April 15, 2008

Ophthalmic Devices Panel
Division of Ophthalmic and ENT Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

By FAX to Ms. Karen Warburton at 240-276-4111.

Dear esteemed members of the Ophthalmic Devices Panel:

I have been informed that you will discuss post-market information about corneal refractive surgery, specifically vision quality and ocular surface disease, at your meeting on April 25, 2008. As an ophthalmologist who has undergone LASIK but does not perform refractive surgery, I am unusually well-positioned to interpret the available medical evidence on these matters without personal financial bias. After several years of immersion in parts of the refractive surgery literature, and review of data sources such as written FDA documents and MDR reports and the minutes of other ODP meetings, I have concluded that there are serious problems with the FDA's management of corneal refractive surgery clinical trials, device approval, and post-market surveillance, to wit:

1. Failure to listen to the visual psychophysicists when they presented optical models incorporating the pupil diameter and predicting the effects of a polyfocal cornea on contrast sensitivity, peripheral retinal sensitivity, and glare disability. Failure to acknowledge the concern that high-contrast best-corrected visual acuity was a poor proxy measure for safety, and that a procedure which reshapes the cornea should be judged topographically (in the pre-wavefront era).

2. Failure to ensure that the clinical trials included tests to *effectively* quantify perceptible visual aberrations (commonly described as starbursts and halos) induced by a polyfocal cornea overlying the entrance pupil, and to determine their impact on daily vision function (glare disability). The "20/happy survey" has proven its general worthlessness.

3. Unjustified statistical dependence on "average" outcomes to determine the safety and efficacy of a device, leading to suppression of important evidence about outlier patients.

4. Failure to enforce manufacturer MDR reporting; failure to determine that manufacturers were in violation of required MDR reporting for protracted periods of time.

5. Failure to adequately consider the financial disincentive of refractive surgeons to report poor post-market outcomes which might be device-related – "don't ask (the patient) and don't tell (the manufacturer or the FDA)." High-volume refractive surgeons have a certain amount of human misery built in to their business plans. As an example of the breakdown of voluntary reporting, for the VISX and Bausch & Lomb lasers there

are more patients described in the formal and informal literature with decreased visual acuity than there are MDR reports. If manufacturers allege that all these cases are surgeon-related, then there is a device-user interface problem.

Refractive surgery for many years was synonymous with corneal re-shaping. Recently several intraocular procedures have entered the marketplace, and I wish to reiterate that I do not refer to these techniques in this letter.

It is my understanding that a number of patients will attend the April 25 meeting to express their concerns in more personal terms. This is not the first time these issues have been raised by ordinary citizens (see the minutes of the ODP meeting, July 23 1999, Open Public Hearing).

Refractive surgery is the only procedure to alter the function of a healthy sensory organ. Compared to other vertebrates, human smell and hearing are nearly rudimentary, but our binocular vision is superior under all but low-light circumstances and accounts for the majority of our conscious sensory input. Abrupt, surgically-induced vision derangement in a previously normal patient can be both functionally and psychologically devastating. In other words, refractive surgery has an extremely high down-side risk. I urge the members of the Ophthalmic Devices Panel to advise the FDA to broaden its definition of "safety" to include *other psychovisual (subjective) components of vision*, and to work with manufacturers, clinical investigators and community eye care providers to reduce the frequency of damaging surgery.

Sincerely,