UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTER FOR DEVICES AND RADIOLOGIC HEALTH

MEDICAL DEVICES ADVISORY COMMITTEE

OPHTHALMIC DEVICES PANEL

110th MEETING

FRIDAY, APRIL 25, 2008

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The Panel met at 8:30 a.m. in the Ballroom of the Gaithersburg Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, Maryland, Jayne S. Weiss, MD, presiding.

PRESENT:

JAYNE S. WEISS, MD	Chairperson
NEIL M. BRESSLER, MD	Voting Member
TIMOTHY EDRINGTON, OD	Voting Member
DALE K. HEUER, MD	Voting Member
ANDREW HUANG, MD,MPH	Voting Member
JANINE A. SMITH, MD	Voting Member
STEPHEN D. MCLEOD, MD	Consultant
DAVID C. MUSCH, PHD,MPH	Consultant
RICHARD T. BUNNER	Consumer Representative
BARBARA A. NIKSCH	Industry Representative
PAULA COFER	Patient Representative
MALVINA EYDELMAN, MD	FDA

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P R O C E E D I N G S

(8:29 a.m.)

CHAIRPERSON WEISS: I would like to call this meeting of the Ophthalmic Devices Panel to order. My name is Dr. Jayne Weiss. I am a cornea and refractive surgeon and Professor of Ophthalmology, Director of Refractive Surgery, at Kresge Eye Institute, Wayne State University, Detroit Medical Center in Detroit, Michigan.

If you haven't already done so, please sign the attendance sheets that are on the table by the doors.

Ms. Warburton, the Executive Secretary for Ophthalmic Devices Panel, to my left, will make some introductory remarks.

MS. WARBURTON: Good morning, everyone. I would like to first read the conflict of interest statement and then the appointment of temporary voting member and Acting Chairperson statement.

FDA conflict of interest disclosure

statement for particular matters of general applicability: Ophthalmic Devices Panel of the Medical Devices Advisory Committee. Date of meeting, April 25, 2008.

The Food and Drug Administration is convening today's meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee under the authority of the Federal Advisory Committee Act of 1972.

With the exception of the Industry Representative, all members and consultants of the Panel are Special Government Employees or regular federal employees from other agencies, and are subject to federal conflict of interest laws and regulations.

The following information on the status of this Panel's compliance with federal ethics and conflict of interest laws covered by, but not limited to, those found at 18 USC Section 208 and Section 712 of the Federal Food, Drug and Cosmetic Act, are being provided to participants in today's meeting

and to the public.

FDA has determined that members and consultants of this Panel are in compliance with federal ethics and conflict of interest laws. Under 18 USC Section 208, Congress has authorized FDA to grant waivers to Special Government Employees who have financial conflicts when it is determined that the agency's need for a particular individual's services outweighs his or her potential financial conflict of interest.

Under Section 712 of the Federal Food, Drug and Cosmetic Act, Congress has authorized FDA to grant waivers to Special Government Employees and regular government employees with potential financial conflicts when necessary to afford the Committee essential expertise.

Related to the discussions of today's meeting, members and consultants of this Panel who are Special Government Employees have been screened for potential

financial conflicts of interest of their own, as well as those imputed to them, including those of their spouses or minor children and, for purposes of the 18 USC Section 208, their employers.

These interests may include investments; consulting; expert witness testimony; contracts; grants or CRADAs; teaching, speaking or writing; patents and royalties; and primary employment.

Today's agenda involves a discussion on general issues concerning the post-market experience with Phakic intraocular lenses and laser-assisted in situ keratomileusis, or LASIK. This is a particular matters meeting involving general applicability.

Based on the agenda for today's meeting and all financial interests reported by the Panel members and consultants, conflict of interest waivers have been issued in accordance with 18 USC Section 208(b)(3)

and Section 712 of the Food, Drug and Cosmetic Act to Dr. Dale Heuer.

Dr. Heuer's waivers address the consulting interests with a firm at issue. He received less than $10,001 for this involvement, which is unrelated to today's agenda.

These waivers allow Dr. Heuer to participate fully in today's deliberations. FDA's reasons for issuing the waivers are described in the waiver documents, which are posted on FDA's website at www.fda.gov/ohrmf/dockets/default.htm.

Copies of the waivers may also be obtained by submitting a written request to the agency's Freedom of Information Office, Room 6-30 of the Parklawn Building. A copy of this statement will be available for review at the registration table during this meeting and will be included as part of the official transcript.

Barbara A. Niksch is serving as the

Industry Representative, acting on behalf of all related industry, and is employed by Visiogen, Incorporated.

Commander David Tanzer, M.D., U.S. Navy, is a guest speaker today.

We would like to remind members and consultants that, if the discussions involve any other products or firms not already on the agenda for which an FDA participant has a personal or imputed financial interest, the participants need to exclude themselves from such involvement, and their exclusion will be noted for the record.

FDA encourages all other participants to advise the Panel of any financial relationships that they may have with any firm at issue. Thank you.

Now I will read the appointment to temporary voting status.

Pursuant to the authority granted under the Medical Devices Advisory Committee charter dated October 27, 1990, and amended

August 18, 2006, I appoint Jayne Weiss, M.D., as temporary voting member and Acting Chairperson of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee for the duration of this meeting on April 25, 2008.

For the record, Dr. Weiss is a Special Government Employee and a consultant to this Panel. She has undergone the customary conflict of interest review and has reviewed the material to be considered at this meeting.

This was signed by Daniel G. Schultz, M.D., Director, Center for Devices and Radiological Health, and dated April 21, 2008.

Before I turn the meeting back over to Dr. Weiss, I would like to make a few general announcements.

Transcripts of today's meeting will be available from Neal Gross & Company, who may be reached by phone at 202-234-4433. Information on purchasing videos of today's

meeting can be found at the table outside of the meeting room.

I would also like to remind everyone that members of the public and the press are not permitted in this Panel area, which is the area just beyond the speaker's podium.

The press contact for today's meeting is Peper Long. Peper, could you please stand? I would also request that reporters please wait to speak to FDA officials until after the Panel meeting has concluded today.

If you are presenting in any of the open public hearing sessions today -- there will be one in the morning and also one in the afternoon -- and have not previously provided an electronic copy of your slide presentation to FDA, please arrange to do so with Ann Marie Williams. Anne Marie, would you please stand? Thank you.

Of course, finally, please silence

your cell phones, if you haven't already done so. Thank you very much. Dr. Weiss?

CHAIRPERSON WEISS: Thank you, Karen. Good morning, everyone. At this meeting, the Panel will discuss the post-market experience of laser-assisted in situ keratomileusis, as well as Phakic intraocular lenses.

Before we begin, I would like to ask our Panel members and FDA staff seated at the table to introduce themselves. We will start with Dr. Eydelman, and I would like each of the members to state their name, area of expertise, position and affiliation. Dr. Eydelman?

DR. EYDELMAN: Malvina Eydelman, Director of the Division of Ophthalmic and Ear, Nose, Throat Devices in the Office of Device Evaluation.

DR. McLEOD: Stephen McLeod. I am the Chairman of the Department of Ophthalmology at University of California, San

Francisco. My expertise is in cornea external disease and refractive surgery.

DR. MUSCH: David Musch. I am at the University of Michigan in the Department of Ophthalmology and Visual Sciences, and I am a professor there. I am also in the Department of Epidemiology there, and that is my area of expertise.

DR. HEUER: Dale Heuer, Professor of Ophthalmology at the Medical College of Wisconsin.

DR. EDRINGTON: Tim Edrington, Southern California College of Optometry, Professor there, cornea and contact lenses.

DR. HUANG: Andrew Huang. I am at Washington University, East St. Louis. I am a cornea specialist. I am a Professor of Ophthalmology there.

DR. BRESSLER: Neil Bressler. I am a professor of Ophthalmology at the Wilmer Eye Institute, Johns Hopkins. I am Chief of the Retina Division there, and I have an expertise

or interest in clinical trials in retinal diseases and quality of life outcomes.

DR. SMITH: Janine Smith, Deputy Clinical Director, National Eye Institute, National Institutes of Health. My areas of expertise are cornea and uveitis.

MS. COFER: Paula Cofer, patient representative.

MR. BUNNER: Richard Bunner. I am consumer representative. I am a volunteer for Prevent Blindness America.

MS. NIKSCH: Barbara Niksch. I am currently a Vice President, Regulatory, Quality, Clinical at Physiogen, and I am serving as the industry representative.

CHAIRPERSON WEISS: Thank you very much. We will now proceed with the general discussion regarding LASIK.

Prior to hearing our presentation from the FDA, we will hold the Open Public Hearing for this meeting topic. The FDA has also received many written comments prior to

this meeting. They are available for public viewing at the table adjacent to the meeting room. They will also be posted on the FDA website with the other meeting records after the meeting at http://www.fda.gov/oc/advisory/acdevices.html.

We will now proceed with the Open Public Hearing portion of the meeting. Public attendees are given an opportunity to address the Panel to present data, information or views relevant to the meeting agenda.

There is an open public hearing statement on disclosure that I will now read:

Both the Food and Drug Administration and the public believe in a transparent process for information-gathering and decision-making. To ensure such transparency at the Open Public Hearing session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an individual's presentation.

For this reason, FDA encourages

you, the open public hearing speaker, at the beginning of your written or oral statement to advise the Committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting.

For example, this financial information may include a company's or a group's payment of your travel, of your lodging or other expenses in connection with your attendance at this meeting.

Likewise, FDA encourages you, at the beginning of your statement, to advise the Committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

As we have a large number of public speakers today, I would like to go over the process to ensure a smooth transition from one speaker to another.

Ann Marie Williams will direct you to the podium. Ann Marie, can you wave? There is the Princess Diana wave. When you speak, the green light will appear. We have to hold assiduously to the five minutes because of the amount of speakers. So, listen up for how the procedure will work.

Five minutes, the green light will appear. At one minute, the yellow light will appear. The next speaker should then approach the podium to be ready to start, because when the yellow light goes out, your time is up. At the end of five minutes, a red light will appear, and your presentation will be completed, and I have master controls here. So I can tell you, whether you stop speaking or whether I have you stop speaking, at five minutes you will stop speaking.

Since we have a large number of speakers, please adhere to these time limitations.

The Panel will be given an

opportunity to ask questions of the public presenters at the conclusion of the Open Public Hearing. If recognized by a Panel member and only if recognized by a Panel member, please approach a podium to answer questions.

I would also like to remind the public observers at this meeting that public attendees may not participate except at the specific request of the Chair.

We will now start the public portion of this meeting. I would request the first speaker, Dr. Michael Patterson, to come up to the podium. We would also ask everyone to speak clearly to allow the transcriptionist to provide an accurate transcription of the proceedings of this meeting, which will eventually appear on the FDA website.

DR. PATTERSON: (A short video is played.)

Stop using medical devices for LASIK. This is a simulation of the vision in

my left eye. LASIK ruined my vision and my quality of life. Not all 20/20 is the same. Eye chart at the bottom here shows what doctors say is a good LASIK outcome versus normal vision. LASIK often causes even more vision quality loss, which is very important. Partial lists of my LASIK complications include: Microkeratome failure, blade reuse scar, et cetera.

The FDA states safety was determined with a risk/benefit analysis, but where is it? Make the formal risk/benefit analyses public. The risks of cutting a flap for LASIK far away the benefits. Quality of vision and Dry Eye risks were not evaluated. I believe no risk/benefit analysis was actually done, and the FDA will not compare the safety of these dangerous devices to any alternative, like contacts.

What value was put on human injury and suffering in the FDA's analysis? Clinical trials are not FDA risk/benefit analyses.

Devices approved for LASIK are not safe, because cutting a flap for LASIK is not safe.

Compared to glasses or contacts, there is no way the benefits of LASIK outweigh the severe risks of permanent injury for life. A failure rate of five percent or higher is not safe, and the post-market standard of care for LASIK is not safe.

LASIK surgeons lied to me and other patients over and over. Why aren't doctors reporting the truth to the public? If the FDA followed federal law, lives can be saved.

Regarding the FDA not taking any action to regulate LASIK centers as ASFs under MDR regulation 21, CFR Part 803, LASIK surgery centers meet the devices or facility definition as an ambulatory surgical facility or ASF. CFR 803 requires the FDA to regulate LASIK centers, including their reporting and written procedures.

What has the FDA done to inspect any LASIK facility for written procedures or

for not making reports to the FDA to assure that each LASIK center follows the ASF procedures, like maintaining files and reporting?

Will the FDA explain how they know these LASIK ASFs are complying? Probably not. What FDA surveillance program confirms that LASIK ASFs are reporting adverse events that occur in the ASFs to the FDA? Disclosing FDA inaction in this public forum is shocking. I am skeptical about the ability of the FDA's CDRH to explain or defend its performance in public.

I would not be surprised to learn that few, if any, of these ASF centers meet the requirements. LASIK is a surgery done on millions of people. MDR regulation appearing in 21 CFR 803 defines devices or facility includes ASFs. I believe this encompasses LASIK centers.

The types of adverse events and serious injuries LASIK victims suffer from

must be reported by the ASFs to the FDA. Annual reporting of MDR events can be submitted on FDA Form 3419.

Publicize the FDA's lack of action, please. If my suspicion is correct, the FDA has been intentionally negligent in the discharge of its responsibility to assure compliance with the regulations.

Why have there been so few adverse event reports to the FDA, despite numerous consumer reports? By statute, ASFs are required under penalty of law to report device malfunctions. The reporting requirements apply, regardless of clearance and approval.

I have presented the FDA with evidence of unreported adverse events, but the FDA did nothing.

Regarding bias in the LASIK quality of life study, the AAO and NEI should be involved, but ASCRS' involvement represents an obvious conflict of interest. Researchers should not already have drawn a conclusion

about quality of life and LASIK, not have a financial interest in LASIK, or a bias. Yet ASCRS is already announced three LASIK surgeons for the study.

Regarding bias in the LASIK quality of life study, the FDA knows there is a study showing a connection between LASIK and suicide -- Emory University. A significant correlation between these two separate events connects them.

The medical community should know that LASIK patients may be committing suicide at four times the expected rate. That's huge. LASIK surgeon Dr. Richard Lindstrom has financial interests in the device manufacturers or the procedure, has already drawn his conclusion about quality of life after LASIK.

Having already stated his bias, I believe he should not be allowed to design and conduct a post-LASIK study in connection with the FDA's post market review of LASIK. I ask

this Panel and the FDA, after submitting four petitions: 1) to redo the FDA risk/benefit analysis for LASIK; report the serious nature of post market LASIK risks; include all the post market risks like vision quality problems and dry eye. We don't do anything to the microkeratome in between eyes, say the doctors.

2) For the FDA to regulate LASIK centers as ASFs under existing FDA MDR regulations. LASIK surgery centers meet the device user facility definition as an ASF.

For the quality of life study to be used, qualify professionals who are completely independent of the LASIK industry; and 4) a moratorium on the devices used for LASIK, because LASIK surgery is far too risky and the research was not ethically done.

5) Evaluate potential LASIK dry eye treatments like unscented natural body butter or those on mercola.com.

6) Stop LASIK.

Dr. Huang e-mailed me that there were 12 patients with a single microkeratome blade reuse. Dr. Huang is sitting on this Panel. We do not need your expertise. We do not need your conflicts of interest.

Say no to LASIK surgeons sitting on any FDA panel evaluating devices used for LASIK.

CHAIRPERSON WEISS: Our next speaker will be Dean Kantis.

MR. KANTIS: Good morning, FDA Panel, honored guests, and fellow victims of the flawed and unpredictable LASIK eye surgical procedure.

My name is Dean Andrew Kantis, founder of lifeafterlasik.com. For the past nine years, I have spent $30,000 seeking restoration of my ruined vision, only to find out there is no cure.

Through my website, hundreds of victims have contacted me expressing their suicidal thoughts. Some have already

committed suicide. It is always the same story: I was lied to. The name says it all, "lay-sick, lay-sick."

When I began to speak out against LASIK years ago, I encountered a severe backlash. Even my own doctor, Nick Caro, St. George in Chicago, tried to sue me for $2 million for exposing his 40 law suits. He then caused my family to get a divorce last year by harassing my wife, attempting to her fired from her nursing profession.

My family has been harassed, has had death threats, and was lied to by this doctor. Yet no one has punished him for his actions. Where was the FDA?

How is it that a doctor in this country can have forty-plus law suits with no known disciplinary action? I feel that my second-opinion doctors also lied to me, and I know they are the problem.

How is a patient ever able to find out they have a problem if all the follow-up

doctors lie to protect the original doctor? Where was the FDA?

After submitting complaints in these same doctors' department of regulations in Florida and Chicago, backed by solid evidence, I soon found all were denied. They all went up to probable cause, and there at the top sits a medical doctor in order to cover a fellow doctor. I feel like I have been raped.

Because of the lies, I was unable to sue my doctor before the statute of limitations ran out. I guess that is why they all kept telling me that it would take three, maybe four, maybe five years, Dean, for you to fully heal. Sound familiar?

I had to go online to find out the truth. I am now out of pocket for medical expenses, lost wages and for daily suffering. I don't know of any other procedure where hundreds of patients have created websites warning the public about the unpredictability

and corruption of LASIK surgery.

I have outlined five key emerging points which should be thoroughly investigated by this Panel to ensure that the LASIK industry does not continue to dupe the misinformed public.

Number 1: What is the truth about the flap and the pupil size? I was told that the flap created heals like a cut on your hand, but the truth is the flap never heals. Isn't that right? It is unpredictable, and leaves the patient with a permanently scarred cornea for life to see through. My pupils were measured off the charts at 9 millimeters. Yet my doctor told me I was the perfect patient candidate for LASIK.

Just remember, today's happy 20/20 LASIK patient may regress and be tomorrow's LASIK casualty driving a school bus picking up your children. Oh, yes, it affects everybody in this room.

Number 2: What is the true

informed consent? I have submitted a complete pamphlet to this Panel that gives the patient true informed consent with full color pictures illustrating the known side effects.

Please consider mandating this pamphlet, for yours is antiquated. Then educate the consumer on the statute of limitations, so they know the time frame to sue their doctor starts from the date of the procedure, not from the date of discovery. The line LASIK doctors all know this.

Number 3: What constitutes a LASIK success? I see double vision, halos, starbursts, fluctuating vision, dry eye syndrome. Yet I was told I was a success. Can you believe that?

In order to believe the LASIK industry's reported satisfaction rate of 95 percent, you must accept these complications to be acceptable normal outcomes. That's the question. Do you believe a patient who has these problems to be a success, because the

LASIK industry does.

Shouldn't patient success be decided by each individual patient, however they define success? How does this Panel define success?

Number 4: What is a breach of the standard of care for LASIK doctors? The FDA has stated over and over that it is not their job to discipline doctors. Then whose job is it, because nobody seems to be doing it?

I am out of a life that I once enjoyed, because money came first. My well-being came last. I ask this Panel to hold the FDA responsible for reviewing the ambulatory code, 21 Charlie-Foxtrot-Romeo 803.17, requiring all LASIK facilities since 1997 to report all adverse patient outcomes.

I feel every LASIK facility in this country is in violation of this mandatory requirement, which should prompt a class action law suit.

If the CDRH has not even bothered

to check the LASIK centers in their own neighborhood, why do they, all of a sudden, set up visionsite.net as a new initiative for their own incompetence? I do hope the media here today will run with this and investigate this.

Lastly, number five: What are the unforeseen emotional consequences of LASIK that affects every LASIK doctor, their family members and patients?

I come today at my own expense after eight years of research to inform this Panel that you have a serious problem on your hands, a very desperate, suicidal and angered patients that know their LASIK doctors lied to them and blame their LASIK doctors for ruining their precious lives.

I ask this Panel to set up an emergency hurt LASIK patient fund immediately in order to help patients with suicidal preventive therapy, ongoing medical expenses, legal representation, and lost wages.

Please take immediate action to protect the people who are under your care and pay you for protecting them. Thank you.

CHAIRPERSON WEISS: Our next speaker will be Glen Hagele, who will be speaking in place of Barbara Berney or presenting her statement.

MR. HAGELE: Thank you. As you said, I am Glen Hagele. I am making the statement on behalf of Dr. David Hartzog and Barbara Berney, co-founders of the Vision Surgery Rehab Network.

The Vision Surgery Rehab Network, VSRN, is a 501(c)(3) nonprofit organization whose purpose is to help patients with complications from any surgery that alters the refractive status of the eye.

The bulk of our work focuses on LASIK patients. We define their condition as refractive surgery syndrome, RSS, a complex, chronic visual, psychological and physiological symptoms following any surgery

that affects the refractive effects of the eye.

This Panel must be prepared to hear the extremes of two sides of an ongoing argument, those who maintain that LASIK does not generate depression and other psychological issues versus those who argue strenuously that their lives have been irretrievably harmed.

VSRN believes that both extremes are at times disingenuous in their arguments and unnecessarily defiant in their perspective. It is our hope that the definition of refractive surgery syndrome and, in particular, its psychological components will be recognized and accepted by the FDA, and that this definition will be a starting point toward dialogue between the two perspectives.

Physical, physiological and psychological symptoms following LASIK may combine to produce varying degrees of RSS. A

common complaint of LASIK, dry eye, may be thought of as a physical symptom, dryness, burning or pain, that may have physiological attributes relative to an inadequate tear film, which creates a psychological awareness of reduced vision.

As a contributing factor to RSS, physical dryness can be an intractable condition. The other end of the RSS spectrum is less tangible and leads to most of the post-surgery frustrations. VSRN contends that vision as a perception is more complex than LASIK advocates acknowledge.

Vision, as described in so many studies and post-operative accounts, concentrates heavily on the measurable optical attributes of the eye's condition. While knowledge of the refractive components of the eye has grown, there has been no proportionate increase in understanding how the alteration of the eye's optical elements adversely affect perception. Clearly, a broader perspective is

needed.

Vision abnormalities induced by LASIK are perceptual in a way that existing technology cannot discern. LASIK has elicited the gamut of subjective response from euphoric elation to panicked angst. While newer technology may be safer and more effective than in the past, even today's advanced procedures can reduce visual quality.

Our world, our reality, is the summation of all of our perceptions, vision being the most powerful. VSRN's experience with patients is that LASIK alters their reality in ways that disrupt their sense of normalcy and well-being.

LASIK is an elective procedure. It is natural for providers to downplay negative outcomes, particularly when there is no causative effect.

Too frequently, patients' frustrations are compounded by denial of the complaints by surgeons and other post-surgery

examiners. They begin to believe that denial is systemic in the industry and that their doctors are uncaring.

Those feelings, combined with aggressive marketing and inadequate informed consent agreements exacerbate the psychological aspects of RSS. Patients' visual perceptions should be validated, not denied.

The loss of visual quality reduces patients' overall sense of well-being and leads to depression and chronic anxiety. How doctors manage LASIK problems is just as critical to their patients' recovery as the optical outcome. Any sense of non-caring creates additional stress for the patient.

The visual complications of LASIK suggest that certain properties in curvatures of the cornea are unique to the individual and may not be subject to generalized nomographic approach.

Even Wavefront analysis, while

elegant and attractive, fails to guarantee a satisfactory surgical result. Patients with Wavefront customized surgeries regularly contact VSRN for help with RSS.

Rigid gas permeable contact lenses and additional surgeries are the most common rehab options. Informed consent agreements fail to mention that neither is consistently satisfactory nor successful. Patients whose rehab efforts fail to restore normal vision suffer a proportionately higher degree of RSS.

The number of patients affected is incalculable, since successful LASIK, in the surgeon's view, is procedural -- you are 20/20 -- while success of LASIK in the patient's view is perceptual -- but it's not clear.

RSS will continue to remain under-reported until the doctor versus patient discrepancy is resolved. VSRN believes that refractive surgery syndrome results in quality of life issues for a significant but unknown number of patients.

Any meaningful investigation of the quality of life after LASIK must be impartial, undertaken by behavioral and perceptual specialists with no vested interest in the outcome. Thank you.

Those are the words of Barbara Berney and David Hartzog.

CHAIRPERSON WEISS: Thank you. Our next speaker will be Mr. Gerard J. Dorrian.

MR. DORRIAN: My name is Gerard Dorrian. I have no financial interests in any LASIK-related entity that I know of.

Can everyone hear? Oh, this one is on. I'm sorry.

My name is Gerard Dorrian. I have no financial interests with any LASIK-related, anything that I am aware of.

I am here to tell the story of my son, Colin. Before Colin had LASIK surgery, he was a very confident, outgoing person. There was no sign of any mental illness. He had never been diagnosed with mental illness,

didn't use illegal or recreational drugs, and he seldom drank.

This is a picture of Colin at his graduation from Cooper Union with a degree in engineering. As you can see, he wasn't much more than a child.

It was a number of months after this that he had LASIK surgery, while he was a law student at the University of Michigan. Before the surgery, he had become intolerant to contact lenses, because of dry eye. This is his justification for getting the surgery. He has large pupils. There's other technical information for all the medical people here.

When he was assessed for this, he was warned that his large pupils would be something to consider, but was told that it was no worse than he would experience with contacts. It is actually noted on the medical forms that I found after his death, that there was less than one percent chance it would be worse.

This is information about his treatment. After the treatment, Colin experienced large starbursts. He said he had triple overlapping images and ghosting off white objects, and he said that he lost contrast sensitivity.

He also complained about dry eye, and that made it impossible for him to tolerate contact lenses. Three times, he tried to be fitted with contact lenses, but couldn't wear them.

This is Colin again, and it's difficult to do this, but I think the thing that best explains where Colin was is to read the last words he left for us: If I can't get my eyes fixed, I am going to kill myself. At the time of this writing, I have lived for six and a half years like this, and it drives me more and more crazy every single day. For a while, I coped fairly well and have gone forward with things I had to do; but this problem has kept me from enjoying life the way

I used to. Every single thing I look at, more or less throughout the entire day, looks ugly and confusing to me. I just cannot accept the fact that I am supposed to live like this. It may not make much sense to someone who has not experienced these symptoms, but I am rotting from the inside out. I have other problems, like most people do. In fact, I might tend toward the depressive side naturally. Who knows? But this is something else. As soon as my eyes went bad, I fell into a deeper depression than I had ever experienced, and I never really came out. I could get down about things before, but I always had my health to rely on. Without that, just getting by is not enough. I can't continue living without my responsibility, my esteem and my happiness. There is nothing at all ennobling or enlightening about suffering. The more I live with this problem, the more it will warp me and the more hateful and bitter I will become. I refuse to picture myself starting a family

that I won't be able to enjoy and love because one mistake has so damaged me mentally and physically. It seems reasonable at this point to say that, if this problem doesn't get resolved by the end of the summer, it never will. I've put up with this this long, because killing myself would be such a blow to those who love me. But I can't and won't continue facing this horror anymore. I am sorry for that. I am sorry for what I've done to you guys, my family and friends, but I have been living with this long enough and I have gone over and over it in my head long enough that I accept and forgive myself for my mistakes, and I hope you guys can do the same for me at some point. If it seems to have come out of nowhere, know that I have been keeping my counsel on this for a long time. I was incredibly afraid that, if anyone found out how badly I was feeling, my only escape would be cut off, and I couldn't risk having what I feel is my only dignified choice taken

away from me. I obviously never meant for this to happen, but after the first mistake, I don't know that there is anything else I could have done differently to change things, and I absolutely know there is nothing you guys could have done differently. You may have trouble following this request, but I am asking that you do not blame yourselves for this. I made a choice six years ago, and I lived with that choice for as long as I could, until one day I decided I simply couldn't take it any longer.

Mom, Dad, Nora and all the rest, know that I enjoyed the bulk of my life, mainly because you were in it. I love you all. I'm sorry, and goodbye.

These are purely my observations as a layperson. I feel that people that are involved with refractive surgery need to take responsibilities for the problems they create, not just point to the successes that they have.

I don't think a patient satisfaction survey, no matter how you dress it up or what else you call it, really gives anyone any information about how people are suffering. It doesn't illuminate what happens to people who have bad outcomes.

Colin said that it wasn't just a matter of what his high order --

CHAIRPERSON WEISS: Mr. Dorrian, you have -- you are very, very compelling. Thank you very much.

MR. DORRIAN: Thank you.

(Applause.)

CHAIRPERSON WEISS: The next speaker will be Mr. Glenn Hagele, who will also be giving the -- speaking for Sandy Keller and Barry Elbasani.

MR. HAGELE: I am Glenn Hagele. These are the words of Sandy Keller.

My name is Sandy Keller. I was a three and a half diopter myope before I had LASIK in Los Angeles in late 1999. I

experienced multiple serious complications and proved through litigation that I had been a victim of malpractice and improper referral.

Virtually all of my pre-op testing was performed after I had taken 5 milligrams of Valium. I met my surgeon five minutes prior to my procedure, and by that time, all concerns and questions I had planned to discuss with him didn't matter to me any longer, due to the drug's effect.

I had dry eyes, plus my topographies demonstrated corneal warpage from 25 years of hard contact lens wear.

My scotopic pupil size was over 8 millimeters, but I was treated with an elliptical 6-millimeter ablation zone. Less than half of my dark adaptive vision was corrected with the laser. All of these issues were ignored by my surgeon.

During my surgery, the blade jammed in my first eye, but the surgeon didn't stop, and left a ridge which is within my dim light

pupil. By 28 hours post-op, inflammation had begun to infiltrate my right cornea, which my optometrist did not recognize as Diffuse Lamellar Keratitis or DLK.

By one week post-op, I had Grade 4 DLK, and one-third of my cornea had been digested. More or less blind in the right eye, I was finally referred back to my surgeon, who blamed my optometrist for the advanced stage of destruction.

At eight weeks post-op, my vision measured six diopters of hyperopia, and my surgeon performed a plus-4.7 treatment with a five to nine millimeter zone, further reducing my effective optical zone.

The result was a return to myopia and multiple images. Eventually, I found the website, which is now Vision Surgery Rehab Network with stories of many other patients who had been damaged by laser eye surgery.

I realized that I had several contraindications for LASIK. My trusted

optometrist of 14 years had told me that I was an excellent candidate, and he referred me to a rookie surgeon, although I had made it clear that I would pay for the best.

I later discovered that he had a financial interest in the laser center I was sent to, and that he received $1100 for referring me, although my surgeon was paid $900 to perform the surgery.

The betrayal I felt was immense and disturbed me so deeply that I was unable to fall asleep at night. I would stay up until 2:00 a.m. or later most nights, seeking information and emotional support on the Internet.

I consulted with many doctors, several of whom told me I would need a corneal transplant. I decided to file a law suit, and in their depositions, my surgeon and optometrist blamed each other for my horrible condition. My case settled out of court.

It was determined during the

litigation that the measure size of my pupils had been altered by my surgeon when they were finally measured just prior to my second surgery. He had publicly stated that an 8 millimeter is no-go for LASIK, and with my measuring above 8 millimeters in the dark, he had a bit of a problem on his hands.

I filed a MAUDE report via the FDA website in 2001. A few months later I discovered that the disposition was that there was no record of me, and according to the Laser Center where my surgery was performed, I didn't exist.

After filing the report, I was given the news that the blade jam had not caused a stop-start ridge in my eye, but since I didn't exist, I had no way to add that information to my adverse event report.

I subsequently had seven additional surgeries, none of which were successful in removing the wrinkles. I was able to discern at least 19 images when viewing a point of

light. The small ablation zones caused intolerable glare at night.

I felt into deep depression over my vision problems, the betrayal of my optometrist and the incompetence of my surgeon. One night while preparing dinner, I looked at a knife on the counter, and I had the thought that if I stabbed my right eye, at least I could put aside the hope that it would ever be fixed. The thought frightened me, and I sought psychiatric help.

Along with severe depression, I was given a diagnosis of post-traumatic stress disorder. I worked with my psychiatrist for many months. My business suffered. I was unable to concentrate or make timely decisions on important matters. There were times that I wanted to die and rid my family of the burden I had become.

The hyper-correction my surgeon performed caused the DLK - I'm sorry.

CHAIRPERSON WEISS: If you would

prefer, we can go to the next speaker.

MR. HAGELE: The unfortunate next speaker is me.

CHAIRPERSON WEISS: Well, Mr. Hagele, no problem. We can go to Mr. Morgan, and we will suspend the rules and come back to your next two talks. So no problem.

MR. HAGELE: Thank you, Madam Speaker.

CHAIRPERSON WEISS: Mr. Morgan, can you come up to the podium, please?

Perhaps, until I give anyone any other notification, if we can just proceed from Mr. Morgan to Mr. Shell and then, when Mr. Hagele wants to come back, he can let Ann Marie know.

MR. MORGAN: Ladies and gentlemen, my name is Dom Morgan. I am legally blind from my surgeon's improper use of an investigational laser, a laser sanctioned by the FDA, known to be responsible for damaging over 30 people.

I had retinopathy prematurity, meaning that my retinas were structurally incomplete at birth. I was 20/50 and barely legal to drive when I had LASIK.

I was never a candidate. The intraocular pressure created by the suction ring destroyed my retinas. My problems are permanent. As retinal problems, they will never be addressed by contact lens. I believe my doctor knew this and did the procedure anyway. I was dropped from their clinical study. So were others.

Those data were never reported to the FDA. The doctor sued me, because I set up a website and told the truth.

I have addressed my concerns to the FDA for over five years, not only on my behalf but also on behalf of others. In 2003, I filed a petition regarding medical devices and safety of refractive surgery, which was ignored.

Help was offered by Ombudsman Les

Weinstein, and then retracted. My concerns today are with those needlessly damaged by refractive surgery. Even with the most modern technology, there are still too many people writing me, telling of the nightmares they now live with on a daily basis.

I received several hundred e-mails this past year from people seeking help. Many of those are depressed. Some of them have confided that they want to commit suicide, and this is just to one website.

Having corresponded with many of those patients, I believe they are just ordinary people caught in unusual circumstances. There is nothing remarkable about them, certainly nothing to suggest perfectionism or any of the other reasons that some LASIK doctors use to excuse their own bad results.

The FDA's capacity to oversee the refractive surgery industry is, in my opinion, no different than the doctors who have

tarnished it. The FDA has been ineffective in overseeing investigational studies, ineffective in enforcing the policies mandated for the industry, and ineffective in providing thus far the protection that many of us here today should have had.

Everyone in this room today is here for a reason. Please do not allow what is presented to you to continue falling on deaf ears. The public must depend on government agencies like the FDA to protect them.

In a recent press release, ASCRS volunteered to contribute funding for the FDA study on LASIK complications and quality of life. The FDA has already received copious amounts of criticism, because of funding received from the pharmaceutical industry.

Essentially, industry funds the FDA, which creates conflicts of interest. I ask the Panel how funding received from ASCRS is any different.

Most of the patients who have e-

mailed my website feel deceived and lied to by surgeons who have exploited the public perception that doctors are healers. Why should damaged patients trust an organization of such surgeons any more than they trusted their own surgeon?

Included with my submission today, I would like to emphasize there are two letters written to the FDA which are already public record. These letters apply not only to me but many others.

The letter written by Dr. Stephen Friedman to the FDA's Office of Criminal Investigation summarizes not only my experience and, I believe, the outright criminal activity of my doctors, but also explains why the civil justice system does not work.

The letter written by Dr. James Salz, respected laser surgeon and principal investigator for past FDA studies, emphasizes that I was not a proper candidate for LASIK,

and tells why.

Also included are a few documents and previous correspondence I sent to the FDA. I believe this further supports what I just outlined. My story, and more, can be found at lasikdecision.com.

I ask the Panel to recommend that FDA conduct its own independent and unbiased study, survey damaged LASIK patients nationwide and ask how many feel lied-to by their LASIK doctors. Conducted without funding from the industry, the results might be believable.

I would also ask that the Criminal Division of the FDA conduct an investigation of specific doctors, such as mine, in regard to their actions in dealing with many of us.

I think a moratorium on advertising by doctors is an intriguing idea, as well.

So much is made on patient selection, but more should be done on doctor selection, maybe a website listing doctor

qualifications in the standardized, verified format.

Thank you for your time, and I would gladly post any presentation unedited on my website.

CHAIRPERSON WEISS: Mr. David Shell is our next speaker.

MR. SHELL: Ladies and gentlemen, I am David Shell. I elected to have LASIK eye surgery for farsightedness in October of 1998, the worst day of my life. In one short procedure, my eyesight was needlessly damaged in both eyes.

I went from a healthy, happy, physically active, skilled engineer with a bright life and career ahead of him to a man able to work only with near-constant eye pain and strain, who now has difficulty reading due to double vision, who can no longer view a TV or computer monitor comfortably and clearly, who is reluctant to drive at night, into a man who has been diagnosed with clinical

depression.

For the record, my eyes were problem free for 50 years. I had crisp, clear vision during the day and night with the aid of a simple pair of glasses. Since LASIK, I am visually handicapped by double vision, starbursts, glare, fluctuating vision, floaters, and impaired vision in dim light. And that is with my glasses or rigid contact lenses. I have not experienced a moment of crisp, clear, good quality vision since my surgery with any form of correction.

What do these visual quirks look like? Well, they say a picture is worth a thousand words. This is a standard E chart, standard Snellen Eye Chart. These are ghosted eye charts. My double vision looks like this chart.

This is the way I see when driving. I have starbursts in my eyes. These are what the headlights look like, before LASIK and after LASIK.

This is what I see when I am walking with someone special at night. I see multiple moons. Anybody want to have LASIK now?

So you see, my quality of life after -- and ability to perform the activities of daily living such as driving, career, hobbies and sports after LASIK has severely been compromised.

In August of 2002 I testified before the FDA concerning my LASIK-induced dry eye. At that time, I chose to focus my testimony on this relatively common and life-altering complication.

My LASIK dry eye is a burning and/or stinging type of pain in your eye, similar magnitude to an ant sting or shampoo in your eye. While this condition comes and goes for me, it can be maddening at times. My eyes never feel comfortable.

I have seen the best ocular surface dryness experts in the country. I have tried

everything from eye plugs to fish oil. To date, no treatment for my LASIK-induced dry eyes has been beneficial to any meaningful degree.

I am back today to tell you that 10 years have passed, and I still suffer from this problem. I recommend the FDA reclassify such life-altering effects as complications.

Failed LASIK eye surgery may affect all aspects of a patient's physical and mental health.

For example, my LASIK-induced dry eye destroyed my ability to obtain a full, restful night of sleep. I typically wake up three to five times during the night because of the burning and stinging in my eyes. I must apply ointment to my eyes to reduce the pain.

Failed LASIK eye surgery may trigger clinical depression. I was never depressed in my life until I had LASIK eye surgery. I had to endure two major health

crises in a short period of time.

Ladies and gentlemen, whether you pick the best surgeon, do your homework, or make sure you are a good candidate, LASIK surgery has inherent problems due to the nature of the procedure.

All eyes have weakened corneas. All eyes have severed corneal nerves that don't grow back fully. All eyes have higher order aberrations, and so on and so on. This happens, whether a patient likes their outcome or not.

I believe too many Americans have been harmed by this procedure, and it is about time this message is heard.

What I am looking for: first, I think it is imperative that the FDA conduct its own investigation independent of any individual or group with financial interests in the LASIK procedure.

Secondly, reclassify LASIK-induced dry eye and visual quality issues such as

double vision, starbursts, glare, ghosts as serious complications of LASIK, not as symptoms or side effects.

Finally, that the FDA should take another look at the safety and effectiveness of LASIK over the decade that has passed since LASIK was introduced. I believe there is now solid scientific evidence that indicates this procedure is not all that safe. Thank you.

CHAIRPERSON WEISS: Thank you. Mr. Glenn Hagele will now give the presentation for Sandy Keller.

MR. HAGELE: Actually, I am going to go ahead and make the presentation for Barry Elbasani.

CHAIRPERSON WEISS: Okay. Very good. Thank you.

MR. HAGELE: Thank you for time to gather my composure.

This is the presentation of Barry Elbasani, a focus on independence. These are his words.

I appreciate the FDA Devices Panel allowing me to present the story of how LASIK has affected my quality of life. Corrective lenses have always been a bit of a nuisance, but they were tolerable until the summer of 2002 when a swimming pool accident left me a quadriplegic. I am paralyzed from the chest down with limited mobility of my arms.

Many tasks that I took for granted became impossible or difficult. In the course of the day, there are an average of 50 things I need help with: Drop a cellphone; your shoelace is untied; buttons, zippers; on and on, you name it.

Glasses are one of those things that tend to be huge. Not being able to see compounds my physical limitations. Each morning I would need someone to put my glasses on. If I dropped my glasses, someone would need to find them and put them on for me.

Let's say I'm driving my vehicle and wearing my glasses. If they come off, get

a smear or anything, I don't have a free hand to mess with them, because I need both hands to operate my van.

As I have recovered and adapted, I have learned many new ways to do things, but just as important is eliminating things to do. Each is a measurable event that helps you become more independent.

I had considered LASIK, but the cost was prohibitive. Then one day I read an article about a Kansas City LASIK doctor who said that he wanted to reach out and help the community. I decided to put that offer to a test.

I will play a brief news article.

(Video played.)

CHAIRPERSON WEISS: I think the microphone may have turned off. If you could move the microphone slightly toward your computer, it might help the audience to hear.

VIDEO NEWS ARTICLE: -- Barry Elbasani always wore contact lenses. He never

had trouble with them. Then a year ago a swimming pool accident left Barry paralyzed, with no use of his legs, limited use of his arms and hands.

Barry soon realized his contacts were going to be a problem. "Probably the first time my Dad was in the restroom putting my contacts in, and I was yelling at him, and when it fell on the floor, it was tough."

And glasses? Barry had trouble putting them on, adjusting them, and hated that others had to do it for him. "I've had this done myself; so I know what it's like." Lucky for Barry, Dr. Daniel Durrie had been thinking about this problem after seeing actor Christopher Reeve on TV. "I just looked at him and said how did he get his glasses on and off, and here is somebody, Superman on television, having to ask a friend or somebody to take his glasses on and off, when we have the tools nowadays to help people like that."

You see, Dr. Durrie is a nationally

known specialist in vision correction. He practices in Overland Park. Barry heard that Dr. Durrie would do LASIK surgery for people whose arms are paralyzed, and the $4500 operation would be free. "What he has done for me, I can never thank him, and that is very, very exciting."

Dr. Durrie cuts a flap on the eye, then uses a laser to flatten the cornea in one eye, then the other. Barry's dad looks on, thinking pretty amazing. It took only minutes to do what Barry had wanted done for a year, to say goodbye to his contacts and glasses.

Dr. Durrie gets a hug from Barry's dad, and Barry gets more freedom, something he wants for others who are paralyzed. "That's my goal, as many people as we can get the word out to," letting them know that a farsighted doctor can help them focus on independence. Melanie McCain, Fox 4 News, Overland park.

MR. HAGELE: Since LASIK, I don't have limitations with my eyes. I see 20/10,

and it is an amazing gift. It is a gift I want available to other quadriplegics. So Dr. Durrie and I founded the nonprofit, Focus On Independence.

Funded by small personal donations, Focus On Independence helps quadriplegics get LASIK from doctors who donate their time and expenses. Already, more than four dozen quadriplegics are free of the limitations of glasses through Focus On Independence. Our website is www.focusonindependence.org.

I no longer fear my glasses falling off. I no longer need to have someone put the contacts lens in, and I no longer need to worry about what to do if I get dust underneath one. I may have my limitations, but thanks to LASIK, bad vision is not one of them.

When you measure a quality of life by what others may consider small acts, freedom from glasses is huge. LASIK has made my life better, and Focus On Independence aims

to do the same for others.

Thank you for your time.

Those are the words of Barry Elbasani.

CHAIRPERSON WEISS: Thank you. Now you are going to go to your last portion, Mr. Hagele?

MR. HAGELE: Yes. These are actually my words.

I am Glenn Hagele. I am the Executive Director of the Council for Refractive Surgery Quality Assurance. By way of disclosure, I have no financial interest in any medical devices. We are a nonprofit organization, but our funding comes from certification fees.

We provide surgeon certification. We distribute objective patient information, including our 50 Tough Questions for Your LASIK Doctor, and the opinions expressed here are not necessarily those of the people who finance this or those who have been certified

by us.

We are known primarily for our website at usaeyes.org. In fact, we are known mostly as USAEyes.

Quality of life has always been the yardstick by which LASIK patients have measured failure or success. It is not Snellen 20/20. It is not a refraction. It is not any objective measurement. It is always how LASIK affects the patient's life.

Procedure and device evaluation chart data is viable, but it is limited. We decided about two years ago to move from doctor's chart to patient's opinion. Our research found that there are three primary factors on which success or failure of LASIK is based: expectations, expectations, and expectations.

If the patient is not fully informed and doesn't know what to expect, or if the patient's expectations are unreasonable, or if the patient doesn't get

what is expected, you are going to have an upset patient.

Madam Chairperson, with your permission, how many people are here because of bad LASIK? Now those of you who have just raised your hand, if you had what you expected from LASIK, would you be here testifying to the FDA how great your vision is? Exactly.

Are patients getting what they expect from LASIK and their doctor? That is the ultimate question. We developed the USAEyes CORE survey. That is short for Confidence Opinion Relative to Expectation.

The survey is structured with as expected as the baseline. So we have as expected and degrees of better than expected or worse than expected.

The survey is multi-center. We currently have six surgeons. We are expanding. It is a retrospective patient opinion survey. Patients are consecutive. All types of refractive surgery, including

lens, laser and mechanical. Patients are targeted for sickness post-op.

They are mailed hard copies of the survey. Responses are mailed directly to our organization. Patient anonymity is provided.

We have mailed 1800 surveys thus far. That is 300 for each of the surgeons, from March 8 to April 16. Yes, that is about a week ago. We have already received 553 responses, which is a 31 percent response rate.

We have excluded for the purposes of this report those that reported they were less than six months post-op, that had prior ocular surgery, and those that had non-LASIK procedures, which gives us 462 eligible, which is a healthy 26 percent response rate.

This is preliminary data. We are still receiving surgery responses. Gender, mostly female, mostly myopes. Several had astigmatism, and the pre-op use of reading glasses -- this is important. We had 40

percent of the people who are reporting the effects of presbyopia.

So we, of course, talk about monovision. Seventeen percent specifically selected monovision, 17 percent specifically declined monovision. Seventy-eight percent of the patients are 6 to 18 months post-op, relative recent patients. This is the target we are looking for.

Post-op use of corrective lenses, including reading glasses. That is important. Eighty-nine percent are seldom or are never wearing corrective lenses. Is this what they expected? By and large, it is.

Ninety-six percent wear corrective lenses as frequently or less frequently than they had expected. Post-op day vision: 98 percent say their quality of day vision is as expected or better. Night vision: 91 percent. That is a seven percent drop.

Pre-op vision with lenses versus post-op vision without lenses: 96 percent

post-op compared to pre-op, expected or better. Post-op overall quality of vision: 96 percent overall quality of vision is as expected or better.

Quality of life -- this is the reason that we are here: 99 percent of the people who reported stated that their quality of life is as expected, better or much better. Nine-tenths of one percent said it was worse than expected, and none in this cohort stated that it was much worse than expected.

Would you have surgery now? Always a good barometer. 97 percent would have surgery now.

Would you recommend surgery? 98 percent would recommend surgery. Apparently one percent would rather recommend than do.

Now we have a lot of detailed information on the different incidents of the adverse events, such as dry eyes, ghosting, but I am going to focus, because of time constraints, just on people who report they

have complications.

We have 91 percent stating that either they didn't have complications or they had complications that had been resolved. But we have identified a very unique group, an important group here, and I am going to run right through this.

There's seven percent who said that they had complications, but they are seldom problematic. We drilled down, took a look. Ninety-one percent of these people -- this is the seven percent who have problems that are seldom problematic -- would have surgery again.

So in summary, I am not going to go through all of these numbers, and all of this data has been provided to the Panel. But what we do have, basically, is the quality of life is much higher than I would have ever expected.

I think that -- I have five seconds. I think what is going to be

important is, if the FDA is going to look at quality of life, don't look at that alone, because it appears, at least in our study, to have much higher positive results than other qualifying factors.

CHAIRPERSON WEISS: Thank you. Our next speaker will be Diana Zuckerman.

DR. ZUCKERMAN: Hi. I am Dr. Diana Zuckerman. I am President of the National Research Center for Women and Families. We are a nonprofit organization that is focused on using research to improve programs and policies that affect the health and safety of adults and children, an we particularly focus on FDA issues.

I am also a Fellow at the Center for Bioethics at the University of Pennsylvania.

I am trained in epidemiology at Yale, and so I am going to use my scientific perspective, not just -- I will be talking about some of the research findings, but also

to put in perspective all the individual stories that you are going to be hearing today, because it is that pattern that is really very important and an important part of epidemiology, not just the data.

I actually do want to start out by saying that in my training as a psychologist and an epidemiologist, there's a lot of problems with self-reports, the kind of subjective research that you have just heard about.

The FDA's mission, as you know, is to ensure the safety and effectiveness of medical products. When we think about LASIK surgery, we have to think of the context, and that is that there are safe and readily available and less expensive alternatives, namely contact lenses and glasses.

Now it is clear, and it will be even more clear as the day goes on, that there are many patients that have been harmed by LASIK. So the question is what are those

benefits, and what are the risks?

There's very good information on the FDA website about the risks, but who reads the FDA website? So as this Advisory Committee is looking and asked about what should be on the FDA website, please keep in mind and remind the FDA that there are other mechanisms that are more effective at getting information to patients than the FDA website, and then product labeling.

Even though the FDA website has good information, there are problems with it. Parts of it are very difficult to navigate, and particularly the parts that have to do with individual devices, individual LASIK devices. That information is really not appropriate for patients.

It does not seem to be geared toward patients, and even the patient booklets that are available on the website and that apparently are available through device manufacturers are really not designed to help

patients. They are much too long. They are much too sophisticated in their use of language, and frankly, they look like grad student homework assignments.

So they are not really designed to be read, because if they were, they wouldn't start out with a rather complicated biology lesson about the eye. So to be blunt, they seem to be -- These patient booklets seem to be designed to satisfy somebody at the FDA who doesn't actually care whether any patient will actually read or understand these booklets.

I want to conclude my remarks by commenting on the questions that you are going to be addressing today, because there are several adverse reactions that really don't seem to be part of those questions that you are talking about, but they should be, and I hope you will make sure that they are.

Most important is eye pain and dry eye, which you have heard some about. Dry eyes are the most common complication from

LASIK. The most recent research shows that half the patients have adverse reactions like dry eye during the first week of surgery, but that 20 percent persisted six months. And these problems are more likely among women patients and those with attempting higher corrections.

Eye pain can be caused by dry eye or it can come from other causes, but whatever, it is terribly debilitating, and these are serious complications that really need to be included in the advice that you are going to be giving today.

The need for additional surgery is also very important, and something that has to be studied appropriately. Research that was just published this year in the American Journal of Ophthalmology reported that 28 percent -- 28 percent of eyes corrected through LASIK needed re-treatment within 10 years because of either under-correction, over-correction or regression, and that is 28

percent of the eyes, and it is even higher if you look at the patients. It is 35 percent of the patients. That's a very high percentage, and patients need to have that kind of information before they make any kind of decisions.

The possibility of a higher suicide rate among patients has been raised, and will be raised. More research and really good quality objective scientific research is needed.

I tried to get that information. I contacted Emory University, but was not able to get better information about that research, which has not been published.

Overall, patients do not seem to have informed consent when they have LASIK surgery --

CHAIRPERSON WEISS: Would you be able to --

DR. ZUCKERMAN; Yes, I will.

CHAIRPERSON WEISS: Thanks.

DR. ZUCKERMAN; Part of the reason is lack of data, but it is also because, as we know, health professionals tend to focus on the consent part of informed consent, not the informed part.

Informed consent is a process. It is not a piece of paper. Even the best -- will be undermined if -- agree with what is there. So I hope that you will address informed consent today, and I'm happy to answer any questions.

CHAIRPERSON WEISS: Not at this time. Thank you very much.

We are going to now move on to Dr. Burch. We are beginning to run over a little bit, and I would like to remind the speakers that the yellow light, one minute; at the red light, you are done. Thank you.

DR. BURCH: I appreciate the opportunity to speak at this FDA hearing on post market LASIK issues.

My name is Lauranell Burch. I have

a PhD in molecular biology and genetics and have been -- Am I not speaking in the microphone? Sorry. -- and have been a medical researcher for over 20 years. I am trained to design, conduct and review medical research studies.

I come here today as a private citizen with no financial interests to report.

We are all aware of recent media attempts by the LASIK industry to reframe the discussion of these hearings around post-LASIK satisfaction and quality of life issues.

The public should be made aware that the proposed task force to examine post-LASIK quality of life issues is dominated by individuals with conflicts in interests. One of these individuals, Dr. Kerry Solomon, was quoted this week by ABC News regarding this meeting, saying this is not about safety and effectiveness of LASIK at all.

If there were no serious concerns about the safety and effectiveness of LASIK,

we wouldn't be here today. What is most important for all of us to consider now is the growing body of evidence accumulating in peer reviewed ophthalmology journals that indicate that LASIK is a harmful procedure.

Despite claims made by surgeons in the industry about patient satisfaction, today's happy 20/20 LASIK patients are often today's dangerous drivers on our highways at night due to LASIK induced loss of contrast sensitivity, and may ultimately experience debilitating late onset complications of LASIK.

Patients who report that they are currently happy with the LASIK procedure likely have no idea of the nature and extent of the damage they incurred during the LASIK procedure, and the consequences of this damage for their future ocular health and vision.

I believe that no patient would want this surgery if they fully understood its consequences.

Here is a short list of permanent adverse effects of LASIK eye surgery. Number one, the flap never heals. It just seals it better on the edges like a Tupperware lid, leading patients who have had LASIK susceptible to traumatic flap injury for life.

Number two: LASIK separates the stronger anterior corner, leaving only the weaker posterior cornea to support the intraocular pressure of the eye. This can lead to corneal ectasia and corneal failure months or years after the surgery.

Number three: LASIK causes permanent pathologic changes in all corneas. According to an Emory University study that examined post mortem LASIK corneas, a spectrum of abnormal histopathologic and ultrastructural findings was present in all corneas.

Some examples of these findings include: Deranged and disordered collagen fibers, granules under the flap, and

epithelial ingrowth under the flap.

Number four: There is no evidence that corneal nerves ever fully regenerate to their normal patterns and density after LASIK.

Number five: LASIK complicates future cataract surgery.

Number six: LASIK invalidates intraocular pressure motion which is critical in the diagnosis of glaucoma.

Number seven: Perhaps gravest of all, Mayo Clinic researchers recently found that all patients undergoing laser corneal refractive surgeries lose coracite or corneal stromal cell density at higher rates even years after surgery.

Apparently, excimer laser ablation to corneal stroma results in progressive cell loss in the cornea. In a peer discussion following this study, LASIK surgeon Dr. Roger S. Steiner commented, and I quote him, "One can speculate that this loss might lead to corneal ectasia."

Clearly, patient satisfaction surveys are no substitute for objective, quantitative testing, particularly when the technology for performing objective tests is widely available.

I ask that the FDA abandon the proposed quality of life study in favor of a study which objectively and quantitatively measures aspects of post-LASIK dry eye disease and post-LASIK visual quality.

These studies can be performed on existing patient populations with unoperated eyes serving as controls. Withdrawal of FDA approval for the LASIK procedure should take place immediately pending the outcome of these studies.

Only then will the FDA be able to achieve evidenced based policy about corneal or refractive surgery devices, and only then will the public receive the benefits of evidence based medicine. Thank you.

(Applause.)

CHAIRPERSON WEISS: Thank you. Our next speaker will be Dr. Burch, Dr. Lauranell Burch. Sorry, excuse me. Mr. Matt Kotsovolos.

MR. KOTSOVOLOS: Thank you. My name is Matt Kotsovolos. I had LASIK surgery in 2006 using the current IntraLase Wavefront technology. At the time of my LASIK, I was the Chief Financial Officer at the Duke eye Center in Durham, North Carolina.

My surgery was considered a success based on my uncorrected visual acuity now being 20/20. However, for the last two years I have suffered from debilitating and unremitting eye pain as a result of LASIK.

The public hears LASIK complication rates quoted by the LASIK industry as ranging from between one to three percent. What the public doesn't know, because the LASIK industry markets this surgery in a most unethical way, is that the complication rate is likely in the 20 to 30 percent range.

Data from the FDA clinical trials for LASIK reveals that the FDA allows laser manufacturers to hide complications such as dry eyes and impaired night vision by reporting these as, quote, "symptoms." The overall percentage of patients reporting these complications in the FDA trials is approximately 20 percent.

In April 2007, researchers from Ohio State University College of Optometry published results from a review of FDA clinical trials of the 12 lasers approved for LASIK between 1998 and 2004, including newer wavefront technology. They reported that six months after LASIK, roughly 20 percent of patients experienced worse or significantly worse dry eyes, and six months after LASIK roughly 15 percent experienced worse or significantly worse night vision disturbances.

Recently, the LASIK industry has hired a media consulting firm in its mass circulated results of a global LASIK patient

satisfaction rate of 95.4 percent. The LASIK industry wants the public to believe that a high satisfaction rate indicates a low complication rate. However, being satisfied with one's visual outcome and being free of complications are two entirely different matters.

Dr. Leo Maquire once wrote the following in an ophthalmology editorial: "The kerato-refractive literature contains disturbing examples of patients who have visual handicaps that place themselves and others at significant risk for nighttime driving accidents, and yet they are happy with their results."

One of the most perplexing cases of patient satisfaction comes from a 2007 report of a patient who developed bilateral ectasia, a serious sight-threatening complication which may require corneal transplantation, who was reportedly satisfied with his surgery.

As illustrated, patients can suffer

significantly complications or "symptoms," and still claim to be satisfied patients. Patient satisfaction surveys in LASIK are guaranteed to lead to skewed results and significant false positive data.

In addition, there is enough evidence for the FDA to investigate that shows the effects of devastating and irreversible physical complications from bad LASIK outcomes often leads to clinical depression.

Clinical depression can lead to suicidal ideation. The length between bad LASIK outcomes and suicidal ideation is real. The link is further evidenced by true stories of LASIK patients taking their own lives and leaving suicide notes behind that detail their struggles due to debilitating post-LASIK complications.

I have met plenty of people who are depressed and considering suicide because of complications that are currently buried in the device labeling and classified as symptoms or

side effects. How is it that patients want to commit suicide because of side effects?

Can the Panel before us today explain this? Why was there no research into what constitutes a symptom, and what constitutes a complication? Was it so that the LASIK industry could obtain approval for medical devices that otherwise would never have seen the light of day?

Patients do not want to continue to exist as helpless victims with no solutions and no voice. The LASIK industry wants to use the upcoming quality of life study that will not commence until sometime in 2009 to stall for an extended period of time. The time for stalling is over.

I urge the FDA Advisory Panel to recommend placing a moratorium on LASIK until a proper comprehensive study of long term LASIK patient complications and symptoms, including clinical depression, is completed.

I ask the FDA to change the

labeling for lasers for LASIK once this moratorium is lifted, to report dry eyes and night vision disturbances as complications and not symptoms. Both of these so called symptoms can last for a patient's entire post-LASIK lifetime.

Those who are familiar with the phenomena of deep capture understand that over time regulatory agencies end up being controlled by the very industries they are supposed to regulate. The FDA is now controlled and works for the benefit of the LASIK surgeons and LASIK manufacturers.

This is easily illustrated by an ASCRS press release on April 7, 2008, a full two weeks before today's hearing. In that press release, the FDA stated that LASIK is safe and effective.

Clearly, the fix is in. ASCRS would not have issued such a --

CHAIRPERSON WEISS: Can you please start closing your remarks?

MR. KOTSOVOLOS: Yes, thank you. Clearly, the fix is in. ASCRS would not have issued such a press release, had they not known in advance that the FDA was going to dismiss --

CHAIRPERSON WEISS: We are going on to our next speaker, please. Thank you.

(Applause.)

CHAIRPERSON WEISS: Our next speaker is Beth Kotsovolos. Again, I would urge the speakers to stop at the red light. Otherwise, I will be cutting off your presentation.

MS. KOTSOVOLOS: My name is Beth Kotsovolos, and Matthew, obviously, the previous speaker, is my husband.

When you look upon my husband and myself, you may not see the battle scars of the past two years, but they are there. Despair, depression, disbelieve, anger, suicidal ideation, and post-traumatic stress disorder. They are there.

To put it bluntly, the post-LASIK symptoms of severe dry eye and unremitting eye pain almost destroyed our family. My children almost lost their father.

As I look upon the Panel today, I see that many of you are LASIK surgeons or have close ties to LASIK surgeons. I truly, truly hope that today you can put your vested ties with LASIK aside and be objective, and really listen to what we have to say, the people who have walked in the shoes of LASIK failure.

So I ask the media now that you hold the FDA accountable for their decisions regarding whether or not the minority matter. I also ask the media to not stop here, and to continue investigating the stories of LASIK failures and shine the light on the link between bad LASIK outcomes and suicidal ideation.

Think of the numbers of LASIK surgeries that are done annually. Based on

the complication rates stated, LASIK is destroying thousands and thousands of patients and family lives. How many will it take for you to recognize that LASIK cannot continue in its current form?

I spoke to a gentleman by the name of Roger from Wisconsin. His brother, Robert, was a great outdoorsman. He was a champion at pack burro racing.

Robert kept a journal in his last months before he took his life. He wrote that the constant unremitting eye pain, burning, post-LASIK was unbearable. He said that the pain was too much to overcome. He couldn't live that way anymore.

A young doctor who had LASIK in the summer of 2003 committed suicide in September of 2004. This doctor consulted with many physicians in search of solutions to his post-LASIK visual disturbances. He committed suicide after realizing that the solutions to his physical post-LASIK complications were

nonexistent.

Major Eric J. Rupert is a military physician serving in Iraq. His LASIK surgery was done in July of 2003. He states, "I strongly believe that the loss of tear function which is deemed an acceptable downside to LASIK surgery is, in fact, not at all acceptable for many people who lead active lifestyles."

Finally, Linda Knuckles had LASIK surgery in January of 2007. She went from doctor to doctor in her city and experts long distance, trying to find help to get her life back. Linda states in her testimonial, "I could not escape the intense burning, even with my eyes closed. I didn't want to get out of bed anymore and face the day. If this is what my life was going to be like, I wasn't even sure I wanted to go on living. I began to think about death being the only escape from misery. Along with the guilt of choosing to have the ill-fated elective surgery, I had

to live with the guilt of what effect this was having on my husband and children. I was an empty shell of my pre-LASIK self in my own personal hell."

As I read those words for the first time, I was astounded as to how very similar her words were to my husband's, and listening to all the testimonials today again it is just over and over I am hearing the same thing from LASIK patients who have similar complications.

Linda goes on further to explain: "Ten years ago I had cancer. Although it was scary and difficult, I got through the surgery and treatment without needing any anti-depressants. In 20 minutes, as the advertisers say, all of our lives were permanently altered."

It is time for the FDA to stand up and protect the public for whom it is entrusted to serve. LASIK has wreaked havoc upon thousands and thousands of families. The eye is the most vital sensory organ that

significantly impacts our quality of life. We use our eyes every second of the day.

When you permanently damage a person's previously healthy eyes, that person's physical and emotional state will be significantly impacted. Anyone who states otherwise lacks common sense or is disingenuous.

Permanently damaging a person's most vital sensory organ with no Plan B fix is not a straw that breaks the camel's back. It's the 200 pound gorilla that brings most post-LASIK complications --

CHAIRPERSON WEISS: Would you be able to wrap up? We are on the red again.

MS. KOTSOVOLOS: Sure. I ask that the FDA begin investigation of post-LASIK depression and suicide ideation and its clinical --

CHAIRPERSON WEISS: Thank you very much. We are now going to go to our next speaker, Mr. Michael Klein. Again, I will cut

you off at the red light. So please, if you have important comments to make, get them in by taking out those comments that may run over that you are less interested in the audience hearing.

We are going to have Dr. Kerry Solomon, who will be presenting for Dr. Richard Lindstrom.

DR. SOLOMON: Good morning. My name is Dr. Kerry Solomon, and I have been asked to read the statement of Dr. Richard L. Lindstrom, who because of illness is unable to join us this morning.

I am Dr. Richard Lindstrom, founder and an attending surgeon at the Minnesota Eye Consultants, an adjunct professor emeritus at the University of Minnesota, Department of Ophthalmology.

I have been involved in the development of laser refractive surgery since 1985 and have participated in several FDA IDE clinical trials. I have performed LASIK on

over 10,000 patients, including three of my partners, six immediate family members, innumerable close friends, and over 100 ophthalmologist colleagues.

Of note, nearly 30 percent of LASIK surgeons themselves have elected to undergo LASIK, nearly five times more than the rate of the population at large.

In the interest of disclosure, I want the Committee to know that I am the co-medical director and serve on the board of directors of TLC Vision. I also have consulting relationships with AMO, Bausch & Lomb and AlCon, all of which manufacture excimer lasers.

I am the immediate past President of the American Society of Cataract and Refractive Surgery, ASCRS. This society was founded in 1974, and it has fostered the development of cataract surgery and refractive surgery, LASIK and other forms of vision correction into highly sophisticated forms of

ophthalmic treatment.

Today the Society is 10,000 members, primarily in the United States with a significant percentage of members from around the world. Through its educational programs and services, ASCRS has become the physician's primary source of up-to-date information on scientific developments within the field domestically and internationally.

After a review of more than 10 years of peer reviewed medical and scientific research, we find that all the available clinical data reinforces the safety and effectiveness of LASIK.

As you will see from today's presentations, the overwhelming majority of patients, more than 95 percent, are satisfied. Yet a small percentage feel they have not experienced the same satisfaction benefit. To those patients, I want to be clear. We hear your concerns. We care, and we respond in a tangible and constructive manner.

The goal of any elective medical procedure is to ensure all patients are satisfied. While the satisfaction rate for LASIK is higher than any other elective procedure, there is always room to improve.

In this case, that means learning more about why some patients are dissatisfied. What are the factors that bear on that subjective experience of quality of life, and what can we do about it to improve it? That is why we are here today.

The joint LASIK study task force is a result of our collaboration with the American Academy of Ophthalmology, the National Eye Institute and the FDA to better understand the small percent of patients who don't get the experience they expected.

A group of ophthalmologists from ASCRS and AAO are working together with the FDA and NEI to look at the impact of LASIK on quality of life. ASCRS and AAO have completed a meta analysis of the global literature. You