single drug out there. So in that case, depending on which drug you're going to select, we may or may not have a review from the ICER. So I think that's why the other states PDAB, they looked at the reviews conducted by the HD agencies abroad, and they did the whole summaries of each agency, what they what their conclusions were. So that's again. We could look at ICER and look at the other agencies abroad. If review from ICER is not available, or if you're not interested at all, we could delete it. I'm just wondering where you are on this aspect.

Douglas Barthold: I think in the absence of an ICER review, if the ICER review does not exist, then yes, the foreign HTA would be helpful.

Marina Suzuki: Okay.

Greg Gipson: I agree with that as well.

Eileen Cody: Yeah, I think any information that we could get that relieves the burden on HCA we should use.

Mike Neuenschwander: I was going to say, and I think, like I mentioned, I think for the top five specialty drugs -- just looking at my list, yeah, there have been ICER reviews done for those and -- just looking at my list here. I think for the top three, or the first and the third on the non-specialty, the first, third, and fifth.

Eileen Cody: Okay.

Hung Truong: Do we know what agency where? Are we talking about NHS, or do we have like a set of those agencies? One that I can talk to.

Marina Suzuki: Yeah. So let me share. So it looks like lets -- I think this is like a Colorado version of their review. Oh, hold on. Okay. I cannot move this somehow again. Uh --

Hung Truong: I concur with everyone that we need to take a look at it, and I think, usually, and it would be focused on pricing.

Marina Suzuki: Yeah. So like, for example, Colorado, I think this is a review on Enbrel. They looked at these agencies what's available. So in addition to, I started to try to look at the lines from [cross-talk] the UK, Canada, and other countries as well. So you know each can have a review or conclusions on the cost effectiveness. I'm not really worried about the clinical effectiveness. It's more interested in this cost effectiveness part. Yeah. So these are the things that they looked at.

Hung Truong: Okay. That was my -- I think my point, too, is that looking at the cost effectiveness and not trying to look at everything and just focus on that piece.

Marina Suzuki: Mm-hmm.

Hung Truong: Okay.

Marina Suzuki: Do you -- when I look at the HTA agencies review from abroad, even when the review exists from the ICER, or we can say you don't need to -- we don't need to look at it once we have a review from the ICER.

Doug Barthold: I think that's reasonable. I would certainly give more priority to the ICER review in those cases.

Mike Neuenschwander: It's Dharia.

Eileen Cody: Dharia. Okay. You have a comment, Dharia?

Dharia McGrew: Hi. Sorry. Apologies, I was late to the meeting. I'm balancing multiple state PDABs happening at the same time and just wanted to first question as an Advisory Board Member and not a PDAB Board Member. One is question what role the Board would like for Advisory Committee to play in these discussions. Do you want me to hold comments until later or jump in if there is an industry-related comment as you're discussing them?

Eileen Cody: Well, since the we're ahead of schedule, I think you can jump in whenever you want.

Dharia McGrew: Great. Thank you so much. I just want to flag in our letter response to these two issues about HCA's [indistinct] HCA's. As you as you noted, we do have a lot of concerns with some countries. Not all, but many of them do use qualities or QALY, sorry, or [indistinct], which would be counter to the Washington statute. Additionally, many of HTAs are used in other countries before a drug comes to market and are used for price setting. And since Washington is reviewing drugs that have been on the market for seven years or more, there will be quite a bit of substantial evidence of actual post-approval pricing and utilization from Washington and the United States across a range of clinical and other benefits. So I want to make sure that the Board is prioritizing in those discussions. The clinical evidence available post approval in the US or in Washington when available over pricing decisions made in other countries, similar to your previous conversation about foreign pricing.

Hung Truong: That's a good point, Dharia. Thank you.

Eileen Cody: So okay. So have we got conclusion then? That's it. Marina, do you think you got enough information from us on that?

Marina Suzuki: Yes. Also what I'm hearing is we can delete the foreign pricing. We [indistinct] we think high prices in the US. And then for the review conducted by the HTA agencies abroad, we will primarily that got the review from the ICER, and if the review is not available from the ICER, then we'll look at the other agencies, but we'll focus on the ICER. So that's -- yeah, that's seems to be the consensus here.

Eileen Cody: Okay. Okay, research and development costs. I would think that that's -- I'll just say from this one, I would think that's when the industry would want us to have in review, but we could -- I mean, if they don't want to, I guess we -- that could be a voluntary or -- I'm blanking out on the word -- but what are other people's thoughts on that?

Douglas Barthold: [Cross-talk] Um.

Marina Suzuki: [Cross-talk] I think -- I'm sorry. It's just one thing to point out. So one recommendation from the portal and what other states are doing is to look at any funding coming from the federal agencies or some funding coming from the taxpayer's money during the development. That is something to be disclosed. So I think the form has the table from other states asking, did you have any funding resources from the federal agency? That kind of stuff. So again, if you're deleting the whole section, we will not have that type of information here. So just pointing out if that's something you still want to know or not. Um, yeah. And I think one comment from the PhRMA, I mean Dharia is here, but the manufacturers is that -- this is difficult information to

submit, and I agree because they have, you know, other [indistinct] to reach one drug to the market, so it's what's to be included or not.

Again that's -- it's a bit difficult thing for them to submit, and I understand that, and that's why we didn't use any Excel sheet or data submission form on this section. It's just more like a descriptive or related information on the Word document, so that they can say, you know, like well overall this is the estimate how much effort used in terms of money, people, time, that kind of stuff, as well as if they know, or if they can identify any sources of funding coming from the taxpayer's money, then please put it in a table. So that's how the section is formatted. Again, we could edit in a way that you'd like to see, but I'm just curious. Do you want to keep it, delete it, or modify it in some way?

Douglas Barthold: I mean, that was largely my point. It was that I don't think it -- as far as I know, I don't think it's possible to isolate the R&D costs for any single product from a manufacturer. You know, it's a lot of fixed costs and a lot of failed products that they have to account for the costs of, and I don't know if Dharia could speak to that, but it might just be impossible for them to provide that number.

Hung Truong; Well, and even if they can, it's going to be a wide range. Right? If you're not specific. it could be $500 million to a billion, depending on how the company is looking at the research and development unless we are asking for very specific information. Like, you know, what kind of support would the Orphan Drug Act helped in this? I mean, he can get pretty complicated on how it is supported by outside agencies or the federal government and in the research, and all the. And so we asked for this. I think it needs to be a level playing ground where the information needs to be consistent from one to another, and so then there's going to be some work in thinking through on what that would be.

Eileen Cody: So, Hung, you're saying that making it optional isn't fair.

Hung Truong: I think. One., I'm not sure. You know, I see some use in knowing the R&D, I think just getting the data is very difficult, and then how we use the data is difficult in the fact that one company can submit something, and another can submit something, and the two are based on different criteria is what they see. I think, you know, just because there are just so many variables in it, unless -- then we have to be very specific in what we ask.

Eileen Cody: Well, I guess I -- it's just that in the legislature all you hear about is that the reason it's high cost of drugs is research and development. So from that perspective we could think they actually know what they spent on research and development. But what you're saying is that it would be very hard to actually quantify it.

Douglas Barthold: For any one product.

Eileen Cody: Yeah. I get you.

Greg Gipson: I can see it as like how much did it cost to raise your children, right? Like, what do you put in there?

Eileen Cody: [Laughter] I like that analogy.

Mike Neuenschwander: A lot.

Greg Gipson: I also kind of see some value in offering the opportunity for manufacturers to share that information, but also, I think to Doug and Hung's point, like I have no idea what we do with that at the end of the day.

Marina Suzuki: Should we -- I mean, if we are doing affordability review in a staggered manner, I'm assuming you will pick like priority [indistinct], but we are reaching out gradually to them. Right? So should we keep it for the first round to see what kind of information you get and whether you know it's going to be helpful or not? And let's say it doesn't help at all, then we can remove it later from the affordability reviews. But for the first round, in case this gives you some additional insight, do you want to keep this section?

Dharia McGrew: Let's just --

Eileen Cody: Dharia?

Dharia McGrew: -- quickly weigh in. Yeah, agree, um, with everything. It is absolutely the cost of R&D is factored into pricing, of course, but it is also very hard to quantify for one particular drug. So agree with all the conversation here. So it is a tough job for you to find the right balance of being specific without being overly specific and limiting that. So being broad and letting the manufacturers define that would be preferred. And also there are -- I'm wondering if you have looked at transparency reporting in states that do have transparency reporting because there are other ways that other states are doing this. And note that Washington does have a Drug Price Transparency Program and wonder if you have spoken to that program about how they define or how they request that information.

Eileen Cody: Do we know?

Ryan Pistoresi: Um, yeah. So we do have a data submission guide for our Drug Price Transparency Program, so we could look at how that is defined. I think the challenge is, is that the criteria for

manufacturers to report to the Drug Price Transparency Program is different than what we have for the Prescription Drug Affordability Board, and so we can't necessarily take existing data from that program for the purposes of this. I think we would have to borrow that, and examine it, and then see if we could leverage it for this affordability review process.

Marina Suzuki: Yes. And if I understand correctly, the information or the data from the DPT program is not to this granularity. So they have, I think, a few, just a few slots, a few slots to put the R&D cost or information, but there is no narratives or no like, what's included or not? We don't know what -- it's like the number, whatever they submit. So I think that's why as part of this affordability review, if we can get some narratives going with those numbers, it's just much more insightful rather than just, here's the number. And we have no idea -- what this number is, so I think that's why the affordability view is more detailed. It's going to be helpful if you are interested in looking at like how much it cost for the drug development and research.

Hung Truong: I think Eileen is correct in that you would imagine that drug manufacturer would want to show how much R&D and that it does cost and how it's justifying the cost. I would at least say that it should be an option for PhRMA to submit that, but perhaps we can come to an agreement on what information is submitted. How is it categorized? What would be less burdensome for PhRMA? What information would they have that could be used consistently across to all the companies that they can submit that? Or at least we have some consistency on how we view the data.

Eileen Cody: Well, and maybe it's a good place to start using the transparency -- what's submitted for the Transparency Group, too. But yeah, I think optional, but I also think we'd want to make sure that we include a disclosure of grants. If they're going to give us an optional about how much they spent, we want to know how much money that was brought in, so that should be -- on the form, too.

Marina Suzuki: Okay. Sounds good.

Eileen Cody: But any other? I mean, did you guys agree, disagree with me? What [cross-talk] --

Douglas Barthold: My general thought is that sure, I'm intellectually curious. I'd love to see what the number is, and I don't -- but I actually don't -- I really don't see how it would come into play in making a decision about a UPL or deeming a drug unaffordable. And so in that sense, I don't know how I would ever use it. I mean, whatever. If we want to make it optional, I think it's fine. You know, I'll be curious to see what it is. Yeah. Just I -- if we, you know, I don't know, if we get pushback, and they're trying to prioritize what, you know, what's feasible for them to report, I don't want to like -- I don't want them to waste their time on that, but they could be providing us with that other information that we -- what we really care about.

Marina Suzuki: [Cross-talk] I think we [cross-talk] --

Eileen Cody: Go ahead.

Marina Suzuki: [Indistinct] yes.

Ronnie Shure: I think that if we include that research and development costs, we should just be asking for a narrative. It's certainly not possible for a manufacturer to really define that, but it is something that we could/should be aware of. We should consider under, you know, at least a narrative to recognize what individual costs or what specialty issues -- not specialty versus non-specialty drugs, but which specific issues a manufacturer faces in developing a drug? And so I think it's something we should consider as a background factor. Even ICER we would use some of the data they provide. It's not going to be the ultimate decision making. And I think one of the issues we've seen in legal cases is that we don't want to restrict people's comments or freedom of speech, essentially a part of some of the lawsuits that Prescription Drug Affordability Boards have been reviewing or been faced with. I think we should include it as a background issue, not as a heavy figure in our decision.

But like Eileen said, we can't ignore the knowledge, the public knowledge and approach or opinion. We can't ignore those costs. We can't ignore that some of those costs are borne by other taxpaying institutions. A simple discussion or narrative I think would be useful and would recognize the manufacturer in their role. I'm not a representative of the manufacturer I'm just looking at it from a more balanced perspective. So I think it's one factor to consider as a narrative in our discussions. Thank you.

Eileen Cody: So any other comments. So did you get an answer out of us?

Marina Suzuki: Um, so do you want to make this section optional? But if they're submitting the narratives, give us enough details to figure out and also any disclosure from the grants. That's what I'm hearing. Is it like a consensus here then?

Eileen Cody: Well, that's what I thought, but [cross-talk] --

Marina Suzuki: [Cross-talk] Okay, sounds good.

Eileen Cody: Does everybody agree with that?

Greg Gipson: I like that.

Mike Neuenschwander: Okay.

Eileen Cody: All right. Working and advertising and lobbying costs. Well, lobbying, I don't know. [laugh] So like what -- I guess, is it -- somebody else start out on this one.

Hung Truong: This feels like the same as would it -- how would it make -- help us make that decision as well? So I --

Douglas Barthold: I agree. I don't know how I'm going to us it any of our decision making. It did -- actually, I think it's less -- even less relevant than the R&D.

Greg Gipson: Yeah, I agree. I lean towards -- I put it on my remove versus optional list, so.

Douglas Barthold: Agreed.

Greg Gipson: I mean, if you spend a billion dollars on marketing, like, why does that make any difference?

Marina Suzuki: Oh, I'm sorry. I just got a message from the DPT Program people saying that for the DPT program it is not a required field to submit research and development. It's optional section, and more than half of them are not submitted, so it's empty. So I guess I can assume kind of similar thing. It's like 50/50 whether you get the information or not. So just, I don't know if that changes your opinion on it or not. But it's just, yeah, I got the text saying that it's likely that information won't be available from the DPT.

Eileen Cody: Oh. [cross-talk] Okay.

Mike Neuenschwander: Oh. So I think the general thought was marketing, advertising, lobbying, don't need?

Eileen Cody: I guess that's it. I mean, the interesting thing about it is it, of course, drives a lot of the price, but I guess it doesn't matter to us if that's what's driving the price. That's your guys' point, right? Yeah. Yeah. Ronnie?

Ronnie Shure: So certainly, we don't know how -- what impact advertising truly has, and I don't think the manufacturer who does the advertising really can pinpoint information. But I don't think we're going to stop it. It's part of the American business system. However, I think we should recognize it and keep it as another background factor to pay attention to. In my opinion as a pharmacist, I found it [audio cuts out] not appropriate and -- but at the same time, the ads are so bad that I think it has just as much negative impact on the choice of a drug as it does a positive

impact. But that's what I think about Coca-Cola advertisements as well. So I don't think this is a factor that will determine how we set the prices, but I think that we, because of the public's perspective of that, I think we should acknowledge it more as a narrative in our discussions about a drug. I don't know if we can add some of the Ozempic songs, too. [cross-talk] --

Eileen Cody: [Cross-talk] They're really bad. [laugh] --

Ronnie Shure -- Is there a way to add audio portion to our reports? I think it's something that's here for a very strong reason. It's an expense for the manufacturer. It has an impact on our healthcare costs. I think we should keep that in mind, but I don't think there's a way for a drug affordability Board to really figure out or analyze those costs. I don't think it's transparent enough. Even to the individual manufacturer, I don't think they can tell you the impact. I'm not a representative of the Pharmaceutical industry. I'm repeating that again. So maybe that's something Dharia should have edited. But I think it's a factor we should consider as more of a narrative position because it is important cost. So have it there, if only to recognize that that's a part of the cost we're paying in our society.

Eileen Cody: Well, Ronnie, even though I'm probably just as curious about it as you are, I got to say that I agree that if we make it optional, nobody's going to fill it out. And I don't see making it mandatory as something that's actually going to give us anything, I mean, that we're going to use. So unfortunately, we probably just have to delete it. That's kind of where you guys were going, too, I think. Right? Yeah. [cross-talk] --

Greg Gipson: [Cross-talk] --

Marina Suzuki: And it's not-- going to affect like how aggressive or conservative you want to be if you are setting upper payment limits. [Cross-talk] And I think -- yeah, if it's not going to affect your decision, then I think we can delete it. I mean, optional doesn't work for this. I don't think if it's optional, [cross-talk] --

Eileen Cody: [Cross-talk] Their not going to do anything. [cross-talk] --

Marina Suzuki: [Cross-talk] nobody's going to submit. Yeah, like Eileen said, so. Well --

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

Eileen Cody: [Cross-talk] I know, Hung -- you didn't say anything on this one, I don't think. Are you?

Hung Truong: Are you talking to me?

Eileen Cody: Yeah. I didn't think you said anything about this one.

Hung Truong: Oh, I did.

Eileen Cody: Oh.

Hung Truong: I said it's -- it doesn't affect how I'm going to view this.

Eileen Cody: Okay.

Hung Truong: Yeah. No.

Eileen Cody: All right. Well, then I guess we're deleting that.

Mike Neuenschwander: And I know we did have a request for a quick break. I don't know if we want to do that for five minutes before we -- we're pretty close to the end, but [cross-talk] --

Eileen Cody: [Cross-talk] Yeah.

Mike Neuenschwander: -- you know, [cross-talk] some of that's [cross-talk] --

Eileen Cody: [Cross-talk] We can -- that's fine. If you guys want to break, 5 minutes? Yeah, Okay. Somebody must need a phone call. [laughter]

Mike Neuenschwander: Okay.

Eileen Cody: All right, we'll be back for public comment.

Mike Neuenschwander: Well, I think we still have a little bit [cross-talk] --

Eileen Cody: [Cross-talk] We have a [cross-talk] --

Mike Neuenschwander: -- little bit more to discuss. [cross-talk] --

Eileen Cody: Okay.

Greg Gipson: Great.

Eileen Cody: [Whisper]

[break]

Eileen Cody: Okay. We're coming back. We'll see -- okay -- see who shows up. There we are. Okay. Okay. What do we have left, Mike? Who is this?

Mike Neuenschwander: So uh [cross-talk] --

Greg Gipson: This is Greg.

Eileen Cody: No, he's there.

Mike Neuenschwander: There we go. So, Marina, do you want to just kind of finish off talking about QALYs, and then I think just opening it up if there is any other categories that the Board Members as you guys were looking through the forum, things that you think would be worthy of discussion that you don't need? So we'll kind of open that up there. Marina?

Marina Suzuki: Uh, yeah. I just want to do a recap on these four sections as well. So the following pricing we will delete, reviews conducted by the HD agencies abroad will look at the ICER reviews. If not available, we'll look at them. Otherwise it's going to be optional. And then budgeting, advertising, and lowering costs is going to be deleted. For the research and development costs, though, we'll make it optional. We ask for any federal grant or funding sources, and then -- but the whole -- the section itself is optional. If they are submitting, give us the details in a narrative form. Okay, so I think that's what I heard. Um, yeah. And any other [cross-talk]--

Eileen Cody: But they [cross-talk]. That's what I got. Anybody any differences? Okay.

Marina Suzuki: Okay. Okay. I think I took a note of that. Okay. And then the last thing I want to point out was the use of QALY. This is a bit controversial, and the law is not super clear. It's not. It's kind of bit gray. But the language we have in our statue is this listed on the slide. So our interpretation was that the use of QALY is not prohibited entirely as long as we follow these rules. So some of the QALY measures we can still use or look at. For example, the ICER used the equal values of life years gained that doesn't identify the subpopulations or give any reduced value, so that was our interpretation that we can still use QALY as long as we follow these languages. But if -- Mike, do we have Michael, the AGA, to hear his thought or if he can give us more insight on this study? Helpful.

Mike Neuenschwander: Michael Tunick? Are you on today? Let me check the guest list and look and see.

Marina Suzuki: Yeah, I didn't see [cross-talk] --

Ryan Pistoresi: An attendee.

Mike Neuenschwander: He's an attendee?

Ryan Pistoresi: Yeah. But he just wrote and raised his hand, so he'll be at the top of the attendee list.

Mike Neuenschwander: Okay.

Douglas Barthold: I can just -- one minor clarification on that. If we're using expected value of life years gained, that means that we are not using the QALY. That's completely -- those are separate, and I think that would be a reasonable approach. And I think ICER reports usually report their results in both QALYs and expected value of life years gained. So we can just, if -- I think if we use the expected value of life years gained, we are complying with the statute, and we are --and we should be good.

Marina Suzuki: Yes. Yeah, that was my interpretation as well.

Mike Neuenschwander: Okay. [cross-talk] I wasn't able to make him a panelist.
[cross-talk]

Douglas Barthold; Actually, I was surprised. I think Dharia mentioned before that we were not allowed to use expected value of life years gained, and I was confused by that because that was not what I was -- not the impression I was under.

Eileen Cody: Go ahead, Dharia.

Dharia McGrew: Thanks. I just, you know, the language does not specifically say QALY, and we do have concerns about the [indistinct]. I can't speak specifically to that right now, but I'll make sure that I [cross-talk] answer. [Audio cuts out] [indistinct] or disability [indistinct] or whatever, yes. It may not employ a measure or metric, which assigns a reduced value to the life extension, so that's sort of a more general [cross-talk] getting at the concept of the QALY, not specifically the QALY, so you know this is a very -- I'll need to talk to my subject matter experts on this one, but my understanding is that just we do have concerns with the [indistinct] as well as the QALY.

Doug Barthold: Okay. Yeah, I'll be interested to hear what they have to say about that. But the, um, I think that the expected value of life years gained does comply -- with that whatever, RCW 74.05.050, item 3. Yeah. [cross-talk] Yeah.

Marina Suzuki: Yes, yeah.

Ryan Pistoresi: Yeah. And this is Ryan. So, Doug, I believe you're right because I believe that as this legislation was being drafted back in, I believe, 2022, that ICER did provide some language for the House and Senate for them to consider where they could use equal valued life years gained, and I think this is the language [cross-talk] --

Eileen Cody: [Cross-talk] I have my recollection, too. I know, but I'm trying to remember this. I believe that is exactly what happened?

Ryan Pistoresi: Yeah. But the other thing I would like to point out. So this RCW 050 is for the upper payment limit section, and we are still in the, you know, affordability review phase, so that's the 040. So just letting you know that as we are in 040 and doing the affordability review and getting the materials and things like this, this quality adjusted life year restriction is in the subsequent section for this, the methodology for upper payment limits. So when it says methodology there, no that's not the methodology for assessing the affordability review, it's the methodology for the upper payment limit.

Eileen Cody: So we can use it, the quality in the [cross-talk] --

Ryan Pistoresi: And that's where Michael Tunick, our AAG will provide more guidance on that, but yeah.

Mike Neuenschwander: And I think we got Michael moved over as a panelist. Michael, are you there?

Michael Tunick: Yes, good morning, Director Mike and the Board. Yeah. So I am here. I, you know, sort of start off by saying, you know, I always loath to provide legal advice in the public forum, just because it is not privileged or confidential then. But I -- that being said, I've been asked to speak. So yes, this 70.405.050 does talk about the methodology to set upper payment limits. Now, when talking about QALYs, yes, it's a very -- it's a fraught term, and there is a legislative limitation on it, and it's not -- doesn't prohibit you from using quality -- QALYs, but it does say that take into account. And if you see the language in blue, you know -- and I'm just trying to remember what else. The -- I guess, were there any other questions or thoughts you wanted me to share?

Eileen Cody: Well, I think that the clarification that this is about the upper payment limits and not about that it's 74.05.040 you said?

Ryan Pistoresi: Yeah, 040 is for the affordability.

Eileen Cody: It's on the affordability reviews, and that's what we're actually discussing. O 5 O 40

Michael Tunick: Yeah. And actually, sorry, and the last thing I did want to also say is that although this is interpretation of a statute, which is squarely a legal interpretation, it's -- I would also just say that we're talking about like health economics terms, and so, you know, so even if I was interpreting this, I would also still defer to experts like Doug and, you know, some of the HCA staff who, you know, do biostatistics and health economics. So yeah, it's not just -- I guess, yeah, even the statutory interpretation is a legal exercise. There would still be the technical terms you would want to refer to those experts as well.

Eileen Cody: So Doug, do you have any more to add?

Doug Barthold: No, I think we can -- I mean we're still going to the ICER reports. It's just what we can do with the ICER reports, and it doesn't sound like there's any restrictions for the affordability reviews. We will have restrictions at the upper payment limit stage, but per our collection of data from the manufacturer, the ICER reports, that's -- we still want it.

Marina Suzuki: Yeah. I think it's fair game to collect information, especially for the affordability review and even from review from other HTA agencies, but for setting up an upper payment limit, we just need to be careful that we follow this language. Yeah. Okay, I think that was it from my end, unless the Board Members have any other things you want to discuss for revising the data collection forms or the document.

Eileen Cody: Okay guys, anything else you want to discuss or any concerns you have? Great. Going once. Okay. Well, then we move on to public comment.

Mike Neuenschwander: Okay, great. So we did receive -- I just want to note we did receive a number of written comments. I forwarded those to the staff and the Board as well. And so I guess opening up the floor to anyone else who wants to do public comment. And I think just remembering keeping to our rule of 3 minutes and yeah. So if you have anything, please raise your hand [cross-talk] --

Eileen Cody: Dharia?

Dharia McGrew: Thank you. For the record, Dharia McGrew, on behalf of PhRMA. I really appreciate the lengthy and thoughtful conversation in all of this. Appreciate Marina the affirmation about secure submission of data. That is very, very important to manufacturers, so that is appreciated. I should have jumped in. I didn't think to jump in exactly when you said it, but it took me a little bit to process. I believe that you said that there would be a pretty limited time

frame to submit the information through the secure portal, and that might be problematic. It depends, you know, how long a lead up time there is for manufacturers to gather the information. You know, even in a more limited form it still is a lot of information to be gathered, and so I just want to make sure that please you provide enough information for manufacturers to gather the information, even if the actual submission date maybe is limited. But it does take quite a while for them to get some of this information together.

Two concerns I just want to highlight with the just the meeting materials in general. And I apologize if you talked about this before I was on the meeting. There is an inclusion of a comparison of other states. The other states are highly variable, as you noted, in what factors go into their eligibility. There are also errors. I'm not an expert in Maryland or Colorado, but I have been involved with Oregon's PDAB since the beginning. The list that is in your meeting materials, I know it's just sort of listed as an interesting comparator, but I just want to highlight that that list was later determined to be quite a few errors. Several of those drugs were later determined not to be eligible and should not have been on the list, and then last year Oregon just decided because of errors and problems in their process that they just stopped affordability reviews in the middle of the year and decided to restart in 2025, so you know just issues with comparing between states.

And then our letter highlights a concern with rolling up drugs based on an active ingredient. We do and have said before, and we do believe that rolling up by NDA and BLA is more appropriate. You can have drugs that have significant developments in delivery or technology, or, you know, patient use of experience, and they will have the same active ingredient but different costs for different conditions that they treat even, so that could complicate affordability review if you're comparing things that would be better compared separate -- you're rolling up drugs that should be considered separate drugs. Thank you.

Eileen Cody: Okay. Is there anybody else?

Mike Neuenschwander: Uh, double check the [indistinct] real quick, but I don't think there is anyone else with comments. Okay.

Eileen Cody: Okay. Boy, quick meeting today. All right. Well, anything for the good of the order or the other Board Members? Well, then I guess you'll -- we'll get an hour back of your time. Thanks. And when's the next meeting? It's July?

Mike Neuenschwander: Yes, July 15th. Yeah.

Eileen Cody: Okay.

Mike Neuenschwander: That sounds about right.

Eileen Cody: Okay. All right. July 15th, guys.

Greg Gipson: Thanks.

Doug Barthold: Okay, thanks.

Mike Neuenschwander: See you then.

Hung Truong: Thank you. Okay. See you then. Bye, everyone.

[end of audio]