

To Whom It May Concern

Date: 3 Apr 2008

I, ----- 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,

(Signed)

Name:-----

Address:-----

Phone:-----

Warburton, Karen

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

As a New York City Firefighter I can't even begin to tell you what this Eye surgery has done to improve my life. I drive the Firetruck to the fires and as you can imagine its alot easier without glasses that fog up and glasses that are hard to see through with rain on them. I Love!! Love !! my new eyes

Warburton, Karen

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

Ms. Karen Warburton,

I wish my comments below to be included as part of the record during the Ophthalmic Devices Panel meeting this month.

It has been two years since my LASIK procedure – and I sincerely wish it was 40 years. To me, the quality of life is much better without corrective eyewear. I have always been a very active person and now there are no concerns about dirty lenses, mist or rain on the glasses, condensation on the lenses, etc. My vision is 20/20 – I can keep up and see all of the action at sporting events, see all road signs clearly, locate all wild animals in the woods or along the side of the road, when lighting is appropriate I can read books, magazines, newspapers, etc. without reading glasses. I also do not have to tote glass cases in my travels, worry about losing my glasses, breaking or bending the frames, and can now buy/wear everyday sunglasses. My vision today is perfect and without any complications.

I would certainly recommend the procedure for anyone having the proper qualifications.

Sincerely,

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen; [REDACTED]
Subject: Lasik

Karen,

I am a patient who just had PRK and it has been the single most beneficial medical procedure I have ever chosen to have. My vision is perfect now, as a talent agent I see lots of shows and not having to wear glasses or contacts is a dream! Really though, I'm a surfer girl and being in the water and able to see is the best!

Its a fantastic procedure, [REDACTED] was my doctor and [REDACTED] treated me with such great care Im wholeheartedly recommend them and this procedure to anyone.

Warburton, Karen

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

To Whom It May Concern,

My name is _____ and my address is _____ my e-mail is [REDACTED]

I would like to coment on my LASIK surgery done in February 2006 by [REDACTED] of _____.

I must say it has been very beneficial to me. I had bifocal glasses before the procedure and after the procedure I ended up with better than 20/20 vision and at present reading glasses are optional for me. It has made my job as a roof inspector much easier and safer as there is no distortion in my vision when going up ladders or transferring from lifts or staging onto pitched roofs. Those factors drove me to investigate LASIK and ultimately have the procedure done. The overall procedure from the actual surgery to final healed eyes was easy with my only complaint of having slightly dry eyes the first six months but I was warned ahead of time and that has disappeared and now I don't even really think about the condition of my eyes. I did not consider LASIK for cosmetic reasons but only for the quality of life upgrade and with that I have been thoroughly satisfied.

Please use these comments in the upcoming FDA hearings at the Ophthalmic Devices Panel meeting.

Warburton, Karen

From:
Sent: Tuesday, April 08, 2008 4:48 PM
To: Warburton, Karen
Subject: LASIK

LASIK

Dear Ms. Warburton,

My name is -----, I live on -----

Phone: -----

e-mail: -----

please include the following comments as part of the record of the Ophthalmic Devices Panel meeting:

Right before Christmas 2007 I had LASIK surgery at [REDACTED] . [REDACTED] did the surgery. Everything went very well and I recovered quickl---

Ever since my life has improved tremendously. I am a Service Engineer and work for a German company that manufactures high precision CNC-controlled turning machines. The quality of my work depends on very accurate eye sight, since I have to be able to read small gages and indicators in my job. Often they are located in hidden and dark areas. Before my surgery I had contacts. Eye glasses didn't work too good, since I had stigmatism. The problem with contacts sometimes was that the area where I am working is not always clean, my hands are usually very oily and dirty. So if a contact had shifted, I had a hard time to put it back into position. All this hassle is now history.

I also can work longer hours, since the dryness of my eyes after a couple of hours with contacts is history, too.

As a service engineer I am travelling a lot by plane, too. Now I don't have any problems with contacts and dry eyes due to the very dry air in the plane anymore. Also I don't have to explain the fluids that I had to carry for the contacts at the security screening at the airports anymore.

My personal life also has improved. Back in Germany I was a wrestler and even a coach. Recently I took up wrestling again. It is so much better now, because while wrestling practice I couldn't wear neither glasses nor contacts. Now I can see the stop watches and even far distant actions. I can go swimming without being afraid to lose the expensive contacts, I can work out without being afraid a drop of sweat makes it into my eye. On top of all that, I don't have to wait any time every day to put the contacts in and out.

If you have any questions, feel free to give me a call.

Best regards,

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: My personal LASIK experience

Dear Ms. Warburton:

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

As you can see by my e-mail address, I am presently the manager of the refractive surgery department at the [REDACTED] [REDACTED] in [REDACTED]. However, when I had LASIK in 1998, I was not an employee here. So, my testimonial is based on what [REDACTED] before and after LASIK. I would like to give you a brief background.

For the past 23 years my expertise has been in the Optical field, both in an Optometric practice and as a trainer for [REDACTED] [REDACTED]. I managed private practices for several years. I had access to unlimited eyewear and was a very successful spectacle and contact lens wearer for 38 years. I had not thought much about having refractive surgery. My husband who is an Optometrist encouraged me to have the procedure done. [REDACTED] was my first and actually only choice. The (monovision) procedure went very smoothly and honestly it brought tears to my eyes when I could see the clock across the room immediately after surgery.

I have continued to enjoy outstanding vision. My near vision is exceptional and my only need for correction is occasionally for night driving. I have not had an enhancement and I will be 10 years post-op in September 2008.

This is by far one of the best things I have done for myself. My respect for [REDACTED] and my stellar outcome was one reason I wanted to work in this practice. I contacted the [REDACTED] for employment.

To be able to counsel potential patients about the benefits of refractive surgery and bring a personal perspective to that counseling is very rewarding to me.

Now, as a grandmother, I feel very safe and confident that I could act quickly in any situation particularly in the middle of the night, at a pool or beach or playing with them inside or outside without looking for glasses or putting in contact lenses.

My personal e-mail address is [REDACTED]

Thank you.

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Warburton, Karen

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

Dear Karen,

I had LASIK done on September 2, 2005. The procedure has been very successful. I am free of glasses and contacts. It has improved the quality of my life. No more hassle of cleaning and wearing/taking off of contacts everyday. Before, I can only wear hard contact lens and I have been wearing them for over 20 years. That's the only option, unless I am willing to wear glasses but it's so thick and heavy because of my high prescriptions. The contact lens make my eyes very dry and sometimes a piece of lint or an eye lash gets between my contact and my eye ball and I'll be tearing and miserable until I can get it out and have it clean. Which it's not always convenient when I am in the middle of a meeting or talking to my clients to run to the restroom and take care of the problem. So having LASIK done has improved my quality of life and help on my work productivity. I am convinced that I have made a good decision to have LASIK done. I felt so wonderful after I had them done that I have refer all my friends to do them.

Thanks for reading my testimonial.

Sincerely,

Warburton, Karen

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

I am writing this with the hope that my comments will be included in your Ophthalmic Devices Panel meeting. I had LASIK surgery on Sept 11th, 2007 after several years of of struggling with contacts and bifocals. My surgeon advised me that with my degree of correction needed and an existing dry eye problem that I may experience some adverse side effects. Much to my relief, I have had no lasting negative results. The surgery has given me 20/20 distance vision once again. I can safely drive at night and in the rain. I can play tennis, swim, bike and run without the need of contacts. I can get up in the middle of the night and see like I should. I can identify people and things at a distance again. The surgery has definitely increased my safety and ease of living. I had a great professional as my Doctor, one who did not try to talk me into anything or make a sale. He discussed the positives and possible negatives and let me as an adult make my own choices. I made an informed decision and I am so happy I mad-----e surgery. If you have any questions please feel free to contact me at ----- of by phone [REDACTED]
Thanks.

Respectfully,

Warburton, Karen

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

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

LASIK has helped me in so many ways. From being able to get up in the night to care for the children without having to fumble for my glasses to being able to provide myself with better overall eye health because I am not abusing contact lenses anymore. I remember back in 1990 I had a contact tear, I could not afford to get another pair and I did not want to wear those glasses the ARMY gives you but that was all I had. I was a -4 sphere and went around with only one contact; since LASIK I don't have to worry about those times anymore. I love to golf and work in the garden. No contacts drying out or glasses falling off my face to worry about. It maybe cliché to say to see the clock at night but it is true; it is even better to wake up in the middle of the night to look across the room and see your child resting comfortably in its crib. I had my LASIK procedure on July 27, 2000. Ever since day one I have seen 20/15. I still send my surgeon a thank you every year. The only regret I have about my LASIK procedure is the fact that I did not do it sooner.

Thank you for your time.

.....

Warburton, Karen

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

Good Afternoon:

I thought you would like to know that getting lasik surgery is one of the best decisions that I have ever made. After dealing with glasses and/or contacts since the age of six, I decided to have lasik surgery in October of 2004. The convenience of being able to see clearly without any additional assistance is amazing to me. The excessive cost of glasses and contact lenses also made my decision much easier. You are more than welcome to use my comments if necessary.

Warburton, Karen

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

Ms. Warburton, this e-mail is in reference to Ophthalmic Devices Panel meeting.

----- . I am a police officer for ----- . I got lasik 7 months ago and it is the -----could do for myself professionally and persoanlly. Glasses and contacts do not get in the way of what I am doing anymore. I do not have to worry about losing or breaking them any more. Since getting the lasik procedure I have had no negative effects. Also, I have better vision then I did while I was wearing glasses. I am amazed at how one day I am basically blind wearing glasses and the next day I can see without glasses and have 20/20 vision.

Thank you for your time

Warburton, Karen

From: -----
Sent: Tuesday, April 08, 2008 3:14 PM
To: Warburton, Karen
Subject: LASIK Quality of Life

Good day, Karen.

I heard that FDA has scheduled a public hearing on "LASIK Quality of Life". Since I had LASIK on both of my eyes, I would like to put in my comments.

Since I had LASIK on 1/6/2006, my vision resumed to 20/20 from nearly blind without eye glasses. I think my investment on LASIK is well worth. The 1st few weeks after the LASIK, I had to wear sun glasses. After that, everything went very well: I no longer have to wear eyeglasses nor sun glasses the 1st thing in the morning; I don't have to wear eye glasses for snorkeling or playing tennis; my face no longer have to touch the mirror when I put on the facial lotion; and there are no more red marks on the 2 sides of my nose due to wearing of the heavy eye glasses.

Just to tell you the truth, the LASIK surgery made my life a lot better and easier. Prior to LASIK, I couldn't imagine that things can be that convenient without eyeglasses; however, now, I can say that I enjoy life much, much, and much more with good vision but no eye glasses. Should you have further questions or concerns regarding my LASIK operation, please feel free to contact me by email or phone.

Warburton, Karen

From: -----
Sent: ----- 08 3:45 PM
To: Warburton, Karen
Subject: lasik

Ms. Warburton,
I had LASIK back in 1999, and I must say that it has been life-changing for me. As a recreational softball player and coach, I have learned to appreciate being out in the dirt and not worrying about dusty contact lenses. Also, as a mother of 4 children, I found it most reassuring to go swimming with my kids when they were younger, and still being able to see each of them at a distance. Swimming became a much more enjoyable experience, without the stress of trying to identify my kids as they played in the water. I would strongly recommend the procedure to anyone considering having it done.

Warburton, Karen

From: [REDACTED]
Sent: Tuesday, April 08, 2008 3:24 PM
To: Warburton, Karen
Cc: [REDACTED]
Subject: Eyes

Dear Ms. Warburton, I had Lasik surgery done in Feb. 2001 under the skilled hands of [REDACTED]. It has been and continues to be a life altering event. To wit - I have 20/15 vision w/no glare issues/ no "haloing" or any other negative issues. Just the ability to see the tennis balls better and the eyes of a performer from most anywhere in a theatre. My ability to see signs driving is also comforting.

Please feel free to make this part of the public record and/or the Ophthalmic Devices Panel meeting.

[REDACTED]

[REDACTED]

Please do not transmit orders or instructions regarding [REDACTED] by e-mail. The information provided in this e-mail or any attachments is not an official transaction confirmation or account statement. For your protection, do not include account numbers, Social Security numbers, credit card numbers, passwords or other non-public information in your e-mail. Because the information contained in this message may be privileged, confidential, proprietary or otherwise protected from disclosure, please notify us immediately by replying to this message and deleting it from your computer if you have received this communication in error. Thank you.

[REDACTED]

Warburton, Karen

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

My name is _____, and I am one of the success stories of Lasik. I have been wearing glasses for 23 yrs and seeing as I am now 31, that is most of my life. In October of 2007 I was able to finally free myself of the burden of glasses which were up to a script of -6 and up. They were a pain in the neck and with 2 small children, I was getting them adjusted just about every time I went somewhere.

Thanks to the fine doctors at _____, within one session of 6-7 seconds for each eye, I am now seeing 20/20 with NO PROBLEMS!!!

My night vision has never been better, and this was not just told to me by the _____ Dr's post op. I also had my annual check up with my family eye doctor and he confirmed that I am now seeing 20/20 and that my eyes look great.

For me, this was the only way out of wearing glasses since I had scars on my eyes due to corneal ulcers from the past. I could no longer wear contact lenses and I miss my vision.

I am not saying that Lasik/Lasek/ PRK(I had this) is fool proof, but you can not tell me of ANY type of surgery that you are guaranteed 100% that nothing will go wrong, it is impossible to do that. I would recommend to anyone who wants this done to go for it. I just believe that you can not go to any Joe Shmoe on the street. Do your research and feel comfortable with the person and what type of surgery and after care you are going to need/receive and go for it. I LOVE IT!

Thank you _____ and _____ for the gift of 20/20 vision once again, something I have not had since I was in 3rd grade! You guys are great and I do and will continue to promote you all to friends and family!

Warburton, Karen

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

I had lasik surgery in March of 2008 through the _____. It was a positive experience through and through with the ultimate return on investment being my sight. You cannot put a price on crystal clear vision without the use of foreign objects in or on your eyes. I see the world in high definition the way it was meant to be. I highly recommend this procedure to anyone with even the slightest need for correction.

Warburton, Karen

From: -----
Sent: -----
To: Warburton, Karen
Subject: LASIK/Impact on my life

Name: -----
Address-----
Contact: -----

I would like to share how LASIK has impacted my life, and I would like my comments to be included in the record of the Ophthalmic Devices Panel meeting.

I am almost 45 (next month) and I had my procedure about 7 years ago. I must say that nothing I have done to improve myself physically can even remotely touch the impact that LASIK has had on my quality of life. I am a very active and athletic person, and being dependent on glasses and contacts restricted what I was able to do--i.e., glasses fog up, slide off, limit peripheral vision, etc. so I could never do anything active while wearing them; and my eyes were very dry, so contacts would stick to my eyes, causing irritation, or they'd tear or want to come out, or they would fog up if I accidentally fell asleep in them. They were a source of constant frustration.

Besides all of these issues (and more), I always feared that if I was in a situation where I lost my glasses or my contacts fell out or tore, and I didn't have any other lenses with me, I'd be in big trouble because I couldn't see much at all without correction. When I started considering scuba diving, something that I'd wanted to do for years, that fear grew because I panicked at the thought of my contacts coming out while deep down in the ocean and being unable to see to get back to the surface, so that fear caused me to not pursue the sport for a long time.

Finally one day my mom told me she and my sister were going to have LASIK. Once they did, they shared how thrilled they were with their results and how great it was to not have to put anything in or on your eyes and yet have great vision! I signed up right away! I went to one of the best surgeons in California, and in a matter of a few minutes, my life was changed unbelievably! I achieved 20/15 vision with the procedure, and life now had incredible and endless new possibilities!

It was unfathomable to me that I could see perfectly without any corrective lenses, and there were even times at the end of the day that I'd go to "take my contacts out" and then realize THERE ARE NO CONTACTS ON MY EYES!!! :-). I was instantly able to do many things I hadn't done before-- getting up and just heading out the door without the ordeal of putting in contacts; seeing movies or plays in air conditioned theaters without my contacts drying out so badly that I had to put drops in the entire time or leave; being active in sports without worrying about glasses falling off or contacts causing irritation or infection due to creams or sweat getting in my eyes; staying up late and not having to worry about my eyes aching because I had my contacts in too long; being ok with situations where water would get in my eyes because if I had lenses or glasses they could be damaged or ruined; driving without correction; being on a speedboat, jetski, skydiving, etc. with incredible wind coming at me and it's no problem; being called to handle an emergency in the middle of the night and not having to take the time to find glasses or put in contacts, etc... and of course scuba diving!!!! These activities and so many more have been improved (or made possible) by having LASIK.

I see this procedure as the most invaluable thing I've ever done and would recommend it to anyone who is "handicapped" in any way by the need for corrective lenses. I feel truly blessed with great sight now and I am grateful to God every day that He would allow me to see like I do!

Thank you for letting me share.

Warburton, Karen

From: _____
Sent: Tuesday, April 08, 2008 1:59 PM
To: Warburton, Karen
Subject: LASIK

Please include my as part of the record of the Ophthalmic Devices Panel meeting.

I'm very happy with my LASIK and please that I no longer have to travel with contacts, glasses, etc.

Warburton, Karen

From:
Sent: Tuesday, April 08, 2008 2:34 PM
To: Warburton, Karen
Subject: Re: LASIK & FDA public hearing in April, 2008

To: Karen Warburton
U.S. Food and Drug Administration

From :

Ms. Warburton,

It has come to my attention that the U.S. Food and Drug Administration (FDA) has scheduled a public hearing on the quality of life impact of LASIK in response to a group of "dissatisfied patients" who have requested this forum with the apparent intention of stopping LASIK from being performed in the U.S.

I respect the the right of any American citizen to dissent or take issue with FDA policy governing medical procedures. I also appreciate the FDA's attempts to insure safe, reliable, effective surgical procedures. However, it is my understanding that the FDA and American Society of Cataract and Refractive Surgeons has already taken, and continues to maintain, reasonable measures to minimize and publicize any known risks associated with LASIK. While my sympathies extend to anyone impacted negatively by LASIK, I cannot support any potential action on the part of a federal agency that compromises my prerogative and/or right as a U.S. citizen to utilize a medical procedure already approved/recognized by the FDA, American Society of Cataract and Refractive Surgeons, and opthamologists world-wide, given that my physician has provided me with opportunity to know and acknowledge any known risks involved in LASIK prior to surgery.

The FDA is keenly aware there are risks involved in ANY medical procedure. I would urge the FDA to continue serving the American public by minimizing known risks through policy and publicity. But, I would also respectfully remind the members of the FDA who will be involved this hearing that it is not the purpose, nor the prerogative, of our FDA to remove the right of personal choice from American citizens as it pertains to what risks citizens knowingly choose to take, or not take, be it LASIK or other.

I personally had LASIK performed on both my eyes in February, 2008. My physician and his staff, thoroughly educated me on the known risks and limitations, as well as potential benefits of LASIK. I signed a written acknowledgement that I understood those known risks and limitations. From that point forward, I believe the risk was mine to choose.

Like 95% of all other LASIK patients, my surgery was successful and without complications. It is wonderful to SEE the world in full, living, detailed color without an "ophtho-prosthesis" (corrective lenses)! The extension of my peripheral vision through LASIK is of great benefit to my own safety and well-being, as well as others - whether I am driving an automobile, operating a farm tractor, crossing a busy street, etc. LASIK makes recreational and athletic activities possible to me now that I could not take full advantage of previously. And while I would not use myself as an example of the ascetic or cosmetic benefits of LASIK, I can testify, as a public speaker and consultant, to greater effectiveness

and connectivity with my audiences/clients after LASIK. No more contending with lighting and angles, whether live, video, or Internet presentations, etc. as when I wore corrective lenses.

Blessings upon you as you continue to serve the American public with integrity and without bias.

Sincerely,

Warburton, Karen

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

I RECEIVED AN EMAIL FROM [REDACTED] IN _____, REQUESTING THAT I EMAIL YOU WITH THE COMMENTS ON MY LASIK SURGERY. I WISH MY COMMENTS TO BE INCLUDED AS PART OF THE RECORD OF THE OPHTHALMIC DEVICES PANEL MEETING.

MY LASIK SURGERY WAS DONE A WEEK BEFORE CHRISTMAS '07. I AM UPSET ABOUT MY LASIK SURGERY, BEFORE THE SURGERY I COULD SEE UP CLOSE TO PLUCK MY EYEBROWS, PUT MY MAKEUP ON, CLEAN AND CUT MY FINGERNAILS, NOW I CAN NOT DO THESE THINGS WITHOUT GLASSES. I HAVE TO WEAR GLASSES ALL OF THE TIME, ESPECIALLY FOR DRIVING, I CAN NOT READ ROAD SIGNS, IT IS SCARY. THE OBJECT I WAS TRYING TO GET AWAY FROM (GLASSES/CONTACTS) ARE NOW A CONSTANT COMPANION AND I PAID \$4,800 FOR THAT..... I JUST WANT TO BE ABLE TO SEE UP CLOSE AGAIN.

I AM GLAD THAT THIS SURGERY WORKS FOR SOME PEOPLE, I UNDERSTAND THAT IT DOES NOT WORK FOR EVERYONE. HOWEVER I TRULY FEEL THAT THERE SHOULD BE MORE CONSULTATION BEFORE YOU HAVE THE SURGERY, PERHAPS SHOWING A PERSON WHAT THEIR EYESIGHT COULD BE AFTERWARDS AND HOW THEY WOULD HAVE TO ADJUST TO FUNCTION. I HAVE WORN GLASSES SINCE I WAS IN THE THIRD GRADE AND ALL I WANTED WAS TO GET RID OF THEM.

I MUST WAIT FOR MY VISION TO BE STABLE FOR THREE MONTHS BEFORE THEY WILL DO AN ENHANCEMENT, I AM SCARED TO DEATH TO HAVE IT. I CAN NOT TELL THAT THERE HAS BEEN AN IMPROVEMENT, MY EYE DR. TELLS ME THERE HAS BEEN AND I BELIEVE HER BUT IT IS HARD WHEN YOU ARE THE ONE TRYING TO SEE AND CONTINUE WORKING AT A COMPUTER ALL DAY, READING, DRIVING.

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 and 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.

.....
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 me if
any questi-----
My name -----
Address : -----

I had my lasik 2 years ago and had is done monovision with different correction in both eyes.

I am extremely pleased with the results and have highly recommended it to others.

My daughter will be have Lasik this summer

From:
Sent: Saturday, April 05, 2008 1:48 PM
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-seven 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 L.A. (-----) (at the suggestion of my original surgeon). Again, I was told not to worry. He----- 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.

----- ho 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.

A bit of an epilog 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 -----
----- . 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,

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-----and show how everything in my life changed for the better after I had LASIK with -----

My name is----- and I am originally from Argentina. My eyesight was really bad since birth (----- eft 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 Dr. Hyver 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 recommende----- edure 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 strong-----that the doctor's role, dedication and honesty are essential for the success of the procedure.

From:-----
Sent:-----
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.

From:-----
Sent: Friday, April 04, 2008 8:36 PM
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,

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.

--

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 i----- given to me prior to a procedure. The extent to which my Doctor [REDACTED]----- 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,

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.

-----O-----
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: Sunday, April 06, 2008 5:38 PM
To: Warburton, Karen
Subject: LASIK

Good morning,

I understand that the FDA is accepting testimonials via email regarding quality of life issues following LASIK. I am nearly 54 years old and had worn glasses since I was 12. I enjoy a lot of activities, including golf, hiking, sailing and swimming. About 5 years ago I started wearing contact lenses, hoping to improve my vision and also to make participating in such activities easier, more comfortable and more satisfying. That worked to a degree, but the combination of astigmatism, nearsightedness and the need for reading glasses brought about due to age drastically reduced the benefits of contacts. Plus, the smallest of objects getting into my eye (which frequently happens with many of those activities) would cause a lot of discomfort.

About a year ago I decided to have LASIK. I have told many people, having that done is one of the best things I have done for myself. I can now swim without worrying about losing lenses but still be able to see where I am going. When I sail, I don't have to worry about losing lenses or have the aggravation of glasses that slide down my nose. I can read the instruments on the boat, see objects in the distance and read a chart, all without having to find or wear any type of corrective lense. In all of my outdoor activities, I can now wear sunglasses that provide optimum protection for my eyes.

LASIK has also improved my quality of life at work. I am an attorney and during the course of a day will be constantly changing between looking at people across the room, a computer screen, and documents or books. Before the procedure, I found that I needed reading glasses to be able to read documents when I was wearing my contacts, which meant I had to find a way to keep reading glasses handy, which was not always easy to do. Many times, I found myself in situations where I really needed those reading glasses but didn't have a pair with me and, perhaps due to vanity, refused to wear them on a chain around my neck.

I would eagerly and enthusiastically recommend this procedure. My only regret is that I did not choose to have this procedure years ago. I hope this information has helped.

Warburton, Karen

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

I think that if you want an unbiased assessment of the merits of LASIK, you need to ask for "patient experiences" as a whole and not just "bad patient experiences".

And even if you did ask for overall experiences of patients who have undergone LASIK treatment, you would still probably get a biased response because those people that had no problems would be less likely to put effort into the survey compared to those that had a profound negative impact from the surgery because those people with bad experiences would be suffering an impact to their daily life.

In fact I can hardly be bothered responding to your original email because LASIK has had nothing but a great effect on my life so it's not an issue to me.

If you divide the number of people who respond to a survey calling for accounts of bad experiences by the total number of people who have had the surgery you might get an indication of the risk. When I had mine done, I think the stated risk was well below 1%.

Please include my comments.

Warburton, Karen

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

Dear Ms. Warburton -

It never fails to amaze me why there is always a group that tries to destroy something of great value!

In this case LASIK/PRK

I am 66yrs old and have worn glasses or contacts since I was six -

I had the PRK procedure on 02-09-08

I was able to see and READ the clock across the room the moment I opened my eyes

I had absolutely no down time and minimal discomfort the 2nd day after surgery

I can **SEE** without glasses or contacts when I:

- 1) Get up in the middle of the night
- 2) Drive at night (without any halos around the lights)
- 3) Read the traffic signs while I driving at night
- 4) Open a hot oven
- 5) Do dishes w/steamy hot water
- 6) Work on the computer
- 7) Give a presentation
- 8) Throw a ball across the lawn to my dogs
- 9) Play rough and tumble with my grandchildren

I extol (██████████ s ████████████) virtues to all that inquire about my new found freedom

It is in everyone s best interest not to remove this procedure from the market -

Please include my comments as part of the record of the Ophthalmic Devices Panel meeting

Thank you -

Warburton, Karen

From:
Sent: Wednesday, April 02, 2008 2:32 PM
To: Warburton, Karen
Subject: Ophthalmic Devices Panel meeting

Hello Ms. Karen Warburton,

I was made aware of an upcoming public hearing in regards to the affects of LASIK procedures on patients. I would like to tell you a little about myself and my outcome after LASIK and would like for this to be a part of the record of the Ophthalmic Devices Panel meeting.

Prior to my procedure I could not read anything clearly 6 inches in front of my face. I wore contacts daily and when my eyes needed a breather I wore glasses. Having an active lifestyle, glasses severely inhibited my activities. Attending college classes could also prove difficult due to contacts becoming "goeey" from being worn all day/night. I work full time during the day and school at night, so I do not have time to worry about glasses/contacts.

After my procedure, I was able to see better immediately. Steadily my vision has improved and I have never had any significant problems due to LASIK. I could not imagine my life without the procedure and it was one of the best decisions I have ever made. I also have been able to enjoy life more by not having to worry about taking my contacts out at night and therefore putting my glasses on. I can focus on life and not taking care of my eyes. Being involved with an Information Systems in healthcare, my vision is tested each day with computers. Headaches have decreased and my overall productivity because of it has also increased. In all aspects of my life (personal, professional, and also in academics) have improved dramatically.

I hope my testimonial helps and stories such as mine are discussed in the upcoming Ophthalmic Devices Panel meeting.

Thank you for your time,

.....

Warburton, Karen

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

Hello!

My name is _____, and I wish to share with you my experience with LASIK surgery, and how it has changed my life for the better. I would like for my comments to be included as part of the record of the upcoming Ophthalmic Devices Panel meeting.

I had LASIK surgery performed on both my eyes about 5 years ago. At that time, I was severely myopic and had some astigmatism, as well, that contact lenses could not fully address and correct. I had worn thick glasses since elementary school—both an inconvenience and something I felt self-conscious about. My glasses and even contact lenses had always interfered with my favorite water sports growing up in Florida, and with my profession as a pediatric phlebotomist and clinical research coordinator. I often had trouble with my glasses sliding down my nose and disrupting my work while I was sitting very close and concentrating, using both hands on a child or infant for a venipuncture procedure. Contact lenses often got dry when I kept my eyes open, carefully watching the needle in my hand, as I directed it and held it in place.

In 2002, after the birth of my first child, corrective lenses presented a new inconvenience: wearing them while caring for a newborn. With the small snatches of sleep at odd times that all new mothers get, I abandoned my contact lenses all together, opting to wear glasses while awake. I spent a lot of time holding and nursing my new baby, looking down at him in my arms, and found my glasses constantly slipping off. As he grew older, he often reached up and pulled them off, dropping them or flinging them away, leaving me unable to see as I was carrying him, a huge inconvenience and a safety issue for both of us. When he woke in the night, I had to first find my glasses before I could even locate him in his crib in the room next to ours. We became used to both of us getting up each time the baby awoke to nurse, my husband making sure I had my glasses and could see, before handing me the baby, or a pillow or whatever I needed. My husband and I agreed it was time to look into LASIK.

I had my procedure done on a Thursday, and could have returned to work on Friday, but chose to take a day off and return Monday. From that point through today, my vision became, and has remained, better than 20/20, and I have no need for any corrective lenses. The surgery absolutely changed my life for the better, and that is no exaggeration. I have encouraged many people in my same position to go for an evaluation to see if they, too, would be a good candidate for LASIK. I have had absolutely no problems with my eyes or my vision at all, since my surgery. I am grateful for the skilled surgeon I had, and for all the hundreds of things in my life that are now possible or much easier without corrective lenses.

I have a second child now, and her whole infancy went along without my wearing any corrective lenses. My husband and I marveled at the differences between having our first child when I could not see without lenses, and our second, where it was not an issue at all. Now that my children are almost 6 and 2, and are getting older and more active in swimming, sports and games, I can participate and keep up with them much better than I ever could wearing glasses or lenses. I am back at work, performing phlebotomy on children as part of our research and health care services, and I know my surgery has helped in the way I can perform my job duties. I no longer need to push my glasses back into place in the middle of a venipuncture, and I can look down on an infant lying prone on the exam table without my glasses falling off onto the floor or onto the child. I strongly urge that you consider how helpful and life changing (for the better!!!) this surgery is and has been for so many of us, in our own lives and in the lives of the people we touch and interact with every day.

Warburton, Karen

From:
Sent: Wednesday, April 02, 2008 11:31 AM
To: Warburton, Karen
Subject: LASIK

My name is:
My address is:
My email is listed above if you need to contact me.

I would like to include my comments regarding my quality of life after LASIK as part of the record of Ophthalmic Devices Panel Meeting.

My LASIK procedure was performed 15 years ago. I had my procedure performed in Canada since it was not yet approved in the US. I was severely nearsighted and my quality of life was dramatically improved. I no longer need my glasses to function in any faze of my life. I sincerely believe that LASIK is a wonderful procedure when performed by a competent surgeon.

Warburton, Karen

From: _____
Sent: ----- 10/02/2008 11:23 AM
To: Warburton, Karen
Subject: LASIK

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

I had my LASIK in October 2002 when I was 45 at [REDACTED] in _____ I had worn toric contact lenses for a period of time, but had trouble with them. I ultimately wore multi-focals for close to 8 years. These were tolerable, but I still did not like the constant up and down I had to do with my head to either see distances or read. I was forever falling asleep with them on and waking up with smashed glasses.

I am a very active outdoors person - enjoying fishing, boating, and summer vacations on the beach. While wearing my glasses, I had trouble with these pastimes, especially at the beach - clip-on sunglasses were a hassle, (not to mention the ribbing I got from my sons), and swimming and boating resulted in less than fun times. I worked in sales at the time, and quite frankly, going from outdoors to indoors in all weather conditions caused my glasses to fog at times, making it difficult to look professional and conduct business.

The day after my LASIK, I woke up feeling I had nothing done, but I could see. Driving to work that morning was truly a joy, and I was on my computer all day, experiencing no problems at all. After my LASIK, actually the second day, I was able to thread a needle on morning to sew a button back on my shirt. Amazing! That evening I was at my son's high school football game and could read the numbers on jerseys across the field. It was raining a little that night, I felt there was something wrong, I went to wipe my glasses due to the rain, and realized I wasn't wearing any. This was after 20 years wearing glasses!!!

[REDACTED] gave me monovision due to the fact that I wore bifocals. I adapted perfectly to this procedure, and now, almost 6 years later, have no problems with my vision. LASIK is truly a miracle and a life changing experience. My quality of life has increased and I have told many people to go to [REDACTED] for their surgery. I will never regret having this procedure.

Warburton, Karen

From:
Sent: -----2008 11:12 AM
To: Warburton, Karen
Subject: LASIK

My name is:
My address is:
My cellphone n----- t the email above

It has been brought to my attention that the FDA is scheduling a hearing on the quality of life after LASIK. I had the procedure 12 years ago and it is one of the best things I have ever done. It has allowed me to function without the constant need for glasses or contact lenses. I no longer have to worry about losing my glasses when swimming in the ocean or my contact while in the pool. I can pick up a chart, work on the computer all without any hassle. Life was so complicated when I wore contacts, I had to lug my solution and glasses with me any time I traveled. Then I was neurotic about having my glasses close by if I needed them for any emergency so I could see. LASIK for me has been a positive, life altering experience. I am thankful everyday!

Please include my comments as part of the record of Ophthalmic Devices Panel Meeting.

Warburton, Karen

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

Dear Karen,

It has been brought to my attention that a task force has been assigned to investigate the quality of life for post LASIK surgery clients. I would like to take a minute to express my complete and overwhelming satisfaction with my LASIK procedure. After much deliberation and research, (and a really horrible haircut that I couldn't see while it was taking shape because I didn't have my glasses on) I decided to have LASIK performed over two years ago. The procedure was successful and the effects it had on most every aspect of my life far exceeded my expectations. I anticipated the convenience of not having to put on my glasses to: look at the clock, tend to my kids in the middle of the night, have my kids yank my glasses off of my face and break them and have my glasses fall off while exercising. What I didn't anticipate was how LASIK affected my professional role. I am involved with close patient care in my job. Often, my glasses would fall off or get knocked while I was in the process of caring for or transferring patients. Since LASIK, this is no longer a problem.

Having worn glasses and being contact intolerant for almost 20 years, I was ready to make a change. My quality of life has certainly improved and the convenience of not wearing glasses has been fabulous. Again, my decision did not come quickly or lightly. As with any procedure, I would not proceed forward without investigating the risks and benefits. Lastly, I would make sure the surgeon performing the procedure carries out his or her responsibilities to make sure one is a good candidate and performs excellent pre and post LASIK care. The procedure itself is only part of the process and if a candidate understands that, they too can have great outcomes.

Please feel free to use all or part of my testimony as part of the record of the Ophthalmic Devices Panel meeting and contact me if you need additional information.

Sincerely,

Warburton, Karen

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

Dear Ms Warburton,

I received an email from [REDACTED] asking satisfied patients to write to the FDA about their satisfactory result of Lasik treatment. This is very unfair as they should at the same time ask patients who have problems after Lasik to tell their affliction.

Also unfair because they do not ask for comments from happy patients who had surface treatment like PRK and are very happy.

Myself as a refractive eye surgeon I see many patients with many serious problems after Lasik, notably keratectasia, and at the same time I see NO serious problems with PRK.

I feel the only reason Lasik is still practised is financial benefits to the industry (keratomes, Femtosecond lasers etc) and the ophthalmologists themselves in the United States who will lose a large portion of work to the Optometrists if surface Excimer Laser treatment is proclaimed safer than Lasik.

I feel there has been a great disservice to the patients by doing Lasik for so many years.

One remarkable point is the new treatment for keratectasia. Prior to the introduction of Cornea Cross Linking treatment every body asked about keratectasia was stating that they did not have any cases.

Standard statement was, I did thousands procedures and I never have keratectasia. Now that CCL is available the very same surgeons present clinical studies with the beneficial results of CCL after Lasik induced keratectasia.

I hope my voice is heard at the FDA Ophthalmic Panel meeting.

Thank you

From:
 Sent: Monday, October 16, 2006 3:30 PM
 To:
 Subject: Residual Stromal Bed

have you ever done the math on this violated the 250 micron residual stromal bed safety rule.

pre-op pachymetry	OD 545	OS 525
microkeratome plate	OD 180	OS 180
pre-op ablation 1st procedure	OD 88.7	OS 89.7
1st enhancement ablation	OD 11.2	OS 9.8
2nd enhancement 6.5 mm treatment zone	OD 45.1	OS 17.8

	220 RSB	227.7 RSB

FYI - spare

10/16/06

Copy of email from a friend
 with similar situation as I
 have. This sheds some
 light on the negative
 outcomes of my LASIK.

ONE PATIENT'S EXPERIENCE WITH ECTASIA/KERATAECTASIA

I. Introduction

I have followed the recent postings with great interest and have compiled an initial "layman's" outline of my LASIK experience. In 1998 -2000, I had LASIK eye surgery on both eyes at what is considered by many as one of the foremost eye clinics and Medical Schools in the nation. Before LASIK, I was completely dependent upon RGP Contact Lenses or Glasses for 35 years. I could not wear soft lenses due to my high degree of astigmatism. Corrected vision before surgery with RGP lenses was 20/20 and comfort was seldom a problem. Relying on name recognition and identity only, I did no due diligence and proceeded to have LASIK eye surgery.

II. Pre Lasik Recommendations¹

Now, after 10 years of going through multiple eye exams, seeking many second opinions, doing my own research, and listening to other LASIK kerataectasia patients, I have arrived at some of the following conclusions regarding the decision of whether to undergo LASIK surgery:

- a. Long term, RGP lens wearers, with high astigmatisms, either avoid LASIK completely, or proceed with very conservative corrections and out come results.
- b. Have the ophthalmologist who follows your case be the same doctor who performs the surgery itself. You want a doctor and staff that will be with you to hopefully share the enjoyment of a successful outcome but all to assist should you have unsuccessful results. You become the "hot potato" patient sometimes when your LASIK is unsuccessful and was performed in a "Joint Venture" type arrangement as in my case.
- c. Make sure you consult with several respected corneal specialists perform LASIK before first making the decision to proceed and second with LASIK in the first place and second, which surgeon\clinic you liked the most.
- d. Do not forget to observe the professionalism and contentment of clinical support staff. Make sure the human element and compassion for you is present.
- e. Try to get a feel for the equipment used. Recent proven equipment and technology is paramount to achieving accuracy of correction and successful outcomes.
- f. Give yourself time to discern. Time is usually on your side before proceeding with LASIK surgery.

III. My LASIK Experience

After initial surgery in 1998, then enhancement in 1999, my vision in both eyes, uncorrected was 20/20. This was truly a miracle for those of us so dependent upon contacts and glasses. I remember disposing of all my old contact lenses and extra cases. No more lens cleaning, scrambling for glasses at night, occasional discomfort etc. This visual quality of life lasted 9 months.

Then, gradually the sight in my right eye deteriorated to 20/100 by December 1999. I also noticed declining vision in my left eye, just to a lesser degree.

My LASIK process from the outset was being handled by both my local OD and surgeons from the nearby Medical School\Clinic. Neither could understand this change but both concluded that in early 2000, I should undergo a 2nd enhancement on both eyes. The out come of this 2nd enhancement made no improvement and further thinned my cornea to 250m R and 275m L.

Eventually, ectasia or Keratectasia became the diagnosis and RGP lenses were prescribed. My average best corrected post LASIK vision with a Rose K RGP in the left eye is 20/25 and a Boston Scleral Lens in the R is 20/40. Typically I am able to wear my lenses with reasonable comfort up to 15 hours daily.

IV. Unsuccessful Results

"Unsuccessful Results" tend to lead to various complications such as Ectasia or Kerataectasia, dry eye problems, depth perception difficulties, and in general, intense disappointment. Most likely the real reason for unsuccessful outcomes is the pre LASIK screening and preparation process was not adequate and the surgeon was too aggressive in the degree of correction. Also, as is the case in all vocations, there are some physicians who are simply not qualified. Another contributing factor to complications after LASIK surgery can occasionally be the result of obsolete or faulty calibrated equipment. Lastly, is the fact that fundamental mistakes are made even by the most qualified doctors. I believe and again emphasize that if attentive pre LASIK screening is adhered to, reasonable margins for error are considered, and detailed checks and balances are built into the LASIK process from beginning to end, complications as a result of LASIK surgery can be significantly mitigated.

When you get to the stage many of us are in, anger, frustration, and major disappointment is natural. We ask; Why did this happen? What should I do? What will be the final result, i.e. will I end up blind? Although still very difficult, I try to objectively negate or offset many of these disappointments and concerns by concentrating first by simply coping but secondly and most importantly, focusing on the prospects that better treatments for ectasia, kerataectasis, and keratoconus are being constantly developed and in the not too distant future, a long-term viable solution will emerge.

V. Treatment Options and Success Observations:

With much confidence I can say that we all have one important and common goal which is;

Within the near future, a safe treatment option will be developed that will give those of us with ectasia, kerataectasia, and keratoconus high quality comfortable vision without the need for daily wear contact lenses or other cumbersome optical devices.

Recognizing that everyone's situation is unique, the following is the list of treatment options that I have heard of so far and my observations as to their degree of success:

- a. **Glasses:** Results: most of us cannot wear glasses due to the distortion of our corneas and the fact doctors are unable to obtain a refraction on the damaged eye(s). If, as in my case, one eye is not as damaged as the other, the physician may be able to at least refract that eye and provide you with a pair of glasses that gives you "emergency" or "relief" vision from the one marginally good eye.
- b. **Regular RGP, Rose K Lenses** (or other somewhat conventional hard contact lens): Results: If tolerable to wear, optimal treatment.
- c. **Scleral Lens Device:** Results: When more traditional lens as referenced in a, Comfort is very good and best corrected vision, slightly worse than the more traditional hard lens, is still very functional. The Boston Foundation for Sight is outstanding.
- d. **Sunglasses:** Results: A quality pair of sunglasses with light orange or copper tinted lenses significantly improves contrast which in turn improves vision. (See Boston Foundation Web Site for helpful links)
- e. **Rings or Intacts:** Results: in thicker corneas, I have heard of some successes but for the most part, there seems to be only limited success overall.
- f. **Collagen Treatments:** Results: not enough data to make a statistically reliable conclusion as to treatment success.
- g. **Corneal Graft or Transplant:** Option of last resort.

Working in our favor is the fact that the medical research community now has at least two decades of LASIK data to observe. As the data base increases exponentially each year and along with this increase is a growing segment of cases where unsuccessful LASIK outcomes is likely to rise as well, it is my belief that a viable treatment for ectasia, kerataectasia, and keratoconus will be developed.

One reason I believe this is the fact that the amount of data is reaching a size that it is becoming a more statistically reliable sample size. Secondly, there are more of us sharing information and seeking treatments. We are networking and exchanging valuable information researchers can factor into the results of their quantitative analysis.

Initially, I anticipate advancements will come out of the optical area in which resources are primarily channeled towards contact lens development. Hopefully, improved optical treatments will accelerate advancement to lenses that can be worn for extended periods of time with both comfort and quality visual acuity.

I further contend that the research eye clinics will begin to benefit as well from the larger data derived from ectasia or kerataectasia patients and develop a synthetic type cornea implant that carries less risk of infection, rejection, and marginal visual acuity.

Successful treatments, however, will be developed. For this to occur in the near future, however, those of us who live daily with the inconvenience of our visual condition must continue to exchange ideas. Also, we need to encourage medical research clinics and schools to compile and analyze the growing data base, find passionate doctors who from the research can develop viable treatments, and in general positively draw more attention to our cause.

VI. My Treatment Choice

A few years ago, I asked a highly respected Corneal Specialist from a nearby Medical School from whom I was obtaining a second opinion regarding both what went wrong and now what should be my treatment plan; "If I were your son, what would you recommend given my condition and current treatment options available?"

He replied unequivocally and with no hesitation; "Absolutely do not consider undergoing more surgery or invasive type procedures. Wear contact lenses as long as you can. Preserve the cornea you have left and its relative integrity or strength until a safe and successful treatment is hopefully developed."

So, for now my plan is to buy as much time as possible wearing contact lenses. I also have a pair of glasses that give me "emergency" or "relief" vision from my one refractable eye. Lastly, I rely on high quality copper shaded sunglasses, mainly when outside to improve contrast which in turn enhances my sight.

1 **Disclaimer:** I am not a physician and have no financial incentive in preparing this summary. In addition, I do not make any judgments nor render any opinions as to the treatments and experiences shared, their results, and physicians and clinics referenced or alluded to herein. This is solely a summary or journal of sorts from my personal experiences. There may be grammatical, spelling, diction, and syntax errors due to time limitations to proof read.

COMPILATION OF EMAIL COMMENTS FROM ECTASIA WEBSITE

Introduction:¹

All of the following information or email excerpts I compiled from responses posted on the [REDACTED] web site over the last several months. I thought it would be informative to capture the various experiences in a relatively concise list.

After reading this compilation in one sitting, you may be able to get a "big picture" understanding of how your own unique experience(s) fit in the universe of others undergoing similar complications. In addition, a potential treatment someone has discussed will enable you to discern through a cognitive dissonance process what direction you may or may not want to pursue. Finally, reading a summary of this nature may expose some trends that can be shared with the medical research community to develop safe, high quality, insured approved treatments. With much confidence I can say that we all have one important and common goal which is;

Within the near future, a safe treatment option will be developed that will give those of us with ectasia, kerataectasia, and keratoconus high quality comfortable vision without the need for daily wear contact lenses or other cumbersome optical devices..

Thank You,

DD M O -

----- Since 2000

Currently wear Rose K Lens left eye (20/25 corrected) and Boston Scleral right eye (20/40 corrected)

¹ **Disclaimer:** I am not a physician and have no financial incentive in preparing this summary. In addition, I do not make any judgments nor render any opinions as to the treatments and experiences shared, their results, and physicians and clinics referenced. This is solely a summary or journal of sorts that I find informative personally and think some of you may as well. There may be grammatical, spelling, diction, and syntax errors due to time limitations to proof read and the "cut and paste" compilation of the excerpts from many different emails.

Introduction From the Webmaster:

My desire is to help make prospective patients better informed before undergoing refractive surgery and to also have an understanding of ectasia as a possible complication. Patient education before refractive surgery has always been important to me.

The website Ask Lasik Docs has recently been updated
<http://www.asklasikdocs.com/>

██████████ is willing to answer your questions in the ██████████
██████████ if you have questions about treatment options for ectasia.

If you would like to register to post and ask a question to protect your privacy, do not use your full name or email address as your user name (login).
<http://www.asklasikdocs.com/forums/forumdisplay.php?f=18>

Summary of Shared Email Excerpts:

- Some of the new treatments for post-lasik ectasia look very promising and I'm hopeful they'll soon have something of a cure. My best wishes to all
- As one who had severe corneal ectasia (56+) my ONLY solution was a FULL corneal transplant I was ruled out after I was over 45 at that point. I was getting more frustrated hearing how well some people did on Intacs and was hoping that they would stop pushing it because it isn't the BEST SOLUTION FOR EVERYONE.... so I have become a contact lens specialist and have worn over 28 different kinds of lenses. I've settled with oaxis soft lens over my grafted eye very comfortable and a hard zwave in the right a comfortable custom fit.
- synergysis lens?
- To make a long story short, I have gone through a cycle of infections, inflammation, intolerable pain with piggy backing and the Synergeyes lens, etc. with about 50 office visits and haven't had vision correction in my left eye since then. I had one Intac removed due to the inability to heal the suture wound and then recently I had the other one removed because it was coming through the surface of my cornea. At last I have been able to confirm my assertion that the Intacs was the cause of my pain as I am able to put any lens in that eye now without feeling the pain I used to. Perhaps something can be learned from this by those studying the use of Intacs. My eye almost immediately began to feel normal and I am now waiting on a Synergeyes lens to come in to try wearing it.

- Don't let anyone make adjustments to your Intacs after they are inserted, like I did. I don't believe a thin cornea can tolerate the trauma. Also, don't assume Intacs are a guarantee of success. When I look back I would have been better off piggy backing from the beginning and skipping the Intacs experience. If what you are doing today works, stick with it and don't have surgery just in case it might fix an inconvenience you are dealing with. Looking back on my life, wearing glasses for nearsightedness doesn't seem at all like the burden or inconvenience it once did!
- I'm inclined to rule out the use of Synergieyes through personal experience prior to trying the Sclera lens.
- I was fitted with the Boston scleral lens (in 2003), which is a remarkable lens in many ways but incredibly high-maintenance. I wear that lens as much as possible but have lately run into problems with the lens -- redness, irritation, discomfort, etc.

This has forced me to pursue other options. I tried the new synergieyes (hybrid) lens but couldn't get a comfortable fit.

I was recently told that the [REDACTED] has a new scleral lens design which they are just fitting patients with now).

- I currently wear the Boston scleral lens and have worn them since August of 2004. From August 2004 until the beginning of 2007 I had great success with these lenses (extremely comfortable for 10 to 12 hours a day) and for that reason would recommend trying them to anyone who is having trouble in corneal lenses (website, bostonsight.org). Since February I have had the usual spate of problems that I've experienced with lenses in the past: dry eye, allergic conjunctivitis. I am now back under the care of [REDACTED] to keep a closer watch on how my eyes are doing with the lenses.
- Just had C3-R done in my left eye--the one that was progressing most recently/rapidly- -this past Thursday in [REDACTED] clinic. So this was the epi-on procedure.
- One of my biggest concerns with the procedure going in was what effect it may have on dry eye. I've battled dry eye issues off and on--and more on of late--ever since my LASIK in 2001. There is a paper suggesting that there is nerve damage following C3-R

I remain concerned that the epi-on C3-R procedure still hasn't had a publication specifically documenting its long-term efficacy. It would be reassuring if this would appear in the near future, as the procedure is now nearly 4 years old.

- I currently wear the Boston scleral lens and have worn them since August of 2004. From August 2004 until the beginning of 2007 I had great success with these lenses (extremely comfortable for 10 to 12 hours a day) and for that reason would recommend trying them to anyone who is having trouble in corneal lenses (website, bostonsight.org). Since February I have had the usual spate of problems that I've experienced with lenses in the past: dry eye, allergic conjunctivitis.
- I had the Boston scleral lens made in October of 2006 and I'm able to wear it for about 5 hours before it becomes too bothersome. When I put it in it takes about 1/2 hour to adjust to it but then the vision is excellent (I test out at 20/20). I'm considering going back to see if the fit can be improved.

When I was there they told me about a new project, called the 20/10 project, that will involve advanced mathematics to fabricate a lens that will compensate for distortions on the posterior surface of the cornea. They anticipate the military may have an interest, such as for pilots, as well as all the other patients they serve.

- I posted because I feel like I am beyond any innovations currently being discussed. Once you have corneal transplants, contact lenses of varying numbers seem to be the only answer. I can function at work with piggyback RPG over soft lenses for 12+ hours, though they do become uncomfortable, and when not working I choose to be visually handicapped with glasses. I have learned to adapt, and have given up my anger over loss of some of my independence.
- I visited [REDACTED] at the University of Southern California, Los Angeles this morning, and he told me about the recent use (within the past few years) of a femtosecond laser (brand name: intralase) to perform corneal transplants, which seems to offer promise for better visual acuity and faster healing over traditional corneal transplants. I wanted to let the group know about this in case it could help anyone and also to see if anyone has had experience with this type of corneal transplant. Apparently they are doing it just three places in the US--Bascom Palmer in Miami, UC Irvine, and the Corneal Research Foundation in Indianapolis.

Warburton, Karen

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

Karen,

Topic: LASIK

I would like my comments to be included as part of the record of the Ophthalmic Devices Panel meeting. I am currently a Federal Law Enforcement Agent and had the Lasik procedure on both my eyes over one year ago. I can not begin to tell you how this made me a much safer law enforcement agent. For years, my concern in a struggle or gun fight was to lose my glasses or a contact. I always knew my life would be over. We had an agent who lost his glasses in a gun fight and could not continue to help his fellow agents in a gun fight that took their lives. This thought was always on my mind my whole career. After having Lasik- I eliminated that thought from my mind. I walk into every situation that more confident not having to worry about my eyesight.

I initially had reservations about the lasik procedure. I waited 16 years on my job to have the procedure done on my eyes. I have many friends in the Law enforcement field both local police officers and State troopers who all had the procedure before me. The only words were to me "it is the base thing I have ever done for my career." Many of us had the same concern about losings our glasses or a contact lens in an altercation on our job. Please allow this procedure to help better the lives of myself and my colleagues. I only hope you allow this procedure to continue. I can attest that this procedure is enhancing the lives and even saving the lives of my fellow law enforcement officers.

Warburton, Karen

From: _____
Sent: Sunday, April 06, 2008 1:57 PM
To: Warburton, Karen
Subject: LASIK

Ms. Karen Warburton,

I had Rk surgery 20 yrs ago which left my right eye some what blurry. Over the years I have asked if there was something that could be done. But was told no because of the Rk. Last year they finally said they thought there was something that would help. So I had PRK and I now can see clearly and even can see the needles on a fir tree at quite a distance.

I would like this e-mail to be included as part of the record of the Ophthalm-----

Thank you, -----

Warburton, Karen

From: _____
Sent: Sunday, April 06, 2008 11:09 AM
To: Warburton, Karen
Subject: LASIK

My name is _____ .I had Lasik's surger about 2 years ago. I have always had 20/20 vision my entire life-----en my vision for granted....until I turned about 40 years of age and noticed I was having trouble reading/focusing. I knew this was the start of presbyopia & finally caved into wearing reading glasses around 41 or 42 years of age. As I got older and my eyes became dependent on the reading glasses I got to the point of not being able to read the newspaper (even larger headlines), look at a menu or see phone numbers on the caller ID of my phones without the use of reading glasses. I was constantly chained to a pair of glasses.

At 50 years of age I decided to have the monovision Lasik surgery, where one eye is made nearsighted and the dominant eye brought to 20/20 (it was 20/30).....2 years later, I have absolutely no problems reading anything and my distance vision has not suffered. As a songwriter, I couldn't read notebook paper writing without glasses. This is a very youth-oriented industry and whipping out a pair of reading glasses always made me feel 'ancient'...probably something most people would consider a vanity issue...but something that is important to me. It has lifted a weight off my shoulders and at least taken that 'stigma' off my mind. I no longer take my vision for granted.

My daughter, _____ also had the Lasik surgery done to correct her extrémè nearsightedness. She could not see anything in the room without contacts or glasses. At 24 years of age she really enjoys the freedom of not having to deal with contacts on a daily basis and being able to see anything....

I would like these comments to be included in the Ophthalmic Devices Panel Meeting. If you need anymore information by email address is _____

Topic: LASIK

Comments:

LASIK liberated me from the brutal tyranny of corrective lenses. I can see.

I had eye glasses starting at age 9, and my vision gradually got worse. I could not function without the corrective lenses. The glasses had thick lenses. Without corrective lenses I could not recognize a person's face more than an arm's length away. With glasses, often I would accidentally bend the frames though everyday activities, especially when playing sports. The glasses would slide down a little on my face, and I would push them back up. I often had to clean the lenses. Sometimes the glasses would break or a screw would go missing, and then I could not see until I could repair them.

I started using contact lenses when I was 19. Contacts were usually an improvement over glasses,

but sometimes glasses were more convenient. Using contacts came with its own set of burdens and retained some of the burdens of glasses. Contacts are somewhat irritating to the eye and they require daily maintenance. There is always the risk of contacts falling out for example when water gets in the eye. Many times during my contact-wearing days I would develop small irritating bumps on the inside of my eye lid. When that happened I would be forced to stop using the contact lenses for a week while my lids returned to normal. When swimming in the pool or at the beach, I could not use glasses or contact lenses, so I had to go without vision and forsake much potential participation and enjoyment. Sometimes a contact lens would become damaged while I was away from home, and in that situation I would be forced to wear my glasses, or sometimes be without complete vision until got a new contact lens. Many times I was interrupted from my activity because the contact lenses stopped functioning properly. Sometimes particles would get into my eye and then caught behind the lenses, so that I would have to stop what I was doing and take time to remedy the situation.

I had LASIK performed on both eyes 5 years ago, just before I turned 25. I absolutely love it. My vision is 20/15, which is even better than when I had corrective lenses! I wake up in the morning, I can see perfectly, and that makes me happy and productive. Freedom from corrective lenses is something I appreciate every day, because I lived with the burden for over 15 years. I can swim and play sports with wonderful vision and without the obstacle of corrective lenses. I have always been an active runner, and it is wonderful not to have to worry about my glasses constantly sliding down my face. When I go on a trip, especially an outdoor trip, it is wonderful to be free of the hassle of wearing and maintaining corrective lenses. When I am at school in a chemistry lab, where contact lenses are not allowed, I don't have to wear glasses. When I work long hours, reading or in front of a computer screen, no longer will my eyes become irritated and eyelids become bumpy from contact lenses. Now I am free from the very real danger of suddenly losing my vision when contact lenses or glasses fail. I can finally rely on my vision. LASIK has immensely improved the quality of my life.

Warburton, Karen

From: _____
Sent: Saturday, April 05, 2008 11:56 AM
To: Warburton, Karen
Subject: Lasik

Dear Ms. Warburton, Lasik has improved my life dramatically. I no longer have to wear glasses after 25 years. I can be more active, not having to worry about my glasses breaking or falling off. I feel more confident about myself. Please include these comments as part of the record of the Ophthalmic Devices Panel meeting. Thank you, _____

Warburton, Karen

From: _____
Sent: Saturday, April 05, 2008 11:32 AM
To: Warburton, Karen
Subject: LASIK

Hello,

-----me is ----- . I live at -----
----- . I am writing to you regarding t-----
and wish for my comments to be included as part of the record. I had LASIK performed on my eyes almost a year ago, and the experience has been completely positive. I have experienced no side effects as a result of the procedure, and my vision is now 20/20 or better. It has been a big help to me as I am a nursing student, and I don't have to worry about glasses, or contacts while learning to work in the healthcare field. When I received an email from the center where my LASIK was performed advising me that some group wanted to ban LASIK I could hardly believe it. I don't see any reason why anyone would want to ban an elective surgery that has been so helpful for so many people. Please DO NOT BAN this procedure!!

Warburton, Karen

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

Dear Ms. Warburton,

I am writing to you regarding the public hearing on the quality of life impact of LASIK. My situation is somewhat unique in that I am not only a patient, but also a resident in training to be an Ophthalmologist. I had LASIK performed in March of 2004 and I am thrilled with the results. My quality of life has only been improved by the procedure and I have had no ill effects of LASIK. This is especially important as I am a physician working not only in the clinic setting but also as a surgeon. I would appreciate my comments being included as part of the record of the Ophthalmic Devices Panel meeting. Thank you very much.

Sincerely,

Warburton, Karen

From: -----
Sent: Saturday, April 05, 2008 9:07 AM
To: Warburton, Karen
Subject: Lasik

Dear Ms. -----,

My understanding is that there may be a group seeking to have Lasik banned.

I had Lasik surgery about 3 months ago in early January 2008. It has changed my life in a dramatic way for the better! I will be 50 years old next week and I have worn glasses for nearly 40 years of my life. After my Lasik surgery my vision improved to 20/15 and I have none of the side effects that they Lasik doctors said I might experience (night halos around lights, dryness). To deny this life-changing surgery to any patient, I believe would be a gross abuse of power. I am sure there are people who are not pleased with their surgery (as with anything)....and may even be experiencing undesired side effects. My belief is that the risks of Lasik (like any surgery) are readily available/known to any potential patient and we each have a responsibility to understand what we are agreeing to and then we make our own decision. Please do not allow the government to step into what should be a relationship between a patient and their doctor.

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

Name:-----

Addre-----

Phone: -----

-----e to share my opinion!

From: -----
Sent: -----
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.

From: [REDACTED]
Sent: Wednesday, April 02, 2008 5:03 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: Friday, April 04, 2008 9:31 PM
To: Warburton, Karen
Subject: LASIK

Dear Ms. Karen Warburton,

I am a licensed-optometrist in the state of California and had received LASIK surgery from the surgeon who I usually co-manage my patients with. I would like this letter to be included as part of the record of the Ophthalmic Devices Panel meeting. In November of 2006, _____ operated on my eyes using Wave-Front LASIK technology, correcting my nearsightedness. I was previously extremely nearsighted and had to wear either glasses or contact lenses. Since the surgery, I feel that my vision feels much more natural and have not had any problems with discomfort. My eyes are somewhat dry, which was expected since they were dry to begin with prior to LASIK. However, my vision is actually crisper than before because the dryness that I had previously experienced was compounded by the dryness of my contact lenses. LASIK has improved the clarity of my vision on the job, when I'm playing sports, and especially night driving. Prior to LASIK, my contact lenses would render my night vision somewhat blurred, and wearing glasses was uncomfortable because my high prescription meant that my glasses were extremely thick. All in all, I have no regrets in getting LASIK surgery. Thank you for your consideration.

Warburton, Karen

From: _____
Sent: _____ 35 PM
To: Warburton, Karen
Subject: Ophthalmic Devices Panel



I am writing this email in hopes that my comments can be included as part of the record of the Ophthalmic Devices Panel meeting. I had LASIK surgery in April 2007. It was one of the best investments that I have made. Prior to my surgery, I wore eyeglasses and/or contact lenses for over 24 years. Wanting the advantage of going to bed and waking up being able to see, I often kept my disposable contact lenses in longer than I should have without cleaning them appropriately. Thus putting the health of my eyes at risk.

Immediately after the completion of my surgery, my vision improved dramatically. I went from requiring glasses to distinguish the face of a person standing directly in front of me to being able to read the news ticker that runs across the bottom of the television screen within a couple of hours of my surgery. My quality of life has improved dramatically. I am now able to see while I swim and my eyes are much healthier without the added risk of the inappropriate maintenance and use of contact lenses. It is amazing that approximately two minutes of surgery is providing a lifetime of benefits!

If you have any questions about my experience or need additional information, please do not hesitate to contact me.

Warburton, Karen

From: -----
Sent: Friday, April 04, 2008 7:22 PM
To: Warburton, Karen
Subject: Re: Lasik

Please do use my comments. My experience with Lasik was very positive. My rotten astigmatism was at the point it could no longer be corrected! I'd suffered with it all my life. Now I see and drive without any correction. GOD BLESS LASIK! I'd hate to see a worthy procedure slammed over what may be inexperienced or incompetent physicians using the Lasik laser clumsily. My procedure was attended by not one but TWO physicians. Pre-op exams were thorough and exhaus-----
Lasik was done by [REDACTED] Regards,-----

Warburton, Karen

From: -----
Sent: ----- 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 ye----- dering the crappy vision I had before the surgery, the dryness is no big deal. regards,-----

Warburton, Karen

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

I wish the following comments to be included as part of the record of the Ophthalmic Devices Panel meeting:

Lasik has changed my life. I had needed eye correction since the age of six. I could not see the board in school without my glasses and throughout my education, would always need to sit in the first two rows of the classroom in order to see. Finally, at age 13, I was able to wear contact lenses and that freed me from wearing glasses in public. However, I was still dependent on glasses if my lenses weren't in. I could not even read my alarm clock next to the bed without pulling it close! Luckily, the clock manufacturers began to make very large digital clocks when I was in my 20's!

I would not have believed if my parents said to me at the tender age of six, "In 40 years, there will be a laser surgery that will correct your eyes and you will not be dependent on these glasses!" It would have seemed too futuristic and impossible. But here I am, at age 46, and a success story because of LASIK correction.

After being severely myopic with an astigmatism in both eyes, I am so thankful to have 20/25 correction after LASIK and I'm able to wake up everyday and see! I now forget that for 40 years I was dependent on correction. It's the most natural thing for me to see perfectly the minute I open my eyes.

(I always wondered what I would do in an emergency if I could not locate my glasses and now I don't have to worry.)

I am a golfer and tennis player, and I don't need to worry about wearing contact lenses. Contacts were not always comfortable (especially first thing in the morning) and if I would get a particle trapped under a contact lens, it was unbearable. Freedom from eye correction is such a blessing! I wish everyone could experience my success.

I travel frequently, and now I don't have to worry about taking contact solution on the airplane with me. I only fly with carry-on luggage, and I would be restricted with the amount of saline allowed by the TSA. Now, this is not a concern!

Please feel free to contact me with any comments or questions:

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

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: re: ophthalmic devices panel input

Hello Karen,

My name is _____ You can contact me by phone
at _____ or email me at _____

I am writing this letter as I wish to participate in the recordings for the Ophthalmic Devices Panel meeting. My Lasik Surgery was performed on my right eye in 1999. My results have been phenomenal!! Before my surgery, I could not see the leaves on the tree or much else without glasses or contacts. My vision was -4.00 and I could not wear glasses without pain due to the fact that my right eye was so much worse than my left eye. My left eye has been a consistent 20/20 as long as I can remember. Glasses never fit me right and were just a big pain for me. Since my lasik surgery, my vision is now 20/20 and my quality of life has really improved. I can do all outside activities without any correction to my vision. I can see even better at night than I did before Lasik!! I feel safer when I wake up in the middle of the night and do not need to search for glasses to see. I also like the fact that I feel more confident without glasses or contacts. Lasik has improved my life in every aspect. From waking in the morning to bed at night it affects my every move!! I would have lasik again if I needed to. I hope my letter will be beneficial to your panel.

Thank you, _____

Warburton, Karen

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

Ms. Karen Warburton,

I am writing in regards to my LASIK surgery that took place approximately 6 years ago. I would like for my comments to be included as part of the record of the Ophthalmic Devices Panel meeting. I am completely happy and satisfied with my surgery. At first, I was apprehensive because it was surgery on my eyes. However, I am glad that I didn't let my nerves get the best of me. No longer do I have to rely on contacts, which were always giving me trouble, or glasses to give me good vision. As a teenager and young adult, I would imagine how wonderful it would be to wake up with perfect (or near perfect) vision. Finally, my dream became a reality. I still wake up amazed that I don't have to stumble to the bathroom to put in my contacts or fumble with eyeglasses every morning. I am forever grateful to the doctors at _____ for their expertise in LASIK surgery. Thank you for your time.

Topic: Lasik

Dear Ms. Warburton-

I had LASIK surgery last year and I am so happy with my decision. LASIK has positively affected my life. I am a college student at DePaul University in Chicago. With a rigorous course workload, I am always rushing and have little time to spend on tedious 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 don't know how I would be able to participate in school held events, be in organizations such as the DePaul Activities Board, or even have a life outside of school off-campus without having the weight of poor eyesight "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.

Sincerely,

Warburton, Karen

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

Dear Ms. Warburton:

I understand that the U.S. Food and Drug Administration (FDA) has scheduled a public hearing on the quality of life impact of LASIK. I would like the comments in this e-mail to be included as part of the record of the Ophthalmic Devices Panel meeting.

I had LASIK surgery about 10 years ago. Prior to the surgery, I primarily relied on contacts and/or prescription glasses to assist with my nearsightedness. I chose LASIK and my surgeon after carefully reading literature on the procedure. My procedure was done without complication and resulted in a corrected vision at 20/20.

I can say that having LASIK surgery was one of the best decisions I have made about my healthcare. Having the freedom to be without all of the hassles of contact lenses and glasses has truly been a positive improvement in my quality of life. I am a "weekend athlete," and any weekend warrior will tell you they would rather play sports without the need for contacts or glasses. Even things as remedial as being able to read the alarm clock in the middle of the night without having to fumble for glasses is fulfilling.

I hope these comments are helpful as the FDA considers the quality of life impact of LASIK.

I am available for questions or follow-up should you desire.

Thanks,

From: -----
Sent: -----
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 have seen the flap dehisce as well as corneal scarring with permanent loss of best corrected

Warburton, Karen

From: -----
Sent: ----- 11:19 AM
To: Warburton, Karen
Subject: Lasik Testimonial

Karen,

I am a patient of [REDACTED] who is located at -----
----- . I had the Lasik surgery performed by [REDACTED] an-----
----- n perfect 20/15. I cannot begin to tell yo----- dously improved my quality of life.

I am employed as a Detective Captain for the----- Police Department. During my career, I had to suffer from the never ending problems while wearing glasses of having them knocked off of my face during a scuffle, getting broken, having the lenses fog up in the winter while getting out of a heated patrol car and going into the extreme cold, or having my vision obscured while it was raining. Wearing glasses, I did not have my peripheral vision. Even changing to contact lenses, I had the occasion of the lens popping out or my eyes becoming extremely tired and dry while wearing the contact lenses. These all presented extreme safety hazards for me in this line of work. Even after coming home from work, I would just want to lay down to relax my eyes, since they were so tired, instead of spending quality time with my young son.

After speaking with [REDACTED], he convinced me that this was the way to go. I can honestly say that I believe this was the best choice that I have made in my life. It is most rewarding to be able to see & read the alarm clock when I am awakened during the middle of the night on a police emergency. The ability to be able to jump up & respond without having to look for my contacts to put in or play around with is most rewarding. At times when we have fatalities, I may be forced to stay up for 36 hours straight, which I certainly would have issues with wearing my contacts, which would make my eyes so tiresome.

Since having my procedure done, I have referred many friends and colleagues to Dr. Norden to have this procedure done also. Everyone that has had this procedure done by him, marvel about the positive results that they have achieved from this, not to mention the warmth, skill, knowledge and professionalism [REDACTED] demonstrates to his patients.

Please have this testimonial included as pa----- of the Ophthalmic Devices panel meeting. Should you have any additional questions, feel free to call me at-----.

Sincerely,

Warburton, Karen

From:
Sent:
To: Warburton, Karen
Subject: LASIK and the quality of life

Dear FDA:

I am writing this letter to describe how my LASIK procedure has positively affected the quality of my life. I would like my comments to be included as part of the record of the Ophthalmic Devices Panel meeting.

I am an IT Project Manager and work at a computer for long periods of time. Prior to LASIK, I wore soft contact lenses for at least 15 hours a day. My eyes would get very irritated (itchy, scratchy and dry) and I couldn't wait to take my contacts out in the evening. Because of my astigmatism, my contacts did not always feel comfortable in my left eye (my fingers were in my eye all the time moving my lens around). Periodically I would get debris in my eye while driving and have to pull over on the side of the road to "fix" my contact lens.

I also refrained from doing a lot of swimming for fear of losing my contacts in the water. I would try not to get my head wet or splash around with my kids for fear of getting water in my eyes.

I hated wearing glasses because they would often feel uncomfortable behind my ears and on the bridge of my nose. It was a pain to go out in the cold, snowy weather growing up in the Midwest. My glasses would fog up or get wet from the precipitation. I was constantly cleaning them. Contacts were my only option back then. Needless to say, I was ecstatic to learn about the advancements in LASIK over the years.

As a former employee of an ophthalmic medical device company, I have seen and read about the countless benefits of LASIK surgery and was encouraged to have LASIK performed on my eyes. After my consultation, my doctor recommended that I have LASIK done on my right eye and PRK done on my left eye due to the position and thickness of a corneal scar. I have to admit that I had concerns about the recovery of my left eye, and was not sure if I should have the procedure done. After further discussion with my doctor and better understanding of the overall risks, I decided to undergo the procedure.

It has only been six weeks since my procedure. My right eye was 20/15 the day after surgery. My left eye is now 20/20 and keeps getting better as the weeks go by. I cannot tell you how liberating this experience has been for me. I don't have to clean my lenses every morning/evening, and I don't have itchy, scratchy eyes anymore. I can see the alarm clock on my nightstand. I am so excited to go swimming with my family this summer, as I truly believe I will enjoy the beach experience a lot more.

I would strongly encourage others to undergo this procedure. The recovery from LASIK is remarkably fast. My left eye (PRK) was slower to recover, but the results are well worth it.

Warburton, Karen

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

I would like for this testimonial to be included in the public hearing on the quality of life impact of LASIK.

Since I was 5 years old I have needed vision correction. I spent most of my childhood blind because I refused to wear my ugly glasses to school. My school work suffered because of this. I would fall asleep at night wearing my glasses and wake up with them bent out of shape. When I was old enough to wear contacts I abused them so bad that my eyes were constantly itchy dry and infected. My eye doctor told me that the risks I faced as a contact lens abuser were far worse than any risk involved with LASIK

On May 9th, 2006 I had EPI-LASIK at [REDACTED] in Margate, NJ. Since then my life has changed. I can now see 20/15. One of the first things I noticed was that I could feel air on my eyes after they have been stuck behind contacts for so long. I have no problems reading signs while I am driving and I can now participate in more activities. I live a block from the ocean and spend a lot of time on the beach. I play volleyball and love to swim. If I wore contacts, I would end up having dry eyes because of the salt water. If I wore my glasses I wouldn't be able to see because I didn't have prescription sunglasses. Now I can go to the beach and wear any pair of sunglasses I want and not worry about the strain on my eyes afterwards. I don't have to worry about my nieces grabbing at my glasses when I am holding them. I don't have to worry about being on vacation and the only pair of contacts I brought ripped. My life after LASIK is 100% better than it was before. If I had to go through it again I would.

Thanks,

Warburton, Karen

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

Dear Ms. Warburton,

I wish for these comments to be included as part of the record of the Ophthalmic Devices Panel meeting (for LASIK).

LASIK has really helped me. I had LASIK in 2004. Since that time, I've been able to do all my work without glasses. Before LASIK, I had to wear my glasses all the time for distance and near work. Now I never have to wear them. As an optometrist, it helps me greatly to be able to do my work (often in dim lighting) without having to depend on my glasses.

I've had no negative side effects, and would have LASIK done again in a heartbeat.

Sincerely,

Warburton, Karen

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

Ms. Karen Warburton,

I am writing to you to express my feelings on how lasik surgery has changed my life. I am a nurse working in surgery. It requires me to work long hours and sometimes through the night when on call. My contacts were getting more and more uncomfortable every day because I was having to wear them for long periods of time. It was impossible to wear glasses because they fog up when I was wearing a mask in surgery. So, it was impossible to see instruments and to assist the surgeon. Since having Lasik surgery my vision has improved, my eyes are much more comfortable. I can work long hours with only having to put lubricating drops in rarely. I feel that my new vision has helped my performance in surgery. I absolutely love it!

I would like for my comments to be included as part of the Ophthalmic Devices Panel meeting. Please let me know if I can be of further assistance.

Thank you

Warburton, Karen

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

I have had my life enhanced by LASIK surgery and would like my comments to be included as part of the record of the Ophthalmic Devices Panel meeting.

For years I was uncomfortable wearing eyeglasses and could not adjust to contact lenses. My LASIK procedure was performed four years ago and I have been very pleased with the results and its positive effects on the professional and social aspects of my life. I no longer have to worry about driving if I forget my eyeglasses and now see better than ever.

Warburton, Karen

From:
Sent: Thursday, April 03, 2008 11:38 AM
To: Warburton, Karen
Subject: LASIK

.....
.....
.....
.....
Topic: LASIK

Dear Karen,

I am writing to you because I would like you to include my comments as part of the record for the Ophthalmic Devices Panel meeting. I had LASIK surgery performed

6 ½ years at the age of 27 and have never regretted it. It's the best thing I ever did! I had to wear glasses since the age of 8 and eventually went into contacts. As I was getting older, I found that my contacts were bothersome from April through October due to allergies. Contacts became very irritating to wear and I found myself not having the crisp vision I used to have due to all the protein/build -up on the contacts. I dreaded wearing glasses due to the limited peripheral vision I had while wearing them and always found that the weather was a constant battle. Between the glasses fogging up, not having the clip-ones available on a bright sunny day, or having to deal with all the smudges on the lenses, I looked into LASIK surgery. I worked as a surgical tech that assisted in numerous eye surgeries from blepharoplasty to Mueller muscle resection and eventually LASIK surgery. I worked with the patients from day one to their one -year follow-up with patients so ecstatic with their results. They were able to legally drive the day after their surgery and they started referring their family and friends to have the surgery.

Once I had the surgery, I was amazed at how well I was seeing the day after surgery also. I had no obstacles to interfere with in my vision. I was able to see 20/20 in the right eye and 20/15 in the left eye 1 day post-op and my vision hasn't changed since! After getting married in the Caribbean shortly after and **not** having to worry about the thought of losing my contacts or breaking my glasses and being able to swim in the ocean was unbelievable. I never have to worry about my contact ripping and trying to drive with one contact in. Many who have great vision naturally take it for granted and I wake-up everyday appreciative to be able to see my alarm clock without the need for my glasses or contacts.

Sincerely,
.....

Warburton, Karen

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

LASIK

I would like this e-mail to be included as part of the record of the Ophthalmic Devices Panel meeting in April.

On April 19th, 2007 when I was 26 years old I had the ALL LASER LASIK. I was not the most myopic person in the world but I had a great deal of astigmatism. With my high astigmatism it was always a challenge to be fitted with glasses or contacts. Contact lenses were uncomfortable and my vision was either really good or really bad and it changed with every blink. Because they were toric made it also very expensive. Glasses were somewhat of the same. If the optical center was not exactly where it was supposed to be my vision was horrible. Glasses always got bent, would fog up in the winter, get smudged, and a royal pain in the rain. Glasses were also very expensive.

Not only did my astigmatism make glasses and contacts a chore but I also would get severe headaches almost on a daily basis. If I forgot my glasses at home I would really pay for it later at work. I worked all day on a computer and with patients, constantly reading and writing. I could see with out my glasses but I was barely legal to drive with out them.

Since having LASIK last year my headaches are GONE! No more crummy glasses or uncomfortable contacts to bother with. I had the all laser LASIK and I only wish the technology was around sooner, I would have done it then. (I was not a candidate with the blade because my corneas were too thin.) There was really not "down" time either. Just 2 days off of work and a few eye drops. What a piece of cake. Now I don't have to worry about forgetting my glasses, and I sure don't miss the hassle with the contacts or glasses. I love the water and now I can go out on the boat and not have glasses to worry about either flying off my face or getting sprayed with water. Yes I could have gone with out them but only if I wanted a severe headache later, and that was not worth it for me.

I recommend the LASIK eye surgery to everyone! It has really been a life changing experience for me.

Thank you

Warburton, Karen

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

Your Name: -----
Your Address:-----
Contact info:-----
Topic: LASI--

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

LASIK had improved my quality of life in many ways.

1. I work at my computer all day and my eyes would dry up or my contacts would make it to where it looked like a fog and would continuously have to take them out and clean them and put them back in and now I do not have to do that anymore. If there were dirt on them, it would hurt and I'd have to take them out and clean them.
2. On vacation, I would always have to remember to pack my glasses, my contact solution, carry the container to put the contacts in and always carry an extra pair in case one became torn. It's SO MUCH easier now not having to remember to take pack all of those items.
3. I can't tell you how much better it is when I drive in the rain. I know that sounds odd but during the 1st week of LASIK everything was so clear. It is amazing.
4. I do have to say that I'm much more cautious when it comes to my eyes. I wear sunglasses all the time, not that they are sensitive I just want to protect them.
5. More time... I do not have to spend time each night taking my contacts out, cleaning them and putting on my glasses. In the morning, I do not have to put my glasses away, put my contacts back in and clean my container.
6. I'm able to play soccer and cheer with my daughters and not have to stop because my contacts have dried up.

I am so happy that I had LASIK and have recommended it to others who were thinking about having the procedure done.

Thanks for your time,

Warburton, Karen

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

My name is -----
My address is -----

I was given information that the FDA is scheduling a hearing on the quality of life after LASIK. I had the procedure 5 years ago and it totally changed my life. Since 2nd grade I had worn some sort of corrective lenses. My vision now is such that, even at the age of 54, I do not need any sort of corrective lenses for distance or up-close vision. I am aware of the fact, every day, how great it is to be able "to see". Please include my comments as a part of the Ophthalmic Devices Panel Meeting.

Warburton, Karen

From: -----
Sent: ----- 10:12 AM
To: Warburton, Karen
Subject: LASIK

I am writing in reference to my vision post LASIK, I had the LASIK procedure done May 2001 and I was quite nearsighted -6.50 & -7.00. I am so pleased with my vision and my quality of life has improved dramatically. I can swim, ride rollercoasters, see my 4 month old twin boys sleeping at night and so much more. I no longer feel bogged down by the having to worry if I have all my contact solution with me when I travel. Or worrying about my glasses breaking or losing a contact because if this happen in the past I would have been blind. I am forever grateful for my surgeon for giving me my new vision and now not having the hassle of dealing glasses and contacts. I wish the comments to be included as part of the record of the Ophthalmic Devices Panel meeting.

Warburton, Karen

From: _____
Sent: Thursday, April 03, 2008 7:28 AM
To: Warburton, Karen
Subject: LASIK surgery

Current address: _____

LASIK

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

I have been wearing glasses for as long as I can remember. The 3rd grade is my first recollection of when Mom took me to the eye doctor and glasses were put on my face. What a pain that was. Then I was finally able to wear contacts the moment I turned 13. What a glorious day that was. Finally, no more REC Specs for playing sports, no more being called four-eyes by my friends. Contacts were awesome. Except for the fact that I had a terrible astigmatism. So gas permeable contacts would be my contacts of choice - not my choice, but that is what I wore for nearly 23 years.

During that time I must have broken, lost, had poked out of my eye hundreds of pairs of contacts. My family spent too much money to keep me "seeing." Upon joining the military at age 18, I received my first pair of military specs - oh what a joy that was. You do know why they are called BCG's right? Anyway, I was lucky and got two pairs; regular and tinted. Ooh la la.

Wearing contacts and glasses for as many years as I can count; going on tons of deployments - Greece, Somalia, Iraq, Kuwait, and Afghanistan. Being in desert conditions wearing contacts just doesn't mix. As soon as the military started the pilot program for Lasik/PRK, I jumped at the opportunity to get my eyes done. But it never materialized as I was always deploying somewhere. I just didn't have enough time on station for follow-up check ups.

Then right after my family and I conducted a permanent change of station to Fort Campbell, KY, the opportunity finally presented the chance for me to get Lasik. Not through the military as they wanted me to wear glasses for 90 days before they would even conduct the eye exam. Instead, I elected to pay the \$4,000 to have my eye surgery at the _____ of Nashville, Tennessee. My reason - deploying to Afghanistan for a second time and I wasn't going to be wearing contacts or glasses. I was sick and tired of not reaping the benefits of seeing the world in a better "clearer" way.

I had my surgery NOV 5, 2007 and that is just about the best day of my life - excluding my wedding day, and the birth of my two sons. I can see, I can see. Free at last, Free at last, thank God Almighty, I am free at last - of contacts and glasses.

Warburton, Karen

From: _____
Sent: Thursday, April 03, 2008 12:22 AM
To: Warburton, Karen
Subject: LASIK

I would like my opinions included as part of the record of the Ophthalmic Devices Panel meeting.

LASIK has changed my life for the better. I wore glasses and contact lenses for almost 15 years and I was getting less tolerant of them. I can enjoy my hobbies of weight lifting, snow skiing, and running to a whole new level. When my small children wake up in the middle of the night and call for "mommy", it is so much easier for me to attend to their needs. I'm no longer feeling for door frames or counting steps to the bathroom in the middle of the night. I feel that I am safer because of LASIK. I could hopefully defend myself better from an intruder since I could actually see them. I could get myself and my family out of my house quicker in case of a fire.

Warburton, Karen

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

I would like my opinions included as part of the record of the Ophthalmic Devices Panel meeting.

LASIK has been a great opportunity for me to really see! When I started wearing glasses, I was amazed at what I could see. Now I get to have that same joy everyday without having to worry about glasses. I enjoy lifting weights and exercising at the gym and I can't imagine having to worry about sweaty, dirty lenses. I work as an accountant and look at a tremendous amount of detailed spreadsheets on the computer. My night vision is better than it was before surgery and I feel that makes me a safer driver for my family and everyone else out there on the road.

Warburton, Karen

From:
Sent: Wednesday, April 02, 2008 8:49 PM
To: Warburton, Karen
Cc: [REDACTED]
Subject: LASIK

Topic: LASIK

I had LASIK 9 years ago. I was never nervous, totally trusted in my good doctor. I even remember laughing when I signed a waiver saying that "no one has ever gone blind from this procedure before, but you could be the first". Well, when I woke up the next day I cried with joy because I could see out the bedroom window, across the street and the leaves on the trees.

What a blessing it is to not have to pack extra glasses, spare contacts, solutions, cleansers etc. everytime I go somewhere for longer than a short period of time. One of my favorite benefits is that I can drive my car and read it all! If I get something in my eye, I don't have to pull over my bicycle, car or stop holding my children to remove the contact lens that is torturing me.

I can swim. I can go outside in the rain and not get spots. I never ever have to take out my contacts to clean them, re-center them, or remove the eyelash.

I am completely satisfied with my LASIK results. I think everyone should have it done, if they are a candidate. I am so thankful for the procedure. Please convey my satisfaction and include my comments as part of the record of the Ophthalmic Devices Panel meeting.

Yahoo for LASIK!!

Thank you,

Warburton, Karen

From:
Sent: Wednesday, April 02, 2008 7:52 PM
To: Warburton, Karen
Subject: Lasik (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

I am _____, and I wanted to express some comments on my experience as a laser refractive surgery patient. I hope that these comments could be included as part of the record of the Ophthalmic Devices Panel meeting. I underwent Laser refractive surgery, PRK in May 2005, and it has transformed my life in a positive direction. I went from being a -4 myope, with 20/400 vision to 20/15 without correction. I have no glare, no haloes, and no dry eye symptoms of any sort. It is as if I was given perfect vision. I enjoy the benefits of this procedure everyday. I no longer have the inconvenience of dealing with glasses or contact lenses. I no longer have the fear of corneal ulcers from contact lenses. When I travel, I no longer have to pack glasses, or contact lenses. Even better, I no longer worry about what I might do if I lose a Contact lens, or break my glasses. Sports are infinitely more enjoyable without the worry of glasses or contact lenses. I do many water sports, and I used to loose contact lenses frequently. I also used to worry about acanthamoeba keratitis from swimming with contact lenses in place.

My concerns about contact lens related ulcers is probably more than most people, but that comes from the fact that I am an Army Ophthalmologist, and I see and treat contact lens related diseases on a daily basis. I have seen people go from a contact lens wearing 20/20 to corneal transplant recipient because of bad corneal scarring an/or perforation from a contact lens related corneal infection. Now that I have had laser refractive surgery, I have one less thing to worry about.

I am also an Army ophthalmologist and the _____ here at _____. Myself and the other ophthalmologists here in our clinic perform approximately 2,000 Lasik and PRK surgeries each year. We track our results with visual acuities and with satisfaction surveys, and the results are outstanding! It is a pleasure to provide this service for our soldiers, sailors, airmen, and marines. There are very few procedures or treatments in medicine or surgery that provide such a lifestyle improvement for our patients, with such a success rate, and such a low risk profile.

To give you an example of our results in 2006, we did 2,430 eyes, 98% saw 20/40 or better, 97% saw 20/25 or better, and 94% saw 20/20 or better. No patients lost more than 1 line of Best corrected visual acuity. 2007 results are similar, we did 2,511 eyes, and 98% saw 20/40 or better, 96% saw 20/25 or better, and 93% saw 20/20 or better uncorrected. Again no eyes lost more than one line of best corrected visual acuity. I doubt you will find such a safety profile with contact lenses.

I receive surveys from soldiers who have had laser refractive surgery and subsequently been deployed to Iraq or Afghanistan, and we ask several questions to see how their experience in the field has been impacted by their laser treatment. To sum up the results of these questionnaires, of the 44 I have received in the past 2 months, every single one answered "Yes" to the question, "If I had it to do over I would have the surgery"

In the comments section, I have comments like, "Highly encourage it. It significantly increased my readiness." and, "Awesome. Made a huge difference."

In conclusion, I want to express my enthusiastic approval of the Lasik procedure, and laser refractive surgery in general. It has helped improve the quality of my life, and it has a positive impact on the lives of my patients. It is amazing surgery with tremendous benefits, and minimal risk.

Sincerely,

Warburton, Karen

From: _____
Sent: Wednesday, April 02, 2008 7:05 PM
To: Warburton, Karen
Subject: LASIK

TOPIC: LASIK

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

LASIK has completely turned my life around. For over 47 years, I have depended on glasses and/or contacts. Within ten minutes all of that was miraculously erased!

I have taught school for over 32 years. I currently still teach elementary school and teach preservice and beginning teachers. Being able to finally "see" at all times and in any situation has definitely enhanced my ability to teach, my ability to work with my students, and my pleasure in my profession.

Additionally, my overall quality of life is vastly increased. I am able to fully participate in and enjoy many of the outdoor activities that were limited before. I am, therefore, in much better mental, physical, and emotional health.

LASIK was expensive, and I had to save up for it. It is not covered by my insurance. It was very much worth the cost. I wish it were considered a needed medical procedure because of the huge positive impact it has!

Warburton, Karen

From: _____
Sent: Wednesday, April 02, 2008 6:53 PM
To: Warburton, Karen
Subject: Quality of life impact of LASIK

Dear Ms. Warburton,

I wish my comments to be included as part of the record of the Ophthalmic Devices Panel meeting to be held April 25, 2007

In 1999, I underwent a successful LASIK surgery by _____ located in _____

LASIK has dramatically changed my life. I struggled with the discomfort contact lenses for years. My night vision was poor due to astigmatism, so poor that I avoided driving at night. More importantly I had a 7 year old daughter at the time and I felt I was missing a lot water activities with my daughter because of the concern over loosing my contacts.

Since my LASIK surgery I now see 20/10, which is far better than 20/20. I can now drive safely at night and I can enjoy all activites with my now 15 year old daughter. I have taken up sports such as snorkely and scub diving. Without LASIK, I would have had a loss of quality of life and never been able to be a full participate with my daughter in many activities.

Please feel free to contact me with any questions.

Thank you for your efforts to keep LASIK a viable option for others to enhance their quality of life.

For your records:

My name is _____

My address is _____

My phone number is _____

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 [REDACTED] in----- Before the surgery I was completely dependant on glasses or contacts and my glasses power was minus -----azing 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.

Warburton, Karen

From: -----
Sent: -----008 4:42 PM
To: Warburton, Karen
Subject: Lasik

My name is ----- and I had Lasik 2 yrs ago. I am very happy with my vision and the surgery changed my life for the better. I -----e teacher. It is wonderful not having to wear contact lens or glasses. My phone number is ----- . I live in----- Thank You -----

Warburton, Karen

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

Dear Ms. Warburton:

I am a refractive surgeon and ophthalmologist and had LASIK on my own eyes in 1998 (10 years ago). And, as a surgeon, I require the best possible vision as I perform microsurgery on thousands of patients every year. I struggled with contact lenses before my surgery and, at times, did not function well due to the irritation of these. Wearing glasses while performing surgery is cumbersome, as the microscopes aren't built with glasses-wearers in mind.

And personally, I have benefitted from having had LASIK surgery as I am able to engage in more athletic activities than I was able to before I had the surgery. Now that I have small children, it is much easier to attend to their middle of the night concerns without fumbling for my glasses to see where I am going in the dark. It really has been a blessing having had LASIK.

I would like this email and my comments included as part of the record of the upcoming Ophthalmic Devices Panel meeting.

Please feel free to contact me if you have any questions.

Best regards,

Warburton, Karen

From: -----
Sent: Wednesday, April 02, 2008 4:32 PM
To: Warburton, Karen
Subject: LASIK Surgery

I had LASIK surgery performed on my eyes in August of 2001. I became intolerant to contact lenses and actually developed a severe corneal ulcer as a result of wearing them. It did not work in my lifestyle to use glasses as my only alternative due to the focusing that I do with certain instruments. I am an Optometrist and I have found that the quality of vision that I have is actually better with my LASIK surgery than it ever was with glasses or contact lenses. I recommend LASIK surgery to my patients that I believe have the right prescription and motivation for surgery and feel that it the only alternative to vision correction for many patients. Please include my comments as part of the record for the Ophthalmic Devices Panel Meeting.

Warburton, Karen

From: _____
Sent: _____ M
To: Warburton, Karen
Subject: (no subject)

----- My name is _____ and I live at _____
_____, my e-mail address is _____ Tel: _____
----- K I had Lasik approx----- _____ in _____
_____ and it has changed my life completely. My participation in social
_____, sports and business has improved 100%. The Lasik has improved my
ability to work more efficiently, become a better athlete and it has improved my
personal relationships with my family in numerous ways. I hope my
**comments can be included as part of the record of the Ophthalmic
Devices Panel meeting. Please advise if I can be of any further help.**
Regards,

Warburton, Karen

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

My name is _____. I recently had LASIK and would like my comments included in the the record of the Ophthalmic Devices Panel meeting.

I noticed a substantial difference immediately after having LASIK surgery. Only weeks after the surgery I was seeing 2010 and my vision still continues to improve. I have a 3 year old daughter and feel much more confident caring for her now. I know that should something happen in the middle of the night I won't lose any reaction time while looking for my glasses. I can concentrate on the important things, like grabbing my daughter and getting her to safety.

The detail that LASIK has brought back to my life is outstanding. I just can't believe I waited that long to get it done. The quality of life is beat by no other. I can swim in the ocean with my daughter and not have to worry about her splashing me. I can see road hazards more clearly and at a much greater distance, thus quickening my reaction time. I can only imagine how much more this would do for someone in the uniformed services.

Thank you.

Warburton, Karen

From: _____
Sent: _____
To: Warburton, Karen
Subject: Ophthalmic Devices Panel

Please make my comments available to the above listed panel. I had LASIK performed about 3 years ago by [REDACTED]. WOW! I cannot say enough about the success of this procedure. It changed my life!!! I no longer sleep in my glasses. I can read the alarm clock, I can lie in bed and watch TV and more importantly, I am able to perform my job at a higher level. I am an administrator of 6 orthopedic clinics. LASIK has truly given me a better quality of life. I cannot imagine going back! I have recommended many, many friends and colleagues for this procedure since mine was so successful. Every person I have recommended have had an equally successful procedure. Thank God for this technology and for skilled surgeons like [REDACTED].

Warburton, Karen

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

Hi Karen...
Please include my comments as part of the record of the Ophthalmic Devices Panel meeting, which I understand will be held in April.
I would like to go on record to say that LASIK was the greatest gift my husband ever gave me. No longer do I struggle to find my way after my contacts are out....with the fear of an emergency occuring and my not being able to react/see appropriately. Also, after wearing contacts/glasses for nearly 40 years my eyes dried out to the point that I had to go back to glasses which I just could not bear...I can now swim and see where the end of the pool is and actually see the tennis ball coming! LASIK gave me the gift of sight, for which I will always be grateful..... I would absolutely recommend it to anyone (and have!!) -- it changed my life for the better. It was worth every penny and I would do it again!!
Please let me know if you would like further testimony from me, as I am a firm believer in LASIK...
Thanks!

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

Dear Karen:

I am writing this letter on behalf of [REDACTED] to express my satisfaction after having lasik surgery.

My entire lasik experience at ----- in-----two years ago was phenomenal. [REDACTED] and his staff were friendly and knowledgeable and they were obviously confident in the service they provided. My time there was enjoyable and, best of all, I'm free of glasses and contacts! I'm especially pleased during this allergy season that's upon us; usually during the allergy season, my contacts dry out, tear or fall out of my eyes, but no longer!

I had an outstanding experience at ----- and with the lasik procedure and would do it all over again given the chance!

Sincerely,

April 9, 2008

To the FDA Advisory Committee:

This letter is to give my views on the market of refractive surgery. First off, my name is ----- . I am a Physician who underwent refractive surgery May 2007(Right Eye) and June 2007(Left Eye). I have been wearing glasses since my 3rd grade year in school. After hearing of the wonders of refractive surgery from numerous people and hearing all of the advertisements of guaranteed 20/20, I started to look into the possibility of having the procedure done myself. I had never heard about or talked to anyone that had a bad experience with refractive surgery to get the other side and didn't even know that they existed. Now, I know that there are many that have had bad experiences with refractive surgery. I am not very certain about the number of people that have had refractive surgery but, since 1996, there has been somewhere in the range of one-million procedures done and the number continues to grow. The latest statistics show a satisfaction/good outcome percentage of about 95%. Well, that means that 5% did not for some reason or another. **That means that about 50,000 people who had the procedure done had a less than perfect/suboptimal outcome.**

Now, I know this is basic statistics and I am sure that the refractive surgeons can explain it in some way that makes it seem that the 5% is really not that large of a population due to certain factors, but does the FDA really know what these 50,000 people went through with their suboptimal results? I think that there are a few questions that need to be addressed. (1)How can one really know what the post-op vision is like if you don't ask the patient themselves? (2)If you just listen to the surgeon's side, aren't the results going to be biased? (3)When has there been a public opportunity up until now for people to freely give their own opinion of their post-op vision? Hmmm... (4)Can the FDA afford to let the physicians sweep the bad results under the rug and continue on? (5)Is there a magic number of bad results that needs to be reached before something is done? (6)Once this number continues to accumulate and it will, do you think that an insurance company would sell you disability insurance at the same rate they would sell someone with normal corneas? Let me give you some first hand advice from a physician's perspective. The eyes are just too precious to a person's well being, quality of life (mental and physical) and future to approve a risky, elective procedure that can potentially ruin the quality of life as they know it. In medicine, I have told many patients myself that some things just should not be tampered with. The one question I wonder if the FDA has asked is, "Is refractive surgery doing more good than harm?" The answer is very simple, "NO", because the people that are happy with their post-op vision would state that they haven't lost anything but the people that had bad outcomes would not have had complications if the procedure were not approved.

I really want to emphasize the point that the complications that arise from bad outcomes are real and there are real people dealing with them. If there are any moral

people that are on the FDA advisory committee, I wonder do they know that a procedure/laser has been approved that has decreased the quality of life for a significant number of people for whatever the reason may have been. I have learned the hard way that if given the permission to do harm, it will be done if the financial reward is worth the risk. The FDA can act now to help prevent future lives from being ruined. By removing the option for refractive surgeons to make a market out of selling a person a dream, you will be saving lives. It is literally like this, if you are happy with your post-op vision, you are written down as a success, but if you are not or there was an error on either the laser or the physician's part, then you are simply invisible, even if you are a fellow physician. The field of ophthalmology was doing just fine financially before refractive surgery and it will be just fine once it is discontinued. Hearing the statement "You knew there was a risk before you did the procedure" is really a foul statement because when you are purchasing anything, no one is going to put emphasis on the negatives. An elective, serious procedure such as refractive surgery should be verbally presented in a way that gives the patient considering it all of the potential complications so that an informed decision can be made.

Using 95% as a sales pitch is very misleading. What these satisfied patients are dealing with since their procedure is not discussed at all. There are many patients that initially after the procedure were very excited, but after about six months to a year were dealing with starbursts, halos, regression, problems reading, and decreased night vision. You don't hear about these patients because they are swept under the rug for fear of a decreased market. Well, there are many factors about refractive surgery that could possibly sway a person to not have the procedure done that are either not told to the patient, downplayed or just ignored by the physician. In the excitement of the whole process, you completely put your trust in the physician that everything will be ok and that this is a physician that has taken the Hippocratic Oath "to do no harm." You would think that someone with the nerve to do an elective surgery on your eyes would give you all the information there is to know about it (good and bad) so that you can make a good decision on whether or not you would be a good candidate. Well, I found out the hard way that this is not the case. What I assume the defense is on bad outcomes is "If you read your pre-surgical application, you should have known about possible complications." Well some things are better said than written especially when it comes to irreversible procedures. I would be the last person to speak badly about another physician because we all make mistakes from time to time, but this sub-specialty has been taken over by money and this procedure is in one word immoral.

Another sales pitch used is guaranteed 20/20 vision. The term 20/20 is used very loosely. Post-operatively, you may see 20/20, but the letters may be doubled, tripled or blurry. It doesn't matter to the surgeon that they aren't clear, it only matters that you can see them. So you see 20/20 to the surgeon. If you can't see them on the Snellen chart, they will tell you to guess, and if for some reason you guess correctly, that is written down as success, not that you had problems recognizing the letters. Things that you will be told if you are not seeing clearly as you expected post-op:

- (1) You are probably still healing
- (2) Your eyes are just dry

(3) Continue steroid drops for a couple of more weeks

These are statements that have been practiced by the optometrist and physician to try to keep the patient from complete nervous breakdown and prolong any chance of litigation. To say that depression is not caused by a bad outcome is absolutely ridiculous. How can you not be depressed if you were able to see perfectly before this elective procedure and now you find that you paid to have irreversible, terrible and in some cases disabling vision. Well, if the choice to have refractive surgery was removed, and not presented in a manner that was so tempting, no one would be going through the disappointment of a suboptimal outcome. They would live normal lives with glasses or contacts just like they were living before 1996 and their vision would be affected only by normal aging or natural causes.

Now, I underwent the procedure known as LASEK. My pre-op prescription was -6.25 and -6.50 in the L and R respectively. This procedure is done for people that may have not been good candidates for conventional LASIK due to large pupil size. My dilated pupils were 9.0mm. Some of the problems that people have with large pupils are halos at night, starbursts, and decreased night vision. Now refractive surgeons are saying that pupil size doesn't matter due to neural adaptation. I don't believe this statement to be true. Neural adaptation can be associated with chronic fatigue due your brain having to over compensate for an unnatural visual field. Before the procedure, I foolishly did not think about my future as a physician or my family's future if things did not come out as planned. I was told that I was a good candidate for the surgery by my surgeon and I trusted him. So, I decided to have one eye done at a time. I asked about what problems had the surgeon encountered in the cases that he has done and he said "None, but a little dry eye and that's temporary." So I underwent LASEK on the R eye in May 2007. I was informed that sometimes it can take up to four weeks for the vision to be completely functional. Initially after the procedure, there was minimal pain and after twenty-four hours I was able to see within about 12 inches from my face. I was very excited! After about 2 weeks, I was able to drive with one eye. I thought that everything was great. My night vision at that time was not complicated by starbursts. I compared my R eye with the vision in the L eye with a prescription contact lens. My L eye with a contact lens showed a visual field that was bigger and brighter, whereas the R eye although clear at the time, showed things slightly smaller and as if there was a tint covering the eye. It was as if the lights were on bright in one eye and on dim in the other. This is called loss of contrast sensitivity. Most people that have the procedure done won't notice this initially because they have both eyes done at the same time. With and without the contact in the L eye, I noticed that my balance was just a little bit off. When this was told to the surgeon, their response was "Well you have to remember, you had a lot of correction done." That one statement scared me because, I knew then that if anything else goes wrong with my particular case, they would use that statement against me. It was not presented that that particular problem might occur due to my high pre-op myopia. That would have been nice to know don't you think? Anyways, I continued on and had to take off a couple of weeks from work due to not being 100% at the job like I was before the surgery. I continued to have problems, now with splitting headaches from the two different visual fields that my brain was trying to put together. Although they were close with a contact lens, it was still enough for me to have problems. So quite naturally, I

thought, I need to go ahead and get the other eye done so that at least I will be level. So, I scheduled to have the L eye done at that time. After having the procedure done on the L eye, the night after the surgery, I noticed that there was excruciating pain in the L eye. My physician did call his patients the day after the surgery to check on them, and I told him about what had happened. He asked if the contact lens had come out and I told him, no. On the follow-up day, I couldn't even see the big "E" on the Snellen chart. My doctor, after doing an exam, told me that "there was an epithelial defect on the cornea," but he thought that it would be alright. "Continue the steroid drops and Vitamin C." At this point, I am scared beyond belief. I am asking myself "How did this happen to me?" "Why did I do this?"

After about four weeks, my vision did start to clear but I was seeing triple (ghosting) and I noticed that my dim light vision was worse and that letters appeared to be smaller than they were in the R eye. On my return visit, my doctor told me that I had been overcorrected about +1.00 and there was (-1) astigmatism. At this time I am really starting to panic, but when I expressed my problems to my doctor, he stated that he had not seen a patient that wasn't happy with their vision yet. So I continued to wait, which is all I could do. Well weeks went by then months and still no improvement in the L eye. I still have ghosting to this day and the dim light vision has gotten worse in both eyes. The overcorrection in the L eye caused me to have imbalance issues. When presented to my doctor, he stated that "Your symptoms of imbalance aren't caused by your eyes, it's probably vertigo." Now, I guess at this time he forgot that he was talking to another physician because I know that vertigo is caused by an inner ear fluid imbalance. What I was experiencing was a mismatch from both eyes being different, which to me was common sense and probably was to him too, but written off to not take the blame. I am a physician too. **I know what it's like to write off a patient.** Although I learned the hard way, this whole experience has changed my whole approach to every patient and made me a much more considerate physician. What I understand now is, to the surgeon, I had to be written off because he couldn't go back and fix what was already done. He had to go on because any one unhappy patient could decrease the number of future cases and therefore decrease business. So there I was, a physician myself, treated like the patient that I myself from time to time had written off. At that moment, I knew that this was a business, not a life saving medical miracle, a business. I bought it hook, line and sinker.

Today, I deal with decreased night vision, starbursts at night, slow reading, eye spasms and worst of all, **unpredictable future vision.** My vision is about 20/40 in the R eye and a blurry 20/15 in the L eye. This has caused some depression, because I am a 29 year old young man that was just ready to start living life. This unnecessary procedure has slowed me down significantly and worrying everyday about something that I had taken for granted before is depressing no matter how you look at it. I can't help but wonder if someone from the AMA or FDA had just said, "**We are drawing the line here, the eyes are just too important,**" myself and about 50,000 others or more would not be dealing with life long complications from a medically unnecessary procedure. Please review and consider what I have said, for this is something that more public awareness must be broadcasted. Is there something wrong about helping prevent future lives from being ruined? The only thing that you will be hurting by **not** making

refractive surgery an option is the surgeon's bank account. Please remember that no one needs refractive surgery and it is not curing anything, it is a risky operation that can potentially increase insurance premiums in the future and potentially ruin your quality of life as you know it. I have to tell you that as a physician, it is sickening to know that if the refractive surgeon is able to sleep at night, there is now the opportunity to get financially rewarded and be fully protected if you are able to deal with knowing that you really did decrease the quality of a person's life. It is so hard to really understand and feel what another person is going through when you don't have that problem. It is much easier to look over them and go on to other "normal" people. I am amazed that the AMA/FDA is willing to allow people to take the risk of having a suboptimal outcome. Please don't have the mentality that, "Well, we're neck deep in this thing, we can't back out now." Yes, I am **one** of a supposed low percentage of unhappy patients, but isn't that enough. I believe that mistakes are part of any medical profession but ethics and morals play a part as well.

Sincerely,

HOW MY LASIK SURGERY AT STANFORD DAMAGED MY VISION AND ALMOST DESTROYED MY LIFE. PLEASE READ THIS BEFORE UNDERGOING LASIK SURGERY!

I. AFTER LASIK SURGERY FROM [REDACTED], THE OVERALL QUALITY OF MY VISION IS MUCH WORSE THAN BEFORE THE SURGERY.

I NOW HAVE:

1. PAINFUL DRY EYE AND FREQUENT HEADACHES
2. **BLURRY, HAZY VISION** IN MY RIGHT EYE, AND CRISP, CLEAR VISION IN MY LEFT EYE. THIS IMBALANCE IS ALMOST INTOLERABLE.
3. A LOSS OF CONTRAST SENSITIVITY IN MY RIGHT EYE – I HAVE PICTURES THAT SIMULATE MY POOR VISION IN THIS EYE. (PLEASE ASK IF YOU WANT TO SEE THEM)
4. LOSS OF CRISP, CLEAR VISION IN MY RIGHT EYE
5. LOSS OF CLEAR VISION IN DARK OR LOW LIGHT SITUATIONS
6. ALMOST CONSTANT SHARP PAIN IN MY RIGHT EYE
7. DIFFICULTY READING FOR LONG PERIODS OF TIME
8. I ALSO SUFFERED MORE THAN A YEAR OF **DEPRESSION** AFTER THE SURGERY. (GOOGLE “LASIK AND DEPRESSION” TO READ SOME VERY INTERESTING ARTICLES)

ALL CAUSED BY LASIK SURGERY! WHILE I CAN SEE 20/20 OUT OF MY LEFT EYE, MY OVERALL VISION IS IMBALANCED AND **FAR WORSE** THAN MY VISION WITH GLASSES OR CONTACTS BEFORE THE LASIK SURGERY. LASIK WAS A LIFE-ALTERING, HORRIBLE EXPERIENCE FOR ME.

II. WHAT [REDACTED] DID NOT TELL ME BEFORE THE SURGERY:

1. SOME STUDIES SHOW THAT AS MANY AS 40% OF PATIENTS SUFFER FROM **LONG-TERM DRY EYE** AFTER LASIK (SEE STUDIES DISCUSSED IN [REDACTED]) THERE IS NO CURE FOR DRY EYE CAUSED BY LASIK.

IF YOU ARE GETTING LASIK BECAUSE YOUR CONTACTS HAVE BECOME UNCOMFORTABLE, THIS MAY BE RELATED TO A DRY EYE CONDITION. LASIK OFTEN MAKES A PRE-EXISTING DRY EYE

CONDITION MUCH WORSE! BE VERY CAREFUL IF THIS IS YOU.
DRY EYE IS HORRIBLE!

2. EVEN THOUGH YOU MAY SEE 20/20 AFTER THE SURGERY, IT COULD BE A **BLURRY 20/20**, AND YOU MAY LOSE THE CRISP, CLEAR 20/20 VISION YOU NOW HAVE. THIS IS WHAT HAPPENED TO MY RIGHT EYE. (██████████ DECLARED MY SURGERY A SUCCESS, EVEN THOUGH THE QUALITY AND SHARPNESS OF MY VISION IN MY RIGHT EYE IS 1000 TIMES WORSE THAN IT WAS BEFORE THE SURGERY.) SOME USE THE PHRASE "LASIK 20/20" TO DESCRIBE THIS BLURRY VISION.

3. LASIK CAN CAUSE A **LOSS OF CONTRAST SENSITIVITY**. WITH LOWER CONTRAST SENSITIVITY, YOUR ABILITY TO DISTINGUISH BETWEEN COLORS AND YOUR OVERALL VISION QUALITY MAY BE SIGNIFICANTLY COMPROMISED. I NOW CANNOT TELL THE DIFFERENCE BETWEEN BLUE AND BLACK SOCKS IN LOW LIGHT.

MANY STUDIES HAVE SHOWN A LINK BETWEEN LASIK AND THE LOSS OF CONTRAST SENSITIVITY. (AGAIN, GOOGLE IT.) ██████████ WILL NOT TEST YOUR CONTRAST SENSITIVITY BEFORE OR AFTER YOUR SURGERY. THIS IS ONE OF THE MOST IMPORTANT MEASURES OF YOUR OVERALL VISION QUALITY.

4. I ██████████ HAS LITTLE INCENTIVE TO WARN YOU ABOUT ALL OF THE RISKS OF LASIK. THIS "MIRACLE" SURGERY HAS MADE HIM ONE OF THE HIGHEST PAID EMPLOYEES AT ----- SINCE 2002, IT APPEARS THAT HE HAS BEEN EARNING BETWEEN **\$2 - 3 MILLION PER YEAR** PERFORMING LASIK SURGERY.

<http://chronicle.com/free/v49/i13/13a03001.htm>

<http://www.philanthropy.com/free/articles/v19/i23/23003401.htm>

TO EARN THIS SALARY, HE RELIES ON A STEADY STREAM OF NEW PATIENTS. IN MY OPINION, HE IS AN ABSOLUTE MASTER AT DOWNPLAYING THE RISKS BEFORE THE SURGERY, AND AVOIDING RESPONSIBILITY FOR VISION PROBLEMS CAUSED BY THE SURGERY.

AND FORGET TRYING TO SUE HIM IF SOMETHING GOES WRONG WITH YOUR SURGERY. HE IS COMPLETELY PROTECTED FROM LITIGATION BY THE CONSENT FORM HE WILL REQUIRE YOU TO SIGN.

READ THIS CONSENT FORM CAREFULLY! IT BASICALLY SAYS THAT NO MATTER HOW BAD YOUR VISION IS AFTER LASIK, YOU HAVE NO LEGAL RIGHTS WHATSOEVER. IT DOES WARN YOU THAT THE SURGERY MAY CAUSE PERMANENT DRY EYE. IF YOU EXPERIENCE

VISION PROBLEMS AFTER THE SURGERY, I CAN TELL YOU EXACTLY WHAT [REDACTED] WILL SAY: "YES, THERE ARE ALWAYS RISKS ASSOCIATED WITH SURGERY. WE WARNED YOU IN THE CONSENT FORM."

I KNOW YOU ARE PROBABLY VERY EXCITED ABOUT THE THOUGHT OF GETTING RID OF YOUR GLASSES (I CERTAINLY WAS). BUT SLOW DOWN AND THINK ABOUT WHAT HAPPENS IF YOU EXPERIENCE ONE OF THE MANY POSSIBLE PERMANENT SIDE EFFECTS OF LASIK, AND HAVE NO LEGAL RECOURSE. I CAN ONLY TELL YOU IT HAS BEEN BY FAR THE MOST FRUSTRATING, DEPRESSING EXPERIENCE OF MY LIFE.

5. YOUR NIGHT VISION MAY BE MUCH WORSE AFTER LASIK. I TRY TO AVOID DRIVING AT NIGHT NOW. [REDACTED] WILL NOT TEST YOUR NIGHT VISION BEFORE OR AFTER THE SURGERY.
6. LASIK OFTEN RESULTS IN AN EARLIER LOSS OF NEAR VISION. I NEVER WORE READING GLASSES BEFORE LASIK. NOW I HAVE TO REACH FOR READING GLASSES EVERY TIME I READ. AFTER THE SURGERY, [REDACTED] TOLD ME THAT MY PRE-LASIK NEAR-SIGHTEDNESS PROBABLY WOULD HAVE ALLOWED ME TO READ WITHOUT READING GLASSES LATE INTO MY LIFE. NOW I HAVE COMPLETELY LOST THAT ABILITY.
7. LAST, BUT NOT LEAST, THERE IS HUGE MONEY TO BE MADE IN THE LASIK INDUSTRY!! I CONSULTED WITH THREE LASIK DOCTORS BEFORE MY SURGERY. THEY ALL DOWNPLAYED AND SIDESTEPED THE RISKS DISCUSSED IN [REDACTED]. FOR A LONG TIME, I COULD NOT UNDERSTAND WHY THEY WOULD DO THIS. THEN I LEARNED THAT THEY MAKE \$2-3 MILLION PER YEAR.

FINAL WARNING - BEFORE HAVING THE SURGERY, PLEASE GO TO [REDACTED]. READ THIS ARTICLE!!! TALK TO AS MANY PEOPLE AS POSSIBLE ABOUT LASIK. GO TO [REDACTED] AND CLOSELY READ THE POSTINGS. YOUR EYES ARE PRECIOUS AND YOU ONLY HAVE ONE PAIR. I AM NOT TRYING TO DISCOURAGE ANYONE FROM THIS SURGERY, BUT I WANT PEOPLE TO FULLY UNDERSTAND THE RISKS.

BEFORE THE SURGERY, I NEVER THOUGHT THESE VISION PROBLEMS WOULD HAPPEN TO ME. WELL, THEY DID...AND IT IS INCREDIBLY FRUSTRATING BECAUSE [REDACTED] HAS NO IDEA HOW TO TREAT OR FIX ANY OF THE VISION PROBLEMS I AM EXPERIENCING.

PLEASE FEEL FREE TO EMAIL ME AT ----- IF YOU HAVE ANY QUESTIONS ABOUT MY L-----

Dear----- ,

... 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 [REDACTED] and Staff:

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 [REDACTED]:

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 [REDACTED]:

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 [REDACTED]:

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 [REDACTED]:

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

Sincerely,

Dear [REDACTED] and Staff:

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 [REDACTED],

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".

Best Regards,

April 14, 2008

To Whom It May Concern:

This letter is in regard to my experience with LASIK surgery. I have worked as a technician with [REDACTED] 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 [REDACTED] office, I decided to have LASIK surgery myself. I am extremely happy with my vision following 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,

April 8, 2008

Center for Devices and Radiological Health
Food and Drug Administration
ATTN: Karen F. Warburton
9200 Corporate Blvd.
Rockville, MD 20850

RE: Satisfied LASIK Testimonial

Ms. Warburton:

I have very strong convictions regarding letters of reference. In my perception, a letter of reference is an invaluable tool for an individual to make an informed, educated decision. In no uncertain terms is it ever a favor for a friend or colleague. It is with these strong convictions that I have felt completely comfortable referring friends and family to [REDACTED] in [REDACTED]. [REDACTED] and his surgical team are unparalleled in the field.

Prior to my LASIK surgery in November of 2007, I thoroughly researched the field of LASIK surgery. Through this very deliberate research, I quickly became aware that while outcomes varied somewhat from patient to patient, even more alarming was the variance of what surgeons considered satisfactory results. Even more outlandish, these less than satisfactory outcomes were addressed as "re-treatments" or "enhancements" to which the patient was billed and the surgeon generously compensated. What incentive does the physician have to perfect his craft when he is compensated for unsatisfactory results?

In my quest to find the best outcomes, I discovered [REDACTED]. While it appears that the industry standard of patients requiring "enhancements" is between 7%-8%, after in excess of 6,000 refractive procedures, [REDACTED]'s post surgical complication rate is less than 1%. Additionally, [REDACTED] is not compensated for any "enhancements", therefore his only incentive is the knowledge that he sets the bar in refractive surgery and the pride of having satisfied patients.

What is the variable that allows [REDACTED] to produce outcomes that transcend the industry standard? Quite simply, it is passion; a passion that led [REDACTED] to develop new technology in the refractive surgical field. Through his own, blood, sweat, tears [REDACTED] developed the [REDACTED] Surgical System. This tool allows for much greater management of the corneal flap, thereby significantly decreasing complication rate. An internationally renowned refractive surgeon in Greece has implemented the [REDACTED]™ Surgical System exclusively and is now enjoying the same outcomes as [REDACTED].

The FDA has convened this committee to discuss post market experience with phakic intraocular lenses and laser-assisted in situ keratomileusis. Perhaps if more refractive surgeons implemented the [REDACTED]™, there would be no need for this meeting. In my perception, the first question that a prospective LASIK patient should ask the surgeon is, "Do you use the [REDACTED] Surgical System?" If the answer is no, continue searching for a refractive surgeon.

It has been six months since my LASIK surgery. Unquestionably, having LASIK surgery was one of the best decisions of my life. Obviously I feel this way because of very successful outcomes. I am quite certain there exists LASIK patients who do not share my exuberance for LASIK surgery. Perhaps if they had researched as I did, they would have located a physician utilizing the [REDACTED]™ and experienced better outcomes. If you have any further questions regarding my experience with LASIK surgery, please feel free to contact me directly at ----- . Thank you for this opportunity to publicly express my gratitude to [REDACTED] and his exceptional surgical team.

Sincerely,
