

1 MR. MCCARLEY: Yes, just one comment for future
2 applications, if in fact this is approved. What
3 justification do you have for cutting off at 5? In other
4 words, what's the distribution of the N? I mean, why 5?
5 Why 5?

6 DR. WEISS: Dr. Maguire, Dr. Huang, either of
7 you want to answer?

8 DR. HUANG: Basically, you know, there were 139
9 eyes in the sphere cohort was reviewed and there's one
10 patient in the -0 to -1 range. There are four patients in
11 the -6 to -7 range. So therefore, I think that N equal to
12 1 doesn't mean anything and equal to 4 may mean something
13 but it's not sufficient. So therefore, my recommended
14 indication rate was from -1 to -6, but if you're going to
15 cut down the cohort from 139 to 5, there's still enough --
16 I have done some preliminary calculation on my own. I
17 think 134 patients, most of the data still holds on.

18 DR. WEISS: I would actually ask the agency for
19 their input on this statistically. Does the agency have
20 any concern concerning the small numbers of patients with
21 high corrections from a statistical basis as far as having
22 approval for these as the small number did very well but
23 there's concern on the panel?

24 Dr. Eydelman, thank you very much.

25 DR. EYDELMAN: Hi. Dr. Eydelman.

1 In the previous approvals for various LASIK
2 devices, we have not requested the sponsors to have
3 statistically significant number of patients in each
4 dioptric range. It is well known that the higher the
5 myopia the harder it is to get large number of patients.

6 In the reviewing of this application, basically
7 there were two considerations taken in my recommendations
8 of giving the full range for the approval. Number 1 is
9 that even though there was small number of eyes in the
10 higher range, we didn't see any significant safety problems
11 in that population, and second of all is that this, as was
12 pointed out, is a second generation of this device. So
13 we're not really anticipating any red flags, anything
14 hidden, and then we have also looked at combined myopic
15 with astigmatism eyes for safety for that range, and you
16 have that cohort not in the efficacy but within the safety.
17 You have a whole bunch of patients -- I would have to look
18 up the exact number -- where the ametropia was between -6
19 and -7 and once again, there were no really safety
20 concerns.

21 If the panel has some reservations about
22 possibility of equivalent approval in optical qualities in
23 this group, I believe that we can definitely handle this in
24 labeling, but otherwise, I would like to understand what
25 exactly the safety concerns are, if you're going to vote on

1 limiting the range.

2 DR. HUANG: Well, on these four patients, one
3 of them is outside 20/40 range, and I think that was
4 addressed by Dr. Hakim earlier today, you know, that he
5 specifically mentioned that patient eventually improved.
6 But one out of four patients has a problem. Even though it
7 exceeded FDA guidance, I still don't think that is
8 sufficient to indicate this is going to be safe in the
9 larger population.

10 DR. WEISS: Thank you very much for those
11 elucidating opinions.

12 I'd like to have just another straw vote just
13 for voting members of the panel. After hearing this
14 additional information, how many would feel comfortable for
15 voting for the full range up to -7?

16 (Show of hands.)

17 MS. THORNTON: Dr. Bullimore, Dr. Matoba, Dr.
18 Grimmett, Dr. Owsley, Dr. Swanson. Five.

19 DR. WEISS: Five. Thank you so much.

20 And how many would say do not feel comfortable
21 voting for the full range?

22 (Show of hands.)

23 MS. THORNTON: Dr. Maguire and Dr. Huang.

24 DR. WEISS: Okay, and then three of you are a
25 maybe?

1 (Show of hands.)

2 DR. WEISS: We have a maybe from Dr. Bradley,
3 maybe from Dr. Bandeen-Roche. Is my math off? What does
4 it add up to? That's right. Do the maybes need any more
5 information or can we move on?

6 Dr. Bradley, yes?

7 DR. BRADLEY: Well, I can just explain why
8 maybe. On the graph that I'm looking at, I only have one
9 eye between 6 and 7 and that eye had a postop refractive
10 error greater than 1 diopter. So that's why I was a bit
11 concerned about perhaps 6, but up to 6 seems fine.

12 DR. WEISS: We could perhaps address that in
13 labeling. We could probably address that in labeling that
14 there were a small number of eyes above, you know, XYZ. So
15 if we address it in labeling, would you feel comfortable
16 then?

17 DR. BRADLEY: Yes.

18 DR. WEISS: Fine. Thank you.

19 Okay. Let's get back to Question 2. "The
20 additional clinical data analysis or criteria needed to
21 evaluate the relative effectiveness of Custom and
22 conventional treatment with regard to higher-order
23 aberrations and visual function."

24 I personally would like, when you have the data
25 for the 19 conventional versus the 19 customized, if you

1 have symptoms as well as if you had any satisfaction data,
2 I think that would be helpful to any patient who's trying
3 to make a decision whether to have the customized versus
4 the conventional treatment.

5 Does anyone have any other suggestions?

6 Otherwise we'll move on. Yes, Dr. Bandeen-Roche?

7 DR. BANDEEN-ROCHE: Yes, this one I forgot from
8 before. In the symptom data, I'd like to see an analysis
9 that is by first eye of patient. So the current analysis
10 just average symptoms over all eyes, but I don't know
11 whether there might be a bias because people who get the
12 second eye done might tend to be those who are more
13 satisfied and didn't have a problem with the first one.

14 I'm sure the substantive members of the panel
15 could address that.

16 DR. WEISS: Did you want to make a comment, Dr.
17 Pettit?

18 DR. PETTIT: If it would be appropriate.

19 DR. WEISS: If you'd like to, it will be
20 appropriate.

21 DR. PETTIT: I hope it will be appropriate.

22 The patients were all treated at the same time.
23 They received both eye treatments in the same surgical
24 session.

25 DR. WEISS: So they didn't have an opportunity

1 to decide whether they were satisfied or not. Okay. Thank
2 you very much. That was appropriate.

3 Ms. Such?

4 MS. SUCH: Yes. One other piece that I
5 actually would like is there's been statements made by the
6 sponsor that -- I'm not sure if it was a friend or one of
7 the people that he worked on under the study had
8 expectations of getting down to 20/16 or was 20/16 and
9 wanted to see better.

10 I'd like to have, if you could, information
11 gathered from the people who we're talking about, what
12 their expectations were and whether or not their
13 expectations were met. If we put a qualifier on it, we
14 would get a sense of if those expectations were within
15 normal human limits.

16 (Laughter.)

17 MS. SUCH: And find out what you're dealing
18 with, because we may be able to just rule them out or at
19 least get a better sense and in your brochure make
20 statements that are indicating that, you know, expectations
21 were met and address people that want to see.

22 DR. WEISS: I think they have the satisfaction
23 data here and if anything, there'll be a bias against
24 satisfaction if they're dealing with people who are
25 unreasonable and have high expectations. So actually the

1 satisfaction might have been higher than what was revealed
2 if these are demanding individuals.

3 Mr. McCarley, and then we're going to move on
4 to Question Number 3.

5 MR. MCCARLEY: Just very quickly from the
6 consumer representative. Again be careful about what you
7 say in terms of general cautions you want to add to LASIK
8 procedures in general because it sounds to me like that's a
9 general LASIK procedure precaution that you wanted to be
10 added to this specific one.

11 DR. WEISS: I think she was just trying to
12 commiserate with the sponsor that some of the patients
13 might have had higher than reasonable expectations.

14 Question Number 3. "What information about
15 measurement, analysis, and correction of higher-order
16 aberrations is needed in the labeling to inform physicians
17 and patients about safety and effectiveness of CustomCornea
18 treatments?"

19 I think we've addressed some of this, but are
20 there other things that -- Dr. Swanson?

21 DR. SWANSON: Well, looking at the thing, in
22 various places, it talks about delivering the correction,
23 making the correction, improving, and what we've seen is it
24 doesn't actually do that. It attempts to, but it says it
25 uses it to correct for the visual errors in the eye. Well,

1 it uses it to correct for some of them and then it induces
2 others. So I think part of the thing that could be stated
3 in here, because if you read it over, it gives the
4 impression that it fixes everything that's wrong, and what
5 we've learned is that it's more complex than that. So I
6 think in those places that there's reference to correct,
7 there could be some modification that made it look less
8 like you're taking something and making it perfect.

9 DR. WEISS: And actually, I should reiterate
10 what was already mentioned, I think, by the agency, is
11 that, some of this is going to have to address the
12 physician booklet as well as the patient booklet so
13 physicians understand what this is about as well.

14 Dr. Grimmatt?

15 DR. GRIMMETT: Yes. Mike Grimmatt.

16 I think Dr. Bradley in his presentation made a
17 statement for labeling that would probably apply to this
18 question. The information about the correction of higher-
19 order aberrations is that Dr. Bradley stated they were
20 promoted as a slight improvement over conventional
21 LADARVision LASIK, although the level of aberrations are
22 higher than preop. I think somehow that needs to be stated
23 in the labeling somewhere.

24 DR. WEISS: Does anyone want to phrase that in
25 any different way because I would agree?

1 Dr. Bullimore, with verbs, adjectives and
2 nouns, some adverbs, if you want.

3 DR. BULLIMORE: In answer to this specific
4 question, I don't think anything technical needs to be in
5 the patient labeling. I think that can only confuse and
6 obfuscate. In terms of the physician labeling, I think
7 it's adequately addressed at the moment through inclusion
8 of the safety and efficacy data. So I don't think we need
9 to ask the sponsor to include, for example, a tutorial on
10 the wavefront measurement correction and evaluation.

11 DR. WEISS: Dr. Bradley?

12 DR. BRADLEY: Yes, this brings us to my other
13 points I was talking about in my presentation about the
14 correlation of analysis and whether or not the sponsor has
15 adequately demonstrated that the CustomCornea really is a
16 correction of the aberrations that existed in that eye, and
17 I think from my analysis, which is rather preliminary, I
18 certainly was not convinced that they had demonstrated
19 correction of the inherent aberrations within an eye, and I
20 would leave it up to the sponsor and the FDA to sort that
21 out to see if they have adequately demonstrated that
22 because the issue is the effectiveness of CustomCornea.
23 The implication of CustomCornea is that you are correcting
24 the aberrations of the eye, and if you haven't demonstrated
25 that, then one has to question the effectiveness of

1 CustomCornea and the end result, as we know, is it's better
2 than conventional LASIK, but is it really as implied a
3 correction for the aberrations of the eye? I think that
4 needs to be demonstrated before we put any statement into
5 the label.

6 DR. WEISS: Would that not be addressed
7 somewhat by Dr. Grimmatt's statement, is that, regardless
8 of what you're treating, the end result is the aberrations
9 go up?

10 DR. BULLIMORE: This is Dr. Bullimore.
11 That statement does need to be in the labeling.

12 DR. WEISS: The aberrations -- which statement?
13 The one that Dr. Grimmatt made or what Dr. Bradley's
14 referring to?

15 DR. BULLIMORE: The one that Dr. Bradley had on
16 his slide.

17 DR. GRIMMATT: I can read it.

18 DR. WEISS: Yes, if you could read that, Dr.
19 Grimmatt.

20 DR. GRIMMATT: Dr. Bradley stated wavefront-
21 guided LASIK does not reduce the level of higher-order
22 aberrations of the preoperative eye, and he also wrote
23 there's no way wavefront-guided LASIK can correct higher-
24 order aberrations and render super-normal vision. That's
25 the second statement. Is that not correct?

1 DR. BRADLEY: Your memory is better than mine,
2 but I can look at the slide.

3 DR. GRIMMETT: No, I believe I transcribed it
4 correctly.

5 DR. BULLIMORE: I agree. This is Dr.
6 Bullimore. I agree with the sentiments of both of those
7 statements. Exactly how the second one is worded, we could
8 come back to, but the first one adequately --

9 DR. WEISS: Can you repeat the first one again?

10 DR. GRIMMETT: Sure. Wavefront-guided LASIK
11 does not reduce the level of higher-order aberrations of
12 the preoperative eye.

13 DR. WEISS: Would that not be confusing to
14 someone? Wouldn't that be confusing?

15 DR. GRIMMETT: Michael Grimmett.

16 It may suggest somehow wording in that wasn't
17 it that the higher-order aberrations were 20 percent higher
18 than the preop eye in the wavefront-guided versus what, 80
19 percent was the number?

20 PARTICIPANT: Seventy-seven percent.

21 DR. WEISS: In here, is there any place saying
22 that LASIK itself increases aberrations and that customized
23 corneal ablation increases them less than conventional
24 treatment?

25 DR. GRIMMETT: I think that's the idea.

1 DR. WEISS: So maybe we could put that
2 wavefront-guided ablation --

3 DR. GRIMMETT: Conventional LADARVision LASIK
4 increases higher-order aberrations by that figure 77
5 percent while wavefront-guided LASIK increases them by
6 whatever, 20 percent, whatever the number is, or you can
7 say reduces them to a 20-percent level, if you want to use
8 the word "reduces."

9 DR. BULLIMORE: I would avoid the term
10 "reducing."

11 DR. WEISS: I would say each of them increases
12 it because basically whether or not you're treating the
13 preexistent or what's induced, the bottom line is you still
14 have more aberrations than you did when you started off.

15 DR. GRIMMETT: Well, the intent is telling the
16 traffic cop that you're speeding less than the other
17 speeders.

18 DR. BURNS: I think it's important. I think we
19 can let staff sort of wordsmith it because aberrations
20 going up or down may not be that clear to the lay public.
21 So I think there's some wording still there.

22 DR. WEISS: Ms. Such?

23 DR. BURNS: But I agree with the sentiment.

24 MS. SUCH: On that note, I would suggest that
25 perhaps we look at, if you were going to say that for the

1 average patient, you might say something that while LASIK
2 surgery does this 77 percent, this other only does it dah,
3 dah, dah or something in that order of while.

4 DR. WEISS: You might also have to have an
5 opening statement, aberrations may reduce visual quality or
6 something, what aberrations mean.

7 MS. SUCH: Yes. I think by doing that, you
8 don't have to say reduces or anything else, you can just
9 use, you know, something simple that says that and while
10 this surgery does it at this level, and the person will
11 draw their own reference from that without getting into
12 trouble.

13 DR. WEISS: Okay. And that's something I think
14 we would need to have both in physicians as well as
15 patient.

16 There are a couple of other items and this is
17 probably not the place to introduce it, but I'll introduce
18 it anyway there. My prerogative, right? There was only
19 one African American patient treated. So I think we would
20 have to say that the safety and effectivity in African
21 Americans is, there's insufficient numbers of patients
22 treated to determine safety and efficacy in African
23 Americans or if anyone can come up with better wording than
24 that.

25 DR. GRIMMETT: Michael Grimmett.

1 Wouldn't just including the demographic mix
2 make the information clear?

3 DR. WEISS: Whatever anyone else wants to do.

4 DR. BURNS: I think it's worth calling out
5 because there really isn't very much in Caucasian stuff.

6 DR. WEISS: The other question that I have at
7 this juncture for other -- yes, Dr. Swanson?

8 DR. SWANSON: You put me on hold.

9 DR. WEISS: I'm sorry.

10 DR. SWANSON: On the last topic. That's fine.

11 DR. WEISS: I'm sorry.

12 DR. SWANSON: You're doing a great job.

13 But the idea, wavefront aberrations are
14 discussed in the patient brochure because we were talking
15 about how to modify that. There's a whole paragraph that
16 describes them.

17 DR. WEISS: Can you refer us to the page?

18 DR. SWANSON: This is page 7 of 24 of the
19 patient information booklet, the next-to-last paragraph on
20 the right-hand side. It introduces the idea. It states,
21 "These small errors called higher-order aberrations may
22 have an effect on vision in addition to any nearsightedness
23 present in the eye." The next sentence says, "In
24 CustomCornea LASIK, the wavefront measurement is used by
25 the LADARVision 4000 System to deliver the correction you

1 need to reshape the surface of your eye." That's actually
2 somewhat of a non-sequitur. It's mentioning the higher-
3 order aberrations and then it's as if it implies it's going
4 to fix them and that's the spot where what's needed to be
5 inserted is after it's introduced what they are, is this
6 kind of surgery makes these things worse and ours is not
7 quite as bad as what it has been because the way it's
8 stated right now, it introduces the fact they're there and
9 then it implies that this method gets rid of them. So
10 there has been a whole effort to educate the person to tell
11 them what they are and then there's this thing where it --
12 you see page 7 of 24 in the patient information booklet?
13 So that's where this whole thing that we're discussing,
14 that's where it would go because they've gone through,
15 they've introduced what the thing -- what it is in the very
16 last sentence, before the last sentence.

17 DR. WEISS: Yes, we're in the next-to-the-last
18 paragraph. So I think you would feel, and I would agree
19 with you, and we can get the opinions of other members of
20 the panel. There's a statement. The rest of it sounds
21 pretty good, but there is a statement saying, "In
22 CustomCornea LASIK, the wavefront measurement is used by
23 the LADARVision 4000 System to deliver the correction you
24 need to reshape the surface of your eye."

25 DR. SWANSON: Right.

1 DR. WEISS: So that's where you want that
2 statement to get changed.

3 DR. SWANSON: Yes, right. That's the topic we
4 were talking about. You've already introduced what it is
5 and that's the point where they need to know that this is
6 not getting rid of those.

7 DR. WEISS: And do you want to just leave that
8 line and then add Dr. Grimmert's couple of lines where
9 basically you will have less aberration than you would have
10 with the other treatment? Because it is still going to be
11 used to reshape your eye.

12 DR. SWANSON: Yes.

13 DR. WEISS: It's just not going to be 100
14 percent effective.

15 DR. SWANSON: I don't have a particular
16 recommendation. I'm sure that they can do that. I just
17 wanted to bring that up in our discussion of that point,
18 that that's where it would fit.

19 DR. WEISS: So the discussion of aberration for
20 the patient booklet would be on page 7. Patient
21 information booklet on page 7.

22 Any other discussion on 3? Otherwise, we'll go
23 on to 4 and 5.

24 DR. BANDEEN-ROCHE: Very briefly, this is Karen
25 Bandeen-Roche.

1 First, going to the point about your vision
2 will be better, whatever, I know FDA will be careful about
3 reporting that averages were thus and such rather than, you
4 know, individual outcomes were thus and such.

5 A question about the physician labeling.
6 Should it include some information about test/retest
7 reliability?

8 DR. WEISS: I don't believe that we usually do
9 that.

10 Mr. Whipple?

11 DR. BANDEEN-ROCHE: In terms of the
12 measurement.

13 DR. WEISS: Any opinions on how? Dr. Bradley?
14 Well, we usually use the least burdensome and I think
15 that's getting burdensome.

16 Mr. McCarley, and then we'll go on to 4.

17 MR. MCCARLEY: Yes, just one question. Rick
18 McCarley, industry rep.

19 Does the FDA typically require gender, age
20 distribution, and race in the labeling for the lasers? Is
21 there a format that's already set up for what they were
22 talking about just a moment ago? Is that something new or
23 coming up?

24 DR. EYDELMAN: Dr. Eydelman.

25 We usually just include demographics

1 distribution table in the labeling.

2 MR. McCARLEY: Including gender and race?

3 DR. EYDELMAN: Yes.

4 DR. WEISS: Fine. We'll move on to Question
5 Number 4. "What additional stability criteria are needed
6 for higher-order aberration treatments?" If there are any
7 additional stability criteria needed.

8 I think things are fairly stable by three
9 months, but between three and six months, trifol kept on
10 decreasing, statistically significant, but as I recall,
11 that was the only one.

12 Dr. Bradley?

13 DR. BRADLEY: I think this is potentially an
14 important point, but it's one where unfortunately science
15 is lagging behind here. We really know very little of the
16 variability, day-to-day variability, month-to-month, year-
17 to-year variability in these higher-order aberrations
18 preop. So trying to put in criteria for how much we want
19 to allow the postop aberrations to vary as we do for
20 refractive error would be inappropriate at this time.

21 DR. WEISS: So because we don't have the
22 knowledge, you don't want to add any specific criteria
23 because we don't have anything to guide us, basically.

24 Dr. Burns?

25 DR. BURNS: I agree with that on average. I

1 think, as Dr. Huang pointed out, there are individuals with
2 high amounts preop of some of the aberrations, like coma,
3 and it might be worthwhile to pull those out as a subgroup
4 and look at the effect of treatment and stability just as
5 we do for sphere or for astigmatism now.

6 DR. WEISS: Dr. Grimmiett?

7 DR. GRIMMETT: Michael Grimmiett.

8 I'm probably out of my league since I'm a
9 clinician, but the question might be would it be reasonable
10 to have some postmarket data tracking changes in RMS
11 values? That may be the intent of the question, maybe, and
12 would that be reasonable? I certainly understand Dr.
13 Bradley's sentiments that we don't have enough data to set
14 guidelines as to what might happen or what might be
15 reasonable, but is it reasonable to request data on
16 tracking RMS values so that at least we know something
17 about what happens to higher-order aberrations?

18 DR. WEISS: I'm going to defer to Dr. Huang and
19 Dr. Bradley. It was my recollection that the higher-order
20 aberration change was stable at around three months, except
21 for trifoil, and if it was, then I would say wonder why you
22 would need to track it if the stability was -- or it
23 appeared stable, but --

24 DR. GRIMMETT: Michael Grimmiett.

25 Due to lack of knowledge about anything about

1 what happens to these, I'm just raising the point for
2 discussion.

3 DR. WEISS: Dr. Huang or Dr. Bradley, what are
4 your feelings on it? Dr. Bradley probably expressed his
5 already. Dr. Huang?

6 DR. HUANG: Andrew Huang.

7 I'm in favor of Dr. Burns's suggestion, is
8 that, because the higher-order aberration, it's changing
9 with age, so as the time goes on, we have an increased
10 higher-order aberrations. So we really don't know, you
11 know, that even though the trifol is stable at three
12 months, what is going to happen on this treated eye, you
13 know, at 12 months or three years from the treatment?

14 DR. WEISS: I think it's important for the
15 panel to distinguish what the sponsor needs to do to
16 establish safety and effectiveness of the device that
17 they're coming forward with versus what we would like to
18 know as clinicians and scientists. The latter should be
19 those studies should be done by us or our members of our
20 community.

21 So does anyone on the panel or who on the panel
22 feels that this is necessary information to safety and
23 efficacy of this device to have postmarket studies? We
24 need to be holding to the least burdensome proof for the
25 sponsor.

1 Dr. Burns?

2 DR. BURNS: Even though I suggested it, I don't
3 think it's necessary for safety and efficacy, but to
4 justify additional claims or something in the future, I
5 think some of this information would be useful postmarket
6 to help evaluate them. I don't know if that's typically
7 done.

8 DR. WEISS: Sally Thornton points out something
9 very relevant, is that, if any future claims were made,
10 then they would need to be justified by further data. So
11 the only claims that we're approving are the claims that
12 we're approving right now and, you know, you can say
13 anything else you want, but right now, we have to address
14 what claims are being made.

15 Yes, Dr. Owsley?

16 DR. OWSLEY: Just a quick question. Is this
17 something that would be useful for the patient to know,
18 that we don't know the long-term effects of this?

19 DR. WEISS: Well, I'll leave that up to the
20 panel.

21 DR. OWSLEY: I don't know. What is usually
22 done on these devices for labeling?

23 DR. WEISS: Well, this is first of a kind.
24 This is first of a kind of this particular device.

25 DR. OWSLEY: It's the first of a kind for this

1 particular device, but we don't have 50 years of wait a
2 sec, you know, where we can evaluate people when they're
3 70. So what's done usually? Is there any comment to the
4 patient as to what we know about this in 40 years when
5 they're old?

6 DR. WEISS: Would anyone want to put a
7 statement in there saying long-term, we don't have long-
8 term -- Malvina?

9 DR. EYDELMAN: Dr. Eydelman again.

10 It's usual for us to put something in the
11 labeling to the effect of no long-term data is available to
12 address X, Y, and Z and that's exactly what we intended to
13 do with this.

14 DR. WEISS: Fine. Excellent. Thank you.

15 Dr. -- Ms. Such?

16 MS. SUCH: I've been promoted as well.

17 DR. WEISS: Yes, yes. I'm handing them out.

18 MS. SUCH: I would also on the manufacturer's
19 side, that when I was reading this, I saw that the studies
20 will be done in six months, my first question, you know,
21 obviously was why and why not longer, and some people
22 really just are not going to know that this hasn't been
23 around for awhile. So I would even suggest that you might
24 put in there that, you know, due to the short time of the
25 existence of this, there's not been long-term studies, you

1 know, because a lot of people just won't know how long this
2 has been out and why you haven't done it as opposed to
3 worry that they haven't done it because you're afraid.

4 DR. WEISS: The curse of long-term follow-up?

5 Any other comments on this question? So
6 basically, I think there's a consensus that we'll put
7 something in the booklet saying that long-term data is not
8 available but that no further studies will be required by
9 the sponsor.

10 Then we'll move on to Question Number 5.

11 "Should stability criteria be more stringent for wavefront-
12 based treatments than for conventional treatments?"

13 Dr. Bradley, Dr. Huang? Dr. Bradley?

14 DR. BRADLEY: Yes, I'm guessing the origin of
15 this question is that by its very nature, this procedure is
16 trying to correct for extremely small subtle imperfections
17 and if that is the goal of the procedure, then presumably
18 for that to be effective in the long run, stability needs
19 to be tighter or the eye has to be more stable for that
20 effectivity to remain. I think that's the origin of the
21 question.

22 Should there be more stringent? I think in the
23 end, still the most important factor here is the correction
24 of the spherical myopia and in the end, that will be the
25 primary determinant of visual quality and patient

1 satisfaction, and I think we already have standards for
2 that stability, and as we saw in the data and in the
3 sponsor's presentation and in mine, the stability is
4 excellent for the spherical myopia correction.

5 DR. WEISS: Dr. Huang, do you have anything to
6 add to that?

7 DR. HUANG: No.

8 DR. WEISS: No one has anything to add to that.

9 So we, I think, have concluded the five
10 questions put forward by the FDA. I have a couple of
11 things that I personally wanted to bring out for the
12 patient information book and also if anyone has any other
13 concerns that they want to introduce and these are fairly
14 trivial.

15 The patient information book is White Tab
16 Number 2 for those who have the book. It indicates to the
17 patient D2, that the vision becomes stable within the first
18 few weeks after surgery. To me, as I recall, the stability
19 line started at one month. So I'd rather say your vision
20 becomes stable in approximately one month after surgery
21 rather than first few weeks where they might assume it
22 might be Week 2 or something. I don't know if anyone has
23 looked at that, has any thoughts, agrees, disagrees. Okay.
24 And we have some nods of agreement. So we'll add that.

25 The other thing, the chart on page 9 on the

1 top. It's Visual Acuity with Glasses Best-Corrected after
2 this procedure, but the chart actually just says Visual
3 Acuity and just a trivial thing that it should just say
4 best-corrected visual acuity, visual acuity with glasses in
5 the body of the chart because if you look at it quickly, it
6 will be sort of deceptive to the patient.

7 On page 11, there's a list of subjective
8 symptoms and the list is the significantly worse, and I
9 think, I would personally like to expand the table to the
10 full Table 35, at least showing the worse and significantly
11 worse because the significantly worse may only be a couple
12 of percent where if you include the worse symptoms, you may
13 have 23 percent, and I think this is sort of alluding to
14 what Mr. Link and the other people were referring to in the
15 public session, is that they don't really have a full idea
16 of what they're getting into.

17 So I personally would prefer if the subjective
18 symptoms had not only the significantly worse but those
19 patients who also had worse symptoms.

20 Mr. -- Dr. Bradley?

21 DR. BRADLEY: I've lost my degree.

22 (Laughter.)

23 MS. SUCH: I took it.

24 DR. BRADLEY: I'm sure if I hang around long
25 enough, I'll get another one.

1 DR. WEISS: You will. Actually you might get
2 two.

3 DR. BRADLEY: Okay. I guess I have pretty
4 strong opinions about these sorts of data reporting tools.
5 As always, if you recall one side of any distribution, you
6 get a skewed view of the reality, and this has already one
7 side of the distribution, essentially the tail is
8 significantly worse, and I think if this table or tables
9 like this should go in, I would like to see both sides of
10 the table.

11 DR. WEISS: Put the whole table. You got it.

12 DR. BRADLEY: So those who got better and those
13 who got worse.

14 DR. WEISS: Table 35, it's yours.

15 I also would bring this out to the panel.
16 Should we include for the patient, maybe also for the docs
17 as well, Table 10 talked about not just two lines of best-
18 corrected visual acuity loss but one line of best-corrected
19 visual acuity loss, and we could also have for Dr. Bradley
20 the gain in visual acuity to be fair because it was 8.6
21 percent of patients who lost one line of best-corrected
22 visual acuity. As a patient, I think I would want to know
23 that.

24 Ms. Such, would you want to know that or is
25 just leaving two lines or more enough?

1 MS. SUCH: No, I'd want to know about the one
2 line. I mean, if I go for this surgery, I'd want to know
3 about any change.

4 DR. WEISS: Fine. I would suggest to include
5 Table 10, and Table 13 had change in low contrast best-
6 corrected visual acuity, and you lose low contrast best-
7 corrected visual acuity and that seemed to be a complaint
8 from those people who came before us today, that they
9 didn't know about it, and if they want to know about it, I
10 think it would make sense to put the whole table in there
11 to be fair, and does anyone have any thoughts on that?

12 DR. BULLIMORE: Which table?

13 DR. WEISS: That's Table 13. It's Change in
14 Low Contrast Best-Corrected Visual Acuity.

15 Mr. McCarley?

16 MR. MCCARLEY: You're going pretty quickly
17 here, and I don't have the benefit of seeing the tables
18 that you're referring to.

19 PARTICIPANT: Which section are you in when
20 you're talking about those tables?

21 DR. WEISS: Table 10. Low Contrast Visual
22 Acuity is pink Tab 6 and actually it's pink Tab 6, actually
23 Table 19, and for the change in symptoms, it's pink Tab 6,
24 it's Table 34, including those who are better, from those
25 who were significantly better to those who were

1 significantly worse.

2 DR. OWSLEY: Excuse me.

3 IF it's the change table, wouldn't it be Table
4 13 for low contrast acuity?

5 DR. WEISS: No, I think they're labeled with
6 more than one -- where is Table 13? I think they have more
7 than one number on them.

8 DR. BULLIMORE: Page 20.

9 DR. WEISS: Dr. Matoba?

10 DR. MATOBA: Now, this patient booklet --

11 DR. WEISS: Actually, Table 13. We'll go back
12 to Table 13, Table 10. Yes.

13 DR. MATOBA: I have just a general question.

14 This patient booklet, the original format was
15 already approved for conventional LASIK, is it not, and
16 then they're just adding the CustomCornea to it, and is it
17 fair to make -- should it list more problems for the
18 CustomCornea while the patient booklet for the conventional
19 LASIK is not going to have all this stuff about contrast
20 sensitivity loss?

21 DR. WEISS: Let's bring that out to the panel.
22 I don't know what's in the conventional book.

23 DR. MATOBA: I mean, wouldn't it be more fair
24 just to add things that pertain to the CustomCornea?

25 DR. WEISS: Well, I would agree with you.

1 DR. MATOBA: It's already approved.

2 DR. WEISS: I would agree with you, we
3 shouldn't make it more detailed for symptoms than the
4 original book. I don't know what the conventional book
5 looks like. So if the conventional book only has
6 significantly worse, then I think we're forced to just put
7 significantly worse in this, but that's something we can
8 probably have to refer to FDA.

9 I'm going to just continue with Mr. McCarley
10 because I cut you off.

11 MR. MCCARLEY: You answered one of my primary
12 questions. One is, I heard someone wanting to see every
13 possible or every complication that happened and the
14 percentage and I don't think that's the normal labeling
15 that the FDA requires. I think there's percentages where
16 it drops into other -- and what the ramifications of that
17 would be to other products, and again I agree, this is
18 simply a new indication for a current device. Why would
19 you want different labeling?

20 Now, the other way is just continuing to add
21 more information in here, just, you know, more information
22 for the patient to try to digest. Loss of one line as far
23 as I know is not a clinically significant issue. Correct
24 me if I'm wrong.

25 DR. WEISS: It may be more clinically

1 significant than the aberrations we're talking about.

2 MR. McCARLEY: I agree, but does it confuse the
3 patient? Does the patient look at one line of visual
4 acuity as a significant clinical issue when in fact it may
5 not be?

6 DR. WEISS: Are you confused by one line in
7 loss of visual acuity?

8 MS. SUCH: I would perhaps give an example of
9 what that could mean acuity-wise.

10 DR. WEISS: I think we should probably maybe
11 get the FDA involved again at this point because we don't
12 want to be more burdensome than the usual approval. So if
13 requiring the whole gamut is too much, we should not.

14 DR. EYDELMAN: Even though the booklet has
15 already established sections for each one for the
16 wavefront-guided LASIK, it will have a separate section per
17 se. So you can certainly specify certain points that
18 you're interested in conveying and then we'll try to work
19 out the details to make sure that it's consistent and not
20 too much for the patient booklet. You don't necessarily
21 need to give us every single table. We'll work it out.

22 DR. WEISS: Dr. Burns, and then Dr. Owsley.

23 DR. BURNS: Yes, Steve Burns.

24 I just wanted to say that because this is the
25 first wavefront-guided, it is sort of a new category, so I

1 think some extra information is potentially valuable to the
2 patient.

3 DR. WEISS: I mean, where I'm coming from is we
4 had more than one person talk about the severity of the
5 dryness they have and the point that they wish they knew
6 and only 7.4 percent had significantly worse but 21.5
7 percent had worse. So you have 32 percent that had worse,
8 and I think I personally would want to know that as a
9 patient without being too burdensome, but I think that's
10 important information. Dryness, glare, halos, night
11 driving difficulty, and fluctuation of vision, all of those
12 had approximately more than 20 percent of people in the
13 worse or significantly worse category which is not trivial.

14 Dr. Owsley?

15 DR. OWSLEY: Yes, I think the spirit of these
16 suggestions that some of the panel members are making is
17 that what we heard today and we hear about this all the
18 time is that patients want more information. So the spirit
19 is not to be overburdensome in providing all this extra
20 information about a new product that has evidence that it's
21 better in some ways. It's to provide the patient with more
22 information which I think they deserve to know.

23 DR. WEISS: Dr. Bradley?

24 DR. BRADLEY: I'm just wondering which table
25 the Chair was viewing when talking about some of the

1 symptoms.

2 DR. WEISS: Table 34.

3 DR. BRADLEY: Which is what I'm looking at,
4 too, and again this is a one-sided view of the table.

5 DR. WEISS: No, we're going to include the
6 whole table.

7 DR. BRADLEY: But I'm seeing 21 percent
8 reported worse, but 17 percent reported better.

9 DR. WEISS: Correct. But from the --

10 DR. BRADLEY: There's a differential of 4
11 percent. Again, it would be nice to have -- and it's not
12 really the sponsor's responsibility. It would be nice to
13 know, for example, if he just took a bunch of people, got
14 these symptoms, came back a month later, six months later,
15 got the symptoms again, how many of these would be
16 identical, and in the end, that's the dataset that we
17 really need to know because in the end, these data may be
18 no different than taking two measurements on a group of
19 people who've not had LASIK, and if that's the truth, then
20 one would draw the conclusion that LASIK has no effect
21 whatsoever on these symptoms, but without those data, we
22 can't really say this.

23 So I'm really nervous about making a lot of
24 these data without the full --

25 DR. WEISS: Dr. Owsley?

1 DR. OWSLEY: That's why you have to do the
2 questionnaires pre and post and that's such a very
3 important piece of information for any future studies in
4 this area.

5 DR. WEISS: Glenda, and then Alice.

6 DR. MATOBA: Alice Matoba.

7 But my question is still what --

8 DR. WEISS: Glenda, and then Alice. Glenda,
9 and then Alice.

10 MS. SUCH: I wanted to comment on the issue
11 that's being brought up over and over again and that is
12 that what we're looking at and what we're trying to figure
13 out and what was already passed and so on and so forth, and
14 I guess part of what I need to respond to as the consumer
15 advocate is this is the document that's being presented in
16 front of me as a consumer advocate on this FDA panel and
17 this is what I'm looking to give feedback on.

18 If this is what's being handed out, and I don't
19 have a copy of something that's being handed out with this,
20 I'm taking this as the replacement, and the replacement
21 needs to have feedback from us now on what we're seeing now
22 and where we are in time as far as what do patients want
23 now and what have we learned in the meantime, you know,
24 including anecdotal stories from people that have come and
25 given testimony or have written letters that we need to

1 have that in hand and the consumers have become much more
2 demanding about what's going to happen.

3 So in response to that, I think that expanding
4 on some of the information is only going to assist in
5 providing this information and benefiting the consumers,
6 and if you're looking at aspects of this where it talks
7 about some of the adverse reactions, again, as I had
8 mentioned earlier answering a question that had nothing
9 with it, and that was talking about some of the terminology
10 of some of the adverse reactions, they talk about dryness.
11 That doesn't sound like what I heard today. What I heard
12 today was somebody was talking about that they've got
13 chronic dry eye. They've got a lot of problems coming with
14 it. Saying that you have problems with driving at night
15 sounds, while it is a good example of an ADL problem, it is
16 not necessarily indicative of what's going on overall, you
17 know, that you've got a reduction in your ability to see at
18 night.

19 So those are the things that I think we are
20 encouraging that we expand upon, not things that are so far
21 in left field that we're talking about one case in eight
22 million, but the fact that we're being more clear so people
23 are making more informed decisions and it benefits you in
24 the long run.

25 DR. WEISS: So perhaps without the panel having

1 to make a final decision, would it be something that the
2 agency could pen in terms of inclusion about more of the
3 symptoms, loss of best-corrected visual acuity, and loss of
4 change of low contrast in visual acuity, or what you would
5 need from us, whether or not we want inclusion of the full
6 table?

7 MR. WHIPPLE: No, I believe we could pen it,
8 but what I want to explain to you is that you really need
9 to give us as much guidance as you can about what you
10 believe needs to be in this application's labeling and
11 don't necessarily let yourself be bound by all the
12 precedents, although some of the precedents are there. You
13 have the right to look at this application as a stand-alone
14 application and decide what you think you need to have in
15 that particular labeling.

16 DR. WEISS: We don't have to make any final
17 decisions now, but when we come down to the final vote, it
18 could be put forward as a motion and those in favor will
19 agree and those who are opposed will disagree and
20 conclusion can be drawn that way.

21 Mr. McCarley?

22 MR. MCCARLEY: Yes, just very quickly. This is
23 Rick McCarley.

24 One thing I would say is that if there are any
25 recommendations I think that the panel would make, in

1 general terms, regarding LASIK, I think it should be
2 separated and then consideration should be taken by the FDA
3 of how you're going to get that out to the rest of the
4 companies. This dry eye issue, as far as I know, isn't
5 inherent to this procedure that you're discussing today for
6 this application. So this is a new issue that's industry-
7 wide. I don't think this PMA application should be
8 burdened with having that as, you know, a portion of their
9 labeling while the other ones don't.

10 DR. WEISS: Dr. Bullimore?

11 DR. BULLIMORE: This is Dr. Bullimore.

12 I welcome the opportunity we have to set a
13 precedent, and I would also welcome the rest of the
14 industry being asked to update their patient and physician
15 information to reflect the current climate. So I mean, if
16 you feel that the industry wants to come back to the FDA
17 and update all of the physician and patient booklets, I
18 think the panel would be generally supportive of that
19 issue.

20 DR. WEISS: I can see them lining up.

21 (Laughter.)

22 DR. WEISS: Dr. Swanson?

23 DR. SWANSON: In terms of this patient booklet
24 but also in the spirit of changing it, under "What Are The
25 Benefits?," the table that we have says what the best-

1 uncorrected and corrected visual acuity are, but the piece
2 of information we got in the slides which isn't really in
3 here was comparison postop uncorrected with preop best
4 spectacle-corrected because what a person runs around
5 thinking the vision is is what I can see now, and the table
6 we got showed that half of the people after LASIK didn't
7 have as good of vision without glasses as they had with
8 glasses before, and so a person sees an ad where they throw
9 the glasses away or something, it'd be useful to
10 communicate to them what's the likelihood that you will be
11 able to see just as well without glasses, and what we saw
12 in the slides today was about half the people were able to
13 do that and the other half were worse and that's not in the
14 patient information booklet, and I don't think it has been
15 for other types of LASIK either.

16 DR. WEISS: Well, actually, I'm trying to --
17 page 9 in the patient information book has best-corrected
18 visual acuity, and it has without astigmatism 99 point --

19 DR. SWANSON: No, that's the postop best-
20 corrected.

21 DR. WEISS: I see.

22 DR. SWANSON: If you compare postop uncorrected
23 with preop best-corrected.

24 DR. WEISS: Well, then in that case, you're
25 sort of referring back to the suggestion that I had that

1 Table 10 be included because that talks about --

2 DR. SWANSON: Is that Table 10?

3 DR. WEISS: -- best-corrected visual acuity.
4 That's in the pink Insert 6. Perhaps too confusing, I
5 don't know.

6 DR. SWANSON: Not loss of best-corrected.

7 DR. WEISS: It has change in best-corrected,
8 best spectacle-correct visual acuity for Custom spherical
9 myopic LASIK eyes.

10 DR. SWANSON: Right. That's not what I'm
11 saying, though. Not change in best-corrected.

12 DR. WEISS: I'm not clear.

13 DR. SWANSON: Maybe I'm not clear. What page
14 is the table on?

15 DR. WEISS: It's Section 6, the pink section.

16 DR. SWANSON: It's 6, the pink section.

17 DR. WEISS: Pink section 6, and it's Table 10,
18 and it talks about, my assumption, preop best-corrected
19 spectacle acuity versus one month, three months, four
20 months, and six months, and the decrease of one, two or
21 more lines, the increase of one, two or more lines.

22 DR. SWANSON: But that's best spectacle-
23 corrected, both pre and post.

24 DR. WEISS: Correct.

25 DR. SWANSON: What I'm saying is in the slides

1 that we got, there was a comparison. The postop
2 uncorrected --

3 DR. WEISS: Oh, versus the preop?

4 DR. SWANSON: -- versus the preop best-
5 corrected, what happens is half of the people are not as
6 good after the surgery as they were with their glasses.
7 The question of whether or not they're going to want to
8 wear glasses or something, but that's really not
9 communicated to the person. What are the benefits? The
10 benefits are you have a 50-percent chance that without
11 glasses, you'll have as good acuity as you do now.

12 DR. WEISS: Dr. Bradley?

13 DR. BRADLEY: Yes, I think Dr. Swanson's point
14 is a very good one, and I recall from previous panel
15 meetings that we have required the FDA and the sponsor to
16 include statements of the form of a certain percentage
17 likely, a certain percentage of patients will require
18 spectacle correction after the procedure to achieve their
19 preop --

20 DR. WEISS: But here, I think the difficulty is
21 that if you look at the table in the patient information
22 book, I think there's a surplus of riches here because
23 you've got a 100 percent of nearsighted eyes -- I see what
24 you're saying -- uncorrected. Okay. Uncorrected, 20/20 or
25 better, with 80 percent.

1 DR. SWANSON: Yes. Maybe a table.

2 DR. WEISS: And that's in here. So the
3 question is -- okay. It shows the patient at six months,
4 91 percent are 20/25 or better and 80 percent are 20/20 or
5 better. So would you like, in addition to the fact,
6 pointing out that only half of the people, 50 to 60
7 percent, were actually as good as they were best-corrected?
8 Do you think that's needed, in addition to the fact of
9 saying that 99 percent are 20/40 or better?

10 DR. SWANSON: Yes, because if a person has
11 corrected to 20/15 and they're walking around with glasses
12 that way and you get them after LASIK to 20/25, they won't
13 be saying I got rid of my glasses because of surgery.

14 DR. WEISS: Is there discussion on that on the
15 panel? Do people want to add that information?

16 Dr. Bradley?

17 DR. BRADLEY: Yes, it may be something that
18 would be very important to patients and they get the sense
19 that LASIK is not as accurate as spectacle or contact lens
20 correction in the sense there is often residual myopia and
21 vision is not quite as good uncorrected as it is
22 pretreatment with a standard correction and really that's
23 what patients want. They want to throw away their glasses,
24 as Bill was saying, and therefore giving a sense of what --

25 DR. WEISS: Not quite yet, Dr. Swanson. After

1 the meeting.

2 DR. BRADLEY: But I think to give patients a
3 sense of how well they're going to do after the procedure
4 without glasses compared to how well they're doing
5 preprocedure with their glasses would be important
6 information, and in fact, I think it would be a very
7 valuable marketing tool really for the company providing
8 the device in that they could say, you know, 50 percent of
9 you will see as well without glasses after as you did with
10 glasses before and say 85 will see within one line, you
11 know. I think this is tremendous news to the myope, and I
12 think that's an effective marketing tool. I think it could
13 be a real positive.

14 DR. WEISS: So maybe we could just add a line
15 that your uncorrected visual acuity after this procedure
16 may not be as good as your vision with glasses.

17 DR. GRIMMETT: This is Mike Grimmett.

18 I'd probably say 50 percent of patients see as
19 well without glasses postop as they did with glasses preop.

20 DR. BRADLEY: Yes, I'd recommend putting the
21 data in. Put another little table in to show.

22 DR. GRIMMETT: That's fine.

23 DR. WEISS: Dr. Owsley?

24 DR. OWSLEY: Doesn't the sponsor provide this
25 information in a qualitative way on page 8 in the patient

1 handbook, information booklet?

2 DR. WEISS: It's not comparing you to what you
3 are with your glasses. It's telling you what the level of
4 visual acuity is, but let's say you were 20/10 with your
5 glasses.

6 DR. OWSLEY: Well, no. In the first paragraph
7 under Section D, it says, "Although some people still
8 needed glasses or contacts after surgery," and I think the
9 recommendation is we just need to quantify that.

10 DR. WEISS: So maybe just add that line there.

11 DR. OWSLEY: It would seem like it would go in
12 that section.

13 DR. WEISS: Okay. Section D, LASIK Correction
14 of Nearsightedness. Section D, page 9. I don't think we
15 have to use the line. I think the sentiment is there.

16 Dr. Swanson?

17 DR. SWANSON: Yes, and I'm sure that the FDA
18 can handle that, but someone who's 20/20 and could be 20/15
19 or 20/10 doesn't need glasses, and so that sentence about
20 who needs glasses is defined a little differently. See,
21 part of the issue is the patient expectation. The
22 patient's expecting I'm going to come here as good or
23 better than I was with glasses, they'll be more
24 disappointed than the patient that understands I'm likely
25 to be 20/20, I may or may not get up to as good as my

1 glasses. Then they have a more reasonable expectation.
2 They're not thinking they're going to get super-vision,
3 whereas this thing about the percentage who need glasses,
4 it depends how you define it. Somebody who's 20/20
5 probably doesn't need glasses.

6 DR. WEISS: I think that's a very good point,
7 Dr. Swanson.

8 Ms. Such?

9 MS. SUCH: Just a very, very non-technical way
10 at the very beginning of this patient information pamphlet
11 where you have some description, very, very lay terms, if
12 you could just add a sentence that would say who should get
13 this. It could say something like -- I'm sorry, not like.
14 It could say something as simple as if you would like to
15 have your glasses, you know, less strength to your glasses
16 or perhaps not need glasses at all, there's a procedure you
17 could consider. That way, it is laid out in the beginning
18 that there's a chance, rather than taking it from the other
19 end that if this doesn't work, you will, but work from a
20 positive endpoint. If you'd like to have a reduction in
21 the strength of your glasses or not need glasses at all,
22 you should consider this surgery.

23 DR. WEISS: Any other additions?

24 Mr. McCarley?

25 MR. MCCARLEY: Again, I'd just like to

1 reiterate, I think this sounds like general labeling that
2 would go to all companies, is that correct?

3 MR. WHIPPLE: All of this is good
4 recommendations for updating everybody's labeling, but
5 we're still trying to focus on this, the needs of this
6 particular application.

7 MR. MCCARLEY: Okay, and my second comment is,
8 if there are any numbers that are placed in there about,
9 you know, what a clinical study has shown as being the
10 number of patients that achieved 20/40 or 20/20 or 20/10, I
11 think it should be very -- you're almost going to have to
12 clarify that by saying what the objective was or using the
13 subgroup where you were trying to achieve emmetropia or
14 something. I mean, there are a lot of studies where the
15 objective, for instance, is not emmetropia, for instance,
16 monovision or something like that.

17 DR. WEISS: I don't believe there are any
18 monovisions that were included in this.

19 MR. MCCARLEY: I'm not specifically talking
20 about this study because it's a general recommendation.

21 DR. WEISS: Well, actually, right now, we're
22 just confining ourselves to recommendations for this study.
23 Whether the FDA chooses to broaden this is their
24 prerogative.

25 If there are no other comments, I'd like to

1 move on then to the FDA Closing Comments for five minutes
2 and then we'll move on to the sponsor. Wait. I guess I
3 don't want to move on. We have the Open Hearing Public
4 Session. Excuse me.

5 So are there any comments from the public? We
6 have a comment from the public. Mr. Link?

7 MR. LINK: Thank you.

8 Just three brief points.

9 MS. THORNTON: Could you identify yourself,
10 please?

11 MR. LINK: I'm Ron Link from Surgical Eyes.

12 Three brief points. Surgical Eyes recommends
13 as a condition of approval that clinical trials on
14 postrefractive eyes be attached to this PMA. Astigmatism
15 above .5 is already not part of the PMA because of efficacy
16 concerns at higher levels of astigmatism. Given the large
17 percentage of patients in a holding pattern after previous
18 refractive surgery with conditions even more complex than
19 simple cylinder, it is incumbent that the efficacy of this
20 wavefront device be monitored under controlled conditions
21 to prevent surgeries on patients who may not be helped and
22 are often limited by other factors, such as residual
23 corneal thickness.

24 The second point. I'm not really picking on
25 the sponsor here. This is something that was alluded to

1 through the course of these proceedings, that perhaps the
2 -- not perhaps. That in fact the labeling and patient
3 information booklets across all laser platforms need to be
4 updated. Referring specifically to the PMA in front of us
5 here, since the highest percentage of complaints in
6 postoperative dry eye, 32 percent as I remember in the much
7 worse to significantly worse category, it stands to reason
8 that these people had preexisting dry eye. It's like, you
9 know, an unexpected pregnancy. I mean, can you get more
10 unexpectedly pregnant? No. I mean, it seems to stand to
11 reason that they had preexisting dry eye.

12 Again, yet another point that this belongs in
13 the professional information and patient information
14 booklets which would then in fact also match the FDA's
15 website which states as a preoperative risk, dry eye, LASIK
16 surgery tends to aggravate this condition.

17 Thirdly, quoting the sponsor, the Zernike
18 coordinate system extends to the edge of the pupil.
19 Therefore, corneal maps of the Zernike-defined aberrations
20 change in pupil size. The FDA website warns under "When Is
21 LASIK Not for Me? Other Risk Factors," "Your doctor should
22 screen you for the following conditions or indicators of
23 risk: large pupils."

24 Surgical Eyes recommends an indication that
25 limits use to a 6.5mm pupil to match the ablation zone of

1 this device. We believe spherical aberrations translated
2 into patient language, night vision complaints, would be
3 lessened by such a limitation. We remain hopeful that
4 after further controlled study, that this device may in
5 fact be appropriate for postrefractive eyes.

6 Thank you.

7 DR. WEISS: Thank you, Mr. Link.

8 Now, I would ask for the FDA closing comments.

9 MR. WHIPPLE: I think the only thing I'd like
10 to say is that I think you can see from this discussion
11 that the labeling issues are really challenging and very
12 difficult, and I kind of think we knew that coming in here.
13 We wanted to let the discussion take its course without
14 interfering too much because we're going to need every bit
15 of guidance and every bit of direction that you can give
16 us, and I think you've done that today. You've given us
17 some pretty good boundaries, and you've given us some what
18 you can say and what you can't say direction, and I think
19 that will be very beneficial when we try to work out
20 labeling issues with the sponsor and it's going to be a
21 long time to try to address this with them. It's going to
22 be as difficult as it is here.

23 Thank you.

24 DR. WEISS: Thank you.

25 I actually just want to divert for one moment.

1 Dr. Grimmert asked me whether dry eyes was a
2 contraindication or precaution, and I don't see that.
3 Without going through the rest of the data here, if I could
4 just ask the sponsor whether this was part of the entry
5 criteria because you'll be coming up, if you can come up
6 for your closing comments in any case, and if you, as part
7 of those, can address that.

8 DR. PETTIT: With regard to the study, the dry
9 eye issue, if the patients had significant dry eye that
10 could not be controlled with drops and what have you, then
11 they were excluded from the study. I don't think we have a
12 specific contraindication in the label to that effect at
13 the present time.

14 DR. WEISS: So would that be listed in the body
15 of the study? Would I find that in the body of the study,
16 that the patients with significantly dry eye were excluded?

17 DR. PETTIT: It's actually in the protocol, and
18 we can find exactly where that is.

19 DR. WEISS: So it's in the protocol, but would
20 it be in the physician's book? Because I don't see it in
21 the physician's book.

22 DR. PETTIT: I don't know.

23 DR. WEISS: And I think Mr. Link's question
24 would be then addressed to why, if it was in the study, why
25 would it not be in the physician's book?

1 DR. PETTIT: It should be in the physician's
2 book.

3 DR. WEISS: So just addressing myself to the
4 panel and to Dr. Grimmett who's scribing for me so kindly,
5 maybe you can put that as an additional.

6 Dr. Matoba?

7 DR. MATOBA: Alice Matoba.

8 But again, that applies generically to all
9 LASIK, not to Custom ablation, and we should separate out
10 those things that we are recommending specifically for
11 Custom ablation and others that are going to apply to all
12 lasers and all LASIK.

13 DR. WEISS: But it is for this application. I
14 think we run into a little bit of a problem. The question
15 is if you want to improve things, are you prevented from
16 improving things because you haven't improved them before,
17 and it would still apply to this PMA, although perhaps it
18 should have applied to other PMAs in the last couple of
19 years. So we don't want to be too burdensome. On the
20 other hand, if we could make things better for patients and
21 doctors alike, we would like to.

22 So I'm going to defer to Mr. Whipple as to
23 whether we should withhold from making improvements because
24 it would be unfair to this manufacturer sponsor or whether
25 these improvements will actually improve the field and not

1 be too burdensome.

2 MR. WHIPPLE: I think you can make those
3 recommendations for approval and we'll deal with them as we
4 go through the labeling with the sponsor.

5 DR. WEISS: And any of those who disagree with
6 that on the panel, obviously when that motion comes
7 forward, you can disagree and vote it down, if you so
8 desire.

9 Dr. Burns? Sally, first.

10 MS. THORNTON: Are we continuing with the panel
11 discussion or are we doing --

12 DR. WEISS: No, actually, we're going to go the
13 FDA response. Excuse me.

14 DR. PETTIT: No problem.

15 Just on behalf of the sponsor, I'd like to
16 thank you for your thoughtful consideration of our
17 application, and we really have nothing else that we need
18 to say at this point.

19 DR. WEISS: Well, in that case, what we're
20 going to do is have the voting options read at this point.

21 MS. THORNTON: These are the panel
22 recommendation options for premarket approval application.

23 "The Medical Device Amendments to the Federal
24 Food, Drug, and Cosmetic Act, as amended by the Safe
25 Medical Devices Act of 1990, allows the Food and Drug

1 Administration to obtain a recommendation from an outside
2 expert advisory panel on designated medical device
3 premarket approval applications or PMAs that are filed with
4 the Agency.

5 "The PMA must stand on its own merits, and
6 your recommendation must be supported by safety and
7 effectiveness data in the application, or by applicable,
8 publicly available information. SAFETY is defined in the
9 Act as reasonable assurance, based on valid scientific
10 evidence, that the probable benefits to health under
11 conditions of intended use outweigh any probable risks.
12 EFFECTIVENESS is defined as reasonable assurance that in a
13 significant portion of the population, the use of the
14 device for its intended uses and conditions of use when
15 labeled will provide clinically significant results.

16 "Your recommendation options for the vote are
17 as follows:

18 "APPROVAL, if there are no conditions attached.

19 "APPROVABLE with conditions. The Panel may
20 recommend that the PMA be found approvable subject to
21 specified conditions, such as physician or patient
22 education, labeling changes, or further analysis of
23 existing data. Prior to voting, all of the conditions
24 should be discussed by the panel.

25 "The third option is NOT APPROVABLE. The Panel

1 may recommend that the PMA is not approvable if: the data
2 DO NOT provide reasonable assurance that the device is
3 safe, OR if a reasonable assurance HAS NOT been given that
4 the device is effective, under the conditions of use
5 prescribed, recommended, or suggested in the proposed
6 labeling.

7 "Following the voting, the Chair will ask each
8 panel member to present a brief statement outlining the
9 reasons for their vote."

10 Thank you, Dr. Weiss.

11 DR. WEISS: Thank you, Sally.

12 I would like to ask for a motion to be made
13 from the floor concerning this PMA.

14 Dr. Bullimore?

15 DR. BULLIMORE: Dr. Bullimore.

16 I move that the PMA is approvable with
17 conditions.

18 DR. WEISS: Do I have a second?

19 DR. SWANSON: Second.

20 DR. GRIMMETT: Second.

21 DR. WEISS: Dr. Swanson and Dr. Grimmett
22 second.

23 A motion has been made and seconded that this
24 is approvable with conditions. Then I would then ask for a
25 motion to be made to introduce each condition. We will

1 second those motions and then vote on those individual
2 motions before we vote on the initial PMA.

3 I think Dr. Grimmatt will list one by one the
4 motions that have already been introduced and perhaps
5 introduce them and then if anyone wants to second them and
6 then we can vote on those individually.

7 Dr. Grimmatt?

8 DR. GRIMMETT: Dr. Grimmatt.

9 Just for clarification, I'm making changes just
10 for labeling, is that correct?

11 DR. WEISS: And the other thing I think that we
12 will need to add as to whether these are labeling for
13 physician booklets or patient booklets or both. Sorry
14 about that. You didn't know it was dangerous to sit next
15 to me.

16 DR. GRIMMETT: Yikes.

17 Labeling Condition 1, I'm going to split it
18 into three parts. There's three different sentences. 1A,
19 a comment by Dr. Bradley. Wavefront-guided LASIK has
20 demonstrated a slightly superior optical quality (reduced
21 monochromatic aberrations) compared with conventional
22 LADARVision LASIK and minor improvements in the visual
23 acuity and contrast sensitivity relative to conventional
24 LADARVision LASIK.

25 DR. WEISS: Does anyone second that motion?

1 Dr. Bradley seconds that motion.

2 Can we have a vote on that motion? All of
3 those in favor, please raise your hands.

4 (Show of hands.)

5 DR. WEISS: Nine in favor.

6 All those opposed?

7 (No response.)

8 DR. WEISS: That's unanimous. Okay. Fine.

9 That motion passes.

10 DR. GRIMMETT: Okay. 1B, related, forwarded by
11 Dr. Bradley. The accuracy of the correction for myopia is
12 still the primary determination of uncorrected image
13 quality and vision. That's the corollary to the first one
14 we just approved.

15 Dr. Bradley's intent, just to describe, Dr.
16 Bradley's intent during the discussion was to make sure
17 that the patient knows that the spherical defocus is still
18 the primary component rather than the aberration statements
19 we just made regarding superior optical quality.

20 Let me read the statement again. 1B, the
21 accuracy of the correction for myopia is still the primary
22 determination of uncorrected image quality and vision.

23 DR. MATOBA: Second.

24 DR. WEISS: We have a second from Dr. Matoba.

25 Can we have a vote? All those in favor, raise

1 your hands.

2 (Show of hands.)

3 DR. WEISS: Nine. It's unanimous. The motion
4 passes.

5 The first two motions, are these for the
6 physician book, for the patient book, for both? So we stay
7 on track, maybe we could just repeat the first one,
8 determine retrospectively if it's for the patient or the
9 physician or both, and then from now on, then do it
10 prospectively.

11 DR. GRIMMETT: These were initially discussed
12 for the patient information booklet.

13 DR. BRADLEY: This is Bradley.

14 I think they should be in both because as we
15 discovered today, amongst the physicians, there's still
16 some confusion about the relative role of aberrations in
17 myopia.

18 DR. GRIMMETT: This is Dr. Grimmatt.

19 I agree with Dr. Bradley that it should be in
20 both. I submit that most of the issues that we raised are
21 actually probably going to be relevant for both.

22 DR. WEISS: So the first two will be in both,
23 and we will assume that all of them are for both physician
24 and the patient book, unless mentioned otherwise.

25 Motion Number 3.

1 DR. GRIMMETT: 1C, related by Dr. Owsley.
2 There are no data to support improved functional
3 performance (activities of daily living, such as reading or
4 driving) or satisfaction rates in patients with wavefront-
5 guided LASIK.

6 DR. WEISS: Do I have a second?

7 PARTICIPANT: Second.

8 DR. WEISS: We have some seconds. Can we have
9 -- we can't discuss it. Well, actually, yes, we can
10 discuss it at this point. So yes.

11 DR. BRADLEY: If I recall, there was a question
12 of the sponsor to provide those data.

13 DR. WEISS: We can put this in there as is and
14 then request that the sponsor provide the data and then the
15 FDA can change that statement on receipt of the data. If
16 it's contrary to that statement, we can make that request.

17 Dr. Swanson?

18 DR. SWANSON: I may not have heard that. It's
19 supposed to be relative to conventional LADAR. Does it say
20 that in there?

21 DR. GRIMMETT: I can add that.

22 DR. SWANSON: Because otherwise, it sounds like
23 there's no benefit. It hasn't been shown. There's got to
24 be some benefit of getting to zero.

25 DR. WEISS: So maybe the statement --

1 DR. OWSLEY: It's true for all of them.

2 DR. WEISS: When you recount it, maybe you can
3 reread it.

4 DR. GRIMMETT: Yes. It's true that it's
5 compared to conventional LADARVision LASIK for all 1A, 1B,
6 and 1C.

7 DR. WEISS: Well, maybe we can just, in ease
8 for Dr. Grimmatt, when we say conventional laser, maybe we
9 can have the FDA understand for all of the time we say
10 conventional laser, we mean conventional LADARVision.

11 DR. GRIMMETT: Correct.

12 DR. WEISS: So that gets added, if it's not
13 stated that way up front.

14 DR. GRIMMETT: Right. So just to reread, to
15 summarize 1C, there are no data that support improved
16 functional performance (activities of daily living, such as
17 reading or driving) or satisfaction rates.

18 MS. THORNTON: Mike.

19 DR. WEISS: Speak into the mike.

20 DR. GRIMMETT: In patients with wavefront-
21 guided LASIK compared to conventional LADARVision LASIK.

22 DR. WEISS: Second, do I have?

23 DR. HUANG: Second.

24 DR. WEISS: We have Dr. Huang seconds.

25 Can we have a vote? All those in favor, raise

1 your hands.

2 (Show of hands.)

3 DR. WEISS: All those opposed?

4 (No response.)

5 DR. WEISS: So it's unanimous.

6 DR. GRIMMETT: Michael Grimmett, again.

7 Labeling Recommendation, related by Dr.

8 Bradley. Add a statement regarding that there is a small

9 number of eyes above 6 diopters.

10 DR. WEISS: Is there a way to rephrase that?

11 DR. GRIMMETT: Dr. Bradley?

12 DR. WEISS: Dr. Bradley?

13 DR. BRADLEY: The small number was one the way

14 I saw it.

15 DR. GRIMMETT: There you go.

16 DR. BRADLEY: But I saw the sponsor checking

17 that. Obviously they know the exact numbers, but I think

18 if the answer really is one, then we should say one.

19 DR. WEISS: Only one eye was treated above.

20 DR. BRADLEY: Between 6 and 7, I think there

21 was one. There was one above 7, I believe.

22 DR. WEISS: Well, you know what? I'm sure the

23 FDA can look it up for us with the help of the sponsor. So

24 we don't have to determine the number now. Whatever that

25 exact number was can be put into that phrase. So X number

1 of eyes were treated.

2 DR. GRIMMETT: Above.

3 DR. WEISS: Above -6.

4 DR. GRIMMETT: Six, with the intent that the
5 strength of the data tapers off for higher myopic ranges.
6 That's the intent for labeling recommendation.

7 DR. WEISS: But the phrase is just to list the
8 number of eyes that were treated above -6.

9 Dr. Matoba?

10 DR. MATOBA: I think Dr. Eydelman stated that
11 the FDA has a standard statement about the fact that there
12 may be fewer numbers for the higher ranges.

13 DR. WEISS: Mr. Whipple?

14 DR. MATOBA: So I'm not sure it's necessary to
15 do that.

16 MR. WHIPPLE: We do have statements like that,
17 and we take what Dr. Grimmert is saying as guidance, and
18 we'll pretty much use the same language we've always used.

19 DR. WEISS: So can that be restated? If you
20 can restate that so we can get a second so we can vote on
21 it?

22 DR. GRIMMETT: Statement. Michael Grimmert.

23 In the study, there were X number of eyes above
24 6 diopters spherical refractive error.

25 DR. WEISS: Do I have a second? Dr. Bradley

1 seconds. Vote? Those in favor, raise your hands.

2 (Show of hands.)

3 DR. WEISS: We have seven in favor and four
4 against.

5 MS. THORNTON: Dr. Matoba and Dr. Huang are
6 against.

7 DR. WEISS: Two against. Seven in favor, two
8 against. I think, Dr. Bradley, if you want to make an
9 amendment to that, you could make an amendment at this
10 point.

11 DR. BRADLEY: It's a very short amendment.

12 DR. WEISS: A shorter or long one can be made.
13 Well, not too long but an amendment can be made.

14 DR. BRADLEY: The statement that we had voted
15 on is that there were X number of dah, dah, dah. I think
16 for the patient, it should be perhaps stated there are only
17 X number, indicating the point of giving them that number
18 is that it's a very small number. The physician will
19 understand this but the patient might not.

20 DR. WEISS: So as I understand, you would like
21 to add the word "only" to that?

22 DR. BRADLEY: Correct.

23 DR. WEISS: For the patient booklet
24 specifically or for both booklets?

25 DR. BRADLEY: Specifically the patient.

1 DR. WEISS: Specifically the patient booklet,
2 add the word "only." Is there a second? Second. Can we
3 have a vote? All in favor?

4 (Show of hands.)

5 MS. THORNTON: Eight.

6 DR. WEISS: Eight in favor. Can we have
7 against?

8 (Show of hands.)

9 MS. THORNTON: Dr. Matoba is against.

10 DR. WEISS: One against. Motion passes.

11 DR. GRIMMETT: Dr. Grimmatt again.

12 This is a consensus statement. Conventional
13 LADARVision LASIK increases higher-order aberrations
14 approximately 77 percent, whatever the correct figure is,
15 77 percent over preoperative levels while wavefront-guided
16 LASIK increases higher-order aberrations approximately 20
17 percent over preop levels. I would caution those numbers
18 need to be verified by the data.

19 DR. WEISS: Do I have a second? Dr. Bradley,
20 Dr. Huang seconds. We will vote. All in favor?

21 (Show of hands.)

22 DR. WEISS: Eight for. Can we have those
23 against?

24 (No response.)

25 DR. WEISS: And then we have those abstaining?

1 (Show of hands.)

2 DR. WEISS: One abstention.

3 MS. THORNTON: Eight for and one abstention.

4 Dr. Matoba abstains.

5 DR. WEISS: The motion passes.

6 DR. GRIMMETT: Dr. Grimmatt.

7 Statement forwarded by Dr. Huang in his
8 presentation. There are no retreatment data available.

9 DR. WEISS: Do I have a second?

10 DR. GRIMMETT: I second.

11 DR. WEISS: I don't think you can second
12 yourself. Dr. Owsley seconds. Can we have a vote? All in
13 favor?

14 (Show of hands.)

15 MS. THORNTON: It's unanimous.

16 DR. WEISS: It's unanimous. It passes.

17 DR. GRIMMETT: Dr. Grimmatt again.

18 Forwarded by Dr. Weiss. Include a statement
19 that the population is primarily Caucasian, Part A, and
20 Part B was include the demographic data, which I think Dr.
21 Eydelman stated is customary in applications.

22 DR. WEISS: Do we have a second? Dr. Bandeen-
23 Roche seconds. Dr. Bandeen-Roche has a comment.

24 DR. BANDEEN-ROCHE: A possible amendment.

25 DR. WEISS: Actually, yes, you can have a

1 comment now.

2 DR. BANDEEN-ROCHE: Yes, a possible amendment
3 would be that --

4 DR. WEISS: You don't have to amend now. You
5 can ask the maker of the motion if he wants to change it.

6 DR. WEISS: Maker of the motion, may it be
7 changed to include individuals 65 and older? It seems to
8 me if we're going to mention African Americans, that older
9 people are equally relevant.

10 DR. WEISS: Were there any people 65 or older?

11 DR. BANDEEN-ROCHE: There were not.

12 DR. GRIMMETT: So you would like to, just for
13 clarification, add a thing of the population is primarily
14 Caucasian and younger than 65 years of age?

15 DR. WEISS: Do I hear a second? Dr. Bandeen-
16 Roche seconds. We can vote on this revised motion.

17 Yes?

18 DR. BRADLEY: Again, I'm not recalling the age
19 distribution, but I don't --

20 PARTICIPANT: Thirty-five.

21 DR. BRADLEY: Thirty-eight. Was there anybody
22 over 55?

23 DR. BANDEEN-ROCHE: To 64, I believe.

24 DR. BRADLEY: Okay.

25 DR. WEISS: What we can do for clarification,

1 I'm sure the agency can look at the highest age and say
2 that there was no one above that highest age, whatever it
3 was. So that could be altered, but in any case, the
4 revised motion would include both age and race.

5 So we did have a second of that motion. We
6 will have a vote. All in favor, raise your hands.

7 (Show of hands.)

8 DR. WEISS: It's unanimous. It passes.

9 Yes, Dr. Grimmett?

10 DR. GRIMMETT: Dr. Grimmett again.

11 I have six labeling recommendations forwarded
12 by Dr. Weiss. Number 1. She pointed out in the patient
13 information booklet a D2 which stated that a statement that
14 vision was stable two weeks after surgery should be changed
15 to reflect the actual data which was put forth as one month
16 after surgery.

17 DR. WEISS: Do we have a second? Second by Dr.
18 Owsley and Dr. Matoba. Do we have a vote? All in favor,
19 raise your hands.

20 (Show of hands.)

21 DR. WEISS: We have nine. It's unanimous. It
22 passes.

23 DR. GRIMMETT: -Number 2 from Dr. Weiss. There
24 was a chart --

25 MS. THORNTON: Excuse me. Is this 6A, 6B? Are

1 we doing 6, 7, 8?

2 DR. GRIMMETT: Sure. Well, they're all
3 separate issues. They're not related.

4 MS. THORNTON: Thank you.

5 DR. GRIMMETT: Sure. I've lost count. Dr.
6 Grimmatt again.

7 There was a chart on page 9 at the top that
8 listed a statement on visual acuity. Dr. Weiss would like
9 it clarified to say that best-corrected visual acuity,
10 implying that it was visual acuity with glasses, for
11 clarification.

12 DR. WEISS: Do we have a second? Dr. Bradley
13 seconds. Vote? All in favor?

14 (Show of hands.)

15 DR. WEISS: We have nine. It's unanimous.

16 DR. GRIMMETT: Dr. Grimmatt again.

17 Include full Table 35 which included, I
18 believe, all the symptom data for the intent of including
19 both the worse and significantly worse categories but for
20 balance including the whole table. So symptom data in the
21 labeling.

22 DR. WEISS: Do I have a second? Dr. Bandeen-
23 Roche. Can we have a vote? All in favor, raise your
24 hands.

25 (Show of hands.)

1 DR. WEISS: Unanimous. That passes.

2 DR. GRIMMETT: Dr. Grimmitt again.

3 A recommendation to add the entire Table 10
4 regarding the gain versus loss of best-corrected visual
5 acuity.

6 DR. WEISS: Do I have a second? Dr. Bullimore
7 seconds. All in favor, raise your hands.

8 (Show of hands.)

9 MS. THORNTON: Eight for.

10 DR. WEISS: Eight for, one against. Motion
11 passes.

12 MS. THORNTON: Was that an against or an
13 abstention? Okay. Dr. Huang is against.

14 DR. GRIMMETT: There's a recommendation to add
15 Table 13 regarding information on low contrast best-
16 corrected visual acuity. I would just make a suggestion
17 here. I'm not sure if it would differ to panel members to
18 add that differently to the patient versus the physician
19 booklet.

20 DR. WEISS: How would you like to --

21 DR. GRIMMETT: Personally, I think it would
22 mean more to physicians in the physician book, but I don't
23 know that patients would understand too much information on
24 contrast stuff.

25 DR. MAGUIRE: I second that.

1 DR. GRIMMETT: We can try it both ways.

2 DR. MAGUIRE: I second that for inclusion only
3 in the physician booklet.

4 DR. WEISS: Okay. So I see consensus for that.

5 DR. GRIMMETT: We can vote both ways, if
6 necessary, but let's start out with that information on low
7 contrast visual acuity in the physician information
8 booklet.

9 DR. WEISS: I see a second. We'll have a vote.
10 All in favor, raise your hands.

11 (Show of hands.)

12 DR. GRIMMETT: One clarification. We're making
13 sure the table I quoted was correct.

14 DR. WEISS: What table was it?

15 MS. THORNTON: Table 13?

16 DR. WEISS: 13.

17 PARTICIPANT: Can we just get a chance to look
18 at it?

19 DR. GRIMMETT: Let's have everybody look at
20 Table 13, Tab 8.

21 DR. WEISS: Has everyone found Table 13?

22 DR. BULLIMORE: Yes, but I thought we wanted --

23 DR. WEISS: I think Table 13 was under the pink
24 Index 6, was that not?

25 PARTICIPANT: It's under Tab 6.

1 DR. WEISS: Tab 6? Well, I have a Tab 6 and a
2 Table 13 on Section 6, page 20 out of 56, which has Change
3 in Low Contrast Best Spectacle-Corrected Visual Acuity.

4 DR. BULLIMORE: This is Mark Bullimore.

5 The one we discussed before was Tab 6, Table
6 13, on page 20.

7 DR. WEISS: Yes, which is what I just
8 mentioned. Is there another table that is identical? Tab
9 8, Table 13. Here's my Tab 6, Table 13. There's your Tab
10 A, if it's the same.

11 DR. BULLIMORE: No. No. Mark Bullimore.

12 Table 13 on Tab 6 is the Change in Low Contrast
13 Visual Acuity. They're different cohorts, basically.

14 PARTICIPANT: They're both Table 13 but
15 different cohorts.

16 DR. BULLIMORE: Different cohorts. Tab 6 was
17 the Efficacy Eyes Tab. Tab 8 was the Safety Eyes.

18 DR. WEISS: So which is the one we would want
19 for inclusion? Tab 6, Table 13. So Tab 6, Table 13, the
20 motion has been read by Dr. Grimmett and has been seconded
21 for inclusion of this table in the physician's booklet.

22 If we're all clear, we -- Dr. Bradley?

23 DR. BRADLEY: Just to iterate the point I made
24 earlier with these tables, if we knew in a non-LASIK
25 population, if we took these datasets twice, six months

1 apart or three months apart, and found the same basic
2 distribution, these tables could be removed and a simple
3 statement that there is no evidence that low contrast
4 acuity changes.

5 DR. WEISS: We can ask, if you'd like, the
6 sponsor.

7 DR. BRADLEY: Well, that was a comment to the
8 FDA in future studies to try and collect some control data
9 of this type over time and that might eliminate this
10 complication that we have because it's quite difficult to
11 interpret a table like this.

12 MR. WHIPPLE: Well, I believe the sponsor can
13 do those kind of studies and submit, you know, additional
14 data thus and have it removed at any time passed the
15 approval.

16 DR. WEISS: The other thing that could be done
17 is instead of including the table, it can be indicated
18 there is a loss of low contrast best spectacle-corrected
19 visual acuity.

20 DR. BULLIMORE: Madam Chairman, I believe
21 there's a motion on the table. Call for the question.

22 DR. WEISS: Well, I think it hasn't been voted
23 on and hasn't been restated by me. So I think it still can
24 get changed, if anyone wants to change it, before I restate
25 it.

1 DR. BULLIMORE: Okay. I'm just trying to move
2 things along.

3 DR. WEISS: It's gone beyond that. It's too
4 late. But it doesn't sound like anyone wants to change
5 that. So if no one wants to change that, and we have a
6 second, we can go ahead with a vote. I'll restate it and
7 I'll ask for the vote and all of those in favor of that,
8 including this table in the physician's booklet, raise
9 their hands.

10 (Show of hands.)

11 DR. WEISS: So it unanimously passes.

12 Any other motions?

13 DR. GRIMMETT: Dr. Grimmitt.

14 Dr. Swanson wanted a statement regarding data
15 that 50 percent of patients see as well without glasses
16 postoperatively as compared to their best-corrected visual
17 acuity preop and/or we can include a table of information
18 regarding that patients want to know what their uncorrected
19 visual acuity will be postop as compared to what their best
20 vision was preop with glasses.

21 DR. WEISS: Do you want to have that motion to
22 include the table?

23 DR. GRIMMETT: I'd have to have a specific to
24 show me the table. I need to see the table. Does someone
25 know what that is?

1 PARTICIPANT: It's in a slide.

2 PARTICIPANT: Page 21.

3 DR. GRIMMETT: We're being directed to page 21
4 of the slides.

5 DR. WEISS: Here it is. The table name is on
6 page 21, bottom slide, Slide Number 139 from the sponsor,
7 "Postop Uncorrected Visual Acuity Versus Preop Best
8 Spectacle-Corrected Visual Acuity" which is at one month,
9 59 percent have it equal, three months 55.4 percent, at six
10 months 52.5 percent.

11 So the motion as it stands is to include the
12 table?

13 DR. GRIMMETT: I'd include the table.

14 DR. WEISS: Okay. So if you could restate the
15 motion and then we'll see if we have a second, then we can
16 vote.

17 DR. GRIMMETT: Include a table as on page 21 of
18 the sponsor's slide presentation entitled "Postop
19 Uncorrected Visual Acuity Versus Preop Best-Corrected
20 Visual Acuity."

21 DR. WEISS: Okay. Do we have a second?

22 DR. SWANSON: Second.

23 DR. WEISS: Dr. Swanson seconds. Can we have a
24 vote? All in favor?

25 (Show of hands.)

1 MS. THORNTON: Can you raise your hands a
2 little higher, please? Eight for.

3 DR. WEISS: Can we have those against?
4 (Show of hands.)

5 MS. THORNTON: Dr. Bullimore is against.

6 DR. BULLIMORE: Against.

7 DR. WEISS: Against. One against, eight for.
8 The motion passes.

9 Any other motions?

10 DR. GRIMMETT: Yes, one more labeling issue.
11 One more labeling issue and then I have two more issues for
12 requesting data from the sponsor, and then Dr. Bradley has
13 a few labeling issues.

14 The one more labeling issue on my list from Dr.
15 Weiss concerns dry eye patients and exclusion criteria in
16 physician labeling to match the protocol criteria. Make a
17 statement relative to that issue.

18 DR. WEISS: And if it was going to be added to
19 the physician booklet, I would add it to the patient
20 booklet as well just to map exactly what was in the
21 exclusion criteria of the study itself.

22 Do we have a second? Dr. Owsley seconds. Do
23 we have a vote? All in favor?

24 (Show of hands.)

25 DR. WEISS: It unanimously passes.

1 DR. GRIMMETT: Now, two requests. Is this
2 request for data a separate labeling issue?

3 MS. THORNTON: Let's put all the labeling
4 together.

5 DR. GRIMMETT: Labelings together.

6 DR. WEISS: We'll do labeling and Dr. Bradley,
7 I guess, will continue and then if we have a request for
8 information, does that get voted on? It will get voted on
9 at the end probably.

10 Dr. Bradley?

11 DR. BRADLEY: At several times today, there was
12 a request that the patient information and certainly the
13 physician information include the contraindications of dry
14 eye and large nighttime pupils. I wondered if that could
15 be a motion.

16 DR. BULLIMORE: I'd make a motion, if you like.

17 DR. BRADLEY: Please do.

18 DR. BULLIMORE: This is Dr. Bullimore.

19 Postoperative status -- let me start again.
20 You try it. I want to capture the spirit of something
21 along the lines of poor patient satisfaction may be
22 associated with dry eye or large pupils and care should be
23 taken to screen patients prior to the procedure for these
24 predisposing factors.

25 DR. BRADLEY: I think screen and educate

1 patients.

2 DR. BULLIMORE: I don't like the word "screen."

3 DR. OWSLEY: It should be preoperative dry eye
4 and large pupils.

5 DR. WEISS: That was Cynthia. Dr. Grimmett
6 just brought up a point. Does that specifically follow
7 from the data in this study?

8 DR. BULLIMORE: I don't care.

9 DR. WEISS: Okay. Be that way.
10 Any discussion on that particular point?

11 DR. BRADLEY: Yes. I don't think it's an issue
12 necessarily for the data in the study, but the issue has
13 been raised today and I think everybody seems to agree
14 that, sure, perhaps you shouldn't do this procedure on
15 somebody with dry eye. It's just going to get worse, and
16 there are these sort of ill-defined but widely held
17 concerns that patients with large pupils may have some
18 problems, and as I think somebody pointed out earlier
19 today, this information is not adequately communicated to
20 the patient. So the intent that I had with this suggestion
21 is that the patient be alerted to these problems and also
22 make sure the physician is alerted and perhaps the patient
23 and the physician can discuss this.

24 DR. WEISS: But when you say large pupils,
25 would you want to be more specific? Larger than the

1 ablation zone or do you want to keep it at that? Keep it
2 broad?

3 DR. BULLIMORE: I'd keep it broad.

4 DR. WEISS: So can you restate that and then
5 maybe we can have a second? Can you just restate what
6 your --

7 DR. BULLIMORE: What did I say originally,
8 Michael?

9 DR. GRIMMETT: I wasn't transcribing.

10 DR. BRADLEY: The preexisting dry eye condition
11 and large nighttime pupils --

12 PARTICIPANT: And/or.

13 DR. BRADLEY: And/or large nighttime pupils may
14 decrease your satisfaction with the LASIK procedure and you
15 should discuss this issue with your physician.

16 DR. BULLIMORE: I second.

17 DR. WEISS: Second. Can we have a vote? All
18 those in favor, please raise your hands.

19 (Show of hands.)

20 DR. WEISS: Nine in favor. It's unanimous.

21 That passes.

22 Dr. Bradley, did you have another motion?

23 DR. BRADLEY: No, that was it.

24 DR. WEISS: That was the end of Dr. Bradley's
25 motions.

1 Dr. Bullimore?

2 DR. BULLIMORE: This may not fly, but I'd like
3 also in the patient information booklet to refer the
4 patient to the FDA's LASIK website.

5 DR. WEISS: Do I have a second for that? I
6 have a second. Mr. Whipple seconds. But I have Dr.
7 Swanson second officially, I guess. Can we have a vote?
8 All in favor, please raise your hands.

9 (Show of hands.)

10 MS. THORNTON: I have five/four.

11 DR. WEISS: We have five in favor. Can I have
12 all of those against?

13 (Show of hands.)

14 DR. WEISS: We have three against. All those
15 abstaining?

16 DR. BRADLEY: I didn't hear what Mark said.

17 DR. BULLIMORE: It's not the first time.

18 DR. WEISS: The motion will be restated.

19 DR. BULLIMORE: The motion was that the patient
20 labeling refer the patient to the FDA's LASIK website.

21 DR. WEISS: So Dr. Bullimore wants to refer
22 patients to the FDA website in the patient labeling.

23 DR. OWSLEY: Can I make a comment?

24 DR. WEISS: No, you can make a comment.

25 DR. OWSLEY: Well, the language maybe. It's

1 not a bad concept, but to refer them, I mean, they should
2 be talking to the physicians about their care. So perhaps
3 if they want more information, they could check out the FDA
4 website.

5 DR. BULLIMORE: I accept that friendly
6 amendment. This is Dr. Bullimore again. I accept Dr.
7 Owsley's friendly amendment.

8 DR. WEISS: So for more information, you can
9 refer to the FDA website.

10 DR. BULLIMORE: Consult.

11 DR. WEISS: You can consult the FDA website.

12 DR. BULLIMORE: Consult the FDA website.

13 DR. WEISS: Do we have a second?

14 DR. SWANSON: Second.

15 DR. WEISS: Second by Dr. Swanson. Do we have
16 a vote? All in favor?

17 (Show of hands.)

18 MS. THORNTON: Five.

19 DR. WEISS: Five.

20 DR. BULLIMORE: Six.

21 DR. WEISS: Six in favor. Those against?

22 (Show of hands.)

23 DR. WEISS: Three against. The motion passes.

24 If there are no other motions, then Dr.

25 Grimmatt will proceed with requests for information. We'll

1 vote on that.

2 DR. GRIMMETT: Dr. Grimmatt.

3 There's a request for the manufacturer to
4 submit the data for the 19 conventional versus wavefront-
5 guided eyes regarding symptom and satisfaction data.

6 DR. WEISS: Do I have a second to that?

7 DR. GRIMMETT: That should be put in the
8 labeling, if indeed it's available.

9 DR. WEISS: Do I have a second for that? Was
10 that a weak second?

11 DR. BULLIMORE: I was waving to Dr. Bradley.

12 DR. WEISS: You'll second. Thank you, Dr.
13 Bradley. You were pointing to Dr. Bradley? Okay. Dr.
14 Bradley seconds. Can I have a vote? All in favor?

15 (Show of hands.)

16 MS. THORNTON: Five in favor.

17 DR. WEISS: Five in favor. All those against?

18 (Show of hands.)

19 MS. THORNTON: Dr. Huang is against.

20 DR. BULLIMORE: Maguire.

21 MS. THORNTON: Dr. Maguire.

22 DR. WEISS: Two against, and those abstaining?
23 Dr. Bandeen.

24 MS. THORNTON: Dr. Swanson abstains.

25 DR. WEISS: And Dr. Bandeen-Roche abstains.

1 MS. THORNTON: And Dr. Bandeen-Roche.

2 DR. WEISS: So the motion passes.

3 If there are no further motions, Dr. Bandeen-
4 Roche?

5 DR. BANDEEN-ROCHE: We discussed a number of
6 analyses that the sponsor should submit or FDA should look
7 at. Is that something we should vote on?

8 DR. WEISS: If there is further information
9 that you want, yes, it could be put forward as a motion,
10 but you need to specify whether it's data that is already
11 obtained and they just need to crunch the numbers and give
12 it to FDA or you're talking about anything postmarket.

13 DR. BANDEEN-ROCHE: Well, then I do move that a
14 matched analysis be done with respect to comparing the
15 conventional and the Custom eyes and that the site-to-site
16 variability be examined. The FDA statisticians, I think,
17 will be able to interpret that data appropriately and the
18 ramifications are biased in the first instance and not
19 correctly stating the strength of evidence in terms of P
20 values and confidence intervals in the latter case.

21 DR. WEISS: Do I have a second for that? Dr.
22 Owsley and Dr. Bradley second that.

23 DR. GRIMMETT: Dr. Grimmett here.

24 Can you define how much data? Define again
25 what you're asking for.

1 DR. BANDEEN-ROCHE: So the first thing I'm
2 asking for is a matched pair analysis of conventional and
3 Custom eyes, and so that would presumably be as many to one
4 matches as can be obtained within reasonable matching
5 specifications that I'm not capable of stating but I've
6 heard pupil size.

7 DR. WEISS: The problem is we only have 19
8 eyes.

9 DR. BANDEEN-ROCHE: No, no, no, no. This is
10 not within --

11 DR. WEISS: Oh, I see. Not within the --

12 DR. BANDEEN-ROCHE: -- the provider by timing.
13 I mean, we discussed this earlier in the transcript.

14 DR. WEISS: Dr. Matoba?

15 DR. MATOBA: But the most number of pairs they
16 can give you is 50, right, because 50 were conventionally
17 treated?

18 DR. BANDEEN-ROCHE: There could be multi-to-one
19 match, and so, you know, if there are more than one patient
20 that appropriately matched to a given conventional, that
21 could be done.

22 PARTICIPANT: Question?

23 DR. WEISS: Mr. McCarley, and then Dr. Bradley.

24 MR. MCCARLEY: Yes. I mean, when the data is
25 submitted to the FDA, then what? That's my question. If

1 it doesn't meet something, then it comes back to the panel
2 or -- I mean, the recommendation is for approval, I think.

3 DR. BANDEEN-ROCHE: Well, it's approvable with
4 conditions, and so if you observed that analysis and saw
5 that in fact the difference between Custom and conventional
6 eyes with respect to aberrations was substantially reduced,
7 then that would suggest that there was bias in the cohorts
8 at work and that you might not want to strongly state there
9 is evidence that this procedure improves, if superior with
10 respect to aberrations. I don't expect that that will be
11 the outcome.

12 DR. WEISS: Dr. Matoba?

13 DR. MATOBA: I'm not sure if this information
14 would change our assessment of safety or efficacy.

15 DR. SWANSON: But it would change --

16 DR. WEISS: Dr. Swanson?

17 DR. SWANSON: Sorry. It would change one of
18 our motions. We voted to put a statement in there that it
19 was better in terms of the optical quality was better, and
20 I think if this reanalysis showed it wasn't, we withdraw
21 that sentence we wanted to add. So I think that's why it's
22 relevant, because we've said we want to add a statement and
23 if the analysis came out differently, we wouldn't want to
24 add that statement.

25 DR. BANDEEN-ROCHE: That's right.

1 DR. WEISS: Dr. Bradley, and then Dr.
2 Bullimore, and then we can go back. Dr. Bradley?

3 DR. BRADLEY: I think it's typical when you do
4 a matched design like this, it's a means of extracting
5 other sources of data from your effect, and it usually
6 results in a more significant result. So that's a likely
7 outcome, but it may not.

8 DR. BANDEEN-ROCHE: Right. I agree with that
9 statement.

10 DR. WEISS: Dr. Matoba?

11 DR. MATOBA: Is it possible to get input from
12 the statisticians at the FDA as to if this is a significant
13 issue, why it was not dealt with before?

14 DR. WEISS: Dr. Eydelman or anyone else from
15 the agency, do you have a comment? Mr. Whipple?

16 MR. WHIPPLE: I think you should just make your
17 recommendation. You know, discuss it and make your
18 recommendation, and we'll deal with it.

19 DR. WEISS: Okay. I think it might be helpful,
20 Dr. Bandeen-Roche, if perhaps you put each of those into a
21 separate motion that we can vote on rather than lumping
22 them. So if you could just put into the motion the first
23 thing you had and we can second it and have a vote and then
24 continue on on those couple of things that you'd like.

25 DR. BANDEEN-ROCHE: So the first motion would

1 be for sponsor to submit a matched analysis comparing
2 aberrations in conventional and Custom eyes.

3 DR. WEISS: Do we have a second? Dr. Owsley
4 and Dr. Bradley second.

5 Dr. Bullimore?

6 DR. BULLIMORE: Dr. Bullimore.

7 Friendly amendment. These patients can be
8 matched for refractive error, preoperative aberrations, or
9 both.

10 DR. WEISS: Do you accept that, Dr. Bandeen-
11 Roche?

12 DR. BANDEEN-ROCHE: Absolutely.

13 DR. WEISS: If there are no other discussion
14 about this, we'll have a vote. All those in favor, raise
15 your hands.

16 (Show of hands.)

17 DR. WEISS: Nine. It's unanimous. That
18 passes.

19 Dr. Bandeen-Roche?

20 DR. BANDEEN-ROCHE: And the second motion is
21 for there to be a presentation of site-to-site variability
22 in the aberration outcomes, the reason being that there was
23 no accounting for correlation within sites. If there's
24 substantial site-to-site variability, then confidence
25 intervals, P values, et cetera, are totally invalid as

1 reported.

2 DR. WEISS: Do I have a second for this? Dr.
3 Bradley. We'll have a vote. All in favor, please raise
4 your hands.

5 (Show of hands.)

6 MS. THORNTON: Three on this side. Seven and
7 four.

8 DR. WEISS: Seven in favor. Can we have those
9 against raise your hands?

10 (Show of hands.)

11 DR. WEISS: Dr. Bullimore is against.

12 MS. THORNTON: Dr. Huang is against.

13 DR. WEISS: Dr. Huang is against. Two against.

14 The motion passes.

15 Dr. Bandeen-Roche, that's the end of the
16 motions.

17 Does anyone else have any other motions?

18 DR. BRADLEY: Jayne?

19 DR. WEISS: Dr. Bradley?

20 DR. BRADLEY: As I raised in the correlational
21 analysis in my presentation, I'm not convinced that the
22 sponsor has demonstrated that they are able to correct
23 inherent aberrations, monochromatic aberrations of the eye,
24 and although often implied in the text of the patient and
25 physician information, it is certainly there the indication

1 that they are able to make these corrections, and I do
2 believe that the sponsor is required to demonstrate that
3 they have corrected the inherent aberrations of each
4 individual eye, and I believe it's possible to do with the
5 correlational analysis, and I would defer to the
6 statistician on whether that is possible, but I think in
7 order to make those sorts of claims, you have to
8 demonstrate that you've done it.

9 DR. WEISS: Would you be able to comment as far
10 as any other data that would be able to support this? Dr.
11 Bandeen-Roche?

12 DR. BANDEEN-ROCHE: My answer would be that it
13 should be possible. I have to admit that my mind was
14 elsewhere during half of the comment, but I am confident
15 that a careful analysis can be designed. I would not be
16 confident in being able to state the best analysis in two
17 minutes off the cuff. I think it's something that should
18 be considered quite carefully.

19 DR. WEISS: Would there be anyone from the
20 agency who would be able to help with this as far as any
21 other data that would satisfy this question?

22 DR. BRADLEY: Let's clarify.

23 This is not an optics question really. It's a
24 statistics question and maybe a motion could be for the FDA
25 to, with sponsor, to examine the validity of the claim that

1 the CustomCornea procedure is able to correct the higher-
2 order monochromatic aberrations of the eye.

3 MR. WHIPPLE: As I see this, you're in the
4 middle of making your recommendations, and I'm afraid if we
5 bring some more people into this right now for your --

6 DR. WEISS: It would confuse things.

7 MR. WHIPPLE: Right. And so I would just
8 rather you just make your recommendations and if it's
9 stated as you said, that would be an appropriate
10 recommendation for us to look at.

11 DR. WEISS: If you want to make that
12 recommendation, we can put it forward as a motion.

13 DR. BRADLEY: That would be my motion.

14 DR. WEISS: Do you want to restate that motion
15 so someone can scribe it, namely my loyal colleague to the
16 left?

17 DR. BRADLEY: The motion is that the FDA and
18 sponsor establish the statistical validity of the claim
19 that the sponsor has been able to correct higher-order
20 monochromatic aberrations of individual eyes with the
21 wavefront-guided LADAR System before any such claim can be
22 included in labeling.

23 DR. WEISS: Does anyone second that motion?

24 DR. HUANG: Second.

25 DR. WEISS: Second, Dr. Huang.

1 Dr. Bullimore has a comment.

2 DR. BULLIMORE: This is Dr. Bullimore.

3 I speak against the motion on the grounds that
4 I find it all too nebulous for this state of the procedure,
5 and (B) I don't think we've included in the claims that it
6 does in any way correct.

7 DR. BRADLEY: Just for clarification.

8 We have not included it but the sponsor has.

9 DR. WEISS: You can make a motion, if you want,
10 to not have it in the labeling. That's another way of
11 going about it.

12 DR. BRADLEY: No, I don't think that would be
13 appropriate because I think there is a possibility in the
14 data that they have done this, and I think if that's
15 correct, then it makes sense for them to put it in the
16 labeling.

17 DR. WEISS: So you want the data.

18 Dr. Swanson?

19 DR. SWANSON: I think we addressed that
20 actually in one of the earlier motions.

21 DR. BULLIMORE: Yes.

22 DR. SWANSON: Because we added the statement
23 that it increases the monochromatic aberrations of the eye
24 in the patient information brochure.

25 DR. WEISS: We added that it increases at less

1 than conventional treatment.

2 DR. SWANSON: Right.

3 DR. WEISS: So would that be satisfactory? Dr.
4 Grimmatt can read it back to us. He'll read it back and
5 then we'll see, Dr. Bradley, if that is satisfactory to you
6 or do you need more data.

7 DR. GRIMMETT: This is Dr. Grimmatt.

8 The prior motion that we voted on and was
9 accepted was that conventional LADARVision LASIK increases
10 higher-order aberrations approximately 77 percent over
11 preoperative levels while wavefront-guided LASIK increases
12 higher-order aberrations approximately 20 percent over
13 preoperative levels.

14 DR. WEISS: Is that satisfactory to you as it
15 reads?

16 DR. BRADLEY: Sure.

17 DR. WEISS: Sure. Hey, who says we don't
18 compromise here? So is that motion withdrawn?

19 DR. BRADLEY: Yes.

20 DR. WEISS: Yes. I think we've hit the high
21 points here and so I personally would like to start
22 wrapping this up, so to speak.

23 Dr. Bandeen-Roche?

24 DR. BANDEEN-ROCHE: I withdraw my comment.

25 DR. WEISS: Thank you so much.

1 (Laughter.)

2 DR. WEISS: So if there are no other comments,
3 we will vote on PMA P70043/S010 with the conditions as
4 stated, and I will point out that this is for correction of
5 myopia up to -7 as listed at the present time, unless
6 anyone wants to vote on any condition before we vote on all
7 the conditions and the main motion.

8 (No response.)

9 DR. WEISS: Hearing no other conditions, then
10 we will vote on the main motion with all the conditions
11 attached. All of those in favor of this PMA, would you
12 please raise your hands? In favor of the main motion with
13 all the conditions that have been listed and voted on.

14 (Show of hands.)

15 MS. THORNTON: It's unanimous.

16 DR. WEISS: We have nine in favor. It's
17 unanimous. The main motion and the side motions pass.

18 I will now poll the panel as far as the reasons
19 they voted the way they did. We can start with Dr.
20 Swanson.

21 MS. THORNTON: Would you state your vote and
22 why you voted that way?

23 DR. SWANSON: I voted yes, and it's because
24 basically as the panel, we reviewed everything carefully
25 and not always unanimous. We pretty much worked to

1 consensus even though it took us more time than we thought.

2 DR. WEISS: Well put.

3 Dr. Owsley?

4 DR. OWSLEY: This is Cynthia Owsley, and I
5 voted yes, because there was a lot of consensus and my own
6 opinion was consensus for all the evidence, including the
7 conditions.

8 DR. WEISS: Thank you.

9 Dr. Maguire?

10 DR. MAGUIRE: Leo Maguire, voting yes,
11 basically because there's not much clinically significant
12 difference between this PMA and earlier approved PMAs.

13 DR. WEISS: Thank you.

14 Dr. Huang?

15 DR. HUANG: Andrew Huang.

16 I voted yes, because I think the data itself
17 show enough on safety and the efficacy, even though I have
18 a personal reservation about the expanded indication.

19 DR. WEISS: Thank you.

20 Dr. Bradley?

21 DR. BRADLEY: I voted approvable with
22 conditions, because I believe the sponsor has effectively
23 demonstrated efficacy and safety well within the FDA
24 Guidance Document standards, and I believe with our
25 conditions that the value of this procedure to the patient

1 can be effectively communicated.

2 DR. WEISS: Dr. Grimmett?

3 DR. GRIMMETT: Dr. Grimmett.

4 I voted approvable with conditions, because I
5 believe the sponsor has effectively demonstrated reasonable
6 safety and efficacy, and the labeling concerns as
7 previously listed will address to the patient the specific
8 issues with wavefront-guided ablations.

9 DR. WEISS: Dr. Matoba?

10 DR. MATOBA: Alice Matoba.

11 I voted approvable with conditions for the
12 reasons that Dr. Grimmett stated, but I hope that the FDA
13 in considering our labeling suggestions will take into
14 consideration those suggestions that pertain specifically
15 to Custom laser ablation versus those suggestions that are
16 generic to all LASIK and consider how to enforce them in a
17 way that will be fair to the sponsor, so they're not
18 singled out to have more stringent labeling criteria than
19 the other laser companies.

20 DR. WEISS: Thank you.

21 Dr. Bullimore?

22 DR. BULLIMORE: Mark Bullimore.

23 I voted yes, approvable with conditions, on the
24 grounds that the sponsor brought a very nice and thoroughly
25 prepared PMA with some very high-quality data, and I would

1 commend them on that. I'd also commend them on their
2 trying to advance the technology in this area.

3 I would like to express some caution and
4 concern that the technology is perhaps not ripe for
5 everybody yet and in postrefractive surgery eyes and in
6 eyes that fall outside of the approvable range, I would
7 hope that caution would be exercised in off-label use of
8 these devices or this device until more data are available
9 in the public domain.

10 DR. WEISS: Dr. Bandeen-Roche?

11 DR. BANDEEN-ROCHE: I voted approvable with
12 conditions, because I thought there was reasonable
13 assurance of safety and efficacy within FDA standards.

14 DR. WEISS: I'd like to thank the members of
15 the panel for their opinions and their vote. We're going
16 to now have comments from the consumer and the industry
17 representatives.

18 Ms. Such?

19 MS. SUCH: Yes, I wanted to thank the sponsors
20 for a very well-put-together submission as well as an
21 excellent presentation today. I also wanted to thank the
22 FDA panel for their presentation on the findings of the
23 study as well as the panel themselves that had put forth a
24 lot of good points and a lot of excellent issues.

25 I would like to thank this panel as well as the

1 FDA and the sponsors for looking at the modifications to
2 the labeling as a move towards improvement rather than
3 burden and to take this as a positive step as we learn more
4 information.

5 Thank you.

6 DR. WEISS: Thank you.

7 Mr. McCarley?

8 MR. MCCARLEY: I'd like to reiterate that I'd
9 request the FDA to consider requiring all refractive laser
10 manufacturers to revise their labeling to include any
11 general labeling restrictions or requirements so as not to
12 disadvantage the current sponsor.

13 DR. WEISS: Thank you.

14 I'd like to thank the FDA for their insightful
15 comments and review and I'd like to thank the sponsor for
16 doing the study the way a study should be done and that's
17 really the highest compliment that I can give you.

18 I think we will now adjourn this open meeting
19 for 15 minutes and then we will begin the closed meeting
20 for the FDA and the panel. So I'll see you back here in 15
21 minutes.

22 (Whereupon, at 4:37 p.m., the meeting was
23 recessed, to reconvene in closed session at 4:52 p.m.)

24

25