

April 9, 2008

To the FDA Advisory Committee:

This letter is to give my views on the market of refractive surgery. First off, my name is ----- . I am a Physician who underwent refractive surgery May 2007(Right Eye) and June 2007(Left Eye). I have been wearing glasses since my 3rd grade year in school. After hearing of the wonders of refractive surgery from numerous people and hearing all of the advertisements of guaranteed 20/20, I started to look into the possibility of having the procedure done myself. I had never heard about or talked to anyone that had a bad experience with refractive surgery to get the other side and didn't even know that they existed. Now, I know that there are many that have had bad experiences with refractive surgery. I am not very certain about the number of people that have had refractive surgery but, since 1996, there has been somewhere in the range of one-million procedures done and the number continues to grow. The latest statistics show a satisfaction/good outcome percentage of about 95%. Well, that means that 5% did not for some reason or another. **That means that about 50,000 people who had the procedure done had a less than perfect/suboptimal outcome.**

Now, I know this is basic statistics and I am sure that the refractive surgeons can explain it in some way that makes it seem that the 5% is really not that large of a population due to certain factors, but does the FDA really know what these 50,000 people went through with their suboptimal results? I think that there are a few questions that need to be addressed. (1)How can one really know what the post-op vision is like if you don't ask the patient themselves? (2)If you just listen to the surgeon's side, aren't the results going to be biased? (3)When has there been a public opportunity up until now for people to freely give their own opinion of their post-op vision? Hmmm... (4)Can the FDA afford to let the physicians sweep the bad results under the rug and continue on? (5)Is there a magic number of bad results that needs to be reached before something is done? (6)Once this number continues to accumulate and it will, do you think that an insurance company would sell you disability insurance at the same rate they would sell someone with normal corneas? Let me give you some first hand advice from a physician's perspective. The eyes are just too precious to a person's well being, quality of life (mental and physical) and future to approve a risky, elective procedure that can potentially ruin the quality of life as they know it. In medicine, I have told many patients myself that some things just should not be tampered with. The one question I wonder if the FDA has asked is, "Is refractive surgery doing more good than harm?" The answer is very simple, "NO", because the people that are happy with their post-op vision would state that they haven't lost anything but the people that had bad outcomes would not have had complications if the procedure were not approved.

I really want to emphasize the point that the complications that arise from bad outcomes are real and there are real people dealing with them. If there are any moral

people that are on the FDA advisory committee, I wonder do they know that a procedure/laser has been approved that has decreased the quality of life for a significant number of people for whatever the reason may have been. I have learned the hard way that if given the permission to do harm, it will be done if the financial reward is worth the risk. The FDA can act now to help prevent future lives from being ruined. By removing the option for refractive surgeons to make a market out of selling a person a dream, you will be saving lives. It is literally like this, if you are happy with your post-op vision, you are written down as a success, but if you are not or there was an error on either the laser or the physician's part, then you are simply invisible, even if you are a fellow physician. The field of ophthalmology was doing just fine financially before refractive surgery and it will be just fine once it is discontinued. Hearing the statement "You knew there was a risk before you did the procedure" is really a foul statement because when you are purchasing anything, no one is going to put emphasis on the negatives. An elective, serious procedure such as refractive surgery should be verbally presented in a way that gives the patient considering it all of the potential complications so that an informed decision can be made.

Using 95% as a sales pitch is very misleading. What these satisfied patients are dealing with since their procedure is not discussed at all. There are many patients that initially after the procedure were very excited, but after about six months to a year were dealing with starbursts, halos, regression, problems reading, and decreased night vision. You don't hear about these patients because they are swept under the rug for fear of a decreased market. Well, there are many factors about refractive surgery that could possibly sway a person to not have the procedure done that are either not told to the patient, downplayed or just ignored by the physician. In the excitement of the whole process, you completely put your trust in the physician that everything will be ok and that this is a physician that has taken the Hippocratic Oath "to do no harm." You would think that someone with the nerve to do an elective surgery on your eyes would give you all the information there is to know about it (good and bad) so that you can make a good decision on whether or not you would be a good candidate. Well, I found out the hard way that this is not the case. What I assume the defense is on bad outcomes is "If you read your pre-surgical application, you should have known about possible complications." Well some things are better said than written especially when it comes to irreversible procedures. I would be the last person to speak badly about another physician because we all make mistakes from time to time, but this sub-specialty has been taken over by money and this procedure is in one word immoral.

Another sales pitch used is guaranteed 20/20 vision. The term 20/20 is used very loosely. Post-operatively, you may see 20/20, but the letters may be doubled, tripled or blurry. It doesn't matter to the surgeon that they aren't clear, it only matters that you can see them. So you see 20/20 to the surgeon. If you can't see them on the Snellen chart, they will tell you to guess, and if for some reason you guess correctly, that is written down as success, not that you had problems recognizing the letters. Things that you will be told if you are not seeing clearly as you expected post-op:

- (1) You are probably still healing
- (2) Your eyes are just dry

(3) Continue steroid drops for a couple of more weeks

These are statements that have been practiced by the optometrist and physician to try to keep the patient from complete nervous breakdown and prolong any chance of litigation. To say that depression is not caused by a bad outcome is absolutely ridiculous. How can you not be depressed if you were able to see perfectly before this elective procedure and now you find that you paid to have irreversible, terrible and in some cases disabling vision. Well, if the choice to have refractive surgery was removed, and not presented in a manner that was so tempting, no one would be going through the disappointment of a suboptimal outcome. They would live normal lives with glasses or contacts just like they were living before 1996 and their vision would be affected only by normal aging or natural causes.

Now, I underwent the procedure known as LASEK. My pre-op prescription was -6.25 and -6.50 in the L and R respectively. This procedure is done for people that may have not been good candidates for conventional LASIK due to large pupil size. My dilated pupils were 9.0mm. Some of the problems that people have with large pupils are halos at night, starbursts, and decreased night vision. Now refractive surgeons are saying that pupil size doesn't matter due to neural adaptation. I don't believe this statement to be true. Neural adaptation can be associated with chronic fatigue due your brain having to over compensate for an unnatural visual field. Before the procedure, I foolishly did not think about my future as a physician or my family's future if things did not come out as planned. I was told that I was a good candidate for the surgery by my surgeon and I trusted him. So, I decided to have one eye done at a time. I asked about what problems had the surgeon encountered in the cases that he has done and he said "None, but a little dry eye and that's temporary." So I underwent LASEK on the R eye in May 2007. I was informed that sometimes it can take up to four weeks for the vision to be completely functional. Initially after the procedure, there was minimal pain and after twenty-four hours I was able to see within about 12 inches from my face. I was very excited! After about 2 weeks, I was able to drive with one eye. I thought that everything was great. My night vision at that time was not complicated by starbursts. I compared my R eye with the vision in the L eye with a prescription contact lens. My L eye with a contact lens showed a visual field that was bigger and brighter, whereas the R eye although clear at the time, showed things slightly smaller and as if there was a tint covering the eye. It was as if the lights were on bright in one eye and on dim in the other. This is called loss of contrast sensitivity. Most people that have the procedure done won't notice this initially because they have both eyes done at the same time. With and without the contact in the L eye, I noticed that my balance was just a little bit off. When this was told to the surgeon, their response was "Well you have to remember, you had a lot of correction done." That one statement scared me because, I knew then that if anything else goes wrong with my particular case, they would use that statement against me. It was not presented that that particular problem might occur due to my high pre-op myopia. That would have been nice to know don't you think? Anyways, I continued on and had to take off a couple of weeks from work due to not being 100% at the job like I was before the surgery. I continued to have problems, now with splitting headaches from the two different visual fields that my brain was trying to put together. Although they were close with a contact lens, it was still enough for me to have problems. So quite naturally, I

thought, I need to go ahead and get the other eye done so that at least I will be level. So, I scheduled to have the L eye done at that time. After having the procedure done on the L eye, the night after the surgery, I noticed that there was excruciating pain in the L eye. My physician did call his patients the day after the surgery to check on them, and I told him about what had happened. He asked if the contact lens had come out and I told him, no. On the follow-up day, I couldn't even see the big "E" on the Snellen chart. My doctor, after doing an exam, told me that "there was an epithelial defect on the cornea," but he thought that it would be alright. "Continue the steroid drops and Vitamin C." At this point, I am scared beyond belief. I am asking myself "How did this happen to me?" "Why did I do this?"

After about four weeks, my vision did start to clear but I was seeing triple (ghosting) and I noticed that my dim light vision was worse and that letters appeared to be smaller than they were in the R eye. On my return visit, my doctor told me that I had been overcorrected about +1.00 and there was (-1) astigmatism. At this time I am really starting to panic, but when I expressed my problems to my doctor, he stated that he had not seen a patient that wasn't happy with their vision yet. So I continued to wait, which is all I could do. Well weeks went by then months and still no improvement in the L eye. I still have ghosting to this day and the dim light vision has gotten worse in both eyes. The overcorrection in the L eye caused me to have imbalance issues. When presented to my doctor, he stated that "Your symptoms of imbalance aren't caused by your eyes, it's probably vertigo." Now, I guess at this time he forgot that he was talking to another physician because I know that vertigo is caused by an inner ear fluid imbalance. What I was experiencing was a mismatch from both eyes being different, which to me was common sense and probably was to him too, but written off to not take the blame. I am a physician too. **I know what it's like to write off a patient.** Although I learned the hard way, this whole experience has changed my whole approach to every patient and made me a much more considerate physician. What I understand now is, to the surgeon, I had to be written off because he couldn't go back and fix what was already done. He had to go on because any one unhappy patient could decrease the number of future cases and therefore decrease business. So there I was, a physician myself, treated like the patient that I myself from time to time had written off. At that moment, I knew that this was a business, not a life saving medical miracle, a business. I bought it hook, line and sinker.

Today, I deal with decreased night vision, starbursts at night, slow reading, eye spasms and worst of all, **unpredictable future vision.** My vision is about 20/40 in the R eye and a blurry 20/15 in the L eye. This has caused some depression, because I am a 29 year old young man that was just ready to start living life. This unnecessary procedure has slowed me down significantly and worrying everyday about something that I had taken for granted before is depressing no matter how you look at it. I can't help but wonder if someone from the AMA or FDA had just said, "**We are drawing the line here, the eyes are just too important,**" myself and about 50,000 others or more would not be dealing with life long complications from a medically unnecessary procedure. Please review and consider what I have said, for this is something that more public awareness must be broadcasted. Is there something wrong about helping prevent future lives from being ruined? The only thing that you will be hurting by **not** making

refractive surgery an option is the surgeon's bank account. Please remember that no one needs refractive surgery and it is not curing anything, it is a risky operation that can potentially increase insurance premiums in the future and potentially ruin your quality of life as you know it. I have to tell you that as a physician, it is sickening to know that if the refractive surgeon is able to sleep at night, there is now the opportunity to get financially rewarded and be fully protected if you are able to deal with knowing that you really did decrease the quality of a person's life. It is so hard to really understand and feel what another person is going through when you don't have that problem. It is much easier to look over them and go on to other "normal" people. I am amazed that the AMA/FDA is willing to allow people to take the risk of having a suboptimal outcome. Please don't have the mentality that, "Well, we're neck deep in this thing, we can't back out now." Yes, I am **one** of a supposed low percentage of unhappy patients, but isn't that enough. I believe that mistakes are part of any medical profession but ethics and morals play a part as well.

Sincerely,
