Lauranell H. Burch, Ph.D.
[redacted]

June 11, 2009

Daniel R. Levinson, Inspector General
Department of Health and Human Services
Room 5541 Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Levinson:

I am writing to bring to your attention a serious matter affecting public health in which the Food and Drug Administration (FDA) has been grossly negligent and has placed patients' interests secondary to interests of medical device manufacturers.

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

We are aware of the October 14, 2008 letter to Congressman John D. Dingall, then Chairman of the House Energy and Commerce Committee, from a group of FDA scientists regarding scientific misconduct at the highest levels of the CDRH. The letter is found here:
http://www.lasikcomplications.com/CDRHscientists(Oct08).pdf

The CDRH scientists alleged corruption of scientific review of medical devices within the CDRH. Congressmen Dingall and Bart Stupak launched an investigation into this matter. Their letter to then-FDA commissioner Andrew C. von Eschenbach, M.D. is found here:
http://www.lasikcomplications.com/Ltr_to_FDA_Commissioner(17Nov2008).pdf

The CDRH is the branch of the FDA that regulates lasers for LASIK. 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 device to receive approval, FDA guidance documents state that complications from its use must fall below 1%. This ceiling for complications ***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 reported 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 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 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.

- LASIK results in inaccurate intraocular lens power calculations for future cataract surgery.[10]

- LASIK results in inaccurate intraocular pressure measurement,[11] exposing patients to risk of undiagnosed glaucoma and associated vision loss.

- LASIK causes persistent and accelerated keratocyte (corneal cell) death.[12] This means that corneas that have undergone LASIK may not last the patient's lifetime.

- LASIK causes a reduction in quality of vision.[13,14]

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 white-wash. Despite compelling open public hearing testimony of permanent adverse effects of LASIK that occur in all patients because they are inherent in the surgical procedure, Panel Chairman Jayne Weiss, M.D., 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". In the fourteen months since the FDA hearing, the FDA has failed to respond to issues raised and requests for a moratorium on LASIK devices.

A month before the 2008 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." Only two small studies in Solomon's literature review 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 press release states, "FDA reaffirms that LASIK is safe and effective".

Some surgeons have been willing to state the obvious; that 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.

And these are Dr. Solomon's *happy patients*! Dr. Solomon's literature review is scientific fraud in my opinion, and a deliberate attempt to distract the public from alarmingly high complication rates reported in these same studies. What should be reported to the public is that the complication rate of LASIK eye surgery is approximately 20%, which is consistent with FDA clinical trials data, and unacceptable for elective surgery performed on a primary sense organ.

There is a very lengthy financial disclosure at the end of the published literature review.

Despite claims made by LASIK surgeons and the LASIK industry about 'patient satisfaction', today's happy 20/20 LASIK patients are often today's dangerous drivers on our highways at night due to LASIK-induced loss of contrast sensitivity, and may ultimately experience debilitating late-onset complications of LASIK. We believe that no patient would want LASIK eye surgery if they fully understood its consequences

Chronic dry eyes and night vision disturbances may lead to diminished quality of life, depression and thoughts of suicide. Three LASIK-related suicides were reported to the FDA at the hearing in April, 2008.

Although 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 substantial risk of permanent visual impairment. As evidenced, LASIK complications occur frequently. With millions of LASIK procedures performed and high complication rates, it follows that LASIK eye surgery has become a leading cause of preventable visual impairment in the United States.

I have submitted a Citizen's Petition to the FDA to withdraw FDA approval of lasers for LASIK and have not received a response within 180 days as required by law. My petition is found at this link:
http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=FDA-2008-P-0319 .
Failure of the CDRH to ensure rigorous clinical trials and to respond to serious post-market safety and effectiveness concerns regarding LASIK *in adherence to established regulatory requirements* have resulted in irreparable harm to millions of Americans and

is indeed a ‘silent danger’ to public health. For the reasons outlined here, I request an immediate withdrawal of FDA approval of LASIK devices.

Sincerely,

Lauranell H. Burch

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