November 2, 2009

Jeffrey Shuren, M.D., J.D.
Acting Director, Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Dear Dr. Shuren,

We are writing to request that the Food and Drug Administration (FDA) issue a public health advisory regarding risks and long-term consequences of LASIK eye surgery. Several hundred reports of harm from LASIK have been filed with the FDA in the past eighteen months. Inaction by the FDA will result in many more Americans being needlessly harmed, which is inconsistent with the FDA mission to protect public health.

BACKGROUND

In the late 1990's through early 2000's when several excimer lasers received initial FDA-approval for LASIK, little was known about long-term safety and efficacy of the procedure. Even less was known about universal adverse effects of LASIK. Furthermore, the FDA never required assessment of quality of life after LASIK, and we are unaware of any FDA post-market studies of LASIK.

What was known at the time LASIK received approval is that the procedure frequently leads to night vision problems and chronic dry eyes which persist beyond the endpoint of the clinical trials. A meta-analysis of Summaries of Safety and Effectiveness for the twelve lasers approved from 1998 through 2004 found that six months after LASIK, 17.5% of patients report halos, 19.7% report glare, 19.3% report night-driving problems and 21% report dry eyes which are worse than before surgery, much worse than before surgery, moderately severe or severe[1] Based on these data, which demonstrate an unreasonable and substantial risk of injury, a citizen petition requesting a ban on excimer lasers for LASIK surgery was filed with the FDA in May 2008. This petition was denied by the FDA, largely for the stated reason of failure to provide data; however, sufficient data were underlined in the body of the petition and references to publications with ample supporting data were provided with the petition.

In the past decade, thousands of articles have been published in the medical literature regarding LASIK surgery. Numerous medical studies have examined LASIK risks and permanent pathologic changes caused by the procedure. Case studies involving undesirable outcomes of LASIK are routinely reported in ophthalmology journals.

There is a huge disconnect between ophthalmologists who perform LASIK and the LASIK patient population regarding what constitutes a LASIK-related adverse event. What a patient considers a bad outcome is often dismissed as an expected "side effect" by

the surgeon who performed the procedure. Risk of intractable dry eyes after LASIK is downplayed in the informed consent process. Night vision problems, which may be permanent and severe, are presented to patients as normal, temporary side effects. **It is time for the FDA to listen to the patient community.** LASIK is an elective surgery involving substantial risk to our most valued sense, and as such, the tolerance for problems with the procedure should be extremely low. Certainly a ~20% risk of potential long-term "side effects" or "symptoms" is not acceptable.

Furthermore, research now demonstrates the following consequences of LASIK in 100% of eyes treated:

- The corneal flap never fully heals,[2-4] exposing patients to life-long risk of traumatic flap dislocation and increased risk of eye infection
- Biomechanical strength of the cornea is reduced after LASIK,[5] which may lead to sight-threatening corneal ectasia months or years after surgery
- Intraocular pressure measurements are falsely low after LASIK,[6] leading to possibility of vision loss from undiagnosed glaucoma
- LASIK causes error in calculation of lens power for cataract surgery,[7] exposing patients to poor vision after cataract extraction

The FDA called a public meeting in April 2008 to discuss issues concerning post-market experiences with LASIK. Strong arguments against the procedure were given during the open public hearing by patients who experienced bad outcomes from LASIK, family members of LASIK patients, doctors, optometrists, and psychologists. Several speakers reported on the emotional toll that LASIK complications takes on patients, even those with no prior history of psychological problems.

MEDICAL DEVICE REPORTING (MDR) AND MEDWATCH

MDR Regulation (21 CFR 803) requires medical device user facilities such as LASIK clinics to report device-related adverse events to the manufacturer or to the FDA if the manufacturer is not known. Consumers may voluntarily report adverse events of LASIK to the FDA through the MedWatch program.

Media reports surrounding the FDA's April 2008 LASIK public meeting resulted in a brief period of heightened public awareness of the MedWatch program for reporting problems associated with LASIK. Since the meeting, several hundred adverse events related to LASIK have been reported to the FDA. Many of these reports involve cases of serious vision loss. The majority of reports involve long-term night vision problems and chronic dry eyes after LASIK, and diminished quality of life is frequently reported as associated with these problems. As stated, federal law requires all LASIK clinics to report LASIK adverse events, however, noncompliance is common. The public generally

remains unaware of the MedWatch program. Although the FDA has received several hundred reports of adverse events related to LASIK, the vast majority are not reported. Another citizen petition calling for inspection of LASIK clinics for compliance with MDR regulations was filed with the FDA in May 2009.

In addition to deficiencies in medical device adverse event reporting, we also believe that excimer laser manufacturers are not investigating LASIK complaints and performing root cause analysis as required by federal law under 21 CFR Section 820.198.

LASIK ADVERTISING

LASIK is widely, heavily advertised to the public. LASIK marketing is intended to entice patients to undergo an unnecessary, irreversible surgery associated with significant risk to vision.

The FDA shares responsibility for enforcement of LASIK advertising with the Federal Trade Commission (FTC).

In May 2009 the FDA sent a reminder letter to eye care professionals regarding LASIK advertising.[8] The letter stated, "A restricted medical device [such as excimer laser] is misbranded under the Federal, Food, Drug, and Cosmetic Act (Act) if its advertising is false or misleading (21 U.S.C. 352(q)). In determining whether the advertisement is misleading, the FDA takes into account not only representations made or suggested by statement, word, or design, but also the extent to which the advertisement fails to reveal facts material in the light of such representations, or material with respect to consequences which may result from the use of the device to which the advertisement relates under the conditions of use prescribed in the advertisement (21 U.S.C. 321(n))."

In October 2008 the FTC published updated guidance for marketing of LASIK surgery.[9] The guidance states, "The FTC enforces Section 5 of the Federal Trade Commission Act (FTC Act), which prohibits deceptive or unfair practices in or affecting commerce, and Section 12 of the FTC Act, which prohibits the dissemination of any false advertisement to induce the purchase of any food, drug, device, or service [such as LASIK surgery]."

There has been little, if any, enforcement of regulations governing LASIK advertising. The overwhelming majority of LASIK advertising is misleading and unsubstantiated.

PATIENT INFORMATION BOOKLET

Although the FDA requires that prospective patients be given the FDA labeling (patient information booklet) prior to undergoing LASIK surgery, most patients do not receive a copy. The FDA does not enforce this requirement upon physicians, leaving prospective patients with insufficient information to make an informed decision to consent for surgery.

PATIENT SATISFACTION

Patient satisfaction after LASIK, as measured by unvalidated surveys or questionnaires, is neither scientific nor a reliable indicator of LASIK safety. LASIK surgeons report high patient satisfaction, even in cases with poor night vision and sight-threatening complications. The "Hawthorne effect" proposes[10] that patients may rate their level of satisfaction with the LASIK procedure higher in an effort to please their physician.

Several weeks prior to the April 2008 public meeting, the American Society of Cataract and Refractive Surgery (ASCRS) -- a professional group of LASIK and cataract surgeons -- issued a press release announcing findings of a literature review led by Kerry Solomon, M.D. alleging a "95.4% global LASIK satisfaction rate".[11] The full text of the article was not published until April 2009. Nineteen articles representing only 2,199 patients were retained by the authors in this "world literature review"[12], although 16 million patients had undergone LASIK worldwide according to the press release. Eighty four percent (16/19) of the articles used questionnaires that were not validated.

Solomon et al report; "Although this database [of 19 articles] also includes information on visual outcomes, night vision symptoms, and dry eyes, for the purpose of this paper, the analysis of the database focuses specifically on patient satisfaction and quality of life." In other words, the authors chose not to disclose complication rates. Only two articles in the literature review actually report quality of life after LASIK... one is a study of 100 patients in Bihar, India,[13] and the other is a study of 49 patients in Ireland.[14] In the study performed in India, the reason the females sought LASIK was to enhance marriage prospects. All levels of satisfaction in this review, ranging from “very” to “somewhat” were grouped and reported as “satisfied” patients.

The majority of articles in the database which reported dry eyes and night vision problems confirm double-digit rates (as high as over 50%)[15] of these serious complications of LASIK. Although Solomon et al chose not to report the incidence of dry eyes and night vision problems, they do state that poor quality of life scores after LASIK were associated with "regression, dry eye, poor vision in low light, and halos at night" -- a fact conveniently missing from their "*95.4% of LASIK patients are satisfied*" sound bite.

Curiously, the FDA apparently gave ASCRS advanced notice of the planned public meeting on LASIK[16] – enough time to conduct a "LASIK world literature review" and prepare talking points for the media. The spin generated by ASCRS surrounding this public meeting included misleading statements such as, "The FDA reaffirms that LASIK is both safe and effective". At the public meeting, Dr. Solomon was asked by FDA consultant, Jayne Weiss, M.D., for clarification concerning FDA's role in ASCRS' public statement and literature review. Dr. Solomon admitted, "This was independent from the FDA or the National Eye Institute. Yes, ma'am."

PROBLEMS WITH FUTURE CATARACT SURGERY

As stated, LASIK surgery results in miscalculation of lens implant power for future cataract surgery.[7] In 2008, the FDA announced on its web site that it had "worked with the American Academy of Ophthalmology to develop a card [K-card] that physicians can fill out with the patient's eye measurements before their LASIK surgery." Unfortunately, LASIK surgeons do not routinely provide patients with a K-card. Retention of medical records by healthcare providers is required by state laws; however, in many states medical records may be destroyed after five years. The majority of LASIK patients in the United States are not aware of the need to obtain their pre-LASIK eye measurement records. Therefore, it is incumbent upon the FDA to include this information in a public health advisory concerning LASIK eye surgery.

SUMMARY

Morris Waxler, former FDA branch chief for ophthalmic surgical devices, recently told Jim Dickinson of FDA Webview (www.fdaweb.com) that the FDA was under enormous industry pressure to approve the LASIK indication for excimer lasers. The FDA failed to require proper scientific assessment of long-term safety and efficacy of LASIK in an apparent attempt to appease powerful ophthalmologists who lobbied for approval.

Current medical literature demonstrates that dry eyes and night vision difficulties after LASIK are common. This is consistent with LASIK clinical trials which reveal an approximate 20% incidence of these problems. Furthermore, it is now known that visual outcomes of LASIK tend to decline over time,[17] and that 100% of eyes treated experience permanent, pathologic changes to the cornea.[18]

Adverse events of LASIK reported to the FDA through MedWatch show a pattern of diminished quality of life associated with LASIK complications. The majority of complaints are related to dry eyes and night vision problems.

The FDA's mission is to serve and protect the public, not to serve industry. For the reasons outlined herein, we ask that the FDA issue a public health advisory regarding the high incidence of adverse events and long-term consequences associated with LASIK surgery.

Sincerely,

See attached 126 electronic signatures.

cc: Timothy A. Ulatowski
Joshua M. Sharfstein, M.D.
Margaret Hamburg, M.D.

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