January 4, 2007

Food and Drug Administration
Dockets Management Branch
IMMEDIATE PETITION REGARDING LASIK/REUSING MICROKERATOME BLADES
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857
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Petition Submission RE: Lasik is still not safe, creating an unpredictable flap that never heals, how doctors are NOT telling the public/patients this, and how doctors are re-using blades to cut the flap creating multiple layers of problems and then trying to sue innocent patients like myself when we have websites like www.LifeAfterLasik.com that tells the public the truths about Lasik, and about doctors such as Nicholas Caro who has over 50++ lawsuits but is still somehow practicing 'slicing and dicing' techniques

FDA/Medical Device Committee/Dockets Management Branch:

Please immediately take steps to approve the following Petition: **I-VI** to insure the safety of Americans regarding the misuses of Lasik going on in America today by refractive surgeons whom are stepping outside the 'ethical' limits on many levels regarding 'breaching the standard of care' we should all be given.

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6. Re-Use of razor blades immediately stopped and discontinued.
7. Proper patient screening and selection re-defined and accurately defined.
8. Proper informed patient consent, honest statistics explaining ALL of the truths, nothing left out.
9. Complications by doctors do happen daily, and there needs to be disciplinary measures in place.
10. CRSQA, www.USAEyes.org, and Glenn Hagele's biased doctor referrals & reason to investigate.

1. Statement of grounds: The FDA Needs To Immediately Define & Implement Safety Measures To Improve Lasik Success Rates, Make Sure Refractive Procedures & Surgeons Are Not Breaching The Defined Standard Of Care That Should Be Given To Every Single Patient's Eyes, & To Work With The AMA & Department of Regulation In Every State To Bring Down A Doctor For Violating 'The Hippocratic Oath'.

1.1 Examples of Devices included in the Scope of the Petition: Each of these medical devices are regulated by the FDA as Class I or Class III medical devices. All FDA approved lasers, intra-lasers and microkeratome blades currently in use to make a flap cut ruining a perfectly virgin cornea.

1.2 Consistency with FDA's Goals: The benefits of this petition outweigh the costs by effectively utilizing the limited FDA resources in an area where they are most needed to meet the goals of the FDA, Assuring Medical Product Safety, and protecting the Public Health (http://www.fda.gov/ope/FY03plan/default.htm). The following statements provide the basis for the benefits of this petition. The costs would be based on which agencies and what specific actions are taken based on this petition.

"Consumers spend $326 billion annually in the U.S. on medical products. An estimated 1.3 million people are accidentally injured by medical therapy in the U.S. each year, and as many as 100,000 die as a result of preventable medical errors. FDA must be vigilant in monitoring the production, distribution and use of these products because FDA's presence raises the likelihood that public health and safety problems associated with these products will be addressed and because it is critical to citizen safety."

"To ensure that these products are safe the Agency must oversee their entire life cycle--from production through distribution, and consumption/use. "

"FDA's three primary strategies for ensuring medical product safety are to: a) enhance global vigilance over product manufacturing and distribution; b) strengthen and focus domestic industry monitoring; and, c) expand and automate the systems which report on adverse events associated with the use of medical products."

The FDA's goals are consistent with preventing injury and protecting the Public Health. Has the FDA ignored or even endorsed another potential Public Health Crisis (e.g., breast implants)?

“A weakened FDA can only move slowly and with uncertainty. Consumer confidence in the Agency suffers, and real health and safety risks may grow.”

http://www.fda.gov/ope/fy03plan/goals3.html

* Reduce the risk of medical devices and radiation-emitting products on the market by assuring product quality and correcting problems associated with their production and use.

(http://www.fda.gov/ope/fy03plan/goals.html)

1.3 Legal Basis for this Petition:

The Petitioner makes a public demand that the Food and Drug Administration (the leading U.S. public health regulatory agency) assert its authority and supremacy in protecting the Public Health.

The Petitioner acknowledges that the FDA does NOT regulate the practice of medicine. The Petitioner further acknowledges that an "off-label" use of any device where benefits clearly outweigh risks may constitute the practice of medicine. However, practice of medicine does not allow anyone, including medical doctors, to break Federal or State laws. Furthermore, any user of these Class I devices (whether licensed physician or not) who violates the labeling of these devices unnecessarily exposing patients to a non-Prudent degree of risk, does not provide informed consent, and therefore, is not practicing medicine by definition. Thus, these practices are within the regulatory authority of the FDA.

The Petitioner asserts that when used in LASIK surgery, every patient MUST receive new Microkeratome components (e.g., blades and cannulas), regardless of whether the device is operated by a physician, or a technician working under the supervision of a physician. Microkeratome components necessarily come into contact with blood and infectious corneal tissues. As such, their reuse is not practice of medicine, or even within the Standard of Care for any licensed physician, for any medical procedure, including LASIK. Moreover, if sterilization of Microkeratome blades and components is not performed at all, or is conducted by third parties whose motives are mainly economic (not necessarily medical) then this also falls under the authority of the FDA. Finally, sterilization techniques commonly used (when they are used) are not effective with regard to HIV/Aids and other infectious diseases (let alone Creutzfeldt-Jakob Disease prions), historically an overriding public health concern which requires these components be used once and only once, then disposed of as hazardous medical waste. Accordingly, the Petitioner concludes that there is NO patient benefit for reuse of these device components, but instead, a very high potential for harm.

There are multiple additional legal bases for this petition because the Microkeratomes are regulated by the FDA as Class I medical devices for use in refractive eye surgery (commonly referred to as LASIK).

1.3.1 In general, the reuse or reprocessing of single use devices on multiple patients is a serious concern (see http://reform.house.gov/UploadedFiles/121605%20FDA%20Medical%20Device%20Letters.pdf).

Reuse also appears to be an off-label use or even violation of the FDA approval. Worse yet, the patients are exposed to the contaminated blades without resterilization. I think patients should be properly educated and informed prior to having LASIK surgery.

In light of present day Medical ethics, patients should be given true informed consent by a licensed medical professional (e.g., the M.D. Ophthalmologist surgeon explaining the true risks to physical and mental health). Unlicensed sales people who may be dressed to look as if they are medical professionals (e.g., wearing white lab coats) should not be allowed to explain things as their information may be incorrect and they may mislead patients.

Reusing a microkeratome blade used on another patient is not prudent and far too risky for patients. No patient should be subjected to a reused medical device that is labeled single use, and disposable even if the patient has informed consent. Reusing blades without patient informed consent violates many medical ethical principles including HHS IRB guidelines (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm), The Declaration of Helsinki "It is the mission of the physician to safeguard the health of the people" (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm#j6), the Belmont Report "Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms. " (see http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm) and the THE NUREMBERG CODE "The voluntary consent of the human subject is absolutely essential." "The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury." (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm#j5).

1.3.2 The FDA does Not regulate the practice of medicine, but the FDA does regulate all users and practitioners of these devices. Not everything that a medical Doctor does is considered the practice of medicine. Being a licensed medical Doctor does Not allow a person to break Federal or State laws. An off-label use of a device explicitly for the potential benefit of a patient (where the benefit clearly outweighs the risk) would be considered a legitimate practice of medicine. However, when there is no patient benefit and/or the risk outweighs any benefit, then Not following the FDA labeling does Not constitute the practice of medicine By definition. Part of the definition of the practice of medicine is to put the patients' best interests ahead of those of the Doctor. Any practitioner or user of these Class I devices (whether or Not he/she happens to be Doctor) who uses them in an unnecessarily risky way (including committing an assault) or who does Not provide informed patient consent would be under the FDA's regulatory authority.

1.3.3 The Petitioner believes that the potential risks versus possible benefits assessment favor the Actions proposed in this petition and are consistent with the FDAs own objectives including Healthy People 2010. "The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a PHS-led national activity announced in January 2000 to eliminate health disparities and improve years and quality of life."

(http://www.fda.gov/OHRMS/DOCKETS/98fr/062502c.pdf).

1.3.4 Section 522(a) states that “In General.--The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class I device the failure of which would be reasonably likely to have serious adverse health consequences”

(http://www.fda.gov/cder/guidance/105-115.htm#SEC.%20212).

The FDA authority to protect the Public from injury and the Public Health in general is based on section 522 (21 U.S.C. 360l). The CDRH has recorded that the failure of these devices has caused serious adverse health consequences

1.3.5 Under the FDA’s authority with the Federal Food Drug and Cosmetic Act and all rules and regulations promulgated or annexed therein, including, but not limited to section 515(d) (g), 520(e) (q) and (r), 21 CFR 801.109, 21 CFR 803.5, 21 CFR 803.10, 21 CFR 814.82, 21 CFR 814.84, 21 CFR 814.39, and the FOOD AND DRUG ADMINISTRATION MODERIZATION ACT OF 1997, the Petitioner ask the FDA to act and to implement the enclosed Actions.

1.3.6 Title 21 et seq., Title 45 et seq., and the Good Manufacturing Practices act, and other Federal Laws may have been violated by the practitioners who used these devices.

1.3.7 FDA regulations state that the FDA may require the submission of the adverse safety and effectiveness data, as described in the Class I summary or citation under title 21 Parts 800 to 898, Sec. 807.94, Sec. 807.100, section 515, and other Acts (http://www.fda.gov/cder/present/DIA62002/risk_mgmt/sld019.htm). (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807). Many adverse events are Not reported.

1.3.8 The FDA is mandated to assure Medical Product Safety. “To ensure that these products are safe the Agency must oversee their entire life cycle--from production through distribution, and consumption/use.”

(http://www.fda.gov/ope/fy03plan/goals3.html).

The FDA does consider petitions (http://www.fda.gov/opacom/backgrounders/voice.html) and comments for the development of future policy (http://www.fda.gov/cder/present/DIA62002/risk_mgmt/sld019.htm) and has authority to change that policy under Title 21 Parts 800 to 898, Sec. 807.94, Sec. 807.100, section 515, and other Acts (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=807.100).

1.3.9 The American Academy of Ophthalmology has supported banning a device (bottle rockets) that since 1995 due to it causing eye injuries similar to those caused by elective refractive eye surgery. From July 1990 to December 1994, for instance the total number of serious eye injuries from all causes reported to the United States Eye Injury Registry (USEIR) was 4,575 cases

(Serious Eye Injuries Associated With Fireworks- United States, 1990-1994 MMWR Vol. 44/No. 24, June 23, 1995, pp. 449-52; Center for Disease Control MMWR journal). On average over that 4 ½ year time period, that amounts to ~1,017 eye injuries per annum. Based on public information that over a million LASIK operations alone are performed every year and the percentage of those operations causing serious eye problems, the number of serious eye injuries per annum of elective eye surgery far exceeds all other causes.

1.3.10 The Federal Government CAN enforce Federal law even when licensed Doctors violate it.

The physicians can use each microkeratome blade ONLY once (one eye only) because Bausch & Lomb (and other microkeratome manufacturers) ONLY license the physician for a single-use only procedure. Only physicians are licensed to purchase this device under Federal law so any other use by the physician would be a violation of that same Federal Law.

2. Reasons for This Petition: The evidence indicates that the users of these FDA 'regulated' devices (the users and Doctors/practitioners) do Not use these Class I and Class III medical devices prudently and took a non-Prudent degree of risks with patients physical and mental health.

3. Action requested: What rule, order, or other administrative action does the petitioner want FDA to issue, amend or revoke? The Petitioner is willing to work with the FDA and any other Federal agencies in assisting with further development of the implementation of any injury prevention efforts including, but not limited to the following actions.

4. No Known Environmental Concerns.

4.1 Superior Technologies Needed To Fix Thousands Of Suffering Patients That Had BAD Lasik: Refractive surgeons should be required by the FDA to maintain 'FDA Approved' refractive technologies: Lasers, Topographers, Wavefront Devices, Slit Lamps, Micro Keratome Blades, etc...Only superior technologies should be allowed, and any older techologies or lasers that have been proven to have 'considerable problems,' should be immediately seized by the FDA and discarded so that no other 3rd world countries get a hold of 'inferior medical devices'. The future of Lasik should be 'no Lasik', and only PRK technologies that are in the best safety and interests of the patients, such technologies exist overseas but not here in the USA:

The following is probably the 'best known' software & hardware technologies for performing Lasik, PRK, Lasek, but is NOT available in the USA:

Software/Topography/Laser Platforms That Should Be The Standard Of Care In The USA:

VIS IRES LASER:
Ligi Tecnologie S.p.A,
via L.Corsi,50
72026 Taranto ITALY
Tel +39 099 779 1680

Fax +39 099 779 7270
Web: http://www.Ligi.It

'*The Ivis Suite' is an ongoing R&D, manufacturing and marketing program intending to take full advantage of the capabilities of dedicated ophthalmic software coupled with innovative hardware; this to overcome the complications so far associated with LVC. Some of these complications are due to the technical limits of the excimer lasers currently on the market. The company believes that, thanks to the innovative Suite, the excimer technology is reaffirming its position as the leading technology for LVC. The Suite started with the software CIPTAÂ® for customised corneal surgery developed and patented in 1999, that has been so far employed in over 700,000 LVC and TCS procedures carried out worldwide. Further software and innovative hardware has subsequently been added. The Suite is now a commercially viable proposition and is finally being marketed. The Suite is composed of 2 software programs and 4 hardware machines. As described to follow, 3 machines are dedicated to collect the patient's ophthalmic data to be processed by one or the other software program. The processed patient's data will then drive the Iresâ„¢ laser to deliver true micrometric customised surgery for LVC and TCS..".*

Artemis Scan: This is a very important scanner used to detect early signs of 'Kerataconus' and also shows subsurface irregularities such as Post Lasik Flap Problems, Ectasia, etc:

More Information On The Artemis 2 Scan:
Artemis 2 *is a very high frequency (VHF) ultrasound eye scanner. In use, the patient leans forward placing their head onto an adjustable headrest. The headrest's unique design permits the patient to pull away quickly from the scanner if desired. An eyecup filled with a saline-based interface fluid couples the ultrasound signal to the eye, while a precision mechanism moves the transducer past the front of the eye. During the accurately controlled arc motion of the transducer, which lasts less than one second, many thousands of ultrasound samples are digitized. Following a scan, signal analysis is performed on a PC-compatible microcomputer, and the data are available for immediate viewing on an LCD monitor or archival storage to disc media. Artemis is very flexible; many adjustments to the scanning parameters are possible to customize the scan to your clinical needs. Functions are provided for centering the scan about the optical axis of the eye. The starting location of the scans as well as the extent can be varied as desired, to view image planes through the eye at different angles.*

5. Certification: The undersigned certifies that to the best of 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.

5.1 Inferior Technologies: Totally Removed & Immediately Replaced:

Schirmer's Test: This test is a start, but still isn't perfect. There needs to be a test that very accurately detects 'dry eye'. With the Schirmer's Test, anything that shows dryer than normal results (under 15) should not be a candidate for Refractive Surgery: PRK, LASEK, LASIK.

Snellen Chart: Refractive surgeons are measuring the patient's success if they can read 1 or more letters off of this chart. Doctors are saying it was a 'successful outcome' if a patient can read any letters on a specific line: 20/20, 20/40, etc. But what is NOT being factored into the equation, is that many patients are seeing 'doubled ghosting vision disturbances', or 'loss of detail', or patients are seeing 2 or 3 images of 1 letter. Yet doctors are still reporting 'lies' to the patients that 'It was a success'. All of us 'post Lasik casualties of War', know that this test is a joke. You can not tell me that it is okay to let the doctor say 'Dean, you are seeing 20/20 perfect vision and are fine'. When I'm seeing 2-3 letters per letter, glow, starbursts, halos, & other aberrations. There should also be a test with a 'red light' in a dark room to measure the size of the halos, starbursts, aberrations that we all are seeing too!

Slit Lamp Tests: Refractive surgeons all over the country are not properly trained and educated in diagnosing other corneal disorders such as EBMD, 'Epithelial Basement Membrane Distrophy', and other irregularities such as Kerataconus (cone bulging of the cornea) or 'thin corneas' such as in the cases of Ectasia, etc. First and foremost, Lasik should never be performed on anyone that has a genetic condition such as EBMD but it is happening. It happened to me. Only 1 doctor in the USA properly diagnosed me with this condition. Dr. Ming Wang. www.WangVisionInstitute.com. Dr. Wang agrees that there needs to be something better in place to make sure that doctors better 'prescreen patients' and practice the 'Hippocratic Oath'. Even Dr. Wang knows that most surgeons can't find and detect these disorders, because they do NOT KNOW WHAT TO LOOK FOR. On myself, he detected EBD in 2 seconds!

6. Re-Use Of Micro-Keratome Blades: Refractive surgeons should in no way shape or form EVER 'reuse a micro keratome' blade on any patient & it should be required by law that the patients take their blades home with them to provide another layer of protection and guarantee, so that the doctor's don't reuse blades! Not only is Lasik unsafe to begin with, but re-using blades is a disgrace on top of that because of the following:

http://www.ophthalmologytimes.com/ophthalmologytimes/article/articleDetail.jsp?id=181087&pageID=1

"Using the confocal scanning microscope, Dr. Bourne and colleagues measured the length of the subbasal nerves per area of field. Between three and six scans of the central cornea, covering slightly different areas of the cornea, will yield distinct samples and allow estimations of the nerve density.

Dr. Bourne described two clinical research studies using these technologies. In the first, a 5-year longitudinal study, he and his colleagues studied the effect of PRK and LASIK on corneal morphology by comparing the corneal nerves preoperatively and postoperatively.

"With PRK," he explained, "the epithelium is removed and Bowman's layer and the anterior stroma are ablated. After the procedure, the epithelium and the nerves heal over the stromal surface. In LASIK, the stroma is ablated behind the flap, leaving Bowman's layer intact. Most of the nerves are cut when the flap is created, and they must eventually return anterior to Bowman's layer," Dr. Bourne explained.

Dr. Bourne and his colleagues found that after PRK, the nerve densities decrease and gradually increase; by 2 years after PRK there is no significant difference in nerve density from preoperatively. After LASIK, the nerve density also decreases and returns much more slowly; 3 years after surgery, there is still a significant difference from the preoperative density, but by 5 years after surgery there is no significant difference from preoperatively"

More Research (On Why Lasik Is Unsafe & Why Re-Use of Microkeratome Blades Is Unsafe) Is Compiled For Your Review At:

http://www.lasikliberty.com/index.php?option=com_content&task=view&id=22&Itemid=46

7. Proper Patient Selection: Refractive surgeons should never perform a refractive procedure, without fully explaining to each and every patient the permanent dangers and possibilities that 'could and do happen' to about 30% of total eyes electing to have Lasik. Such permanent side effects include, but aren't only limited to: dry eye syndrome that doesn't go away, nighttime visual disturbances, double vision, halos, starbursts, ghosting, loss of contrast, loss of detail, loss of visual acuity, loss of eye coordination, higher order aberrations, cause of corneal surface and sub-surface irregularities, etc.! The following are a list of just some of the patient's website to 'spread the word' that Lasik isn't safe.

Pupil Size Does Matter: It is a commonality in the medical world amongst Refractive Surgeons, that pupil size and lack of treatment zone size, does play an important role in the "outcome" for the patient. Unfortunately, many if not hundreds or even into the thousands of doctors performing refractive procedures are not paying attention to the size of the treatment zone/dark room dilated pupil ratios of the patient. They are flat out lying & deceiving patients into thinking that they "are the perfect candidates" and that the procedure "is 100% SAFE".

"Dr. Boxer Wachler estimates that 50 percent of patients who have the LASIK procedure done have large pupils and would benefit from large laser treatment zones because they would be less likely to have night vision disturbances. "

What changed between 2003 and 2005/6?

>Brian S. Boxer Wachler, MD, co-author of the study and a faculty member at the UCLA Medical Center, Jules Stein Eye Institute, said, "We know that corneal aberrations and night vision disturbances after LASIK are directly proportional to the degree of nearsightedness corrected and the size of the clearance zone, that is, the difference between pupil size and the optical zone treated by the laser. With this study, we now know use of large optical zones is safe and effective in preventing nighttime glare and haloes in patients with large pupils."

"This study shows using ablation zones from six to eight millimeters did not pose a problem in terms of safety. If anything, the larger optical zones had a higher percentage of eyes achieving 20/20 and 20/40 uncorrected visual acuity than the smaller zones," said Academy spokesperson James J. Salz, MD, clinical professor of ophthalmology at the

University of Southern California and attending ophthalmic surgeon at Cedars-Sinai Medical Center in Los Angeles. "A subjective report on the patients' satisfaction with their night vision outcomes and measuring these treated eyes with wavefront studies to determine the level of postoperative higher order aberrations would be a good follow-up to this study."

Dr. Boxer Wachler estimates that 50 percent of patients who have the LASIK procedure done have large pupils and would benefit from large laser treatment zones because they would be less likely to have night vision disturbances.

http://www.innovations-report.com/html/reports/medicine_health/report-20154.html

Obviously, there are a lot of people that feel their doctor's didn't properly screen them; Thus, have put the word out in a big way on the world wide web to warn others:

http://www.kathygriffin.net/lasik.php (yes, you guessed right. Kathy is the famous actress/comedian and she tells about how badly her Lasik procedure went even after going to a great Dr. and doing her du-diligence first, and she tells about her 5 surgeries that still have not corrected what she lost...Also, did you know that Jennifer Capriati went to one of the best Lasik Drs. and she no longer can play tennis at night under the lights because of the problem with glares and halos. She can no longer play her competitive game.

http://www.LasikMemorial.com Dedicated to those whose lives have been damaged or destroyed by refractive surgery, this site contains true stories written by the victims themselves. When complications occur, your life splits in two. There is the person you were before LASIK, and the person you are now...the person whose dry eyes hurt all the time, the person who sees multiple images of everything, who can't drive at night, who can't fulfill his or her responsibilities as a parent, or

his or her potential as a human being, the person who suffers from PTSD, depression, and various states of dread about the future. You realize that maybe human nature isn't fundamentally good, or at least that doctors aren't what you thought they were.

http://www.LaserMyEye.org Started by United Kingdom refractive surgery activist Rebecca Petris, this site offers both great content and great web design. Don't miss the D'ialogues forum, where you can ask frank questions about risk and receive input from both patients and optometrists. Also has an encyclopedia of terms relevant to refractive surgery, as well as breaking news articles.

http://www.SurgicalEyes.org From the site, "The purpose of the Surgical Eyes Foundation is to empower past, present and future patients who live with complications of refractive surgery. Towards this end, it will maintain a website as a primary resource for those with complications of refractive surgery to accomplish the following: 1. Coordinating with eye care professionals to facilitate understanding of the needs of those with complications from refractive surgery and advocating for treatment alternatives. 2. Increasing public awareness of the potential risks in refractive surgery and advocating for informed decision making 3. Disseminating information about typical and emerging treatments to individuals with complications of refractive surgery.

http://www.FlawedLasik.com Created by patient activist Dominic Morgan, this site chronicles Dominic's legal struggle with his surgeon and with the FDA. The site states, "Most Lasik websites are advertisements for

having Lasik eye surgery. This website is to educate you to the dangers of having Lasik when you are not a proper candidate. Before you consider Lasik, you must be sure it can be done safely, and that you are a proper candidate. I went to a doctor who advertised that anyone who was nearsighted, farsighted, or had astigmatism could be done safely...that's almost everybody! I trusted these doctors, and now I'm legally blind. My name is Dom Morgan, and I tell my story because it may be useful to anyone considering Lasik.

http://www.LasikFraud.com Created by patient activist Brent Hanson, this site states, "Are you planning to have laser eye surgery at TLC? Are you impressed with TLC's success stories? Do you believe that TLC will honor their "Lifetime Commitment" to you? Do you have confidence in the integrity and surgical skill of TLC's founder, Dr. Jeffery Machat? If you answered yes to any of these four questions, then please read about my experiences with eye surgery at TLC. Your decision to have eye surgery may result in permanently damaging results that are devastating to you. You may also discover that TLC will not back up their "Lifetime Commitment Program" if they damage your vision. I am going to share my personal story with you so that you can get a more realistic view of what your experience could be like. This story is unpleasant for me to tell, but you deserve to know that TLC personnel are fully capable of damaging your vision, deceiving you, abandoning you as a patient, harassing you, and threatening you with lawsuits for speaking out.

http://www.DoctorMyEye.com Created by activist Optometrist Ken Minarik, OD, this site states: "The internet is full of websites that are owned by laser

companies, clinics and LASIK providers that will tell you all about the good cases and sell you on the â€œjoysâ€ of LASIK. We will leave the pro-arguments to the salesmen. We are here to talk about things that go wrong and the people who can help you when it happens. Bookmark this site, and if you or a loved one are considering LASIKâ€¦please read all of our cautions first. If you or a loved one are suffering from LASIK complicationsâ€¦welcome to your online support group. We are here for you."

http://www.LifeAfterLasik.com Created by Dean Andrew Kantis, a lasik patient that flew from Florida to Chicago to ensure that the procedure would be given extra detail, and it turns out that just the opposite happened. The doctor, Nick Caro & St George Corrective Vision Center out of Chicago, IL happens to have 50+ lawsuits from disgruntled lasik patients, and for some strange reason, still has an active license to practice in the state of Illinois. Needless to say, Dean started a huge investigation where the www.IDFPR.com is going back 10 years on Nick Caro. Nick Caro is very concerned about the information on this website in that he is a "DEFENDANT" in over 50+ lawsuits, so he started what many are saying is a "frivolous lawsuit" to sue Dean for $2,000,000.00 to try to "quiet" him, and it seems that Nick Caro has a lot of people trying to get "search placement" to try to push our results down, but so far, it has NOT worked and must have set Nick back even more money. it ended up hurting Dr. Caro's reputation even more.

http://www.VisionSimulations.com Created by author and psychologist Roger D. Davis, PhD, this site features photorealistic images of the visual aberrations incuded

by LASIK and other refractive surgeries, including starbursting, halos, glare, ghosting, blurry vision, and night driving scenes. Also contain numerous animations, as well as simulators that allow patients to approximate and communicate their vision to friends, family, and physicians. If you want help simulating your vision for others, start here.

http://www.LasikSucks4U.com Created by patient activist Dominic Morgan, this site chronicles Dominic's legal struggle with his surgeon and with the FDA. The site states, "Most Lasik websites are advertisements for having Lasik eye surgery. This website is to educate you to the dangers of having Lasik when you are not a proper candidate. Before you consider Lasik, you must be sure it can be done safely, and that you are a proper candidate. I went to a doctor who advertised that anyone who was nearsighted, farsighted, or had astigmatism could be done safely...that's almost everybody! I trusted these doctors, and now I'm legally blind. My name is Dom Morgan, and I tell my story because it may be useful to anyone considering Lasik.

http://www.LasikLiberty.com (Want to see what the FDA is doing or is NOT doing regarding the FDA's responsibility to Lasik Patients in informing the public, and in establishing a strict "standard of care?" This website was created by Dr. Michael Patterson, who has been suffering with Post Lasik for over 6+ years...and to date, has found no cure for his post lasik challenges.)

http://www.DrDoka.com Read the website of a woman's life completely destroyed in June of 2004 from having Lasik Surgery. Elivra Galindo, continues to make it a mission to let others know how bad Lasik is and that

she has gone to over 15 doctors and not one of them have been able to help her with her "post lasik dry eye syndrome. In fact, it is so bad that she wants to take her life. As of today, Elvira continues to suffer from this and "sleep deprivation" because her dry eye is that bad.

http://www.EyeFreedom.com (get an honest opinions on Lasik by a Dr. who treats hundreds of Post Lasik victims: Dr. Edward Boshnick, Scleral Lenses for Post Lasik problems)

http://www.noblur.com (get an honest opinion prior to your Lasik, by a Dr. who treats hundres of Post Lasik victims from all over. Dr. Ken Maller, RGP lenses for Post Lasik problems)

http://www.kcfreedom.org or http://www.kcglobal.org/ (Very informative forum and focused on Keratoconus, a cone shaping/bubbling eye disorder).

http://www.Lasikdisaster.com (very informative Post Lasik Information)â€¦

http://www.LasikInfoCenter.net (very legally informative/has Glare Charts)â€¦

http://www.foxchicago.com/_ezpost/data/16747.shtml (F ox Chicago news on how bad Lasik really is to inform you)

http://www.lasikfraud.com/ (very informative A-Z of Lasik & problems with Lasik)

http://www.fda.gov/cdrh/lasik/contact.htm (FDA file a LASIK complaint)â€¦

http://www.visionsimulations.com/ (exactly what to expect to see like after Lasik)

http://www.doctormyeye.com (some honest information about Lasik and Post Lasik)

http://www.lasikmemorial.com (some honest information about Lasik and Post Lasik)

http://www.lasermyeye.org (some honest information about Lasik and Post Lasik)

http://www.flawedlasik.com (some honest information about Lasik and Post Lasik)

http://www.surgicaleyes.org (patient nightmare stories, good Post Lasik Doctors to help you)

http://www.lasikmemorial.com (some honest information about Lasik and Post Lasik)

http://www.lasiksos.com (some honest information about Lasik and Post Lasik)

http://www.lasiksucks4u.com (some honest information about Lasik and Post Lasik)

http://www.lasikreality.com (some honest information about Lasik and Post Lasik)

http://www.refractivesource.com (some honest information about Lasik and Post Lasik)

http://www.kcsupport.org (make sure your doctor correctly evaluates you before Lasik)

http://www.cleareyeclinic.com/lasik.html (clinical results of Lasik, 3 questions to ask, but not the right question)

http://www.anattorneyforyou.com/legal/lasik-litigation.htm (list of Lasik Litigation Attorneys to help you)

http://www.ophthalmic.hyperguides.com/default.asp?section=body.asp (pain management & other eye problems/treatments)

http://www.crstoday.com/PDF%20Articles/0105/F3_Daya.html (additional problems Post Lasik)

8. Proper Patient Education Color Test Booklet Handout Made Mandatory: Refractive surgeons should be required to show potential patients pictures that illustrate â€œpoor Lasik outcomesâ€ and what causes these outcomes. Patients should understand exactly what is going to happen with this procedure and why they are at risk for known and unknown side effects. Then there should be a multiple choice test given to insure that the patient fully understands what Lasik is about!

Please see the below pictures to fully understand what patients have to see through for the rest of their lives because these doctors needed to swipe their credit card for $3,000 to make their Benz or BMW payment & maintain the â€œCountry Club Lifestyleâ€ so their wives would be happy:

Post Lasik Starburst Disturbances Looks Like This:

Post Lasik Nightime Vision Disturbances Look Like This:

Post Lasik Blurry Vision Disturbances Looks Like This:

Post Lasik Double Vision / Ghosted Disturbances Look Like This:

Post Lasik Halo Disturbances Look Like This:

Post Lasik Loss of Contrast Color Disturbances Look Like This:

(The above photos courtesy of www.VisionSimulations.com)

9. Complications Do Happen & There Needs To Be Disciplinary Measures Taken: When asked about complications by the patient, doctors are replying and lying by stating “oh, those complications are because the patient had a disorder such as Glaucoma or Cataracts; that won’t effect your outcome Mr./Mrs. Patient. Don’t worry about those, they won’t effect you. You are the PERFECT candidate!” Then the patient signs a form that signs their “rights away to sue the doctor for uninformed consent and thievery.” Please don’t turn your back to what’s going on. It is still happening everyday, just as much as it was 9 years ago, but probably more now. Here’s another sited example of what happened to me when I confronted my doctor, Nick Caro / Saint George Corrective (should be destructive) Vision Center out of Chicago, who did an absolute “horrendous” job and breached multiple layers of “standard of care.” Not only that, but then lied to me over the course of 5 years, as well as did the follow up physician, Dr. Jaswant Pannu of www.PannuLaser.com, and both told me that it “was MY EYES that healed differently and that I was in the 1-5% category of patients that heal differently” I then went to see 4-6 other refractive surgeons, and NOT ONE had the “Hippocratic Oath Ability of Integrity or Ethics,” to do the right thing and let me know that the procedure went terribly wrong, and work with me to get it fixed correctly. I have waited 7 years now, and find myself going out of the corrupt country to get the best medical help so that I can do what’s in MY BEST INTERESTS, and not the doctor’s deep pockets.

#1 Complication Is Dry Eye Syndrome: The most common post Lasik condition, defined amongst the refractive surgeons all over the world. The following table offers you precise, objective evidence that there is a serious flaw with Lasik & in slashing through the nerves that never fully recover. Remember, these are the corneal nerves that “are the phone lines, that go from the eyes to the brain to say BRAIN, please send the EYES some more tears, we’re starting to burn and we need them now”

FDA	According to " LASIK Eye Surgery: What are the risks?," an article

	published on the U.S. Food and Drug Administration web site, one of several risks of lasik surgery is the risk that "Some patients may develop severe dry eye syndrome. As a result of surgery, your eye may not be able to produce enough tears to keep the eye moist and comfortable. Dry eye not only causes discomfort, but can reduce visual quality due to intermittent blurring and other visual symptoms. This condition may be permanent."
Ophthalmology Times	According to " Awareness facilitates treatment of LASIK-associated dry eye," published in Ophthalmology Times in May 15, 2003), a study shows that "dry eye is both the most common complication after LASIK as well as the most common reason for patient dissatisfaction" and that "up to 80% of patients who undergo LASIK experience symptoms of dry eye postoperatively."
Eric D. Donnenfeld, MD	According to "Prevention and Management of Post-LASIK Dry Eye," an online medical lecture dated March 2004 given by Eric D. Donnenfeld, MD, dry eye is a potential complication of lasik surgery. His first slide states: "The most common and potentially one of the most devastating ... complications of LASIK is dry eye." A later slide states, "Every patient gets dry eye after lasik." He mentions severing of the corneal nerve as one possible cause of post-lasik dry eye, and also mentions several other possible causes, including specific surgical techniques.
SurgicalEyes.org	According to SurgicalEyes.org, undergoing surgery to correct vision is reported to cause or increase dry eye pain for some people. The goal of the Surgical Eyes Web site is to assist people who have had unsuccessful LASIK, PRK, RK, AK, ALK or other elective refractive and laser surgeries.
DryEyeInfo.org	According to the DryEyeInfo.Org Web site, people without Sjogren's Syndrome can also have dry eye and thus dry eye pain**:** "Tear production can also decrease from any condition that decreases corneal sensation.... Causes for decreased corneal sensation include long-term contact lens wear, **LASIK eye surgery**, trauma to the 5th nerve, and certain viral infections.
LadarVision.com	According to the LadarVision.com safety page, "People with the following conditions *should not* have LASIK: ... Blepharitis (inflammation of the eyelids with crusting of the eyelashes....)" (and you might want to also take a look at the other conditions listed on that page). According to the LadarVision.com risks page, "In some cases, LASIK surgery may result in an inability to produce enough tears to keep eyes moist. This complication is the most common among LASIK side effects. Most patients suffer mildly from this for a short period of time.... The condition, however, can cause discomfort and may be permanent."

Sjogren's Syndrome Foundation newsletter (11/02)	According to a Japanese study of 290 people who underwent LASIK surgery, some of whom had healthy eyes and some of whom were classified as having dry eyes or probable dry eyes, "patients with dry eyes can have significant dry eye symptoms, which may worsen after [LASIK] surgery. Those with probable dry eyes are also at risk for worsening dry eye criteria."

The Flap Never Heals: This should be posted on every patients and post lasik patients forehead! They should walk around with “yellow stickies” letting everyone know the truth. That is why refractive surgeons can “peel” it back and re-shoot, re-shoot, and re-shoot the cornea some more, 2,5,12 years down the road. Patients definitely need to better understand the severity of this, and how they can’t open their eyes anymore while swimming, nor engage in any rough sport, nor wipe their eyes without worrying for the rest of their lives if the flap will become “dislodged”, and then they will need a “corneal transplant”.

10. Glenn Hagele / CRSQA.org / USAEYES.org / ComplicatedEyes.org: An immediate investigation of a Glenn Hagele should be issued. Glenn is telling innocent patients what many would call ‘lies’ about what is best for them. He is giving medical advice and is NOT a doctor. He charges like $5,000 per year to give a refractive surgeon a ‘phony certification’, and I guess guarantees those membership fees back many times over. So here is an example of how it works: Example: You type into a search engine (Google): “hurt lasik patient”. You will see Glenn’s website as #3 (guess), and you will be redirected to his website www.UsaEyes.org thinking that this is an organization looking out for you, the patient, and will then send an email or contact Glenn. Glenn will seem very knowledgeable about your Lasik problem, and will probably only refer you out to a CRSQA stamped surgeon. Unfortunately, this is a conflict of interest. These are “paid referrals”. What happened to redirecting and recommending to the patient what’s “in the best interests of the patient?” Glenn then went on a rampage to try to financially hurt and threaten any patient that owns and operates a ‘Anti-Lasik Websites’ such as mine. See for yourself:

http://groups.google.de/group/alt.lasik-eyes/browse_thread/thread/aebc2801ec4d3af6/968c9a787baab97d?hl=de

http://lasikflap.com/forum/viewtopic.php?t=356

http://www.lasikflap.com/crsqa/

http://lasikflap.com/forum/viewtopic.php?t=356

http://lasikflap.com/forum/viewtopic.php?t=788

http://lasikflap.com/forum/viewtopic.php?t=217

http://lasikflap.com/forum/viewtopic.php?t=780

http://lasikflap.com/forum/viewtopic.php?t=389

http://lasikflap.com/forum/viewtopic.php?t=549

http://lasikflap.com/forum/viewtopic.php?t=152

http://lasikflap.com/forum/viewtopic.php?t=166

So I ask you FDA:

"What are you doing currently to make sure that doctors are not breaching levels of the standard of care patients like you and I should be getting?"

"What disciplinary actions are you willing to enforce and define (if you don't have any in place currently) to move to "ACTION", so that you do what you are supposed to do which is to "look after the safety of the devices to protect Americans, and exterminate / terminate any known medical devices that are lacking safe results, and do this today".

"If you do NOT have anything in place currently, don't you think that the doctor's all talk amongst each other and know this?"

"I would suggest you immediately implement an 'ORDER' to massively contact each and every doctor & refractive surgeon across America, & inform them of the "can" and "can not's," so that you know there is a level of standard for medical care DEFINED"

"Immediately, call a meeting of the minds, define and dissect the problems that you are informed about, and then answer these by researching 'true statistics' and 'not skewed data statistics' that the doctor's are lying about"

"Immediately make every attempt to make the refractive medical devices safest, and seize & destroy all unsatisfactory/inferior technologies that are used on the human eye"

My story about how Nick Caro has ruined hundreds of patients & how I'm working with the Department of Regulation / Chicago, to close his doors for life. If it were up to me, & hundreds of other patients that he has ruined, we would put him in "jail for life", put 13 locks on his jail cell door, and then destroy all of the keys:

http://www.LifeAfterLasik.com/nickcarolawsuits.htm

http://www.LifeAfterLasik.com

Nick then tried to sue me for $2,000,000.00 after I put all 50 of his lawsuits on my website.

http://www.lifeafterlasik.com/nickcarolawsuithearing1.htm

Nick lost a lot of money and time trying to “sue and quiet me”, & in the end he will be used as an example “of what NOT TO DO / NOR BECOME”, by classrooms all over the world. My point is much simpler: “All he had to do was admit that he made a mistake, & then work with me to get the best medical treatment no matter where in the world, & live by the Hippocratic Oath he swore years ago which again is sited below, so that you can see how corrupt the medical community has gotten and how “BIG BUSINESS OWNS & CONTROLS YOU & EVERYTHING REGARDLESS OF THE SAFETY OF THE AMERICANS THEY ARE HURTING DAILY”

Hippocrates ‘The Father Of Medicine’

“*I swear by Apollo Physician and Asclepius and Hygieia and Panaceia and all the gods and goddesses, making them my witnesses, that I will fulfil according to my ability and judgment this oath and this covenant:*

To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage and to teach them this art - if they desire to learn it - without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken an oath according to the medical law, but no one else. I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.

I will neither give a deadly drug to anybody who asked for it, nor will I make a suggestion to this effect. Similarly I will not give to a woman an abortive remedy. In purity and holiness I will guard my life and my art. I will not use the knife, not even on sufferers from stone, but will withdraw in favor of such men as are engaged in this work. Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons, be they free or slaves.

What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about. If I fulfill this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot”

Regards,

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