

1 whatever risk/benefit we decide is appropriate at some
2 level, given that there is previous literature on the
3 failure of these devices before, having to be banned from
4 the market, at some level we need to justify that the
5 devices are safe. So, that would suggest a higher level of
6 power probably than the typical 0.8.

7 It might also suggest taking as the null that the
8 lenses don't comply with the standard and setting out to
9 demonstrate that they do.

10 Then, finally, this is not a discussion that I
11 think we want to get into in great detail here, but there
12 are certainly alternative methods, other than the standard
13 decision theory sort of approaches which, you know, are in a
14 sense ill defined for this problem if your goal is to
15 establish what is the risk and what the level of evidence is
16 for various levels of risk. Over lunch we talked about two
17 alternative likelihood approaches and Bayesian approaches
18 that might well be worth considering.

19 DR. SUGAR: Any other comment on question three?

20 DR. PULIDO: I agree with Karen.

21 [Laughter]

22 DR. BULLIMORE: I agree with Karen. The
23 statistical power does have to be higher, or should be
24 higher than it would be for, say, a research study where you
25 are interested in discriminating between the two groups.

1 Here, if you are interested in saying that this one is no
2 worse than the other, then you have to set the bar a little
3 higher.

4 DR. SUGAR: Question number four, if a case-
5 control study is being done, in order to achieve greater
6 sensitivity and power, would the panel recommend one or both
7 of the following: waiting until 30 percent market
8 penetration is achieved, or accumulating cases over a 2-year
9 period? Comments? Go ahead, Arthur.

10 DR. BRADLEY: Is the issue here one of
11 convenience, or is there some scientific reason why one
12 approach is better than the other? I didn't quite catch
13 that.

14 DR. HILMANTEL: I think the question here is one
15 of balance, whether you want to wait to get the results,
16 whether you want to wait four, five, six years to get the
17 results, or whether you consider that getting rapid results
18 is more important to help limit an unsafe product from being
19 on the market.

20 DR. BRADLEY: So again, is the issue one of
21 convenience? That it takes more investment of time to do it
22 up front because you have a low --

23 DR. HILMANTEL: Yes, cost and difficulty of the
24 study.

25 DR. BRADLEY: So, maybe it should be left to the

1 sponsor and give them the choice.

2 DR. BULLIMORE: Wait at least 30 days.

3 [Laughter]

4 DR. PULIDO: You don't want to wait six years to
5 find out you have a 20-fold increase.

6 DR. SUGAR: In Ollie Schein's study or in Poggio
7 and Schein's study they estimated there was 20 percent
8 market penetration at the time that they did their study.
9 Certainly, waiting for 30 percent market penetration, which
10 I hope never happens -- you know, my own personal expressed
11 open bias against extended wear lenses -- 30 percent market
12 penetration is very high for extended wear lenses for 30
13 days, and I would think 10 percent we be a more realistic
14 number.

15 DR. HILMANTEL: Well, this 30 percent -- I just
16 want to clarify, we are considering that as a percentage of
17 the extended wear market.

18 DR. SUGAR: Oh, the extended wear market? That is
19 a very different thing. Okay.

20 DR. SCOTT: By setting percentage, it could
21 conceivably be that you would never reach it.

22 [Several participants note "that's true."]

23 DR. WEISS: I think most of us would agree that
24 you would want, as far as it is practical, as speedy results
25 as you could. So, any study that you would propose that

1 would take five or six years would not be tenable.

2 DR. SUGAR: Presumably, you don't have to set a
3 time frame. In a case-control study, once you have a
4 certain penetration in the market so your controls are also
5 potential wearers, once you achieve an appropriate number of
6 cases and gather the controls, whether that takes you six
7 months or four years, then you analyze the data. So, you do
8 it on in ongoing way and you don't need to set an exact time
9 frame. Am I incorrect?

10 DR. JURKUS: One other comment is when you are
11 looking at market penetration it can become very difficult,
12 if you look merely as sale of units for market penetration
13 people may not be wearing lenses that have 30-day approval
14 on a 30-day basis. They may be wearing them on a daily wear
15 basis, or whatever. So you have to be certain that the
16 people that you are studying are actually wearing the lenses
17 on a 30-day basis.

18 DR. SUGAR: Again, enough?

19 Number five, what type of clinical setting would
20 the panel recommend for implementation of a post-approval
21 cohort study? Private practitioners? Commercial chains?
22 HMOs? All of the above? Sponsor's discretion? Eve? I am
23 sorry, I have been ignoring you all afternoon.

24 DR. HIGGINBOTHAM: No, I have been quiet on
25 purpose, but I think I can handle this one. I wouldn't

1 leave it up to the sponsor based on our previous experience,
2 and certainly I would consider all of the above with strong
3 direction from the FDA, just so we can get good sampling
4 across the board. Certainly, I think commercial chains may
5 not necessarily contribute but I would certainly invite all
6 participants. Thank you.

7 DR. SUGAR: I would think HMOs would have zero.
8 Do HMOs do lens fittings?

9 DR. LEPRI: In my experience in practicing in an
10 HMO, we fit numerous patients with contact lenses who pay
11 for them out of pocket.

12 DR. SUGAR: So, the sense is whatever it takes.
13 Right?

14 Next, what type of study would the panel
15 recommend? A case-control? Cohort? Both?

16 DR. BANDEEN-ROCHE: Everybody around me is saying
17 both, and that would obviously be my preference as well.
18 But the one thing I hope you will keep in mind is the bias
19 variance tradeoff. So, in other words, a situation in which
20 both could really be useful would be the cohort study is the
21 one that should best be able to estimate the incidence rate.
22 But if there are all sorts of biases in who continues
23 through the study and who participates in the study, and you
24 believe that those biases can be minimized in a case-control
25 study, then certainly the two together would be very

1 valuable and probably necessary.

2 DR. YAROSS: I would just comment from a burden
3 standpoint. We have to make sure that we are not looking at
4 just pure science of trying to understand everything we can,
5 but identifying whether or not there is a reasonable
6 assurance. So, if you are saying you need this early study
7 to essentially rule out a disaster in the early time period,
8 do you really need that later precision? I would put that
9 question forward.

10 DR. BULLIMORE: Given the question that we are
11 being asked here and the need to get data in a timely
12 fashion, I would lean firmly in the direction of a case-
13 control study. It will be that much more easy to accrue
14 cases than in a large cohort study and waiting for a cohort
15 of people to develop ulcers.

16 DR. SUGAR: Dr. Bradley?

17 DR. BRADLEY: Again, I think Gene explained that
18 if we do a case-control study we can't get at the absolute
19 incidence levels. And that, again, was my question earlier
20 in terms of what risk we are willing to tolerate. There are
21 two ways of evaluating risk. One is absolute incidence
22 level and one is relative incidence, relative to daily wear.
23 So, if we are going to recommend a case-control study, then
24 we can't recommend a risk based upon absolute incidence.

25 DR. BULLIMORE: Arthur, you make a great point and

1 I would throw this question back to the panel, do we think
2 that there has been a change in the underlying incidence of
3 contact lens related ulcers since the Poggio study? I
4 hadn't heard of the word Acanthamoeba keratitis -- I guess
5 that is two words -- until relatively recently. That may
6 impact, or are things just the same as usual and people are
7 doing the same with lenses as they were?

8 DR. SUGAR: I don't know the answer. Eve?

9 DR. HIGGINBOTHAM: Well, I cannot answer that
10 question but one of the comments that I have been thinking
11 as I have been sitting here is I haven't heard anyone
12 acknowledge the fact that we are having more difficulty with
13 antibiotic resistant organisms out there, and that is going
14 to be an ongoing issue as time goes on. So, it is
15 conceivable -- I mean, we are seeing it in systemic
16 diseases. I can't comment on ocular diseases, but it is a
17 problem. So, this is a real issue as time goes on. So, I
18 am not going to project who is going to be President, but my
19 projection is that this will be increasingly important.

20 DR. BANDEEN-ROCHE: Probably just an obvious
21 point, but particularly if you go with the case-control
22 study, the case ascertainment has to be extremely rigorous
23 and representative of cases or else all the advantages that
24 you have listed are not there.

25 DR. SUGAR: That is again question seven.

1 DR. ROSENTHAL: Dr. Yaross raised the issue of
2 burden. What is the burden of doing a cohort study?

3 DR. YAROSS: In this particular instance, if there
4 is someone from the Contact Lens Institute that could
5 comment, that might be helpful because they are the ones who
6 really work with these products and I thought they had
7 discussed these issues.

8 DR. ROSENTHAL: Well, I mean, Schein's study was
9 an enormous burden. The one where they surveyed New York
10 and New England, it cost how many millions? Lots.

11 DR. BULLIMORE: Yes, that is basically where I was
12 going. It is likely we are placing an unreasonable burden
13 on the industry to come up with numbers on absolute risk
14 when what we really want is data on relative risk. Okay?
15 So, I go back to the original question, if you are just
16 trying to compare the risk associated with 30-day wear of
17 these new materials with 7-day wear with the existing
18 materials, then what you want to find out is relative risk
19 and you can do that more economically, no less rigorously,
20 with a case-control study.

21 DR. BRIGHT: One of the things we were thinking is
22 that if the corneal ulcer rate with 7-day existing materials
23 has actually been declining over time, then we might be
24 setting a standard that is harder to meet than necessary to
25 compare the 30 days to. So, it might be that it would be

1 harder. Say the rate is no longer 20; say it is 10 per
2 10,000 and we do a case-control study and we want the rate
3 to be equivalent to the current 7-day users, well, then we
4 are asking them to meet 10 per 10,000 when it used to be
5 that we had thought 20 per 10,000 was fine. So, that is the
6 argument for finding out what the rate is now. It is going
7 to be more than 10 years later when the study is finally
8 under way. That, for us, is the main reason for finding out
9 what the new incidence rate is. If the panel thinks that
10 the rate is basically the same and it couldn't have
11 fluctuated much from 20 in the last 15 years, then we can
12 stop worrying about that issue I think.

13 DR. SUGAR: I don't think we have any way of
14 assessing it because referral patterns have changed, and
15 there are more people in the community who treat these
16 without referring. All the people on the panel tend to be
17 in centers where they get referred patients. So, our
18 referral bases have changed but we don't know that the
19 overall incidence is more or less and, I agree, you want to
20 know the number but we don't have the answer.

21 DR. BRIGHT: It is something to balance against
22 the cost. If the panel thinks it is not worth that extra
23 nicety of information -- if the panel thinks it is a nicety
24 of information that is not necessary or crucial, then we can
25 drop that as something we are going to ask the companies to

1 do. If the panel thinks it is really important and we need
2 it to be fair, then we are going to push harder for it. So,
3 we are asking for your experience out there.

4 DR. JURKUS: At least one of the newer materials
5 has been used on a 30-day extended wear basis elsewhere in
6 the world for at least over a year. Reviewing the
7 literature that will be coming out from international
8 studies may be a basis of giving you some of the information
9 that you are looking form, for the incidence.

10 DR. LEPRI: The original rates that were
11 identified years ago that resulted in these contact lenses
12 being cut back from 30-day to 7-day wear have been
13 challenged over the years. We have already mentioned that
14 there is a tremendous amount of variability in definition of
15 what these ulcers are, and there is a tremendous amount of
16 variability in the reporting of them. So, that true rate,
17 even though we have it cited in literature articles and
18 probably in current literature articles is subject to the
19 same variability. I think we need to be very cautious in
20 making decisions based on those rates reported. That
21 particular survey is the way they defined that particular
22 population and that isn't necessarily going to be
23 representative overall.

24 DR. BRADLEY: I guess we are returning to the
25 point I tried, and clearly failed, to make earlier but,

1 again, if we are thinking in terms of the patients and
2 saying we are willing to accept a certain risk, the risk
3 being an absolute incidence level, say, 20 per 10,000, and
4 then we go to a case-control study in which we assess
5 relative risk, the point I tried to make earlier is if the
6 lens materials are a moving target and all you now know is
7 relative risk between new 7-day and new 30-day and your
8 absolute incidence data are based upon the old materials,
9 you really will never know if the 30-day with the new
10 materials are producing a risk greater than the one that we
11 are setting. That is the point I tried to make earlier and
12 it seems like it is a problem still, at least for me.

13 DR. SCOTT: I think before we were talking about
14 comparing the new material 7-day interval with the new
15 material 30-day interval. We hadn't yet established that we
16 were going to use the currently accepted level as being the
17 standard. We not only had two variables, but we had two
18 variables and a moving target that we hadn't established
19 yet. If we use the 7-day current standard, the 20 per
20 10,000, then it really doesn't make a whole lot of
21 difference if we know the 7-day because the companies aren't
22 asking for that; they are asking for 30-day. And, it is up
23 to the sponsor to decide what they want to ask for. If they
24 want to come back and say we do want to request a 7-day
25 approval, then we do have to find out that information. But

1 that is not what they are requesting. We are putting a
2 burden upon them that doesn't give us any more information
3 because what we want to do is compare, as you said, to what
4 is currently out there and it is something that they are not
5 even requesting.

6 DR. BRIGHT: I don't quite follow what you said,
7 Dr. Scott. Are you saying we just want to know new 30
8 versus old 7-day?

9 DR. SCOTT: Why do we want to know the new 7-day,
10 new material 7-day?

11 DR. BRADLEY: Isn't that the way the case-control
12 study is designed.

13 DR. BRIGHT: The case control can be set up with
14 any comparison that people think is reasonable. So, if a
15 reasonable comparison is 30-day new to 7-day old, and a
16 control of 7-day new to the control for the material, then
17 that is something that can be asked for.

18 DR. SCOTT: But it is not separating out another
19 cohort. It is simply establishing what happens at the end
20 of 7 days. Oh -- I see what you are saying. Never mind.

21 DR. HILMANTEL: I think to answer to Arthur's
22 question, just as a practical matter, when these new lenses
23 come on the market -- I mean, I believe that they will be
24 marketed essentially as 30-day lenses, not as 7-day lenses.
25 They will be more costly and people who will come up with

1 that extra money to pay for it generally will be wearing
2 them at least 7 days. What I am trying to get at is I don't
3 think you are going to get these new lens materials taking
4 over the current 7-day market. They are going to be a small
5 percentage of that market.

6 DR. BRADLEY: Yes, I think you may be right, Gene,
7 but there is a potential Catch-22 there, and in the end that
8 study design might fail to achieve the goal that we have all
9 been talking about, that is, what is the risk to the patient
10 that we want to tolerate. That is the point I was trying to
11 make. I am not saying it will fail, but it could.

12 DR. HILMANTEL: I see your point.

13 DR. BRADLEY: If a moving target problem really
14 materializes, then it could be a problem.

15 MS. NEWMAN: I disagree with you. I think the
16 benefits, unless there is a complication, people will go to
17 the 30-day. It will be cheaper than buying four a month. I
18 don't have to take them out every week. I mean, there are
19 so many benefits that I don't know why you think it wouldn't
20 override the 7-day market over time.

21 DR. BRIGHT: He was just saying that people
22 wouldn't pay the price for the new lens just to wear it 7
23 days. That is all he was saying.

24 MS. NEWMAN: No, I heard him to say that it will
25 not eliminate the 7-day lenses.

1 DR. YAROSS: I think what he meant was for those
2 people who were going to stay with 7-day schedules, they
3 wouldn't switch to the new material because of cost. So, if
4 they intend to go to the new material, it would be because
5 they want the longer wear.

6 DR. BRADLEY: Perhaps to clarify, it seems that if
7 the new material lenses cost less than four times the old
8 ones then, of course, why use the old ones four times a week
9 instead of the new ones?

10 MS. NEWMAN: And I believe the cost would be less
11 than buying four a month.

12 DR. SUGAR: The last issue is how would the panel
13 define the endpoints that we are interested in for the
14 study? I think we have talked around that quite a bit.

15 DR. WEISS: We should just use the same
16 correlation as the Schein study because that would make it
17 very simple.

18 DR. SUGAR: Actually, there were two different
19 studies. The first Schein study was the case-control study.
20 Their definition I thought was relatively strict -- had a
21 corneal epithelial defect with an underlying stromal
22 infiltrate; underwent corneal scraping for culture; were
23 treated with antibiotics and underwent verification of their
24 case status by corneal specialists from the participating
25 centers. It didn't require that the cultures be positive

1 but that is a very strict definition.

2 I think Brian Holden from Australia gave us a
3 presentation of different kinds of infiltrates and ulcers
4 when we got back into this issue of extended wear and lenses
5 that modify the corneal shape, and there is a whole
6 spectrum, and I think this is actually a very tough issue to
7 define. Probably the most common ulcer I see now is a
8 Staph. toxic infiltrate that is not infectious.

9 DR. BULLIMORE: In the contact lens wearer.

10 DR. SUGAR: In the contact lens wearer.

11 DR. WEISS: Just one thing, using Schein's
12 definition, I think the index for suspicion for corneal
13 ulcers has gone down in the last decade. So, it would
14 decrease the number for culturing an ulcer. I don't think
15 we culture as often as we did. So, it would decrease your
16 catchment of these cases if you required that definition.
17 Was that the one where he got 20 ulcers per 10,000? Was
18 that the study or was it the next study?

19 DR. SUGAR: No, this was the case-control study so
20 it wasn't an incidence study. The Poggio, which was also
21 with Ollie Schein, was where we got 20 per 10,000. That was
22 the other definition which didn't require culture. It
23 required an epithelial abnormality, a stromal infiltrate and
24 treatment with antibiotics.

25 DR. WEISS: Well, I would go with that one.

1 DR. BULLIMORE: From what you said, neither of the
2 studies required culture.

3 DR. SUGAR: The first study required scraping for
4 culture. It didn't require culture positivity but required
5 the culture to be done.

6 DR. BULLIMORE: So, I would argue there is no
7 difference in the definition.

8 DR. SUGAR: Oh, no, I think there is quite a bit
9 of difference in terms of the degree of suspicion that it
10 was a suppurative keratitis and they had to be referred to a
11 cornea specialist for confirmation.

12 DR. BULLIMORE: I am trying to sort of
13 discriminate between subjectivity on the part of the
14 clinician seeing the patient and a definition as one might
15 like to define it.

16 DR. SUGAR: This was sort of after the fact
17 definition and was very subjective I think in both
18 instances.

19 DR. MATOBA: Also, I would like to add that in
20 John Dart's case-control study that came out shortly
21 thereafter, they defined a significant keratitis as an
22 infiltrate that the attending physician thought was
23 infected. They didn't require any culture. So, I think,
24 being practical and with the standard of care now, more
25 people treat empirically, and to be consistent with these

1 older standards -- an infiltrate that a physician thinks is
2 infected and that he treated with an antibiotic should be
3 the criteria and cultures should not be required.

4 DR. SUGAR: Other comments?

5 DR. HILMANTEL: What about requiring scarring? We
6 were just talking to a contact lens company the other day,
7 and we were asking them how many ulcers they were finding
8 in their product and they gave us a number and they said,
9 but in half of these we didn't have an scarring.

10 DR. SUGAR: That is real tough. What do you mean
11 by an ulcer? When the FDA is asking for frequency of
12 ulcers, are you talking about infectious ulcers? Are you
13 talking about infiltrates? I mean, I don't think you have a
14 definition on the receiving end or they have a definition in
15 the industry.

16 DR. SAVIOLA: For the premarket arena, recent
17 guidance has included grading scales for infiltrates. Our
18 sense, coming into this discussion for what we mean by an
19 ulcer is something that is more than just an infiltrate,
20 certainly more than an asymptomatic peripheral infiltrate,
21 something where the patient had some symptomatology,
22 redness. Location is always a tough question. If it is
23 symptomatic and there are clinical signs but it is still
24 peripheral, how would you grade that? Clearly, we all agree
25 if it is central and vision-threatening it is going to be a

1 catch-all for the nasty event. But we can't really measure
2 the real rate of the significantly morbid events in
3 premarket. That is why we have been concentrating on these
4 sort of other indicators, such as infiltrative events and
5 combinations of slit lamp findings, and things like that.
6 So, our concept of ulcer for this discussion is more severe
7 than mild to moderate.

8 DR. SUGAR: But not necessarily infectious or are
9 you saying necessarily infectious?

10 DR. SAVIOLA: I guess interventional from the
11 standpoint that you are going to want to cover with an
12 antibiotic of some sort and there is a break in the
13 epithelium. I mean, whether or not it really cultures
14 positive -- like you said, today's standard is just to treat
15 it and not to do that culture.

16 DR. PULIDO: Like I said before though, the more
17 you sway from the original descriptions, which is the
18 benchmark that you all have accepted, the more this
19 benchmark doesn't mean anything.

20 DR. SAVIOLA: That is true. The kicker though is
21 that if you look at the rates in the literature over the
22 last ten years or so, even though these definitions may be
23 slightly variant from Dart to Schein, to whatever, there is
24 a consistency in the ball park of what they had in terms of
25 events. So. Yes, we all agree that it is good to try to

1 define it as tight as we possibly can, but I don't know if
2 we really can get cohesive agreement even among the people
3 who participate.

4 DR. MATOBA: Well, Dr. Schein's study that
5 required the cultures didn't require culture positivity, and
6 even in the best labs cultures are only positive about 65,
7 70 percent of the time. So, I don't think you are losing
8 that much by not requiring cultures.

9 DR. JURKUS: A totally different way of looking at
10 this would be if the patients were polled at some point by
11 saying, "have you ever had a situation" -- not even calling
12 it an ulcer -- "where you had to stop wearing your contact
13 lenses and take antibiotic drops to heal your cornea" that
14 would then practically give us the information that I, as
15 clinicians, would be looking for because that will tell me
16 how often this might be happening.

17 DR. YAROSS: Are you talking about exit polling?

18 [Laughter]

19 DR. SUGAR: The threshold for using antibiotic
20 drops really varies very broadly, and there are many people
21 who will put in antibiotics because the patient says their
22 eye bothers them. I think your suggestion is worthwhile but
23 I don't think we have gotten any closer to the definition
24 you want.

25 DR. BULLIMORE: I think we have reached some

1 resolution but I do want to put in a plug here for the issue
2 of visual acuity and visual acuity loss. I mean, that is
3 one thing that is sadly lacking from all of the previous
4 studies -- the Poggio study, the Schein et al. studies. We
5 don't know how many of these patients actually suffered
6 visual loss which, for most of the PMAs we discuss would be
7 the laser intraocular lens -- that is our gold standard. I
8 think we really want to concentrate on getting that
9 information so we can at some stage differentiate between a
10 non-visually significant ulcer, one that doesn't produce a
11 long-term impairment in the patient's vision and those which
12 do because of we are going to be comparing the risk of these
13 devices with others, that is important information to have
14 and I would certainly want to see it collected in a way that
15 it wasn't collected in the Schein and Poggio studies.

16 DR. SAVIOLA: The only real discussion of
17 morbidity associated with ulcers that we have heard has been
18 through Holden and sort of ball parking how many people he
19 has seen -- yes, 3, 5 percent had visual loss, whatever. I
20 agree that is something that has not been well reported in
21 the literature and it would be good to have a handle on it.

22 DR. COLEMAN: I would also encourage quality of
23 life measures because you do want to have standard
24 instruments used to measure quality of life in these
25 comparisons to look at the risk/benefit ratios.

1 DR. SAVIOLA: There is the concept, as Dr. Jurkus
2 has described, and there are lots of ways to do this -- if
3 you are proposing a cohort and you enroll the first 5000 or
4 10,000 patients and then send them a survey at some point
5 down the road, 6 months, 12 months, what-have-you, then with
6 the content of that how do you construct it, etc? That gets
7 into a big discussion. If we are thing to determine was
8 there an event, do we take a secondary investigation and try
9 to determine additional information? There are lots of ways
10 to try to approach it. None of us is going to have a good
11 overall answer, but something like that is a good point
12 because they are developing these instruments for refractory
13 surgery and maybe we can use something along those lines.

14 DR. SUGAR: Does the FDA have other issues you
15 want us to address or attempt to address?

16 DR. SAVIOLA: We are not going to go back to
17 question one, right? No, I think you have given us a lot of
18 good opinions here today and I appreciate the time that you
19 took to consider these. I was hopeful at the outset that we
20 would have a good exchange of ideas, and I think we have
21 achieved that. This was a good opportunity for us to pose
22 these questions to the panel because of the concentration of
23 the statistician being here and the cornea specialists and
24 people with historical information over the years.

25 DR. PULIDO: And a retina specialist too.

1 [Laughter]

2 DR. SAVIOLA: The timing for us somewhat critical
3 and we do expect to see a submission of some sort in the
4 next six to nine months, and we do anticipate having a post-
5 market protocol included in that type of submission, and
6 certainly we will be bringing the clinical data for
7 discussion and also potentially the proposed protocol. So,
8 we wanted to sort of set the table early and give you folks
9 an idea to think about this. So, I appreciate your time.

10 DR. SUGAR: Thank you. There is an opportunity
11 now for anyone from the audience who wishes to make comments
12 to do so. Would you come to the podium and identify
13 yourself?

14 **Open Public Hearing**

15 MR. MATHERS: I am Peter Mathers, of Kleinfeld,
16 Kaplan and Becker, here in Washington, D.C., and I am
17 counsel to the Contact Lens Institute. I want to express my
18 appreciation and appreciation of the members of CLI to the
19 panel and to the FDA representatives here today for an
20 exchange of views which is extremely helpful to us. As you
21 are aware, the members of CLI, like the FDA and the panel,
22 are also studying the issues involved in devising meaningful
23 and practical post-market follow-up for new contact lens
24 products currently being developed for greater than 7-day
25 wear.

1 The issues addressed today, both in FDA's
2 presentation and in the panel's comments, involve many
3 complex statistical and other study design tradeoffs which
4 we have yet to resolve. We look forward to a chance to
5 study carefully the comments made today, and to working out
6 with FDA the specific commitments for a post-market study
7 that will provide the additional information about these
8 rare experiences with extended wear contact lens products.
9 Thank you.

10 DR. SUGAR: Thank you. Are there other comments?

11 DR. YAROSS: A question, will there be a guidance
12 put together on this, and then will it go through GGP, Good
13 Guidance Practices, or will this just be handled on a case
14 by case basis?

15 DR. SAVIOLA: Ultimately, that is our goal, to
16 propose a draft and through level one.

17 DR. SUGAR: Listed here is final panel comments.
18 I don't personally want to hear any --

19 [Laughter]

20 -- but if anyone from the panel has any issues
21 that we haven't raised that they would like to raise -- you
22 have to take me with a grain of sugar --

23 [Laughter]

24 -- anyone but Eve can comment.

25 [Laughter]

1 If not, Sally has final comments.

2 MS. THORNTON: Just a few things for those in the
3 audience and the panel and the staff, if they are still
4 here. We are going to be canceling the January 11 and 12
5 meeting. I will be posting the March meeting status about
6 the middle of January on the FDA web site. So, stay tuned
7 for that and I will be in contact with all the panel
8 individually through your e-mails.

9 I would ask you to please leave your materials on
10 the table, however, I did give you all organizational charts
11 which you are free to take home and put on your bulletin
12 board or in your telephone book. Those are for you to keep.
13 Any of the non-confidential materials that we have been
14 discussing this afternoon, you are certainly are free to
15 take with you.

16 I would like to thank Diane. She just had to
17 leave, unfortunately, for pinch-hitting for Lynne Morris
18 today. She just did another panel about a week ago. So,
19 she is above and beyond the call of duty here. And I want
20 to thank the rest of the panel. I hope the new voting
21 members have enjoyed their day with us. We hope to see you
22 again in March perhaps. But thank you, all, for the time
23 you have taken to prepare for the meeting. It is very clear
24 you have been involved in the issues and sought to give us
25 your best thinking. Thank you and good afternoon.

1

DR. SUGAR: Thank you.

2

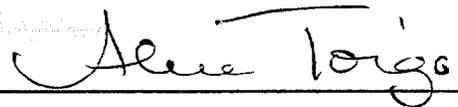
[Whereupon, at 3:50 p.m., the proceedings were

3

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.

A handwritten signature in cursive script that reads "Alice Toigo". The signature is written in black ink and is positioned above a solid horizontal line.

ALICE TOIGO