



September 13, 2009

Jeffrey Shuren, M.D., J.D.
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Dear Dr. Shuren:

The *LASIK Surgery Watch (LSW)* is a non-profit patient advocacy organization comprised of doctors, patients, families of patients, researchers, psychologists and other interested parties whose lives have been adversely affected by LASIK eye surgery. We believe that LASIK is an inherently harmful procedure whose approval violated Food and Drug Administration's (FDA) own safety guidelines.

We are writing to bring to your attention this serious matter affecting public health in which the FDA has been grossly negligent and has placed patients' interests secondary to interests of surgeons and medical device manufacturers.

Regulation of ophthalmic laser devices used for LASIK eye surgery is under the purview of the FDA. Approximately 700,000 people undergo LASIK annually in the United States, largely as a result of aggressive and often misleading advertising.

LASIK devices received FDA approval despite an approximately 20% incidence of the complications 'dry eyes' and 'night vision disturbances' at six months after surgery. 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.¹ For a LASIK device to receive approval, FDA guidance requires that adverse events from its use fall below 1%. This ceiling for adverse events *was exceeded by approximately 20-fold* in the FDA approval of lasers for LASIK. It should be noted that of the 14 FDA approvals for LASIK, no study of safety and effectiveness of LASIK met the guidance by reporting adverse events in less than one percent of eyes. Furthermore, LASIK clinical trials study designs lacked sufficient duration of follow-up to detect potentially blinding late-onset complications of LASIK that have since emerged.

Articles published in the body of medical literature now reveal permanent adverse effects of LASIK eye surgery:

- LASIK reduces the biomechanical integrity of the cornea, which may lead to late onset corneal ectasia requiring corneal transplant.²
- The LASIK flap never completely heals and may be accidentally dislodged indefinitely.^{3,4,5}
- LASIK patients are at life-long increased risk of corneal infection due to flap margin wounds that never fully heal,⁶ leaving an open portal for microorganisms.
- Corneal nerves responsible for comfortable wetting of the eye, which are severed and burned during LASIK never fully regenerate normal densities and patterns,^{7,8,9} resulting in dry eye disease that can be permanent and debilitating.
- LASIK complicates intraocular lens power calculations for future cataract surgery.¹⁰ This may result in poor vision following cataract surgery and increased risk of repeat surgeries.
- LASIK results in inaccurate intraocular pressure measurement,¹¹ exposing patients to risk of undiagnosed glaucoma and associated vision loss.
- LASIK causes persistent keratocyte (corneal cell) death, which is suggested to lead to corneal ectasia.¹²
- LASIK causes a reduction in quality of vision.^{13,14}

The importance of pupil size in LASIK screening and surgical planning has been systemically ignored in LASIK clinical trials, and dismissed by the FDA. Objective tests demonstrate that visual aberrations induced by LASIK increase with increasing pupil size. Failure of the FDA to place pupil size restrictions in device labeling leads to improper treatment, which continues to result in permanent visual impairment of many thousands of Americans who have large pupils. Measuring corneal distortions across a standard 6 mm scan diameter is a deceptive practice of LASIK clinical trials investigators and the FDA, which serves to hide the severe visual disturbances experienced by patients with larger pupils.

In response to pressure from injured LASIK patients, the FDA called a special meeting of the Ophthalmic Devices Panel on April 25, 2008. This meeting was a sham. Despite compelling open public hearing testimony of problems inherent in the surgical procedure, Panel Chairman Jayne Weiss, M.D., herself a LASIK surgeon, concluded the meeting by stating;

"It appears to me from hearing what has been said today that this has really been a referendum on the performance of LASIK by some surgeons who should be doing a better job".

It should be noted that during the panel's April 25, 2008 hearing, panel members were asked why so many of them wear glasses. Jayne Weiss responded, explaining that she chooses not to have LASIK surgery because she is uncomfortable with the level of risk involved. Almost all of the ophthalmologists on the panel wore glasses.

In the eighteen months since the FDA hearing, the FDA has failed to respond appropriately to issues raised and requests for a moratorium on LASIK devices.

A month before the panel meeting, the American Society of Cataract and Refractive Surgery (ASCRS) issued a press release announcing a literature review conducted by a group of LASIK surgeons alleging a "95.4% global LASIK satisfaction rate". Nineteen studies representing only 2,199 patients were retained by the authors in this meta-analysis, although 16 million patients had undergone LASIK worldwide according to the press release. LASIK surgeon Kerry Solomon, M.D. was the lead author of the review. The article states:

"Although this database 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."

Two studies in Solomon's literature review actually reported quality of life after LASIK ... one is a study of 100 patients in the socio-economically poor state of Bihar, India,¹⁵ and the other is a study of 49 patients in Ireland.¹⁶ In the first study, the reason the females had LASIK *was to enhance marriage prospects*.

The literature review was conducted independently of the FDA, yet the ASCRS press release states, "*FDA reaffirms that LASIK is safe and effective*".

Patient satisfaction is not a reliable measure of LASIK safety and efficacy:

- "When evaluating outcome measures, we disregarded patient satisfaction and quality-of-life measures as these can be subjective and might be biased by the patient's age, preoperative myopia status, and expectations of the surgery."¹⁷
- "A keratorefractive patient may simultaneously be happy with the result of surgery and have degraded vision - how can refractive surgery be a potential public health problem if patients are happy with the results? Inherent in this question is the assumption that a patient without complaint is a patient without optical degradation. That argument does not hold up to closer scrutiny. The keratorefractive literature contains disturbing examples of patients who have visual handicaps that place themselves and others at significant risk for nighttime driving accidents and yet they are happy with the results."¹⁸

An inspection of articles cited in the 'global LASIK satisfaction rate' literature review reveals alarmingly high LASIK complication rates:

- "Twenty four percent of patients reported glare and night vision problems postoperatively." O'Doherty M, O'Keeffe M, Kelleher C. Five year follow up of laser in situ keratomileusis for all levels of myopia. *Br J Ophthalmol* 2006;90:20–3.
- "Overall, 30.0% of the subjects reported experiencing halos, 27.2% reported glare, and 24.5% reported starbursts." Bailey MD, Mitchell GL, Dhaliwal DK, et al. Patient satisfaction and visual symptoms after laser in situ keratomileusis. *Ophthalmology* 2003;110:1371–8.
- "Commonly reported symptoms included eye soreness in 43 patients (44.3%), tearing in 20 (20.8%), itching in 38 (39.6%), and moderate dryness or worse in 28 (20.8%)." Schmidt GW, Yoon M, McGwin G, et al. Evaluation of the relationship between ablation diameter, pupil size, and visual function with vision-specific quality-of-life measures after laser in situ keratomileusis. *Arch Ophthalmol* 2007;125:1037–42.
- "Night vision was considered worse or much worse than before surgery by 33.8% of patients... After surgery, 40.9% of patients reported experiencing more difficulty with night driving than before surgery." Tahzib NG, Bootsma SJ, Eggink FA, Nabar VA, Nuijts RM. Functional outcomes and patient satisfaction after laser in situ keratomileusis for correction of myopia. *J Cataract Refract Surg.* 2005 Oct;31(10):1943-51.
- "Twenty-nine percent reported reduced night vision clarity following LASIK and 27% noted more eye dryness following LASIK." *CLAO J.* 2001 Apr;27(2):84-8. Patient satisfaction after LASIK for myopia. Miller AE, McCulley JP, Bowman RW, Cavanagh HD, Wang XH.

Dr. Solomon's literature review is scientific fraud in our opinion. What should be reported to the public is that the complication rate of LASIK eye surgery is at least 20%, which is consistent with FDA clinical trials data, and unacceptable for elective surgery performed on a primary sense organ.

There is a lengthy financial disclosure at the end of Dr. Solomon's article.

Protocols for newer LASIK product platforms continue to allow both dry eye and night vision disturbances to be listed as 'symptoms' rather than the adverse events that even the FDA now concedes that they are. For example, the clinical trials for the Alcon 6000 Custom Cornea Platform approved in 2006 had a rate of dry eye at six months post-op of 39.1% and a 14.5% reported rate of night driving difficulties. Since these rates markedly exceed FDA's own guidance document stating clinical trials related to the excimer laser demonstrate an adverse event rate of less than 1%, one can only conclude that a moratorium on the use of the excimer laser for LASIK is immediately indicated.

Chronic dry eyes and night vision disturbances may lead to diminished quality of life, depression and suicidal ideation. LASIK-related suicides were reported to the FDA at the

hearing in April 2008. There were several examples of suicides due to LASIK adverse events where suicide notes were left behind to corroborate that LASIK adverse events were the reason for the suicide. Examples include Brentwood, Tennessee police officer Lawrence Campbell and patent lawyer and aspiring medical student Colin Dorrian.

On February 3, 2008, Sabine Vollmer, a reporter with the Raleigh News & Observer reported that "Scientists at the Emory Eye Center in Atlanta reviewed suicides among organ donors who had had laser eye surgery. Preliminary results suggested the suicide rate might be four times as high among cornea donors who had had LASIK as among cornea donors who had not." www.newsobserver.com/news/health_science/story/920341.html.

Morris Waxler, Ph.D., Former Chief, Diagnostic and Surgical Devices Branch, Division of Ophthalmic Devices came forward on September 3, 2009 to admit that FDA approvals of excimer lasers for LASIK, which took place during his tenure, were a mistake. Excerpts from his interview are provided below and the full article is available at www.FDAweb.com:

The former CDRH division director in charge of LASIK device reviews, Morris Waxler, tells us the agency "screwed up" in the standards it set for the procedure in 1995, due to a lack of in-house expertise and pressure from the industry.

When it first approved laser devices for LASIK indications in 1995, CDRH "screwed up" in not applying its own less-than-1% standard for acceptable adverse events reported from clinical studies, former ophthalmic devices division director Morris Waxler told FDA Webview in a teleconference interview 9/3. Waxler said FDA was under enormous industry pressure when it approved the new indication and its standards for the procedure "were cobbled together."

Primarily, he said, CDRH totally lacked in-house LASIK expertise at the time and incorrectly judged the significance of adverse events, which the division's own standards said should be less than 1% of all procedures. Actual experience was above 5% in permanent adverse events that the agency listed in the wrong column as so-called "second-tier complications" such as patient-reported persistent pain, blurred images and night-vision difficulties that were not counted as first-tier adverse events (retinal detachment, lost visual acuity, induction of astigmatism, etc.).

"I think we screwed up," Waxler said. "Nobody's going to admit that. Basically, I think people made some of those judgments incorrectly. We were getting advice from very renowned ophthalmologists — more renowned than anyone we had in the agency. We dropped the ball with regard to enhancements with in excess of 10% retreatment rates because

there was a great deal of pressure from individual doctors who said they had the freedom as a physician to re-treat when they felt it was necessary for the sight of the patient. We waffled on that, we collapsed on that issue. In some of the clinical trials we were very tough on particular companies that came in with high re-treatment rates, and none of that got translated into a requirement for all the manufacturers. So I think we screwed up. ”

“It’s very difficult to get them to admit there’s been an error. I just think that’s not going to happen until there’s such a crisis that they’re forced to do so.”

“Until enough patients have been injured to get together and mount a big lawsuit”, Waxler observed, “neither the independent ophthalmologists nor the agency is going to stand up and do anything.”

FDAWebview also published an FDA response to the Waxler interview. LASIK Surgery Watch disputes most of FDA’s response to Dr. Waxler’s statements. First, any inclusion of caveats or disclaimers by the FDA stating guidance documents are “only guidance” in no way exonerate the FDA for approving excimer laser devices for LASIK, a procedure with complications in excess of 20%. Second, no number of subsequent meetings or revisions to the guidance could justify such damage to millions of American eyes. LSW agrees with the FDA statement that LASIK retreatments were never FDA approved. Yet, retreatments are common. The fact that retreatments are commonly performed after LASIK speaks to lack of efficacy of the first LASIK procedure, and adds to an already vast body of evidence that use of excimer lasers for LASIK never merited FDA approval.

The FDA response addressed adverse event reporting to the FDA database:

“With regard to the adverse event numbers,”... “preliminary search indicates that subsequent to the 4/25/08 Panel, we received reports of 537 events. However, only 97 of them had a date of the event subsequent to the panel meeting. Only 18 of these were received as voluntary reports.”

FDA’s emphasis that most reports were not recent serves only to demonstrate that damaged patients have no idea where to report their adverse events.

Statements made by the FDA regarding adverse events reported in its own database are incorrect:

- ASCRS reported prior to the panel hearing on April 25, 2008 that "the agency received 140 reports of Lasik-related problems between 1998 and 2006". However, ASCRS revealed only voluntary complaints between 1998 and 2006 and not reports from user facilities or manufacturers.

- The FDA claimed that only 18/537 (3%) of adverse event reports it received after the April 2008 panel hearing were voluntary. Data from the FDA MedWatch database reveal that at least 58% (310/537) of adverse event reports received after the panel hearing were voluntary.
- From January 1998 to July 2009, there have been at least 420 voluntary LASIK adverse event reports. ***At least 50% of these reports were received by the FDA over the brief 35 day period from 4/20/08 to 5/25/08.***

Although there is a regulatory obligation [21 CFR 803] to participate in post-market surveillance by reporting adverse events, failure to do so is common. With millions of LASIK surgeries performed in the United States from 1998 to 2009, and adverse event case reports common in peer reviewed literature, why has the FDA received only ~550 adverse event reports from user facilities and manufacturers combined? Most patients remain unaware of the existence of a voluntary adverse event reporting process. Therefore, the true incidence of permanent vision loss and/or symptomatic ocular surface disease following LASIK is not known. Additional information concerning underreporting of adverse events is provided in Exhibit A attached to this document.

LASIK Surgery Watch would like to know why the FDA provided misleading data to the public regarding its own adverse event database.

Although daylight visual outcomes of LASIK can be relatively good in the short-term, refractive results of LASIK decline over time.¹⁹ LASIK is a medically unnecessary surgery that carries with it permanent adverse effects and substantial risk of permanent visual impairment. As evidenced, LASIK complications occur frequently. It is reasonable to conclude that LASIK eye surgery has become a leading cause of preventable visual impairment in the United States.

Finally, we urge all recipients of this letter to read an Ophthalmologist's compelling and well-documented insights into flaws in the LASIK approval process and adverse event reporting with implications for public health and safety. This letter is available at the following link and is also attached as Exhibit A:

www.lasikcomplications.com/RegGovComment1.pdf

Although we disagree with this doctor's position about suitability and continued use of excimer lasers for correction of refractive error, we would like to emphasize his point that without proper clinical trials data, no patient can provide proper informed consent. Failure to provide fully informed consent for a surgical procedure constitutes medical malpractice in every state. For the reasons outlined here, we request that the best interests of the public be served by the immediate withdrawal of FDA approval of LASIK devices.

Sincerely,

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Exhibit A: Anonymous comment by an Ophthalmologist as referenced on page 7 of 10 of the LSW letter

September 23, 2008

Public Submission: FDA-2008-P-0319-0023

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Docket [FDA-2008-P-0319](#)

Docket Title Ban the Use of All Refractive Surgery Lasers for LASIK Surgery

Docket Type Nonrulemaking

Document [FDA-2008-P-0319-0001](#)

Document Title Laurantell H. Burch - Citizen Petition

Public Submission FDA-2008-P-0319-0023

Public Submission Title Anonymous - Comment

Views 

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How To Comment

Title Anonymous - Comment

Abstract

Document Type PUBLIC SUBMISSIONS

Document Sub-Type EREG-Electronic Regulation from Form

CFR Part/Citation & Source Citat

Form Letter Count

Attachment Type

Exhibit Type and Location

Page Start

Document Date 09/22/2008

OMB Control Number

RIN

Date Posted 09/22/2008

Comment Start Date 09/22/2008

Comments Due

Effective Date

Submitter Information

Comment Tracking Number 80716cc3

First Name Anonymous

Last Name

Submitter Category Health Professional - A0007

Country United States

State or Province

Organization Name ophthalmology

Third Party

General Comment

Comment I am an ophthalmologist but I do not perform refractive surgery. I have no financial relationships with corporations in the refractive surgery industry. I do not believe that excimer laser surgery should be "banned". I refer patients to my conservative, ethical associate if they express an interest in surgical reduction of refractive error.

The statement that "one percent" or "less than one percent" of patients undergoing refractive surgery experiences complications is widely quoted in the lay press and is often stated by refractive surgeons, who also report their anecdotal experience with many satisfied patients. My purpose in writing today is to debunk this number.

Effect of the Euphoria Period

When first liberated from glasses and/or contact lenses, patients are understandably astonished and euphoric over their ability to navigate through life without optical correction. Many of the superlatives applied by patients are garnered during this early post-operative period. Poor contrast sensitivity, night vision difficulties, and pain from dry eye symptoms are dismissed as expected, short term issues which do not (yet) detract from satisfaction with the final

outcome.

Refractive surgeons who perform their final patient examination less than 6 months after surgery have no experience with long-term patient satisfaction or the frequency of permanent vision difficulties which interfere with daily function. Sporadic reports from co-managing optometrists are not sufficient to create a detailed professional understanding of these issues.

Therefore, the personal anecdotal experience of typical high volume refractive surgeons is suspect, since most do not follow their patients long-term.

Inadequate Measurement of Induced Visual Aberrations

The original phase III FDA trials of excimer laser refractive surgery contained a fatal conceptual flaw as regards assessment of vision. Vision, broadly defined, encompasses many psychovisual phenomenon, of which high-contrast visual acuity is not the most functionally important in many situations. Yet, the FDA allowed high-contrast visual acuity, residual refractive error and 6-month refractive stability to be the major determinants of the "safety and efficacy" of excimer laser devices(1-3). No formal testing of point-light-source scatter (the origin of halos and starbursts around car headlights at night) was performed, despite the fact that it could be accomplished with relatively simple computer software(4-7). Contrast sensitivity testing was not routinely incorporated into study designs(8). Even accurate measurement of pupil diameter was neglected during the trials of fixed-zone treatments(2), despite the fact that principles of physiologic optics clearly predicted the hazards of creating an optical zone smaller than the low-light pupil (9).

Instead, these early trials depended exclusively on "patient satisfaction surveys" and "better or worse" symptom questionnaires(1, 2) as indirect measures of overall vision function. The original surveys were not published and there is no evidence that they were validated prior to use(10). One person's "highly satisfied" may be another patient's functional disaster, especially as regards vision performance in low light environments (for an illustrative patient/study subject story, see the comments of Mr. Rick Kwiecinski at the July 23, 1999 meeting of the Ophthalmic Devices Panel; <http://www.fda.gov/ohrms/dockets/AC/99/transcpt/3528t2.pdf>).

In published clinical trial reports, the use of statistical averages prevented neutral readers from identifying worrisome groups of outlier patients. Vague wording and favorable opinion were applied frequently. How are we to interpret the statement (2) that "Overall, at least 82.8% of spherical subjects and 81.5% of astigmatic subjects were satisfied or extremely satisfied with the results of their surgery"? Perhaps the answer is that nearly 20% of subjects in this trial were not satisfied with the overall effect of refractive surgery on their visual function. It is amusing to find "at least" juxtaposed with statistical precision to one-tenth of a patient.

The FDA has no idea of the true rate of permanent, functionally important induced vision aberrations or reduction in overall vision performance.

As a separate but related issue, the FDA has no idea of the scope of the public health issue which may arise as millions of post-refractive surgery patients grow older, develop inter-current eye disease, and drive with halos/starbursts and degraded contrast sensitivity. A level of reduced low-light driving performance which is "satisfactory" to one individual may, in the aggregate(11, 12), present a significant risk to the populace at large.

Failure of Post-Market Surveillance

Manufacturers have a regulatory obligation [21 CFR 803] to participate in post-market surveillance and to report adverse events. This process is easily circumvented. Several market forces combine to make it particularly ineffective in refractive surgery.

First, refractive surgeons dismiss or ignore patient complaints which should be reported as adverse events. For evidence of this, see the public comments of the Ophthalmic Devices Panel meeting held on April 25, 2008. In particular, the true incidence of permanently symptomatic dry eye syndrome after LASIK is probably higher than 1%, especially in middle-aged female patients.

Second, excimer laser manufacturers "hold all the cards" when a surgeon reports a poor outcome to the company. Surgeons are usually told "the laser is fine". Since we are entertaining anecdotal commentary, I, personally and anecdotally, have never heard of a single incident in which the surgeon was told by the field technician "the laser malfunctioned". The excimer laser in refractive surgery is an open-loop engineering system and no surgeon can ever be positive that the device achieved the desired ablation profile. Surgeons must face multiple patients with poor results (vis the recall of the Alcon LADARvision 6000) or compare notes at national meetings to detect patterns of poor outcome that cannot be explained by

similarly incorrect surgical technique on the part of many practitioners.

Third, laser manufacturers may use internal complaint review processes to "determine" that no device fault occurred, and then fail to create a manufacturer device report (MDR) as required by regulation. At least one manufacturer (Alcon Laboratories Inc.) has been caught by the FDA suppressing surgeon complaints regarding retreatment by declaring that retreatment is "not a complication" and "not a reportable adverse event" [see the letter dated July 16, 2005 from Timothy Couzins, Compliance Officer, Florida District, FDA to Rebecca G. Walker, Vice President, Regulatory Compliance, Alcon Laboratories Inc.; see the letter dated December 30, 2005 from Sharon Kapsch, Branch Chief, Reporting Systems Monitoring Branch, FDA to Rebecca G. Walker].

Summary

The true incidence of permanent vision loss and/or symptomatic ocular surface disease following laser refractive surgery is unknown for the following reasons:

- 1) The original clinical trials were poorly designed and failed to incorporate relevant visual performance metrics beyond high-contrast visual acuity and refractive error.
- 2) The original clinical trials were poorly designed and failed to capture data on the effects on vision function beyond self-reported, subjective patient surveys.
- 3) The original clinical trials were poorly designed and failed to capture sufficient data regarding the induction and/or exacerbation of permanently symptomatic ocular surface disease ("dry eye syndrome") and to identify sub-populations at greater risk.
- 4) Refractive surgeons tend to dismiss patient complaints in the early post-operative period, and many do not provide long-term follow-up.
- 5) When surgeons do complain to manufacturers, they are dismissed as being "at fault" for a poor outcome and are subjected to financial penalty if they persist (see Brian Will MD vs Alcon Laboratories Inc.)
- 5) Laser manufacturers can (and have) violated FDA adverse event reporting requirements, nullifying efforts at post-market surveillance.

Implications

Many commentators have asserted that laser refractive surgery is an elective procedure and that the consent process – which has become increasingly elaborate – fully informs the patient of the risks it entails. In fact, the true frequency of various adverse events is not known therefore patients cannot be accurately and fully informed. Further, patients are provided with flawed "satisfaction" data as a proxy for the effects of refractive surgery on ordinary activities of daily living, which does not create the context for a truly individual decision to accept the risks inherent in these procedures: one patient's "highly satisfied" result may encapsulate poor contrast and night vision disturbances that another patient finds nearly intolerable. What is needed is a consent process which states (for example): 12 months after surgery, 25% of formerly myopic patients see car headlights which look like this standard clinical trial photograph. Do you feel you could drive safely at night with similar vision? If no, do not proceed.

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