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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Comments of the National Research Center for Women & Families
on
“Medical Devices: Ophthalmic Devices; Laser-Assisted *In Situ* Keratomileusis
(LASIK) Devices; Establishing a Docket”
[Docket No. FDA-2009-N-0488]**

The National Research Center for Women & Families submits the following comments regarding the laser-assisted *in situ* keratomileusis (LASIK) and the post market experience associated with the use of LASIK devices.

More than 8 million people in the U.S. have had vision-corrective LASIK procedures. Despite its popularity, the surgery has serious risks such as impaired vision, chronic dry eye and pain, and other eye injuries. Although a 95% satisfaction rate has been reported, that figure is not scientifically valid for several reasons. For example, “satisfaction ratings” reported to the providers of medical treatment are notoriously biased by patients who want to stay on good terms with their health care providers, and underreporting of problems is inevitable because problems that are thought to be temporary may instead be chronic. In addition, sometimes weeks, months, or even years go by before complications are obvious.

Moreover, even a 5% dissatisfaction rate would translate to 400,000 people—a major public health concern.

The FDA has approved lasers used in LASIK surgery that had reported complication rates of more than 20% in the clinical studies used to support their FDA approval applications. The clinical trials included no long-term follow up, thus leaving possibility of detecting any late-onset complications.

The FDA’s mission is to ensure that medical products are safe and effective. For LASIK, it is essential that we remember that safe alternatives—glasses and contact lens—are less expensive and readily available. The risks of LASIK have to be examined and understood by patients in that context.

In 2008, the FDA held a public hearing to listen to testimony from patients and doctors, including testimony from patients who reported that LASIK surgery left them with serious vision problems that could not be corrected with glasses or contact lenses, chronic pain, problems with night vision, and other debilitating complications.¹ The public testimony also included personal stories of depression, suicide or suicidal ideation, and

other psychological problems that had been the results of unrelenting pain and other adverse LASIK outcomes. The FDA's response to that meeting has been profoundly disappointing.

Research studies have documented difficulties with night vision and dry eyes, the latter of which can be extremely painful.² While one study found that approximately half of the LASIK patients experienced dry eyes within the first week,³ a more worrisome research finding was that 20% of the LASIK patients had dry eyes for more than 6 months.⁴

An analysis of FDA Summaries of Safety and Effectiveness for the twelve LASIK lasers approved by the FDA from 1998 through 2004, found that six months after LASIK, 8% of patients reported halos, 20% reported glare, 19% reported night driving problems, and 21% reported dry eyes that were worse, or much worse, than before surgery.⁵ Other complications have been reported, including infection, inflammation, haze, free caps (where the flap was completely cut off), flap striae (wrinkles), and flap dislocation. A 2008 study published in the *American Journal of Ophthalmology* by Dr. Jorge Alio and his colleagues reported that 28% of the eyes treated with LASIK needed re-treatment within 10 years because of under-correction, over-correction, or regression. The percentage of patients was even higher: 35%.⁶

Given the severe and potentially life-long nature of many of these complications, it is not surprising that reports have indicated elevated rates of suicide among LASIK patients. For example, in 2008, preliminary findings of an Emory Eye Center study suggested a four-fold increased suicide rate among cornea donors who had LASIK surgery, compared to cornea donors who had not had LASIK.⁷ We have serious concerns about why that important study has not been published. It is not unusual for academic research to remain unpublished when findings are inconsistent with the financial interests of medical school faculty or administrators.

Recognizing the profound negative impact that LASIK can have on quality of life, some doctors have revised their post-operative information packets to include language regarding risk of possible psychological damage from a less-than-ideal LASIK procedure.⁸

Are patients adequately warned of these risks before deciding to have LASIK surgery? The problems are rarely publicized and patients tell us that they did not have adequate informed consent prior to undergoing LASIK surgery.

The FDA's web page on LASIK provides important information, but most patients will never read the FDA web page. In addition, the FDA information on LASIK would better serve people considering LASIK surgery if the FDA placed the following statement in a more prominent spot (instead of at the bottom of a lengthy article): "It is also important to note that no laser company has presented enough evidence for the FDA to make conclusions about the safety or effectiveness of enhancement surgery."⁹

To ensure informed consent, the FDA should reach out more effectively to mass media about their LASIK warnings and require that physicians using LASIK devices provide short-easy to understand booklets about LASIK risks at least one week prior to the procedure. The information in the booklets should be reiterated by the health professionals, not undermined with reassuring statements such as “this procedure is very safe” or “all my patients are very happy.”

Sincerely,

Diana Zuckerman, President
National Research Center for Women & Families

The National Research Center for Women & Families is a nonprofit dedicated to improving the health and safety of adults and children by using research to develop more effective programs and policies. We do not accept funding from drug or medical device companies.

¹ FDA, 110th Meeting of the Medical Devices Advisory Committee, “Summary Minutes, Medical Devices Advisory Committee” April 25, 2008, available at <http://www.fda.gov/ohrms/dockets/ac/08/minutes/2008-4353m1.htm>.

² Sugar A, et al., “Laser in situ keratomileusis for myopia and astigmatism: safety and efficacy: a report by the American Academy of Ophthalmology.” *Ophthalmology*. 2002 Jan; 109(1): 175-87.

³ Hovanesian JA, Shah SS, Maloney RK, “Symptoms of dry eye and recurrent erosion syndrome after refractive surgery” *Journal of Cataract & Refractive Surgery*. 2001 Apr; 27(4): 577-584.

⁴ Shoja & Beharati. *European Journal of Ophthalmology*. 2007 Jan-Feb;17(1):1-6.

⁵ Bailey MD, Zadnik K. “Outcomes of LASIK for myopia with FDA-approved lasers.” *Cornea*. 2007 Apr; 26(3): 246-54.

⁶ Alio J et al. “Ten-year follow up of laser in situ keratomileusis for myopia of up to – 10 diopters.” *American Journal of Ophthalmology* 2008; 145: 46-54.

⁷ Sabine Vollmer, “Some link depression, failed LASIK.” (February 3, 2008, The News Observer) available at <http://www.newsobserver.com/150/story/920341.html> .

⁸ Ocular Surgery News, “Surgeon Shares Refractive Surgery Trends in Clinic in Australia” (May 18, 2009) available at <http://www.osnsupersite.com/view.aspx?rid=40013>.

⁹ U.S. Food and Drug Administration (2009). What should I expect before, during, and after surgery? <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm061270.htm>