

APRIL 25th 2008

**OPHTHALMIC DEVICES PANEL
MEETING**

**WRITTEN
COMMENTS**

Warburton, Karen

From: -----
Sent: Friday, April 04, 2008 11:05 AM
To: Warburton, Karen
Cc: [REDACTED]
Subject: Lasik

My name is ----- I had the Lasik procedure done almost a year ago. It has changed my life for the better. I can see clearer ----- don't need to mess around with contacts or remember where my glasses are. I was put into contacts 2-3 years ago and within a short time I became contact intolerant. There is not a day that goes by that I am not grateful to the procedure and what it has done for me. My friends and family have all said this was the best decision I had ever made. A lot of what makes the Lasik procedure so successful has to do with a wonderful informed doctor. Which I was very lucky to find in [REDACTED].

I believe people who have had negative effects from this procedure is not just related to Lasik itself. I believe it has to do with the quality of the doctor, underlying health issues, and doctors allowing this procedure to take place when it may not be an appropriate avenue for a patient.

There is always good and bad in any surgical procedure as well as with any medication. Instead of pulling services like Lasik off the market, maybe we should have a better criteria in choosing patients who would make good candidates for this procedure.

Thank you for your time

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: EFFECTS OF LASIK

MS. WARBURTON

I HAD LASIK EYE SURGERY ABOUT SEVEN YEARS AGO AND HAVE BEEN EXTREMELY PLEASED WITH THE RESULTS. MY VISION WITHOUT GLASSES WAS VERY BAD AS I COULD NOT SEE THE ALARM CLOCK BY THE BED ONE FOOT IN FRONT OF MY FACE WITHOUT PUTTING ON GLASSES.

BEFORE THE SURGERY, I NEEDED GLASSES ALL THE TIME WHICH CAUSED PROBLEMS EVERY TIME I WANTED TO DO SOMETHING WHERE GLASSES COULD NOT BE WORN. EXAMPLES TAKING MY KIDS ON SOME FAST RIDES AT THEME PARKS, GOING IN THE OCEAN, POOL OR WATER PARKS, AND JUST COMING INTO THE HOUSE FROM THE COLD THE GLASSES WOULD FOG UP.

THESE ARE JUST SOME OF THE AREAS THAT GLASSES WERE A PROBLEM. NOW I CAN DO OR GO ANYWHERE I WANT AND NOT HAVE TO REMOVE GLASSES CAUSING ME TO NOT SEE WHAT WA-----

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: _____

Dear Ms. Warburton-

I had LASIK surgery last year. My decision. LASIK has positively affected my life. I am a college student at _____. With a rigorous course workload, I am always rushing and have little time for things such as putting on contacts. Also, there is always the chance of one ripping or falling out, disabling me to participate fully in my classes. Luckily, having done LASIK I don't have to worry about bringing my glasses or an extra contact in the event of anything happening to them. That has decreased the amount of stress in my day and has allowed me to live more free in a sense. As for social activities, it goes without saying that my social life makes up the other half of my academic career for the most part. I know how I would be able to participate in school held events, be in organizations such as the Activities Board, or even have a life outside of school off-campus without having the weight of my "responsibilities" lifted off my shoulders." I used to do service work at a local nursing home and rehabilitation center for the elderly in high school. After getting my LASIK done during the second half of my service career, I felt relieved and better equipped to assist the elderly to my best ability. Hopefully this is sufficient in expressing my happiness with the quality of life effects of LASIK. If you need anymore, please contact me at the above email address. I look forward to hearing other positive reviews about this surgery.

Warburton, Karen

From: _____
Sent: _____ PM
To: Warburton, Karen
Subject: lasik -odp meeting April 2008

This is to inform you I am in total support of the LASIK PROCEDURES.

I am a Operating Room Technician/OR Assitant.

I had this procedure done in 1997, I had no problems post op, I was told as I grew older I would require reading glasses.

I am presently 61 yrs. old have 20/20 vision in both eyes. I wear reading glasses for fine print.

I believe that patients who do not comply with post op instructions, and did not listen to the preop explanation of the procedure have unreal expectations as to the outcome.

Warburton, Karen

From: _____
Sent: Wednesday, April 02, 2008 4:57 PM
To: Warburton, Karen
Subject: lazik

Dear Karen,

My name is _____ and I had lazik surgery on both my eyes by _____ in 2001. I feel that the quality _____ improved by this surgery by no longer having to wear eyeglasses. I have two children and in 2001 a newborn and toddler. To not have my glasses pulled off my face may sound silly but with children it happens all the time. I loved the procedure and would do it in a heartbeat again if needed (after all these years _____ ect eyesight). Please feel free to contact me either via return e-mail or by phone _____ if I can be of any assistance. I should mention too that not wearing glasses has improved my self confidence as a woman just by feeling that I look better without the old "4 eyes".

Sincerely,

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: LASIK hearing

I would like to relate to you my very positive experience after LASIK surgery to add to the cases presented in the upcoming FDA public hearing.

I had LASIK in 1999 by _____ in _____ Before the surgery I was completely dependant on glasses or contacts and my glasses power was minus 6. He did an amazing job and I now see 20/15 in each eye, yes better than I ever could see with glasses before the surgery. The first year I had some issues at dusk with a slight haze to the vision but that has resolved and been more than offset since, with an incredible increase in my quality of life. I love it. Nowadays, with custom LASIK, pupil sizing, and eye-tracking software my friends are having great success from the start. I can't imagine what the future will hold but it seems to be just getting better with LASIK. As with anything, I'm sure there are some fly-by-night operations that offer kickbacks to optometrists for referrals and I've heard that sometimes people only see their surgeon on the day of surgery and he/she doesn't even meet or examine the patient before the surgery or take care of them after the surgery, but these hopefully are the exceptions. The public does need to be aware that if someone is offering to do their LASIK for \$299 there has to be something fishy about that.

In summary, I only wish that I could have had LASIK sooner in life so that I could have enjoyed water-skiing, and snorkeling, and have been a safer driver, but the technology wasn't advanced enough back then. Please include my comments as part of the Ophthalmic Devices Panel meeting.

April 14, 2008

To Whom It May Concern:

This letter is in reg-----erience with LASIK surgery. I have worked as a technician with Dr----- for almost two years. In that time, I have seen thousands of post operative LASIK patients who were extremely happy with their vision following their procedures. Our patients have referred family, friends, coworkers and acquaintances to us for LASIK surgery based on their excellent results.

Based on the thousands of good results I have witnessed at-----office, I decided to have LASIK surgery myself. I am extremely happy with m-----llowing my procedure. I have recommended LASIK surgery for my parents, who have also been very happy with their vision following surgery. I would not hesitate to recommend LASIK surgery to anyone considering it in the future.

Please feel free to contact me if necessary at -----

Sincerely,

Warburton, Karen

From: -----
Sent: ----- 08 11:49 AM
To: Warburton, Karen
Subject: LASIK

I had bladeless LASIK surgery in December 2004. Before my surgery, I was wearing glasses and was unable to function without them. It had gotten to the point where I would sleep in my glasses in order to see the alarm clock as well as be assured that in an emergency, I could find my way to my children. I was never able to wear contacts and my glasses kept me from doing many things that I enjoyed. For instance, I was out on my boat alone one day and my glasses fell off and into the river. I had to call for someone to get a boat to me with someone to drive my boat into dock. It was frightening to think what would have happened had my cellphone not worked. That's when I knew it was time to consider LASIK.

Since my surgery, I have had 20/15 vision in both eyes. The freedom it has allowed me is immeasurable. I no longer have to worry what would happen if I lost my glasses. [REDACTED] truly helped me get a new view on life.

Ophthalmic Devices Panel meeting. In your own words, how has LASIK affected the quality of your life. Examples may include your enhanced personal safety, your ability to do your job, your participation in social activities, and, if you are involved in public safety activities (police, firefighter, nurse, doctor, etc.) how has LASIK helped you to be more effective?

Thank you,

~~_____~~

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~~Pack up or back up - use SkyDrive to transfer files or keep extra copies. Learn how~~

: Sun, 6 Apr 2008 22:21:24 +0800 (CST)
:
:
: Pat-----r - LASIK
:
: -----

To Whom It May Concern

Date: 06 April 2008

I'm received LASIK surgery on 03.03.2008.

After the LASIK procedure, I am no longer dependent on my glasses or contact lenses. This has enhanced my personal safety. My quality of life has improved since then. The LASIK procedure has helped me to be more effective in performing my job without visual aids. I could also participate in sports and social activities more freely.

Thank you for your attention.

Yours sincerely,

Name: -----
Address-----
Phone: -----

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Cc: _____
Subject: _____d your help

I started wearing glasses when I was 6 years old. I bought my first pair of contacts when I was 13 years old. I tried contacts but they would irritate my eyes because I was not producing enough tears. Every year I would have to buy new glasses because they would break. I had the Lasik surgery done almost 2 years ago and it has changed my life for the best financially, physically and emotional. Being a single mom and now with 20/20 vision, I am able to enjoy life with my daughter and without paying the extra-----g new glasses every year. The doctors, nurses and receptionist (S-----) were exceptional. They were very professional and took great care of my needs from start to finish. This-----e best decision I have ever made. I thank ----- for their excellent service every day. I am so grateful that for the first time in my life I don't have to wear glasses. I recommended their service to all my friends and colleagues which they have also had the procedure done and are extremely happy as well of out come. Banning this service is a huge mistake. There are so many things in this world that should be ban except this service.

Thank you for listening.

Topic: Lasik/PRK

-----Original Message-----

From: S----- [mailto:-----]
Sen- -----, April 05, 2008-----
To: -----
Sub- ----- E N T - We need your help

Dear Patient:

An anti-LASIK group has asked the FDA to ban LASIK.

We need your help now: please tell the FDA that LASIK (or LASEK, or PRK) is a great procedure and that the opportunity to have LASIK should not be denied to future generations. Send your e-mails to Ms. Karen Warburton at the FDA: karen.warburton@fda.hhs.gov. Be sure to include the following:

Your Name
Your Address
Contact info: email or phone
Topic: LASIK

The deadline for sending your email is April 14.

State in your email that you want the comments to be included as part of the record of the Ophthalmic Devices Panel meeting.

The FDA wants to know how LASIK has changed your quality of life - for example, your every day life,

your leisure, your ability to do your job, even your personal safety. If you are a police, firefighter, nurse, doctor, etc, how has LASIK helped you to be more effective? The more specific you can be, the more effective your letter will be.

Thank you for working with us to help future patients enjoy life without glasses or contact lenses.

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: LASIK

Contact info: _____
Topic: LASIK

I am writing this E-mail to inform you of my incredible experience after having the LASIK procedure by _____. Prior to having the LASIK procedure, I was wearing contacts for approximately 12 years. My eyes would always irritate me, my contacts would break, and they became a constant nuisance. I had the LASIK procedure performed in May 2007. I ca----- never been happier and it is the best thing I have spent my money on. I have been a Deputy Sheriff with the ----- Office for three years now. After having the LASIK procedure, I can see clearer than contacts, perform dail----- efficiently, have no eye irritation besides the slight dry eye from time to time, perform better at work and safer, and have an overall better quality of life. Having LASIK allows me to not worry about getting into physical confrontations at work and my contacts falling out. I can see license plates better and other details that allow for an efficient means of performing my job responsibilities. I was quite hesitant to first get LASIK after knowing the possible side effects and recovery. However, _____ and his staff made me feel comfortable and relaxed and my eyesight is now perfect. I recommend LASIK to anyone who has problems with glasses or contacts and would have to say it is the best investment I have ever made. I wish the comments contained here could be a part of the Ophthalmic Devices Panel Meeting.

Thank you,

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: LASIK

April 7, 2008

Ms. Karen Warburton

Food and Drug Administration

Via Email: karen.warburton@fda.hhs.gov

Dear Ms. Warburton:

Good afternoon, my name is [redacted] [redacted] [redacted] [redacted] I understand there is to be a public hearing on the quality of life impact concerning LASIK. Please accept this email as a testimonial of the amazing difference in my life since my LASIK surgery on November 19, 1999.

I consider LASIK a modern-day miracle. I am now 50 years old and enjoy perfect vision! It was exactly 3 days after my 42nd birthday over 8 years ago that I was set free from the burden of contacts and glasses. I remember being able to read automobile license plates on the way home from my LASIK procedure that very day! A miracle indeed for someone as severely nearsighted as I was – totally dependent on glasses and contacts from age 7 to age 42.

Today I enjoy all activities without the stress of being unable to see. From being able to swim at the beach to simply setting my alarm clock, or seeing the shampoo bottle in the shower. (I was considered legally blind.) I feel safe when alone at night, because I can wake up and see without having to fumble for glasses should there be a nighttime emergency. Oh how I wish I

had had this perfect vision when my boys were babies – getting up with them all hours of the night.

I feel truly blessed to have the vision I enjoy every single day. Please do not hesitate to contact me if I may provide further information. I will be most happy to assist you so that others may be able to benefit from the miracle of LASIK.

Sincerely,

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: LASIK

Karen –

My name is _____ and I received LASIK eye surgery in October 2007 at the _____ I wanted to correspond _____ t you know how much LASIK has improved my quality of life. It has significantly enhanced my overall vision. I was a long-time contact lens wearer but about 10 years ago, my eyes dried out and I was forced to become a full-time glasses wearer. The LASIK has allowed me to be free from my glasses, which are a significant burden. It really has been a life changing event for me and I wouldn't change it for anything. I had a little bit of dry eyes early on in the process but it went away fairly quickly and has been excellent since that time.

You can contact me if you need any additional information.

Thank you for your time,

From: -----
Sent: Sunday, April 06, 2008 10:38 AM
To: Warburton, Karen
Subject: LASIK

Name: -----

Address-----

Contact info: -----

Topic: LASIK

As----- City Firefighter, I have come to expect a high degree of quality and service from the city I work for and grew up in. It is the policy of my department that we provide high quality customer service to our community. It was therefore important to me to have the best vision that I could possibly have. Wearing glasses was dangerous and required that I keep many extra pairs should something happen to one of them. LASIK has given me the freedom to focus on public safety and well as my own. This is why it was surprising and distressing that there is any question on the benefits and freedom that LASIK provides to those individuals, like myself that has had the procedure.

Suffice to say that I feel considerable disappointment with the direction the FDA is considering taking. Please consider those individuals who have not had the benefit of corrected vision that LASIK provides.

Thank you,

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: lasik surgery

Hi Karen

My name is _____ and I am a police officer in _____. I had lasik about 4 years ago and not a day goes by that I do _____ ate what it has done for me. As a police officer I need to see things more clearly for not only observing occurrences that occur around me but also for officer safety.

I would not change a thing and my doctor was great.

Thanks for reading

Warburton, Karen

From: _____
Sent: _____ PM
To: Warburton, Karen
Subject: lasik

As an ophthalmologist I have concerns regarding the long term results of lasik. although I do not perform lasik I have seen several patients with problems, most seem to be related to dryness but I _____e as well as corneal scarring with permanent loss of best corrected vision.

April 14, 2008

To all parties concerned:

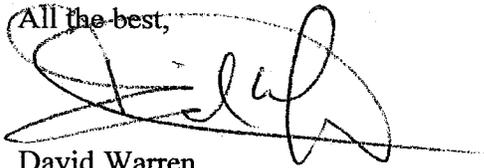
On March 21, 2008, I underwent "Cool-Touch LASIK" surgery performed by Dr. Jeffrey Whitman at the Key-Whitman Eye Surgery Center in Dallas, Texas. This is a testament to the satisfaction that I have received as a successful LASIK patient.

Prior to this corrective procedure my vision was so poor that I required glasses or contact lenses to perform most daily activities with any degree of satisfaction or enjoyment; I had simply grown accustomed to this lifestyle adjustment since my early teenage years. Now that I have enjoyed the benefits of clear vision I am very excited that I made the decision to undergo the LASIK procedure. I am experiencing enjoyment in nearly all areas of my day-to-day life: from waking up in the morning and being able to see immediately, to the benefit of exercising without the burden of contacts or glasses, I find that I am more energized during the day, and enjoying life more than ever before.

The staff at the Key-Whitman Surgery Center worked well together to ensure that I was informed, comfortable, and successfully treated in the pre-operative, operative, and post-operative stages of my vision correction. The biggest obstacle to overcome was the psychological component of the procedure: the idea that something was happening to my eyes. Dr. Whitman and his staff worked well in assuring me at all times, and I felt confident in all stages of my experience. There was actually minimal to no physical discomfort during my procedure, and the following days of healing went very smoothly. Now that my friends, family, and co-workers have seen my positive results, they, too, are interested in the LASIK procedure.

I am very happy and extremely satisfied as a successful LASIK patient. I look forward to years of renewed life and energy thanks to my corrected vision, and thanks to Dr. Whitman and his staff.

All the best,

A handwritten signature in black ink, appearing to read "David Warren", written over a horizontal line.

David Warren

2007 Orange County, Florida, Teacher of the Year

Classroom Teacher and Faculty Coach
Scott Johnson Middle School
McKinney, Texas

davemightbe@htomail.com



April 15, 2008

Ophthalmic Devices Panel
Division of Ophthalmic and ENT Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

By FAX to Ms. Karen Warburton at 240-276-4111.

Dear esteemed members of the Ophthalmic Devices Panel:

I have been informed that you will discuss post-market information about corneal refractive surgery, specifically vision quality and ocular surface disease, at your meeting on April 25, 2008. As an ophthalmologist who has undergone LASIK but does not perform refractive surgery, I am unusually well-positioned to interpret the available medical evidence on these matters without personal financial bias. After several years of immersion in parts of the refractive surgery literature, and review of data sources such as written FDA documents and MDR reports and the minutes of other ODP meetings, I have concluded that there are serious problems with the FDA's management of corneal refractive surgery clinical trials, device approval, and post-market surveillance, to wit:

1. Failure to listen to the visual psychophysicists when they presented optical models incorporating the pupil diameter and predicting the effects of a polyfocal cornea on contrast sensitivity, peripheral retinal sensitivity, and glare disability. Failure to acknowledge the concern that high-contrast best-corrected visual acuity was a poor proxy measure for safety, and that a procedure which reshapes the cornea should be judged topographically (in the pre-wavefront era).
2. Failure to ensure that the clinical trials included tests to *effectively* quantify perceptible visual aberrations (commonly described as starbursts and halos) induced by a polyfocal cornea overlying the entrance pupil, and to determine their impact on daily vision function (glare disability). The "20/happy survey" has proven its general worthlessness.
3. Unjustified statistical dependence on "average" outcomes to determine the safety and efficacy of a device, leading to suppression of important evidence about outlier patients.
4. Failure to enforce manufacturer MDR reporting; failure to determine that manufacturers were in violation of required MDR reporting for protracted periods of time.
5. Failure to adequately consider the financial disincentive of refractive surgeons to report poor post-market outcomes which might be device-related – "don't ask (the patient) and don't tell (the manufacturer or the FDA)." High-volume refractive surgeons have a certain amount of human misery built in to their business plans. As an example of the breakdown of voluntary reporting, for the VISX and Bausch & Lomb lasers there

are more patients described in the formal and informal literature with decreased visual acuity than there are MDR reports. If manufacturers allege that all these cases are surgeon-related, then there is a device-user interface problem.

Refractive surgery for many years was synonymous with corneal re-shaping. Recently several intraocular procedures have entered the marketplace, and I wish to reiterate that I do not refer to these techniques in this letter.

It is my understanding that a number of patients will attend the April 25 meeting to express their concerns in more personal terms. This is not the first time these issues have been raised by ordinary citizens (see the minutes of the ODP meeting, July 23 1999, Open Public Hearing).

Refractive surgery is the only procedure to alter the function of a healthy sensory organ. Compared to other vertebrates, human smell and hearing are nearly rudimentary, but our binocular vision is superior under all but low-light circumstances and accounts for the majority of our conscious sensory input. Abrupt, surgically-induced vision derangement in a previously normal patient can be both functionally and psychologically devastating. In other words, refractive surgery has an extremely high down-side risk. I urge the members of the Ophthalmic Devices Panel to advise the FDA to broaden its definition of "safety" to include *other psychovisual (subjective) components of vision*, and to work with manufacturers, clinical investigators and community eye care providers to reduce the frequency of damaging surgery.

Sincerely,

May 2000

David Shell
XXXXXXXXXXXXXX
XXXXXXXXXXXXXX

The Honorable James P. Moran
U.S. House of Representatives
Washington, DC 20515-4608

Re: LASIK SURGERY

1. Lack of FDA Regulation & Standards
2. Medical Specialty Credentialing & Peer Review
3. Outcomes Measurement Protocol
4. Truth in Advertising & Accountability

Dear Congressman Moran:

I am writing you, specifically, because of your well-respected integrity in the legislative process. When you talk, people listen.

I have discovered, through a devastating trauma in my life, that there are now thousands upon thousands of Americans who need someone in Washington to become an advocate for them in one particular aspect of the healthcare industry. The public needs to know what is happening in the field of ophthalmology. I hope that this letter results in your advocacy. Someone who is strong and astute in the political arena needs to save future victims from the same heartache and ill health that I have experienced as a result of an elective medical procedure I underwent over a year ago. I'm referring to laser vision correction (LASIK).

I have gone from a healthy, physically active, productive member of society to a man who has been diagnosed with clinical depression. A man whose eyesight, although reported post-op to be 20/20, is now destroyed, probably forever. A man who is becoming less efficient and productive, day by day, in his profession. A man who now spends over \$1,000 a month for psychotherapy, medication, glasses, eyedrops, for ongoing medical care and for travelling to visit medical specialists around the country, trying to get someone to correct a surgical procedure that perhaps never should have been done.

For over 20 years, I have resided in XXXXXXXXX. I am XX and employed by the XXXXXXXXXXXXXXXXXXXXXXXX as a XXXXXXXXXXXXXXXX. Prior to my elective surgical procedure, I enjoyed a lifetime of physical fitness and sports

activities including kayaking, hiking and gardening. I had been blessed with excellent vision with the aid of eyeglasses. But, the idea of being free of glasses appealed to me.

For nearly a year, just as the rest of the television-watching American public was bombarded by the enthusiastic sales pitches of surgeons who perform LASIK surgery, I began to believe that, as they say, the procedure is essentially "safe and effective". Reported statistics are phenomenal mainly that 98 percent of patients who have the surgery experience 20/40 vision, or better, without glasses. If this sounds too good to be true, it is.

Congressman, perhaps this will encapsulate for you the point I want to make. After undergoing the LASIK procedure in October 1998, I was reported to have 20/20 eyesight without glasses, but no one on earth would want my vision because the *quality* of 20/20 vision I have includes the following:

- ◆ Difficulty in reading due to ghosted letters caused by this surgery. I can no longer read effectively for any meaningful length of time.
- ◆ Increased sensitivity to light, eyes burn and sting or sometimes water profusely on bright days. This also occurs while watching television or working at a computer station.
- ◆ When looking at streetlights, starbursts like laser-light sabers from Star Wars emanate from them. Tail-lights on cars have plumes of light shooting from them. My nightlife has been ruined.
- ◆ Severe and persistent dryness causing burning and stinging of my eyes. I can not do my job as well due to the pain. Some days I need to apply eye drops twenty or more times that further blur my vision and only allow me temporary relief.
- ◆ Glare that once was not a problem now so strong that a hat, hand, or sun visor is needed for relief.

Please remember that my wearing glasses does nothing to correct these visual aberrations and this is the case for thousands of us.

My vision now fluctuates in three different ways: throughout the day (poorer vision in morning than afternoon), based on amount of light (poorer vision in shade than in light) and regression (unexplained permanent change in vision that occurs periodically). In the past

year, my vision has changed so that I have been required to purchase no less than seven pairs of glasses, at \$250 per pair. So rather than "Throwing away my glasses" as the ads say, I am far from that goal. The last time I had stable vision was before this surgery. I've given up trying to keep up with the changes. Glasses don't help much anyway.

I have traveled to the finest eye care clinics and ophthalmologists in the country, from Houston to Atlanta and finally to Johns Hopkins, all to hear that "you have irregular astigmatism in both eyes, caused by this surgery." Although each physician has remained guarded, as if they need to protect their colleagues, still, this has been the general consensus. There is no proven procedure to adequately fix my eyes.

I paid \$6,000 for this privilege. In investigating others with similar experiences, through the Internet, I have found web sites and bulletin boards of thousands of people describing the same experience I have had. Experiences of patients who like me, are post-op with what the LASIK surgeons are touting as 20/20 vision. How irresponsible is that? I'm not an isolated case this is a trend. There are thousands of us out there having these problems. What ever happened to "First do no harm".

And it's worsening, the blatant advertising, the infomercials disguised as public affairs shows, with physicians in white coats and their happy patients who basically can now come to shopping centers to have their eyes operated on. It's even more of a "Get your eyes done during your coffee break" mentality. A quick fix. A DANGEROUS quick fix. I learned after my surgery about the myth of the 20/20 measurement of success. The big "E" eye chart does not measure pain, stinging and burning of the eyes, it does not tell you anything about all the types of variable vision a person now inherits, it does not measure double vision, glare, starbursts, or contrast sensitivity. The big "E" eye chart is useless in measuring the success of this surgery - the general public does not realize this. The industry is misleading the public and interfering with a person's ability to make an informed decision about this surgery by using this chart to measure the success of the surgery. People make decisions based on these statistics derived from ones ability to read the big "E" eye chart. This is deception pure and simple and the eye doctors all know it. Shouldn't the FDA step in? Shouldn't someone in a position of responsibility and authority develop protocols and outcomes measurements that are accurate and meaningful? *Shouldn't someone be in a watchdog position to regulate*

this procedure and the false and misleading claims made in the advertising campaigns?

People need to know that even though this procedure only takes minutes, LASIK is a very serious surgery.

Congressman Moran, I am including various consumer reports for your reference as well as web sites that you may access to actually experience firsthand what we victims see. If I can provide you with any further documentation or information, please do not hesitate to contact me. Also I'm sending a copy of this letter to the Surgical Eyes Foundation.

Again, I thank you for your continued public service, for your integrity, and for your time in reviewing my letter and my circumstance. I wish only to protect those people who are setting up appointments every day because of slick TV ads that do not speak the truth.

Respectfully,

David Shell

April 11, 2008

Dear Ms. Warburton:

I applaud the formation of a task force convened by the FDA to document outcome and patient satisfaction from LASIK. A reported 5% of patients are not satisfied with their results and would not recommend that others undergo this procedure. One could argue that these are not bad results but for an elective procedure many disagree as evident by this call to task. Also we cannot ignore the fact that for every 100 people treated this 5% generates negativity to 65 people!

Although laser vision correction surgery has been performed for over 15 years, apparently the technical aspects of the procedures are in need of standardization, improved sterile technique, and implementation of design specific technology to better facilitate surgical maneuvers.

The persistent sub-optimal issues that cause DLK, infectious keratitis, epithelial under / in-growth, toxic keratitis, de-centered / off-axis ablations and an undesirable rate of under / over corrections must be better dealt with.

Enclosed is information on a system and method that I have designed and developed to specifically address most of the suboptimal issues that collectively result in less-than-desired outcomes and patient dissatisfaction.

In short, the surgical operations provided by this single instrument facilitate and allow for: enhancement of sterile technique, intra-operative flap protection, at-the-site plume evacuation, on-axis / centered ablations, a no-touch method of removing excessive beam masking surface fluids, backwash-free irrigation, instant aspiration of surgical debris, effortless flap repositioning, and accelerated, uniform flap adhesion.

Using this multifunction tool allows me to perform a cleaner, more standardized, efficient procedure while eliminating extraneous manipulations and instrumentation resulting in fewer re-operations and complications.

The use of this device is also advantageous for surface ablation procedures. In addition to desired functions common to both lamellar and surface procedures, the instrument delivers chilled BSS in a unique way to cool the target stroma and anterior segment of the eye to significantly lessen post operative pain and inflammation typical of traditional PRK. Postoperatively, the patients require minimal to no pain medication and their eyes are exceptionally white and quiet. It is also my belief that this method of comprehensively lowering tissue temperature may reduce incidence of stromal hazing.

Enrichment will only be achieved through our professional commitment to time and energy, to advance technology and surgical techniques. The challenge is on and the bar must be raised! Please call me on my cell 337-280-1321 if you have questions and if you would be interested in visiting and joining me in surgery.

Sincerely,

April 9th, 2008

Karen Warburton
Center for Devices and Radiological Health
US Food and Drug Administration Via: U.S. Mail & Email
9200 Corporate Blvd
Rockville, MD 20850

Re: Request for comments regarding vision correction surgery

Dear Ms. Warburton,

The intention of this correspondence is to respond to a US Food and Drug Administration's, request for information related to my vision correction surgery. My vision correction surgery was conducted some twelve (12) years ago. Dr. Marc Werner, of _____ was the physician on my case.

To say that I was absolutely thrilled with the results would be an understatement. My vision was 20/20 the day following the surgery and remains that way today. Dr. Werner and his staff provided me with a comprehensive education on what the procedure would entail, a clear understanding of the risks associated with the operation, a realistic post-operative recovery time-line, and finally, the requirements of diligent follow-up. At no time did I feel pressured.

Most importantly, Dr. Werner answered every one of my questions, put me at ease by explaining the procedure in a way that I could understand, went so far as to contact me at home the evening of the procedure to check on my comfort, and extraordinarily, provided me with his cellular telephone number in the event I needed to reach him. That being said, I have recommended Dr. Werner to my entire family and, no less than four (4) have had the surgery. Each of those procedures went off without a hitch.

The vision correction surgery and Dr. Werner have made a huge difference in both my personal and professional activities. I am able to do simple things like read an alarm clock, see a movie, play competitive tennis, do presentations from afar, drive a car, and more importantly, watch my children's school plays without the aid of glasses, which I frequently forgot or lost.

Please do not hesitate to contact me if you have any questions or comments.

Sincerely,

A handwritten signature in black ink, appearing to read "David A. Wind". The signature is fluid and cursive, with a large loop at the end.

David A. Wind JD, MS

Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

8 April 2008

To Whom It May Concern:

My LASIK experience has been nothing but positive. I was 27 when I decided to correct my vision with refractive surgery. My contacts constantly left my eyes dry and my vision blurry; my glasses were too strong and I had to take them off to read. It was definitely time for a change.

I had a thorough understanding of the risks and benefits of the procedure for at least 8 months before I finally decided to have it done. Though my sister works at a refractive surgery eye center, I do not consider myself biased toward refractive surgery. Certainly I was more informed than the average consumer in this particular instance, but her experience with LASIK did not stop me from being slightly nervous about the outcome.

I know my nerves were not necessary, I know there are plenty of safety procedures in place. Still, it's hard not to be nervous before a medical procedure – elective or no. Of course everything went well, the entire procedure felt routine, and I left the table with significantly improved vision. The next day I was seeing 20/15 in both eyes. It has been 6 months since I had LASIK and I am still seeing 20/15. I couldn't be more pleased with my results.

Regards,

April 8, 2008

Karen F. Warburton
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Dear Karen,

It is my understanding that letters have been requested from patients who have had Lasik. Although it has only been a month since my surgery, I have been very pleased with my results.

I am twenty-eight years old and had been in glasses since I was eight. When I was eleven, my mom let me get contacts but I had a terrible time adjusting. Even up until my surgery, I was getting eye infections every couple of months. My glasses prescription was never as good as my contacts, so driving at night was really a problem for me.

Because I had been in contacts for so long, I was a little apprehensive. My doctor made the entire process seem like second nature. Prior to the surgery, the counselor informed me of all the risks involved and was not guaranteed perfect vision. The improvement is miraculous. I see just as good after Lasik as I did with my contacts. I have recommended Lasik to all my friends and family and anyone who will listen to me brag about it.

Sincerely,

Dear FDA panel,

I had LASIK surgery in June of 2007, and it has been the best thing I have ever done for myself. Before surgery, I was wearing glasses and soft contact lens. I was not fortunate with wearing contacts it seemed that I always had an eye infection. It was so bad that I couldn't drive myself to work sometimes, so when I had this surgery done, it definitely changed my life, I now can go to bed at night and see the alarm clock across the room (which was very difficult to get use to after my surgery, I had to constantly remind myself that I didn't forget to take my contacts out). It is life changing and I have even sent my family members to have it done.

Sincerely,

Warburton, Karen

From: -
Sent: Friday, April 04, 2008 10:49 AM
To: [REDACTED]
Cc: Warburton, Karen
Subject: RE: [REDACTED]

NAME: -----
ADDRE- -----
E-MAIL: -----
TOPIC: -----

I WISH THAT MY COMMENTS BE INCLUDED AS PART OF THE MEETING.
THE QUALITY OF LIFE HAS BEEN LESS STRESSFUL, IN RESPECT TO THE CONSTANT DUTIES THAT GO ALONG WITH CONTACTS, AND HAVING TO FIND MY GLASSES, AS WELL AS THE ECONOMIC IMPACT THAT USE TO BE, AND NO LONGER IS. I DO NOT HAVE THE CONCERN OF AN EMERGENCY (EARTHQUAKE/FIRE, ETC) HAVING TO FIND MY GLASSES IN THE DARK, OR HAVING TO HAVE SOLUTION FOR CONTACTS IN CASE I AM UNABLE TO GET IN MY RESIDENCE. ALTHOUGH I AM NOT IN PUBLIC SERVICE I CONSIDER MY EYES HASSEL FREE, BUT A FEELING OF FREEDOM WITH MY EYES. I RECOMMEND THIS PROCEEDURE STRONGLY, I FIND DRIVING WITHOUT GLASS FRAMES IS MUCH BETTER, AND AM ABLE TO DO MY WORK WITH MORE ZEST AND ENERGY. MIGHT I MIGHT ADD THAT THE EXCEL LASER VISION INSTITUTE DID A SUPER JOB IN MY CASE AFTER WEARING CONTACTS FOR 20+ YEARS, IN MAKING SURE MY EYES WERE READY FOR THE LASER, THEY ALSO SHOWED ME THE BEFORE AND AFTER.

Date: ----- 14 -0700
From: -----
Sub----- titute
To:-----

Dear----- :

The U.S. Food and Drug Administration (FDA) has scheduled a public hearing on the quality of life impact of LASIK. The hearing will be held in April, but the FDA will accept e-mail testimonials sent by patients.

We strongly urge you to take a few minutes to write to the FDA, **the deadline for submitting comments is April 15**. It is critically important that the FDA get an accurate representation of how patients feel about the quality of life effects of LASIK, and you can make a significant contribution.

Send e-mails to Ms. Karen Warburton at the FDA: karen.warburton@fda.hhs.gov . Be sure your note includes the following:

- Your Name
 - Your Address
 - Contact info: email or phone
 - Topic: LASIK
- State in your email that you wish the comments to be included as part of the record of the

Ophthalmic Devices Panel meeting. In your own words, how has LASIK affected the quality of your life. Examples may include your enhanced personal safety, your ability to do your job, your participation in social activities, and, if you are involved in public safety activities (police, firefighter, nurse, doctor, etc.) how has LASIK helped you to be more effective?

Thank you,

████████████████████

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: Lasik

Ms. Karen Warburton,
My wife [REDACTED] and I recently made the decision to undergo lasik eye surgery. This was not a spur of the moment reaction to some advertisement. We spent several months consulting with friends and family members who have undergone this procedure as well as receiving a recommendation from our family physician. After carefully interviewing the surgeon of our choice and undergoing extensive pretesting we proceeded with the surgery. The day of the surgery we did experience slight discomfort, however I was driving the next day and within three days we resumed our active lifestyle which includes tennis, golf, night driving and biking.
I can emphatically state that this surgery enhanced our personal confidence and safety as well as improved our everyday quality of life.
For the record, before the surgery my vision was 20/275 with astigmatism, my wife [REDACTED] had similar circumstances, we now have 20/20 vision in both eyes and have the confidence to safely drive at night.
Please include my comments as part of the record in the upcoming Ophthalmic Device Panel hearings.

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: LASIK

Name: _____
Address: _____

E-Mail Address: _____
Phone Number: _____

I would like to express my overwhelmingly positive experience with LASIK surgery. Three years ago, after long deliberation and careful consideration, I decided to have the procedure done by a local ophthalmologist who specializes in LASIK. I am an emergency physician and clearly understand that any and all surgical carry with them some risks. I read about the risks and [REDACTED], the ophthalmologist who did my LASIK procedure discussed those risks carefully with me. My procedure went extremely well. I went from having very poor distance vision to having almost 20/20 vision. I had no complications and virtually no pain during the procedure. The procedure changed my life much for the better. I no longer have to wear uncomfortable contact lenses or glasses. I can actually see the clock when I awake. I must say this procedure, in my judgement, has much greater immediate benefits and much less risks (with much less pain) than most any other elective surgical procedure of which I am aware. Thank-you for allowing me to share my experience. Several of my colleagues have also had the procedure done by [REDACTED], and I believe each would simply echo my positive remarks. Do not hesitate to contact me if you need a more detailed testimony or further information.

Sincerely,

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: Topic: LASIK

Ms. Karen Warburton at the FDA:

I want to state that LASIK is a great procedure, I had it done January 2006 and it was the greatest gift I could ever have. It really shouldn't be denied to future generations. I've had the pleasure of not having to wear contacts or glasses since then. It was such a trauma to my eyes for 15 years. My eyes grew worse and worse every day to the point that I could no longer see without those devices. My occupation is a Physician Assistant and I no longer have to get up in the middle of the night to answer a pager I cannot find because of my ailing vision. This gift needs to be available to the appropriate candidates. I support it 100%

I want my comments to be included as part of the record of the Ophthalmic Devices Panel Meeting.
Thank you

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: Lasik

Hi: I have LASIK done February 2008 and is the best invesment I ever made. Change my life all around job, sports, and at home even improve my reading site. Thanks to [REDACTED]

Warburton, Karen

From: -----
Sent: -----:48 PM
To: Warburton, Karen
Subject: Lasik Eye Surgery

Attachments: spring_01.gif



spring_01.gif.gif (5 KB)

I just wanted to give a testimonial re: my experience with Lasik. I had my surgery 4 1/2 years ago and it was the BEST thing I ever did. I am in sales and am the mother of 2 children, I cant tell you how waking up in the middle of the night and fumbling for my glasses got in the way of taking care of my children. We also love to go to the beach and play at the pool and contacts were always a problem. Then in October of 2003 I went to see [REDACTED] in-----and was throughly impressed with the care I received there. It is very unfortunate-----s and centers are like this. I know there are cases were things have gone wrong...people should do their research!! This is an ELECTIVE procedure!!! To make this surgery unavailable would be a diservice to the millions of people who have had a good result. There are many centers out there who are just after the \$ and do not care what equipment they use and the potential harm they are causing. They FDA should be stricter for those discount centers that use bladed instruments and outdated lasers and surgeons of not the best qualifications. This is just one story of an EXTREMELY happy lasik patient.

Warburton, Karen

From: -----
Sent: Wednesday, April 02, 2008 2:17 PM
To: Warburton, Karen
Subject: LASIK

Attachments: ATT148459.gif

Since getting my LASIK surgery in August 2006, I have been able to enjoy swimming and sports at a whole different level. There is no worry that I will lose a contact. I also notice a huge difference after working a long day in front of the computer. My eyes are no longer dry and tired.

I would like my comments to be included as part of the record of the Ophthalmic Devices Panel meeting.

Thank you,

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: LASIK

Attachments: final.jpg; imstp_pets_cat1_en.gif

Hello my name is ----- . I recently had LASIK done to my left eye. I would like my comments to be included as part of the record of the Ophthalmic Devices Panel meeting.

I have wore glasses since age two. Prior to having LASIK done on my left eye I had something like 20/500 vision. With LASIK I now have 20/40 vision and can operate a motor vehicle without glasses. It is great to be able to get up in the morning and not have to look for my glasses before moving around. I will sometimes get up and will have been up for several hours before realizing that I should put on my glasses (which are needed primarily for reading). I'm 53 years old and have had a life of blurred vision. Now I find myself doing things without my glasses. I believe that LASIK has certainly changed my life for the better.

Thank-you

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: LASIK

Attachments: ATT159683.gif

Hello, my name is ----- and my contact information is below. I had Lasik surgery with ----- in 1999 and it was th----- r did! I have had absolutely no issues and happily recommended it to at least 40 other people at the company I worked for at the time. Everyone was very happy with the outcome. I feel much safer driving at night and I can do my job more effectively since I am on the computer all day long and must rely on my eyes. The difference was life changing and one I would highly recommend to any one who is a candidate for the surgery.

To Whom It May Concern

Date: 3 Apr 2008

I, [REDACTED] received LASIK surgery on 21 Jan 2008.

After the LASIK procedure, I am no longer dependent on my glasses or contact lenses. This has enhanced my personal safety. My quality of life has improved since then. The LASIK procedure has helped me to be more effective in performing my job without visual aids. I could also participate in sports and social activities more freely.

Thank you for your attention.

Yours sincerely,

March 31, 2008

To: The Members of the Ophthalmic Devices Panel, FDA

Dear Esteemed Members:

I am a certified optometrist who has been practicing in Israel for the past 45 years and I am addressing this letter in an attempt to point out a possible problem associated with the LASIK procedure.

In my practice I often meet pre and post LASIK patients. When I compare pre and post LASIK vision tests, I find that many of those patients have lost 10% to 30% of their quality of vision, regardless of vision acuity, even 3 to 6 month post op. My observations are obviously based on a limited number of patients and are therefore insufficient for drawing any statistically valid conclusions. However; these observations do establish a cause for concern and in my personal opinion, the reduction in the quality of vision could be the result of a loss of Contrast Sensitivity (CS) among the post LASIK patients.

To the best of my knowledge, there is no reliable study that had been conducted in the past in an attempt to research whether there is a loss of quality of vision among post LASIK patients. I would therefore like to submit for your consideration the idea that your task force recommend mandatory CS testing of all pre and post LASIK patients. The collected data could then be analyzed and the impact of LASIK on CS evaluated for its possible contribution to patient dissatisfaction and also for defining new or updated vision requirements for vehicle drivers, aircraft pilots, and other safety-critical occupations.

Thank you for your consideration.

Sincerely,



To Whom It May Concern

Date: 03 April, 2008

I [REDACTED] received LASIK surgery on 28 January, 2008.

After the LASIK procedure, I am no longer dependent on my glasses or contact lenses. This has enhanced my personal safety. My quality of life has improved since then. The LASIK procedure has helped me to be more effective in performing my job without visual aids. I could also participate in sports and social activities more freely.

Thank you for your attention.

Yours sincerely,

Warburton, Karen

From: [REDACTED]
 Sent: Friday, April 04, 2008 10:49 AM
 To: Excel Laser Vision Institute
 Cc: Warburton, Karen
 Subject: RE: [REDACTED]

NAME: [REDACTED]
 ADDRESS: [REDACTED]
 E-MAIL: [REDACTED]
 TOPIC: LASIK

I WISH THAT MY COMMENTS BE INCLUDED AS PART OF THE MEETING.
 THE QUALITY OF LIFE HAS BEEN LESS STRESSFUL, IN RESPECT TO THE CONSTANT DUTIES THAT GO ALONG WITH CONTACTS, AND HAVING TO FIND MY GLASSES, AS WELL AS THE ECONOMIC IMPACT THAT USE TO BE, AND NO LONGER IS. I DO NOT HAVE THE CONCERN OF AN EMERGENCY (EARTHQUAKE/FIRE, ETC) HAVING TO FIND MY GLASSES IN THE DARK, OR HAVING TO HAVE SOLUTION FOR CONTACTS IN CASE I AM UNABLE TO GET IN MY RESIDENCE. ALTHOUGH I AM NOT IN PUBLIC SERVICE I CONSIDER MY EYES HASSEL FREE, BUT A FEELING OF FREEDOM WITH MY EYES. I RECOMMEND THIS PROCEEDURE STRONGLY, I FIND DRIVING WITHOUT GLASS FRAMES IS MUCH BETTER, AND AM ABLE TO DO MY WORK WITH MORE ZEST AND ENERGY. MIGHT I MIGHT ADD THAT THE EXCEL LASER VISION INSTITUTE DID A SUPER JOB IN MY CASE AFTER WEARING CONTACTS FOR 20+ YEARS, IN MAKING SURE MY EYES WERE READY FOR THE LASER, THEY ALSO SHOWED ME THE BEFORE AND AFTER.
 SINCERELY,
 [REDACTED]

Date: Thu, 3 Apr 2008 13:33:14 -0700
 From: [REDACTED]
 Subject: [REDACTED]
 To: [REDACTED]

Dear [REDACTED]

The U.S. Food and Drug Administration (FDA) has scheduled a public hearing on the quality of life impact of LASIK. The hearing will be held in April, but the FDA will accept e-mail testimonials sent by patients.

We strongly urge you to take a few minutes to write to the FDA, **the deadline for submitting comments is April 15**. It is critically important that the FDA get an accurate representation of how patients feel about the quality of life effects of LASIK, and you can make a significant contribution.

Send e-mails to Ms. Karen Warburton at the FDA: karen.warburton@fda.hhs.gov . Be sure your note includes the following:

Your Name
 Your Address
 Contact info: email or phone
 Topic: LASIK

State in your email that you wish the comments to be included as part of the record of the

4/23/2008

Warburton, Karen

From: -----
Sent: -----8 2:33 PM
To: Warburton, Karen
Subject: Lasik

I had Lasik about 9 years ago after struggling for years with my thick glasses and contacts that dried my eyes out. I was tired of packing a whole bag just for my eyewear when I traveled. I had clear glasses, prescription sunglasses, contacts, backup contacts and all of the fluids that went with them. I really wanted to go scuba diving but I was afraid of my contacts floating off into the sea (or at least inside my mask).

I was nervous about surgery, but I did fine and my vision went from not being able to see the big E on the eyechart to 20/40 the next day. After a few days I was 20/20.

I went scuba diving without having to even think about my eyes! It was awesome. Still is.

----- comments to be included in the record of the Ophthalmic Devices Panel meeting.

Warburton, Karen

From: -----
Sent: Monday, April 07, 2008 2:47 PM
To: Warburton, Karen
Subject: LASIK

Ms. Warburton,

I am writing this after hearing troubling news about a lobbyist group petitioning the FDA to ban LASIK and PRK procedures. I have recently received PRK, and now have vision better than 20/20. The affect this procedure has had on my life has been profound. No longer am I forced to deal with the hassel of contact lenses, and I feel much safer when driving to work or school with my improved vision. Constant changing of prescriptions, even blinking out lenses has made it very dangerous to travel to and from work, especially in poor weather. After my procedure, I am fully confident in my abilities to see what is necessary to keep myself and others on the road safe. Also, I no longer have the nuisance of conjuntivitis, which made it difficult to wear contact lenses when playing sports for my collegiate team. Glasses were not really an option because of a helmet, but now, that is no longer a problem. Banning such a procedure would be taking away others from being able to lead a life unburdened by glasses or contacts. I would appreciate it if my comments were included on record in the Ophthalmic Devices Panel meeting. Thank you for your time, and I trust you will allow others the freedom of unaided sight.

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: LASIK

To Whom it may concern:

Im wrtting on behalf of the quality of life post-LASIK. I would like my co----- included as a part of the record of the Ophthalmic Devices Panel meeting. My name is-----, and the best thing ive ever done for myself was taken place on November 6, 2006. W-----IK.

Without corrective lenses my vision was CF (count fingers). Now since my surgery my vision is 20/15, better than perfect. My night driving has improved since surgery as well as my distance vision.

With having the LASIK life has improved. Before I could do the things, but now I can enjoy them so much better. Im able to spot so many things easier than I used to at work and at home. Life is easier with LASIK. Thanks for your time.

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen

LASIK

I wish the comments I'm about to make be part of the record of the Ophthalmic Devices Panel meeting. I had Lasik just about a year ago, and before that I was uncomfortable driving at night, and always squinting. I knew what was involved with lasik because I have been in the business for about 12 years. I had dryness for about a week, but that was my only set back. I see wonderful and my eyes are comfortable. It has helped in my career because I am now able to share my wonderful experiece with others who may be looking to have the procedure done, but have been nervous or scared.

Thank You.

Warburton, Karen

From: _____
Sent: Monday, April 07, 2008 12:53 PM
To: _____
Cc: _____
Subject: _____

Dear Karen -

WOW!!! Where do I begin?.....I can honestly say that having Lasik Eye Surgery was the 2nd best day of my life - the 1st being my wedding day. :) I had contemplated having Lasik done for several years but was too nervous, fearful or any pain and of course the cost. Finally I sat down in front of my computer did my research and came to the conclusion that my future would not involve glasses or contacts. I explained everything to my husband (who by the way has perfect vision - no glasses, no contacts, no Lasik) and thankfully he was very supportive with everything from the procedure to the cost. In the midst of our conversation he asked me "What is so wrong with wearing glasses? I think you look beautiful with them." (Typical question from someone who has never worn glasses or had to deal with poor vision). I explained to him the annoyances that come with wearing glasses as follows: Lens scratches, glasses fogging up, spotted from raindrops, mild pain from the indentation on the nose, can't wear a baseball cap (sounds silly I know but an easy bad hair day fix), can't fall asleep watching, have no idea what time it is unless I have my glasses on OR sit 4 inches from the alarm clock, can't see to put makeup on, etc.....I think after about the 4th annoyance he was exhausted from the list. I know that some of the annoyances I have listed above sound so minute and silly, but trust me when I tell you that now that I have had Lasik Eye Surgery I can't even imagine how I dealt with all those annoyances!!!

I work in an office setting where I work on the computer 8 hours a day and I can honestly say that I think I see the computer screen better now (after having the lasik done) than when I had my glasses on. It has been almost 2 months since I had Lasik and my vision is currently 20/15 (better than 20/20) and the only thing I regret is that I waited so long before choosing to have it done....what was I thinking???

The staff at [REDACTED] in _____ have made my whole Lasik experience absolute "heaven." From the first phone call to schedule m_____ follow up appointments, I have been made to feel like their # 1 patient, not just a name and number on a chart. Just another added bonus to having the Lasik surgery done. :)

Please let me know if you need anything further...

Thank you!

Warburton, Karen

From: _____
Sent: Monday, April 07, 2008 12:40 PM
To: Warburton, Karen
Subject: Lasik eye treatments

Dear Karen,

I wanted to express my gratitude to [REDACTED] and his group for the wonder full care and treatment I received from them. I recently went to [REDACTED]'s office to have the Lasik procedure done. The procedure was quick, painless and very effective. My vision is better than it was 20 years ago. [REDACTED] and his staff were highly professional. They were very thorough in taking care of my concerns. I have nothing but the highest regards for both the procedure and [REDACTED].

Respectfully Submitted,

Warburton, Karen

From: -----
Sent: Monday, April 07, 2008 11:52 AM
To: Warburton, Karen
Subject: lasik

FDA,

My lasik experience has been wonderful. My vision was 20/550 since childhood.

I seems like a miracle to wake up and be able to see what time it is or what the weather looks like outside without glasses.

I wish I could have done this many years ago.

I have had not problems with my eyes since having this done Jan 2008.

Thank you,

Warburton, Karen

From: -----
Sent: ----- 2008 12:37 PM
To: Warburton, Karen
Subject: LASIK

Dear Karen Warburton,

My name is -----, I had LASIK back in 2000. It was a joy in the morning to get up and be able to see -----glasses or contacts on. I was playing softball and my contacts had begun to irritate my eyes a lot. To go out in the field and not worry about contacts blurring or a bug getting under my contact,was wonderful. I didn't like to wear glasses due to my peripheral vision being so poor. I loved going swimming with my children but always had to keep my contacts on. I couldn't enjoy swimming as much as I would have liked due to wearing the contacts. After surgery it was wonderful to go swimming with my children and not worry about my contacts getting lost in the water.

You may use my comments as part of the record of the Ophthamlmic Devices Panel meeting.

Thank you,

Warburton, Karen

From: -----
Sent: -----
To: karen.warburton@fda.hhs.gov.
Subject: LASIK

I have worn glasses or contacts since I was in the fourth grade. I hated the glasses because they fogged up, gave me no peripheral vision, and often rubbed or irritated someplace. Then I got hard contacts and thought that was great. And contacts were a tremendous improvement, until pollen season, windy days, etc.

In January 2006, I started having problems with dryness and was unable to wear my contacts for several days. I also had to use reading glasses for small print, so I decided to investigate LASIK. I was a good candidate for the procedure and [REDACTED] at the [REDACTED] performed the procedure in March 2006. It was like a miracle. It is wonderful to wake up and be able to see. I can see to read without reading glasses and I can see at a distance (I have monovision). I love being outside working in the garden or watching birds now that the wind and pollen do not bother my eyes. I feel much safer driving because I don't have the problem of getting something under a contact & having my eyes tear up going down the road and I read more now because I can read easily without having to find a pair of glasses. In my job as a forensic chemist I am more productive since I do not have to keep switching from reading glasses to distance vision.

I have been extremely pleased with the results of my LASIK surgery. I encourage you not to let a few dissatisfied patients obscure the fact that over 95% of post LASIK patients are very satisfied with the results of the procedure.

Warburton, Karen

From: -----
Sent: Monday, April 07, 2008 9:37 AM
To: -----
Cc: -----
Subject: -----

I am writing to tell you about my experience with Lasik Eye Surgery

I love it! My vision is 20/15...it was quick and the recovery time was only one day. Big fan of the Lasik!!!

Warburton, Karen

From: _____
Sent: Monday, April 07, 2008 7:39 AM
To: Warburton, Karen
Subject: lasik

topic lasik

I want the comments to be included as part of the record of the Ophthalmic Devices Panel meeting. I'm an engineer and lasik has helped me be more efficient. I would work 16 hour shifts and contacts would bother me alot, in fact I grew a vessel to close to my cornea becuase of the over extended use of contacts. I'm very happy with Lasik and I would recommend the further use of it to everyone.

Warburton, Karen

From: _____
Sent: _____:26 AM
To: Warburton, Karen
Subject: PRK

Dear Ms. Warburton

I am wr-----o inform you of my great success with PRK surgery from [REDACTED]. As a member of the -----PD i find it a great tactical advantage to not having to wear contacts or glasses while workin----- d of course my quality of life has increased. I would definitely recommend it to all my friends. As a Police Officer the tactics of not having to worry about my glasses coming off during an arrest or foot pursuit greatly outweighs any negative aspects associated with the surgery. I have been wearing glasses for over 25 years and I feel I have a new life without it. A lot of Police Officers I know have had it done and not one would have anything to say negative about it. Though the procedure is expensive we as -----PD are known to be a little tight around the wallet, not one person has complained of the cost after results. Please consider not banning Lasik/PRK surgery as it really is a great change of life experience and a great asset to any person working in Law Enforcement.

For your Consideration

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: Quality of life after Lasik surgery

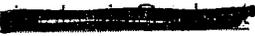
Hi Karen,
I have had Lasik eye surgery about 6 months ago. I am happy that I do not have to wear glasses any more. But I am not happy about the quality of the vision. I am a dentist and I could see images sharper and more defined before the surgery. I am still hoping for improvement.

Name: _____
Address: _____
email : _____
Topic: -----

Warburton, Karen

From: _____
Sent: Sunday, April 06, 2008 4:04 PM
To: Warburton, Karen
Subject: LASIK

Dear Ms. Warburton
I here by declare that I had LASIK surgery done few years ago.
It has done great benefit for me.
I used to have irritation on bridge of nose due to glasses.
I had severe pain on my mastoids due to glasses.
These two problems are completely gone and I donot have to wear glasses any more.
I had LASIK done both eyes at one sitting.
Contact m----- ions.
My name :-----
Address :-----

Contact info :----- and e-mail : 
Thank you

Warburton, Karen

From: -----
Sent: ----- PM
To: Warburton, Karen
Subject: Rk Problems

Karen,

I don't know if you want any information but I had RK surgery in Michigan in 1991 and my eyes have been ruined. I have unstable vision throughout the day.

If this will be involved in your lawsuit and you want further information, please let me know.

Warburton, Karen

From: -----
Sent: Sunday, April 06, 2008 7:51 PM
To: Warburton, Karen
Subject: PRK

I underwent PRK laser vision correction at [REDACTED] in January of this year. The results have been excellent. My vision is approaching 20/20 (from 20/80 and 20/70). I experienced a brief period of discomfort aafter the procedure and my vision steadily improved thereafter with no further adverse effects.

I am a Battalion Chief in the-----Fire Department and also an attorney. In these careers my vision is extremely important and my-----improved vision allows me to function more efficiently and comfortably. Also, just being rid of my glasses after almost 40 years has changed my life for the better.

I was thoroughly advised of all aspects of the procedure and all possible problems before undergoing surgery. I was and remain completely satisfied with my treatment with [REDACTED] and the results of the surgery.

Warburton, Karen

From: _____
Sent: Sunday, April 06, 2008 8:13 AM
To: Warburton, Karen
Subject: Ban Lasik?

Lasik surgery is one of the best decisions I have ever made. It has improved my quality of life and saved me hundreds of dollars. I used to spend \$300-\$400 a year on glasses. This must be a ploy by insurance companies who don't want to cover Lasik o----- anies who want to stay in business. Why take steps backward, move forward. -----

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: lasik

Karen,
I had custom (\$4500.00) lasik in September of 2006. I had an enhancement in January of 2007 and a second enhancement (via my Doctor's advice) just one month ago. I paid extra for the custom because they told me it was better... "like a fingerprint of your eye". My vision is absolutely horrible now. The enhancement made it worse, not better. It is affecting my job and my every day life. The doctors aren't held accountable because you have to sign your life away before having the surgery. I don't know what to do! Thanks for pursuing this!

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: LASIK Experience

Hi Karen

I had LASIK surgery to both eyes a few years ago and it was the best thing I ever did! I went from -8.5 myopia to near 20-20 in one eye and had the other eye "tuned" for reading (I'm 55).

I'm sure you could mount a slur campaign upon any medical procedure as nothing is 100% safe.

What we really need to know is the odds that something will go wrong.

Gathering bad experiences from patients rather than just experiences will slant your results to the extreme and will be next to useless for assessing risk.

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: LASIK

Hi:

Having received LASIK surgery on both my eyes, I can testify to its efficacy. I now am able to work, drive and read without glasses or contacts. No more eye irritation or tearing hampering my vision.

--

Warburton, Karen

From: -----
Sent: Saturday, April 05, 2008 2:50 PM
To: Warburton, Karen
Subject: LASIK.....

DEAR KAREN.....I HAD MY EYES DONE 4 MONTHS AGO! AGO....

MY LIFE HAS BEEN...SO MUCH BETTER AT 63, BEING ABLE TO SEE IN THE MORNING, WITHOUT GLASSES. I HAD NO IDEA, THIS WAS AVAILABLE AND HAVE 19 PEOPLE DO THE SAME WITH MY DOCTOR IN -----.

PLEASE DO----- THAT IS GREAT AND WORKS, FOR THIS IS TRULY.....A BLESSING.-----

BESIDES I MET THE PRESIDENT!!!!!!!!!!!!-----

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: Lasik

Ms. Karen Warburton

I told that there is a group trying to ban Lasik surgery. This would be a huge mistake. After 20 years of wearing glasses I have 20/20 vision. It has truly improved the quality of my life in a variety of ways. I constantly tell people it was one of the best 20 minutes and money that have spent.

Please don't let this happen. If you would like to talk live you can give me a call.

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: Lasik

This letter is to confirm I elected to have Lasik surgery performed on my eyes and have been extremely satisfied with the results and the quality of life after the procedure. I was a -5.5 in both eyes and after Lasik I now have 20/15 in both eyes. It is awesome to wake up and not have to fool with glasses or contact lenses. Every aspect of my life has been enhanced with this procedure. From swimming, to taking a shower, to driving, etc. It is great to be able to drive without contacts/glasses.

I had the procedure about 7 years ago and have had no side effects or other issues surrounding the procedure.

Please feel free to contact me if you have questions or would like to discuss this topic further.

Thank you!

Warburton, Karen

From: -----
Sent: Friday, April 04, 2008 5:07 PM
To: Warburton, Karen
Subject: Lasik

Hi, had Precision Lasik performed on my right eye in Oct. '06. I am doing well with the surgery and am happy with the results, in just a few days I was seeing great. I had severe astigmatism and some near sightedness. My vision has improved to 20/25 or so. Only beef I have is some dryness at night. Might be age related as I am 58 years old. Considering the crappy vision I had before the surgery, the dryness is no big deal. regards,-----

Warburton, Karen

From: -----
Sent: Saturday, April 05, 2008 9:18 AM
To: Warburton, Karen
Subject: Lasik

Hello,

My husband and I both had Bladeless Lasik surgery last year with [REDACTED]. It has changed our quality of life dramatically. The convenience of not having to wear glasses and contacts is fabulous. I have since recommended this procedure to my family members. My brother-in-law had it done and my sister is having the procedure done next week. I hope that you do not ban this for future generations to come.

Thank you.

Warburton, Karen

From: _____
Sent: Thursday, April 03, 2008 10:53 AM
To: Warburton, Karen
Subject: LASIK

Dear Ms. Warburton,

I am writing this letter to you in response to an email newsletter I received about an upcoming panel on the quality and impact of the LASIK procedure. I strongly recommend my observations and experiences with the procedure to be used. Before having the LASIK procedure, my vision had been stigmatized by the frequent frustrations of utilizing reading glasses to see from afar. At the age of 18 I sought to change that. My _____, _____ and _____ at the _____, _____ in _____, performed the LASIK procedure on me and the results were astounding. Right off _____, I was able to see 20/20. My personal confidence, in addition to the way others perceived me changed dramatically. At 23, I am still reaping the benefits of the procedure. I am able to look at the world in a different manner. There are not enough positives that come out of the LASIK procedure.

Throughout the past two years, I have been constantly dealing with a deranged individual named _____, one who may be attending this meeting along with other dissatisfied LASIK patients. Mr. _____ has not only attacked me, but also my _____ ll. Blaming my father, who did nothing _____ towards Mr. _____ on a medical level, _____ created a website devoted solely to the negative aspects o _____ ocedure. You may _____ ebsite if you wish to see how psychologically twisted his mind is. _____ To give you an example of his sadistic ploys, while still attending college, he emailed the director of student life telling him how horrible of a person I was and to watch out for me. How degradedating is that? There are three things I believe should be discussed at this meeting with _____ and the other dissatisfied patients in attendance:

1. Physicians are not "Gods". Is it not the purpose of the medical profession as a whole to better the lives of others, taking into account that some things may and do go wrong during surgery at times?
2. They are the minority for wanting to banish a procedure that has helped over 6 million people; celebrities such as Tiger Woods have had LASIK and are incredibly satisfied with the procedure
3. Do these dissatisfied patients remember the consent forms and the video that was shown to them prior to having the procedure done on them? I find it very disturbing that these individuals immediately blame the physician when it was they themselves that chose to have the procedure done.

In closing, I can only hope that after this panel meeting that the area of Ophthalmology can move on and continue its cause towards bettering the vision of others, not having to deal with the scrutiny of individuals who constantly not only attack Ophthalmology in its entirety but the physicians looking to better the lives of others.

Thank you,

Dear [REDACTED],

... I can actually see when I body surf those big waves. WOW! It was phenomenal! Never could body surf with glasses or contacts. I guess this means the next time I loose a pair of fins I may actually be able to see them and find them. Thanks again.

Sincerely,

Dear Dr. -----

There are no words to describe how happy and amazed and I feel having obtained 20/20 vision, following my LASIK procedure... It is like a miracle... I don't know what to say but THANK YOU, THANK YOU!!! Please feel free to give my name and telephone number to any patient considering LASIK who might want to speak with a satisfied (no, make that THRILLED) patient.

You're the best!!!

Sincerely,

Dear Dr. -----

I had been wearing glasses for at least 30 years. For my 44th birthday I had the LASIK procedure done... The surgery was painless and I didn't need any of the medication you had dispensed. It still seems "strange" not wearing glasses. I'm leaving on vacation next week. It should be more enjoyable jet skiing, snorkeling and white water rafting now that I don't need corrective lenses and I can see everything.

Sincerely,

Dear Dr.-----

I just wanted to take this opportunity to thank you for my new and improved 20/20 vision. After 40 plus years of annoying eyeglasses, painful hard contact lenses...it was

almost too good to be true to wake up the next day following the LASIK procedure and to see more clearly and sharply than I can recall in my entire life, even with the aid of all the above.

The LASIK vision correction procedure was so fast, painless and simple that it easily surpassed my highest expectations. Your friendly, professional and helpful demeanor....is truly commendable.

As someone who has spent 27 years in law enforcement I do sincerely believe that this is an option that every police officer should seriously consider. The benefits of not having to wear clumsy glasses or of not having a contact slip in the moment of a crisis speak for themselves. I cannot think of any other single occupation where clear vision would play a more important role than in the day to day activities of a law enforcement officer.

Very Truly Yours,

Dear Dr. -----

As you know, I am a Police Officer, and this past week I had to again qualify with on-duty and off-duty weapon with day and night conditions.

I am happy to say, this is the first time in 28 years of qualifying that I did not need glasses....because of LASIK.

Thanks you again for making this possible.

Sincerely,

Dear Dr-----

Thank you very much, my vision is superb. Looking forward to seeing. I will refer as many patients to you as possible.

Sincerely,

Dear Dr.-----:

I cannot believe the "miracle" you performed on my eyes. My vision is 20/15 in each eye.... God bless all of you for your wonderful care, concern, and medical expertise.

I look forward to seeing like a "normal" person as time continues on. It has indeed changed my life.

Thanks you again.

Dear D-----

I want to tell you how happy I am with the results of my LASIK surgery. It has been only three weeks since my procedure, and already I have forgotten that I have worn glasses for the last 35 years. What a thrill it is to wake up in the morning without having to reach for my glasses!

As a surgeon, I could appreciate your surgical expertise and the competence of your staff. I was confident that I would "see" the results that I hoped for. Just as you had explained, the procedure was very quick, completely painless, and the results immediate. What more could I ask for?

Please feel free to have any of your patients contact me for any reason, even if only to allay any fear they may have about their procedure.

Once again, my sincerest thanks for the excellent care you and your staff gave to me along with the wonderful gift of "no more glasses".

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: LASIK Quality of Life

Dear Ms. Warburton:

It has come to my attention that the FDA is having a hearing this month to evaluate how LASIK really affects the quality of life of LASIK patients. I would like to share my experience and show how everything in my life changed for the better after I had LASIK with [REDACTED].

My name is-----, and I am originally from Argentina. My eyesight was really bad since birth (I was minus 10 on the left eye, and minus 13 on the right one, aggravated by amblyopia). Because they do not have the right equipment, I was told that I had to forget about having LASIK (literally). I was devastated, until [REDACTED] told me the words I had been looking forward to hearing for so long: "you are a good candidate". He did not lie about not being able to correct the amblyopia, but he assured me that my life was going to be more comfortable once I had LASIK. After many tests and check ups, I had LASIK on June 10th 2003.

Personally, LASIK has affected the quality of my life in all the possible ways one can imagine. Those blurred images I was so used to seeing, are history. Being able to see the time on the clock when I wake up in the morning, or the leaves on the trees (things that many people take for granted), are just small examples of what has meant a huge change in my life. My life began to be so much simpler. As a teacher, I stopped feeling so tired, because I was now able to focus more and did not feel the tension in my neck as I used to. Moreover, the headaches I had for so long, stopped. I was so happy to throw all my contacts liquids and my old glasses away. I had been so unhappy for such a long time! I could now live my life the way I had always wanted. I had my son after having LASIK, and I also decided it was time for me to start driving.

I have recommended this procedure several times, and I will keep doing so. I know two people who had LASIK with ----- and, like me, do not regret it. I understand that every case is different and I strongly believe-----ctor's role, dedication and honesty are essential for the success of the procedure.

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: LASIK

Name: -----

Address: -----

Contact info: e-mail -----

Topic: LASIK

As ----- City Firefighter, I have come to expect a high degree of quality and service from the city I work----- w up in. It is the policy of my department that we provide high quality customer service to our community. It was therefore important to me to have the best vision that I could possibly have. Wearing glasses was dangerous and required that I keep many extra pairs should something happen to one of them. LASIK has given me the freedom to focus on public safety and well as my own. This is why it was surprising and distressing that there is any question on the benefits and freedom that LASIK provides to those individuals, like myself that has had the procedure.

Suffice to say that I feel considerable disappointment with the direction the FDA is considering taking. Please consider those individuals who have not had the benefit of corrected vision that LASIK provides.

Thank you,

□

□

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: Lasik Eye Surgery

Dear Karen,

I understand that you are accepting comments from Lasik patients that have had bad outcomes. Below is my story. Thanks for listening.

I was born a -7.00 myope. I cannot remember a time in my life when I did not wear glasses. Glasses were as much a part of me as my hair color. At forty-six years of age (March 05), I walked into my eye surgeon's office (██████████) with the dream of not having to wear glasses ever again. After all, my sister and brother both had Lasik with great results. I elected to have an epi-lasik procedure confident with the knowledge it was the conservative "safe" route to take.

I knew something was wrong within days after the surgery. At first my fear focused on being overcorrected. After a lifetime as a myope, I hated being farsighted. I was terrified. I didn't sleep for weeks. I didn't eat. I lost 20 pounds. I did not feel comfortable in my own skin. Things only got worse. My left eye stabilized at +1.00 while my right eye went into a tailspin. When the dust settled three months post op, my right eye was +1.75.

As it turns out, the hyperopia was not the worst symptom. Since, I had my surgery in the spring, the long periods of sunlight masked the glare, halos and starbursts that would be the focus of my most intense fears. I soon discovered that stop lights at night were an unrecognizable mess of glare, LED lights created huge streaks of light, etc. My fear now became panic.

I saw several "specialists" during this period. I was desperately seeking answers/solutions. To a person, they told me that my situation was not that dire and that additional surgery would most likely fix all of my symptoms. In September 05, my surgeon had an idea: perform an epithelium debridement on my right eye. He believed that irregular epithelium healing was the cause of much of my hyperopia. He told me it was a safe procedure and healing would only be a few weeks. No such luck. Shortly after the surgery, I developed severe haze in the right eye that did not diminish with time. My apprehension was now a total obsession.

I saw another specialist, a world class surgeon in _____ (at the suggestion of my original surgeon). Again, I was told not to wor_____ e haze scrapped, allow the eye to heal, then have another laser surgery performed. I had the haze scrapped from my eye in January 06. This further flattened my right eye and left me at +3.00. The real problem was that the +3.00 did not tell the whole story. Contacts and/or glasses no longer corrected my right eye. Night vision was an even bigger mess. While my right eye healed from the haze scraping, I had a second surgery (PRK) performed on my left eye in March 06. I so wanted the hell to be over. After a couple months, the left eye healed okay; however, the glare, starbursts and halos were still extremely prominent.

In July 06, I flew to Vancouver to see another world class eye surgeon _____ at the suggestion of my original surgeon) regarding my right eye. Due to the FDA approval process, Canadian eye surgeons have several tools available that American surgeons do not. After a short consultation, I consented to have a topographic guided PRK procedure performed on my right eye.

Sixteen months of hell for me and my family; untold thousands of dollars on surgery, optometrists, glasses, and contact lenses and I still had terrible vision. My left eye was near plano but my right eye was now -2.50. I wanted to celebrate my left eye but the glare, starbursts, and halos were ruining my life. I avoided the night like the plague.

I hit rock bottom after trying RGP lenses with a local optometrist. The local optometrist I saw did not have much experience fitting post refractive patients. The lenses did not mitigate the glare and were incredibly uncomfortable.

-----o specializes in fitting post refractive patients with contact lens in -----
----- . The first lens iteration, using a Macrolens, fixed my eye chart vision but did not mitigate the glare. Not to worry, a larger optical zone might be necessary. The next day, the second iteration lenses, again the Macrolens (14mm diameter lens with a 10mm optic zone), arrived. I could see 20/15 and the glare was significantly reduced. In addition, the lenses were comfortable. In fact, the lenses were no less comfortable than the soft silicon hydrogel lenses I was previously wearing. I immediately wore the lenses for a full day. Another iteration was necessary to find the "perfect" fit, but I now had hope that I could live a normal life.

I wish this story had a perfect ending; however, it does not. I still see excessive amounts of glare. It can be mentally debilitating. Streaks of light shoot out from bright sources (i.e. overhead track lights, street lights, etc.) like dancing spikes of light every time I blink or move my eyes. No one seems to understand why. It is not a function of the contact lenses. Sometimes I can mentally erase these streaks and sometimes I cannot. I also still see large starbursts (with the contact lenses). Green stop lights at night are the worst. I hold out hope that my remaining symptoms will mitigate over time or there is some kind of alternative. I continue searching for the perfect solution.

----- ilog to this story is that contact lenses continue to get better, and -----
----- , has led the effort in this regard.

The contact lenses that currently help are custom manufactured using data obtained from a [REDACTED] [REDACTED]. The lenses are very large 15mm with a huge 10mm optic zone. Luck and skill would have it that they are comfortable; however, they do not completely eliminate the starbursting which has become the bane of my existence. My hope is that technology catches up with my situation. Any additional laser surgery is out of the question (only 400mm of central cornea left in my right eye), even considering custom topo. New wavefront contact lenses offer some hope. One company is going to release soft wavefront lenses soon. Who knows if they will work. I tend to doubt it but wavefront RGP lenses should be next. If they can be made rotationally stable, they might work.

Life in Lasik Hell,

Warburton, Karen

From: _____
Sent: _____
To: _____n
Cc: _____
Subject: LASIK impact.

Dear Ms. Warburton,

I am a 61 year old male and have had vision problems all my life. Never without glasses, I lived with the cruelty school age kids hand out to "Four eyes", "Sightless" and much worse. Knowing then what I know now if this procedure had been available and as thoroughly vetted when I became the age of consent, I would have jumped at the opportunity to have LASIX surgery. And were it available to youth, the quality of life is expanded so much I would have begged for it then.

Even now, the freedom from glasses when I sit at a computer is beyond explanation. I am going to have a touch up so that my distance vision will dominant and I will need "Reading" glasses only. The procedure had a side effect for me in that even though right now I need glasses to see road signs properly, I have NEVER had the crispness of vision I have now.

Great pains were taken to inform me of all risks, no matter how remote. I have had many major operations in my life time; I have never had the amount of information given to me prior to a procedure. The extent to which my Doctor (_____) went to in order to explain ALL possible side effect was far beyond what I really needed. _____ will not let any short cuts be taken in this area. Again, knowing before the procedure what I know now, there could have even a greater risk and because of the end product I would have still gone forward. No matter what the event, there is a small risk that something can happen. LASIX has come so far it has very little risk for reward. Put into context, think of how many Botox procedures have had poor to tragic endings.

LASIX is safe and life changing. Please keep this medical benefit available. Police the surgeons that may take short cuts, not inform or not follow up properly with their patients. I am including contact information if you would like to have this information verbally.

Sincerely,

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: LASIK

Ms. Karen Warburton

Food and Drug Administration

Dear Ms. Warburton,

I want to express my concern over the lack of oversight of surgeons performing LASIK. As the former President and CFO of a large LASIK provider in California, I have been appalled at the nonchalant attitude so many surgeons have when performing this procedure. I've seen patient after patient have 'unusual' results. Surgeons, who have barely glanced at the patient's charts, much less performed an exam on the patient, take somebody else's word that the patient is suited for the procedure, only to end up later with significant complications including ectasia, loss of bcva, unresolved pain and retreatments too numerous to mention.

The fact that so many surgeons routinely operate on patients beyond the FDA device labeling without appropriate patient informed consent is also concerning. I've settled too many LASIK claims and spoken with too many dissatisfied patients to mention.

I would encourage greater study and scrutiny of the practices surrounding the LASIK field, including restricting the procedure to those practitioners whose specialty is the cornea. I also believe the studies showing 1 out of 20 are dissatisfied under represent the real numbers.

Sincerely,

Your Name
Your Address

Warburton, Karen

From: -----
Sent: -----
To: Excel Laser Vision Institute
Cc: Warburton, Karen
Subject: RE: [REDACTED]

NAME: -----
ADDRE-----
E-MAIL: -----
TOPIC: -----

I WISH THAT MY COMMENTS BE INCLUDED AS PART OF THE MEETING.
THE QUALITY OF LIFE HAS BEEN LESS STRESSFUL, IN RESPECT TO THE CONSTANT
DUTIES THAT GO ALONG
WITH CONTACTS, AND HAVING TO FIND MY GLASSES, AS WELL AS THE ECONOMIC IMPACT
THAT USE TO
BE, AND NO LONGER IS. I DO NOT HAVE THE CONCERN OF AN EMERGENCY
(EARTHQUAKE/FIRE, ETC) HAVING
TO FIND MY GLASSES IN THE DARK, OR HAVING TO HAVE SOLUTION FOR CONTACTS IN
CASE I AM UNABLE
TO GET IN MY RESIDENCE. ALTHOUGH I AM NOT IN PUBLIC SERVICE I CONSIDER MY EYES
HASSEL FREE,
BUT A FEELING OF FREEDOM WITH MY EYES. I RECOMMEND THIS PROCEEDURE
STRONGLY, I FIND DRIVING
WITHOUT GLASS FRAMES IS MUCH BETTER, AND AM ABLE TO DO MY WORK WITH MORE
ZEST AND
ENERGY. MIGHT I MIGHT ADD THAT THE [REDACTED] DID A SUPER JOB
IN MY CASE
AFTER WEARING CONTACTS FOR 20+ YEARS, IN MAKING SURE MY EYES WERE READY
FOR THE LASER,
THEY ALSO SHOWED ME THE BEFORE AND AFTER.

Date: Thu, 3 Apr 2008 13:33:14 -0700
From: -----
Subjec-----titute
To:-----

Dear [REDACTED]

The U.S. Food and Drug Administration (FDA) has scheduled a public hearing on the quality of life impact of LASIK. The hearing will be held in April, but the FDA will accept e-mail testimonials sent

Warburton, Karen

From: _____
Sent: Monday, April 07, 2008 10:19 AM
To: Warburton, Karen
Subject: LASIK

Dear Ms. Warburton,

I am writing this email to you today to inform you of the positive impact that Lasik surgery has had on my life. Before I had Lasik surgery, I wore contacts for 18 years. Every year I would go to the doctor and my prescription would get worse. I was told by the Doctor that it would be ok to sleep in my contacts for up to a week at a time with no problem. Due to this fact, I constantly had sore, red eyes, which I did not realize until I replaced the contacts with the Lasik surgery. In addition, as a certified PADI scuba instructor, I was constantly concerned about losing a contact during a training dive and not being able to safely keep up with my students. Since the surgery, I can confidently go through demonstrating basic skills such as mask removal underwater without the concern of losing a contact. When I did wear contacts, on the weekends when I would actually take them out to clean or dispose of them, I would have to worry about going through the night without being able to see anything further than a foot away, or deal with headaches caused by adjusting to wearing glasses. All of these concerns and issues have disappeared since I've had Lasik surgery. I no longer have to pack extra contacts and glasses when I go on a trip, or worry about having to have my contact prescription refilled. I also no longer have to wait a week while my Doctor gets my particular prescription in, which occurred more often than I care to remember.

Overall, the Lasik surgery I had has deeply improved my life. I did a lot of research before I had the procedure, so I was surprised when I found out that there was even an issue raised with this surgery. I have experienced no discomfort whatsoever because of my surgery, and as I indicated above, it has actually increased my personal comfort level. My surgery was performed by _____ at the _____ in _____ in November of 2007. _____ was very professional and went out of his way to answer any of my questions. His staff was just as professional as he was, and made sure that I was informed of any possible problems or adverse effects that might occur. I experienced no discomfort during or after the procedure, and the results are fantastic. I can now see 20/20 out of both eyes, something I haven't experienced since my early teenage years. I believe that any surgery has its risks, however, I believe that the benefits of this surgery far exceed any of the minor risks involved.

There are numerous surgeries out there that need to be monitored, and as a taxpayer, I believe that any more effort put towards this issue would be a waste of your time, and my tax dollars. I appreciate the job that you and your team at the FDA do to help protect me and my family from harmful procedures and drugs on a daily basis. However, where Lasik is concerned, I feel that there are better places that you can expend your energy. Thank you for the great job your doing for us, and for your concern for the safety of the public.

Should you have any questions, feel free to contact me at:

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: lasik

I had lasik surgery done in December 1996 because the doctor who examined my eyes told me I had the same disease as [REDACTED] and needed the surgery within a week or I will go blind suddenly like he did.

He did not tell me what the disease was but I got so scared I agreed

to have it done . Complications arose from the surgery and the doctor suggested an artificial lenses implant to restore the lost vision .

He implanted the wrong lenses and I ended up with one eye seeing close-up and the eye that had not been touched was seeing distances. My vision was so distorted and the eye with the implant was so blurry and cloudy I could not see anything . On my next visit the doctor told me I developed cataract and needed

yag laser surgery . I was so desperate I accept .

The yag surgery only made my vision worse !

His last words to me will always be in my mind , he said : You have to realize I'm not God , I'm sorry things didn't work out for you .

After that I went to see many eye doctors hoping something could be done to regain my vision but I got the same answer every time :

" Your eye has been damaged beyond repair "

I did not go blind like he told me ! I still have one good eye !

I could never advise anyone to have lasik surgery , not after what I went through ! And as a public service I will continue spreading the

horror of lasik which is dangerous . I read so many horror stories about lasik and yet the media advertises for these money hungry doctors pretending lasik surgery is the best thing for your eyes .

As long as the FDA approves it people will believe it is safe . It's not .

Warburton, Karen

From: _____
Sent: Sunday, April 06, 2008 10:30 PM
To: Warburton, Karen
Subject: LASIK

Dear Dr. Warburton,

----- spend a few moments discussing my Lasik procedure. I had Lasik, performed by _____, in
----- in January of 2005, using the completely bladeless technique.

I was thoroughly evaluated beforehand and given ample information, especially covering risks, potential discomfort and potential limitations of the procedure. At the time of my initial evaluation, my mild dry eyes were thoroughly addressed, my punctal plugs checked (in good condition and position,) and I was seen once again before surgery to make sure the dryness was well controlled and would not lead to complication.

On the day of the procedure, I and the person driving me home were thoroughly educated on what to expect and exactly how to handle the first 24 hours post-op. I was kept comfortable and given a mild and perfectly effective sedative in the proper dose for my body size and history.

The procedure went perfectly, and I was able to follow the directions easily for my post-op care. I continue to have 20/20 vision today, have had no complications or eye infections since my procedure, suffer no ill effects to my night/dark vision, and have no other deficits. In addition, my "pain" post-op - a mild headache - for which I was fully prepared, was easily treated with acetaminophen. I was seen the very next morning, even though it was Saturday.

I am also a board certified Family Nurse Practitioner, in practice for over 10 years. I'm easily able to detect errors or quality issues in the care I receive, the skill of those giving care, and the quality of the patient education I receive. My Lasik experience was one of the best I've had in terms of any type of health care delivery. I found the entire system to be of the highest quality, and have experienced excellent results.

Having Lasik changed my personal life, allowing me to be free of contacts and the relative hazards I was beginning to experience due to dry eyes, and increased the quality of my own ability to care for patients. I was no longer hampered by constantly adjusting my glasses to see clearly, particularly during procedures such as applying sutures. It has allowed me to work with more freedom, and to immediately be able to see upon arising from sleep, which is essential in any health care position involving on-call care of patients. It has been especially wonderful to be able to go camping without glasses or contacts, to be able to drive long distance without eye strain, and to be able to swim and snorkel and be able to see clearly.

Thank you for your time.

Sincerely,

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: LASIK

April 7, 2008

Drear Ms. Warburton,

I wanted to share with you how LASIK has greatly improved not only my vision, but many aspects of my life.

For years I've needed to wear several pair of glasses and prescription sunglasses simply to do the most basic functions in life. I've always considered LASIK but wanted two things; the reassurance of family and friends who previously had LASIK surgery performed and secondly, the ability to find a reputable and quality doctor who would guide me through what admittedly was one of the biggest and scariest decisions of my life. After all, these are my eyes!!!

The concern of how I looked in glasses socially never bothered me. The fear I had was of potentially losing my glasses. Not only the financial loss but how would I see!?? This unfortunately became a reality when at the beach a wave crashed down on me and my glasses were gone in an instant. Not being able to see more than 2 feet in front of me, I knew things would get interesting knowing I would have to drive home with very limited vision. Luckily, this day there happened to be a nice person on the beach with a metal detector who was kind enough to search the waters for me. Like a miracle, he found them 10 minutes later without even a scratch. I drove home safely, but knew that I never wanted to be that vulnerable again.

Having both of my above concerns addressed I had the surgery two years ago and have been loving the freedom ever since. The simple ability to get up and enjoy the day without having to worry about glasses has become something very important to me and something I will never take for granted. I see leaves on the trees and my night vision has surpassed any distance abilities I ever had when previously wearing glasses. When it is all said and done, I've saved thousands of dollars over the next 40 plus years of life that I would have otherwise spent on numerous prescriptions, doctor visits, contact lenses and various other products.

I wish for the following comments to be included as part of the record of the Ophthalmic Devices Panel meeting as I'm a huge advocate of LASIK surgery.

Thank you,

Warburton, Karen

From: _____
Sent: _____ PM
To: Warburton, Karen
Subject: LASIK

Ms. Karen Warburton,

I am writing today because I am concerned about the upcoming meetings re: the Quality of Life of patients following LASIK surgery.

I am a dentist practicing in central Illinois. I have had LASIK treatment done following years of wearing contact lenses for distance correction. My vision is better and sharper than it ever was with contacts. My eyes are very important to me in my profession as I have to have sharp vision as I perform dental procedures. I am able to drive without glasses or contacts and can read upcoming signs at night better than I ever could. I have recommended the procedure to others and they, too, have been very pleased. I could never go back to glasses or contacts after experiencing the vision that I now have.

I hope the FDA hears from the patients who are as pleased as I am with my treatment! Sometimes we only hear from the people with problems. My experience in talking with patients who have had Lasik is that they also are pleased.

Sincerely,

by patients.

We strongly urge you to take a few minutes to write to the FDA, **the deadline for submitting comments is April 15**. It is critically important that the FDA get an accurate representation of how patients feel about the quality of life effects of LASIK, and you can make a significant contribution.

Send e-mails to Ms. Karen Warburton at the FDA: karen.warburton@fda.hhs.gov . Be sure your note includes the following:

Your Name
Your Address
Contact info: email or phone

Topic: LASIK

State in your email that you wish the comments to be included as part of the record of the Ophthalmic Devices Panel meeting. In your own words, how has LASIK affected the quality of your life. Examples may include your enhanced personal safety, your ability to do your job, your participation in social activities, and, if you are involved in public safety activities (police, firefighter, nurse, doctor, etc.) how has LASIK helped you to be more effective?

Thank you,

[Redacted signature]

Warburton, Karen

From: -----
Sent: Friday, April 04, 2008 10:54 AM
To: Warburton, Karen
Subject: LASIK

--Forw----- Attachment--
From:-----
To: ka----- fda.hhs.gov
Subject: lasik
Date: Wed, 2 Apr 2008 16:35:46 -0400

I had my LASIK procedure performed by [Redacted] in-----in 1998 on my left eye. He performed PRK on my right eye in 1996. I have had perfect 20/20 vis----- both eyes. I have worn glasses since I was seven, and became contact lens intolerant in my twenties. Not only has this surgery given me perfect vision, it has given me freedom. I am very active and participate in numerous water and land sports. I can't tell you how incredible it is to be able to see clearly and not have to worry about glasses or contacts. I also have three children who are very busy and this freedom touches all aspects of my life (including middle of the night visits from sick children). I am so thankful for my "new eyes" and marvel at my vision frequently. I thank God that this was available to me. It has changed my life. I recommend it to all who will listen.

Warburton, Karen

From: _____
Sent: Tuesday, April 08, 2008 12:50 PM
To: Warburton, Karen
Subject: LASIK

Ms Warburton,

I wore glasees from the time I was 4 years old. The very first time the doctor put those horrible things on my face I turned to my mother and said "Mom - can't you send me to the hospital to fix my eyes? I asked every doctor I came in contact with until I was 49 years old when a surgeon told me I could go to Canada or Mexico to have a procedure that would free me from dependence on glasses and/or contacts. It has been 11 years now and I am still as happy as can be. I only wish the FDA had approved the procedure sooner so I would not have had to leave the counry.

Please use my name and this email to **KEEP LASIK** approved.

Thanks for your time.

Warburton, Karen

From: _____
Sent: _____ 9 PM
To: Warburton, Karen
Subject: LASIK

Hi Karen,

My name is _____ and I'm an Oral and Maxillofacial Surgeon practicing in _____. My practice consists mainly _____ the mouth, face, and jaws. I've graduated from both De_____ Medical school and completed my residency at accredited programs in the United States.

I had LASIK performed on me several years ago. The decision to proceed wasn't taken lightly by me. I did research, and gave it careful consideration. I make my living with my eyes and my hands.....and the possibility of an adverse outcome would have been devastating not only to me personally, but also my wife and children. The more I read about the procedure and talked to several close friends that had LASIK done, the more comfortable I was with the tremendous safety margin that exists with current LASIK techniques.

The procedure was completely flawlessly. I could see better immediately. The next day I was checked by my Ophthalmologist and then went and worked a 12 hour day. I couldn't believe how much easier it was to see and do my job well. Not having to deal with contact lenses or glasses was such a wonderful quality change in my life. I honestly believe the quality of care that I render was enhanced by having LASIK. If you would like any additional information from me, please don't hesitate to call or co_____ phone numbers are as follows:

Warburton, Karen

From: _____
Sent: Tuesday, April 08, 2008 12:03 PM
To: Warburton, Karen
Subject: Lasik Surgery

Ms. Warburton,

I had Lasik eye surgery in April of 1998. It was one of the best decisions I ever made. I wake up in the morning and can see the alarm clock. I lay in bed at night and can see the scores across the bottom of ESPN and I can ski and play golf without having to hassle with contacts or glasses. I am very satisfied with my lasik surgery 10 years latter.

Sincerely,

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Cc: _____
Subject: FDA - LASIK Surgery

Ms. Warburton,

My name is _____ . I live at _____ . You may contact me at the _____ My work email address is _____ . I am _____ ou for a pet _____ keep LASIK surgery as an option to correct vision for those who would choose. You may include my comments in the record of the Ophthalmic Devices Panel meeting.

I was in the first grade when I received my very first pair of glasses. My eyes continually got worse until in the third grade when they had me wear a hard contact lens to keep my eyes from changing so rapidly. I know that I was very young (at age 9) to be wearing contact lenses, but my parents were told this was the only choice I had or I would definitely be legally blind by the time I was in high school. It worked - and the progression of the vision change had slowed down. I felt very lucky to have my vision at all, but I can't say that having contact lenses or glasses did not slow me down.

At age 35, after much contemplation, I made a very informed decision to consult _____ for correcting my vision. At this point my vision was -6.0 and -5.5 with moderate astigmatism, 20/20 in my left eye with corrective lenses and 20/40 BEST VISION in my right eye with corrective lenses. I researched different practices and procedures. I chose to have the CustomVue LASIK Surgery on January 18, 2008. I can not say that I wasn't nervous. As with any surgery complications can and do sometimes happen.

Although I am still healing and I know that the numbers can change with age - I now have 20/15 vision in both eyes. I know my family is sick of me reading things from far away - just because I can! I am amazed at my vision. I feel it is nothing short of a miracle and I can't express my gratitude enough to Diamond Vision. I see things in a world that I have not seen since I was a child (if I ever have at all). When I am outside - I am amazed at the clarity of what I can see. I am grateful every day that I can wake up and not have to put my glasses on or put my contacts in. Things that would seem so simple, such as shaving my legs in the shower... are so much easier. I don't have to worry about separate glasses for being in the sun, or contacts washing away in the pool - as with countless other improvements to my life.

It would be a shame if LASIK surgery would not be available as an option to others to make this choice for a better quality of life.

Thank you for your consideration.

Sincerely,

Warburton, Karen

From: _____
Sent: Tuesday, April 08, 2008 11:38 AM
To: Warburton, Karen
Subject: Lasik

Karen,

I had Lasik surgery done back on April 29, 1999. As of today, my vision is still 20/20. Getting Lasik has been the best decision I've ever made. I would have this surgery again without thinking twice.

Before my surgery I wore contact lenses and glasses for 10 years. I experienced many hassles wearing contacts and glasses which prevented me from enjoying life activities to the full extent.

I believe that our vision is our lifeline and now I see life in a way that I was born to!

I would like you to use this e-mail to go on record as part of the Ophthalmic Devices Panel meeting.

Sincerely,

Warburton, Karen

From: _____
Sent: Tuesday, April 08, 2008 11:29 AM
To: Warburton, Karen
Subject: LASIK

Ms Warburton,

My name is [REDACTED] and I am writing to you urging you to allow Lasik operations to continue. Since my surgery my quality of life has increased significantly. I feel better about myself, I read more and I am better at my job. I feel safer driving because my peripheral vision is better. I would like my email to be included as part of the record of the Ophthalmic Devices Panel meeting.

Thank You,

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: LASIK

Hi Karen,

This is ----- from ----- . I recently read a series of stories concerning the FDA's upcoming
hearin----- t of L-----

My experience after undergoing a LASIK procedure at [REDACTED] on December 5, 2007 has been exceptionally positive. The care provided to me by [REDACTED] before, during and after surgery was tremendous and my overall results are better than I could have possibly imagined. I'm a sportscaster who had never broadcasted a game, played a round of golf or watched a movie without the assistance of glasses. Now, I can do all of those things without glasses or contacts and actually see better now than I ever did before. In addition, I've not experienced any post-surgical discomfort.

During a recent post-op check-up, my vision registered better than 20-15!

Needless to say, my decision to undergo LASIK surgery has provided me with a life-changing experience.

I wish that my comments be used as part of the record of the Ophthalmic Devices Panel meeting. And if you need further information, please don't hesitate to contact me through this e-mail address.

Best regards,

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: Comments for the Ophthalmic Devices Panel Meeting LASIK

Dear Karen,
Please include my comments in the Ophthalmic Panel Devices Meeting.

Topic: LASIK

I had the LASIK surgery on June 19, 2006. Until that time in my life I had never been able to see the trees, the grass, the leaves and even my child's face or anything else without putting on my glasses or contacts first. As a child I can remember the first time putting on glasses at the age of 7. What a miracle that was to me! I have no recollection of anything in my early childhood before those glasses! I don't remember my parents faces as a child or any of my brothers and sisters of which there were many.

My vision was horrible as I could not see past 3 inches of my face. I never participated in school sports, water sports, and many activities, as I was afraid I would loose my glasses or break them. I was not able to learn to swim, because my vision was so bad when taking off my glasses to go into the pool, following instructions without seeing, was impossible. As a child growing up with glasses I know my self esteem had really suffered, being called names, and just not feeling as attractive as the others.

I was resigned to wear contacts and glasses for the rest of my life.
THERE WERE NO OTHER OPTIONS!

Then came the technology of Lasik surgery!! I was extremely hesitant as well as hopeful, that maybe I could be candidate for this procedure. I did my homework and research and decided to at least have a consultation. I decided to go to a cornea specialist who was highly recommended with an excellent reputation. The day I had the consultation to see if I was a candidate, I did not get my hopes up.

and when he told me I was a candidate for this procedure I was extremely happy! At least I now had a choice. I decided to have the procedure with him and I would do it "in a heartbeat" again! I was able to wake up after the procedure and "SEE" for the first time in my life!! WOW! I can not tell you how I felt!! I felt that I had experienced a miracle! It seemed amazing that this technology could change my life so much. I am able to swim, do sports I had never tried before and experience the freedom without glasses and contacts!! What freedom that is, no more "ball and chain". My vision is better now than it has ever been through all my life!!

I know that the Dr. I went to who did my procedure, meant all the difference in the world, and I would have gladly paid allot more to have this 'Miracle'. Price was not the issue as these were my eyes!

After this procedure I feel much more safe when walking to my car at night in the dark parking lot, not worried "what if my glasses would be knocked off". I work at a computer and I am also very active during the day, I sometimes would have to go up and down steps a lot all day and with glasses the peripheral vision was a real problem. I would be constantly "missing steps" or "over stepping the steps" and almost falling down the stairs. My social life is much more improved as I feel "normal". I am able to go to the beach and participate in volleyball, and enjoy life so much more without having to think about that "ball and chain" anymore. FREEDOM is the best description I can give!

I am very grateful for the wonderful talents of the Dr. and the very advanced technology that is available to have had this procedure.

Please include this email for your testimonies for the lasik procedure.

Sincerely,

Warburton, Karen

From: _____
Sent: Tuesday, April 08, 2008 9:57 AM
To: Warburton, Karen
Subject: LASIK

Name: _____
Address: _____
E-mail: _____

First off, I like to say that I wish the comments to be included as part of the record of the Ophthalmic Devices Panel meeting.

I had Custom LA-----in October of 2006 with [REDACTED] in _____. LASIK has done nothing but improve my qual-----y 1 and on, I have seen 20/20 or better. Never had a dry eye issue. I can read things from a distance that I would not have been able to read with my glasses or contacts. I have not had to worry about contacts popping out while playing sports or worrying about falling asleep with my glasses on and possibly having them break, which had happened a couple times to me prior to having LASIK. Since having my surgery, I have had 3 friends and 1 colleague have surgery as well and they have had good results just as I have. I would recommend it to anyone.

Sincerely,

Warburton, Karen

From: _____
Sent: _____
To: _____en
Cc: _____
Subject: _____

Dear Ms. Warburton,

I am writing today to let you know how satisfied I am with the lasik surgery performed on my eyes more than two years ago by [REDACTED] of_____. Until the surgery I had worn bifocal glasses for 10 years to correct both reading and distance vision. I was informed by Dr. [REDACTED] before proceeding that there were serious risks, although they were uncommon and a very small percentile, and that there were compromises to expect.

I have accepted the compromises of completely clear distance and reading in order to enjoy the freedom from glasses and contact lenses. I have been completely satisfied with both the procedure and the results from my surgery with Dr. Eisner and have recommended his services to friends and family.

As with all medical procedures, I fully expect there will be changes and advances in the future which I will take advantage of. However, for the time being my sight has checked out at 20/20, and I am completely satisfied with the results.

Sincerely, _____

Warburton, Karen

From: _____
Sent: Tuesday, April 08, 2008 9:09 AM
To: Warburton, Karen
Cc: _____
Subject: LASIK

To whom it may concern.

In regards of the recent issue about the Lasik procedure, I'd like to express my opinion and share my story of a very successful outcome of the application of Lasik in my case.

I was wearing eye glasses since the age of 13 and my condition of myopia worsen year by year putting severe limitations to the many activities I was involved like motorcycle racing, car racing, tactical shooting, trap shooting, swimming and martial arts. I went from glasses to contact lenses only to discover that some of my activities were still limited by the presence of dust, water and other elements that would contaminate the lenses and make them useless if not dangerous.

In December 2006 I contacted _____ in _____ and went for an evaluation to see if I was a candid----- was examined, I received all the information in a very professional way and I scheduled my Lasik for the 22nd at 10:45. The procedure was conducted by highly qualified personnel, it was very quick and totally pain free. Immediately I was able to read and observe at a 20/20 level. The recovery was very quick and thanks to the clear instructions of the medical staff, it was very easy to accomplish. The follow up was very accurate and right after the second visit, I was able to see 20/15. No side effects, no glares, no ghosts. Nothing at all. Reading, driving, computer work and all the other activities were immediately available to me, dramatically improving my quality of life. At over a year after the procedure, I am totally satisfy and my eyesight has never been better.

For any further questions you may have, please contact me

.....
.....
.....
.....

Warburton, Karen

From: -----
Sent: Tuesday, April 08, 2008 9:00 AM
To: Warburton, Karen
Subject: FW: Lasik/PRK Benefit

My name is -----

From: -----
Sent: Tuesday, April 08, 2008 8:57 AM
To: 'karen.warburton@fda.hhs.gov'
Subject: Lasik/PRK Benefit

I do not understand why someone will try to ban Lasik/prk. It must be the interest group supported and created by eyeglass industry.

Please do not take this wonderful choice away from us. I went through it. Then my wife did it . Now we will offer this opportunity to our kids so that they can benefit from this opportunity throughout their life.

Remember the old days when interest groups used to threaten, even kill the scientists to stop the advancement of science.

Thanks

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: Lasik/PRK Benefit

I do not understand why someone will try to ban Lasik/prk. It must be the interest group supported and created by eyeglass industry.

Please do not take this wonderful choice away from us. I went through it. Then my wife did it. Now we will offer this opportunity to our kids so that they can benefit from this opportunity throughout their life.

Remember the old days when interest groups used to threaten, even kill the scientists to stop the advancement of science.

Thanks

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: LASIK (clear)

Dear Ms. Warburton:

Please accept my comments as part of the hearing on effects of Lasik surgery on quality of life issues.

"I do not know how you can put a price on being able to see with uncorrected vision of 20/20 or less. From my experience, at age 50 being able to see the big E on the eye chart without glasses was a revelation. I now enjoy swimming with the grandchildren, being able to ski and enjoy winter sports without glasses or contact lenses."

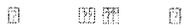
My surgery was performed January 5, 2006, at the [REDACTED] in

Thank you.

Warburton, Karen

From: -----
Sent: Tuesday, April 08, 2008 8:49 AM
To: Warburton, Karen
Subject: LASIK

Importance: High









Good Morning Karen,

I would love to have my comments included in the record of the Ophthalmic Devices Panel meeting.

When I first considered Lasik surgery, everyone around me thought I was nuts to put something like my vision in harms way, you see, I was a fire fighter for West Des Moines at the time. I was an on-call firefighter, which means in the middle of the night when the pager went off, I had 3-4 minutes to respond to the station get my gear on and get on the truck and head out into the unknown. When I would get up in the early morning hours, contacts and my eyes really didn't get along well with each other, glasses were dangerous to wear when going into a fire, so it really left me no choice. Just the thought of being able to wake up and see was amazing to me.

I decided to go for it and had the surgery done in 2006, my surgery was on a Friday morning, I drove to Wisconsin for work on Sunday morning with a vision of 20/10 (better than perfect). Everything was as if I was seeing it for the first time, I actually enjoyed just looking around at all the stuff I have missed for so long! I enjoy riding motorcycles and by having the Lasik surgery, it has improved my safety as well when on my bike, I don't have to worry about my contacts falling out or my glasses falling off. I don't get eye infections from my contacts anymore, I don't have any light sensitivity, it's just amazing!

The improvement on the fire ground was amazing too, I didn't have to worry about my contacts getting dirty or falling out if my eyes watered up. The only negative effects I have had are the sensitivity to Cigar or cigarette smoke, but, in all honesty, I always hated being around smoky places, so it may not have any result from the surgery. Please feel free to contact me if you have any questions. I am one happy customer!! I am recommending others in my family to go through the Lasik process at [REDACTED] they are the best!

--

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: LASIK

Dear Ms. Karen Warburton:

I have become aware of a forum with the FDA that has been requested by a small group of dissatisfied recipients of LASIK surgery with the intent of stopping LASIK from being performed in the U.S. As a member of the 95% other of us that are ecstatic with our positive results, I just wanted to share a few positives resulting from my surgery:

- I work at my desk free of glasses and without headaches reducing the quality of life for my family or me.
- I am able to watch my son and daughters play sports without glare, squinting or the blur of rain drenched lens clouding the view.
- I see clearly while driving at night ensuring the safety of family while traveling.
- I am normal again.

All laws, rules, guidelines are as a result of that small percentage of people who will take advantage and risk with out regard to others. Those controls are needed. But in the case of LASIK surgery, it is a choice. A choice made by many with a full understanding of the risks.

Please take no action to penalize the majority for the satisfaction of a few.

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: Lasik

The FDA wants to know how LASIK has changed your quality of life - for example, your every day life, your leisure, your ability to do your job, even your personal safety

I actually feel more secure since I have had LASIK surgery. I just returned from a trip and I didn't have to worry about loosing my glasses, changing from regular glasses to sunglasses. When I woke up in a hotel room I could see with out feeling around for my glasses. I can play ball with my nieces and not worry about my glasses.

I love it.

Why would you want to discontinue this? I think it's a good think that you are keeping tabs on the people who are performing the surgeries.

Regards

Warburton, Karen

From: -----
Sent: Tuesday, April 08, 2008 7:46 AM
To: Warburton, Karen
Subject: LASIK

Importance: High

I am very pleased with the outcome of my PRK eye surgery which was completed a few years ago on my left eye. My right eye was not touched and I easily made the necessary transistion/adjustment. I had a wonderful expeerience at the [REDACTED] and would recommend this option and the Center to others. feel free to contact me at the number below for additional questions.

Warburton, Karen

From: _____
Sent: Tuesday, April 08, 2008 5:03 AM
To: Warburton, Karen
Subject: LASIK

Dear FDA,

I would like to tell you how my life has been changed since having LASIK. I was -250 in each eye where normal is 20/20. I had worn glasses since the 2nd grade and contact lens since 16 yrs of age. I am now 50 years old and happy to say I have worn neither in 9 years since I had the procedure. Having the procedure was a life change for me. No more afraid of getting up from bed and not having my glasses next to my bedside in case of an emergency. Going on vacation with contact lens, spare set of glasses...in case luggage was lost or contact lens were lost. I play golf and the wind would bother the contacts and sweat in outdoor sports would bother the glasses. I would not go swimming in the ocean (I live in Florida) nor a pool because I couldn't see. I use to not be able to drive at night very well because of my contacts-I have better night vision now since LASIK.

At the time of my procedure I worked in front of a computer 8 hours a day and my eyes would get dried out which with the contacts would alter my vision but after Lasik I could work overtime and still have clear vision.

Meeting [REDACTED] and his staff in ----- and having the procedure is in the top 5 of the b----- for myself.

Warburton, Karen

From: -----
Sent: Tuesday, April 08, 2008 1:25 AM
To: Warburton, Karen
Subject: LASIK

Ms. Warburton,

Last summer I had Lasik Eye Surgery done in-----by [REDACTED]
[REDACTED]. I am 21 years old and I'm the point guard for the Kansas
State Women's basketball team. Being an athlete causes my lifestyle to
be very active and contacts just weren't sufficient anymore. I now
have 20/20 vision and see colors like I've never seen them before.
Recovery from the surgery was even faster than I expected. My quality
of life has improved because of this surgery because not only do I not
have to hassle with contacts anymore, I can see better now than when I
wore contacts.

My eyes are sensitive so I battled with dry eyes when I wore contacts
for extended periods of time. Now that I've had Lasik surgery my eyes
aren't dry and I can play sports and live an active lifestyle. The
worst part of wearing contacts for me was driving at night. Before I
had surgery I used to see halo's from car lights and my eyes were very
irritated when I drove in the dark. Since I've had this surgery I no
longer see halo's and driving in the dark isn't painful. The decision
to have Lasik eye surgery has been one of the best decisions I have
ever made. [REDACTED] and his staff were tremendous to work with and I
am grateful they were able to perform this surgery and give me vision
like I've never known before.

I would like these comments to be included as part of the record of
Ophthalmic Devices Panel meeting.

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: TLC Lasik Eye Center

Ms. Warburton,

My name is _____ . I had lasik done by _____ back in October, shortly before my w_____ ame then was _____. I lived at _____ w live at _____ . I'm writing because I would like to add some comments to be included as _____ e Ophthalmic Devices Panel meeting.

Before Lasik, I had been wearing contacts for 8 years. It was a big hassle for me since my eyes were always getting dry. I work in a dry, dusty environment which only irritated my contacts more. After Lasik, my work environment no longer irritates my eyes, and it's much easier driving to work since I work very early in the morning (4 a.m.) and my vision is much sharper after getting lasik than it was with contacts. I live in a rather rural area and need my vision to be sharp in order to avoid any animals that may run onto the road at that hour of the morning, not to mention normal driving activities require good vision. I have a much easier time going out with friends and enjoying myself because I don't always have to stop to go fix my contacts. It's very nice knowing that my vision is now 20/20. Lasik has definitely improved my life.

Thank you for your time.

Warburton, Karen

From: _____
Sent: Tuesday, April 08, 2008 12:28 AM
To: Warburton, Karen; _____
Subject: Positive experience after LASIK surgery

I am writing in response to your FDA hearings regarding patient satisfaction with LASIK surgery. I want to write that my life has truly changed because of LASIK surgery. Not being dependent on glasses or contacts gives me control of my own life again. I had a good outcome with LASIK, not needing glasses even for reading or driving. 7 years later (I had my surgery in 2001) I still have perfect vision, still can read small print, drive and see distance. My family always relies on me to read the far away signs when navigating new roads in the car. I have almost forgotten what it is like to be dependent on glasses, especially when I wake up at night and can see or now when I fly on a plane without itchy dry contacts. Or when traveling, I used to take so many extra cases of contacts just in case... None of that anymore. My surgeon took the extra time and care to make sure my measurements were done accurately, and he personally saw me before and after surgery so I trusted him fully. And the results show for themselves.

Thank you for taking the time to listen to my story. I am so grateful for this life changing surgery.

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: LASIK Surgery testimonial for the Ophthalmic Devices Panel

Hi Karen,

I received a notice from my eye doctor that the FDA is going to be having a public hearing on the quality of life impact of LASIK. They provided me with your email address so I could submit my own testimonial for review. Please include my comments as part of the record for the upcoming Ophthalmic Devices Panel meeting.

I had LASIK surgery 2 years ago (26 months, to be exact) and am incredibly happy with the results. My vision prior to surgery was pretty poor (contact lens prescription was 6.25 for one eye and 6.5 for the other, with corrections for astigmatism). I had been wearing glasses since I was 6 years old, and had worn contacts for a few years, but after developing an irritation in my eyes caused in part by the early perma-lens contacts in the late 1980s, I could only wear contacts about once a month for special occasions.

LASIK surgery has changed my life in many ways. For starters, it's amazing to wake up -- in the morning, in the middle of the night -- and be able to *see*. I'm no longer struggling to find my glasses (it's hard to find your glasses when you can't see!) and I can actually see in the shower again! When I pull on a shirt I don't have to "take my glasses off" first... When I'm tired, I can rub my eyes without bumping into my glasses... I don't have "permanent" marks on my nose anymore, and my hair isn't perpetually getting caught... It's the little things that go a long way!

I go kayaking, swimming, and sailing without any concern about not being able to see, and without fear of losing my glasses. I'm a software engineer and I spend all day looking at my monitors without any difficulty. When I'm driving, I am more aware of the cars around me now that I can see peripherally again.

I have no problems with my eyes other than dryness and occasional abrasions due to having a thin epithelium. [REDACTED] performed the Custom Waveform LASIK, so I don't have halos or blurred lights at night at all. Night vision is excellent.

I hope my comments are helpful in the FDA's analysis of LASIK surgery. Please feel free to contact me using the information below:

April 8, 2008

RE: Ophthalmic Devices Panel of the Medical Devices Advisory Committee

Karen Warburton, MT, MHS

Dear Ms. Warburton,

Subject: Comment Submission

Hello. I am a concerned victim of LASIK, encouraged to see that the FDA might be recognizing the "laser vision correction" tragedy and looming epidemic. Prior to the "surgery," I thought that my vision was poor. Unfortunately, like so many, I now know what it is to have poor vision.

I have largely remained in denial and mental seclusion since the surgery, afraid to learn more about what really happened to me, and wanting it all just to go away. The deception in this extremely profit driven industry must stop. Too many people are losing, not gaining, quality of life. Some are so riddled with horror and guilt that they are choosing to end their own existence.

Let me make an attempt to describe my pre-LASIK condition. I was an OD - 5.50+2.50X113, OS -7.00+1.75X090 before the slice and burn. I don't exactly know what all of that means, but I do know that I was referred to at one point as a "high myopia, moderately high astigmatism" patient. I have just over 6 mm pupils. My higher order aberrations were measured at fewer than 5% by the VISX CustomVue machine.

I never got along well with contact lenses. Originally, I was fitted with rigid gas permeable lenses for my astigmatism. Later on, when toric lenses were developed, I got those. In the end, the results were always the same. I never was able to get comfortable with the lenses. Mostly, my eyes felt dry and itchy. I was sold on the lie that LASIK was some kind of ticket to a new life freedom. I would be able to gain quality of life, have more fun, be a better golfer, go inside on a cold day and not have a pair of lenses fog up, etc. What I wouldn't give to just go back.

Anyway, I decided to go through with it. I am a natural pessimist, so I struggled mightily with the decision. I knew that there were risks. Of course, I was lied to and told that new technology has "virtually eliminated" the risks. I was sold the biggest bottle of snake oil of all time, and drank it all, because I wanted to believe. I was told that I needed the "custom" procedure due to my prescription.

I could continue to write a book about all of my pre- and during surgery details. In retrospect, there were so many warning signs that day. I had every opportunity to bail out, and I didn't. Let me cut to the chase. I am now suffering from an all too common list of "complications;" ghost images from both eyes in all lighting conditions, starbursts, halos, dry eyes, and floaters. If I were forced to chose which was the most troublesome, I

would say the floaters. I have a desk job, and looking at the computer screen all day is just torture.

I have visited several independent Ophthalmologists and specialists since my eyes were destroyed. Each of them has agreed on one very important aspect of my post-surgical condition. They all agree that I DID NOT receive a Custom laser treatment. Again, I was told that I needed to have Custom in order to “achieve my best personal visual result.” I paid for Custom. My understanding, however limited, is that the non-Custom version of LASIK only has an effective treatment zone of 5-6 mm, and that Custom was designed specifically to deal with higher prescription patients. Does an “oversight” like this constitute medical malpractice? At the very least, is it consumer fraud? In addition, I have since been shown from my file set that my pupils were mis-measured prior to the surgery, resulting in an insufficient treatment zone size. Unfortunately, these medical errors currently do not constitute malpractice according to the attorneys and “experts” I have consulted. Can the FDA continue to support a Standard of Care that doesn’t protect the consumer against negligence?

What is more, currently there is no technology available to help those with damaged vision as a result of laser surgery. My options include glasses and special post surgical contact lenses that cost thousands of dollars and restore only a fraction of lost vision – that is, if I can tolerate wearing them at all. I have no options for treatment of the vitreous floaters created by the pressure induced by the ocular ring, or for my chronic dry eyes.

Thank you again for taking the time to hear my story. I hope that the FDA will carefully consider the mounting evidence that LASIK is not safe, and discontinue its support of this procedure as well as advocate the development of technologies to address the complications.

Respectfully,

[REDACTED]

[REDACTED]

March 31, 2008

To: The Members of the Ophthalmic Devices Panel, FDA

Dear Esteemed Members:

I am a certified optometrist who has been practicing in Israel for the past 45 years and I am addressing this letter in an attempt to point out a possible problem associated with the LASIK procedure.

In my practice I often meet pre and post LASIK patients. When I compare pre and post LASIK vision tests, I find that many of those patients have lost 10% to 30% of their quality of vision, regardless of vision acuity, even 3 to 6 month post op. My observations are obviously based on a limited number of patients and are therefore insufficient for drawing any statistically valid conclusions. However; these observations do establish a cause for concern and in my personal opinion, the reduction in the quality of vision could be the result of a loss of Contrast Sensitivity (CS) among the post LASIK patients.

To the best of my knowledge, there is no reliable study that had been conducted in the past in an attempt to research whether there is a loss of quality of vision among post LASIK patients. I would therefore like to submit for your consideration the idea that your task force recommend mandatory CS testing of all pre and post LASIK patients. The collected data could then be analyzed and the impact of LASIK on CS evaluated for its possible contribution to patient dissatisfaction and also for defining new or updated vision requirements for vehicle drivers, aircraft pilots, and other safety-critical occupations.

Thank you for your consideration.

Sincerely,

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[REDACTED]

April 8, 2008

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