DR. WEISS: Okay. So you would not want to follow them. Would anyone want to continue the present study with the currently implanted IMT patients to seven years? Dr. Ferris.

DR. FERRIS: Well, I have a question at least, and that is there has been discussion of this concern about a disaster, and if you do a five year follow-up study, you'll have zero information on long-term follow-up, and I'm fully aware of burden on the sponsor, and I'm very supporting of what Oliver said. I would like a little bit of information, but those 100 patients or so that they're still following, if they could follow them for a few more years, to have some sort of sense that there isn't this lurking disaster, I would think that that would be reasonable.

Now, you could say, well, if there are these disasters, they're supported to report them anyway but, you know, the reporting of SAEs, as you know, is not too good after the study's over. So it's at least a concern that I'd like to bring up because it's a concern of mine. I have no way to know whether -- there was a pretty big cluster of edema patients at 30 months, and if all of a sudden there were other big clusters of patients, I don't

think it would change the way I feel about the device other than what I would tell patients.

DR. WEISS: Dr. Schein. Yes.

DR. BONHOMME: I'd like to make two points of clarification. The first is that in considering what the postapproval studies might or might not be, we would ask that you consider the questions that you would want the study to answer and perhaps be guided by that, and the other point relates to the public health concern. I know we weigh the issues of burden and don't want to be burdensome, but you also need to consider very importantly the public health concerns. Thank you.

DR. WEISS: Dr. Schein.

DR. SCHEIN: So I think the question to address her question is an estimate in a real live population of the rate of clinically significant adverse events. And to address Rick's question, which I think is worthwhile, is it would make sense then to follow to seven or eight or beyond, but only for those major events, not for the full protocol.

DR. FERRIS: I've seen enough endothelial cell counts.

DR. WEISS: So I'm hearing that we would want a prospective study to be looking at specific

issues such as corneal transplant, explantability. Would we include specular microscopy in that prospective or we would not?

DR. SUNNESS: What about corneal edema?

DR. WEISS: Corneal edema would definitely be an endpoint. Dr. Ferris.

DR. FERRIS: Clinically important outcomes is what we're --

DR. WEISS: So clinically important outcomes when this is released to the broad surgical and the broad patient population at hand, but in addition, and if anyone does not agree with this, please let me know, expand this out to seven or more years. Is there an indication in terms of how many years we would want this extended out and we would have clinically significant events? Would we want the specular microscopy as well? Dr. Bandeen-Roche.

DR. BANDEEN-ROCHE: I mean if a parallel study is going to be going on, something like five years anyway, and we're collecting clinically significant events, I would suggest rather than 7, why not 5 more, I'm sorry, a total of 10, 5 more years for the original cohort in terms of their clinically significant events as well?

DR. WEISS: Dr. Eydelman, how -- what's the

typical length of time that -- beyond which you'd say it's not least burdensome?

DR. EYDELMAN: I'll defer to my epidemiology friends.

DR. BONHOMME: Again, the prevailing guide here is the public health concerns. So if you have an endpoint that you're concerned about that occurs at the second year, then you might have a two year study or a three year study. If you have an endpoint that you're concerned about that might occur in 5 or 10 years, that would guide the duration of the study.

DR. FERRIS: So that's what I was going -- I think there is a public health point here, and that the average life expectancy of somebody who's 75 or 80, if you get to 80, you have about a 10 year life expectancy. If you get to 75, you actually have about a 10 years life expectancy. They may be bumped up a little bit now, but the 10 year is the average life expectancy of these people, and I think the burden is not so big if you're just focusing on these clinically important outcomes that at least I would like to say, I'd like it simple, but I'd like them followed for the 10-year period while this other study's ongoing.

DR. EYDELMAN: Yes, I was just going to add

to that that one needs to consider also how many patients are alive in this cohort and what is the life expectancy of those patients that are still remaining. That may be also something that you need to consider as you design or help us design this study.

DR. WEISS: Do you need more specifics from the Panel as far as -- you sort of get the sentiment in terms of the things that we're looking for. Certainly corneal edema and then operative complications from perhaps a less experienced surgical group. Is there anything else you need from the Panel in terms of more specifics on this or is this --

UNIDENTIFIED SPEAKER: There's a D.

DR. WEISS: No, no.

DR. EYDELMAN: This is the first one we're talking about.

DR. FERRIS: So the one that nobody's mentioned is retinal detachment. I mean if glaucoma is going to come up, I've got to say retinal detachment. It's a miracle that none of these 200 patients have had a retinal detachment, but that would surely be one of the serious complications that you would want to follow.

DR. WEISS: Dr. Higginbotham.

DR. HIGGINBOTHAM: Well, I guess I just need a point of clarification. So are we suggesting two PAS at least?

DR. WEISS: Yes, two postapproval studies.

DR. HIGGINBOTHAM: Continuing the original cohort as well as initiating a new.

DR. WEISS: Yes.

DR. HIGGINBOTHAM: I guess from my standpoint, the original cohort is certainly going to be increasingly more difficult to get them in, and so I would suggest a very simple protocol and maybe just an annual check and not necessarily bringing them in as frequently as was done for the original, but I guess my feeling is that I wouldn't want to burden this group anymore than they've already been burdened in general.

DR. WEISS: Okay.

DR. MATOBA: So could you please clarify what exactly we're asking now?

DR. WEISS: What are we asking them to do in the seven-year follow-up?

DR. MATOBA: Yes.

DR. WEISS: Well, I know we're looking for clinically significant events. I do not know if

we're including specular microscopy, and I don't know if the FDA wants to even comment on that as far as what's included in the follow-up of the original IMT group.

DR. EYDELMAN: Well, if you have a comment, please share with us.

UNIDENTIFIED SPEAKER: Corneal edema.

DR. FERRIS: I have a recommendation, and that's those clinically important outcomes that we mentioned assessed yearly is all I need and --

DR. WEISS: That's for the long term.

DR. FERRIS: -- for a 10-year follow-up --

DR. WEISS: Okay.

DR. FERRIS: -- on the survivors of that cohort. They're down to 100 something now, 130 or something, and so for that 130, try to follow them once a year.

DR. WEISS: Dr. Eydelman.

DR. EYDELMAN: The proposed protocol by the sponsor, I think it's LTME was not just to follow the LTM patients but to try to take some of the patients that were enrolled under 002 which did not necessarily agree to enter LTM so that the LTME cohort will comprise LTM plus some of the patients from 002. That's my understanding.

DR. WEISS: I think we're in agreement with that. The question is what happens to them at different time points? So I think everyone's agreeing, we would want history, if you went somewhere for a retinal detachment operation, we'd what to know if you have a corneal transplant operation, we'd want you examined on a yearly basis if you could get in. Would you want corneal pachymetry? Do you want specular microscopy?

DR. FERRIS: I'm happy with really simple. I'm perfectly happy with trying to get them in. If you can't get them in, having a phone interview. Did you have a retinal detachment? They're not going to know, of course, but at least they'll know they went to the doctor and they fiddled with them, and then you can try to find out what happened, but I think probably most are going to say, you know, I've been doing fine, and I assume most of them are coming back for some sort of regular follow-up at some point.

DR. WEISS: Dr. Eydelman.

DR. EYDELMAN: No.

DR. WEISS: So we're basically making the following out the largest group possible that has already had the IMT-implanted, having clinical exams and following them out for a decade to try to

determine incidents of retinal detachment, incidents of corneal transplants, et cetera.

DR. EYDELMAN: The only comment I would have is that if you are interested in the long-term ECD, that's probably the only group you're going to get good numbers on.

UNIDENTIFIED SPEAKER: I don't care.

DR. WEISS: I mean I personally would if they come in, if we're talking about seeing them yearly, I would say throw in the specular microscopy because even at 8 years down the line, if you have 40 percent of the people at a 750 cell count, that's still going to tell you something even if -- that will tell you, you may not want to expand this into the 50-year-old age group. So that will give you information for some age population. So if it's possible to do it, I would think it would be helpful to do. That's my opinion.

Does anyone agree or disagree on that?

DR. MATOBA: I agree with you, but I would think about it the other way. If 40 percent had 750 and they didn't have corneal edema, well, maybe 750 is not, you know, maybe those numbers are not what we should be looking at anyway.

DR. EYDELMAN: So either way you want to

see the numbers?

DR. MATOBA: I mean if -- I guess if they were coming back to a center.

DR. EYDELMAN: I understand your point.

DR. MATOBA: I don't know if that would obligate everybody to get it, you know.

DR. WEISS: Okay. Can we move onto d? If a postapproval study is recommended, then what do you recommend for the follow postapproval study elements?

The objectives. I think we've mentioned the objectives, complication rates surgically, retinal detachment rate, incidence of glaucoma, corneal transplant.

DR. EYDELMAN: I believe this particular, Michele, please correct me if I'm wrong, I believe you were talking about the newly enrolled patients. So we're talking about the other study.

DR. FERRIS: That's correct. So this would be -- I don't know how many, whether it's 100, whether it's 200. The consecutive patients that have this device implanted, that they're followed for the next five years. I thought Oliver did a wonderful job of summarizing those clinically important outcomes that you would collect annually, and that would be sufficient from my perspective.

DR. WEISS: Is that -- do you have the information or do you need more specifics from us? Well, do you want to go five years on that?

DR. FERRIS: Pardon.

DR. WEISS: Do you want to go five years on that?

DR. FERRIS: Yes.

DR. EYDELMAN: Again, I would just like to clarify without leading the Panel that we would like the sample size to be based on what we are looking for, and I just would like to make sure that we still have some room for coming up with the final sample size based on what our expectations of this study is.

DR. WEISS: So we can't give you an expectation here of what we would expect certain complication rates to be. We would defer to you about that?

DR. EYDELMAN: That's absolutely correct. But if you say what would be clinically meaningful endpoints, that will give us certainly sufficient information for us to figure out the sample size.

DR. WEISS: Well, is there an endpoint -- we don't know what the retinal detachment rate is.

DR. FERRIS: Yeah, I would not do it on retinal detachment because it would be a humongous

study. I'd want to collect them just to make sure there isn't some epidemic of retinal detachments that we didn't expect. The number that would drive the epidemiologic study for these new patients, I would think, are I'd want to make sure how many have to be explanted. I want to make sure how many develop edema, how many develop corneal transplant. I think I'd use maybe the corneal edema numbers that you have to say, you know, I'd want some reasonable confidence intervals around that expected rate of 20 percent or something. Well, in 5 years, it's going to be 10 percent, you know, assuming that this group is worse than the controlled study group.

DR. MATOBA: Well, I mean, for example, there were seven patients who had posterior capsular rupture, that's a lot, and that was 200 some patients. I'd want to know that that didn't double in the new group, and there was one suspected choroidal hemorrhage. I'd want to make sure that didn't happen again. And then there's a certain number that were not implanted for some other reason, and I'd like to know that that didn't double in that range.

DR. FERRIS: All of the operative complications I think should be --

DR. MATOBA: Yeah, all of the operative complications.

DR. WEISS: Dr. Eydelman.

DR. EYDELMAN: Yeah, if I can just belabor the point. Now, thank you for providing the key safety endpoints. Now, could you venture as to the targets which would be acceptable or which you would like to be detectable with the study? So the sample going back so that we are all talking the sample size. Obviously I'm not asking you to do the calculations but --

DR. BANDEEN-ROCHE: I agree with Dr. Ferris. I think that the key is the precision of estimation, you know, that's what I would want to determine the sample size, not power against an alternative which would probably -- I mean against -- alternative which might be somewhat arbitrary anyway. It's the precision of estimation.

DR. WEISS: I don't think we're giving you what you want, but that's what we're giving you.

DR. EYDELMAN: Accepted.

DR. WEISS: Accepted. Okay. You're amenable.

DR. EYDELMAN: We need to have an open public hearing.

DR. WEISS: Okay. Yeah, I was looking at that. So now we're onto the clinically tolerable rate of severe adverse events, which we did not give you, and it sounds like we're not giving you.

Duration of follow-up of study subjects. We said five years. Five years.

Other specific issues we would like addressed. Any other issues?

DR. MATOBA: Well, can I --

DR. WEISS: Yes, Dr. Matoba.

DR. MATOBA: I just want to say, personally, I don't think we need to ask for five years. We already have a long-term study. So I mean I'm more interested in what happens when everyone else starts doing it. Is there a sudden uptake in intraoperative complications and perioperative complications, and if we don't see that, and it's not seen within the first year, I don't necessarily think we need to ask for four more years of data.

DR. WEISS: Well, the question is when do you think the cornea -- let's say someone is not doing the best job or it's a more challenging case, how long do you have to follow them before you see the cornea decompensate because not all the corneal edemas will be in the acute period.

DR. FERRIS: Well, in fact, there was that -- at 30 or 40 months.

DR. WEISS: That's what I'm asking.

DR. MATOBA: I guess I'm not as concerned about that.

DR. WEISS: What do most people want to do? So are we talking a one-year study, a two-year study, a five-year prospective study? What's the opinion of the group?

DR. SUNNESS: I think you're talking at least four years. We don't have any information what happened between four and five years but, you know --

DR. WEISS: So you'd say at least four years. Dr. Matoba, you'd say --

DR. MATOBA: I will defer to the majority opinion, but I just wanted to say that I don't necessarily think that that's necessary.

DR. WEISS: Dr. Ferris, you'd say how many years?

DR. FERRIS: My view is we've got actually good data on two years and we have pretty tight estimates as to what they are. Our concern is there were a lot of dropouts. We're unsure whether their complication rates were the same as the ones that we followed, the 100 that we followed, the 100 followed

and the 100 we didn't follow, and so if I have any concerns at all, it's in that 2 to 5 year range, not the -- in the 1 to 2, I'm worried about new surgeons and the operative risks and those complications, and I'd want to capture them, and them I'm a little bit worried from the data that we saw that there may be some 3 year, 4 year, that that's when the corneal edema is going to show up, and I don't have any way to prove that it's not. So that's why I'm worried about that.

DR. WEISS: Oliver, a quick comment.

DR. SCHEIN: To address Alice's concern, it would be possible and not burdensome to collect operative data on a large cohort so you could see whether the rate of capsular rupture, et cetera, was much higher than expected, and that would indicate more training was needed.

DR. WEISS: Well, that's one part of it, but what I'm hearing also is that if we're not doing the specular microscopy, we do want to follow them out for a long enough period of time to see what the effect is. So I would also second a longer study, and think what? I've heard four years mentioned. I've heard five years mentioned. Is that good enough for FDA? I think we are -- Dave.

DR. MUSCH: One more comment. Maybe it's obvious, but I think abrupt loss of vision should be detected. So I assume you're measuring best-corrected visual acuity?

DR. WEISS: That's a good point. Is FDA satisfied that we are finished with the questions? Because we're running behind, we will take a short break before we vote, but I'd like to go onto the second open public hearing. We have three open public speakers. Dr. Hudson is the first.

DR. HUDSON: Good afternoon. The first thing I've been asked to do is read a letter from one of the patients who participated in the trial who is my patient, Mrs. Janet Grant.

Janet states, "I regret that I'm unable to attend the meeting to discuss my intraocular implant this month. I was scheduled for surgery during the same time as I had a compression fracture in my back, and gratefully, the surgery was successful. I hope you will read my letter during the public comment period since this device has been so important to me.

"I've had my implant for five years now. I was at the meeting two years ago when I spoke to you. For those of you that remember me, I'm still able to ride my recumbent three-wheel bicycle and never hit

rocks in the road or bump into garbage cans. I use this lens for this activity as well as for watching television. However, my bike riding is my primary exercise to strengthen my body and improve my quality of life.

"Indeed, I believe all the benefits of exercise have helped me fight off various medical issues, including my recent back surgery.

"There are other benefits as well. The lens has also given me the ability to identify people when I'm sitting at a gathering of friends and neighbors. Also I've gotten a lot of joy and peace by being able to see the lake as I walk along the beach." She lives along Lake Michigan.

"The lens helps me keep safe as I walk by allowing me to avoid obstacles washed up on the beach.

"Just before my implant, I had had cataract surgery in my right eye. Although my vision improved, my macular degeneration was so severe that I couldn't see at distance. My implant allows me to see distances, and I can automatically turn it on and off using my brain."

As an aside, all she does is think the word telescope.

"It's my implant that has allowed me to stay active. In closing, I want you to know that I can still look across the room at my six granddaughters and pick out Erin from Esther, Claire from Marlie, and Sophia from Hannah. Even if this were the only benefit, it would be enough for a beautiful life. Thank you for this time. Sincerely, Janet Grant."

So now you've heard from 2 percent of the IMT populations.

My personal reason for being here is I'm one of the few retina specialists that was involved with the IMT-002 trial. I was also the number one enroller in the clinical trial and the lead author on two of the three papers. And I wanted to let you know my perspective and my patients' perspective about having this device.

As you've heard before, before the IMT was available, essentially what we did with our end-stage patients is we referred them to low vision specialists for evaluation after counseling them that we had no therapeutic options.

Unfortunately, what hasn't been mentioned is these services are expensive, not readily available in all areas, and not covered by health

insurance. And the patients would still come saying, well, Doc, it helped some, but I still can't see faces, and I still have other limitations including in a social environment. Many of them didn't like the look of the telescope on the glasses.

After attending the investigator meeting, with a lot of strong, preconceived doubts by the way, I was convinced that we deserved this opportunity to investigate this device. After I enrolled my first patient and saw that he was able to recognize faces on 3 x 5 photographs, 2 months postop, and he hadn't been able to do this for 15 years, he became very excited. He hadn't seen anything like that with low vision tools. He had used low vision tools with only mild success until the IMT implantation.

As further patients were very carefully selected, enrolled, and implanted, I heard more stories like this first one. Janet was able to paint again, and she's a fabulous painter. I don't know if you've seen her picture, but I think it's one of the Journal articles. I was able to watch another patient who was only one week out from surgery sitting in a truck, as she was told not to be out in the dust and dirt, watch her great grandson lose a little league game by dropping a play at the plate, a thrown ball at

the plate. I've never seen so many smiles in this group.

Now we finally have something new to offer our patients. It's an offer that we haven't had before. The low vision specialists tell us that there's more things that they can do with these patients because of the on-the-go and direct and hands-free nature of the device.

Will all the patients be like the ones I've mentioned? Well, clearly from all the evidence you've heard today, they won't, but the vast majority improved, and in my experience, we got better and better in patient selection and aligning patient expectations, and you guys covered a lot of that today.

I went on to enroll the largest cohort of patients, and I've seen the full spectrum of the benefits and limitations, including the suspected choroidal hemorrhage that wasn't. That was my patient. The doctor saw darkening of the red reflex, took a look after suturing the incision, still was uncertain, sent her to my office five hours later, nothing.

What we've also noticed is that a lot of these patients are very satisfied with the results of their implantation. I did have one patient request an explant because of his loss of dynamic range. He was a

Stargardt's patient. Despite the fact that he could see 20/20 at near, he felt he couldn't drive his tractor safely due to the aniseikonia.

One key consideration, the key consideration, is proper patient expectations and selection to get the maximum effect from the technology.

So based on my personal experience, I would love to offer this treatment to my patients. When I speak at meetings, everyone asks me what's the word, and I tell them we should have information soon. It's my opinion this is long overdue, and we should offer it to the correctly selected group.

Most of my patients, if not almost all, would do it again. So I'm asking you if not this, then what? If not now, then when? Thank you.

DR. WEISS: Thank you. Mr. Dan Roberts.

MR. ROBERTS: Thank you very much. I'm founding director of Macular Degeneration Support, which is an international organization offering information and support for people affected by age-related macular degeneration. I'm speaking on behalf of a large internet low vision community of about 4 million hits a year on the website plus over 200 live affiliate groups representing about 3200 previously

unconnected senior adults in retirement centers around the world.

I have no financial interest or commitment to VisionCare Ophthalmic Technologies or any of its constituents. I've just come here on my own to speak with a thousand voices.

A large part of the mission of MD Support is to keep people aware of new developments in the field of vision research. Over the past 15 years, we have introduced many treatments, surgical techniques, and assistive devices to our low vision population, and such information is typically devoured with much enthusiasm. None, however, has received more attention than VisionCare's development of the Implantable Miniature Telescope.

Since we started tracking its progress back in 2004, it's been written about and discussed by our community more than any other device, and the reason being that it's unique and that it appears to be both safe and efficacious.

People who have reached their senior years and developed serious vision loss are interested in potential treatments and cures, but their main focus is on maintaining a reasonable quality of life. This means they gravitate more toward devices that hold

the promise of seeing better during their remaining years.

We realize that the IMT may not work for everyone, and we respect VisionCare Technologies' honesty in making that clear to the public. We're also impressed with the care they take in presenting the option to the patient, specifically the opportunity to see whether the IMT will work for them by having advanced hands-on experience with a non-implanted version of the device.

Most important, we need to see research like this continue. Since all but a few issues have been satisfied by VisionCare, we're hopeful that these issues will be settled and that this Panel will decide in favor of continued progress with the IMT. If, after all reports are in, we find that it will not come to pass, at least we will know that our government has provided every possible opportunity for us to have access to better vision.

By approving further progress in the field, you will be signaling to patients, sponsors, investors, practitioners, and scientists alike that such research is welcome and potentially worthwhile, and we, on the other hand, will benefit by knowing that that's still going on and still happening

because of your encouragement.

In 2008, Dr. Hudson wrote that "three-line improvement that we had previously shown makes a real impact on our patients' independence and quality of life." This is the most significant benefit from the development of the IMT. It's not going to cure our disease. It's not going to give us back our normal vision. The surgery might even destroy a few corneal cells, but it will give us a chance for better eyesight, even if only temporarily, and anything better is an improvement over the years of progressive vision loss we are all experiencing.

We believe that doctors and patients should be allowed to choose for themselves whether devices like the IMT will work in individual cases. We hope this Panel will do everything possible to give us that opportunity, just as it gave my mother the opportunity to decide for herself whether cataract surgery, in spite of its very high risk at the time, was going to work for her and improve her failing eyesight.

For those of us who are still in the process of losing vision, favoring such research will also offer us hope. Our future will be less threatening just knowing that such devices as the IMT

might be available when the time comes, and just that little bit of hope can significantly relieve the fear that is one of the biggest reasons for diminished quality of life. I speak for many when I say that I can walk with more confidence down this road if I know that help is waiting for me at each crossing.

And finally, by approving further development of the IMT, you'll be adding another weapon to the low vision rehabilitation arsenal. Over the past two decades, our physicians and therapists have developed a good number of defenses for us to use against the emotional effects of vision loss. Such defenses include training in daily living skills, training in working around our scotomas, adapting our environment and optimizing our vision through magnification and better lighting.

Until now, however, none of them have offered long-term vision restoration for people in the advanced stage of the disease. That stage has traditionally been one of transition to non-visual skills such as cane use and Braille. With the use of IMT, it may be possible for some of us to put that off indefinitely, and that gives us one more cannon to fire.

I speak with several thousand voices when I

ask that you give thoughtful consideration to the IMT and its potential to enhance the welfare and the quality of life of all of us.

Thank you for your perseverance and your incisiveness in ensuring that such research as this be safely and effectively available to all of us. We appreciate your time.

DR. WEISS: Thank you very much.

MR. ROBERTS: Thank you.

DR. WEISS: We will take a five-minute break, and then we will be concluding with FDA and sponsor summations before we vote.

(Off the record.)

(On the record.)

DR. WEISS: Okay. We're going to now resume the meeting, and we're going onto FDA and sponsor summations. Are there any further comments or clarifications from FDA, Dr. Eydelman?

DR. EYDELMAN: No, thank you.

DR. WEISS: There are not. Okay. Are there further comments or clarifications from sponsor, and if so, if you could confine it to five minutes, I'd appreciate it. I also had a question for sponsor. If a patient has a capsular tear, can the IMT still be implanted? And if it cannot, is

that in the warnings to the physician? Judy.

DR. GORDON: Judy Gordon. If you recall from the data that we showed, the main reason for aborting the IMT, meaning the implantation wasn't even attempted, was for capsular ruptures. That is in the labeling.

DR. WEISS: I don't mean capsular rupture. I mean a capsular tear.

DR. GORDON: A capsular tear.

DR. WEISS: So if you don't have a central capsular rhexis at 7 millimeters or 6.5, if you have a capsular tear --

DR. GORDON: I think Dr. Lane can answer that.

DR. WEISS: -- in the anterior capsule, can you still put this in? Steve.

DR. LANE: Steve Lane. If there was a small tear in the anterior capsule, I think you'd have to assess, you know, where it is in relation to how you're pushing the implant. The haptics are stiffer than if you remember the old PMMA single piece haptics. It's a little stiffer than that. I think it can be done. It depends on the degree of the tear. If it was a small little nick in the anterior capsule, I think I would try and put it in.

If it was a large tear that looked like it was getting out toward the equator, I would not.

DR. WEISS: Is there anything in the physician labeling that addresses anterior capsular tears?

DR. LANE: It addresses anterior -- not anterior capsular tears, Jayne. I think it would have to be a surgeon call based upon how much and the direction that it is.

DR. WEISS: Okay. That's fine, Steve. I would just suggest that perhaps we add that, something about how a physician would address an anterior capsular tear if they encounter that. So that's not part of your five minutes, but if you've got anything that you want to clarify and comment on, this would be the time.

DR. STULTING: We don't need to clarify and comment, but we would like to use our five minutes, actually use a lot less.

Today you heard from patients who reported that the IMT "changed my life" and gave clear examples of this as they reported their positive personal experience with the device.

You also heard from two physicians who expressed concern about their inability to offer this

treatment to their patients today. Indeed, patients with advanced macular degeneration have a progressive debilitating disease, and many of them would like to have the opportunity to have an IMT implanted after informed consent, acknowledging the risk of corneal decompensation.

We agree with Panel comments that the key here is to inform the patient adequately about the risk and benefit of the IMT implantation so that he or she and his or her physician can together make a decision about the implantation of the IMT. And we believe that it is possible for the sponsor to do so. We believe that the data on the entire cohort support the safety and efficacy of the device for its intended use. They also provide enough information to communicate the benefits and the risks of adverse reactions to patients as they consider this treatment option for their incurable disease.

We thank the Panel for its thoughtful consideration of this application.

DR. WEISS: Thank you. Before we proceed to a vote, I'd like to ask Richard Bunner, our consumer representative, and Barbara Niksch, our industry representative, if they have additional comments? Mr. Bunner.

MR. BUNNER: From a consumer's perspective, I do appreciate the due diligence of both the FDA and the sponsors in looking at this healthcare issue. You know, from the general press perspective, it seems like at times our governmental agencies, the FDA gets beat up pretty bad, and to be able to sit here as a consumer and see the great care that is given to just one healthcare issue is very, very impressive. So kudos to both sides of the issue, from the sponsor's side and from the FDA's side.

I also want to say, too, that it was interesting from the consumer's perspective having been here before at the first session and seeing the concern obviously with the endothelial cell loss being a big issue and the concern related to that, and having as a consumer sort of feelings of misgivings about a product like this, and coming back again to see the further research and really hearing the continued testimony of the consumers of this product. I thought it was very compelling. I know that those kinds of anecdotal presentations are not hard science, but they certainly are impressive for the general public to hear these positive outcomes.

So I appreciate the opportunity to participate in this, and I'm also heartened by the

fact that we're going to be giving very careful consideration to risk education. I think all of us are consumers of healthcare, and we can all sort of put ourselves into situations where we've been there face-to-face with the doctor discussing a medical procedure and wondering am I getting a clear description of the risks factors involved with the procedure I'm considering, and I'm impressed that we're giving a lot of high priority to the issue of adequate risk concern for the consumers. So thank you.

MS. NIKSCH: Barbara Niksch. I want to also thank the Panel today. I think that focus was maintained, balance was brought forth. I want to say to the sponsor, on behalf of industry, I think the sponsor demonstrated extreme diligence and persistence in their 10 years of running the IMT U.S. trial. It's a lot of work, and they should be commended on continuing to collaborate with the Agency and bring forth the information that they've continued to do.

I do think the Panel's been given sufficient information on safety and effectiveness to justify the approval of the device. I think that the risks have been fully identified. The risk

mitigation plan I think was very thoroughly conducted. The labeling and such we talked about today I think will offer the consumers, the physicians the education they need to choose the right patients, to counsel the patients, to make the right decision.

So on behalf of my role as industry representative, I appreciate being asked to be here, and I'm pleased with the information that was provided, and I hope that the Panel has all the information they need to find this device approvable.

DR. WEISS: Thank you. We are now ready to vote on the Panel's recommendation to FDA for this PMA. Mr. Swink will now read the Panel recommendation options for premarket approval applications. Mr. Swink.

MR. SWINK: The Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, as amended by the Safe Medical Devices Act of 1990, allows the Food and Drug Administration to obtain a recommendation from an expert advisory panel on designated medical device premarket approval applications that are filed with the Agency. The PMA must stand on its own merits, and your recommendations must be supported by safety and

effectiveness data in the application or by applicable, publicly available information.

The definitions of safety, effectiveness, and valid scientific evidence are as follows:

Safety as defined in 21 C.F.R. Section 860.7(d)(1) - There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.

Effectiveness as defined in 21 C.F.R. 860.7(e)(1) - There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Valid Scientific Evidence as defined in 21 C.F.R. 860.7(c)(2) is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-

documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions, are not regarded as valid scientific evidence to show safety or effectiveness.

Your recommendation options for the vote are as follows:

1. APPROVAL - If there are no conditions attached.

2. APPROVABLE with conditions - The Panel may recommend that the PMA be found approvable subject to specified conditions, such as physician or patient education, labeling changes, or a further analysis of existing data. Prior to voting, all of the conditions should be discussed by the Panel.

3. NOT APPROVABLE - The Panel may recommend that a PMA is not approvable if:

- the data do not provide a reasonable assurance that the device is safe or

- the data do not provide a reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in proposed labeling.

Following the voting, the Chair will ask each Panel member to present a brief statement outlining the reasons for his or her vote.

Thank you.

DR. WEISS: Are there any questions from the Panel about each of these voting options before I ask main motion for the PMA?

DR. SUNNESS: The conditions, does that mean -- so in other words, if we accept what the indications are now and the contraindications, would that mean we would accept it without conditions or are those conditions?

DR. WEISS: Typically when I've chaired meetings, many of these meetings, the way this runs is someone will propose for approval with conditions, and the conditions are many of the things or all of the things that we suggested. So it could be labeling. It could be which grid gets used. It could be removing one of the contraindications. Each of these can be a condition after someone, let's say, suggests that be the motion, then that gets seconded,

then each condition is then introduced, discussed, and voted on separately. Once we decide which conditions are included in that main motion and conditions, then we vote on the total thing, the motion of the approval with conditions. Any other questions?

And I would also direct you to the chart in your folder in terms of how this works.

Is there a motion from any of the Panel members for either approvable, approvable with conditions, or not approvable? Dr. Edrington?

DR. EDRINGTON: I move that we approve with conditions.

DR. WEISS: Is there a second?

UNIDENTIFIED SPEAKER: Second.

DR. WEISS: I hear a second for the motion. Is there any discussion on the motion, and by that I mean any general discussion, or we can then go onto introduction of the conditions that have been scribed.

Hearing no discussion, if I could have read -- we're going to read each condition that has been discussed up to this point.

It has been moved that the PMA be approved with conditions. Please refer to the yellow portion

of the voting procedure flowchart in your folder.

We are now, as I mentioned, voting on each of the individual conditions of approval for this PMA as it stands. So what will be done is a condition be first recommended, then it will be seconded, and then there will be discussion about the recommended condition as it was worded, and then we'll vote on that condition. If that condition is approved, it will be the first condition to the main motion approvable with conditions. We'll then move onto a new condition and repeat this process until there are no new conditions and to repeat what I had previously said. After we have all the conditions, with the motion, then we will vote on the main motion, which is whether or not to approve or not approve the application with all the conditions that have just been approved by the majority vote.

I had Mr. Swink and Dr. Bandeen-Roche do scribing as we were doing the conditions during discussion. So if anyone has a particular condition, we can discuss that or we can just -- if there are any conditions that you want to recommend, this is the time to do it. And if there are any ones that you recall that we've already discussed, you can recommend those. If there's anything new, you can

recommend those, and then we need a second before we have discussion and a vote.

Dr. Bandeen-Roche, do you --

DR. BANDEEN-ROCHE: So just state one of them?

DR. WEISS: Yes, state one of them, and if someone wants to second it, we can second it and then discuss and have a vote.

DR. BANDEEN-ROCHE: So I'll state the recommendation that there be developed an informed consent procedure a/k/a the analogy that was drawn with silicone breast implants, that would include informed consent capability with respect to cognitive function being assessed, and in that consent form, there would be a careful delineation of risks that the Panel has described, and in some cases that would include new analyses to delineate those risks as we've recommended.

MR. SWINK: Is there a second?

DR. WEISS: Second.

MR. SWINK: Discussion.

DR. WEISS: Would that be broken up into two different conditions or is that all the same one? Would that be the same one?

DR. BANDEEN-ROCHE: I consider it the same

one but --

DR. WEISS: There's second. Discussion. I see Dr. Eydelman, you --

DR. EYDELMAN: It's a prerogative of how you do it.

DR. WEISS: Dr. Szlyk.

DR. SZLYK: I have a comment. Would that include a brochure that would be provided with the consent form describing the risks?

DR. BANDEEN-ROCHE: I would think -- I mean yes, I was assuming that.

DR. WEISS: Dr. Eydelman and then Dr. Higginbotham.

DR. EYDELMAN: Is it your recommendation that FDA discusses with the sponsor the best way to educate the patients, or do they want to be more specific and more prescriptive than that?

DR. BANDEEN-ROCHE: So my understanding of the discussion was that there was a desire to have some documentation and verification that patient education had occurred.

DR. WEISS: Dr. Higginbotham.

DR. HIGGINBOTHAM: Just a point of clarification. You've noted assess. Do you use the word assess? I guess the spirit of the discussion

was that we would consider cognitive functioning but not necessarily ask that a neurological assessment be done.

DR. WEISS: Correct.

DR. EYDELMAN: I guess I'm not clear. Who's going to be doing the assessing?

DR. WEISS: Would you be able to repeat the condition and we may need to -- and maybe in the discussion, what we can do is rephrase it or wordsmith it so that it's as clear as we want it to be. So --

DR. BANDEEN-ROCHE: So the main part of the recommendation that they develop an informed consent procedure, in analogy to the silicone breast implant procedure that was described to us, that we communicate to patients the risks associated with the procedure as we have been discussing them. A number of specific things were discussed, including a brochure that would lay out those risks, would include some additional analyses that do not occur in the PMA that we discussed, and would be documented that the education occurred. That's the main part of the motion. If you want to leave the cognitive part of it separately, that's okay.

DR. WEISS: So sort of to reiterate,

something that was more formal and more standardized from patient to patient of an informed consent process, that we could be more assured that would be a standard part of everyone's experience with the IMT. Dr. Eydelman.

DR. EYDELMAN: If I may, I think it would be clearer if you do break it up into two conditions and if you specify which analysis. There was a lot going around. So I understand one about the informed consent. If the second condition is to do particular analysis, if you don't mind, I would like it for the record that you specify which ones it is that you're actually talking about.

DR. WEISS: So what we can do at this point, would you want us to do an amendment to the condition or have a vote and basically vote down the condition and then just rephrase it.

DR. FERRIS: Can I make a friendly amendment?

DR. WEISS: Can we make a friendly amendment to the condition?

DR. FERRIS: Or a hostile amendment.

DR. WEISS: So I believe she would have to amend it. Robert's Rules of Order. I should have brought it with me. Dr. Bandeen-Roche, you're going

to offer an amendment to your condition, which is perhaps what yours might be is to remove the second portion of your condition and just let's, you know, address the first portion.

DR. BANDEEN-ROCHE: So I do propose to move the second part of the condition --

DR. WEISS: Okay.

DR. BANDEEN-ROCHE: -- which I take it is the cognitive aspect of the condition.

DR. WEISS: Do I have a second for that?

DR. FERRIS: Second.

DR. WEISS: So now we're going to just address the first portion of the condition, which is basically the informed consent process of the patient which will be developed with FDA's input along how the breast implant consent process was developed. Is there any discussion on that? Dr. Ferris.

DR. FERRIS: I'd like to get the details out of it. I'd like to say that we would like the sponsor and the FDA to work utilizing the model set up by the breast implant post-consent model, or whatever we're going to call it, and let them work out the details.

DR. WEISS: And I would say specifically to underscore that we would like the discussion of risk

of corneal edema, uncertainty about future risks of corneal edema and how corneal edema will be treated in worst case scenario surgically and what the experience of corneal edema might be like, namely decreased vision and/or pain in more severe cases.

DR. FERRIS: In addition to the perioperative risks.

DR. WEISS: Any other discussion on this? Dr. Bandeen-Roche.

DR. BANDEEN-ROCHE: So I would ask the Panel whether there should also be information on estimating the proportion falling below an ECD cutoff in a certain period of time.

MR. SWINK: Are we amending the same condition?

DR. BANDEEN-ROCHE: I think this is a piece of information to be provided. So I think it's amending the same condition.

MR. SWINK: Okay.

DR. WEISS: Dr. Eydelman.

DR. EYDELMAN: Can I just bring it back? Okay. The first condition of approval is that there is some kind of an informed consent. Now, the second condition I believe is that there are additional analyses. So I thought that it was left that the

informed consent was going to be -- are you telling us exactly what you want in the informed consent or is it that you're trying to do what Dr. Ferris recommended, that the sponsor and the FDA work interactively to address what needs to be in it?

DR. WEISS: Yeah, I think Dr. Bandeen-Roche was getting more involved in the specifics of what should be in that informed consent --

DR. EYDELMAN: Okay.

DR. WEISS: -- packet.

DR. BANDEEN-ROCHE: But I mean what I would say is that we've had robust discussion all day long in which a number of very specific things were mentioned.

DR. WEISS: Right.

DR. EYDELMAN: That's fine.

DR. BANDEEN-ROCHE: And so I --

DR. EYDELMAN: We can definitely capture all of that.

DR. BANDEEN-ROCHE: Yes. But then a few specific things were mentioned by Dr. Ferris, and then my question to the Panel is whether the Panel wishes to advise FDA on making information about risk of falling below a ECD cutoff also available to the patient or not.

DR. WEISS: I'm not sure. That seems quite complicated to me personally in terms of how that would get conveyed.

DR. FERRIS: I'm perfectly happy to have the FDA and the sponsor who know the risks well outline the relevant risks in this document and not try to wordsmith it tonight.

DR. WEISS: Okay.

DR. MUSCH: I would second Rick's motion.

DR. WEISS: Essentially there is, from what I understand, consensus that we want a clarified informed consent process, perhaps likely with a brochure, likely with a standardized form that the patient would sign, and there would be confirming by the patient signing this as part of enrolling in the IMT process, and the details of what would be put in that packet would be decided between FDA and the sponsor. Is this basically --

DR. SZLYK: Yes.

DR. WEISS: -- the sentiment? Is this --

DR. EYDELMAN: More than sufficient.

DR. WEISS: That's more than sufficient. So since that can be the condition that we just discussed, so now I would ask for us to vote on that condition. All in favor of that specific condition,

please raise your hand. And all opposed raise your hand. Any abstentions?

So that first condition has passed.

Is there a second condition?

DR. BANDEEN-ROCHE: So a second condition would be that the informed consent process would explicitly attend to the cognitive ability of the patient to, in fact, consent.

DR. FERRIS: I thought we covered that, that they're going to work that out and we don't have to.

DR. BANDEEN-ROCHE: I mean that's okay with me. I was just trying to read what I had scribed.

DR. FERRIS: I understand. So it's my suggestion that we move to the next one.

DR. BANDEEN-ROCHE: So there seems to be general agreement around the Panel that the condition is sufficiently clear as we've already stated it without now augmenting it with a second related condition.

DR. WEISS: Okay. I would also want to indicate, because I have to, for FDA's purposes, they need me to indicate who votes on every condition. So for the first condition, for the record, it was unanimous among all of the voting Panel members.

The second condition that you just discussed in terms of mental status, the Panel felt that that was not necessary. So is there a third condition? Or is there a second condition that you would like to propose?

DR. BANDEEN-ROCHE: So there was a proposal to make sure that there is a warning to patients about eye rubbing.

DR. WEISS: So would that condition --

DR. FERRIS: It's part of this other one.

DR. WEISS: Well, I think -- do you need us to have discussion or to second it or not second it at this point? Can we discuss it before --

MR. SWINK: It has to be seconded first.

DR. WEISS: I'll second that only because we have three aspects here. We have the patient labeling, we have the physician labeling, and we have the informed consent, separate informed consent process. We already have patient labeling in the book. We already have physician labeling in the book, and if we're going to talk about eye rubbing, my presumption is that that would likely be in both physician and patient labeling, and it can certainly, probably should get included in the informed consent process but we -- just because we're having an

informed consent process doesn't mean we're not still discussing the labeling that has already been put together.

So I would second that. With that understanding, is there any discussion? Do people want the eye rubbing to be put in physician and patient labeling?

DR. MATOBA: It's in the patient --

DR. WEISS: It's already in the patient brochure. Is it in the physician brochure?

DR. EYDELMAN: We can make sure that it's in everywhere. I don't think that needs to be a condition of approval.

DR. WEISS: So it doesn't need to be a condition. Fine.

MR. BUNNER: Richard Bunner. I heard an earlier comment this morning, when you read it in the patient brochure, just from my consumer prospective, you know, it was a prohibition against it, but the next question hanging out there is be why? I mean that's part of the informed consent. It just says you cannot do it, and I know if I'm having this operation done, I'd like to know, well, what's going to happen? I got a little bit of counseling on that a little while ago, so what the effects of that would

be. So I think it would be helpful for the patient to know what is the result of this habit if they do it.

DR. WEISS: And that can go into the informed consent process. We don't have to have that as a separate condition.

So we can go onto now another -- we're still trying for a second condition. This is our third try. This one will be a gem.

DR. BANDEEN-ROCHE: Well, it is, I can assure you. But this was just a wordsmithing request that in the contraindications, anterior chamber depth less than 3 millimeters be changed to central anterior chamber depth less than 3 millimeters.

DR. WEISS: Is there a second for this motion? Is there a second for the motion?

UNIDENTIFIED SPEAKER: That's a refinement.

DR. WEISS: I'll second it.

UNIDENTIFIED SPEAKER: Does it qualify as a condition? That's just a refinement of language.

DR. EYDELMAN: We can argue over it, and then we can move on.

DR. WEISS: So we don't need to have that as a condition. Okay. Let's keep on going.

DR. BANDEEN-ROCHE: Do you want the --

DR. WEISS: We're going to read out. If they get rejected, that's okay, but we'll reach out each of the things that were mentioned to make sure they get --

DR. BANDEEN-ROCHE: We'll see if I can go, what is it, one for four? So there was a request, and I will need help with this if I get this wrong, in the physician labeling stating that the physician's view of the back of the eye will be limited by the IMT and that this may change the risk of missing retinal detachment or make surgery more difficult and the patient should be made aware of this risk.

UNIDENTIFIED SPEAKER: That's part of --

DR. BANDEEN-ROCHE: So that's all part of the same.

DR. WEISS: I would -- I guess we need -- I'll second that, but I think we need clarification. In terms of some of the specifics that we want patients or physicians to be informed of in labeling, do you want us putting that in one big package for --

DR. EYDELMAN: You can -- I suggest that you say that you have a condition that a particular list is be included and then leave it to the FDA to wordsmith potentially, and that will be one

condition, and then you can read the whole list.

DR. WEISS: So I think what we're saying now is instead of having them separate, any of the things that you have mentioned for patient labeling, physician labeling, or informed consent, we can read to get, you know, read one after another, we can -- if it's seconded, we can second it, and then we can discuss it in one group.

MS. WOOD: Madam Chairman, if I could, I'm Jerretta Wood, the Director of the Advisory Panel Program. The conversation and the discussion that the Panel has held today regarding the changes in the labeling have been heard and will be taken into account by the Agency.

What we're looking for on the conditions of approval are more of the big ticket items. And if you remember from all of your Panel training, this would include postapproval studies, changes to the indication, or other items that might be major ticket items.

Again, the FDA will review the transcript, and the changes to the labeling will be taken into account as well as all other discussion. Does that help?

DR. WEISS: I think that helps. I would

want to just clarify, so something in terms of taking out how -- a recommendation of how a YAG laser gets done when no YAG lasers have been done in physician labeling, you've already heard that. You do not need us to vote on that.

MS. WOOD: Right. If it's a major issue clinically, and I can't weigh in on that, if it's a major clinical issue that you feel is pertinent, then you could make that a condition.

DR. EYDELMAN: And that's why Dr. Bandeen-Roche was talking about additional analysis. I thought that's where you were going, and that's why I was suggesting that you have that as a condition of approval which was specifically -- I know Dr. Ferris was recommending a particular way of analyzing the endothelial cell data, but we never heard the consensus. That's a big ticket item.

MS. WOOD: That's correct. Again a condition of approval, it could be a reanalysis of the existing data or it could be a condition of approval. It could be changes to the training program, but if you're looking at the patient labeling and the indications, the warnings are already there. That doesn't need to be a condition of approval. Does anyone have questions about this

before you go on?

DR. SUNNESS: So do you need a condition for the postapproval studies then?

MS. WOOD: That's correct.

DR. SUNNESS: So I move that we add the two postapproval studies that we discussed, the first extending out the current study to 10 years and the second one a 4-year study of the first numbers of patients, the sample size to be decided by the FDA.

DR. FERRIS: Second.

MR. SWINK: Discussion.

DR. WEISS: Discussion. Dr. Ferris.

DR. FERRIS: I'm voting.

DR. WEISS: If there's no discussion, can you repeat that condition and then we can have a vote.

DR. SUNNESS: I move that there be two postapproval studies, the first an extension of the initial IMT study out to again I guess this could be determined by you, 7 to 10 years, and the second, a study of the sequential patients who are implanted with an IMT and the specific serious outcomes that we were interested in.

DR. WEISS: Clarified enough? If there's no further discussion, how many vote in favor of this

condition?

MR. SWINK: It's unanimous.

DR. WEISS: It's unanimous. So for the record, this condition passes.

Is there any other conditions that -- Dr. Bandeen-Roche?

DR. BANDEEN-ROCHE: Well, given what Dr. Eydelman has said, I thought it was within the first condition, but just to make clear, I would propose as a condition that analyses of risks of adverse events be conducted as survival analyses, and that the results of those analyses, and again, I'm not going to specify exactly how, between FDA and the sponsor, be included in the communication of risk to patients.

DR. WEISS: Dr. Matoba, did you have --

DR. FERRIS: Second.

DR. WEISS: Second.

DR. MUSCH: Let me just seek clarification then since we're discussing this. I assume you mean adverse events that are not reversible when you mention survival analysis as the specific technique to use.

DR. FERRIS: They were specifically --

DR. BANDEEN-ROCHE: Time to event --

DR. FERRIS: -- corneal edema and corneal transplant.

DR. MUSCH: Do you want --

DR. BANDEEN-ROCHE: Yes, time to event analysis --

DR. MUSCH: -- time to event analysis?

DR. BANDEEN-ROCHE: -- of these, you know, corneal edema, decompensation, the visual loss, you know, to the extent that that can be defined as an event, you know, in a method that appropriately accounts for censoring.

DR. WEISS: Is there any further discussion? Otherwise, we can have a vote. How many vote in favor?

Again, the decision is passed unanimously by the Panel.

Are there any other conditions that anyone wants to propose? Dr. Musch.

DR. MUSCH: Well, I think we need to at least decide if the grid is a clear contraindication or whether we're going to suggest at least that the FDA and sponsor look at whether it should be modified. Dr. Eydelman suggested one modification we might consider, and that is that in the youngest age bracket, a warning be issued regarding the

appropriateness of having a sufficient cell count and maintain the grid for the remainder of the age brackets, but I don't know whether we want to get so detailed. So I don't know how to phrase a motion there.

DR. WEISS: Well, what do you want? So if you put a motion as far as what you would like as far as the table to be contraindication -- Dr. Eydelman.

DR. EYDELMAN: Can I just clarify something? I just wanted to make sure that everybody is clear on that. If there is no contraindication at all for 65 to 75 age group, and there's only a warning, that means that anybody can implant any patient within that age group regardless what the endothelial cell density is. And there is just sort of a FYI as a warning letting you know that it would be nice, but here is information. Just wanted you to be aware of that.

DR. WEISS: So with that information, would you want to make that as a motion or not?

DR. MUSCH: No.

DR. WEISS: No condition. Any other conditions?

So just to confirm because many of the things that were scribed here were labeling issues,

because they were in the main transcript, we do not have to repeat the labeling issues --

DR. EYDELMAN: That's correct.

DR. WEISS: -- at this point in terms of conditions, and we have conditions in terms of the survival analysis and the postmarket studies and the brochure and -- if you have to leave, Dr. Ferris, now we probably can -- if we have no other conditions, then we can just go ahead with the formal vote.

Are there any other conditions?

So we will now go forward with the final vote on the main motion. It has been moved and seconded that the VisionCare Technologies, Inc., PMA Application P050034 for the IMT, Implantable Miniature Telescope, be found approvable with three conditions that the Panel has just voted on.

We will now vote on the main motion of the approvable with conditions with a show of hands. Please indicate if you concur with the recommendation that the above named PMA be found approvable with conditions. All in favor, please raise your hand.

And I believe we had a unanimous vote on that. And the voting members which are unanimous who raised their hand indicated they concur with the recommendation that the above-stated PMA is

approvable with conditions.

We do not then need to ask if anyone opposes or is abstaining.

It is then the recommendation of the Panel to the FDA that the VisionCare Technologies' PMA Application P050034 for the IMT, Implantable Miniature Telescope, is approved with the previously voted upon conditions.

I will now ask each Panel member to state the reason for his or her vote, starting with Dr. Ferris.

DR. FERRIS: I think I've explained in detail over the course of the day why I voted the way I did.

DR. WEISS: Dr. Szlyk.

DR. SZLYK: I agree that in the hands of a trained surgeon, this will benefit a large number of people and that the sponsor and the FDA have provided sufficient information.

DR. MATOBA: I agree.

DR. BANDEEN-ROCHE: I felt that the data provided reasonable assurance of safety and effectiveness subject to the conditions and stringent patient education as to the risks. I view the specific contraindications are prudent but really

stress that it's most important to characterize the risks as accurately as possible with the most representative patient data and to provide those estimates, for those estimates to be clearly communicated to prospective patients.

DR. SUNNESS: I think that the safety and effectiveness was discussed comprehensively, and I feel that's why I voted the way I did.

DR. EDRINGTON: It's a wonderful treatment option for the patient who would benefit from this.

DR. HIGGINBOTHAM: Given the burden of disease, of age-related macular degeneration in this country and the data that was presented today, I certainly think that this is a wonderful addition to the augmentation of our surgeons.

DR. MUSCH: When I reviewed the packet provided by the FDA and sponsor, I was just overwhelmed with the efficacy of this device, and it was supported by the anecdotal evidence from people in this room. I was concerned a bit about some aspects of the safety, but I was assured by our corneal and ophthalmologist experts on the Panel here that it was within reason, and given patients will be well-informed of the risks, I think we have a reasonably safe and effective device that we are

approving today.

DR. WEISS: I'm going to ask the consumer and the industry reps if they have any comments.

MR. BUNNER: Nothing further.

MS. NIKSCH: Nothing further. Thanks.

DR. WEISS: Then I'd like to thank everyone for doing a good job. That's my summation. Dr. Eydelman.

DR. EYDELMAN: I just wanted to take this time to thank my review team who has worked beyond the reasonable number of hours to make this a clear, concise presentation. I also want to have a special thanks to James and Deborah who stepped up and made sure that today flew very smoothly, which was no small deed by any means. Also thanks to Dr. Weiss for making sure we stay on the agenda and actually finish very close to 5:00 p.m. And thank you all for doing a great job in your deliberations.

DR. WEISS: Meeting adjourned.

(Whereupon, the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

OPHTHALMIC DEVICES PANEL

March 27, 2009

Gaithersburg, Maryland

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health, Medical Devices Advisory Committee.

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