

1 DR. WEISS: The motion is withdrawn.

2 I would like to ask for a motion to be  
3 made from the floor. Yes, Dr. Harris.

4 DR. HARRIS: I would like to move approval  
5 of the Paragon CRT submission with conditions.

6 DR. WEISS: Do I hear a second?

7 DR. McMAHON: Second.

8 DR. WEISS: What I would suggest is that  
9 there be motions made for each of the conditions,  
10 they can be seconded, and then voted on, and then  
11 we can go for a final vote in favor of the main  
12 motion.

13 Does anyone have a motion for any  
14 condition?

15 DR. HARRIS: Can we incorporate by  
16 reference the conditions that we have discussed?

17 DR. WEISS: Yes, you certainly can.

18 DR. HARRIS: I would like to do that.

19 DR. WEISS: You can do it, let's say,  
20 specifically saying labeling and then perhaps we  
21 can do education or physician's booklet, et cetera.

22 MS. THORNTON: You can't do just a flat  
23 referral. You can group the labeling conditions as  
24 one condition, but you have to indicate what that  
25 one condition contains. You only then need to vote

1 on that condition.

2 DR. WEISS: Dr. Grimmett has scribed the  
3 labeling, so you can refer to him.

4 DR. GRIMMETT: I have a suggestion. There  
5 may be some duplicates because I was scribing  
6 chronologically as we went. I scribed who made the  
7 comments and what the condition would be. Perhaps  
8 I can refresh that person's memory of each comment,  
9 and maybe they could make the motion, if that would  
10 be satisfactory.

11 DR. WEISS: I think it would be too  
12 lengthy to go to a motion for each of the labeling  
13 issues. I think it would be better to include it  
14 in one motion, if someone is interested in raising  
15 that motion.

16 DR. HARRIS: I would like to amend my  
17 motion to include the labeling issues that have  
18 been discussed and scribed by Dr. Grimmett.

19 DR. McMAHON: Second.

20 DR. WEISS: Dr. Grimmett, would you be so  
21 kind as to list those?

22 DR. GRIMMETT: You would like me to list  
23 them all?

24 DR. WEISS: I would like you to list them  
25 all.

1 DR. GRIMMETT: Certainly. A motion was  
2 made that clinicians should have a training or  
3 certification program to assure correct fitting by  
4 practitioners. That was No. 1.

5 DR. HARRIS: That's another issue.

6 DR. GRIMMETT: All right. The labeling  
7 should include information regarding ethnicity  
8 given that this study included mostly Caucasian  
9 patients, and Dr. McMahon suggested that other  
10 information be included that there is evidence that  
11 corneal curvature may be different, a different  
12 ethnicity.

13 No. 2. Dr. McMahon suggested including  
14 information in the labeling regarding the  
15 discontinuation rate of 34.6 percent with reasons  
16 for the discontinuation as suggested by Dr. Matoba.

17 No. 3. This may be indication rather than  
18 labeling. I think we leaned to indication.

19 DR. WEISS: The efficacy was taken out.

20 DR. GRIMMETT: Regarding age.

21 DR. WEISS: That's out.

22 DR. ROSENTHAL: That's indication.

23 DR. GRIMMETT: No. 3. Additional  
24 labeling. Specifically state the exclusion  
25 criteria in the labeling and that there is no data

1 known regarding those issues.

2           No. 4. Include information regarding the  
3 post-treatment uncorrected visual acuity stratified  
4 by manifest refraction spherical equivalent in  
5 those patients targeted for emmetropia. That was  
6 one of the slide Dr. McMahon presented.

7           No. 5. Include a statement in the  
8 labeling that the CRT treatment does not affect the  
9 magnitude of pretreatment cylinder.

10           No. 6. Include information in the  
11 labeling regarding the post-removal decline in  
12 treatment effect with time stratified by refractive  
13 error.

14           No. 7. Suggestion by Dr. Matoba. Include  
15 information regarding the transient changes in  
16 post-treatment best spectacle corrected visual  
17 acuity, perhaps including a table of best spectacle  
18 correct visual acuity.

19           Pardon me while I take a moment to review  
20 if these are duplicates from other panel members.

21           DR. McMAHON: Point of information. With  
22 regard to the labeling of conditions excluded, more  
23 specifically, that addresses the fact that current  
24 labeling does not address those conditions that are  
25 excluded in the PMA specifically.

1 DR. WEISS: I think what we will do is,  
2 for scribing, include the last sheet of your  
3 handout, which will make it a little bit more  
4 specific.

5 DR. McMAHON: One more. I think we can  
6 drop the astigmatism one because that actually is  
7 in it.

8 DR. WEISS: That is in it. Okay.

9 DR. GRIMMETT: Amendments accepted by Dr.  
10 McMahan.

11 No. 8. Include in the labeling  
12 information regarding the emphasis on every night  
13 wear given the fact of Dr. Bradley's comment that  
14 failure to comply with the regime could result in  
15 an inability to wear spectacles and possibly the  
16 regression of effect may adversely alter activities  
17 of daily living.

18 DR. BRADLEY: Mike, just on the wording of  
19 that, the regression at night, at this point we  
20 don't know, so it would be necessary I think to  
21 state unless the sponsor can clarify to the FDA's  
22 satisfaction the data, but at this point we don't  
23 know that there is any regression that is going to  
24 happen during the night, so at this point it is  
25 unknown, so potential, as yet unknown, regression.

1           But again, the sponsor could either  
2 convince the FDA that there is no regression during  
3 the evening.

4           DR. WEISS: What is the statement?

5           DR. GRIMMETT: I was compiling multiple  
6 people's comments while I was making the statement.  
7 My statement was to have a statement in the  
8 labeling emphasizing that the data pertained to  
9 every night lens wear as a failure to comply with  
10 the specified regime could result in an alteration  
11 in activities of daily living the next day, because  
12 there is simply no data to indicate what the  
13 refractive state of the patient would be.

14           DR. BRADLEY: Ignore what I just said  
15 then.

16           DR. WEISS: There was also an additional  
17 comment about the altitude effects on altitude.

18           DR. GRIMMETT: That's coming up.

19           DR. WEISS: Okay.

20           DR. GRIMMETT: I am not done yet. I have  
21 got six pages. I am on page 2.

22           No. 9. A suggestion by Dr. Bradley.  
23 Include in the labeling that 10 to 15 percent do  
24 not achieve 20/40 uncorrected visual acuity, worse  
25 for higher myopic errors.

1           No. 10. Statement made by Dr. Weiss,  
2 seconded by Dr. Van Meter, that a cautionary  
3 statement be added to the labeling regarding the  
4 presence of corneal edema being more prevalent in  
5 high altitude areas. Possibly a recommendation for  
6 using the higher DK material in those areas  
7 although the data, as we heard, spread out, didn't  
8 support it one way or another, so I don't know if  
9 the panel sensed there was a recommendation for a  
10 higher DK, the data didn't really bear that out,  
11 but certainly a cautionary statement regarding that  
12 edema was more prevalent in high altitude areas, I  
13 believe everyone agreed on that.

14           DR. WEISS: Yes.

15           DR. GRIMMETT: (A) then, we will make this  
16 cautionary statement regarding high altitude areas.  
17 We will not make a recommendation for higher DK  
18 material.

19           No. 11. Better delineated information in  
20 the labeling regarding recovery of both baseline  
21 visual acuity and refraction data stratified by  
22 pre-op manifest refraction spherical equivalent.

23           No. 12. Include information in the  
24 labeling including known side effects to include,  
25 but not limited to, discomfort rates, punctate

1 keratopathy, and others.

2           No. 13. Include information in labeling  
3 regarding alternative therapies that a patient may  
4 consider in light of the marketplace, to include,  
5 but not limited to, spectacles, contact lenses,  
6 other refractive surgery techniques.

7           No. 14. As suggested by Dr. Coleman,  
8 include statement in the labeling regarding  
9 satisfaction rates.

10           I have something written here by Dr.  
11 Edrington. I don't know if there was uniform  
12 agreement regarding -- I will delete it, I don't  
13 think there was uniform agreement. Oh, it's  
14 regarding the surface regularity index information.

15           DR. EDRINGTON: No agreement.

16           DR. GRIMMETT: Okay. No. 15. Suggested  
17 by Dr. McMahon. Include information regarding the  
18 transmissibility data of the two materials,  
19 possibly with a table. That is Point (A) on that.  
20 Point (B) was explain the significance of the  
21 Holden-Mertz criteria with the DK table as  
22 suggested by Dr. Harris. I believe everyone agreed  
23 on Point (A), I don't know about Point (B).

24           DR. WEISS: I don't believe there was  
25 agreement on Point (B). I thought there was

1 agreement on Point (A) to have it in the  
2 physician's information, but not in the patient  
3 information.

4 DR. HARRIS: That is my understanding, as  
5 well.

6 DR. GRIMMETT: Let's leave for this motion  
7 (A) since we are all in agreement. We will get  
8 back to 15(B).

9 Give me just a moment to screen the other  
10 ones.

11 DR. WEISS: Dr. Harris.

12 DR. HARRIS: There was one additional one,  
13 Mike, that was part of what Arthur said, and that  
14 is the fact that patients need to be advised that  
15 they may need to wear corrective lenses during the  
16 day in order to see properly.

17 DR. GRIMMETT: I accept that amendment.  
18 That was part of No. 8 in the labeling suggestion,  
19 that type of modification, that type of information  
20 I believe was the intent of No. 8, but I certainly  
21 agree with that.

22 Those are all that I see right now through  
23 15(A), that I believe we had agreement on for  
24 information in the labeling. We will address a  
25 couple of other issues in just a moment.

1 DR. WEISS: Any other labeling issues? I  
2 think Dr. Grimmett has a complete list. What did  
3 you want to address? I think 15(B) was already  
4 discussed, and not agreed to, of the DK, if that  
5 was one of the ones you were going to discuss.

6 DR. GRIMMETT: Yes, the Holden-Mertz  
7 information.

8 DR. WEISS: I don't think anyone agreed to  
9 that.

10 Any other? Is there any discussion on the  
11 labeling that has just been listed?

12 DR. HARRIS: That is obviously in addition  
13 to the labeling that has been submitted already.

14 DR. WEISS: Yes.

15 DR. HARRIS: The labeling issues that we  
16 have delineated are in addition to the labeling  
17 that has already been submitted as part of the  
18 proposal.

19 DR. WEISS: Yes. Any additional labeling  
20 issues? Dr. Bradley.

21 DR. BRADLEY: I recall earlier in our  
22 discussion, there was some concern that the  
23 labeling or the patient information document was  
24 rather confused.

25 DR. GRIMMETT: Right. I have got that.

1 That was another issue I was going to discuss.

2           Glenda Such pointed out the fact that the  
3 patient information booklet and physician  
4 information crossed over, and it was hard to tell  
5 the audience that they were writing, and had asked  
6 to better delineate the audience in those  
7 materials.

8           DR. BRADLEY: Was that separate to  
9 labeling?

10           DR. GRIMMETT: I thought that was separate  
11 to labeling. That was a suggestion for the  
12 manufacturer to consider. I am not sure if that is  
13 a labeling issue.

14           DR. BRADLEY: Let's treat it separately  
15 and move on.

16           DR. GRIMMETT: We can make it No. 16, and  
17 make a suggestion if that is the case. Let's make  
18 it No. 16. We will say better delineation of the  
19 target audience in the physician information  
20 booklet and the patient information booklet. That  
21 is No. 16.

22           DR. WEISS: Fine. If that completes the  
23 list of labeling issues, we can bring this separate  
24 motion to a vote before we go on to other motions.

25           Yes, Dr. Harris.

1 DR. HARRIS: There are additional  
2 conditions?

3 DR. WEISS: One hundred percent, yes. We  
4 won't go through this conditions at this point.  
5 This motion just includes the labeling issues, and  
6 we will confine it to that, vote on it, and then we  
7 will go on to other motions concerning indications,  
8 other conditions, whatever.

9 DR. GRIMMETT: So, to clarify, Dr. Harris  
10 put on the table an approval of the Paragon CRT PMA  
11 with conditions of labeling as the first motion,  
12 and we just listed 16.

13 DR. WEISS: The main motion, we are doing  
14 the separate motions for the main motion, which  
15 concerns the CRT lens, and this motion specifically  
16 that we are going to vote on in a moment concerns  
17 the labeling for the CRT lens.

18 For the labeling that we just listed, the  
19 16 points, I would like a vote.

20 All of those in favor of this motion,  
21 signify by raising your hand.

22 [Show of hands.]

23 DR. WEISS: So, that is unanimous and  
24 passes.

25 Is there another motion? Yes, Dr. Harris.

1 DR. HARRIS: One of the other conditions  
2 is an exclusion criteria or an inclusion criteria,  
3 whichever way you want to look at it, that the lens  
4 is approved for use in patients 18 years old and  
5 older.

6 DR. WEISS: Do I have a second?

7 DR. GRIMMETT: I second that.

8 DR. WEISS: So, now we are discussing  
9 indications for the lens, which would basically be  
10 for patients 18 and older. Any discussion of this?

11 If there is no discussion, I would like to  
12 have a vote.

13 Those in favor, signify by raising your  
14 hand.

15 [Show of hands.]

16 DR. WEISS: Those opposed?

17 [No response.]

18 DR. WEISS: Those abstaining?

19 [No response.]

20 DR. WEISS: I knew there were only three  
21 possibilities here.

22 Any other motions? Dr. Harris.

23 DR. HARRIS: One other condition would be  
24 that there be some type of a training procedure put  
25 together for practitioners who wish to utilize this

1 lens for this indication.

2 DR. GRIMMETT: Second.

3 DR. WEISS: Any discussion?

4 Seeing no discussion, everyone in favor,  
5 please signify by raising your hand.

6 [Show of hands.]

7 MS. THORNTON: Unanimous.

8 DR. WEISS: This is unanimous and passes.  
9 Any other motions?

10 DR. WEISS: I just want to confirm, Mike,  
11 that the physician's book and the patient  
12 information book were both listed in the labeling,  
13 so those have already been covered? The patient  
14 book, I know was listed in the labeling. In the  
15 physician's book, I know we wanted the information  
16 on the DK/A. Was the physician's book mentioned in  
17 the labeling?

18 DR. GRIMMETT: We mentioned it certainly  
19 in the fact that the target audience needed to be  
20 better delineated, and I think most of the  
21 statements were in terms of labeling in a general  
22 sense, labeling indications included to appropriate  
23 target audience.

24 DR. WEISS: If that is the case, are there  
25 any other conditions or motions that anyone wants

1 to introduce for this main motion?

2 If not, then, we can vote on the main  
3 motion for approval of PMA P870024/SO43 for the CRT  
4 lens.

5 DR. ROSENTHAL: With the conditions.

6 DR. WEISS: With the conditions that were  
7 already approved, namely, the labeling and the  
8 indications and the teaching.

9 All those in favor of the main motion, can  
10 you signify by raising your hand.

11 [Show of hands.]

12 MS. THORNTON: It's unanimous.

13 DR. WEISS: So, this main motion passes  
14 unanimously for the CRT lens.

15 Any other motions?

16 DR. VAN METER: I would move that the  
17 Quadra lens be made approvable with the same  
18 conditions.

19 DR. McMAHON: Second.

20 DR. WEISS: Dr. Bradley?

21 DR. BRADLEY: Can we make this motion  
22 conditional upon the sponsor presenting to the FDA  
23 data that establish its safety and efficacy?

24 DR. VAN METER: That would be a separate  
25 condition. That would be an additional condition.

1 DR. WEISS: First, we need your main  
2 motion, we need it seconded, and then --

3 DR. VAN METER: It has been seconded. I  
4 would like to make one amendment to my motion, and  
5 that is that also labeling would reflect that data  
6 does not suggest -- we do not have data on the  
7 efficacy of this lens.

8 DR. WEISS: I am getting a second opinion  
9 here from Sally, because usually these are done as  
10 side motions. I don't know if they can be done as  
11 a main motion.

12 MS. THORNTON: Your main motion, I believe  
13 it should be approvable with conditions for the  
14 Quadra lens. That is your main motion, which gets  
15 seconded. Then, you go down to the conditions, and  
16 you start all over again with the labeling, and if  
17 they are the same, you can say that if you want to.

18 DR. VAN METER: May I restate my motion,  
19 then.

20 MS. THORNTON: Okay.

21 DR. VAN METER: I would move the Quadra  
22 lens be approvable with conditions.

23 DR. McMAHON: Second.

24 DR. WEISS: Discussion? Dr. Grimmitt.

25 DR. GRIMMETT: I agree with the sentiments

1 of Dr. Bradley, and I think that requiring  
2 information for some type of data for safety and  
3 efficacy does not mean that a full-blown study has  
4 to be done.

5           The valid scientific evidence takes  
6 multiple forms, and the sponsor indicated that some  
7 data does currently exist that they would be able  
8 to submit to the FDA for the appropriate due  
9 diligence.

10           In that light, I would agree with Dr.  
11 Bradley's sentiments as a condition of the motion  
12 for approval for the Quadra requires some type of  
13 valid scientific evidence in addition to what we  
14 may or may not know to show that the lens is doing  
15 what it is supposed to do.

16           DR. WEISS: Dr. Bradley.

17           DR. BRADLEY: I move that we include all  
18 the conditions for the Quadra that we have just  
19 approved for the CRT.

20           DR. WEISS: Does anyone want to second  
21 that?

22           DR. McMAHON: Second.

23           MS. THORNTON: Excuse me. I am a little  
24 confused. Are you talking about existing data?  
25 Your problems is that you don't have existing data.

1 DR. VAN METER: That's correct.

2 MS. THORNTON: When you don't have  
3 existing data, you don't have an approvable with  
4 conditions, you have a disapproval.

5 DR. ROSENTHAL: That is essentially  
6 correct. If you are requiring additional data, you  
7 really don't have the appropriate data in this PMA  
8 to allow you to approve it.

9 DR. GRIMMETT: That is my opinion, yes.

10 DR. HARRIS: That was the point I was  
11 trying to make several times.

12 DR. WEISS: Since there is a difference of  
13 opinion here --

14 DR. GRIMMETT: This is where the straw  
15 vote came down, the motion that Woody put on the  
16 table on the straw vote was defeated by one vote.

17 DR. WEISS: No, actually, it was accepted  
18 by one vote last time. Basically, what I am  
19 understanding from Sally is the condition that you  
20 put forward can't be a condition if you intend to  
21 approve this.

22 So, from what I hear --

23 DR. VAN METER: That was not my condition.

24 DR. WEISS: I understand. I am directing  
25 this to Dr. Grimmatt. Dr. Van Meter, I understand

1 that you put the main motion forward, and it was  
2 seconded, and your main motion is approvable with  
3 conditions for the Quadra lens.

4 From what I understand from Dr. Grimmett,  
5 he is of a different sentiment. Yes, Dr. Harris.

6 DR. HARRIS: May I suggest that we go  
7 forward with Dr. Van Meter's motion, which is  
8 essentially the same motion with the same  
9 conditions, the same labeling as was voted on for  
10 the CRT lens.

11 DR. WEISS: I think we have to go through  
12 the whole procedure just like we did with the other  
13 one. He can restate that he wants the side motions  
14 to be similar labeling and stuff, but I don't think  
15 we can do a blanket.

16 Dr. Rosenthal.

17 DR. ROSENTHAL: That's correct.

18 DR. WEISS: Dr. Bradley.

19 DR. BRADLEY: Just a point of procedural  
20 clarification.

21 DR. ROSENTHAL: You just have to mention  
22 the same labeling conditions.

23 DR. HARRIS: That is what I said.

24 If I can finish my statement?

25 DR. WEISS: Dr. Harris.

1 DR. HARRIS: The idea would be that if  
2 that got a majority vote, then, obviously, the  
3 issue is closed. If it did not get a majority  
4 vote, then, there would be an opportunity for an  
5 alternate motion.

6 MS. THORNTON: You have to finish out  
7 where you have started, which is to vote on the  
8 main motion plus whatever conditions. If you don't  
9 have any conditions, obviously, you don't have an  
10 approvable with conditions.

11 DR. HARRIS: The conditions that I  
12 understand Dr. Van Meter and his seconder want  
13 indicated are the exact same conditions, the  
14 labeling issues that we just discussed that are on  
15 the record, the inclusion, quote, exclusion  
16 criteria, and the training criteria.

17 DR. VAN METER: Other conditions can be  
18 added once the motion is passed.

19 DR. WEISS: I would request, in my ability  
20 to be Chair here, is that we can just quickly run  
21 through the usual format, which is we have the main  
22 motion. In terms of conditions, are there any side  
23 motions, and we don't have to list each individual  
24 condition, but Dr. Van Meter, do you have any  
25 conditions that you would like to put a motion

1 forward for?

2 DR. VAN METER: I would like to  
3 specifically list those conditions that were listed  
4 with the CRT lens in addition to one which  
5 specifies that data on the Quadra lens of efficacy  
6 is not known. Data on the efficacy of the Quadra  
7 lens is not know.

8 DR. WEISS: Would like to say efficacy and  
9 safety, or just leave it at efficacy?

10 DR. VAN METER: I would leave it as just  
11 efficacy.

12 DR. McMAHON: May I make a suggestion that  
13 it's overnight efficacy data, that FDA has  
14 information on daily wear efficacy?

15 DR. VAN METER: For this indication.

16 DR. GRIMMETT: Just to clarify, so the  
17 statement regarding the data on overnight efficacy  
18 is not known, would be an additional labeling  
19 criteria.

20 DR. McMAHON: Yes.

21 DR. WEISS: Dr. Harris.

22 DR. HARRIS: Folks, look, if we are  
23 stating that we don't have information on the  
24 efficacy, then, we cannot vote for approval. It  
25 has been stated by Sally. I mean we need to have

1 valid scientific evidence that the device is safe  
2 and effective for the intended use.

3           If a condition is we don't have that  
4 information, then, we can't make that judgment. My  
5 suggestion is that if you are in favor of approving  
6 the Quadra design, that you make an identical  
7 motion to the one that we made for the CRT.

8           If it is approved by a majority of the  
9 members of this panel, then, obviously, the  
10 majority feels that there is sufficient evidence to  
11 support the safety and efficacy of that design.

12           DR. WEISS: I would say, Dr. Harris,  
13 evidence and data are two different things.

14           MS. THORNTON: We don't have the numbers.

15           DR. VAN METER: Let me make this real  
16 simple and restate my motion, that the Quadra lens  
17 be approved with conditions, and that the  
18 conditions be identical to that list that we listed  
19 for the CRT lens.

20           DR. McMAHON: If that is a restatement, I  
21 second.

22           DR. ROSENTHAL: That is to say labeling,  
23 training --

24           MS. THORNTON: Indications approved for  
25 over --

1 DR. GRIMMETT: Over 18 years old, yes,  
2 sir.

3 DR. WEISS: Is that motion seconded?

4 DR. McMAHON: Yes.

5 DR. WEISS: We will have discussion, but I  
6 have a question for Dr. Rosenthal. Is there any  
7 way to indicate that we do not have the same amount  
8 of data, we don't have the same data for the Quadra  
9 that we do for the CRT without putting it in a  
10 situation that it is not approvable? Any way to  
11 wordsmith it?

12 DR. ROSENTHAL: I think Sally would have  
13 to read the voting options again, and I would like  
14 her to do so, so you are clear on what it is  
15 required for a vote approvable with conditions.

16 DR. WEISS: Dr. Bradley.

17 DR. BRADLEY: A question for Dr. Rosenthal  
18 and Ms. Thornton, and perhaps Dr. Ravioli.

19 [Laughter.]

20 DR. BRADLEY: Sorry.

21 DR. SAVIOLA: That is what I get for  
22 skipping lunch.

23 DR. BRADLEY: Excuse me. That is all I am  
24 thinking about right now.

25 I am just a bit confused that we have been

1 brought here to vote on a PMA, and I have just  
2 learned that we cannot vote to approve it because  
3 of the fact that there are no data to back up the  
4 approval of the Quadra lens.

5           Something doesn't seem right there. You  
6 would not have brought us to Washington if that is  
7 the case. So, I just need some clarification.

8           DR. GRIMMETT: I have got a comment.

9           DR. WEISS: Does FDA have a comment first?

10          DR. SAVIOLA: I have to apologize for my  
11 earlier lack of eloquence because I, too, am in a  
12 hypoglycemic state.

13          DR. BRADLEY: It's the ravioli.

14          DR. SAVIOLA: The basis for the Quadra RG  
15 approval is the safety, as you have already seemed  
16 to agree upon, perhaps on the safety and material  
17 in this design, and then also the concept that as  
18 an alternate design to the CRT, the differential in  
19 the two designs and the peripheral geometry is not  
20 that significant. So by de facto, the efficacy  
21 data for one is comparable to the efficacy data for  
22 the other one.

23                 It is the same concept I was trying to  
24 describe before, about how alternate designs change  
25 over time. We look at certain types of data to

1 make a decision. So, the need for additional  
2 clinical data to differentiate the outcomes for  
3 those two designs is sort of the question at hand.

4 DR. ROSENTHAL: Correct me if I am wrong.  
5 If you do not feel that you can make that leap of  
6 faith based upon the data you have been given, you  
7 will have to say that it does not provide  
8 reasonable assurance of safety and efficacy.

9 DR. WEISS: What I am hearing from Dr. Van  
10 Meter and from some other members of the panel, Dr.  
11 Rosenthal, is that they feel comfortable making  
12 that leap of faith, however, they would like the  
13 patient to understand that the actual data, the  
14 numbers are not available although they feel there  
15 is significant evidence to show that it is probably  
16 clinically equivalent, they don't have the actual  
17 numbers.

18 From what I understand from what Dr.  
19 Harris has said, that there is no way to put that  
20 in there without making it unapprovable.

21 DR. ROSENTHAL: This panel can make  
22 recommendations to the agency, and if that is the  
23 motion --

24 DR. VAN METER: The basis of my motion is  
25 that this material has been approved for extended

1 wear. The agency in the past has allowed base  
2 curve changes without full panel review, and this,  
3 in effect, amounts to a base curve change.

4 So, I think that it is within reason to at  
5 least bring the motion before the panel, the lens  
6 is approvable with conditions.

7 DR. WEISS: Dr. McMahon, Dr. Matoba, and  
8 then Dr. Bradley.

9 DR. McMAHON: I would like to call the  
10 question. If it survives, it survives, and if it  
11 doesn't, we can discuss other ones.

12 DR. WEISS: If it what?

13 DR. McMAHON: I would like to call the  
14 question and vote.

15 DR. WEISS: You would like to vote. I  
16 would like to make sure that we all know the extent  
17 of the motion on the table. Did you want to add  
18 any other phrase to that, or it is going to be the  
19 exact phrasing as the CRT? Did you want a  
20 statement saying we don't have the same data or  
21 not?

22 DR. VAN METER: I want it to be exactly  
23 the same as the CRT.

24 DR. WEISS: You want it to be exactly the  
25 same as the CRT, and that has been seconded, and we

1 have a call for a vote. So, let's have a vote.

2 All of those in favor of this motion,  
3 signify by raising your hands.

4 [Show of hands.]

5 DR. WEISS: All opposed? Signify by  
6 raising your hands.

7 [Show of hands.]

8 DR. WEISS: Any abstaining votes?

9 [Show of hands.]

10 DR. WEISS: So, the motion does not pass.

11 Dr. Matoba?

12 DR. MATOBA: I wish to change my vote.

13 The basis for that was based on what Dr. Bradley  
14 said, and my understanding of what he suggested at  
15 that time was that we ask the sponsor to come back  
16 to us with not new data, but the data that they do  
17 have on the Quadra lens, and for them to give us  
18 some persuasive arguments as to why that lens  
19 should be treated in the same way --

20 DR. WEISS: Dr. Rosenthal.

21 DR. ROSENTHAL: That is certainly an  
22 option for this sponsor.

23 DR. WEISS: So, you can raise a motion.

24 DR. MATOBA: [Off mike.]

25 DR. WEISS: That is why I wanted to make

1 sure what the conditions were.

2 Dr. Harris is going to have a comment.

3 Dr. Van Meter, and then you can make another motion  
4 and do it differently.

5 DR. HARRIS: I view there are two options  
6 at this point. One is to deny the application.  
7 The other is to do what I believe Dr. Van Meter is  
8 attempting to do, but to do it in a slightly  
9 different manner.

10 That is to indicate a condition of  
11 approval, not a labeling issue, but a condition of  
12 approval requiring the sponsor to provide the  
13 agency with supporting data to give us the valid  
14 scientific evidence that they claim is available to  
15 support the safety and efficacy of this indication  
16 for the Quadra lens.

17 DR. VAN METER: According to the voting  
18 options, approvable with conditions, is first you  
19 vote, and then you vote on the conditions which are  
20 brought forth afterwards.

21 Is that not correct, Ms. Secretary?

22 MS. THORNTON: You vote on the main  
23 motion, which is approvable with conditions.

24 DR. VAN METER: And then you add  
25 conditions later.

1 MS. THORNTON: Right. If you want to add  
2 that, you want to refer back to the three that you  
3 pointed out for the CRT, just say the labeling as  
4 we have discussed for the other, as in the record,  
5 the other three, and then add the one that you want  
6 to do regarding the data.

7 DR. VAN METER: But the conditions are  
8 added after you vote for approvable with  
9 conditions, is that not correct?

10 DR. WEISS: Yes, that's correct. The  
11 individual conditions are put forward after you put  
12 the main motion forward.

13 MS. THORNTON: Yes, but you don't vote on  
14 the main motion until you have voted on all the  
15 conditions that are attached to it. Then, that  
16 becomes the main motion.

17 DR. WEISS: Dr. Grimmett.

18 DR. GRIMMETT: Just as a point of  
19 clarification, supplying additional valid  
20 scientific evidence, to get the intent correct,  
21 supply it to the panel, supply it to the FDA?

22 DR. HARRIS: Agency.

23 MR. McCARLEY: May I ask a question?

24 DR. WEISS: Yes.

25 MR. McCARLEY: Are you requiring clinical

1 data, is that what you are telling the sponsor to  
2 do, or valid scientific evidence?

3 DR. GRIMMETT: Evidence, the latter.

4 DR. WEISS: Dr. Harris, you are going to  
5 leave it up to the sponsor to determine what  
6 qualifies --

7 DR. HARRIS: Let me, first of all, state I  
8 am not in favor of this particular proposal.

9 DR. WEISS: I got that drift.

10 DR. HARRIS: Thank you very much. But I  
11 sense that there are a number of panel members who  
12 do want to go in this direction, and I am giving  
13 them a methodology to go about this and doing it in  
14 a reasonably logical fashion.

15 It is valid scientific evidence submitted  
16 to the agency, it is not another clinical study.  
17 It is whatever they can provide that will satisfy  
18 the agency to the fact that this is a safe and  
19 effective use of this particular design.

20 DR. WEISS: Dr. Bradley.

21 DR. BRADLEY: I need to know where we are.  
22 We just voted against a motion on the Quadra, to  
23 approve the Quadra with the same conditions. As  
24 Sally just pointed out, normally, we have the  
25 motion to approve with conditions, and then we take

1 votes on the conditions, and then we come back to  
2 the main motion.

3 We didn't do that. We voted on the main  
4 motion, so is that motion dead, or can we come back  
5 and have the same motion again?

6 DR. WEISS: You can come back with the  
7 same motion with different conditions. It was  
8 those conditions that were not approved.

9 DR. ROSENTHAL: Can I go back and ask  
10 Sally to read what you have an option to do. I  
11 want to be you understand that approvable with  
12 conditions, what it means.

13 MS. THORNTON: Approvable with conditions.  
14 The panel may recommend that the PMA be found  
15 approvable subject to specified conditions, such as  
16 physician or patient education, labeling changes,  
17 or a further analysis of existing data.

18 Prior to voting, all of the conditions  
19 should be discussed by the panel.

20 The operative word is existing.

21 DR. WEISS: Dr. Rosenthal, I think he is  
22 giving us a hint here. With that small hint, does  
23 anyone want to make a motion? Does anyone want to  
24 stay here for the rest of the afternoon?

25 Dr. Van Meter, can I entice you to make a

1 motion?

2 DR. VAN METER: I would move that the  
3 Quadra lens be approvable with conditions and that  
4 these conditions would include all of the  
5 conditions that were listed for the CRT lens, which  
6 include labeling, training, and exclusionary  
7 criteria, and we would ask the sponsor to provide -  
8 - help me with the wording here -- valid scientific  
9 evidence on the safety and efficacy --

10 DR. ROSENTHAL: Could I help you?

11 DR. VAN METER: Yes, please.

12 DR. ROSENTHAL: Analysis of existing data.

13 DR. VAN METER: -- of existing data.

14 DR. WEISS: Further analysis of existing  
15 data.

16 DR. VAN METER: Further analysis of  
17 existing data.

18 DR. MATOBA: Second.

19 DR. WEISS: If there is no further  
20 discussion of this, then, I would suggest a vote.

21 DR. VAN METER: It hasn't been seconded  
22 yet.

23 DR. WEISS: I thought it was seconded. It  
24 was seconded by Alice.

25 All of those in favor, signify by raising

1 your hand.

2 [Show of hands.]

3 MS. THORNTON: Ten for.

4 DR. WEISS: All of those against?

5 [Show of hands.]

6 DR. WEISS: That motion has passed.

7 We are going to backtrack a little bit.

8 We are going to poll each of the panel members on  
9 the two distinct main motion votes, and first, for  
10 the CRT, if you can give us your comment why you  
11 voted the way you did for that, and then for the  
12 Quadra lens, if you can give us your opinion why  
13 you voted the way you did for that.

14 Why don't we start with Dr. Harris today.

15 **Polling of Panel Votes**

16 DR. HARRIS: The material presented on the  
17 CRT lens supported with reasonable assurance the  
18 safety and efficacy of that design for the  
19 indicated use.

20 Do you want me to comment on the other  
21 one, too?

22 DR. WEISS: If you desire, sure.

23 DR. HARRIS: I did not find with  
24 reasonable assurance evidence indicating the safety  
25 and efficacy of the Quadra design in any of the

1 materials submitted to me either in writing or  
2 presented at this panel meeting.

3 DR. WEISS: Dr. Casey.

4 DR. CASEY: I think for the CRT lens, the  
5 study was well designed and well conducted, and as  
6 a result, in large part, were significant and  
7 clearly conveyed today. The device appears to be  
8 safe and effective, and thus, my approval for the  
9 CRT.

10 With regards for the Quadra, I think that  
11 the available data and experience and guidance of  
12 my colleagues here on the panel suggested it should  
13 be approved, as well.

14 DR. WEISS: Dr. Edrington.

15 DR. EDRINGTON: The data supplied to us by  
16 the sponsor, I felt was compelling to show the  
17 safety and efficacy of the CRT for the intended use  
18 of overnight wear for keratology.

19 As far as the Quadra, it seems to me just  
20 based on materials and such, that the safety is not  
21 an issue, and I would also just clinically think  
22 that it also should be efficacious, as well.

23 DR. WEISS: Dr. McMahon.

24 DR. McMAHON: I voted in favor with  
25 conditions on both of the motions, for the CRT and

1 for the Quadra. The sponsor is to be congratulated  
2 on a well-conducted study.

3 I voted specifically for the CRT on the  
4 basis of adequate safety and efficacy data  
5 presented.

6 I voted for the Quadra on the basis that  
7 there is great enough similarity and based upon  
8 years of clinical practice dealing with RGP's, that  
9 the efficacy of that lens design is likely to be  
10 similar to or equivalent.

11 DR. WEISS: Dr. Matoba.

12 DR. MATOBA: I vote approval with  
13 conditions for both the CRT and the Quadra lens. I  
14 felt that with the conditions that we have  
15 stipulated, it will be safe and effective.

16 DR. WEISS: Dr. Bradley.

17 DR. BRADLEY: I voted for approval with  
18 conditions. My major concern, as with most of the  
19 other more permanent refractive strategies that  
20 come to this panel, is that this particular one, as  
21 with others, is not as effective as I would like  
22 it, and it still leaves a significant proportion of  
23 the subjects with what I would consider to be  
24 ineffective treatment in that their visual acuity  
25 does not achieve 20/40.

1 DR. WEISS: Dr. Grimmett.

2 DR. GRIMMETT: I voted approvable with  
3 conditions for the CRT lens because I believe the  
4 PMA provided reasonable assurance of safety and  
5 effectiveness.

6 Regarding the Quadra lens, I agree with  
7 Dr. Harris' sentiments regarding that valid  
8 scientific evidence was not in my hands to evaluate  
9 it, but I feel comfortable with having such data  
10 submitted to the agency for further analysis and  
11 the FDA's due diligence. Therefore, I voted  
12 approval with conditions for the Quadra lens, as  
13 well.

14 I would like to just congratulate the  
15 sponsor for a very well done study, well presented  
16 both in writing and verbally here today. I greatly  
17 appreciate all your efforts, and good job.

18 DR. WEISS: Dr. Coleman.

19 DR. COLEMAN: I vote approvable with  
20 conditions because I did have reasonable assurance  
21 of the safety and effectiveness of both the Quadra  
22 and CRT lenses given the conditions that we placed  
23 on them.

24 DR. WEISS: Dr. Ho.

25 DR. HO: I voted approvable with

1 conditions for CRT. Some of my concerns,  
2 particularly with the regression of the effect of  
3 the temporary correction in the potential safety  
4 issues that Dr. Bradley brought up so nicely, I  
5 think are well addressed in labeling and in  
6 education of potential fitters.

7 I vote approvable with conditions for the  
8 Quadra lens based predominantly upon the experience  
9 of the panelists who do these fittings here  
10 although, as I look at the panelist, the contact  
11 lens fitters are all wearing glasses, which doesn't  
12 reassure me, but I think given the base of  
13 knowledge that is out there, that the sponsor has  
14 told us exists, that that can be analyzed, and I am  
15 comfortable with that.

16 DR. WEISS: Dr. Van Meter.

17 DR. VAN METER: I agree with Allen. That  
18 is like a bald man selling hair tonic. But I voted  
19 approvable for both PMAs using the Quadra and CRT  
20 lens. I think the sponsor did an excellent study.  
21 The data was very convincing for safety and  
22 efficacy for CRT lens, and as a practitioner, I  
23 think a base curve change is not going to cast much  
24 of a shadow on the reasonable safety and efficacy  
25 of the Quadra lens.

1 DR. WEISS: Dr. Smith.

2 DR. SMITH: I voted appovable with  
3 conditions for both the CRT and the Quadra lens  
4 system. I believe that safety and efficacy has  
5 been shown for the first, and that further analysis  
6 of existing data will permit the FDA to be assured  
7 of safety and efficacy of the second.

8 DR. WEISS: Thank you.

9 We are going to now hear from Glenda Such,  
10 the consumer representative.

11 **Comments from Consumer and Industry Representatives**

12 MS. SUCH: I support and am pleased by the  
13 voting outcomes that occurred for this PMA. Also,  
14 I am very pleased with the study that was  
15 presented, both written and orally, as well as the  
16 testimony that was given this morning in the public  
17 session. I thought that was very helpful to hear  
18 from the investigator.

19 I am very pleased also with the different  
20 pieces that are going to be more clarified through  
21 the conditions.

22 DR. WEISS: Ronald McCarley, the industry  
23 representative.

24 MR. MCCARLEY: Again, I am glad the  
25 decision was made today to approve I guess both

1 portions of this PMA, however, I would that the  
2 FDA, if they would, provide a little bit better  
3 preparation to the panel as far as when they bring  
4 a PMA to the panel without data, what their options  
5 are.

6 I think that probably in the future, FDA  
7 will handle these types of things simply by  
8 directing it directly to the FDA instead of coming  
9 to the panel.

10 Again, a significant amount of time today  
11 was spent on an issue that boiled down to you  
12 didn't have the data that you needed to approve it,  
13 so you went over and over, and I think a lot more  
14 constructive I guess approval time could have been  
15 put toward that issue with the FDA rather than  
16 bringing it here to the panel.

17 DR. WEISS: I wanted to thank the sponsor  
18 for doing an excellent job and having a very clear  
19 presentation, and the FDA, for their presentations,  
20 as well as the panel reviewers, and Sara Thornton  
21 has closing remarks.

22 MS. THORNTON: I just wanted to thank all  
23 of the panel and particularly our new people here  
24 today. I hope you will be interested in returning  
25 at some time in the future.

1 DR. HARRIS: What about us old people?

2 MS. THORNTON: You are always welcome

3 back.

4 I wanted to ask all of the panel people at  
5 the table, please leave all of your materials with  
6 us. The only thing, I did indicate that you have  
7 an organizational chart. That is a take-home piece  
8 for you at this time, but please all of your  
9 materials here to be collected, so that we can  
10 destroy them. I wish you all safe journeys home.

11 [Whereupon, at 1:52 p.m., the meeting was  
12 adjourned.]