vision, which is very, very poor, 20/25 vision looks like. I don't know if this is possible in patient labeling, or maybe it would only be possible on the website, but to have some -- give a patient some diagrammatic idea of what the words actually translate to in terms of what they'd be looking at. Dr. Smith.

DR. SMITH: I don't have anything for the patient labeling.

DR. WEISS: Ms. Cofer.

MS. COFER: I believe, based on the latest scientific data, and I probably should just, just for background information, when LASIK was approved originally many years ago, we didn't know a lot of the things that we do know now. There have been thousands of scientific studies about LASIK since its approval by the FDA, and so there's a lot of new information out there that's not incorporated into the labeling. So I actually have what you would call a laundry list of things that I think would be appropriate in

the labeling, if I could go through those.

DR. WEISS: That's fine.

MS. COFER: We now know that future cataract surgery is complicated by having had corneal refractive surgery. And I believe that's an issue that patients are not being informed of before they go into LASIK, or any form of corneal refractive surgery. We'll all face cataracts sooner or later if we live long enough, and I think that's something that patients would like to know, that when they reach the age that their natural lens becomes cloudy and they need cataract surgery, that they are going to have problems with their cataract surgery because they've had LASIK. And I believe that would be something that should be in the labeling.

Do you want me just to continue?

DR. WEISS: Yes. I'm listening, but I want to make sure we get everything down.

MS. COFER: Okay.

DR. WEISS: So, yes, please continue.

MS. COFER: It's also clear now that the change in the cornea after LASIK or other corneal refractive surgeries causes a problem with intraocular pressure measurements, and that's something that patients are not aware of. I don't even know if most eye doctors or optometrists are aware of it. Maybe they are, but it's certainly something that could become a problem for patients, especially a patient that is beginning to develop ocular hypertension, and possibly glaucoma. And patients do not know that they need particular attention paid to their optic nerve, and any signs of ocular hypertension, so that should be in the labeling.

And something that is fairly new in the literature coming out of the Mayo Clinic, is these reports of persistent decrease in corneal keratocyte density. I know the long-

term implications of that on the health of the cornea seem to be unknown. Maybe that should be listed as a labeling warning, that we do see this long-term persistent increase in corneal keratocyte deaths, and we don't know what that will do to the health of the cornea, and the function of the cornea long-term.

I don't think patients are being informed that the LASIK flap heals only very minimally. I believe the research out of Emory showed that the flap itself heals to only 2 percent of the original tensile strength of normal cornea. There is a scar at the margin that heals stronger, about 28 percent, but if that scar is broken through trauma or surgical relift of the flap, the LASIK flap easily lifts. It can be easily lifted, many years or forever. And I think patients are told that the LASIK flap heals, they go on with their life. They're not warned to wear protective eye wear, and I think that's something that patients should

know, that the flap heals only minimally after LASIK.

Also, we know now, based on literature, that creation of a corneal flap and ablation of tissue into the anterior portion of the cornea leaves the cornea much, much weaker. And I'm talking about the biomechanical strength of the cornea is much weaker after LASIK than prior to LASIK. The cornea has to withstand the intraocular pressure of the eye, and this weakened state of the cornea, which is a permanent state. It doesn't recover biomechanical strength. This permanent weakened state of the cornea could pose problems for patients.

We've seen many, many case reports of late onset ectasia occurring many months or several years after seemingly successful LASIK, and I believe patients should be warned of that.

I think it's also unclear that surgical correction of myopia will take away a

patient's ability to see up close after the age of 40 simply by removing their glasses. I can talk from my personal experience. I was told you'll need reading glasses after the age of 40, whether you have LASIK or not. I now know that I would not have needed reading glasses after the age of 40. I could have kept my myopia and just removed my glasses, and I would have been able to see up close. And I think that's misleading to tell patients that they'll need reading glasses whether they have LASIK or not. If they're myopic, if they're nearsighted, they can remove their glasses and see up close, and I think that needs to be in the labeling.

I think the labeling should warn patients about - and maybe it does now, I'm not sure - about bilateral simultaneous LASIK being a risk for vision loss in both eyes.

DR. WEISS: I believe that's in there already. I wonder, since you have a long laundry list, perhaps you could read the

list. If you could maybe read the individual items, and then if we need clarification, I could ask you.

MS. COFER: The next one is that I'm asking that there's something in the labeling that communicates to patients that loss of visual quality after LASIK is frequent. It's not a rare event. It's a common event. And I don't think patients are expecting to loss visual quality after LASIK, but that's what happens. And that's been shown in clinical trials, including Wavefront LASIK, is that there is a loss of visual quality, which can be measured by wavefront aberrometry.

DR. WEISS: That I might disagree with you on, because I think then we're getting into statistics. And then the question is, how detailed do we want to be in the patient labeling? And we may want to be more detailed. However, the question is, do we want to then list every single aspect? If

we speak to the presentation by Dr. Tanzer, it appeared that it was overwhelming these people were happy with the visual quality. So then it gets somewhat open to discussion. And we can open it up to the panel in terms of how detailed does the patient labeling become.

We had heard a criticism in the public session that already this is too difficult for the average patient, and so it may, if they even get it, get tossed aside. We do want something that people will read and see if they have the opportunity to. And part of the discussion here today will be how best to give patients the opportunity to see this data.

Does any other members of the panel have any comments on that? Do you think these -- what should be the statement about patient visual quality? Is it sufficient what is presently in the patient labeling, that halos, et cetera, may be experienced. What are other people's thoughts? Dr. Huang, and then Dr.

McLeod.

DR. HUANG: I second the Chairman's recommendation.

DR. McLEOD: At this point, I would agree. When Ms. Cofer gets to the end of her list, I probably want to bring up some questions about some of those issues.

DR. WEISS: Okay. Why don't we keep on going?

MS. COFER: Okay. I'd like to see symptoms, such as dry eyes and night vision impairment moved from the table called "Symptoms", to the table called "Adverse Events and Complications", because I don't -- we heard a lot of testimony here today about dry eyes and night vision impairment. And these are complications, they're clearly complications, and I don't think -- I think it's deceptive to put those in a separate category, and call them "symptoms", and downplay those. They're very serious life-altering issues.

DR. WEISS: I'm going to defer to Dr. Eydelman, because much of this has to do with the way these studies were originally put together for the PMAs, and consistency among how the FDA looks at these things for all devices. Dr. Eydelman.

DR. EYDELMAN: Actually, I believe that all of the pros, and you all know what that means, are usually reported in labeling under "Adverse Events and Complications", a compiled section that would address both objective and subjective outcomes. So the dry eyes would be in that section already.

MS. COFER: I don't recall seeing the night vision impairment under the "Adverse Events". It's always been under a table called "Symptoms".

DR. EYDELMAN: We'll take your note into consideration.

MS. COFER: I believe it's the MEL 80, the most recent approval of LASIK. I'm using that one as a sample for my next

request, which is that pupil size be listed actually a contraindication for pupil size over -- that's larger than the optical zone of the LASIK. And I do believe that's in one of the most recent approvals. And I would like to see that on all lasers, because anyone that has LASIK with an optical zone that's smaller than their scotopic pupil size is going to see these night vision disturbances.

DR. WEISS: Okay. I think we've just heard testimony, and I think Dr. Schallhorn had done that study, and Dr. Tanzer participated, that there was no evidence for that. We may want to go back to Dr. Schallhorn, but do any other members of the panel want to comment on this? Dr. McLeod.

DR. McLEOD: So this is specifically on the pupil size issue?

DR. WEISS: Yes. Should you warn the patient that if, let's say, the ablation zone is less than their pupil, they should not have this procedure performed?

DR. McLEOD: Yes. One of the reasons that I'd asked Dr. Tanzer the question, is that many of us in the community are familiar with the original study that was published. However, publishing the study does not, necessarily, correlate with actual practice. If, indeed, the practice is as described, certainly, that would be consistent with the literature that's established that does not, at this point, strongly link the two. So I think that it would be -- it's a very difficult area, and I don't think that the patients' interests would be well-served by an inaccurate description of the situation.

DR. WEISS: Dr. Smith.

DR. SMITH: I would agree with Dr. McLeod's comments. And, also, you're really getting into more complicated issues related to that specific patient if you say a specific pupil size and a specific laser. There are a variety of factors that are considered by refractive surgeons in individual patient

assessments, and while providing as much information to patients as possible is important, I think overwhelming patients with a lot of information that may be difficult to interpret, putting it in the contraindication section, specifically, isn't warranted at this time.

DR. WEISS: Ms. Niksch.

MS. NIKSCH: Yes. I would also agree with the comments from Dr. McLeod. And, again, every sponsor brings forward data from their clinical trial to FDA. The last part of the approval process is a significant negotiation process, and detailed review of all of the claims, and all of the contraindications, and all of that detailed information specific to that particular device, so, in general, on this particular one, but in general on many of these comments, unless they can be specifically related to the specific device in question, industry would be opposed to making these sort of blanket

changes to all of the patient labeling.

DR. WEISS: We are going to need to proceed to the other questions, so I understand that you have a long list. I would like to give you the opportunity, if you could just read off the list, because I do want to give Mr. Bunner an opportunity to comment, and Ms. Niksch, and then go on to the second question.

MS. COFER: Depression is commonly seen in LASIK patients with dry eyes and/or night vision disturbances. Depression and suicidal ideation must be studied by unbiased mental health practitioners, including in the warning in the device labeling.

Recommended labeling changes cannot wait until FDA has the results of a future study of patient quality of life. FDA must take action now to protect the public health. Perhaps there should be a device recall until proper study of complications, both short and long-term, permanent pathologic changes to the

cornea, quality of life, and depression is completed.

DR. WEISS: Thank you. Mr. Bunner.

MR. BUNNER: Nothing.

DR. WEISS: Thank you. Ms. Niksch.

MS. NIKSCH: Just a comment on the last comment. I'm certainly opposed to any sort of drastic action, such as any recall, or discontinuation of any LASIK products based on the anecdotal information. I think we are looking forward to results from the prospective quality of life study, and at that time, would be appropriate to reconvene, and determine what appropriate changes might be required to physician and patient labeling.

DR. WEISS: Dr. Huang.

DR. HUANG: Perhaps I recommend FDA to consider post-consultation evaluation of the patient's mental status, or the patient's comprehension of the consultation. Oftentimes that after the patient come to my clinic, and for various consultation, I ask them to repeat