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May 10, 2010

To Whom It May Concern:

I am Morris Waxler, Ph.D., former Food and Drug Administration (FDA) official in charge of approving laser vision correction (LASIK) devices between 1996-2000 (resume attached). Thanks to pointed questioning by LASIK-injured patients, I have re-examined the data FDA used to approve LASIK devices as well as the data from subsequent scientific studies and now conclude that LASIK-induced risks of permanent loss of vision overwhelm the temporary benefit of visual acuity improvement. Please warn members of your organization that LASIK causes:

- ❖ The cornea to thin and bulge (keratectasia)¹
- ❖ At least 15-30%² risk of complications including permanent eye pain, glare, halos, dry eyes, night vision and other problems.
- ❖ Only a sixty percent (~60%) chance of temporary reduction in dependence on glasses or contact lenses³

Doctor-induced keratectasia will occur in over 3,000 patients in 2010 (rate of 0.87⁴ of about 700,000 LASIK surgeries expected to be performed annually). Between 700,000 to 1,000,000 eyes will undergo LASIK surgery in 2010 and tens of thousands will have permanent eye problems. Your sons, daughters, parents, and friends may be future victims, your grandchildren. Warn them.

If they, or you, have had LASIK surgery already and have a vision problem, or are concerned about potentially thin/bulging corneas then take the following steps:

- Report the problem to FDA immediately
<https://www.accessdata.fda.gov/scripts/medwatch/>
- Contact an independent ophthalmologist or optometrist
- Obtain the medical record of the LASIK surgery

Glasses and contact lenses are safer alternatives to LASIK. Take good care of your eyes.

Regards,



Morris Waxler, Ph.D.

President

Attachment: Resume

¹ Ezra Maguen, Yaron S. Rabinowitz, Lee Regev, Mehrnoosh Saghizadeh, Takako Sasaki, and Alexander V. Ljubimov. Alterations of Extracellular Matrix Components and Proteinases in Human Corneal Buttons With INTACS for Post-Laser In Situ Keratomileusis Keratectasia and Keratoconus. *Cornea*. 2008 June; 27(5): 565–573.

² Murray A, Jones L, Milne A, Fraser C, Lourenco T, and Burr, J. “A systematic review of the safety and efficacy of elective photorefractive surgery for the correction of refractive error.” Review Body for Interventional Procedures, April 2005.

³ P970053 Patient Information Booklet (p9 3rd bullet under #8) – This is a typical value for refractive lasers and better than some.

⁴ Pallikaris IG, Kymionis GD, Astyrakakis NI. Corneal ectasia induced by laser in situ keratomileusis. *J Cataract Refract Surg* 2001;27(11):1796-802.