Washington State Health Care Authority
Health Technology Assessment

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**Health Technology Clinical Committee Public Meeting**
July 8, 2016

Josh Morse: Good morning, everyone. This is the Health Technology Clinical Committee Meeting for today, July 08. Is Dr. Standaert on the phone?

Chris Standaert: Hi. It's Chris.

Josh Morse: Hi, Chris. So, Chris, here in our conference room at the Health Care Authority monitoring the webinar, if you have access to a screen you can see what the information is on the agenda. I (inaudible) on the line at this point.

Kris Ur-Wong: I have seven people on the line, eight, well including me there's seven, eight.

Josh Morse: Okay. Chris, we can start with the roll call now if you're ready.

Chris Standaert: I'm ready.

Josh Morse: Okay.

Chris Standaert: Okay. Can we have a roll call who is on the phone? This is Chris Standaert.

Maria Stewart: Morning. This is Maria Stewart with Boston Scientific Corporation.

Lisa: Hi. This is Lisa from Regence.

Steve Hammond: Steve Hammond, Department of Corrections.

Gary Franklin: Gary Franklin, L&I.

Louise Kaplan: Louise Kaplan from the clinical committee.

Michelle Simon: Michelle Simon from the clinical committee.

Michael (inaudible):

Carson Odegard: Carson Odegard from the committee.

David McCulloch: This is David McCulloch from the clinical committee.

Tony Yen: This is Tony Yen from the clinical committee.

(inaudible) Moore: Hi. This is (inaudible) Moore. Good morning everyone.

Kris Ur-Wong: I'm sorry . . .

Chris Standaert: Is that . . . is that . . .

Kris Ur-Wong: . . . (inaudible) for Danielle Moore.

Tony Yen: Tony Yen.

Josh Morse: So, we do have a quorum at this point, Chris.

Chris Standaert: And I heard Lisa from Regence. Can you give me a full name?

Lisa Huston: Yeah, Lisa Huston, H-U-S-T-O-N-.

Chris Standaert: Okay. Thank you. Which committee members do we have present, Josh?

Josh Morse: Louise Kaplan, Carson Odegard, David McCulloch, Michelle Simon, you, Chris, and Tony Yen. Are there other committee members on the call at this point?

Joann Elmore: Joann Elmore.

Chris Standaert: I don't know what happened, but my webinar seems to have disappeared. I went to the webinar and it vanished and some other . . . the webinar website showed up. So, I'm still trying to get to the webinar.

Joann Elmore: Yeah, I don't really have much on my webinar. Can we get the distribute materials via email the old fashioned way?

Chris Standaert: Yeah. It just sort of vanished on me.

Carson Odegard: Yeah. I've got a blank screen on my webinar.

Josh Morse: So, Kris is working on . . .

Chris Standaert: Click the webinar again.

Josh Morse: So, all of the materials for today's meeting are available on the program website, and I can email out a link to committee members.

Chris Standaert: Why, Josh, do you have the webinar up? Do you have things in front of you, like, I saw for a second the agenda, but it vanished and now I have this sort of Gotowebinar thing that keeps coming up.

Kris Ur-Wong: Okay. That's us.

Josh Morse: Yeah, Chris . . .

Chris Standaert: So, there's nothing else on it beyond that?

Josh Morse: It would only be . . .

Chris Standaert: (inaudible). Do other . . . other committee members, do you have the webinar? Do you see the agenda on your computer screen or do you all see nothing?

David McCulloch: No, I'm seeing it on my screen.

Darren: This is Darren. My agenda just came back up.

David McCulloch: Yep, the agenda is up and then I've also screen loaded the HTC website, so. I'm sitting good to go.

Chris Standaert: Yeah. I have the latter. I don't have the webinar. I don't know what happened. I have, like, the Citrix home page is what's staring at me. It doesn't let me get to the webinar. Interesting. Alright, I will go back to the agenda just at the HTCC website. So, anyway, our . . .

Joann Elmore: It pops up on another area of my screen. It keeps popping up and going away. It does come up every once in a while.

Chris Standaert: Well, let's get started then. So, we have the . . . I'm also, again, the committee chair. We're here to discuss essentially the meeting from May and finalize our decisions and determinations and approve the minutes if we feel all that is appropriate and discuss input we've received in the interim. We have a quorum, so we'll go ahead. The minutes are

on the website and/or referred to us by committee staff. If you haven't read them, please read the minutes briefly. I read through them myself. Does everybody have the minutes or see the minutes?

Tony Yen: Can you please send out the link to the . . . exactly where in the website?

David McCulloch: Yeah, Josh, I think, just did that. So, I have the agenda, yeah. Thank you.

Tony Yen: Okay. I see that now.

Kris Urv-Wong: I don't know why it stops every time I switch.

Chris Standaert: No. I can't get on the webinar. This is confusing now, because we can't all see that we're seeing the same thing. So, have committee members read the minutes?

Josh Morse: Chris, we identified one typo in the minutes.

Chris Standaert: Where is that?

Josh Morse: It would be on page four of five in the paragraph of the discussion, the word patellar is misspelled with an H, and we can correct that in the minutes and in the . . . related to the autologous blood.

Chris Standaert: Patellar tendinopathy, yes.

Josh Morse: I apologize for that.

Chris Standaert: No problem. I did not see any other corrections, myself. Committee members, have you been able to see the minutes yet?

Group: Yes.

Chris Standaert: Anybody have any questions, comments, or corrections for the minutes from the May meeting? If not, I would appreciate a motion to approve.

David McCulloch: Moving to approve the minutes.

Chris Standaert: Second.

Tony Yen: Second.

Josh Morse: For the vote, I'd like to just go through a roll call. I have a list and I'll just call out a name and then you can tell me your vote, and we'll do the

subsequent, Okay? So, we'll start out with Dr. Brown, Greg Brown. Joann Elmore?

Joann Elmore: Approved.

Josh Morse: Louise Kaplan?

Louise Kaplan: Approve.

Josh Morse: Carson Odegard?

Carson Odegard: Approve.

Josh Morse: David McCulloch?

David McCulloch: Approve.

Josh Morse: Seth Schwartz? Michelle Simon?

Michelle Simon: Approve.

Josh Morse: Mike Souter?

Michael Souter: Approved.

Josh Morse: Chris Standaert:

Chris Standaert: Approved.

Josh Morse: Kevin Walsh? Tony Yen?

Tony Yen: Approve.

David McCulloch: Are you there, Kevin?

Louise Kaplan: He said he would be late.

David McCulloch: Yeah. He sent an email saying he was going to be late missing a flight but he would join us.

Josh Morse: Oh, thank you. So, that is one, two, three, four, five, six, seven, eight approved and, uh, I think we have three absent.

David McCulloch: Okay.

Chris Standaert: Okay. So, we will move on. We have two decisions to finalize, one did not receive any public comment. The other received four comments. Can we switch the order, Josh, and talk about PRP, as maybe Dr. Walsh will show up?

Josh Morse: That's okay with me.

Chris Standaert: Is that okay with people?

David McCulloch: Yep, that's fine.

Chris Standaert: Okay. Let's talk about the platelet-rich plasma decision initially. So, we made our decision, which is on the document as a noncovered condition, noncovered technology, and we have received no public comment. So, there, again, we . . . it's important the public comment if they have opinions one way or the other to help us, but we have no additional input. We actually did not receive any public comment anywhere through the entire process it looks like regarding this particular technology. Is that correct, Josh?

Josh Morse: Well, this . . .

Chris Standaert: Well there's only comments on the decision, sorry. Yeah, we . . .

Josh Morse: . . . yeah, there's . . .

Chris Standaert: (inaudible).

Josh Morse: . . . (inaudible). Yeah. Yeah.

Chris Standaert: Sorry (inaudible).

Josh Morse: I can go back and look if you'd like me to.

Chris Standaert: So, if committee members could review their, review our decision and discussion pieces of that document. It states the majority of the committee members felt like it was unproven in terms of efficacy, safety, and cost-effectiveness. Prior to the vote on coverage, we discussed the conditions for coverage, and the majority of the committee voted not to cover autologous blood injections and platelet-rich plasma injections for any of the conditions considered in the review. Are there any comments or discussion on this?

David McCulloch: No.

Chris Standaert: If not, a motion to approve.

David McCulloch: Motion to approve.

Chris Standaert: A second.

Seth Schwartz: Second.

Chris Standaert: Josh, can you go through the roll call again, and we'll vote to finalize our decision on platelet-rich plasma.

Josh Morse: Okay, Dr. Brown? Elmore?

Joann Elmore: Approve.

Josh Morse: Kaplan?

Louise Kaplan: Approve.

Josh Morse: Odegard?

Carson Odegard: Approve.

Josh Morse: McCulloch?

David McCulloch: Approve.

Josh Morse: Schwartz? Simon?

Michelle Simon: Approve.

Josh Morse: Souter?

Michael Souter: Approve.

Josh Morse: Standaert?

Chris Standaert: Approve.

Josh Morse: Walsh? Yen?

Tony Yen: Approve.

Josh Morse: Okay. That is eight approve and three absent. Thank you.

Chris Standaert: Okay. Our next topic, then, is the bronchial thermoplasty for asthma. We received a number of comments on this, one from Dr. Markezich, who was our clinical expert, one from a physician, uh, Dr. Rai, one from Boston Scientific, who I believe they have a representative on the phone. I'm going to the fourth to make sure I get the author correct, and the other one is from all the way down in . . . it's from Dr. Wechsler who was at the meeting and presented to us and was one of the investigators of one of the studies we considered. Have people read through, had a chance to read through the public comment? The people who have commented have brought up a number of issues or concerns with the scope of our discussion, assessment of the data, and final decision in the role of this particular technology and clinical care. Do the committee members have these comments in front of them?

David McCulloch: Yeah. I'm just re-reading them now, Chris.

Chris Standaert: Okay. If people are still looking, let me know if we're ready to start talking about them. We can do so. I'm going to start. So, Dr. Markezich's comments, she made several, including the comment about the perception of severe asthma, other relative risks of alternative therapies, and considering these in the context of bronchial thermoplasty. Some of the other comments include similar things in terms of our understanding of severe asthma and what that meant in the implication of that. Her letter shows we are perhaps, in fact, even dismissive of that, of understanding the severity of asthma. I don't know that is my personal perception. I think we're all clinicians and all quite familiar, at least, with the concept and implications of . . .

Gregory Brown: Hi. It's Greg Brown. I'm sorry. I'm just getting in between cases in the operating room.

Chris Standaert: Hi, Greg. This is Chris. We are talking . . . we have gone through the minutes and the decision on platelet-rich plasma. We are talking about the public comments we received on bronchial thermoplasty.

Gregory Brown: Okay.

Chris Standaert: Is where we are. We've received four comments.

Michael Souter: So, Chris, this is Mike Souter here. I'll be honest and candid, because I think I can be, because I'm exiting. This is my last communication with

you guys in this respect. I still remain uncomfortable about this decision. I just need to say that because I do think that, you know, I see patients who, literally, are dying from or have died from asthma, as a consequence, and I remain concerned about access to treatment of the most severe cases in these circumstances. I understand, you know, I go along with the committee decisions usually and for the most part, you know, we have a collective voice and that probably operates to the best the majority of the times, but I still remain concerned about this one. Just reading some of the . . . I think that there is possibly some merit to the concerns expressed by Boston Scientific. Far be it for me to actually be an advocate of theirs. It's not a company I generally . . . I don't find myself on the side of industry a lot of the time, but I think that there are some issues surrounding Bayesian statistics that (inaudible) more elaboration. So, that's all I'll say.

Chris Standaert: Okay. Are there other thoughts on a similar concern? Both, I guess, the Bayesian issue and whether we had the expertise available to help us adequately sift through the data.

Gregory Brown: So, this is Greg. I would just say I think what you just said was well said, and I agree. I have concerns. I mean, I don't… we raised all these issues before. So, I don't know if this changes a vote, but I would reiterate those same concerns. I mean, I think this is a life and death situation and it does not seem to me like it's a technology that's being overused and I think that's where we really, you know, focus on high volume use technologies that have a potential for overuse, and it just doesn't seem like this is one of those. So, to not give the option for people that actually may have life-threatening asthma just seems not being open enough.

Tony Yen: This is Tony. I'm looking at the chest article that is referred to in Dr. Markezich's public comment, and it does recommend bronchial thermoplasty as a therapeutic option with patients with severe asthma, though I do wonder, at least in this particular setting, that maybe the data is not complete, but why is it that expert societies would recommend something like this?

Chris Standaert: You know, some of this gets a bit tricky in that our evidentiary standards aren't the same as a society recommendation. Our recommendation isn't necessarily the same as a formal clinical guideline process with comments on strength of literature and similar things.

Louise Kaplan: This is Louise, and I think the other aspect of this that has to be considered is, if we are using an evidence report and comments . . . let

me restate this. I think that the comments are saying, essentially, that the evidence report was inaccurate or insufficient. It seems to me that's the fundamental issue, and are we questioning the quality of the evidence report?

Chris Standaert: I seem to pick up more that our discussion was incorrect or under-informed depending on how one chooses to put the wording. The comments about the Bayesian statistics and the role of them and comments about our collective statistical familiarity. Some of them, with the Bayesian issue, again, there are comments about the FDA and what they require and where they find them appropriate and a comment that some of the prior data from which the Bayesian statistics were based in the study in question were not published because of space limitations. That makes it difficult for us. We don't have access to them, and the evidence report commented on that, that . . . how do you note if they're appropriate if they're not actually publically available in the paper, and we only have what we have. So, it led to some significant issues there.

Female: Good morning? Hello?

Chris Standaert: Hello? Who is this? Hello? I'm not sure who just said good morning. So, those who are concerned, it wasn't the uniform vote not to cover, it was a majority vote. The issue of conditions and identifying and within the data identifying the population in question was a bit of a challenge.

Gary Franklin: This is Gary Franklin. Could I ask . . . this is not my field at all, but it looks like there is a dispute over what constitutes severe asthma, and they are pointing out in here that Health Care Authority considered the definition of severe asthma as stated in the HESERS guidelines. Was that address in the report?

Chris Standaert: I don't know about the report. We certainly discussed the concept of what . . . the idea of what constitutes severe asthma, and there are multiple comments in the public comments, and we relied a lot on FEV-1, which isn't necessarily correct. We talked about the full definition of severe asthma, as applied to the clinical trials and clinical guidelines, as I recall.

Gary Franklin: I guess what I'm asking is . . .

Chris Standaert: I don't know if it was defined in the evidence report or not.

Gary Franklin: . . . what I'm asking is whether the evidence vendor addressed that adequately.

Louise Kaplan: This is Louise, and I would say that I feel confident that we, as a group, had an understanding of what severe asthma is. I don't consider that the weak link in our conversation, and I think the Bayesian statistic issue is an interesting one because anything that I've looked at in terms of Bayesian analysis is that it's very controversial. There are advocates and there are dissenters, detractors. So, you know, if the whole issue relates or, you know, it pivots around Bayesian analysis, I don't know that that's reason enough to discount this, and I don't accept that we did not understand the meaning of what severe asthma is to an individual. I think we were all very sensitive to that.

Chris Standaert: I, personally, would agree with, yeah.

Michael Souter: Yeah, and this is Mike Souter here and I agree with that. I think everybody appreciates the severity of asthma. I do, again, have concerns on how we concentrated upon possible safety issues there, but I'm not certain that our evidence base for such was well developed, and I am convinced that there still is a select group of patients who need to be identified who could be seen to benefit from this procedure by virtue of the severity of their disease and the fact that when it occurs, it is life-threatening, and there is not a lot of opportunities to undertake in or to request or, you know, prior planning in our compassionate fields when you're in the extremis of an asthma attack. I, you know, obviously this is something that you're not going to do in reaction to a severe event, but, you know, I'll try to start just by saying that I think that there is a definable population. Yes, it may be tricky to do so accurately, but we've managed to do such things before, but I'm also very aware of the fact that rotating off the committee that I don't have to be the one to deal with that. So, anyway, I'll stop at that.

Chris Standaert: And I believe part of our issue was, you know, the level of evidence that we had, and even in the, you know, the major study they, you know, with the Bayesian statistics, they did not meet significance for their primary outcome measure. Other measures, yes, and other measures no, and even in the Boston Scientific report there are, you know, there are issues of non-inferiority studies and issues of . . . people didn't necessarily deteriorate and they may have gotten better and may becomes the operative word there. What does the strength of evidence suggest, that they do get better and improving things because they don't make people worse isn't quite adequate for the most part. Approving coverage in this setting because we had safety concerns, you know, we need evidence of benefit to override those.

Joann Elmore: Chris, this is Joann. I had a couple of comments.

Chris Standaert: Yeah.

Joann Elmore: I guess five comments. The first is that I think that all of the members of the committee, as clinicians, we care about patients. We understand the severity of the disease. We were thorough and thoughtful and careful, as much as we could be with the material that was presented and with our ability to go back and forth and ask questions during the meeting. Secondly, a process question going forward. I would like to see the signed conflict of interest forms for people that submit letters.

Chris Standaert: (inaudible) similar.

Joann Elmore: Third, yeah, yeah, because remember the conflict of interest form that was signed by our clinical expert was actually potentially incorrect on that day when we really reviewed it. Third, the first letter from Amy mentions how challenging it might be to get a compassionate use, and from what we have heard, that is feasible and an approach that can be used, and we weren't blocking that by our vote. She goes on to mention how hard it is to set up research and, indeed, compassionate use doesn't need to involve research.

Chris Standaert: No.

Joann Elmore: The fourth comment is that some of the issues raised in multiple letters would be potentially easy to address. For example, if there are other guidelines, we can simply add them, but the final comment I will make is that there are questions being raised about the evidence report. We, as a committee, rely on that evidence report. I would say most of us actually pull the original data and review it ourselves. The evidence base itself was not well developed, you know? The literature was not well developed, you know? Whether there are inaccuracies or problems with the evidence base that was provided to us is being questioned, and I agree with you that the literature itself was not well developed. I actually have published statistics in medicine and done Bayesian modeling, and I did not pull up the one article that everyone is citing about Bayesian statistical modeling, but from what I remember, you know, we need the underlying data that goes into a model.

Chris Standaert: Yes.

Joann Elmore: Otherwise, we are not able to assess its quality. So, at this point, we need to ask, are there enough questions about the quality of our

evidence report that we need to go back to the vendor or get a second vendor to review some of these specific issues?

Chris Standaert: We have issues of evidence, but, you know, the . . . certainly I agree with you on all those points, and I think, you know, the literature base on this procedure is not deep. This is not a large number of studies. There were none that were high quality, I believe, and it's not a lot to dig into. So, when there are inconsistencies, when the effect is not dramatic, and when the literature base is shallow, it makes it difficult for the evidence vendor to sort of pull this out. There was a comment that our vendor didn't respond thoroughly to questions on Bayesian statistics, which I would agree with that comment, but I, again, don't mean . . . don't think that means that we, as a committee, don't understand them well enough to sort through the document and sort through the article. From a practical standpoint, you know, we have a decision. We can approve it or not approve it. To redo the literature, the report, we'd have to figure out whether we really have grounds to sort of redo the whole report. They thoroughly described the papers in question and like you just said Joann, I had them sitting right next to me while we were going through all the discussion, all the key trials, which were pulled in a hard copy. So, whether there's enough to really warrant that, we have on one occasion previously, with which I'm familiar, formed a subcommittee, to say can we dig deeper in the literature and talk to clinical experts, and see if there really is a definable subpopulation where things may apply better, and I think the majority of the committee did not see that subpopulation defined in the available literature, as outlined in the report or in the individual review of that literature, or our discussion, but that is an option theoretically, to form a subcommittee to review the topic again and see if there is any recommendation they could come to on a definable subpopulation, because I don't think the majority of the committee would move for cover without conditions, would be my guess. We could take a straw poll, but that wasn't what I was getting from our meeting, certainly.

Michelle Simon: This is Michelle. This whole topic really is sort of emblematic of the mission of this committee, really. We're finding ourselves in the position we find ourselves in often. We're asked to look at the primary evidence, and I think that the evidence that was collected was the best available. It was fairly presented, and as a group of clinicians, many of us deal with primary care, we fully appreciate the severity of asthma. I do think that's true, as well, and I think we find ourselves in this really difficult position of making an objective decision when subjectively, you might be drawn to the side otherwise, but that's really why we're here. We're trying to put objectivity into this equation, and I feel that our decision was handled

well, you know, creating a subcommittee, what more are we going to find that we weren't considering at the time. I don't think that that's going to prove fruitful, but that's my solution.

Chris Standaert: Personally, I didn't see the . . . I didn't see a population to define well enough based on the existing evidence and the standards we try to apply to the literature and the procedure.

Michelle Simon: And I think that would be the direction for research development, and certainly evidence collection going forward, but projecting that into what it might be is not really our job.

Chris Standaert: No, and I agree that research is hard, and I agree that obtaining compassionate use coverage is hard, but at the same time, if you're going to do the right thing for patients with a device or technology, the research to define its benefit, or absence of benefit, or define populations in whom it is appropriate, is clearly essentially.

Michelle Simon: Absolutely.

Chris Standaert: And if that isn't there, then it makes it very hard for a group like ours.

Marie Stewart: Is it possible for representatives who are not on the panel to just ask a question. This is Maria Stewart from Boston Scientific?

Chris Standaert: You can ask a question, sure.

Marie Stewart: I guess, I'm listening to the discussion, and I'm wondering what the difference is between deeming it compassionate exception where the committee would have to consider specific qualifications or eligibility criteria and coverage with condition. I heard you mention that, you know, you didn't think the panel would recommend coverage with no conditions. To be frank, nor would we or any of the clinicians who provide bronchial thermoplasty ask for coverage without conditions. We firmly believe there should be conditions in place. This procedure is not for every patient with asthma. It's for patients who have failed other therapies and for whom there are no other options, and the recent chest article that you referred to specifies an eligible patient population that's very much in line with guidelines that are issued by specialty societies using evidentiary standards very similar to Washington State's own, not recommendations or supportive statements, but actual guidelines, and so I'm just wondering if that could be something that could be considered by the committee. The providers of insurance who do cover bronchial thermoplasty have established a very rigorous set of conditions that

might be a possible reference for the committee to provide access to patients who need the therapy but also avoid extended access.

Chris Standaert: So, the first question of this committee has nothing to do with the compassionate use decision, right? So, this committee would make its decision and if there is a request for compassionate use given to a state agency that would be decided by the agency, but that's not the role of this committee, and defining what they would consider in terms of compassionate use or requirements there for that wouldn't be up to us. It would be up to the given state agency, I assume. Correct, Josh?

Josh Morse? Yes, Chris. Can we get a name on the . . . from the commenter, please, for the record?

Maria Stewart: Yes, Maria Stewart.

Chris Standaert: And the committee has, when we make our decision, we have all the coverage guidelines that are pulled for us, which are coverage policies, sorry, of major payers are pulled for us . . .

Maria Stewart: Yes, but (inaudible).

Chris Standaert: . . . so they are generally available to the committee.

Maria Stewart: As we pointed out in our comment, there was a significant discussion of noncoverage policies and omission of mention of the many coverage policies that we do have that specify criteria and, in fact, were not even listed in the report provided by Hayes.

Chris Standaert: Well, again, I'm sorry. I don't want to engage in a debate about the report with you in the context of this meeting.

Maria Stewart: Understood.

Chris Standaert: To clarify some things, the noncoverage issue, our discussion there simply was that we are meant, you know, the committee is meant to be aligned with Medicare policies, particularly national coverage decisions, and our comment that there isn't a national coverage decision is just that. There isn't a national coverage decision on a given technology. Therefore, we can't be aligned or malaligned with a Medicare national coverage decision. That doesn't imply . . . and these aren't noncoverage decisions. It isn't taken in any context to mean that Medicare won't pay for it. It just means that they haven't created a formal national coverage decision that we are essentially obligated to making sure we are aligned with that

policy. So, that statement regarding that, that's all our requirement is. Again, we don't take the absence of a national coverage decision to mean that it is not covered. We just take it to mean that there is no policy from the CMS in terms of national policy, with which we need to be aligned or specify our reasons for disagreement.

Marie Stewart: Thank you for that clarification. I guess I'm just . . . this is not necessarily a Medicare population. So, what is the panel's process when you're dealing with a therapy that's intended for a non-Medicare population?

Chris Standaert: We don't cover Medicare populations, right? So, our, again, this may not be the place to hold this discussion. Our decisions apply to the Washington State Health Agencies, which Medicaid, Uniform Health Plan, and Labor and Industries. They cover . . . whatever ages they cover. Uniform Health Plan covers, you know, birth to whatever as does Medicare, I believe, or Medicaid, Medicaid, sorry. So, our decisions apply to those populations. They are not . . . our decisions have nothing particularly to do with a Medicare population, and they do not apply to Medicare. They apply to Washington State Agencies, health agencies, but going back to the committee, are there other comments on these . . . on the public comments or on how . . . thoughts on how people might want to proceed?

Louise Kaplan: This is Louise, and . . .

Chris Standaert: I know I haven't from everybody. I'm sorry, go ahead, Louise.

Louise Kaplan: . . . well, I, I was just going to make a motion to approve our decision. I'd like to have a vote, and I think we could proceed after we have a vote if we need to do something different.

Chris Standaert: Fair enough, and after we approve we certainly can . . . we'll offer discussion if people want to talk more. Do I have a motion to approve our final decision on bronchial thermoplasty?

Louise Kaplan: We need a second.

Chris Standaert: Oh, you're making a motion?

Louise Kaplan: I, yes. I made a motion.

Chris Standaert: Okay. Do I have a second?

David McCulloch: I second.

Chris Standaert: Is there a discussion? Are there more issues someone wants to bring up before we make a vote? There being none, Josh, can you move through the roll call?

Josh Morse: Yes. Dr. Brown?

Gregory Brown: No, not approve.

Josh Morse: Dr. Elmore?

Joann Elmore: Approve.

Josh Morse: Dr. Kaplan?

Louise Kaplan: Approve.

Josh Morse: Dr. Odegard?

Carson Odegard: Approve.

Josh Morse: McCulloch?

David McCulloch: Approve.

Josh Morse: Schwartz?

Seth Schwartz: Not approve.

Josh Morse: Simon?

Michelle Simon: Approve.

Josh Morse: Souter?

Michael Souter: Not approve.

Josh Morse: Standaert?

Chris Standaert: Approve.

Josh Morse: Walsh? Yen?

Tony Yen: Not approve.

Josh Morse: So, I have one, two, three, four, five, six approve; one, two, three, four not approve; one absent.

Chris Standaert: Alright. I believe that concludes our agenda for today, yes, Josh?

Josh Morse: Let me confirm. Yes, that does conclude our agenda for today, with the exception of Dr. Kaplan, Dr. Souter, and Dr. Simon for their tremendous service. Thank you, very much.

Chris Standaert: I cannot thank them enough.

Group: Yes, thank you.

Gregory Brown: Can I ask a question? Has there ever been a vote like this previously?

Chris Standaert: Who is this?

Gregory Brown: This is Greg.

Chris Standaert: Greg, sorry. A vote like this, meaning?

Gregory Brown: Where we've gone through the vote and you have a six to four majority vote for approval on something like this?

Chris Standaert: I don't know about the number, but they are not always uniform, no. Everybody does not always agree with our final decision.

Gregory Brown: Okay.

Chris Standaert: Correct, Josh?

Josh Morse: That's correct.

Chris Standaert: Yes, yeah.

Gregory Brown: Thank you for clarifying or explaining.

Chris Standaert: Alright. Thank you, all, for your time and your thoughtfulness, and I really do appreciate all the comments, and I think they drive discussion, and they increase understanding for all of us, which is helpful. Thank you. I guess we are adjourned.