

1 initial fitting of this.

2 DR. SUGAR: Dr. Weiss.

3 DR. WEISS: I am not sure if the fitting  
4 of this lens is different than any other lens.  
5 There aren't many lenses we fit that only have one  
6 base curve. You think the fitting of this -- it  
7 has to be fit differently?

8 DR. JURKUS: I don't know.

9 DR. WEISS: That is the operative word.  
10 So if none of us know how it should get fit, I  
11 think maybe we shouldn't make recommendations and  
12 leave it to the company.

13 DR. SUGAR: So the sense of the panel  
14 appears to be that we not make an additional  
15 recommendation concerning the fitting.

16 Next?

17 DR. GRIMMETT: Next Jan Jurkus discussed  
18 that the timing of the infiltrates are sooner with  
19 the SEE3 lens and that should be mentioned in the  
20 labeling.

21 DR. SUGAR: Comments? No comments,  
22 because everyone feels it shouldn't be mentioned?  
23 Because everyone feels it should be mentioned? Is  
24 there anyone who feels? I'm sorry.

25 DR. GRIMMETT: Dr. Weiss is asking to

1 clarify or repeat. Perhaps, I should go to Dr.  
2 Jurkus for this but I understood that the timing of  
3 the infiltrates in the SEE3 lens versus the Acuvue  
4 were seen sooner with the test lens. And, if not  
5 already done, that should be a statement in the  
6 labeling.

7 DR. SUGAR: Hearing no disagreement, I am  
8 going to interpret that as agreement. Next?

9 DR. GRIMMETT: Pardon me for a moment as I  
10 write "yes" on that one. A comment was made by Dr.  
11 Jurkus and both by Dr. Matoba that GPC was at a  
12 higher rate with the SEE3 lens versus the Acuvue  
13 and that that should be in the labeling if not  
14 already done.

15 DR. SUGAR: Comments? One option would be  
16 to ask that the specific data be presented and let  
17 that be interpreted by the practitioner as they see  
18 fit.

19 DR. GRIMMETT: Sure.

20 DR. SUGAR: We have done that, certainly,  
21 in many other situations. Go ahead

22 DR. WEISS: We mentioned before, and I  
23 would just emphasize that somehow somebody who has  
24 had GPC before, the sponsor insert something that  
25 makes it evident that that person might be at

1 higher risk for it to recur with this particular  
2 lens.

3 DR. GRIMMETT: Dr. Grimmatt. I believe  
4 Dr. Sugar's recommendation of simply including the  
5 data as we previously discussed, the 3 percent with  
6 the SEE3 versus 0.9 percent with the Acuvue without  
7 a prior history. That will all elucidate those  
8 factors.

9 DR. SUGAR: Dr. Bandeen-Roche?

10 DR. BANDEEN-ROCHE: I would support that  
11 recommendation more broadly. So, for instance, the  
12 rates for the primary endpoint should be reported  
13 and, as I mentioned earlier, they should be  
14 estimates that take into account the amount of time  
15 at risk and don't just take the denominator as the  
16 total number of dispenses.

17 DR. SUGAR: I think that is already in the  
18 insert although Jose debated which percentages  
19 should be used.

20 DR. WEISS: Jayne Weiss. Just for that  
21 one particular point, I would like there to be  
22 three aspects of it; one, which has already been  
23 mentioned, that if you already have GPC, you have a  
24 higher chance with this lens of getting a repeat  
25 episode. Two, which is a different percentage than

1 the 0.9 percent versus 3 percent if you didn't have  
2 GPC, and three, that, in the overall groups, the  
3 onset of GPC in the SEE3 group was earlier than in  
4 the Acuvue group.

5 DR. SUGAR: Next?

6 DR. GRIMMETT: I think I got all that.  
7 The fourth thing Dr. Jurkus mentioned I believe we  
8 have already covered regarding the dryness  
9 labeling. We changed that in the indications  
10 statement. I think we just deleted it on a  
11 previous question.

12 DR. SUGAR: Again, the sponsor could  
13 include the data on dryness symptoms in their  
14 package insert but deleting it from the  
15 indications.

16 DR. GRIMMETT: Correct. Dr. Jurkus made a  
17 comment about LASIK and daily-wear contact lenses.

18 DR. JURKUS: That was alternatives of use.

19 DR. GRIMMETT: Alternative modalities.

20 DR. JURKUS: Right. I did not see that in  
21 the descriptors when they were talking about when  
22 this lens could be used, that maybe other options  
23 would be -- and it did not have daily wear nor  
24 LASIK included in the other potential options

25 DR. ZADNIK: Did it have spectacles?

1 DR. SUGAR: Just what I was going to ask.

2 DR. YAROSS: This is Marcia Yaross.

3 Again, I would ask the same question; is that a  
4 typical part of contact-lens labeling. If so, it  
5 should be there. If not, perhaps it is not needed  
6 in this one either.

7 DR. SUGAR: I don't know. Jim Saviola?

8 DR. SAVIOLA: Are you talking about what  
9 is in the summary or it is in the product labeling.

10 DR. SUGAR: In the product labeling,  
11 whether alternatives are listed or not.

12 DR. SAVIOLA: Could we refer to the  
13 sponsor because they are more familiar with the  
14 specific wording at the moment than I am.

15 MS. PLESNARSKI: Alicia Plesnarski. The  
16 recommendation for alternative practices only  
17 appears in the summary of safety and effectiveness  
18 which gets published after approval. There is no  
19 recommendation in contact-lens labeling regarding  
20 alternate practices and procedures.

21 DR. SUGAR: That is an industry standard,  
22 Marcia. So we are not really in a position, I  
23 don't think, to want to impose that.

24 DR. YAROSS: It would be a unique request.

25 DR. SUGAR: And though we have been unique

1 before, this is not a good time.

2 MS. PLESNARSKI: We could certainly update  
3 the summary of safety and effectiveness to include  
4 that recommendation.

5 DR. SUGAR: Are there other labeling or  
6 package-insert and labeling suggestions?

7 DR. GRIMMETT: From Dr. Matoba's  
8 discussion, she had mentioned specifically  
9 rewording or being more specific regarding aqueous-  
10 tear deficiency and ocular-surface disease  
11 regarding --

12 DR. MATOBA: That was in the indications.

13 DR. GRIMMETT: In the indication  
14 statement? You didn't want any specific mention  
15 with regard to aqueous-tear deficiency in the  
16 labeling.

17 DR. SUGAR: So that was obviated by our  
18 taking out that fourth bullet.

19 DR. GRIMMETT: Okay; that is withdrawn.  
20 She mentioned the GPC issue that we previously  
21 mentioned from Dr. Jurkus. She wanted a statement  
22 regarding that once you have one infiltrate, there  
23 is, I believe, it is a six-fold increase rate for  
24 the second event and more caution is required on  
25 the part of a practitioner.

1 Is everyone in general agreement?

2 DR. SUGAR: There is agreement.

3 DR. GRIMMETT: That, I believe, is the  
4 majority from Dr. Matoba unless she has another --  
5 the others have been previously mentioned. Dr.  
6 Weissman, again, we brought up this issue  
7 previously regarding that there were no aphaks  
8 tested in this study and this would be a time to  
9 have it specifically in labeling. Did we all agree  
10 to that in the labeling section?

11 DR. SUGAR: Yes; not in the indications.

12 DR. GRIMMETT: Not in the indications.

13 DR. SUGAR: Dr. Weiss?

14 DR. WEISS: Also, if the new base curve is  
15 going to be included in this, I would feel more  
16 comfortable if we indicated that that base curve  
17 was not a part of the study. Can we say that?

18 DR. SUGAR: I think that this gets to an  
19 industry issue that the modifications of lens  
20 parameters in terms of shape do not require  
21 approval from the agency; is that correct? If that  
22 is correct, we could have a statement that this  
23 lens was studied at only the 8.6 base curve.

24 DR. GRIMMETT: +6.00 to -6.00 as well.

25 DR. SUGAR: Go ahead, Dr. Edrington..

1 DR. EDRINGTON: I think this might fall  
2 under one of the situations where somebody already  
3 has a product approved and adds another base curve  
4 to it. I don't always read these as well as I  
5 should, the inserts, but I don't think that is  
6 added in there that there was no testing done on  
7 that new base curve.

8 DR. SUGAR: So that is a suggestion that  
9 that not be included.

10 DR. ROSENTHAL: Rosenthal. Similarly,  
11 when an intraocular is modified, we don't change  
12 the labeling to say that they done a little this,  
13 or a little that.

14 DR. SUGAR: Dr. Saviola.

15 DR. SAVIOLA: If someone has the labeling  
16 handy --

17 DR. ROSENTHAL: Unless it is significant.

18 DR. SAVIOLA: There is a general  
19 precautionary statement that is included in all the  
20 contact-lens labeling that says that all power  
21 ranges and designs, et cetera, sort of haven't been  
22 studied in all patients and practitioners need to  
23 exercise care in monitoring their patients. So it  
24 is addressed as a precautionary note.

25 DR. SUGAR: So that issue appears to be

1 handled and we don't need to have a specific  
2 statement.

3 Mike, do you have other --

4 DR. GRIMMETT: The only one other that I  
5 had is Dr. Pulido in his questions to sponsor was  
6 concerned about the seeming doubling of rate or at  
7 least one of the data to appear in the labeling  
8 that the infiltrate rate was 3 percent with Acuvue  
9 and 6 percent with SEE3 and just wanted that data  
10 to appear.

11 Is that correct? Did I get the essence of  
12 your --

13 DR. PULIDO: Dr. Bandeen-Roche thought the  
14 same.

15 DR. BANDEEN-ROCHE: Absolutely.

16 DR. SUGAR: So we are suggesting that the  
17 aggregate numbers for infiltrative events be  
18 included in the labeling, or package insert. Is  
19 there any disagreement? Are there other suggested  
20 labeling changes from the panel? Dr. McMahon?

21 DR. McMAHON: On page 1259, under the  
22 warnings, the last bullet in the first section, the  
23 risk of ulcerative keratitis, yada, yada, yada. I  
24 think a phrase needs to be put in there that the  
25 risk of ulcerative keratitis in this lens has not

1 been determined.

2 DR. SUGAR: I assume that in the other --  
3 it is not just in this one package insert but in  
4 the other one, also. That gets to the issue of the  
5 risk of ulcerative keratitis has not been  
6 determined. Postmarketing studies are in progress,  
7 or are to be in progress. I don't know what we  
8 should say about that.

9 Go ahead, Jose.

10 DR. PULIDO: Just continuing in that same  
11 vein, maybe adding, "Postmarketing studies are  
12 under way and any adverse events noted in your  
13 practice, please call 1-800-Ciba-Vision. Operators  
14 are on call."

15 DR. SUGAR: Dr. Jurkus?

16 DR. JURKUS: The question I would have if  
17 we did recommend that to be included in the  
18 packaging when the postmarket study is then  
19 completed, would Ciba then have to come back and  
20 get all packaging to delete that?

21 DR. ROSENTHAL: Yes.

22 DR. JURKUS: I don't know if it is worth  
23 putting in.

24 DR. ROSENTHAL: Rosenthal. It is like  
25 anything. If you put something in the labeling, in

1 order to change it, you have to have data to  
2 support the change, generally.

3 DR. SUGAR: So the sense is in favor of  
4 highlighting the fact that the risk of ulcerative  
5 keratitis has not been determined and that there  
6 are studies ongoing and that adverse events should  
7 be reported.

8 DR. ZADNIK: If we say yes to question 5,  
9 of course.

10 DR. SUGAR: Right. Thou shalt say yes to  
11 question 5.

12 DR. ZADNIK: Only if a good study can be  
13 designed.

14 DR. SUGAR: Are there other labeling -- go  
15 ahead, Dr. Weiss, and then Dr. Bandeen-Roche.

16 DR. WEISS: This is Jayne Weiss. I would  
17 feel a little bit better if we said the long-term  
18 risk of ulcerative keratitis because the sponsor  
19 did present data in this period of time. It is  
20 just that we don't know what it is long term.

21 The other sort of implies to me that no  
22 one even looked at it.

23 DR. SUGAR: That's fair, although, again,  
24 we looked at it with a power that wasn't there  
25 because of the frequency being so low; that is, in

1 700 patients, we couldn't determine.

2 DR. YAROSS: Marcia Yaross. But that does  
3 give you an upper bound so I think her point is  
4 well taken.

5 DR. SUGAR: Yes. Dr. Bandeen-Roche.

6 DR. BANDEEN-ROCHE: This goes to the  
7 question about wearing time, whether we had any  
8 recommendations about how to display the data about  
9 wearing time. The only thing that came to mind is  
10 that the current wearing-time statistics are  
11 pooling eyes per month, I believe, beginning with  
12 the very beginning of the study.

13 I just wonder, from the clinician's point  
14 of view, whether that is the right way to do it or  
15 whether you should allow some breaking-in period  
16 and then report wearing time after some breaking-in  
17 period. I don't know. I just thought I would  
18 raise it.

19 DR. PULIDO: Page 1253. Is that  
20 sufficient for you?

21 DR. BANDEEN-ROCHE: Well, again, this  
22 pools data from the very first month of the study  
23 in people who -- maybe people who dropped out.  
24 Yes; and so I am not sure that it correctly conveys  
25 the ultimate experience of people who stick with

1 the lens and whether it might be more informative  
2 to report a percentage who make it past 3 months  
3 and then, after 3 months, this sort of a statistic.

4 But, again, it is just a question.

5 DR. SUGAR: Could you leave that table and  
6 add the statement that at 9 months, or whatever it  
7 was, 92.4 percent, or whatever it was, were wearing  
8 the lenses for 21 to 30 days. That would cover  
9 that.

10 DR. PULIDO: And, again, they are going to  
11 revisit their annual-rate data because the annual-  
12 rate data on page 1251 doesn't add up to the  
13 annual-rate data presented elsewhere.

14 DR. SUGAR: Right; we discussed that. We  
15 were going to add the aggregate data.

16 Can we then move on to No. 5 which is, I  
17 think, somewhat intimately related to No. 6. No. 5  
18 is, does the panel recommend that the sponsor  
19 conduct a prospective postapproval study within the  
20 U.S. population to gather information on the  
21 incidence of microbial keratitis.

22 I assume there is unanimity of agreement  
23 with that. There is unanimity of agreement with  
24 that; yes.

25 DR. ZADNIK: No. I'm sorry. Do I think

1 there should be a postapproval study?

2 DR. SUGAR: Yes.

3 DR. ZADNIK: Maybe, to gather information  
4 on the incidence of microbial keratitis, I don't  
5 think you can design one that is feasible and  
6 affordable. So I think to delude ourselves that we  
7 are actually going to learn about the incidence of  
8 microbial keratitis -- if you want to make that say  
9 to learn more about incidence and risk of  
10 infiltrative keratitis with this contact lens,  
11 maybe so. But I really think, whether it is 2,000  
12 or even as many as 10,000 I don't think you can  
13 answer the question that is listed there.

14 Do I think there should be postapproval  
15 studies? I think that would be prudent, well-  
16 designed to answer certain questions, but not that  
17 one.

18 DR. SUGAR: We are not discussing their  
19 specific study, my understanding is. We are  
20 discussing the issue whether they should conduct a  
21 study or not. A study could include retrieval of  
22 adverse events. So we are not talking about 1,000  
23 patients for one year -- was it 1,000 or 2,000,  
24 whatever, 2,000. We are talking about whether  
25 there should or should not be a study. Do you

1 still feel the same way?

2 DR. ZADNIK: I think there should be a  
3 postapproval study, period.

4 DR. SUGAR: Not to badger you or anything.

5 DR. ZADNIK: Its purpose to be determined.

6 DR. SUGAR: Is there anyone who disagrees  
7 with the fact that there should be a study. I  
8 don't think we are going to be able to -- we did  
9 this in November, I think. We tried to and we  
10 could not come up with a specific study. I think  
11 that the industry is still looking at guidelines  
12 for postapproval studies; am I correct? So we are  
13 saying that there should be a study. Okay?

14 No. 6; in consideration of potential  
15 differences in the standard of care and device  
16 usage patterns outside of the U.S., does the panel  
17 have any recommendation concerning the use of  
18 foreign data in the postapproval study?

19 I am naive and did not realize that there  
20 are, apparently, well-recognized significant  
21 differences between, for example, Western European  
22 and Northern European contact-lens management and  
23 U.S. contact-lens management.

24 I wonder if someone, one of the contact-  
25 lens specialists here, could comment on that, or if

1 Jim Saviola could comment on that.

2 DR. WEISSMAN: I will take a stab at it.  
3 Weissman. That really is a tough question and the  
4 reason it is tough is because when you deal with  
5 contact-lens care on a worldwide basis, the  
6 variance is dramatically great.

7 You could say that someone in Western  
8 Europe or Australia would probably be managed  
9 fairly similarly to the way in which we manage  
10 patients here, but I strongly doubt if anyone in  
11 India or China was managed the same way and I  
12 question whether Northern European and Southern  
13 European are managed very similarly whereas Britain  
14 probably is managed fairly similarly.

15 So I think you are going to get into a  
16 great diversity unless you are very, very careful.

17 DR. SUGAR: Dr. Yaross?

18 DR. YAROSS: I would just point out that  
19 the regulations already address the applicability  
20 of foreign data and there is a three-part test that  
21 sponsors are supposed to meet if you want to use  
22 foreign data and it is the applicability to a U.S.  
23 population, that the data are verifiable and I  
24 think one other.

25 So I am not sure that it is fair to put

1 any additional expectations on the sponsor beyond  
2 what is already covered in the regulations.

3 DR. SUGAR: Dr. Pulido?

4 DR. PULIDO: I agree with Dr. Yaross. I  
5 think it should be left to industry and the FDA to  
6 determine what data centers get into the study and  
7 which not and for us to determine which countries  
8 are acceptable and not acceptable is way beyond the  
9 duty of this panel.

10 DR. SUGAR: Does the agency wish any  
11 further discussion of that issue? Ralph?

12 DR. ROSENTHAL: Sorry?

13 DR. SUGAR: Do you want any more from us  
14 on that issue?

15 DR. ROSENTHAL: Rosenthal. No; I think  
16 that is satisfactory.

17 DR. SUGAR: I think we are a point now  
18 where we need to hear what our options are. This  
19 is pro forma. And then proceed with a motion and a  
20 vote.

21 DR. ROSENTHAL: Excuse me, Dr. Sugar.

22 DR. SUGAR: I'm sorry; I skipped a step.  
23 Is that what you were going to tell me, Ralph?

24 DR. ROSENTHAL: Yes, sir.

25 **Open Public Hearing**

1 DR. SUGAR: We have a 30-minute open  
2 public hearing session. Is there anyone from the  
3 audience who would like to make a public statement?

4 DR. HOLDEN: I think, Mr. Chairman, I will  
5 be brief.

6 DR. SUGAR: You need to identify yourself.

7 DR. HOLDEN: My name is Brien Holden from  
8 Sydney, Australia. On the issue of aphakics, I  
9 just thought it might be worth bringing the panel's  
10 attention that the greatest difficulty around the  
11 world at the present time is to get aphakic contact  
12 lenses. The Dk over L of the average aphakic lens  
13 available today is 1. Here we are talking about a  
14 potential for Dk over L of 10.

15 Secondly, the difficulty in encouraging  
16 the manufacturer to make aphakic lenses. Anything  
17 that can be done for all those patients with  
18 secondary cataracts, all those kids with cataracts  
19 who are going to be operated on, there are no  
20 lenses around the world today of any respectable Dk  
21 over L to be used.

22 So I would just like the panel to consider  
23 that encouraging this manufacturer or any other  
24 manufacturer of high Dk materials to make higher  
25 plus lenses is not going to do a disservice to the

1 public. I take Barry's point that the studies show  
2 that aphakic extended wear is more risky, but one  
3 of the reasons is that corneas are constantly under  
4 anoxic conditions and this may well help.

5 The second comment I would like to make is  
6 about contact-lens for papillary conjunctivitis.  
7 Acuvue has an extremely low rate of CLPC. I just  
8 thought I should bring that to your attention. It  
9 is related to the water content and the ionicity of  
10 the material.

11 But low water content lenses in general  
12 have a higher rate of CLPC. So I would not be too  
13 distracted by the fact that these lenses have a  
14 higher rate of CLPC. It is a common thing for low-  
15 water-content lenses to do that, especially on  
16 extended wear.

17 On the issue of the early nature of the  
18 infiltrative responses, in our experience over the  
19 last four years with a thousand patients in high Dk  
20 soft, a lot of that is to do with fit and  
21 mechanical issues. You are provoking the eye if  
22 the fit is not correct and as new base curves and  
23 things become available, some of that eases back  
24 into the wearing time.

25 The final issue about ulcerative

1 keratitis, I would have thought that if  
2 recommendations had been given to people about the  
3 incidence rate, a statement like, "Although no  
4 cases of ulcerative keratitis were seen in these  
5 studies, studies are continuing because these rare  
6 events are difficult to quantify," or something  
7 like that.

8           One other comment I would like to make is  
9 that the issue of dryness with contact lenses is a  
10 very important one. About 50 percent of people who  
11 give up wearing contact lenses do so because of  
12 dryness and any indications the panel can give to  
13 people about whether you are better off or worse  
14 off with a lens for dryness symptoms would be  
15 helpful to consumers as well as to practitioners.

16           Thank you.

17           DR. SUGAR: Thank you, Dr. Holden.

18           Are there any other public comments?

19                           **Closing Comments**

20           DR. SUGAR: Are there any comments from  
21 the agency? Are there any comments from the  
22 sponsor?

23           DR. HEAP: I guess I am the elephant in  
24 the room we talked about earlier. My name is  
25 Stuart Heap. I am President of Ciba Vision's

1 contact-lens business so I have an interest in  
2 being here.

3 I would like to thank all of you for the  
4 time and effort you have taken in reviewing our  
5 PMA. We know it has been a lot of work and we  
6 appreciate the thought and the challenge that you  
7 put into your comments.

8 While we understand the clouded history  
9 and risks associated with extended-wear lenses from  
10 the '80's, we believe that we should continue to  
11 work to strive to develop new 30-night extended-  
12 wear lenses. The market demands it of us and we  
13 believe that with the lotrafilcon A material, we  
14 have a safer material to help satisfy those market  
15 needs.

16 There are five reasons why Ciba Vision  
17 wants to continue to invest in research and  
18 development for extended-wear lenses and I would  
19 like to enunciate them.

20 Firstly, this product provides more  
21 options for the eye-care practitioner for their  
22 patient. We know that the lack of convenience is  
23 on factor that dissatisfies contact-lens wearers  
24 and dissuades other patients from using the  
25 contact-lens option. Many contact-lens users today

1 abuse the products that they have wearing them  
2 beyond the time approved by the FDA and recommended  
3 by their eye-care practitioners.

4 In fact, 20 percent of contact-lens  
5 wearers sleep in their lenses. We believe that the  
6 high oxygen transmissibility of our product  
7 provides a margin of safety, as you have heard from  
8 my colleagues. Overnight edema with this lens is  
9 equivalent to a no-lens-wearing eye.

10 Secondly, we believe the market needs an  
11 alternative to LASIK. Practitioners with Focus  
12 Night and Day can offer their patients another  
13 option for around-the-clock vision correction.  
14 Also, this product offers a lower cost option that  
15 is flexible to the change in vision correction that  
16 often occurs in patients.

17 Market research, again, shows that 40  
18 percent of contact-lens wearers want to wear their  
19 lenses for 30 nights. This product also offers an  
20 excellent option for those who are not suitable for  
21 LASIK but who also want the around-the-clock vision  
22 correction.

23 Thirdly, with our 30-night extended-wear  
24 product, we have demonstrated, through one of the  
25 largest, if not the largest, clinical in contact-

1 lens history, that Focus Night and Day on a 30-  
2 night extended-wear basis performs equivalently in  
3 some attributes and better in other attributes than  
4 currently approved six-night extended-wear lenses.

5 Fourthly, practitioner response to the  
6 performance of this lens has been overwhelmingly  
7 positive. Eye-care practitioners worldwide are  
8 reversing their stance on extended wear. Doctors  
9 who once told their patients that extended wear is  
10 not safe are, with Focus Night and Day, reversing  
11 their positions.

12 I have many quotes with me from  
13 international ophthalmologists and optometrists  
14 that positively support the clinical performance of  
15 Focus Night and Day in the marketplace. I won't  
16 take your time to read those comments but I would  
17 like to paraphrase one from Dr. Sparholt who is the  
18 President of the European Contact Lens Society of  
19 Ophthalmologists.

20 I quote; "The risk of serious  
21 complications with silicon hydrogels has been  
22 amazingly small. These complications can be easily  
23 managed with no resulting loss of vision."

24 Fifthly, my care practitioners are not  
25 naive and I don't want to convey that they are

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1 showing blind acceptance of our marketing messages.  
2 They are starting slowly and assessing patient  
3 suitability on a "walk before you run" basis. The  
4 training, knowledge and experience in handling  
5 contact-lens complications amongst eye-care  
6 practitioners today has grown enormously and there  
7 is a wider range of tools available for patient  
8 management including therapeutic drugs.

9           As you have heard already, Focus Night and  
10 Day is available in over forty countries worldwide.  
11 We estimate a quarter of a million patients wearing  
12 the product and have consumed approximately 2.5  
13 million lenses which means that we have accumulated  
14 over 100,000 patient years of experience.

15           Our rates of serious complications is,  
16 therefore, estimated to be 0.5 in 10,000. If we  
17 are a factor of 10 out, we still have experienced  
18 so far low serious complication rates.

19           So, in summary, 30-night extended wear is  
20 made possible because of the development  
21 breakthroughs with our silicon hydrogel material  
22 lotrafilcon A. With its high oxygen transmission,  
23 we believe this material should become the new  
24 standard for contact lenses.

25           Thanks again for your time and effort.

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1 DR. SUGAR: Thank you for your comments.  
2 We will now have the voting options read  
3 by Sally Thornton.

4 **Voting Options Read**

5 MS. THORNTON: These are the panel  
6 recommendation options for premarket approval  
7 applications. The Medical Device Amendments to the  
8 Federal Food, Drug and Cosmetic Act, as amended by  
9 the Safe Medical Devices Act of 1990, allows the  
10 Food and Drug Administration to obtain a  
11 recommendation from an expert advisory panel on  
12 designated medical-device premarket approval  
13 applications, or PMAs, that are filed with the  
14 agency.

15 The PMA must stand on its own merits and  
16 your recommendation must be supported by safety and  
17 effectiveness data in the application or by  
18 applicable publicly available information.

19 Safety is defined in the Act as reasonable  
20 assurance based on valid scientific evidence that  
21 the probable benefits to health under conditions on  
22 intended use outweigh any probable risks.  
23 Effectiveness is defined as reasonable assurance  
24 that, in a significant portion of the population,  
25 the use of the device for its intended uses and

1 conditions of use, when labeled, will provide  
2 clinically significant results.

3           Your recommendation options for the vote  
4 are as follows: No. 1, approval if there are no  
5 conditions attached; No. 2, approvable with  
6 conditions. The panel may recommend that the PMA  
7 be found approvable subject to specified conditions  
8 such as physician or patient education, labeling  
9 changes or a further analysis of existing data.  
10 Prior to voting, all of the conditions should be  
11 discussed by the panel.

12           Not approvable is the third option. The  
13 panel may recommend that the PMA is not approvable  
14 if the data do not provide a reasonable assurance  
15 that the device is safe or if a reasonable  
16 assurance has not been given that the device is  
17 effective under the conditions of use prescribed,  
18 recommended or suggested in the proposed labeling.

19           Following the voting, the chair will ask  
20 each panel member to present a brief statement  
21 outlining the reasons for their vote.

22           Thank you, Dr. Sugar.

23           DR. SUGAR: Thank you.

24           **Panel Recommendations**

25           DR. SUGAR: The floor is now open for a

1 motion. If the motion is approvable with  
2 conditions, we will not vote on the motion. We  
3 will then have a discussion which includes  
4 specifying the conditions, voting on each condition  
5 and then we will go back and vote on the main  
6 motion.

7 Is there a motion from the floor? Dr.  
8 Grimmett?

9 DR. GRIMMETT: Dr. Grimmett. I move that  
10 the PMA is approvable with conditions.

11 DR. PULIDO: Second.

12 DR. SUGAR: Is there discussion? There  
13 needs to be discussion to specify those conditions.  
14 If Dr. Grimmett could list the conditions that we  
15 have already discussed.

16 DR. GRIMMETT: Certainly.

17 DR. SUGAR: Apparently, we have to vote on  
18 them one-by-one, not as a group.

19 MS. THORNTON: That's true.

20 DR. SUGAR: Go through them and then we  
21 will go back and vote on each one.

22 DR. GRIMMETT: You want them all listed  
23 first?

24 DR. ROSENTHAL: Can they just say labeling  
25 recommendations?

1 MS. THORNTON: No. They cannot.

2 DR. GRIMMETT: Let me clarify, please.

3 You would like me to list them one-by-one and we  
4 will vote after I list each one?

5 DR. SUGAR: I would like for you to just  
6 read through the list and then we will go back and  
7 vote on each one. Is that unnecessary?  
8 Unnecessary? Okay; let's just go through them one-  
9 by-one and we will vote on each one.

10 DR. GRIMMETT: We will vote on each one.  
11 Okay. Regarding the indication statement, we  
12 wanted to delete the fourth bullet point that  
13 related to less dryness complaints for the SEE3  
14 lens.

15 DR. SUGAR: All those in favor of that  
16 deletion signify by raising their hand.

17 [Show of hands.]

18 DR. SUGAR: All those opposed?

19 [No response.]

20 DR. SUGAR: It carries unanimously. Next?

21 DR. GRIMMETT: With regards to the  
22 indications statement, we decided to leave the word  
23 "aphakia" in the indications statement and later  
24 add information in the warnings section of the  
25 labeling regarding aphakia.

1 DR. SUGAR: We will let the wordsmithing  
2 remain with the FDA and with the sponsor, I guess.

3 All those in favor?

4 [Show of hands.]

5 DR. SUGAR: Opposed?

6 [No response.]

7 DR. SUGAR: One abstention.

8 Next?

9 DR. GRIMMETT: With regard to the  
10 indications statement, due to a direct question by  
11 the FDA, we wanted to leave up to 30 days in the  
12 indications statement.

13 DR. SUGAR: So we don't really need to  
14 vote on that because we are not modifying.

15 DR. GRIMMETT: Okay. Regarding specific  
16 labeling issues regarding GPC, we wanted to include  
17 data specifically related to the higher rate of GPC  
18 with the SEE3 lens with Dr. Weiss modifying in  
19 three ways; the onset is sooner with SEE3 lens,  
20 there is a higher rate without a prior GPC history  
21 and a higher rate with a prior GPC history.

22 DR. SUGAR: Although, considering Dr.  
23 Holden's statement, maybe we should add, "as  
24 compared to the Acuvue lens."

25 DR. GRIMMETT: Correct.

1 DR. SUGAR: Is that acceptable, that  
2 modification?

3 DR. GRIMMETT: Yes.

4 DR. SUGAR: All those in favor.

5 [Show of hands.]

6 DR. SUGAR: Opposed?

7 [No response.]

8 DR. SUGAR: It carries unanimously.

9 DR. GRIMMETT: With regard to general  
10 labeling, add data and/or statement regarding the  
11 timing of infiltrates are seen sooner with the SEE3  
12 lens.

13 DR. SUGAR: Discussion? All those in  
14 favor?

15 DR. PULIDO: In comparison to the Acuvue  
16 lens.

17 DR. GRIMMETT: Yes; once we include the  
18 data specifically, it will show both of those.

19 DR. SUGAR: All those in favor.

20 [Show of hands.]

21 DR. SUGAR: Seven. All those opposed?

22 [Show of hands.]

23 DR. SUGAR: Three. Abstentions?

24 [No response.]

25 DR. SUGAR: So that carries. Next?

1 DR. GRIMMETT: Data and/or statement in  
2 the labeling regarding once had one infiltrate  
3 event, there is a six-fold increased rate for a  
4 second event and more caution is advised on the  
5 part of the practitioner.

6 DR. SUGAR: Any discussion? All those in  
7 favor.

8 [Show of hands.]

9 DR. SUGAR: Opposed?

10 [No response.]

11 DR. SUGAR: It was unanimous.

12 DR. GRIMMETT: Statement and/or data in  
13 the labeling regarding the aggregate numbers of  
14 infiltrate rates with both the SEE3 and the Acuvue  
15 lens, the 6 percent versus the 3 percent, as Dr.  
16 Pulido suggested.

17 DR. SUGAR: Any discussion? All those in  
18 favor.

19 [Show of hands.]

20 DR. SUGAR: It is unanimous.

21 DR. GRIMMETT: And a statement, and this  
22 may require some wordsmithing, that the risk of  
23 microbial keratitis in this lens has not been  
24 established. "Postmarket studies are underway and  
25 episodes of microbial keratitis should be reported

1 to," dot, dot, dot.

2 DR. PULIDO: Or serious adverse events  
3 should be reported.

4 DR. SUGAR: Discussion? All those in  
5 favor.

6 [Show of hands.]

7 DR. SUGAR: Unanimous.

8 DR. GRIMMETT: That concludes my list.

9 DR. SUGAR: We need a statement that we  
10 require a postmarketing study; is that correct? So  
11 that should be an additional condition. Would  
12 someone like to move that?

13 DR. GRIMMETT: I will. Dr. Grimmatt will  
14 move that as a condition of approval, that a  
15 postmarket study is advised by the panel.

16 [Secoded.]

17 DR. SUGAR: Is there discussion? We are  
18 not specifying the study nor -- we have commented  
19 on and have given a sense to what the sponsor  
20 proposed but we are not specifying the study. All  
21 those in favor.

22 [Show of hands.]

23 DR. SUGAR: It is unanimous. Are there  
24 other conditions that the panel would like to  
25 suggest? Seeing, none, are we ready to vote on the

1 main motion?

2 MS. THORNTON: Yes.

3 DR. SUGAR: The main motion I don't think  
4 needs to be restated unless you feel --

5 MS. THORNTON: The main motion was  
6 approvable with conditions and the conditions are  
7 those that have been previously stated and voted  
8 on.

9 DR. SUGAR: All those in favor of the  
10 motion signify by raising by raising your hand.  
11 You will be individually polled to comment on your  
12 vote.

13 [Show of hands.]

14 DR. SUGAR: All those opposed?

15 [No response.]

16 DR. SUGAR: It was unanimous. So the  
17 motion carries. The committee has recommended  
18 approvable with conditions for PMA P010019. I  
19 would like to have the panel now specifically state  
20 the reason for their vote. Is that what we are  
21 asking?

22 MS. THORNTON: Yes. What your vote was  
23 and what your reasons for voting were.

24 DR. SUGAR: How you voted and what your  
25 reason was. Jayne?

1 DR. WEISS: Jayne Weiss. I voted  
2 approvable with conditions because I think the  
3 sponsor effectively showed that the lens will be a  
4 benefit and an excellent alternative for those who  
5 would like a long-term contact lens possibility.

6 DR. GRIMMETT: Dr. Grimmett. I voted  
7 approvable with conditions because the sponsor  
8 showed reasonable assurance of safety and efficacy  
9 and I would, again, like to congratulate the  
10 sponsor on a well-done study.

11 DR. MATOBA: Alice Matoba. I voted for  
12 approval with modifications and for the same  
13 reasons as Dr. Grimmett.

14 DR. JURKUS: Jan Jurkus. I voted  
15 approvable with conditions, recommendations,  
16 because I believe the sponsor, again, did show the  
17 safety and efficacy of this device and, as a  
18 practitioner, I truly welcome this new advance in  
19 the contact-lens field.

20 DR. SUGAR: Dr. Pulido?

21 DR. PULIDO: Jose Pulido. I voted  
22 approvable with conditions for the conditions  
23 already mentioned before.

24 DR. EDRINGTON: Tim Edrington. I voted  
25 for approval with conditions. I am looking forward

1 to using the product and especially for my aphakic  
2 patients.

3 DR. ZADNIK: Karla Zadnik. I voted  
4 approvable with conditions based on the data of  
5 this well-done and thorough study presented by the  
6 sponsor.

7 DR. BANDEEN-ROCHE: Karen Bandeen-Roche.  
8 I voted approvable with conditions. And, as Ms.  
9 Thornton reminded us, safety is a matter of benefit  
10 outweighing risk and so I do feel strongly that  
11 patients should have the means to evaluate their  
12 risks as well as they can evaluate the benefits to  
13 them.

14 Subject to statistical analysis,  
15 recommendations already made, I found the data  
16 compelling to support safety and effectiveness.

17 DR. McMAHON: Tim McMahon. I voted  
18 approvable with conditions for reasons previously  
19 stated by other panel members. I also would like  
20 to congratulate the sponsor for the marvelously  
21 well-conducted study and presented study and  
22 appreciate the efforts on their behalf.

23 DR. WEISSMAN: Barry Weissman. I voted  
24 approvable with conditions for reasons previously  
25 stated before we got flooded out. I do appreciate

1 all the efforts of everyone involved.

2 DR. SUGAR: Dr. Yaross, would you like to  
3 make a comment?

4 DR. YAROSS: I would just congratulate  
5 sponsor, FDA and the panel on what has been an  
6 excellent discussion today.

7 DR. SUGAR: I would like to thank the  
8 sponsor for making our job easier. I would like to  
9 thank the FDA for doing that exceptionally well and  
10 the primary reviewers for doing an excellent job  
11 and especially the panel for all the hard work and  
12 difficulties of the day.

13 We do have a closed session for the panel  
14 only. The audience will not be allowed to stay for  
15 that, and that will begin at 3:30.

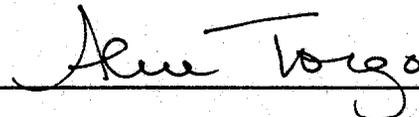
16 MS. THORNTON: As soon as the room is  
17 vacated.

18 DR. SUGAR: So, 3:30 or sooner.

19 [Whereupon, at 3:15 p.m., the open session  
20 was adjourned.]

**C E R T I F I C A T E**

I, ALICE TOIGO, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.



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ALICE TOIGO