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CITIZEN PETITION

The undersigned submits this petition under section 519 of the Federal Food Drug & Cosmetic Act (21 USC 360i), or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs to request the Commissioner enforce compliance with medical device reporting (MDR) regulations by LASIK device user facilities and ASFs - Ambulatory Surgical Facilities (hereinafter referred to as "LASIK clinics").

ACTION REQUESTED

The petitioner requests the Commissioner of Food and Drugs inspect LASIK clinics to ensure compliance with 21 CFR 803, Subpart C User Facility Reporting Requirements. Part 803 requires medical device user facilities to (1) establish written MDR procedures, (2) report adverse events to the manufacturer or to the FDA, and (3) submit annual reports to the FDA.

Further, the petitioner requests the Commissioner of Food and Drugs impose sanctions on non-compliant LASIK clinics as authorized under 21 USC 331 – 337. The regulation authorizes sanctions ranging from warning letters to injunction proceedings, civil penalties, and criminal penalties.

STATEMENT OF GROUNDS

In 1998, the FDA approved the first excimer laser for LASIK. Since then, approximately 8 million United States citizens have undergone the surgery.

It is now well-documented that problems after LASIK, such as night vision difficulties and dry eyes, occur frequently after LASIK.[1] A meta-analysis of Summaries of Safety and Effectiveness for the twelve lasers approved for LASIK from 1998 through 2004 found that six months after LASIK, 17.5% of patients report halos, 19.7%

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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.[2]

Other complications of LASIK, such as irregular-thickness flaps, partial or incomplete flaps, buttonholed flaps, free caps (the flap is cut completely off), flap striae (wrinkles), decentered flaps, flap dislocation, infection, inflammation, haze, epithelial ingrowth, vitreoretinal complications, optic neuropathy, induced cataract, and corneal ectasia occur infrequently but may lead to irreversible vision loss. Complications may emerge weeks, months, or years after seemingly successful LASIK, which contributes to underreporting.

Long-term consequences of LASIK include problems with future cataract surgery, risk of undiagnosed glaucoma due to inaccurate intraocular pressure measurements, permanent biomechanical weakening of the cornea with associated risk of late-onset keratectasia (corneal failure), life-long increased risk of corneal infection due to a permanent portal in the corneal periphery for microorganisms to penetrate, persistent loss of keratocytes (corneal cells), reduced corneal nerve density, reduced visual quality, and non-healing healing of the LASIK flap (exhibit 1) with associated risk of late flap dislocation. These issues affect virtually 100% of LASIK patients.

The FDA requires that all prospective LASIK patients receive the Patient Information Booklet (device labeling) from their surgeon prior to surgery. Device labeling is intended to inform patients of contraindications and risks. LASIK surgeons commonly fail to provide the device labeling to patients, which denies patients access to information that could affect their decision to have the surgery.

Microkeratome blades which are used to cut the LASIK flap are cleared by the FDA for single-use, although surgeons routinely reuse the blade on the 2nd eye of the same patient. Reuse of blades on multiple patients has also been reported, which may expose patients to infectious contaminants. It is reported in the medical literature that quality of the flap-cut is reduced with reuse of blades. This exposes patients to an increased risk of complications in the second eye. Furthermore, tissues remnants left on the blade from the first eye may be dragged into the interface of the second eye, leaving debris trapped in the interface.

Over the past several years, patients who suffered serious complications, visual impairment, or chronic dry eyes after LASIK petitioned the FDA to ban LASIK or otherwise restrict the devices to provide greater protection to the public from improper use of LASIK devices. The most recent petition (located at http://www.regulations.gov, Docket ID FDA-2008-P-0319) was received by the FDA in May, 2008. No response has been issued as required by law, and no action has been taken by the FDA to provide better protection for the public.

In 2007, reports of LASIK-related suicides began circulating in the mass media.[3] In February 2008, preliminary findings of an Emory Eye Center study of suicides among organ donors were reported in the media. These findings suggested a four-fold increased suicide rate among cornea donors who had had LASIK compared to cornea donors who had not had LASIK.[4] These media reports were vigorously disputed by LASIK surgeons and LASIK industry consultants who openly denied any connection between a bad outcome from LASIK and diminished quality of life, depression, and suicide.[5]

On April 7, 2008, the American Society of Cataract and Refractive Surgery (ASCRS), a LASIK professional group, issued a press release[6] announcing collaboration with the Agency to study post-LASIK quality of life and stated that only "140 comments relating to LASIK dissatisfaction" had been reported to the FDA in the past decade. This number, in contrast to the reported incidence of complications in FDA clinical trials, is a clear indication that LASIK clinics are not reporting LASIK adverse events as required by law. ASCRS speaks on behalf of the FDA in the press release stating, "The FDA reaffirms that LASIK is both safe and effective." Injured LASIK patients would like to know the name of the FDA source for that statement. Earlier statements by Dr. Daniel Schultz, Director of the Center for Devices and Radiological Health (CDRH) reported in Reuters[7] on March 17, 2008, seem to contradict ASCRS.

In March 2008, the FDA announced a special hearing of the Ophthalmic Devices Panel to be held on April 25, 2008 to address patient experiences with LASIK. Injured LASIK patients who spoke during the open public hearing had harsh criticism of the FDA's unprecedented partnership with LASIK professional groups to study LASIK dissatisfaction.[8] Injured LASIK patients believe that LASIK surgeons are biased and lack objectivity, and that the proposed study amounts to the FDA putting the fox in charge of guarding the hen house.

At the hearing, injured LASIK patients and family members of LASIK patients testified to the devastating psychological impact of post-LASIK dry eyes and night vision disturbances, including depression, suicidal thoughts, and actual suicides.[9] Several speakers called for a moratorium on LASIK.[10]

An FDA Patient Representative brought several serious concerns surrounding LASIK to the attention of the FDA at the April 25, 2008 advisory panel meeting. Her testimony is published on the FDA website at http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-4353t1-04.pdf beginning on page 315.

As media reports of the FDA hearing circulated, self-reporting of LASIK adverse events by patients to the FDA surged to over 500 in one year. Undoubtedly, patients were previously unaware of the FDA's voluntary MedWatch program for reporting problems after LASIK. A disturbing trend can be seen in the patient reports – poor night vision, halos, starbursts, debilitating dry eyes, diminished quality of life, and denial by the LASIK surgeon.

In September 2008, the FDA updated its LASIK webpage to clearly define halos, glare, night vision problems and dry eye as adverse events which should be reported to the FDA.

In April 2009, LASIK surgeons led by Kerry Solomon, M.D. published results of a "world literature review" on LASIK satisfaction,[11] which combined data from 19 peer-reviewed studies of 2,199 patients. The articles report that 95.4% of LASIK patients are satisfied with their surgical outcome. The authors state, "*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*". Incidence of night vision disturbances and dry eyes reported by patients in the 19 studies was known by Solomon's group, but not published. Injured LASIK patients who believe the literature review was a deceptive marketing ploy located several of the 19 studies and found the incidence of dry eyes and night vision disturbances in the 20 – 30 percent range.

Injured LASIK patients allege that the LASIK industry has engaged in a cover-up of the frequency and life-altering nature of LASIK complications, such as night vision disturbances and chronic dry eyes, and have consistently ignored MDR reporting requirements. Based on the number of LASIK MedWatch reports which are self-reported by patients, there is compelling reason to believe that most LASIK device user facilities have never filed a single MedWatch report.

The petitioner has no knowledge of data or information which are unfavorable to the petition.

ENVIRONMENTAL IMPACT STATEMENT

This petition qualifies for categorical exclusion under 21 CFR 25.30(a) from the requirement of an environmental impact assessment.

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.

Scott A. Tolchin

(Signature)

Scott A. Tolchin
[redacted]

1. Sugar A, Rapuano CJ, Culbertson WW, Huang D, Varley GA, Agapitos PJ, de Luise VP, Koch DD. 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.
2. Bailey MD, Zadnik K. Outcomes of LASIK for myopia with FDA-approved lasers. Cornea. 2007 Apr;26(3):246-54.
3. Puglionesi, L (2007, July 6). "Haverford man found dead at old hospital site." Accessed 5/21/2009 from Delaware County Daily Times online at http://www.delcotimes.com/articles/2007/07/06/past%20stories/19986762.txt; "Suicide Series Part 1: Mid-Life Suicides" (2008, March). Accessed 5/22/2009 from WXOW ABC 19 online at http://www.wxow.com/Global/story.asp?s=8571827; "Brentwood Officer Found Dead In Apparent Suicide". (2008, March 17). Accessed 5/22/2009 from NewsChannel5.com online at http://www.newschannel5.com/Global/story.asp?S=8029702 (LASIK blamed in suicide note presented at April 25, 2008 FDA panel meeting located at http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4353oph1-07%20TODD%20KROUNER.pdf, slides 6 – 8)
4. Vollmer, S. (2008, February 3) Some link depression, failed LASIK. Retrieved 5/21/2009 from http://www.newsobserver.com/150/story/920341.html
5. Lindstrom, Richard. (2008, March 12) Letter to the News & Observer: http://www.newsobserver.com/opinion/letters/story/996053.html; Morse M.D., Jennifer (2008, April 25) FDA Special Hearing on Post-LASIK Quality of Life: http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-4353t1-02.pdf; Schallhorn, Steven C. (2008, February 3) Some link depression, failed LASIK: http://www.newsobserver.com/150/story/920341.html
6. "ASCRS to participate in and co-fund study on post-lasik quality of life with US Food and Drug Administration" (2008, April 7). Accessed 5/22/2009 at http://www.ascrs.org/press_releases/ASCRS-TO-PARTICIPATE-IN-AND-CO-D-STUDY-ON-POST-LASIK-QUALITY-OF-LIFE-WITH-US-FOOD-AND-DRUG-ADMINISTRATION.cfm
7. Heavey, S. "FDA panel to review laser eye surgery" (2008, March 17). Reuters. Accessed 5/22/2009 at http://www.reuters.com/article/hotStocksNews/idUSN17614713200803l7?sp=true
8. See 4/25/2008 testimony of Matt Kotsovolos, Dr. Lauranell Burch, Dom Morgan, Dr. Michael Patterson, David Shell, and Dr. Michael Mullery on the FDA website at http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-4353t1-01.pdf, and http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-4353t1-02.pdf
9. See 4/25/2008 testimony of Beth Kotsovolos, Gerard Dorrian, Dr. Michael Mullery, Dr. Roger Davis, Dr. Edward Boshnick, and Todd Krouner on the FDA website at http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-4353t1-01.pdf, and http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-4353t1-02.pdf
10. See 4/25/2008 testimony of Dr. Michael Patterson, Matt Kotsovolos, Dr. Lauranell Burch, Dr. Michael Mullery, and Dr. Roger Davis on the FDA website at http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-4353t1-01.pdf, and http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-4353t1-02.pdf
11. Solomon KD, Fernández de Castro LE, Sandoval HP, Biber JM, Groat B, Neff KD, Ying MS, French JW, Donnenfeld ED, Lindstrom RL; Joint LASIK Study Task Force. LASIK world literature review: quality of life and patient satisfaction. Ophthalmology. 2009 Apr;116(4):691-701.

Exhibit 1

"Your corneal flap will never adhere to the surface of the eye with quite the same strength it did prior to the surgery, so there is a rare but possible risk of the flap becoming displaced with sufficient force." Source: October, 2008 publication of the American Academy of Ophthalmology (AAO), International Society of Refractive Surgery (ISRS), and Opthalmic Mutual Insurance Company (OMIC) titled "Is LASIK For Me? A Patient's Guide to Refractive Surgery" located online at http://www.geteyesmart.org/correction/upload/LASIK_guide.pdf

"The corneal flap can be easily displaced following trauma many months after LASIK." Source: Ramírez M, Quiroz-Mercado H, Hernandez-Quintela E, Naranjo-Tackman R. Traumatic flap dislocation 4 years after LASIK due to air bag injury. J Refract Surg. 2007 Sep;23(7):729-30.

"The LASIK flap once cut may contribute little to the mechanical stability of the cornea and probably never completely adheres to the underlying stromal bed, with late traumatic flap displacement being reported as an infrequent complication." Source: O'Brart DP, Mellington F, Jones S, Marshall J. Laser epithelial keratomileusis for the correction of hyperopia using a 7.0-mm optical zone with the Schwind ESIRIS laser. J Refract Surg. 2007 Apr;23(4):343-54.

"Our report, as well as the related literature, indicates that the healing of the flap is incomplete even 6 years after LASIK surgery." Source: Landau D, Levy J, Solomon A, Lifshitz T, Orucov F, Strassman E, Frucht-Pery J. Traumatic corneal flap dislocation one to six years after LASIK in nine eyes with a favorable outcome. J Refract Surg. 2006 Nov;22(9):884-9.

"Although ocular trauma with corneal laceration can occur, we report that the lamellar flap is still susceptible to ocular trauma 7 years after LASIK. Informed consent should include discussion of long-term flap complications and patients should be advised to protect their eyes after LASIK, especially during high risk activities." Source: Jin GJ, Merkley KH. Laceration and partial dislocation of LASIK flaps 7 and 4 years postoperatively with 20/20 visual acuity after repair. J Refract Surg. 2006 Nov;22(9):904-5.

"The fact that this potential plane can be disrupted many years after LASIK (7 years after the initial surgery in patient 1) indicates that corneal integrity is compromised by the surgical procedure and takes a long time, if ever, to restore." Source: Cheng AC, Rao SK, Leung GY, Young AL, Lam DS. Late Traumatic Flap Dislocations After LASIK. J Refract Surg Vol 22, May 2006

"Another aspect of LASIK surgery is that during this procedure, a corneal flap is made, which will create lifelong lamellar corneal potential space." Source: Galal A, Artola A, Belda J, Rodriguez-Prats J, Claramonte P, Sánchez A, Ruiz-Moreno O, Merayo J, Alió J. Interface corneal edema secondary to steroid-induced elevation of intraocular pressure simulating diffuse lamellar keratitis. J Refract Surg. 2006 May;22(5):441-7.

"However, one aspect still in discussion is the wound-healing process in the created interface that leads to an easily removable flap even years after treatment." Source: Priglinger SG, May CA, Alge CS, Wolf A, Neubauer AS, Haritoglou C, Kampik A, Welge-Lussen U. Immunohistochemical Findings After LASIK Confirm In Vitro LASIK Model. Cornea, Volume 25(3), April 2006, pp 331-335

"Corneal stromal LASIK wounds were found to heal weaker than normal because these structures were not regenerated during the healing response. Moreover, the central and paracentral stromal LASIK wounds were found to heal by producing a hypocellular primitive stromal scar that is very weak in tensile strength, averaging 2.4% of normal, and displays no evidence of remodeling over time in specimens out to 6.5 years after surgery." Source: Schmack I, Dawson DG, McCarey BE, Waring GO 3rd, Grossniklaus HE, Edelhauser HF. Cohesive tensile strength of human LASIK wounds with histologic, ultrastructural, and clinical correlations.
J Refract Surg. 2005 Sep-Oct;21(5):433-45.

"However, this case illustrates that even 4 years following the procedure, the lamellar flap remains an inherently weakened area of the eye, susceptible to traumatic disruption." Source: Nilforoushan MR, Speaker MG, Latkany R. Traumatic flap dislocation 4 years after laser in situ keratomileusis. J Cataract Refract Surg. 2005 Aug;31(8):1664-5.

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