



October 20th, 2009

CC: Mr. Jeffrey Shuren  
CC: Mr. Timothy Ulatowski  
CC: Mr. Larry Pilot  
CC: Mr. Morris Waxler  
CC: Mr. Jim Dickinson

**Attn: Dr. Margaret Hamburg**

**Attn: Dr. Joshua Sharfstein**  
Food and Drug Administration  
10903 New Hampshire Ave  
1-888-INFO-FDA

**Dear Dr. Margaret Hamburg and Dr. Joshua Sharfstein:**

It has come to our attention that the "Post LASIK Quality of Life Study" is being performed by (2) individuals that have continued to show a biased attitude to LASIK, and have shown that they can control these actual studies. We feel (The public feels) that having Dr. Schillhorn and Dr. Jennifer Morse involved in the "Post LASIK Quality of Life Studies" is a biased attempt for the LASIK industry to continue to "skew patient satisfaction rates" as "the biased industry sees fit." By not allowing hurt LASIK patient Advocacy Groups to participate in the involvement/outcome of these studies, further shows the control they exert upon the FDA/CDRH to control and fabricate "the outcomes of the clinical studies." Dr. Schillhorn sits on the very committees that decide which permanent patient outcomes are to be considered mere "TEMPORARY SYMPTOMS/SIDE EFFECTS" and which are to be considered "PERMANENT ADVERSE EVENT/COMPLICATIONS." This is a huge conflict of interest is it not? We are in talks with various media outlets stating our concerns that you are allowing this to happen. We ask that you involve us in these studies to make sure that this does not happen, so the American consumer can hear the results of a "truthful study" so that the LASIK patient can "decide and define whether or not their elective surgery was a success or a failure, not the profitable doctor/staff."

As you may already know, I too am a long time LASIK Advocate that isn't afraid to speak out about certain truths to make sure the public's interests are put first, representing the opinions of hundreds/thousands/tens of thousands of damaged hurt LASIK patients that would like to have a voice in how the "profitable industry" is setting the standards for labeling, satisfaction rates, and length of post LASIK timeframes used to measure their patients.

As a hurt LASIK patient myself, now going on 11 years, I have spoken to hundreds of other hurt LASIK patients and I feel from my 11 years of experience in specifically this part of the industry, that LASIK patient AE/Complications come out mostly after 12-24 months. Some come out with eye regression showing up 5, 7, 9+ years later. Because of this late regression, you too must decide if you feel 12-24 months post LASIK is enough of a period in which to measure "long term stability" of an elective procedure that is marketed as being "quick and painless" but is then "unpredictable and devastating" when the horrific irreversible results that occur in about 20% of the post LASIK eyes can be debilitating daily, and even can be linked to severe depression and suicide. After all, change your vision, and your entire life changes.

If the industry is stating "there are no long-term known complications" at this time and this has been the statement since 1997, then that is a complete fabrication of lies because it is a fact that many who sit upon the ISO and ANSI panels have a "profitable greed factor incentive" to keep as many permanent damages on the columns called "SYMPTOMS OR SIDE EFFECTS" and off of the only columns that are given any credit, which are of course "AE/Complications" defined as "death or permanent complications."

One would then ask, "why aren't these permanent complications/AE's being counted in the correct column?" The simple, yet correct answer is: "because then the numbers would be so skewed that LASIK would have a MORATORIUM put out along with a Health Advisory."

The bottom line, is that these studies are not properly listening to the patients and how the "patient defines whether or not they are a success." **These studies are performed by industry leaders such as Dr. Schallhorn and psychologist Jennifer Morse (paid by ASCRS) whom also have a "financial interest in having LASIK studies show 100% success rates," so they continue to perform**

**studies "to validate only the efficacy that LASIK is safe while still defining whether or not the patient is satisfied or not however the doctors measure satisfaction or dissatisfaction." This is not honest, and this is certainly a violation of the MHO "Medical Hippocratic Oath."**

Again, repeating, "if I knew and if we all knew what we knew now about this elective surgery, none of us would have elected to pay any LASIK surgeon \$5,000 to create a permanently scarred cornea, with a permanent flap that loses 98% of its strength where needed most, creating permanent dry eye syndrome (#1 AE/Complications) with permanent long term damages to the corneal nerves that never are able to regenerate," while we continue to hear from industry professionals that have a biased money incentive involved "how safe LASIK is and that just some doctors need to be doing a better job."

Every LASIK doctor is creating this and has permanently ruined many of their own patients. That is why attorneys like Todd Krouner have to import an Ophthalmologist from another country to testify against a US LASIK surgeon. These cases are very difficult to prove because the industry frowns on anybody within or outside of it, trying to dampen the "grave train" of LASIK that still enables these surgeons to earn \$1m, \$2m, \$5m and more per year (more than cardiovascular respected physicians).

So again, I have a problem (we have a problem) that these studies are only going out 1-24 months Post LASIK. If you do the honest research, (1,3,6,9,12 years Post LASIK) and ask the patient honestly (and you as a doctor should want to know this) how they feel about it, I will guarantee you that you will find at least a 20% dissatisfaction of eyeballs (each eye = 1 patient) which would validate a Public Health Advisory, LASIK Moratorium, or other public press release to substantiate the seriousness of this deadly procedure.

What is NOT known about these same patients is how they are doing 5-10 years later after their eyes have changed, they begin to regress, and then can no longer be treated through the simplest of means as prior to having LASIK, by being fitted with soft comfortable contact lenses or glasses. It was even admitted by Dr. Daniel Schultz that only (3) LASIF ASF's were inspected since inception, meaning that none of them were being monitored to make sure that all hurt LASIK cases were filing Medwatch Complaints into the FDA's internal reporting system so that the FDA/CDRH would know whether or not a "Public Health Advisory" was happening. No complaints/Few complaints = everything is okay, no one is being hurt. Lots of complaints weekly = RED FLAG that many patients are being hurt which could prompt the Public Health Advisory or even a possible LASIK MORATORIUM.

If I swore the HO "Hippocratic Oath" to first "do no harm to my patients and not protect a fellow Ophthalmologist," then I would have my staff perform follow up questionnaires like these 5 questions below at 1, 4, 8, 12 years Post LASIK. **Why don't you consider having all of your readers, your peers, do exactly this to prove "that there are no long term known complications from elective LASIK?"**

**1. Did your LASIK surgeon/staff tell you that the LASIK flap:**

- a. Heals back to the original strength?
- b. Heals like a cut on your hand?
- c. Never heals?
- d. Is forever open to infection and flap displacement?
- e. Both c and d.

**2. How would you rate your LASIK outcome?**

- a. Extremely happy at first, but then after 5 years, had regression and now I'm not happy.
- b. Extremely happy and it's been over 5 years.
- c. Extremely unhappy since immediately after having LASIK.
- d. Somewhat happy, one eye is good after 5 years and 1 eye is poor quality after 5 years.

**3. How do you the patient define "what is a successful LASIK surgery?"**

- a. Obtaining the "same quality of vision or better" without the use of contacts or glasses, have no AE/Complications whatsoever such as halos, double vision, contrast problems, dry eye feeling, and have no dependency on corrective devices or rewetting prescription drugs/dry eye pain medications, and going on 10+ years post LASIK.
- b. Obtaining the "same quality of vision or better" without the use of contacts or glasses, but have some night time disturbances, some dry eye AE/Complications at times, but they are livable and not too noticeable, and going on 10+ years post LASIK.
- c. Obtaining "satisfactory livable vision" to be able to work, play, sleep and perform leisure activities, but lack "high definition quality of vision" that I was once able to achieve with corrective devices such as contacts and glasses. I am okay with this because I don't have to use contacts or glasses, and am now going on 10+ years post LASIK.
- d. Obtaining "satisfactory livable vision" without having any corrective devices, even though I have much dry eye pain and night time disturbances, the good vision without corrective devices "outweighs" the AE/Complications of halos or starbursts or dry eye drops/rewetting drops daily, because I felt it was worst in having to deal with daily contacts or glasses.

**4. How would you as a patient consumer rate "risk" as LASIK is a irreversible procedure meaning that you can never "put back" creation of a permanent flap and thinning/reshaping of the cornea underneath the flap with the Excimer Laser?**

- a. TOO MUCH RISK: to substantiate having "permanently altered eyes" for the rest of my life. I can live with contacts and glasses daily even with the daily nuisance of having to take them out and put them back in. I could never live with altered vision that would never again give me the "High Definition" or "Quality of Vision" that I can achieve by using contacts or glasses, so this risk would be a huge "NO WAY" for me. Not worth the risk!
- b. SOME RISK: to substantiate the benefit of "not having to use contacts and glasses daily" but worried about "what if the post LASIK vision regresses later on say after 4,5,6,8,10+ years and I have to go back into contacts or glasses then? Will I be able to? Will I be able to as easily as I was able to before I had LASIK? Will I be having permanent problems which would keep me from being able to attain to same "High Definition" of vision that I once enjoyed pre LASIK? I couldn't live with myself or live a life, nor would I want to, if I

permanently altered my vision/eyes to the point where I could never attain the "Quality of Vision" pre LASIK through contacts and glasses. So, this is a big "NO WAY" for me. Not worth the risk!

c. LITTLE RISK: I believe if you go to the best LASIK doctors, they will do a better job prequalifying their patients, which should ensure an excellent/happy outcome even if I have a "permanent flap that never heals the rest of my life," I'm okay with that because most of the patients that I have spoken to are telling me that they are happier having had LASIK than they were in having to wear daily contacts or glasses. I believe that there are only a small percentage of patients with horrific daily vision post LASIK and that it was because they went to a lousy doctor. There are no long term known damages/complications to LASIK said my LASIK doctor/staff. Everybody's doing it. It's worth the risk, go for it!

d. NO RISK: I believe LASIK is safe. Just because only a few reported hurt LASIK patient cases out of millions, doesn't mean that all LASIK procedures are dangerous or permanently damaging to the patient's eyes. The eyes heal anyway, back to the original state says/said my LASIK doctor/staff, and that it is very safe for the long term. My doctor/staff even shared a recent article with me further proving that "LASIK is safer than CONTACTS" and that the US Gov't is recommending LASIK for astronauts and military personnel. Absolutely go for it! You have nothing to lose because it's proven!

##### **5. Psychological Evaluation of patient Pre/Post LASIK should include:**

a. JOB DESCRIPTION: testing of eyes in various segments of patient's life/day: morning at work on computer, afternoon walk outside, sporting event inside, watching television, watching outside concert at night, and driving one's car at night. If one of these simple daily tasks is "RUINED FOR LIFE," and LASIK elective surgery can "NOT GUARANTEE ME THAT I WILL NOT LOSE ANY ONE OF THESE VERY IMPORTANT DAILY ACTIVITIES," then I will choose to "NEVER HAVE LASIK ELECTIVE SURGERY." NO WAY, NOT WORST THE RISK OF LOSING ANY OF THESE.

b. JOB DESCRIPTION: Same daily tasks as above, but "I am okay with having some of the following daily AE/Complications with no known cure: Dry Eye (needing daily dry eye rewetting drops and prescription pain killers to get through the day), seeing a little halos, starbursts and have a little trouble at night time driving but can do it, having just a little bit of color contrast problems and glare, or seeing slightly "double vision" daily, but not to the point at which it really bothers me, and I find this easier/better than having to wear daily contacts or glasses. I PROBABLY WOULD HAVE LASIK ANYWAY EVEN IF I HAD THESE PERMANENT AE/COMPLICATIONS DAILY FOR THE REST OF MY LIFE.

c. JOB DESCRIPTION: Same daily tasks as above, but because I didn't have to wear contacts or glasses anymore, I would be happy even knowing that I could get by without having to daily pop contacts or glasses in and out. Anything would be better than having to wear contacts or glasses daily. So even if I am not able to ever get the "Quality of Vision" that I once was able to get with contacts or glasses and I'm left with some or all of the above permanent AE/Complications, I would absolutely get LASIK so I don't have to fuss with corrective devices again.

d. JOB DESCRIPTION: Same daily tasks as above, but would try getting LASIK knowing that I could be left with all or any of the above mentioned problems, even if it lasts for several years and then I my vision regresses back to glasses or contacts, then worst case scenario, I'm back to them or even have a problem where my eyes no longer produce enough tear film and I can't get my "Quality of Vision" back through "Normal Means," I would still take the risk anyway!

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If you then go back to the original LASIK clinical study (shown at the link below) you will determine that many of the doctors on staff were uncomfortable with the large patient group (Labeled as the "Non PMA Group") that "appeared missing" from the studies, and it is noted that they had only a 43% satisfaction rate, yet the sponsor kept pressing forward and prompting attention away from this serious flaw: <http://www.fda.gov/ohrms/dockets/AC/99/transcpt/352811.rtf>. **If you do not wish to take the time to read or re-read this clinical study, I have it succinctly summarized below (in two minutes) to show all of our concerns which should have prompted a big "REJECTED" stamp on having this study approve LASIK when so many doctors showed concerns about "permanent injured patient problems" being only called "SYMPTOMS" instead of being listed in the appropriate column called Adverse Event "AE"/Complication:**

*Read pages 23-25: Then page 40-41 to see clinical study percentages. Page 64 about how only one Micro Keratome was approved for LASIK. Page 67-70 makes a good case as to why more follow up is needed with unhappy patients saying they didn't come back (maybe they didn't want them to come back and didn't want them to complain about the halos, starbursts, dry eye, and headaches?? Page 81, they're stating the 80% patient cut off was set by the sponsor, going on to say that they had a 43 success rate with 7 myopes like myself at the smaller centers blaming that on "physician learning curve." Page 76, they're dismissing the "non-pma group" of only 43% success, saying that the PMA justified LASIK's safety anyway. Page 81, they're talking about the "high retreatment rates" and how this should be dealt with in the labeling and that it's important. Need for patient satisfaction to be defined by a questionnaire (I never was asked anything after LASIK if I was satisfied with halos, burning, dry eye, double vision, nothing, this of course would happen with almost every eye at some point). Page 84, they talk about this again, so it "doesn't come back and haunt us in the future." (and I hope I'm haunting all of these bastards). They're stating accountability is only at 57%. This is shit! Page 88, and I agree: "perceived is that there are different standards for investigator-sponsored PMAs brought to this Panel than for industry-sponsored PMAs, and I think that is something the Panel should be aware of." Page 89, every doctor has a learning curve. (great where is this on the FDA website and why weren't any of us informed??) Page 90, retreatment rates at 40% then lowered to 10%, but yet this isn't so, just look at the Alcon Documentary I showed you and Morris Waxler confirmed this was a huge problem. Page 91, read about the "missing information" and their concern if it is 1%, 5%, or greater since so much data is missing. Dr. Rick Ferris is talking about his concern that the studies are "biased" excluding the worst LASIK cases, which skews the numbers. Page 92-95, the guidance document says 90% is the goal, confirmed by Dr. Matoba. Dr. Macsai "I have difficulty with accountability at 50-76% at six months." Since when is the eye stable and stabilized only measured at 3 months? Who in the hell's idea of this law started this idiotic thinking, and for these idiots to not ask this question just shows the lack of talent there that day involved. I would have asked, how are these 2 eyeballs doing at 2, 4, 6, 8, 10 years later? (Jim and Larry, read how much these guys are distraught and confused about labeling/guidance for this PMA). Page 95, Dr. Rosenthal interjects "guidance is guidance" and 80% accountability is okay. Page 96: Now, this is a procedure that is being, and I am not arguing one way or the other. I am just presenting something to you. This is a procedure that is being done quite extensively throughout this country in which there is no information publicly available except what doctors want to give to patients based upon off-label use. It is the practice of medicine. It is not being done one or two times. It is being done thousands of times,*

and I think part of your deliberation has to be you have to weigh the issue, that is it important to have some information even though it is not perfect science, and that is your decision that one has to make. Page 97: Ming Wang, "put something in the PMA so the FDA shows concerns about accountability of THIS study and need for a better study to be done." Page 97, Dr. Ferris: "I have heard advertisements suggesting that there are no side effects to laser and I take it that if this was approved and there are documented levels of side effects that those advertisements would no longer be appropriate. So, I think we have to be careful about going too far in the other direction and trashing this because there is a public health implication of saying nothing, and if we defer saying something the only comment I would have is that my concern is that I don't know what the complication rate truly is lurking out there. Page 111: "the doctor left the clinic and the clinic was shut down." Why would a good LASIK doctor/clinic shut down unless they had really bad results? Page 113-118: "20% complained of worsening glare, 26% of patients were complaining of Halos and 26% complaining of fluctuating vision." Page 121: Wang: "Specifically regarding halo, we know that clinically the halo experience after LASIK tends to be more visually significant and affecting the quality of vision than halos that occur naturally in patients without ever having surgery." Page 122, Dr. Casebeer/Dr. McCulley: "pupil size important?" Basically, they didn't research this it appears. (No wonder Dean Kantis with 10mm pupils is so miserable daily especially at night). Suggestion was made to randomly sample 20% of patients, and it was quickly shot down by Dr. McCulley saying: "I don't think we care whether they do if we think that is appropriate. It may be a very good suggestion, but whether they think that they can do it or not or it is appropriate on their part is not relevant. We decide." Page 124: "only one microkeratome shaper (Chiron ACS) was used for this study, but many are out there." Dr. Casebeer confirmed this. Page 126: "DR. LEPRI: Mr. Chairman, there is one point I would like to address one of the questions regarding the labeling in pupil size. The current VISX labeling states that astigmatic patients between the ages of 21 and 30 should be reminded that due to their larger pupils they are more likely than the over 30-year-old population to experience a degradation in visual performance under these conditions." Page 127: Dr. Mannis: "When I came to the meeting I didn't feel as uncertain about the missing 43 percent as it were as I do now, and I would like to recommend that the obstacles notwithstanding that the sponsor turn back to its cohort and try to provide us with additional follow-up data." Up to Page 134, they still don't have an answer to the "patients done as a Non PMA" and wanted answers suggesting "to contact both the patients and the doctors, and that this is vital missing data." So, they moved on to the next question. Page 135: "PARTICIPANT; In the guidance document it is 1 year, 90 percent at 1 year. I mean is that what you are getting at? DR. MC CULLEY: No, that has been clarified at another meeting before. I thought the same thing, but the way it reads and it was Morris that corrected it, it was that stability at two points 3 months apart." (this decision by Morris, made the standard of care much lower in my opinion). (again, who made any of these guys GOD even thinking there is stability at 3, 6 or 12 months with the human eye??) Page 140: "In addition there are other treatment modalities out there even outside of spectacles to correct these patients and this doesn't mean that they cannot have LASIK, but I am not sure that we should approve the higher range based on the information that we have now. We can get around this with appropriate informed consent. DR. MC CULLEY: What we decided before when we discussed whether to add specifics to the guidance document for the higher ranges is that we would not try to create artificial numbers but take into consideration our realization and the reality that those patients typically do less well, and we would make a judgment as to what the performance was whether it was acceptable or not. So, we left it soft so that we would bring judgment to it and did not change the guidance but with the understanding that those patients would typically not respond as well as the lower ranges. Up to page 153, they talk about the "labeling ranges that should set the standard of care."

Page 155: "DR. SUGAR: I would like to add that there be a statement concerning the possible adverse effect of pupil size on patient's symptoms and that this be taken into account and this be placed both in the patient brochure and the physician labeling.

DR. MC CULLEY: Okay, and Dr. Bullimore you had, we had a couple that you were scribing. Dr. Matoba had one, and then we had one other that brought product labeling in line. You didn't write it, huh? Okay, he will write it this time, Alice.

DR. MATOBA: My suggestion was that the labeling be modified to be consistent with the exclusion criteria that were used for the clinical trial, specifically previous intraocular procedures, surgery. Patients with that indication were excluded.

DR. MC CULLEY: Why?

DR. MATOBA: I don't know why, but I think that there should be a warning. It shouldn't necessarily be an exclusion criterion in the labeling, but it should be a caution that this procedure was not investigated for those subgroups.

DR. MC CULLEY: And the why is you can blow the wound, but anyway let us not. I should just shut up.

Dr. Wang?

DR. WANG: I would like to suggest in the same paragraph Dr. Sugar suggested adding a sentence saying that cautionary statements such as for high range of correction visually significant halo or glaring may be present.

Page 156: Importance of Pupil Size to have sufficient warnings in the Labeling: (yet even today, doctors are not agreeing on the importance of dilated pupil size having a negative LASIK outcome, why not?)

MS. MORRIS: Lynn Morris. I wanted to be clear that pupil size was included. I thought I heard the sponsor say that that wasn't part of the study. They didn't collect that data.

DR. MC CULLEY: That is correct. They did not study it, but the fact that they did not study it does not alleviate our concern that it might be an issue. So, we are saying that we want that in.

MS. MORRIS: Oh, no, I want you to assure me that that is going to be in the labeling.

DR. MC CULLEY: Yes, that was added.

Page 159: MS. MORRIS: Lynn Morris. I wanted to be clear that pupil size was included. I thought I heard the sponsor say that that wasn't part of the study. They didn't collect that data.

Page 275: DR. WANG: I think my answer is yes. In particular, the treatment is circular. The fact we are going to use 65 percent against-the-rule, I'm just wondering if that is suggesting in any way a weakening of the cornea. Again, the context of examining refractive stability. So the answer is yes.

DR. MC CULLEY: Next question.

DR. EYDELMAN: Question 5, visual symptoms data reveal photophobia and double vision to be the symptoms with the greatest change from pre-operative levels. Do increases in these visual symptoms constitute a safety concern? (symptoms, they meant to say: AE/Complications correct?)

DR. MACSAL: Well, it seems the sponsor has tried to address this by questioning these patients with a phone questionnaire. But it's my understanding that this data wasn't submitted for FDA review, the tabulations. Were they, of the phone questionnaire, or weren't they?

DR. EYDELMAN: The summary of this was submitted.

DR. MACSAI: Sorry. Got it.

(great, they couldn't reach people via phone so they rounded it up again, saying LASIK was safer than it really is).

DR. EYDELMAN: What was not submitted was the information on the updated cohort. But the phone questionnaire, the original was submitted.

DR. MACSAI: The original, but not the updated.

DR. MC CULLEY: Again, if we're going the route that we're going, which is requesting more, it's a moot point; 5b.

DR. EYDELMAN: Is the analysis of the updated patient questionnaire necessary prior to making a recommendation regarding approvability of this device?

DR. MACSAI: Yes.

DR. GRIMMETT: It seems to redundant to me to the last question. Didn't we just agree that we would like the updated questionnaire information? So certainly we would like that information on the review.

DR. MC CULLEY: Next question.

Page 276:

DR. JURKUS: I am also wondering if a more detailed analysis about near-front acuity would be available.

DR. MACSAI: I would like to expand on Dr. Higginbotham's request for gender analysis in that this is the patient population at high risk for dry eyes and keratoconjunctivitis and that may have an influence on the efficacy of the laser. So if they could make an analysis of that as a barrier.

DR. PULIDO: I'd like to thank again the sponsor for supplying, one, good accountability, and number two a good data set from which we could see the strengths and weaknesses.

DR. FERRIS: I'd like to follow-up on something Dr. Wang said. That is although I know we are not going to rewrite the guidance document, I'm concerned if the data at two years is showing a decrease, whether at least with the other laser system we have asked about documenting stability, and so I worry that we may or may not find two years to be the endpoint.

At some point you need to go until you document stability, or at least it would seem to me that I would I might know about stability, because my patients would probably want to know more than a two year effect. Is it going to level off or is it not. If hasn't leveled off, I think there may be concern bringing it back here.

DR. MC CULLEY: So what one would say if we were writing the guidance document would be minimum of two years for a new device, assuming that stability is demonstrated at two years?

DR. PULIDO: And stability being what?

DR. MC CULLEY: It would have to be redefined for this group, as has been pointed out. That would be to be determined in the guidance. We don't have that.

DR. PULIDO: Shouldn't we tell the sponsor what we would like for stability, since we were asking for long-term results now? We need to be able to help them in that regard. What will we be happy with?

DR. MC CULLEY: Dr. Grimmitt or Dr. Bullimore, either one.

DR. BULLIMORE: Primarily, I would like to see a little more data. I mean it's very difficult to make decisions on stability with so little data at the 24 months. I reiterate my impression that at two years the technique appears to be on the order of 50 percent effective. I base that both on the cross-sectional data that has been presented -- I'm sorry, the longitudinal data that has been presented, but also the pair-wise comparison, looking at the change in the elegant integration of that data that was done in various people's heads. I think that will remain my primary concern.

Page 285-287: LOOK AT ALL OF THE DOCTORS THAT WANTED TO "NOT APPROVE" THE LASER and showed concern about the studies saying more "info was needed, not just that 90% of patients attained 20/20 while discrediting the symptoms which should have been AE/Complications, also they all showed concern that the LASIK results were "temporary" and they set the labeling standard at 90% at 2 years. (NOT GOOD). Who in their right mind would do LASIK if it only lasted 2 years and then regressed?

DR. VAN METER: I voted not approvable. I believe the device is reasonably safe. I think the sponsors have shown that to my satisfaction. I have questions about the efficacy because the instability of the refraction and the regression.

The last table that was shown showed seemingly stability had percent of patients in the Y axis. And it would be more helpful to have the actual refraction data, ideally a cycloplegic refraction data, and show that to be stable, rather than have a percentage of patients that is 20/20.

DR. MACSAI: I voted not approvable. This is a new refractive laser. Despite the fact that the sponsor has done a great job in providing data in an organized, reviewable manner, it is just too soon to tell. The data reviewed to date demonstrates refractive drift and decreased efficacy over time. There is an increase in astigmatism with a progressive axis shift. Analysis of the total hyperopia as measured by cycloplegic refraction will determine the true efficacy of this procedure, and with further follow-up we will be able to better determine the safety and efficacy.

DR. JURKUS: I voted not approvable for the same reasons that have been indicated.

DR. HIGGINBOTHAM: I voted not approvable considering I think the need for additional follow-up as evidenced by the increasing symptoms that patients are complaining about, as well as the lack of refractive stability long-term. I think we really do need to see what happens with these patients over time.

DR. PULIDO: I voted not approvable, again because I think not so much the safety data, but the effectiveness data. We need to have longer-term results to make sure we're not putting out to the American public, a new technique that is not stable over the long run.

DR. SUGAR: I voted not approvable. I believe the procedure is safe. I believe that the effectiveness is disappointing and further data will either confirm or refute that. I disagree with the 90 percent requirement. I don't think that that is realistic, but otherwise I agree with the vote.

DR. BULLIMORE: I voted not approvable. While I will accept that the device is reasonably safe, the efficacy data is somewhat disappointing. I believe that both sponsor and reviewers and indeed FDA have been hampered by the lack of a guidance document, but nonetheless one can apply some common sense to this data and look at the degree of change that has been attempted, and place the actual achieved change at different time intervals in the context of what is being attempted. Based on that, I don't think that the sponsor has to date demonstrated efficacy.

DR. GRIMMETT: **The average consumer will likely want more than a temporary refractive effect. Since there is a paucity of reliable, long-term data that cannot reasonably substantiate critical stability issues, I voted that the PMA is not approvable primarily due to effectiveness issues. I do believe the PMA shows that the procedure is reasonably safe.**

DR. MATOBA: **I voted that this procedure is not approvable for reasons elucidated by Dr. Grimmert and Dr. Macsai. I also agree with Dr. Sugar's comments regarding the accountability.**

DR. MANNIS: **I voted not approval primarily based on lack of demonstration of efficacy.**

DR. WANG: **I voted for not approvable.** I do want to share the sentiment. As a refractive surgeon there is a need of the American public to have refractive surgical procedures offered to them in a timely manner, with good conscious consideration of all parameters. This study is well conducted. It does fit the myopic guidance document, however, it's not approvable based on our discussion. **This heightens further the need of FDA to come up with specific guidance document for the correction of hyperopia, since it is a different animal.**

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For the industry to have a short term study again only going out (1) month, (3) months Post LASIK or even any study up to a (2) year deadline is even against the advice of the very Ophthalmologists mentioned in the original clinical study above (highlighted in yellow and highlighted in red). Stating "there are no long term known complications" known from elective LASIK surgery, and still stating this now after 12 years after 18 million American eyes have had elective LASIK surgery, is not acceptable.

If you were a caring doctor, wouldn't you want to know what your patients think and have them answer your questions/our questions, without you telling them they are seeing 20/20 on the Snellen Chart up from uncorrected 20/200 that was able to get High Definition Crystal Clear Vision through simple means using soft contacts or glasses, and having no dry eye pain daily in order to do so (even though it is now blurred with contrast streaks and halos, something you will write off as "temporary side effects" when they should have been filed into Medwatch as serious AE/Complications).

I hope you will do the right thing. What is the right thing? **Answer:** "Making sure that the patients are being heard and that they are being able to define "success" however they define "success." Then and only then, will we all know the level of patient satisfaction or dissatisfaction that truly exists. And it doesn't start with a "Quality of Life Study" headed by Schallhorn or Morse who have been known to have financial interests/incentives into the outcome of such an important study. Does this make sense?

Repeating, **"we along with other LASIK patients want to hear the truth."** We will define success when you pick up the phone, email us, or send us a questionnaire in the mail **"asking us about how we feel 2,4,6,8,10, 12 years post LASIK."** Until then, the LASIK community is going to continue to "dupe" the world into thinking this elective "pain free" procedure is safe, when in reality, the numbers are fabricated to attract the herd. This of course, is a daily violation of the very Hippocratic Medical Oath these same LASIK doctors swore so long ago: **"To put the patient's best health interests first, be truthful to each and every patient, and tell each of them what all known long term risks are..."**

PS-I have asked Dr. Waring III, Editor of 'The Journal of Refractive Surgery,' **"As a sign of good faith, would please encourage his readers and peers, into reaching out to every LASIK patient they have operated on, asking their patients if they are happy."** And if they are not happy and (1) or (BOTH) eyes have permanent daily/weekly AE/Complications, **then to do the right ethical thing and to teach their staff how to correctly file a Medwatch Case into the Maude FDA Database here:**

<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm> so the FDA/CDRH is aware of these patients that also suffer permanent AE/Complications as a result of elective LASIK, and that way you know they are being counted properly which should make you happy that you are one of the very few doctors that has honor in upholding the HO you swore so long ago..."

Warm Regards,

**Dean A. Kantis**

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