April 8, 2008

RE: Ophthalmic Devices Panel of the Medical Devices Advisory Committee

Karen Warburton, MT, MHS

Dear Ms. Warburton,

Subject: Comment Submission

Hello. I am a concerned victim of LASIK, encouraged to see that the FDA might be recognizing the "laser vision correction" tragedy and looming epidemic. Prior to the "surgery," I thought that my vision was poor. Unfortunately, like so many, I now know what it is to have poor vision.

I have largely remained in denial and mental seclusion since the surgery, afraid to learn more about what really happened to me, and wanting it all just to go away. The deception in this extremely profit driven industry must stop. Too many people are losing, not gaining, quality of life. Some are so riddled with horror and guilt that they are choosing to end their own existence.

Let me make an attempt to describe my pre-LASIK condition. I was an OD -5.50+2.50X113, OS -7.00+1.75X090 before the slice and burn. I don't exactly know what all of that means, but I do know that I was referred to at one point as a "high myopia, moderately high astigmatism" patient. I have just over 6 mm pupils. My higher order aberrations were measured at fewer than 5% by the VISX CustomVue machine.

I never got along well with contact lenses. Originally, I was fitted with rigid gas permeable lenses for my astigmatism. Later on, when toric lenses were developed, I got those. In the end, the results were always the same. I never was able to get comfortable with the lenses. Mostly, my eyes felt dry and itchy. I was sold on the lie that LASIK was some kind of ticket to a new life freedom. I would be able to gain quality of life, have more fun, be a better golfer, go inside on a cold day and not have a pair of lenses fog up, etc. What I wouldn't give to just go back.

Anyway, I decided to go through with it. I am a natural pessimist, so I struggled mightily with the decision. I knew that there were risks. Of course, I was lied to and told that new technology has "virtually eliminated" the risks. I was sold the biggest bottle of snake oil of all time, and drank it all, because I wanted to believe. I was told that I needed the "custom" procedure due to my prescription.

I could continue to write a book about all of my pre- and during surgery details. In retrospect, there were so many warning signs that day. I had every opportunity to bail out, and I didn't. Let me cut to the chase. I am now suffering from an all too common list of "complications;" ghost images from both eyes in all lighting conditions, starbursts, halos, dry eyes, and floaters. If I were forced to chose which was the most troublesome, I

would say the floaters. I have a desk job, and looking at the computer screen all day is just torture.

I have visited several independent Ophthalmologists and specialists since my eyes were destroyed. Each of them has agreed on one very important aspect of my post-surgical condition. They all agree that I DID NOT receive a Custom laser treatment. Again, I was told that I needed to have Custom in order to "achieve my best personal visual result." I paid for Custom. My understanding, however limited, is that the non-Custom version of LASIK only has an effective treatment zone of 5-6 mm, and that Custom was designed specifically to deal with higher prescription patients. Does an "oversight" like this constitute medical malpractice? At the very least, is it consumer fraud? In addition, I have since been shown from my file set that my pupils were mis-measured prior to the surgery, resulting in an insufficient treatment zone size. Unfortunately, these medical errors currently do not constitute malpractice according to the attorneys and "experts" I have consulted. Can the FDA continue to support a Standard of Care that doesn't protect the consumer against negligence?

What is more, currently there is no technology available to help those with damaged vision as a result of laser surgery. My options include glasses and special post surgical contact lenses that cost thousands of dollars and restore only a fraction of lost vision – that is, if I can tolerate wearing them at all. I have no options for treatment of the vitreous floaters created by the pressure induced by the ocular ring, or for my chronic dry eyes.

Thank you again for taking the time to hear my story. I hope that the FDA will carefully consider the mounting evidence that LASIK is not safe, and discontinue its support of this procedure as well as advocate the development of technologies to address the complications.

Respectfully,

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