M Patterson
12/13/2006

Food and Drug Administration
Dockets Management Branch
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857
(301) 827-6860

Dear FDA:

**Petition to the Food and Drug Administration to stop all approvals of medical devices and their components used for LASIK (in accordance with existing regulations) Or to place a moratorium on their use (a partial or full withdrawal of approval) because Medical device approval for LASIK is Not safe because the risks of LASIK outweigh the benefits. LASIK is not as safe as PRK OR EPI-LASEK and PRK OR EPI-LASEK has the same benefits as LASIK.**

Class I, II and/or Class III medical devices should Only be approved for PRK OR EPI-LASEK because LASIK is not as safe as PRK OR EPI-LASEK and PRK has the same benefits as LASIK. The Petitioner further states that his personal belief is that the risks of PRK OR EPI-LASEK outweigh the benefits and additionally request the FDA to conduct and provide a thorough Risk-Benefit Analysis of both LASIK and PRK OR EPI-LASEK.

The scope of this petition involves ALL Lasers, Microkeratomes, etc. that currently have or are in the process of obtaining FDA PMAs, 510Ks approvals for use in LASIK refractive eye surgery.

Although this petition is lengthy, one of the main points of this petition is very brief and compelling. **PRK or epi-LASEK is indisputably safer than LASIK (how much can be debated), but there is NO known benefit for LASIK vs. this alternative.** Contact lenses are riskier than eyeglasses, but they also have an additional benefit. Because LASIK has NO additional benefit vs. PRK/LASEK (hereby referred to as PRK or epi-LASEK), LASIK MUST STOP according to the FDA's criteria based on a proper risk-benefit analysis.

A brief synopsis of Potential disadvantages of LASIK vs. PRK for the patient are:

1) an increased risk of serious complications leading to significant visual loss
2) an increased possibility of an unpredictable outcome
3) an increased risk of potential dissatisfaction with the side effects of the surgery

To recommend LASIK surgery, the FDA or a medical Doctor would have to be certain there will not be an unnecessary risk of a vision threatening complication, that the outcome will be predictable, and if the outcome is predictable that the patient will be satisfied with the quality of their vision in the real world. Because these three conditions and more are uncertain, the FDA or Doctors cannot in good conscience recommend this to patients. If the primary responsibility as physicians is to always do what is in the patient's best medical interest, it's impossible to justify elective LASIK surgery. The disadvantage to the government is the potential magnitude of a Public Health claim in the event of significant loss of vision.



2006P-0518

CP 1

My hope is that the FDA and CDC, and any other appropriate regulatory authorities investigate and stop harmful patient practices as soon as possible. Up to ten million patients have had LASIK so far in the US.

Prior Petitions are hereby incorporated in this petition (All words, information, and/or references, etc.). Petitions are titled:
**A. "Petition to the Food and Drug Administration regarding Medical Devices used for Elective Refractive Eye Surgery with Premarket Approvals (PMAs)" submitted by Dominic Morgan and is hereby incorporated by reference.**
**http://www.lasiksucks4u.com/index.php?option=com_content&task=view&id=21&Itemid=30**

**B. "Petition to the Food and Drug Administration to enforce the single-use requirement for all Microkeratomes and their components used for LASIK (in accordance with existing regulations) Or to place a moratorium on their use (a partial or full withdrawal of approval)."**

C. **"Petition to the FDA to stop LASIK due to the use of research from experiments conducted on human beings without a proper basis to believe it is in the patients' best interests and improper patient informed consent."**

The above petitions support this petition with additional references, examples, bases, reasons and potential actions for the FDA to consider. In addition, this petition expands on and includes additional information relevant to the prior petitions.

If additional information, separate comments or any other modification to this submission is required to comply with the FDA's procedures, please contact the Petitioner as soon as possible. The undersigned hereby petition the FDA to change or cancel a regulation, or to take other action as outlined in the FDA's published procedures (http://www.fda.gov/opacom/backgrounders/voice.html).

Many Doctors know and agree. For instance,
**"Dr. Johnny Gayton Declares LASIK to be Excessively Risky"**
Ophthalmologists debating safety of Lasik procedure
**"Gayton said one in 9,000 is one too many. He doesn't dispute that Lasik can be done safely. He disputes whether it is the safest procedure."**
**"When we're talking about people's eyesight, the stakes are high," he said.**
http://www.lasikfraud.com/news/archives/000077.html

**LASEK Gains Ground on LASIK**
**New techniques and post-op regimens make it a competitive alternative.**
***BY MARGUERITE MCDONALD, M.D.***

http://www.ophmanagement.com/article.aspx?article=86062

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1.3 Legal Basis of this Petition

2. Reasons for this Petition

LASIK risks outweigh the benefits vs. PRK OR EPI-LASEK.
This relevant information should have come out in the clinical trials. The clinical trials investigators were using some means of determining the risks. If the company was recommending LASIK and there's really no benefit vs. alternative treatments, a lot of patients may have been dropped from the clinical trials data because of these known problems- especially given there were a lot of patients in the initial trials who were Not evaluated at follow-up.

Although this petition is lengthy, one of the main points of this petition is very brief and compelling. **PRK or epi-LASEK is indisputably safer than LASIK (how much can be debated), but there is NO known benefit for LASIK vs. this alternative.** Contact lenses are riskier than eyeglasses, but they also have an additional benefit. Because LASIK has NO additional benefit vs. PRK/LASEK (hereby referred to as PRK or epi-LASEK), LASIK MUST STOP according to the FDA's criteria based on a proper risk-benefit analysis.

A brief synopsis of Potential disadvantages of LASIK vs. PRK for the patient are:

1) an increased risk of serious complications leading to significant visual loss
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3) an increased risk of potential dissatisfaction with the side effects of the surgery

To recommend LASIK surgery, the FDA or a medical Doctor would have to be certain there will not be an unnecessary risk of a vision threatening complication, that the outcome will be predictable, and if the outcome is predictable that the patient will be satisfied with the quality of their vision in the real world. Because these three conditions and more are uncertain, the FDA or Doctors cannot in good conscience recommend this to patients. If the primary responsibility as physicians is to always do what is in the patient's best medical interest, it's impossible to justify elective LASIK surgery. The disadvantage to the government is the potential magnitude of a Public Health claim in the event of significant loss of vision.

There is NO benefit for a patient to have LASIK vs. PRK and a LOT more risks. For example, see the text below (this is the outline).

2.1 Risk of Dry eye
2.2 Risk of Flap complications
2.3 Risk of Ectasia
2.4 Risk of Loss of Best Corrected Vision
2.5 Risk of Haze
2.6 Risk of Pain
2.7 Risk of Extensive Vision Recovery Time including Time off Work
2.8 Lifetime Risk of Longer Term Complications (the flap created for LASIK NEVER EVER heals).
2.9 Risk and Degree of Vision Quality Loss
2.10 Odds and Degree of Rehabilitation in the event of patient dissatisfaction (contacts or further surgery)

2.11 Odds and Degree of Rehabilitation after an adverse event (contacts or further surgery)
2.12. Willful ignorance, negligence or outright fraud is intolerable.
2.13. The Petitioner believes that Ophthalmologist have demonstrated a willful disregard for safety and fundamental human rights. Further, they have put their own totally self-serving interests ahead of their patients contrary to medical ethics and the law.
2.14. Commonsense and scientifically based guidelines to provide guidance to the FDA for IDEs are Not followed by the users of these FDA regulated medical devices.
2.15. FDA regulated medical devices are supposed to be "regulated" by the FDA and follow public health guidelines established by the CDC (including sterilization), but they are Not.
2.16. There is a history of numerous users of FDA regulated medical devices (Medical Doctors practicing LASIK) using "adulterated" devices contrary to the FDA's regulations and/or outside the practice of medicine.
2.17. Risk of Night Driving Difficulty
2.18. Other

3. Actions requested

4. Certification

5. No known Environmental Concerns.

1. Statement of grounds
**Class I, II and/or Class III medical devices should Only be approved for PRK OR EPI-LASEK because LASIK is not as safe as PRK OR EPI-LASEK and PRK has the same benefits as LASIK.**

The scope of this petition involves ALL Lasers, Microkeratomes, etc. that currently have or are in the process of obtaining FDA PMAs, 510Ks approvals for use in LASIK refractive eye surgery.

**The Petitioner further states that his personal belief is that the risks of PRK OR EPI-LASEK outweigh the benefits and additionally request the FDA to conduct and provide a thorough Risk-Benefit Analysis of both LASIK and PRK OR EPI-LASEK.**

Each of these medical devices are regulated by the FDA as Class I, II or Class III medical devices.

Examples of some of the Devices (and their components) included in the Scope of the Petition listed on the FDA website including all lasers currently approved or in review, see http://www.fda.gov/cdrh/LASIK/lasers.htm, and all the microkeratomes with 510Ks or currently under review (including approved substantially equivalent or predicate devices), for instance, see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=103724
HANSATOME MICROKERATOME
CHIRON VISION CORP.
510(k) Number K972808.

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 FDA is required by law to determine that the benefits of a regulated medical device (Class I, II, or III) outweigh the risks of the device for its intended use. Further, the FDA has an obligation to protect the public from injury and/or an adulterated or misbranded use of any regulated (or non-regulated) medical device whether or not practice of medicine is involved. This just makes common sense and is clearly within the FDA's regulatory authority and jurisdiction.

Among other things, I am asking for a comparable review regarding the safety of LASIK and for a halt to occur during this review.
http://www.the-lasik-directory.com/lasik_prk_chart.html
http://www.the-lasik-directory.com/lasik_prk_chart.pdf

The FDA has a history of conducting "safety reviews".

For instance, "A key question will be how to weigh the chances of blood clots against the risk of reclosing from a bare metal stent. "

**"This is a public health issue of great importance," said Dr. Daniel Schultz, director of the FDA's Center for Devices and Radiological Health. The agency "didn't want to wait until we had every last piece of information" before trying to provide guidance about stent use, he told reporters on Tuesday.**

**http://today.reuters.com/news/articlebusiness.aspx?type=ousiv&storyID=2006-12-07T115251Z_01_N06481257_RTRIDST_0_BUSINESSPRO-HEART-STENTS-DC.XML&from=business&src=120706_0935_FEATURES_drug_developments**

The FDA has a history of "seizing" adulterated or misbranded medical devices. Further, the FDA officials cannot redelegate this authority.
**REDELEGATION**. These officials may not further redelegate this authority.
http://www.fda.gov/smg/1410_403.html

Regulatory Delegations of Authority
Medical Devices and Radiological Health
(Updated 8/6/03)
http://www.fda.gov/smg/smg400.html

**Adulterated Medical Devices Seized**
**http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01278.html**

The General Controls in the Amendments apply to all **medical devices**. ... A **device** is held to be **adulterated or misbranded** if it includes any filthy, putrid, or decomposed ...
http://www.fda.gov/cdrh/devadvice/363.html
http://www.fda.gov/fdac/summarys/1999/299_sjs.html

http://www.fda.gov/cdrh/devadvice/39.html

The United States has filed a Complaint in the U.S. District Court in New Haven that seeks the seizure and ultimate forfeiture of numerous medical devices and their component parts and accessories that were stored in a distribution warehouse in Meriden, Connecticut
http://www.fda.gov/bbs/topics/NEWS/2006/NEW01389.html

http://www.fda.gov/ola/1997/devices.htm

http://www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg300-750.html

"According to FDA's Center for Devices and Radiological Health, clinical studies showed that about 5 percent of patients continued to always need glasses following PRK for distance, and up to

15 percent needed glasses occasionally, such as when driving. In addition, many patients experienced mild corneal haze following surgery, which is part of the normal healing process. The haze appeared to have little or no effect on final vision, and could only be seen by a doctor with a microscope. Some patients experienced glare and halos around lights. These conditions, however, diminished or disappeared in most patients in six months. For about 5 percent of patients, however, best-corrected vision without corrective lenses was slightly worse after surgery than before. In view of these findings, FDA and the Federal Trade Commission (which oversees advertising) issued a letter to the eye-care community in May 1996 warning that unrealistic advertising claims, such as "throw away your eyeglasses," and unsubstantiated claims about success rates could be misleading to consumers."

http://www.fda.gov/fdac/features/1998/498_eye.html

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.

Furthermore, Off-label use without informed patient consent is also an adulterated use of a regulated medical device. ALL additional surgeries after the first surgery are Off-label uses of medical devices for LASIK (because they are Not proven to be safe or effective) and the Petitioner is aware that almost all patients are Not receiving informed consent of this fact.

Regardless of what reprocessing is allowed, based on these 2 articles below my interpretation is that Doctors reusing microkeratome blades or other medical devices is occurring illegally without FDA regulation [].

According to the information in the article below, a microkeratome is clearly in the critical category under Federal law MDUFMA (an amendment to the *Food, Drug, and Cosmetic Act (FD&C Act)* was effected, via the *Medical Device User Fee and Modernization Act (MDUFMA)*.

I do Not see where the 9/18/06 FDA guidance indicates they are in the critical category according to the "Spaulding" definition.

Was the "risk evaluation" for these single-use disposable devices performed properly according to Federal law?

>The term "single-use device" (SUD) refers to a medical device that, by virtue of its intended use, is meant to be used just once, i.e., used on a single patient during a single procedure.

>On 1 June 2004, FDA revised an earlier guidance on this subject, incorporating current thinking on the timeframe for supplemental validation data review and actions that the agency intends to take on reprocessed SUDs deemed not substantially equivalent to a predicate device.

>*MDUFMA* was enacted 26 October 2002, and one of its amendments adds section 510(o) to the Act, providing the regulatory requirements for reprocessing SUDs. This specific amendment stipulates that 510(k) (premarket notification) submissions for certain reprocessed SUDs must include validation data to support substantial equivalence with predicate devices.

>Reprocessed SUDs are divided into three categories: critical, semi-critical, and non-critical, based upon their degree of contact with the human body (this is commonly referred to in the industry as the "Spaulding" definition, after the author who first published a paper on this topic in 1971)[1] Critical reprocessed SUDs come into contact with sterile tissue or body spaces during use. Semi-critical reprocessed SUDs come into contact with intact mucous membranes, but normally sterile body areas are not penetrated. In the third category, non-critical reprocessed SUDs do not penetrate intact skin and have only topical contact with the human body.

>Under *MDUFMA*, FDA is tasked with reviewing the list of critical SUDs currently exempt from premarket notification to determine which of these devices require submission of a 510(k) and the supplemental validation data. In making this determination, FDA used the Spaulding definitions to categorize the devices. A risk evaluation was also utilized, to determine whether the reprocessed device poses is a risk of infection and/or inadequate performance. Devices were then assigned a high, moderate or low risk level.

http://www.raps.org/s_raps/rafocus_article.asp?TRACKID=&CID=61&DID=25810

>FDA decided that the unregulated reuse of single-use devices is not acceptable and circulated a draft regulation, which proposes that at the end of a transition period all reprocessors including hospitals will be regulated the same way as Original Equipment Manufacturers. In Europe, health authorities and the European Commission are still deciding if controls for recycling single-use devices are necessary and at what level of regulation.

http://www.raps.org/s_raps/rafocus_article.asp?TRACKID=&CID=61&DID=6222

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 I think patients should be properly educated and informed prior to having LASIK surgery.

In general, Among other things, I am asking for a comparable review regarding the safety of LASIK and for a halt to occur during this review. For instance,
http://www.the-lasik-directory.com/lasik_prk_chart.html
http://www.the-lasik-directory.com/lasik_prk_chart.pdf

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.

Informed consent was lacking and the FDA approved LASIK when complication rates were FAR higher than those reported in the clinical trials. This was wrong.

"Complications generally were more common in the early years of LASIK, when studies in the late 1990s indicated that up to 5% of people undergoing the procedure experienced some type of problem."

http://www.allaboutvision.com/visionsurgery/lasik_complication_1.htm

Lack of informed patient 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 regulated medical 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.

Furthermore, Off-label use without informed patient consent is also an adulterated use of a regulated medical device. ALL additional surgeries after the first surgery are Off-label uses of medical devices for LASIK (because they are Not proven to be safe or effective) and the Petitioner is aware that almost all patients are Not receiving informed consent of this fact.

Two Doctors in CA admitted to reusing a single blade on multiple patients and were placed on probation by the medical board, and I believe the penalty should be higher than this decision.

"LaserVue reused microkeratome blades among patients rather than sterilizing or replacing them. Former patients may have been exposed to infectious diseases such as HIV or Hepatitis. "
"Class Action o/b/o 2,700 former LaserVue patients. In a settlement to an investigation brought by Medical Board of California (MBC), defendants admitted that their protocol was to rinse and reuse a blade on up to 4 eyes. MBC concluded that defendants departed from standard of care and placed them on probation."
(see
http://www.lasikinfocenter.net/Webpages/Ongoing%20Litigation%20Against%20RS%20Webpage.htm.)

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).

In general, Among other things, I am asking for a comparable review regarding the safety of LASIK and for a halt of the use of these medical devices to occur during this review. For instance,
http://www.the-lasik-directory.com/lasik_prk_chart.html
http://www.the-lasik-directory.com/lasik_prk_chart.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 FDA is required by law to determine that the benefits of a regulated medical device (Class I, II, or III) outweigh the risks of the device for its intended use. Further, the FDA has an obligation to protect the public from injury and/or an adulterated or misbranded use of any regulated (or non-regulated) medical device whether or not practice of medicine is involved. This just makes common sense and is clearly within the FDA's regulatory authority and jurisdiction.

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

The FDA has a history of "seizing" adulterated or misbranded medical devices. Further, the FDA officials cannot redelegate this authority.
**REDELEGATION**. These officials may not further redelegate this authority.

http://www.fda.gov/smg/1410_403.html

Regulatory Delegations of Authority
Medical Devices and Radiological Health
(Updated 8/6/03)
http://www.fda.gov/smg/smg400.html

**Adulterated Medical Devices Seized**
**http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01278.html**

The General Controls in the Amendments apply to all **medical devices. ...** A **device** is held to be **adulterated or misbranded** if it includes any filthy, putrid, or decomposed ...
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the United States has filed a Complaint in the U.S. District Court in New Haven that seeks the seizure and ultimate forfeiture of numerous medical devices and their component parts and accessories that were stored in a distribution warehouse in Meriden, Connecticut
http://www.fda.gov/bbs/topics/NEWS/2006/NEW01389.html

http://www.fda.gov/ola/1997/devices.htm

http://www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg300-750.html

Federal law MDUFMA (an amendment to the *Food, Drug, and Cosmetic Act (FD&C Act)* was effected, via the *Medical Device User Fee and Modernization Act (MDUFMA)*.

Was the "risk evaluation" performed properly according to Federal law?

1.3.11. >*MDUFMA* was enacted 26 October 2002, and one of its amendments adds section 510(o) to the Act, providing the regulatory requirements for reprocessing SUDs. This specific amendment stipulates that 510(k) (premarket notification) submissions for certain reprocessed SUDs must include validation data to support substantial equivalence with predicate devices.

1.3.12. The same laws used for other recalls can be applied to the lasers, microkeratomes, the blades and cannulas. Do Not allow them to be used anymore just like the contact lens solutions and cadaver tissue that has harmed the public health.

Two recalls recently by the FDA and the CDC- one for eye drops that spread fungus, and one for tissue that was Not properly screened. BOTH of these problems are obviously caused by the reuse of microkeratome parts but the FDA and CDC are still deciding and monitoring the problem. I sent peer reviewed literature showing that the problems caused by blade reuse have been studied with unethical research and without informed consent from patients.

Why aren't LASIK patients now told to get screened too?

1.3.13 Just because a physician does something during a surgery does Not mean that it constitutes the practice of medicine. The FDA can regulate anything that does Not constitute the practice of medicine and obviously any violation of the FDA labeling or Federal law does Not constitute the practice of medicine.

Operating 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). "

1.3.14. Federal and International law requires that Patients MUST HAVE true informed consent. Patients were coerced deceptively into paying money for something that was known to permanently damage patients in 100% of cases. The flap never heals after LASIK and there is NO KNOWN physical benefit to the cornea from LASIK. Instead the cornea is permanently injured by LASIK.

1.3.15. The Petitioner asks the FDA to review whether or Not a 510K approval is even appropriate for a dangerous medical device that can and does cause serious injury including blindness. The Petitioner believes only a PMA is a sufficient degree of approval. In addition if warranted and appropriate, The petitioner requests multiple criminal investigations and seeks to press criminal charges. There is a lot of Federal and State law in support of this request. For instance,

1.3.16. Health and Safety Code
Criminal penalties. While it is not the author's intent to make failure to report an adverse drug event a crime, SB 380 will amend the Sherman Food, Drug, and Cosmetics Act (the Act) by adding Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code. As such, the provisions of the bill would be subject to the penalties and remedies outlined in Chapter 8 of the Act, which include a maximum sentence of up to one year in a county jail, a maximum fine of $1,000, or both.
http://info.sen.ca.gov/pub/bill/sen/sb_0351-0400/sb_380_cfa_20050329_163425_sen_comm.html
1.3.17. There are common laws applicable at both the Federal and State level regarding these issues.
Willful ignorance, negligence or outright fraud is intolerable.

1.3.18. The Petitioner believes that Ophthalmologist have demonstrated a willful disregard for fundamental human rights and have put their own totally self-serving interests ahead of their patients. In addition, the FDA and other Federal agencies have obviously been involved in collaborating and corruption. Thus, the petitioner requests that all medical devices used by Ophthalmologists be legally evaluated and reviewed.

2. Reasons for This Petition

**The evidence indicates that the Risks outweigh the Benefits for LASIK rather than the other way around. Use of Medical devices and their components used for LASIK (in accordance with existing regulations) should be stopped Or a moratorium placed on their use (a partial or full withdrawal of approval) because Medical device approval for LASIK is Not safe because the risks of LASIK outweigh the benefits. LASIK is not as safe as PRK OR EPI-LASEK and PRK has the same benefits as LASIK.**

**References and thorough RESEARCH can be provided on request. The information included in this petition is so commonly known to the Ophthalmic Devices panel and researchers who have done clinical trials on LASIK that the petitioner believes it is Not necessary to provide the detailed research. The Petitioner can provide hundreds or thousands of references as additional supporting evidence on request.**

My hope is that the appropriate government agencies (e.g., the FDA and CDC), and any other appropriate regulatory authorities investigate and stop harmful patient practices as soon as possible. As many as eight million patients have had LASIK so far.

Has the FDA working group or the CDC reached any conclusions yet about whether Doctors can violate Federal laws? Why does the Federal Government Not enforce Federal law when licensed Doctors violate it to make MORE money by injuring patients unnecessarily?

With new advancements and improvement in technology, the Risks of LASIK are far higher than PRK OR EPI-LASEK and the Benefits are comparable. More Doctors are starting to promote epi-LASEK or other PRK techniques over LASIK for a number of reasons.

"a number of specific reasons they've come to favor epi-LASIK:"

***It eliminates potential flap complications.***

***More patients can be treated.***

***Epi-LASIK doesn't weaken the cornea.***

***Healing is better than [before]***

***Epi-LASIK may reduce the need for enhancements.***

***It's easier on the surgeon.***

**Patients Benefit, Too**

***Patients see it as safer.***

***Patients may get better visual outcomes.***

***Epi-LASIK doesn't denervate the cornea***

***Recovery only take two to three days***

http://www.shealyeye.com/epilasiktheperfectprocedure.htm

**Dr. Johnny Gayton Declares LASIK to be Excessively Risky**
Ophthalmologists debating safety of Lasik procedure
**Gayton said one in 9,000 is one too many. He doesn't dispute that Lasik can be done safely. He disputes whether it is the safest procedure.**
http://www.lasikfraud.com/news/archives/000077.html

**LASEK Gains Ground on LASIK**
**New techniques and post-op regimens make it a competitive alternative.**
***BY MARGUERITE MCDONALD, M.D.***

http://www.ophmanagement.com/article.aspx?article=86062

Are 1 in 2,000 at high risk from LASIK? 1 in 10? 1 in 2?
http://www.abcactionnews.com/video/news/2006/11/1101health.shtml

This relevant information should have come out in the clinical trials. The clinical trials investigators were using some means of determining the risks. If the company was recommending LASIK and there's really no benefit vs. alternative treatments, a lot of patients may have been dropped from the clinical trials data because of these known problems- especially given there were a lot of patients in the initial trials who were Not evaluated at follow-up.

Although this petition is lengthy, one of the main points of this petition is very brief and compelling. **PRK or epi-LASEK is indisputably safer than LASIK (how much can be debated), but there is NO known benefit for LASIK vs. this alternative.** Contact lenses are riskier than eyeglasses, but they also have an additional benefit. Because LASIK has NO additional benefit vs. PRK/LASEK (hereby referred to as PRK or epi-LASEK), LASIK MUST STOP according to the FDA's criteria based on a proper risk-benefit analysis.

A brief synopsis of Potential disadvantages of LASIK vs. PRK for the patient are:

1) an increased risk of serious complications leading to significant visual loss
2) an increased possibility of an unpredictable outcome
3) an increased risk of potential dissatisfaction with the side effects of the surgery

To recommend LASIK surgery, the FDA or a medical Doctor would have to be certain there will not be an unnecessary risk of a vision threatening complication, that the outcome will be predictable, and if the outcome is predictable that the patient will be satisfied with the quality of their vision in the real world. Because these three conditions and more are uncertain, the FDA or Doctors cannot in good conscience recommend this to patients. If the primary responsibility as physicians is to always do what is in the patient's best medical interest, it's impossible to justify

elective LASIK surgery. The disadvantage to the government is the potential magnitude of a Public Health claim in the event of significant loss of vision.

There is no benefit of LASIK vs. PRK and a LOT more risks. For example,

**2.1** Risk of Dry eye

PRK OR EPI-LASEK causes FAR LESS dry eye problems so the risks of LASIK outweigh the benefits for dry eye, See below- **Less Dry Eye With Surface Ablation.** Dry eye is a very serious medical condition that severely impacts quality of life. For example, see

> **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. Intensive drop therapy and use of plugs or other procedures may be required. http://www.fda.gov/cdrh/LASIK/risks.htm

> **"Dry eye occurs when people don't have either enough tears, or the correct composition of tears, on the surface of their eyes to lubricate the eyes and keep them comfortable.". . ."If you have dry eye, your eyes can** feel persistently gritty, itchy, burning, and painful." **http://www.theschepens.org/dry_eye_fact_sheet.htm**

**And** "Patients who said dry eye symptoms interfered with activities most or all of the time (%)",http://www.lasikliberty.com/index.php?option=com_content&task=view&id=37&Itemid=57)

For LASIK surgery, a flap is created. The very fine cornea nerves are severed as a normal part of the LASIK procedure, but NOT with PRK OR EPI-LASEK. These nerves are required in order "signal" the Lacrimal Gland to produce tears. The interruption of the corneal nerve impulses can actually cause a lesser amount of tears to be produced, resulting in Dry Eyes after LASIK. Further, these nerves are involved in the proper function of the tear film feed back loop involving the Mebomian Glands (which LASIK patients have a reduction in tear film quality and tear film break up time causing multiple types of "itis", but not limited to, Mebomianitis- Mebomian Gland dysfunction, keratitis, SPK, PEK, and other disorders).

For a sample of some evidence, see below:

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Chronic Dry Eye after LASIK

If post-LASIK dry eye symptoms persist, they can develop into chronic dry eye syndrome. In a certain percentage of patients, dry eye after LASIK may last for a prolonged period of time and can even become permanent. It is crucial that patients consider the potential for chronic dry eye after LASIK among the risks associated with refractive surgery. Although there are several dry eye

treatment options available for post-LASIK dry eye, prevention should always be a top priority. Be sure your doctor screens for pre-LASIK dry eye symptoms before you undergo refractive surgery.

Xx

Refractive Surgery and Dry Eye Syndrome

Post-LASIK dry eye syndrome is one of the most frequent side effects of laser vision correction. Refractive surgery and dry eye symptoms go hand in hand, as dry eyes are simply a physical response to the nature of the procedure. In normal, healthy eyes, the corneal nerves supply information to the lacrimal (tear-producing) glands, maintaining a constant stream of tears. During refractive surgery, the corneal nerves are temporarily damaged, and are thus unable to produce adequate tears while the eyes are healing. As the patient recovers, so do the corneal nerves, and in most cases the tear ducts resume their normal functioning within a few weeks.

However, some patients with dry eye after LASIK will suffer more severe symptoms than others. For this reason, it is imperative that patients discuss any preexisting symptoms with their doctor before undergoing refractive surgery. The link between refractive surgery and dry eye symptoms is well established, and for this reason, most surgeons insist on screening for dry eye prior to refractive surgery. They evaluate the patient's current tear film and decide whether they should be treated for dry eyes in advance.

http://www.docshop.com/education/vision/eye-diseases/dry-eye/after-lasik/

>these nerves are required in order "signal" the Lacrimal Gland to produce tears. So, sometimes, the temporary interruption of the corneal nerve impulses can actually cause a lesser amount of tears to be produced, resulting in Dry Eyes after LASIK. Sometimes if the Dry Eyes after LASIK are moderate or severe, your vision may actually be blurry due to the tear film instability.

Why Does LASIK Cause Dry Eyes?

LASIK may cause some patients to experience Dry Eyes after their surgery. This is especially true if there was tendency toward dry Eyes before the LASIK procedure. During the LASIK procedure, a thin layer of tissue is created, called a flap, under which the actual laser energy is applied to reshape the cornea to correct nearsightedness, farsightedness and astigmatism. Anatomically, when the flap is created, the very fine cornea nerves may be severed as part of the LASIK procedure. This is a normal part of the procedure. However, these nerves are required in order "signal" the Lacrimal Gland to produce tears. So, sometimes, the temporary interruption of the corneal nerve impulses can actually cause a lesser amount of tears to be produced, resulting in Dry Eyes after LASIK. Sometimes if the Dry Eyes after LASIK are moderate or severe, your vision may actually be blurry due to the tear film instability. Your LASIK surgeon may elect to treat you for Dry Eyes before your LASIK procedure in order to fortify your tear film so that you will have a comfortable and asymptomatic post operative period. ALL LASIK patients will need to use artificial tears or lubricating drops as a matter of course as it helps the tear film reestablish itself after the LASIK procedure. During your consultation it is important to disclose any symptoms you may have of Dry Eyes and to disclose any medications you are taking that might predispose you to dry eyes after

your LASIK procedure. In this way, your LASIK surgeon can take the necessary steps to prescribe whatever is necessary to obtain the best possible results for you. Fortunately, virtually all Dry Eyes symptoms after LASIK are temporary and gradually decrease over time until they end within a few months of having your LASIK procedure.

http://www.seewithlasik.com/docs/lasik-dry-eyes.html

Less Dry Eye With Surface Ablation

Although PRK, LASEK, and Epi-Lasik may induce dry eye symptoms, Lasik and IntraLasik seem to be the more commonly associated with dry eyes. This is partly because the Lasik techniques are more disruptive to the corneal nerves than PRK and LASEK. For this reason, patients with preexisting dry eyes may find PRK, LASEK, or Epi-Lasik a better choice.

http://www.usaeyes.org/lasik/faq/lasik-dry-eyes.htm

Reinnervation in the Cornea After LASIK

A recent study by the Mayo Clinic's Department of Ophthalmology (Rochester, Minn.) showed that the number of subbasal and stromal nerve fiber bundles in the corneal flap decreases by 90 percent immediately after laser in situ keratomileusis (LASIK). During the first year after LASIK, subbasal nerve fiber bundles gradually return, but by 1 year the number remains less than half of the number before LASIK.

Researchers evaluated the denervation and reinnervation of human central corneas using sequential, quantitative measurements of nerves viewed by confocal microscopy in vivo during the first year after LASIK. They studied 17 eyes of 11 patients who had undergone LASIK to correct myopia from -2.0 D to -11.0 D; eyes were treated with an excimer laser with a planned 180-microm flap. Clinicians scanned central corneas throughout their full thicknesses by confocal microscopy before and at 1 week and 1, 3, 6 and 12 months after LASIK. They determined the number of nerve fiber bundles per scan in two to eight scans per eye per visit in the subbasal region, the full-thickness stroma, the stromal flap (layer between the most anterior keratocyte and the flap interface) and the stromal bed (layer between the flap interface and the endothelium).

In the subbasal region, the number of nerve fiber bundles decreased by more than 90 percent 1 week after LASIK and was significantly lower at all times after surgery than before. It increased 6 and 12 months after LASIK, but remained less than half of the preoperative value. In the stromal flap, the number of nerves at all times after surgery was also significantly lower than before surgery and did not increase significantly by 1 year. In the stromal bed, researchers found no significant differences among any of the nerve measurements before and after LASIK.

SOURCE: Lee BH, McLaren JW, Erie JC, et. al. Reinnervation in the cornea after LASIK. Invest Ophthalmol Vis Sci 2002;43(12):3660-64.

http://www.lasikdisastercom/dryeye.htm

Dry Eye after LASIK surgery

Under normal circumstances, the very sensitive nerves in the cornea send signals to the Lacrimal Gland which produces tears in response to dryness or irritation. However, during LASIK, the surgeon prepares a thin flap under which the Laser energy is applied in order to shape the cornea and eliminate your nearsightedness, farsightedness or astigmatism. It is normal and expected that during the creation of the flap a certain number of the corneal nerves will be temporarily damaged. What does this mean? It means that for some period of time after your LASIK, the regular nerve impulses that would have ordinarily told the Lacrimal Gland to produce tears will be interrupted. This is a normal and expected part of the healing process after LASIK. It can be accompanied by Dry Eyes that result in dry, gritty and uncomfortable sensations. In order to avoid this, your surgeon will have carefully examined your tearful beforehand. But, more importantly, every LASIK patient will need to use lubricating and moisturizing drops very often after their procedure.

http://www.eyecaresource.com/conditions/dry-eyes/lasik.html

2.2 Risk of Flap complications

PRK has NO flap complications so the risks of LASIK outweigh the benefits. Flap complications are very serious medical conditions that often severely impact quality of life and cause other medical conditions (including psychological reactive depression, etc.).

Some flap complications (not all include).

2.2.1. **LASIK flap dislocation**

This is a lifetime risk that can occur from common everyday life events.

One Middle Georgia patient, he said, had his flap knocked loose while playing basketball more than a year after surgery.

The risk is so great, Gayton maintained, that he wouldn't have the surgery himself.

"I would not have Lasik, and I would not recommend it to my family and friends," he said.

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Gayton said one in 9,000 is one too many. He doesn't dispute that Lasik can be done safely. He disputes whether it is the safest procedure.

Xxxx

"When we're talking about people's eyesight, the stakes are high," he said.

http://www.lasikfraud.com/news/archives/000077.html

Late dislocation of LASIK flap following fingernail injury.

http://www.ijo.in/article.asp?issn=0301-4738;year=2004;volume=52;issue=4;spage=327;epage=8;aulast=Srinivasan

**http://www.aao.org/education/focal_points/upload/6202_Mod13.04-2.pdf**

**2.2.2.** Flap Striae

Microstriae or thick folds in the flap can occur with LASIK, but not PRK.

**Including "undulations of Bowman's layer"**
Cornea. 2005 Jan;24(1):92-102.

**Also, http://www.aao.org/education/focal_points/upload/6202_Mod13.04-2.pdf**

2.2.3. Diffuse Lamellar Keratitis (DLK)
"Stromal melting, and potentially permanent and visually significant topographic abnormalities (Stage IV DLK)." P.8

**http://www.aao.org/education/focal_points/upload/6202_Mod13.04-2.pdf**

2.2.4. Acute Postoperative Glaucoma

This is caused by the microkeratome suction elevating the eye pressure beyond what the eye is designed to handle properly. PRK does Not create this suction because there is no microkeratome creating a flap.

"Thin or irregular flaps, partial or incomplete flaps, buttonholed or donut-shaped flaps, and free caps. The etiology of these complications is varied, but a common denominator is inadequate suction generated by the
microkeratome. In order to create consistent LASIK flaps, the microkeratome must generate at least 65 mm
Hg of vacuum." P.4

**http://www.aao.org/education/focal_points/upload/6202_Mod13.04-2.pdf**

2.2.5. Post-LASIK Inflammation or Infection
This can occur with PRK, but is less likely. Creating a flap opens up the eye to infection more so than a surface PRK treatment.

**http://www.aao.org/education/focal_points/upload/6202_Mod13.04-2.pdf**

"Gayton said patients he has performed Lasik on have experienced inflammation of the cornea, infection and other complications."
http://www.lasikfraud.com/news/archives/000077.html

**2.2.6.** "Thin or irregular flaps, partial or incomplete flaps, buttonholed or donut-shaped flaps, and free caps. The etiology of these complications is varied, but a common denominator is inadequate suction generated by the microkeratome. In order to create consistent LASIK flaps, the microkeratome must generate at least 65 mm Hg of vacuum." P.4
http://www.aao.org/education/focal_points/upload/6202_Mod13.04-2.pdf

2.2.7. Epithelial Ingrowth and epithelial Erosions (e.g., SPK, PEK, EBMD, flap melt, etc.)
Unlike LASIK, PRK has no flap for the epithelium to grow under.
http://www.aao.org/education/focal_points/upload/6202_Mod13.04-2.pdf

Also,
"Just because epithelium lies within the interface does not necessarily mean it has to be removed. Progression of the ingrowth, staining of the flap epithelium overlying the ingrowth, reduction of the best corrected or uncorrected visual acuity, or distortion of the keratometry mires, with or without visual complaints, are indications for removing ingrown epithelium. Once a decision is made to remove the epithelium, it is best to mechanically elevate the flap, remove the epithelium from both surfaces using a dull blade or spatula followed by a dry cellulose sponge, and then irrigate copiously."
http://www.aao.org/education/focal_points/upload/6202_Mod13.04-2.pdf

2.2.8. stromal melting (i.e., "flap melt")

2.2.9. Irregular astigmatism is caused by the creation of a lasik flap. Potentially permanent and visually significant topographic abnormalities caused by flap complications.

Further other problems are increased by creation of a flap. "Over time, most central islands resolve spontaneously, as the corneal epithelium and stroma undergo remodeling. For patients who have significant visual aberrations, rigid, gas-permeable contact lens fitting may promptly restore best-corrected visual acuity.
Central islands that last beyond 6 months may require surgery. Prior to the advent of topographically assisted ablation, analysis of the topographic map would allow the surgeon to determine the diameter and distance of the island from the corneal center."

2.2.10. An increase in epithelial problems for PRK vs. LASIK.

Cornea. 2005 Jan;24(1):92-102.

2.2.11 Permanent pathologic changes are MOST prevalent in the lamellar interface wound between the flap and the stromal bed. This wound only exists in LASIK, Not PRK.

"Findings at the flap surface included elongated basal epithelial cells, epithelial hyperplasia, thickening and undulations of the epithelial basement membrane (EBM), and undulations of Bowman's layer. Findings in or adjacent to the wound included collagen lamellar disarray; activated keratocytes; quiescent keratocytes with small vacuoles; epithelial ingrowth; eosinophilic deposits; PAS-positive, electron-dense granular material interspersed with randomly ordered collagen fibrils; increased spacing between collagen fibrils; and widely spaced banded collagen. "

"CONCLUSIONS: Permanent pathologic changes were present in all post-LASIK corneas. These changes were most prevalent in the lamellar interface wound. These changes along with other pathologic alterations in post-LASIK corneas may change the functionality of the cornea after LASIK."

Cornea. 2005 Jan;24(1):92-102.

**Pathologic findings in postmortem corneas after successful laser in situ keratomileusis.**

Kramer TR, Chuckpaiwong V, Dawson DG, L'Hernault N, Grossniklaus HE, Edelhauser HF.

Emory Eye Center, Emory University, Atlanta, GA 30322, USA.
Theresa_Kramer@emoryhealthcare.org

Also, http://www.aao.org/education/focal_points/upload/6202_Mod13.04-2.pdf

**2.2.12.** Regression and Overcorrection are more likely with LASIK than with PRK because creating a corneal flap increases the variability of the results.

2.2.13. Incidence of corneal Scarring and other problems increase.
"Those with thinner corneas may suffer less than ideal results, flap may dislodge with trauma, increases higher order aberrations (HOA)**, uneven flap edges may lead to astigmatism, flap may result in scars, post-operational treatment is needed in approximately 5% of patients.
** Higher order aberrations (HOA) affect the contrast sensitivity and fine detail of vision, such as night vision, glare, contrast."
http://www.the-lasik-directory.com/lasik_prk_chart.pdf

2.3 Risk of Ectasia

Ectasia is caused by the strength of the cornea being reduced by a reduction in the thickness and number of collagen fibers supporting the structure of the eye's shape. The thickest fibers are located in the outer 1/3 to ¼ of the cornea. Creation of the LASIK flap Not only reduces the strength of the cornea unnecessarily. It reduces the strength most in the strongest part of the cornea (the outer section where the collagen fibers are thickest and strongest). Removing MOST of the strength in the outer 100 to 180um of the cornea (the thickness of the flap itself) and then removing tissue under the flap, most of the strongest section of the cornea is effectively removed from supporting the structure of the eyeball itself. With PRK, there is no flap so the tissue removed is only at the other area of the cornea and not below another piece of flap.

Ectasia is a very serious medical condition that often severely impacts quality of life and causes other medical conditions (including psychological reactive depression, etc.).

The center area of the flap itself only has 7% of the original uncut strength this tissue had before lasik and would be maintained with PRK. PRK results in the cornea being ~14 times stronger versus LASIK for the tissue area that is cut for creating the LASIK flap.

Because PRK does not involve a permanent flap in the deeper corneal layers (the LASIK procedure involves a mechanical microkeratome using a metal blade or a femtosecond laser microkeratome to create a 'flap' out of the outer cornea), the cornea's structural integrity is less altered by PRK
http://en.wikipedia.org/wiki/Photorefractive_keratectomy

2.4 Risk of Loss of Best Corrected Vision
LASIK has a higher incidence and risk of loss of BCVA. There are several reasons.
Loss of Best Corrected Vision is a very serious medical condition that often severely impacts quality of life and causes other medical conditions (including psychological reactive depression, etc.).

2.4.1. Creation of the flap itself and flap complications.

"The biggest risk is a 1% chance of induced irregular astigmatism from an irregularly-healed flap (provided you choose an experienced surgeon). This complication can cause **permanent** loss of from one to four lines of best-corrected visual acuity, or BCVA (*i.e.*, if you saw 20/15 with your glasses before surgery, then even though you may see 20/70 unaided after surgery, you might not see any better than 20/40 with glasses after surgery. That's a significant blur, and anyone who tries to brush that risk under the rug is doing you a vast disservice."
http://www.users.fast.net/~behanna/lasik.html

2.4.2. Increased dry eye and risk thereof.
http://www.aao.org/education/focal_points/upload/6202_Mod13.04-2.pdf

2.4.3. Epithelial ingrowth, etc.
http://www.aao.org/education/focal_points/upload/6202_Mod13.04-2.pdf

2.5 Risk of Haze

Both LASIK and PRK have a risk of Haze. PRK using older laser technologies where the lasers do Not create a smooth corneal surface has a higher risk of Haze than LASIK with these same technologies. However, use of mitomycin C and other medications (e.g., topical NSAIDs or steroids) reduces the risk of Haze after PRK to comparable level EVEN ON these older technologies that produce unnecessarily rough corneal surface ablations (the LASIK flap covers up the rough surface under the flap instead of leaving it on the surface of the eye). After the healing period, the epithelium smoothes out this rough surface after PRK.
Often times a low grade haze does Not impact the patients' quality of life.

Further with the newer technologies available on the market (e.g., the mel-80, Allegretto and/or especially the 1000 hz Ligi/iVis technology), the cornea surface is Not as rough and the risk of Haze from PRK is also comparable to LASIK.

"many patients experienced mild corneal haze following surgery, which is part of the normal healing process. The haze appeared to have little or no effect on final vision, and could only be seen by a doctor with a microscope."
http://www.fda.gov/fdac/features/1998/498_eye.html

The use of the anti-metabolite mitomycin can minimize the risk of post-operative haze in persons requiring larger PRK corrections.
http://en.wikipedia.org/wiki/Photorefractive_keratectomy

"How do they minimize patient pain and prevent haze [with PRK]?"
http://www.shealyeye.com/epilasiktheperfectprocedure.htm

2.6 Risk of Pain

For 95% of patients or more, there is no pain from epi-LASIK or PRK. For almost all of the 5% with pain and no other complication, the pain is moderate and lasts for less than 72 hours (they may take over the counter pain medication for a day or prescription pain medication for a couple of days). Short term pain for a few days that goes away has No impact on patients' long-term qualify of life.

Many patients have had severe pain after LASIK that does Not occur with PRK (caused by flap melt, dry eye and other conditions).

"Epi-LASIK: Closing In On The Perfect Procedure

As patient pain is minimized and recovery time shrinks, more surgeons are trying it - and many prefer it to LASIK."

"The healing is a lot faster and pain is almost nonexistent, especially with the medications we use."

http://www.shealyeye.com/epilasiktheperfectprocedure.htm

2.7 Risk of Extensive Vision Recovery Time including Time off Work
With no other complications, Patients can have bilateral epi-LASEK/PRK surgery on a Thursday and be back at work the following Monday which is only 1 to 2 days off of work. This is comparable to the vision recovery in LASIK.

"The healing is a lot faster and pain is almost nonexistent, especially with the medications we use."
http://www.shealyeye.com/epilasiktheperfectprocedure.htm

2.8 Lifetime Risk of Longer Term Complications

See risks above including flap complications. Many of these LASIK risks are LIFETIME risks that do Not exist with PRK.

In addition, the flap created for LASIK NEVER EVER heals. The Doctors know this or should know it, but instead their "technicians" lie to patients that the cornea heals in a few days (the typical lie is 3 to 5 days). An omission of specific details is just as much a lie as a commission. It still counts as an intentional fraud in a court of law.

Airbags or ordinary lifetime activities that ordinarily would cause no injury can injure the LASIK flap and cause severe problems.

2.9 Risk and Degree of Vision Quality Loss
See above. LASIK has an unnecessarily high risk and a much higher risk of vision quality loss than PRK.

Potentially permanent and visually significant topographic abnormalities are caused by flap complications.

"Those with thinner corneas may suffer less than ideal results, flap may dislodge with trauma, increases higher order aberrations (HOA)**, uneven flap edges may lead to astigmatism, flap may result in scars, post-operational treatment is needed in approximately 5% of patients.
** Higher order aberrations (HOA) affect the contrast sensitivity and fine detail of vision, such as night vision, glare, contrast."
http://www.the-lasik-directory.com/lasik_prk_chart.pdf

2.10 Odds and Degree of Rehabilitation in the event of patient dissatisfaction (contacts or further surgery)

After LASIK, patients have a much higher risk of inability to tolerate contact lenses. This is for several reasons. See above for the increased risks of LASIK.

To briefly mention a few LASIK problems that can make it much more difficult to wear contact lenses:

2.10.1 Epithelial and stromal problems (e.g., SPK, PEK, EBMD, DLK)
2.10.2 Scarring
2.10.3 Dry eye
2.10.4 Irregular astigmatism
2.10.5 Problems at the interface between the flap and the rest of the cornea (e.g., a "ridge" can occur if the flap overlaps the untreated area).
2.10.6 Some LASIK specific problems cannot be corrected by contact lenses (e.g., Breaks in bowmans membrane).

Also, http://www.the-lasik-directory.com/lasik_prk_chart.pdf

Dry eye alone adversely effects patient satisfaction from LASIK and their ability to be rehabilitated.

"Stabilization of the wavefront image suggests that the tear film has become stable. If a suspected dry eye patient cannot achieve a stable refraction or best corrected visual acuity prior to surgery, no matter what the clinical examination findings, it is probably best to avoid doing surgery on that patient.

Dry eye candidates are managed differently from normal cases requiring routine lubrication during the day and bedtime following surgery. Routine use of punctal occlusion is usually not necessary for most LASIK patients."
**http://www.aao.org/education/focal_points/upload/6202_Mod13.04-2.pdf**

2.11 Odds and Degree of Rehabilitation after an adverse event (contacts or further surgery)

After PRK, there is more corneal tissue left. This alone allows the possibility of more tissue left for additional corrective surgeries if necessary. Up to 180um of tissue can be taken by the LASIK flap alone. This would be enough tissue for up to 4 additional PRK retreatments (vs. LASIK) depending on the depth of each treatment.

For retreatments after PRK, there is no increased risk of flap complications and other problems like there are for retreatments after LASIK.

2.12. Willful ignorance, negligence or outright fraud is intolerable.
Aristophanes once wrote "Youth ages, immaturity is outgrown, ignorance can be educated, and drunkenness sobered, but STUPID lasts forever." There are common laws applicable at both the Federal and State level regarding these issues.

2.13. The Petitioner believes that Ophthalmologist have demonstrated a willful disregard for safety and fundamental human rights. Further, they have put their own totally self-serving interests ahead of their patients contrary to medical ethics and the law. In addition, the FDA and other Federal agencies have obviously been involved in collaborating and corruption. Thus, the petitioner requests that all medical devices used by Ophthalmologists be legally evaluated and reviewed.

2.14. Commonsense and scientifically based guidelines to provide guidance to the FDA for IDEs are Not followed by the users of these FDA regulated medical devices.

Apparently Dr. Morris Waxler, for instance, provided guidelines including "exclusion criteria" for patients. These guidelines were Not followed by the FDA to the Petitioner's knowledge. For instance, LASIK Doctors are Not required to even measure intraocular pressure or even ask about or test for a history of glaucoma. Yet the microkeratome exerts a serious amount of pressure during LASIK and is obviously harmful for patients who may already have glaucoma.

These and other ommisssions are obviously intentional and known to harm patients.

"History of glaucoma or an intraocular pressure > 21 mm of Hg."

Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers

**This document is intended to provide guidance in the preparation of a regulatory submission. It does not bind the FDA or the regulated industry in any manner.**

**http://www.lasikinfocenter.net/Regulatory%20Agencies/FDA%20Checklist%20for%20Device%20Approval.htm**

Dr. Waxler clearly assisted the FDA and the Ophthalmic devices panel.
http://216.239.51.104/search?q=cache:MVEBvrMVIwsJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/99/transcpt/3528t1.doc+morris+waxler+lasik&hl=en&gl=us&ct=clnk&cd=30

As an innovative regulatory manager and regulatory scientist at FDA for 26 years, Morris provided key leadership in regulating eye, ear, nose and throat devices. The following accomplishments are particularly noteworthy:

- He managed a team of 6 scientists in the evaluation of approximately 1,000 medical device applications each year.
- He built consensus on key engineering and clinical criteria needed for marketing approval of lasers for refractive surgery.
- He increased the number of marketing applications approved for lasers to treat refractive errors from two to 17 (eight different lasers).
- He widened the scope of refractive indications for marketed lasers from "surface" (PRK) to "flap" (LASIK) treatment and from treatment of a restricted range of nearsightedness to treatment of a wide refractive range of nearsightedness, farsightedness, and astigmatism.
- He helped formulate enforcement actions that eliminated more than 100 illegal refractive lasers from the marketplace while maintaining the scientific and regulatory integrity of the pre-market approval process.
- He negotiated resolution of FDA disputes with ophthalmologists and manufacturers on clinical trials resulting in FDA approval of the VISX and Summit lasers for LASIK treatment of nearsightedness with astigmatism.

http://www.gklaw.com/attorney.cfm?attorney_id=394

2.15. FDA regulated medical devices are supposed to be "regulated" by the FDA and follow public health guidelines established by the CDC (including sterilization), but they are Not. Also, the CDC guidelines that exist are woefully inadequate to protect the public health. Specifically single-use devices cannot be sufficiently cleaned and effectively sterilized and thus any reuse is an adulterated use of the device. Further, this reuse has no patient benefit and lacks informed consent from patients. Therefore, it is an adulterated use (potentially a criminal use) rather than an off-label use for the benefit of a patient. Even worse, the FDA has knowingly waived conflicts of interest regarding those who advise them on what to do (it's in the transcripts of the medical device panel meetings- e.g., the ophthalmic devices panel regarding the approval of devices for lasik including microkeratome blades).

Furthermore, Off-label use without informed patient consent is also an adulterated use of a regulated medical device. ALL additional surgeries after the first surgery are Off-label uses of medical devices for LASIK (because they are Not proven to be safe or effective) and the Petitioner is aware that almost all patients are Not receiving informed consent of this fact.

2.16. There is a history of numerous users of FDA regulated medical devices (Medical Doctors practicing LASIK) using "adulterated" devices contrary to the FDA's regulations and/or outside the practice of medicine. The FDA in fact has fined several Doctors and even seized several adulterated lasers.

The FDA has an obligation to protect the public from injury and/or an adulterated or misbranded use of any regulated (or non-regulated) medical device whether or not practice of medicine is involved. This just makes common sense and is clearly within the FDA's regulatory authority and jurisdiction.

For instance, in a national survey of thousands of medical Doctors, 21%+ admitted to reusing microkeratome blades contrary to their single-use disposable device labeling (an adulterated and misbranded use). 70% of these Doctors admitted to intentionally doing treatment zones smaller than the patients' pupil size contrary to more recent FDA labeling guidelines. Likely these practices are continuing to this day (see J Cataract Refract Surg. 2005 Jan;31(1):221-33; http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15721716&query_hl=1 ).

2.17. Risk of Night Driving Difficulty
Due to the creation of the flap and the fact that the flap size alone prohibits wider treatment zones (flaps are Not perfectly centered and are often less than the allowable size of the treatment zone), LASIK has a substantially higher risk of night vision problems than PRK including actual difficulty with night driving.

LASIK with the Nidek laser is known from the clinical trials to CAUSE actual night driving difficulty in over 2 out of 3 patients (69%).

On p.24 of 31 of the pdf (p.9 of the document) here
http://www.fda.gov/cdrh/pdf/P970053S002c.pdf

- **Difficulty in night driving (26.2% pre-operatively vs. 69.0% post-operativcly).**

2.19. Other

**Incidence of corneal Scarring and a lot of other problems increase (e.g., cell migration, cellular lose including, but not limited to endothelial cells, collagen fiber loss, etc).**

3. Actions requested--What rule, order, or other administrative action does the petitioner want FDA to issue, amend or revoke?

Although this petition is lengthy, one of the main points of this petition is very brief and compelling. **PRK or epi-LASEK is indisputably safer than LASIK (how much can be debated), but there is NO known benefit for LASIK vs. this alternative.** Contact lenses are riskier than eyeglasses, but they also have an additional benefit. Because LASIK has NO additional benefit vs. PRK/LASEK (hereby referred to as PRK or epi-LASEK), LASIK MUST STOP according to the FDA's criteria based on a proper risk-benefit analysis.

A brief synopsis of Potential disadvantages of LASIK vs. PRK for the patient are:

1) an increased risk of serious complications leading to significant visual loss
2) an increased possibility of an unpredictable outcome
3) an increased risk of potential dissatisfaction with the side effects of the surgery

To recommend LASIK surgery, the FDA or a medical Doctor would have to be certain there will not be an unnecessary risk of a vision threatening complication, that the outcome will be predictable, and if the outcome is predictable that the patient will be satisfied with the quality of their vision in the real world. Because these three conditions and more are uncertain, the FDA or Doctors cannot in good conscience recommend this to patients. If the primary responsibility as physicians is to always do what is in the patient's best medical interest, it's impossible to justify elective LASIK surgery. The disadvantage to the government is the potential magnitude of a Public Health claim in the event of significant loss of vision.

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.

**3.1** ACTION 1. The Petitioner requests that the Use of Medical devices and their components used for LASIK (in accordance with existing regulations) should be stopped Or a moratorium placed on their use (a partial or full withdrawal of approval).

The severity, totality of the risks (and their likelihood) of actual injuries to the public that have occurred from the actual practice (including non-research centers) of non-medically necessary elective Refractive Eye Surgeries are a larger risk to the public health than identified in previous research and Prudent injury intervention strategies are Not feasible to adequately protect the Public from injury.

There is a precedent for this recommendation: "The Food and Drug Administration today called for a moratorium on the use of silicone gel breast implants until new information on their safety can be thoroughly reviewed by an independent advisory panel and the agency can make a final decision in light of the panel's review." (http://www.fda.gov//bbs/topics/NEWS/NEW00263.html).

> "There is a solution to many of the problems that undermine sound health. In a word that solution is prevention. Prevention, which includes health promotion and education, saves lives, improves the quality of life, and, in the long run, saves money."

The Encyclopedia of Health, p.8. C. Everett Koop, M.D., Sc.D. former Surgeon General, U.S. Public Health Service. "PREVENTION AND EDUCATION: THE KEYS TO GOOD HEALTH.". Medical Issues. MEDICAL ETHICS. Dale C. Garell, M.D. General Editor. Jeffrey Finn and Eliot L. Marshall.

**PRK or epi-LASEK is indisputably safer than LASIK (how much can be debated), but there is NO known benefit for LASIK vs. this alternative.** Contact lenses are riskier than eyeglasses, but they also have an additional benefit. Because LASIK has NO additional benefit vs. PRK/LASEK (hereby referred to as PRK or epi-LASEK), LASIK MUST STOP according to the FDA's criteria based on a proper risk-benefit analysis.

3.2 ACTION 2. The Petitioner believe that the potential risks versus possible benefits assessment favor a moratorium and/or withdrawal of FDA approval for these devices Or a moratorium on any further non-medically necessary elective eye surgeries other than for strict humanitarian purposes

Conduct and provide a thorough Risk-Benefit Analysis.

There is a precedent for this recommendation: "The FDA brings together its General and Plastic Surgery Devices Panel to review all of the safety data from the manufacturers' PMA's. The purpose of the panel is to advise FDA as to what they could tell the public about the safety and effectiveness of the silicone breast implants based on the PMA's. The panel is composed of a broad range of experts, including representatives from the fields of plastic surgery, oncology, epidemiology, internal medicine, immunology, radiology, pathology, gynecology, toxicology, sociology, biomaterials and psychology, as well as industry and consumer groups. The panel hearing rejects the data from Dow Corning, Mentor, McGhan, and Bioplasty, concluding there is not sufficient data about the risks and benefits of the devices. The panel recommends the devices stay on the market temporarily and with limited access. The need for more safety data is stressed." (http://www.pbs.org/wgbh/pages/frontline/implants/cron.html)
Review each of these class I devices to assess whether the device is EITHER as safe or substantially equivalent to the legally marketed devices that were or are currently on the U.S. market that the manufacturers used for comparison purposes in their 510(k) submissions for their PMA approvals (http://www.fda.gov/cdrh/dsma/pmaman/front.html; http://www.fda.gov/cdrh/dsma/pmaman/Table%20of%20Contents.html#TopOfPage). As part of this surveillance process, the Petitioner also ask the FDA to consider whether the manufacturers certification that "a reasonable search of all information known or otherwise available about the class I device and other similar legally marketed devices has been conducted (class I certification) (k) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted." Is reasonable based on the available evidence at this time. (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807). See Appendix B and C for further discussion and consideration of this action.

3.3 ACTION 3. Hold an Ophthalmologic advisory panel meeting to consider the research, medical ethics, and any surveillance data to decide whether there is now sufficient data on safety and effectiveness for these class I devices to continue to serve a public health need and whether they

should continue to be approved by the FDA. At what point are the risks of certain types of procedures, equipment or procedures significantly higher such that they should banned?

3.4 ACTION 4. Oversee the entire life cycle of these devices--from production through distribution, and consumption/use of these class I devices to assess whether the products are as safe as labeled and safe period as stipulated in their PMA approvals.
The Petitioner challenges you to review suggestive findings regularly to identify how some modifications to the potential "candidates" might be safer for the Public Health. Isn't the first priority to "first do no harm"?

For the Agency to oversee their entire life cycle--from production through distribution, and consumption/use of these class I devices to assess whether the products are as safe as labeled and safe period as stipulated in their PMA approvals. Along with this after market surveillance process, the Petitioner also ask the FDA to reconsider whether the potential risks versus possible benefits assessment favor this action, whether SSED documents provide a reasonable assurance of safety and effectiveness for the device as labeled based on the non-clinical and clinical studies described in the PMA, and whether the SSED accurately summarizes both the positive and negative aspects of the scientific evidence as required for each PMA (http://www.fda.gov/cdrh/dsma/pmaman/sec03.html#P784_26552). The Petitioner also ask the FDA to consider whether the manufacturers certification that "a reasonable search of all information known or otherwise available about the class I device and other similar legally marketed devices has been conducted (class I certification) (k), and whether all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted and was reasonable based on the available evidence at that time" (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807).

3.5 ACTION 5. Conduct a retrospective comprehensive study of the incidence and prevalence of injuries to track ALL the relevant risks. Gather and collect all surveillance and monitoring data to allow proper education and targeting of interventions. Could the Medical Device Surveillance Network, MedSuN program be used for this purpose? The United Sates Eye Injury Registry (USEIR; http://www.useironline.org/Index2.html), a federation of state eye registries, uses a standardized form to obtain voluntarily reported data on eye injuries.
Many public health safety issues have Not been adequately researched.

3.6 ACTION 6. If newer devices become available which have better safety records, then remove the approvals for the older devices. For instance, Intralase lasers have been shown to have a much better safety record (as much as 10 times fewer problems and less serious problems) than mechanical Microkeratome blades for making LASIK flaps. Simply remove the approvals for the older mechanical Microkeratome blades unless they can be shown to be as safe as the newer Intralase lasers.

3.7 ACTION 7. Develop a national agenda for the prevention of injuries from elective refractive eye surgery and implement it through coordination of federal efforts across a variety of private and public agencies including the Department of Health and Human Services.

Uniform legislation should be required by law, enacted and enforced in every state to mandate specific minimal safety practices.

3.7.1. Standardized methodological procedures should be identified and addressed. Doctors should be contacted and notified about their ethical DUTY TO WARN. Please contact the Doctors who no longer do LASIK for verification of this information.

3.7.2. Improper use of equipment or procedures, or product malfunctions must be reported to CDRH. The FDA must enforce penalties that require accurate reporting.

3.7.3. Other requirements to be determined by future research.

3.7.4. Standardized equipment preparation and cleaning procedures should be identified and addressed. For instance, other instruments used with these PMA devices could be evaluated to minimize bacteria and other problems (that can cause DLK or the transmission of diseases between patients such as CJD). The Only way to adequately protect the public health from the adulterated reuse of microkeratome blades is for the FDA and HHS to say ANY sterilization is Not sufficient. That's the truth. It would take 5 minutes for anyone there to just put it in writing to the FDA and stop this travesty. The benefits outweigh the cost.

3.8 ACTION 8. Request an independent investigation of the Government including specifically the FDA. These investigations could be conducted by the Office of the Inspector General, the Department of Justice, Congress, the Senate, Office of the Attorney General, or other departments of the Federal Government. The purpose of the investigation could be to correct the problems pointed out in this petition and/or evaluate pressing charges against advisors or employees of the FDA or government officials involved in any criminal activity including, but not limited to racketeering or breach of Federal laws.

**For instance, the Petitioner believes an FDA Document (see** http://www.fda.gov/cdrh/ode/guidance/1604.html) **issued on: September 18, 2006** may violate Title 21 and other Federal laws regarding Class I microkeratome blades that are licensed as single-use disposable devices. I also believe that the devices should Not be allowed to be reused (reprocessed or otherwise) on multiple patients due to their contact with highly infectious material, increase in complication rates, and degradation.

The FDA has decided to continue to say that 2 out of 3 people having "night driving difficulty" after LASIK on the Nidek EC5000 laser used on me is "safe", but "not perfectly safe" even though there are other lasers out there like the Allegretto with 0% incidence of night driving difficulty afterwards. The FDA continues to approve lying to patients before they have LASIK, RAMPANT adulterated use of these Class I and Class III medical devices (telling patients it's FDA approved when in fact it's a DANGEROUS off-label use known to injure a percentage of patients), violating the labeling of the devices, etc. Just one of many examples is that the Doctors tell patients they provide a "taper zone", "treatment zone", or "blend zone" that goes wider (e.g., 9mm) when in fact it's a doughnut shaped ring of fixed depth that does not taper or add to the actual optical zone.

The FDA exerts a Federal pre-emption in court when patients litigate against their Doctors or the manufacturers for lack of informed consent or any other issue within their jurisdiction. There must be some way to get justice from a corrupt government.

I believe a jury would agree that when the government says a Class III medical device (the MOST dangerous) is "safe" to use on patients knowing it seriously injures 1% or more patients that it should be as safe and as heavily regulated as flying. Everyone would be shocked if they got on a plane and had a 69% chance of being injured when you get off. Everyone would be shocked if their Doctor reused a blade on them that was required to be a single-use device under Federal law and the government and other regulatory agencies did Nothing about it- didn't even investigate at all. The medical board said they wouldn't do anything about Dr. O'Day despite the evidence I submitted- including a letter specifying 9 breaches of the standard of care and his own website where he admits reusing the blades.

3.9 ACTION 9. The Petitioner asks the FDA to review whether or Not a 510K approval is even appropriate for a dangerous medical device that can and does cause serious injury including blindness. The Petitioner believes only a PMA is a sufficient degree of approval. In addition if warranted and appropriate, the petitioner requests multiple investigations and seeks to press criminal charges. There is a lot of Federal and State law in support of this request.

3.10 ACTION 10. The Petitioner asks the FDA to launch an investigation of any and ALL users of these regulated medical devices (e.g., Doctors) suspected of violating the FDA labeling and/or using these devices in any type of adulterated manner (including evaluating criminal charges) OR off-label use without patient benefit or without informed patient consent (which is also an adulterated use of a regulated medical device). ALL additional surgeries after the first surgery are Off-label uses of medical devices for LASIK (because they are Not proven to be safe or effective) and the Petitioner is aware that almost all patients are Not receiving informed consent of this fact.

3.11 ACTION 11. Work with the petitioner, medical Doctors, and/or others to come up with other ways to adequately protect the public health.

4. Certification
To the best of the Petitioner' knowledge, the petition includes the information relevant to the petition, favorable or not.

5. No known Environmental Concerns.

Sincerely,

Michael Patterson 12/13/2006

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