December 24, 2014

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
WO 2200
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Dr. Hamburg:

We, the undersigned LASIK consumer advocates, hereby petition the Food and Drug Administration (FDA), pursuant to the Federal Food, Drug and Cosmetic Act 21 U.S.C. ß 352, 21 C.F.R. ß 10.30, and any other applicable statute, to immediately take the following actions with respect to excimer lasers used in laser eye surgery currently on the market in the U.S.

Actions Requested

We hereby petition the FDA to add a black box warning concerning the high incidence of induced visual symptoms (double vision/ghosting, starbursts, glare, and halos) and dry eyes to the device labeling of all excimer lasers used in laser eye surgery presently on the market in the U.S., and to send letters to the American Society of Cataract and Refractive Surgery (ASCRS) and the American Academy of Ophthalmology (AAO) to advise physicians of the addition of a black box warning on excimer lasers.

Statement of Grounds

The FDA recently completed a LASIK study, known as the LASIK Quality of Life Collaboration Project, which demonstrated that 3 months after LASIK eye surgery, up to 45% of patients who had no visual symptoms before LASIK report visual symptoms (double vision/ghosting, glare, halos, and starbursts) after LASIK, and up to 30% of patients who had no dry eyes symptoms before LASIK report dry eyes after LASIK.

Visual symptoms were "very" or "extremely" bothersome in up to 4% of patients, and up to 1% of patients experienced a lot of difficulty with or were unable to do usual activities due to visual symptoms.

A 2007 published review of data from twelve FDA clinical trials for LASIK reveals that six months after LASIK, approximately 20% of patients reported that visual symptoms and dry eyes were worse than before surgery, much worse than before surgery, moderately severe after surgery, or severe after surgery.(Bailey MD, Zadnik K. Outcomes of LASIK for myopia with FDA-approved lasers. Cornea 2007 Apr; 26(3):246-54.)

The body of medical literature confirms that dry eyes and night vision problems (visual symptoms) after laser eye surgery are common; however, prospective patients are not routinely informed of the frequency and potential severity and permanence of these problems.

Thousands of LASIK injuries have been reported to the FDA through the MedWatch program**.**

LASIK is an unnecessary surgical procedure performed on a necessary sensory organ of the body; therefore, from the FDA's public health perspective, there should be virtually zero tolerance for risks and adverse effects.

Conclusion

Four years prior to the original FDA approval of LASIK, Dr. Leo Maguire forewarned of the threat to public health posed by impaired night vision following refractive surgery. The following is an excerpt from an editorial published in the March, 1994 edition of American Journal of Ophthalmology:

''Night driving presents a hazardous visual experience to adults without aberrations. When we discuss aberration at night we are considering a possible morbid effect of refractive surgery.'' (Maguire L. J. Keratorefractive surgery, success, and the public health. Am J Ophthalmol. 1994 Mar 15;117(3):394-8.)

With millions of people having undergone laser eye surgery with such frequent problems, it follows that there is an epidemic of visual symptoms/night vision problems and dry eyes caused by this unnecessary surgery. Unless the FDA immediately begins to provide adequately strong black box warnings about the risks and adverse effects of laser eye surgery, the epidemic will continue to grow. There have already been several reports of LASIK-related suicide and countless reports of suicidal ideation. A black-box warning would help reduce the number of

such negative outcomes and therefore falls well within the FDA's mandate of protecting and promoting public health.

Environmental Impact

Nothing requested in this petition will have an impact on the environment.

Economic Impact

We will supply economic impact information at the request of the Commissioner.

Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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