

1 will hear findings from this here today.

2 Working with the NEI, we are
3 developing a reliable research tool that will
4 allow us to look at quality of life post-
5 LASIK. This web-based tool will be an
6 important addition to our study. There has
7 been a great deal of progress with this, but
8 it is not yet complete.

9 Finally, we are developing a study
10 design under the leadership of Dr. Steve
11 Schallhorn. You will hear more on this today
12 as well.

13 Both the ASCRS and AAO have
14 announced their support, participation and co-
15 funding of the study to look at quality of
16 life post-LASIK. We believe the primary
17 patient advocate is their physician. The
18 study and the work of the task force are
19 consistent with this mission.

20 After the task force's careful
21 review, we have learned that there is a need
22 to understand quality of life after LASIK

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1 better so we can incorporate key findings that
2 will enable an even greater percentage of
3 LASIK patients to have the experience they
4 expect.

5 We understand fully that quality of
6 life is not the same thing as safety or
7 effectiveness. Those can be measured
8 objectively, but quality of life is a
9 subjective experience.

10 Many factors bear on it, from the
11 medical to the psychological, people's
12 expectations for their vision and for the
13 outcome of the procedure, to the way we
14 address both of those in our communication
15 with patients and in our patient screening.

16 Again, that is the level of
17 understanding that we are trying to achieve
18 through this study so that we can maintain our
19 already high satisfaction rates, continue to
20 improve them, and address the concerns we are
21 hearing today. Thank you for your time.

22 CHAIRPERSON WEISS: Thank you. Our

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1 last speaker before we take a 15 minute break
2 will be Dr. Eric Donnenfeld.

3 DR. DONNENFELD: Good morning. My
4 name is Dr. Eric Donnenfeld. I am a clinical
5 professor of ophthalmology at NYU and chair
6 the Board of Overseers at Dartmouth Medical
7 School.

8 I represent the American Society of
9 Cataract and Refractive Surgery where I serve
10 as Chairman of the Cornea Clinical Committee.

11 Most importantly, I am here to represent the
12 interests of my patients.

13 I am a consultant to excimer laser
14 manufacturers, AMO and Bausch & Lomb. I was
15 an original FDA investigator for the excimer
16 laser, and I have been performing laser vision
17 correction for 18 years.

18 Approximately 40 percent of the
19 adult population in the United States is
20 hindered by poor uncorrected vision. Among
21 the most significant advances during my career
22 has been LASIK. My passion and the passion of

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1 my colleagues has been to reduce the
2 dependence of patients on glasses and contact
3 lenses, and to improve their quality of life.

4 I have performed LASIK on over 800
5 eye doctors and their families. The reality
6 is that following LASIK, the great majority of
7 our patients see as well or better than they
8 ever saw with their glasses or the contact
9 lenses with which they were unhappy, the
10 reason they chose to explore LASIK in the
11 first place.

12 As surgeons, we rejoice in our
13 patients' success, and we understand the
14 immense responsibility that comes with this
15 option. We are deeply committed to both the
16 well-being of our patients and the safety and
17 efficacy of LASIK.

18 LASIK has always been very safe,
19 and with technological advances has continued
20 to improve. The risk of infection over a
21 lifetime is more than 100 times greater with
22 contact lenses than with LASIK.

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1 The majority of our patients have
2 less glare and halo after LASIK than before.
3 However, we cannot be satisfied until all
4 complications have been eliminated.

5 Today, I will discuss dry eye. Dry
6 eye is extremely common and is the number one
7 medical reason patients are evaluated by an
8 eye care professional. Dry eye affects an
9 estimated 55 million Americans and impacts our
10 patients' quality of life, their comfort and
11 their ability to perform everyday activities.

12 In an effort to better understand
13 dry eye, the LASIK Task Force reviewed the
14 world's literature on dry eye following LASIK.

15 Today I am presenting the preliminary results
16 for the first time.

17 There are 113 peer review articles
18 on dry eye following LASIK and 46 papers
19 containing reviewable data. The papers were
20 published in 13 journals, representing 15
21 countries. The data represents over 32,000
22 eyes.

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1 Thirty-two percent of these
2 patients were diagnosed with dry eye before
3 LASIK. A similar 35 percent had dry eye
4 following surgery.

5 The great majority of patients have
6 complete resolution of their dry eye symptoms
7 over a two- to four-week period following
8 surgery. Severe dry eye following LASIK is
9 extremely rare.

10 Modern, thin-flap LASIK, advances
11 in artificial tears, topical cyclosporine-A,
12 nutritional supplements, and the treatment of
13 eyelid disease are improving outcomes.

14 Ophthalmology is committed to
15 developing treatment options, and there are
16 many exciting therapies currently undergoing
17 FDA evaluation that offer great promise, not
18 only for LASIK patients but to the tens of
19 millions of patients with dry eye disease who
20 have not had LASIK. Conclusively, LASIK
21 improves patient lives.

22 I would like to close by recalling

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1 a remarkable young man I first met when he was
2 three. Nick had chickenpox like millions of
3 other children, but in his case the virus
4 spread to his left eye. When he was nine
5 years old, he required a corneal transplant.

6 Wheeling him into the operating
7 room, this remarkable child handed me a note.

8 I unrolled the crumbled piece of paper. I
9 keep it to this day. The note read: "Dr.
10 Donnenfeld, I sure hope you know what you are
11 doing." True words of wisdom.

12 The transplant went well, but Nick
13 remained functionally blind in his left for
14 six additional years until I performed LASIK.

15 Nick graduated from college last year and
16 doesn't worry about his vision, because thanks
17 to his corneal transplant and LASIK, his
18 vision is now normal.

19 Please allow me to introduce Nick
20 Anderson and his mother, Clara. Nick, Clara.

21 (Applause.)

22 CHAIRPERSON WEISS: We've got about

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1 13 seconds.

2 DR. DONNENFELD: You've got five
3 seconds, Nick.

4 MR. ANDERSON: I would just like to
5 thank the family that donated the cornea to
6 me, and Dr. Donnenfeld for giving me my
7 eyesight back. Thank you.

8 CHAIRPERSON WEISS: Thank you.

9 MS. ANDERSON: I would just like to
10 say thank you to Dr. Donnenfeld and to God.
11 having a child who can't see, no depth
12 perception, no peripheral vision -- He can
13 see. He can run. He can walk. He can
14 participate.

15 CHAIRPERSON WEISS: Thank you very
16 much.

17 We are going to now proceed with
18 our break for 15 minutes. Be back here
19 promptly. We will start on time. Thank you.

20 (Whereupon, the foregoing matter
21 went off the record at 10:06 a.m. and went
22 back on the record at 10:19 a.m.)

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1 CHAIRPERSON WEISS: Could everyone
2 take their seats, please. We are going to If
3 we could have Dr. Roger Barnes come up to the
4 podium. He will be the next speaker, and he
5 will be speaking for Dr. Doyle Stulting.

6 We are going to begin the second
7 portion of this morning's open public hearing
8 on LASIK. Our next speaker is Dr. Roger
9 Barnes.

10 DR. BARNES: Good morning. I am
11 Dr. Scott Barnes, and I would like the Chair's
12 permission to read the written comments of Dr.
13 Stulting. I will be reading in the third
14 person, as it is a little easier for me.

15 Dr. Stulting is Professor of
16 Ophthalmology and Director of the Cornea and
17 Refractive Surgery Service at Emory University
18 in Atlanta, Georgia. He represents the
19 American Society of Cataract and Refractive
20 Surgery.

21 Dr. Stulting has been performing
22 refractive surgery for 25 years and has

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1 participated in a clinical trial of LASIK
2 before the first excimer laser was approved
3 for us in the United States.

4 He was also a member of the
5 Ophthalmic Devices Panel for 10 years and
6 Chairman of that Panel for three. During that
7 time, he helped write the first FDA guideline
8 for evaluation of excimer lasers for the
9 correction of myopia, and was a member of the
10 panel when the first excimer laser was
11 approved more than a decade ago.

12 In addition to practicing medicine,
13 Dr. Stulting is a consultant for AMO which
14 manufactures an excimer laser.

15 Since the first clinical trials, we
16 have worked diligently to improve the quality
17 of vision after LASIK. We have come to
18 understand that every 20/20 vision is not
19 necessarily the same. For example, functional
20 night driving vision may not be the same as
21 the vision that we measure in our offices.

22 Today most patients who undergo

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1 LASIK achieve vision that is 20/20 or even
2 better. In fact, 61 percent of patients
3 achieved vision that was better than 20/20 in
4 a recent clinical trial.

5 In addition, these patients
6 actually reported less glare, less light
7 sensitivity, and less night driving difficulty
8 than they did before they had their LASIK.

9 Despite these advances in
10 technology, we know that a small number of
11 individuals do not obtain the results that we
12 have come to expect for this extremely
13 effective procedure.

14 We are concerned about any
15 disappointing outcomes, and to help us better
16 understand the issue we have developed methods
17 for evaluating the optical system of the eye
18 in greater detail than ever before.

19 We have also developed methods to
20 correct abnormalities of the optical system
21 with treatments customized to address the
22 unique needs of every patient.

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1 In addition, we have instituted
2 screening procedures that can help to identify
3 those few patients who might have less than
4 optimal results after the procedure.

5 At Dr. Stulting's laser center, the
6 patient's initial examination lasts for
7 approximately two hours. This comprehensive
8 evaluation includes a complete eye
9 examination, wavefront measurements, detailed
10 analysis of the curvature and thickness of the
11 cornea, measurements of the pupil diameter in
12 various lighting conditions, assessment of
13 tear production, evaluation of the ocular
14 surface, and a personalized discussion of the
15 procedure with each patient.

16 His goal is to be certain that the
17 results of the procedure will meet the
18 individual needs and expectations of each
19 patient. In fact, Dr. Stulting routinely
20 tells a number of patients who come to him
21 seeking refractive surgery that they are not
22 candidates for LASIK under any circumstances.

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1 The results of our collaboration
2 with the American Academy of Ophthalmology,
3 the National Eye Institute, and the FDA will
4 allow us to refine our screening procedures
5 even further. Our goal, like the goal of
6 everyone here today, is to do everything
7 possible to be certain that each patient
8 achieves a result consistent with his or her
9 visual needs and expectations.

10 In closing, I would like to add a
11 brief personal comment. A young Captain who
12 was leading 120 men in his company lost his
13 glasses in ambush and a subsequent firefight.

14 Couldn't locate his glasses, but he was able
15 to make it himself back to his Humvee, which
16 was his Jeep or his vehicle.

17 He jumped in and told the 18-year-
18 old corporal that he just needed to drive to
19 safety. The corporal asked, what do I do?
20 The Captain said, I can't even see you, much
21 less where to go; you've got to get us to
22 safety.

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1 To his platoon, to that Captain's
2 platoon, this leader is now a combat risk,
3 unable to lead anytime that he should happen
4 to lose his glasses. Thankfully, that 18-
5 year-old corporal was able to lead the patrol
6 to safety.

7 Well, as soon as they all returned
8 home, however, this Captain came to my office
9 essentially demanding laser refractive
10 surgery. He said he will never put himself or
11 his men in that kind of position again. After
12 successful refractive surgery, he told me,
13 doc, I've gone from a combat risk to a combat
14 asset now that my eyes allow me to lead in the
15 way in which I had been trained, the way that
16 my guys deserve.

17 I can't tell you how often I hear
18 these kinds of stories from soldiers after
19 their laser refractive surgery. In fact, the
20 command I hear most often is this: Doc, laser
21 refractive surgery is the best thing the Army
22 has ever done for me.

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1 Personally, I know that to be true,
2 because back when I used to be wearing a green
3 beret for my job, I had laser eye surgery
4 myself. I didn't know how to spell
5 ophthalmology. I didn't know anything about
6 eyes. But I was so impressed with it that I
7 decided I was going to become an eye surgeon,
8 and I was going to bring this back to the
9 Special Operations community, which is what I
10 am currently doing in my role as the Chief of
11 the Warfighter Refractive Eye Surgery Program
12 at Fort Bragg, North Carolina.

13 Thank you for allowing Dr.
14 Stulting's and my comments to be added today.

15 CHAIRPERSON WEISS: Thank you. Our
16 next speaker will be Dr. Kerry Solomon.

17 DR. SOLOMON: Good morning. My
18 name is Dr. Kerry Solomon, and I welcome the
19 opportunity to discuss the recently completed
20 meta analysis of patient satisfaction after
21 laser eye surgery.

22 Just to give you a little

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1 background, I was fortunate to be one of the
2 original investigators of laser vision
3 correction, and have been performing this
4 procedure for 13 years.

5 Concurrently, I have a full time
6 academic practice, specializing in cataract
7 and refractive surgery as well as corneal
8 transplantation at the Medical University of
9 South Carolina where I am a Professor of
10 Ophthalmology and Director of the McGill
11 Vision Center. I am also a LASIK patient.

12 Before I begin, it is appropriate
13 for me to disclose that I consult with AMO,
14 Alcon and Bausch & Lomb, all companies which
15 are manufacturers of excimer lasers used to
16 perform LASIK.

17 To avoid any appearance of
18 conflict, this analysis of the studies I will
19 discuss today was completed by my colleagues,
20 research students and faculty and resident
21 physicians, none of whom work as consultants
22 to any of the before mentioned companies.

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1 I am here to represent the American
2 Society of Cataract and Refractive Surgery,
3 ASCRS, where I have served as the Chairman of
4 the FDA Liaison Committee for the past four
5 and a half years. The goal of this committee
6 is, and has been, to facilitate communication
7 between the FDA and ASCRS membership. I also
8 serve as co-chair of the Joint LASIK Study
9 Task Force.

10 The ASCRS was contacted by the FDA
11 in response to various inquiries the FDA
12 received from LASIK patients. Although the
13 FDA had already conducted a review of the
14 medical literature, finding the majority of
15 patients were satisfied after their LASIK
16 surgery, I was asked to perform an independent
17 review of the world's literature regarding
18 LASIK patient satisfaction, or meta analysis.

19 The review of the world's
20 literature demonstrates a greater than 95
21 percent of patients from around the world are
22 satisfied after their LASIK eye surgery. This

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1 is amongst the highest percentage of patient
2 satisfaction reported for any elective
3 surgery.

4 This review encompasses all
5 articles from the inception of LASIK to the
6 most recent articles published in 2008.
7 First, all databases available online at the
8 Medical University of South Carolina were
9 searched using search terms to be inclusive of
10 every article ever written about LASIK eye
11 surgery since the inception of LASIK.

12 2,915 abstracts were identified,
13 and each abstract was reviewed. 1,581
14 articles were pertinent. They were obtained,
15 reviewed, and read, and based on the strength
16 of the evidence, 309 articles were identified
17 and entered into the database.

18 These 309 articles represent peer
19 reviewed, well performed prospective,
20 retrospective or case controlled studies.
21 These have all been published in major
22 ophthalmic journals from all over the world.

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1 The locations of these studies also represent
2 a global distribution.

3 Nineteen of the 309 articles
4 identified specifically addressed patient
5 satisfaction and quality of life. These
6 articles represent surgeries from 1995 to
7 2003, performed in 13 different countries,
8 seven of which were in the United States. The
9 remaining 12 were performed in 12 different
10 countries.

11 As stated, the overall review of
12 the world's literature shows the vast majority
13 of patients are satisfied with their LASIK
14 surgery, 95.4 percent. When further looking
15 into these studies, no matter how the data was
16 evaluated, the same 95 percent satisfaction
17 rate still appears.

18 There is the same level of
19 satisfaction, regardless of the type of
20 prescription treated with LASIK. Whether the
21 surgery was at the inception of LASIK or the
22 most recently published study for which we

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1 have data, whether the surgery was performed
2 in the United States or elsewhere, whether
3 validated questionnaires were used or not,
4 whether questionnaires were administered
5 anonymously or not, whether the questions were
6 asked in the first six months or after the
7 first six months and out as far as five years,
8 the same conclusion exists. Ninety-five
9 percent satisfaction rate is consistent.

10 In conclusion, this review of the
11 world's literature has shown that the majority
12 of patients are satisfied with their LASIK
13 surgery and confirms the findings of the FDA.

14 This study is meant to set a
15 baseline of knowledge regarding patient
16 satisfaction. As a physician, our goal is to
17 improve the quality of patients' lives every
18 day. That is why I get up every morning
19 excited to go to the office. It is why I
20 chose this profession. However, no surgery is
21 without risks. No surgery is perfect, and not
22 every patient is a candidate for this surgery.

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1 It was with the goal of identifying
2 and reducing these risks that this analysis
3 was done. It is this goal that drives us to
4 do more than just see and treat patients, but
5 to be involved in task forces like this, to do
6 research, to teach, to publish, and to
7 consult. It is why we are here today.

8 When a patient experiences a
9 complication or is dissatisfied with the
10 outcome of their LASIK surgery, it affects all
11 of us. I am confident that today's meeting
12 will be a key step toward taking what is
13 already a very successful procedure to an even
14 higher level. Thank you very much for your
15 time today.

16 CHAIRPERSON WEISS: Thank you. And
17 just for clarification, I believe that the
18 ASCRS independently decided to do this
19 literature review, and there was no
20 participation or request from either the FDA
21 or the American Academy of Ophthalmology.

22 DR. SOLOMON: This was independent

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1 from the FDA or the National Eye Institute.
2 Yes, ma'am.

3 CHAIRPERSON WEISS: I would like
4 the audience to understand that point. Thank
5 you very much, Dr. Solomon.

6 Our next speaker will be Todd
7 Krouner. Thank you.

8 MR. KROUNER: My name is Todd J.
9 Krouner. I am a plaintiff's medical
10 malpractice attorney from Chappaqua, New York.

11 I am here at my own expense today.

12 I represent victims of LASIK and
13 related eye malpractice on a national basis.
14 Most of my cases involve high volume LASIK
15 facilities that fail to screen properly for
16 keratakonis or other contraindications to
17 surgery.

18 I am not here to criticize the
19 safety of LASIK. I am not here to criticize
20 ophthalmologists generally or LASIK surgeons
21 in particular. I am here to encourage the FDA
22 to do whatever it can to prevent the

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1 conversion of eyes to commodities by doing
2 four things:

3 First, encouraging the effective
4 and safe training of LASIK surgeons; second,
5 encouraging the reporting of adverse outcomes
6 by the industry; third, commissioning an
7 independent study of LASIK patient
8 satisfaction; and fourth, reporting on its
9 findings and making its data available on a
10 timely basis.

11 The LASIK industry does not police
12 itself effectively. Many doctors have
13 completed rigorous training with cornea
14 fellowships. However, many LASIK surgeons
15 have not.

16 The surgery itself is not that
17 complex. However, the screening process can
18 be. More time, skill and care need to be
19 invested to assure that unsuitable LASIK
20 candidates are screened out.

21 The LASIK industry under-reports
22 adverse outcomes. Even doctors with a duty to

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1 report have failed to do so. Voluntary
2 reporting should be encouraged. Mandatory
3 reporting failures should be enforced with
4 meaningful sanctions.

5 If the LASIK community really
6 believes that patient satisfaction at runs
7 upwards of 95 percent, then I suggest it
8 should welcome with open arms an independent
9 study to prove this.

10 Patient satisfaction must be
11 measured by both qualitative and quantitative
12 measures. It is not enough to say the patient
13 has good visual acuity.

14 My client, Mark Schiffer, had good
15 visual acuity. He had poor visual quality.
16 When his eye doctor saw this iTrace result,
17 and focus on the top right quadrant where
18 there is an "E," which depicted how the
19 patient saw an E on the eye chart, the doctor
20 scheduled his corneal transplant.

21 When Ros Martinez in Virginia Beach
22 complained of poor visual quality, her

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1 optometrist used this NIDEK technology to
2 demonstrate how poor her vision was, even
3 though her LASIK surgeon boasted of 20/30
4 corrected visual acuity and 20/40 uncorrected
5 visual acuity.

6 In March 2008, in a biographical
7 story in the New York Times, Abby Ellin
8 described her own LASIK surgery regret. She
9 described her doctor's false measure of
10 success based solely on her good visual
11 acuity. However, it is only half of one's
12 vision. Visual quality comprises the other
13 half.

14 For an impeccably credentialed
15 LASIK surgeon to say the surgery was
16 successful because the patient has good visual
17 acuity is, frankly, dishonest. Yet I hear it
18 often, of the homemaker from West Virginia
19 who took her cat's medication while the cat
20 took her thyroid medication for three days due
21 to blurred vision, of the surgical assistant
22 in Virginia Beach who cut the patient instead

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1 of the surgical thread due to poor contrast
2 sensitivity and impaired depth perception, and
3 of the executive in New Jersey whose son asks,
4 daddy, why don't you play with me anymore, due
5 to photosensitivity and irritation from the
6 elements, including wind, dust and sand.

7 If just one percent of LASIK
8 patients have a bad outcome, depending on
9 one's numbers, that may mean upwards of 10,000
10 patients per year will suffer potentially
11 serious visual disability.

12 It is reported that the
13 overwhelming majority of such cases are
14 avoidable or, in my view, constitute
15 presumptive evidence of medical malpractice.
16 Studies indicate that these cases are a result
17 of either the doctor's failure to screen
18 properly or missing warning signs such as
19 keratakonis, or the surgeon cutting the cornea
20 too thin, giving rise to post-LASIK ectasia.

21 The likelihood of serious visual
22 disability in this patient population is high.

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1 As visual learners, 85 percent of what we
2 perceive comes through our eyes.
3 Consequently, the likelihood of clinical
4 depression in this visually disabled
5 population is high. The incidence of suicide
6 in this population, while exceedingly rare, is
7 not hard to fathom.

8 I look forward to coming back and
9 speaking on behalf of Amanda Campbell. Thank
10 you.

11 CHAIRPERSON WEISS: Thank you. Our
12 next speaker will be Dr. Peter McDonnell.

13 DR. McDONNELL: Good morning. My
14 name is Dr. Peter McDonnell, and I appreciate
15 the opportunity to address the Panel this
16 morning.

17 I am the William Holland Wilmer
18 Professor of Ophthalmology and Director of the
19 Wilmer Eye Institute of the Johns Hopkins
20 School of Medicine. I am a corneal surgeon
21 and was involved in the early clinical and
22 preclinical studies of excimer laser surgery.

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1 Two of my sisters had the LASIK procedure
2 performed on their eyes several years ago.

3 I wish to make the following
4 disclosures. My research has been, and is
5 currently, supported by Federal grant funding.

6 I have in the past served as a clinical
7 investigator in industry sponsored clinical
8 trials of excimer laser technology.

9 I currently serve in a consultative
10 role for the Scientific Advisory Board for a
11 company that markets an excimer laser used in
12 LASIK surgery, but my consultation has not
13 involved this area of the company's research.

14 Today I represent the International
15 Society of Refractive Surgeons of the American
16 Academy of Ophthalmology, known as ISRSAAO,
17 the world's largest eye care organization
18 solely dedicated to refractive surgery. It
19 has more than 2300 members from more than 80
20 different countries.

21 ISRSAAO wishes to bring the
22 following information to the attention of the

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1 FDA and Panel members.

2 Nearsightedness, farsightedness,
3 astigmatism, and presbyopia affect 40 percent
4 or more of the U.S. Population. These
5 conditions are associated with measurable
6 negative impacts upon quality of life and
7 require correction with glasses, contact
8 lenses or surgery.

9 About 700,000 Americans have LASIK
10 surgery annually. Over 90 percent of people
11 who have LASIK for nearsightedness achieve
12 somewhere between 20/20 and 20/40 vision
13 without glasses or contact lenses.

14 LASIK is the most studied elective
15 ophthalmic procedure. Collectively, 7,830
16 patients representing 16,502 eyes participated
17 in FDA clinical trials between 1993 and 2005.

18 Initial findings from a world review of the
19 scientific literature found an average
20 satisfaction rate of 95.4 percent among post-
21 operative patients.

22 I believe it is safe to say that no

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1 elective ophthalmic surgical procedure has
2 been as fully studied as has this procedure.

3 From its approval by the FDA in the
4 mid-Nineties, LASIK has benefitted millions of
5 patients. Over the years, incremental
6 improvements have made this procedure even
7 better. These improvements are very similar
8 to the evolution of modern day cataract
9 surgery, a procedure that has benefitted
10 millions from the very moment of its approval,
11 and that only continues to improve with time.

12 As with any surgical procedure,
13 there are complications that may occur after
14 LASIK. Fortunately, these are uncommon. No
15 matter how uncommon, however, when
16 complications occur, they can be quite
17 distressing to both patients and surgeons.

18 Most complications can be treated
19 without any loss of vision. Some patients
20 experience temporary side effects after LASIK
21 that usually disappear within three to six
22 months. In rare situations, these effects may

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1 be permanent.

2 No surgery is without risk, but the
3 physician members of the organization I
4 represent today are dedicated to doing
5 everything in our power to make the LASIK
6 procedure even better for all of our patients.

7 It is important to recognize that,
8 as is typical with other surgical procedures,
9 the techniques and technology have improved
10 over time as surgeons and manufacturers have
11 endeavored to improve outcomes.

12 Examples include making the
13 ablations smoother, fine tuning the ablations
14 to enhance quality of vision, custom ablations
15 designed to sharpen the visual results in
16 individual patients, improvements in the
17 instruments used to create the LASIK flaps in
18 order to reduce the risks associated with this
19 part of the procedure, as well as to improve
20 the visual results.

21 Many patients seeking LASIK do so
22 because their dry eye prevents them from

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1 wearing contact lenses successfully, and some
2 patients develop this problem after surgery.
3 Better treatments designed to prevent or treat
4 dry eye have also developed over time.

5 Results of the LASIK procedure have
6 reached the point where some believe it is now
7 safer over a long period of time than the
8 alternative of contact lens wear. Contact
9 lens wear is, of course, subject to its own
10 set of risks, including infection.

11 The ISRSAAO supports efforts to
12 further improve the technology and techniques
13 used in the procedure, and to identify those
14 patients who might not respond well to the
15 surgery or who have characteristics that might
16 make them poor candidates for surgery so that
17 these individuals can be counseled to avoid
18 surgery.

19 In summary, ISRSAAO agrees that the
20 safety and efficacy of the LASIK procedure has
21 been well studied and documented in hundreds
22 of scientific publications, and millions of

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1 patients have benefitted by this procedure.
2 As instruments and techniques are further
3 refined, this procedure will continue to be
4 improved with time.

5 Thank you for allowing me to speak
6 to you today.

7 CHAIRPERSON WEISS: Thank you. Our
8 next speaker will be Dr. Schallhorn.

9 DR. SCHALLHORN: I would like to
10 request that Jennifer Morse speak in my place,
11 and I will speak in hers.

12 CHAIRPERSON WEISS: Our next
13 speaker will be Dr. Morse, followed by Dr.
14 Schallhorn.

15 DR. MORSE: Thank you. I am Dr.
16 Jennifer Morse, a psychiatrist, and I am an
17 invited member of the Joint LASIK Study Task
18 Force.

19 For financial disclosure, I am a
20 consultant to ASCRS, and ASCRS paid my travel
21 here.

22 Ten years ago while I was serving

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1 as the Navy's Program Director for Psychiatry
2 in San Diego, I became involved in research to
3 investigate the role of psychological factors
4 and quality of life in refractive surgery.

5 I am Board certified in psychiatry
6 with subspecialty certification in
7 psychosomatic medicine, an area of medicine
8 that focuses on the interrelationship between
9 psychological factors and physical symptoms.

10 I served 20 years as a Navy
11 physician, retiring in 2004 as the Chairman of
12 Psychiatry at Naval Medical Center, San Diego.

13 Over the course of my career, I have worked
14 clinically with thousands of patients, as well
15 as being an educator and researcher.

16 I am Distinguished Fellow of the
17 American Psychiatric Association, and I have
18 been an invited member of the NASA Astronaut
19 Selection Psychological Support Team.

20 We know a great deal about the
21 safety, effectiveness and very real benefits
22 of LASIK. I've had a chance to see these

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1 benefits in both military personnel and people
2 outside the military. Clearly, however, based
3 on what we have heard today, there are people
4 who are raising concerns about quality of life
5 issues.

6 The patient's subjective experience
7 before, during and after the procedure is
8 something we need to better understand. That
9 is why we are here today, and that is why the
10 Task Force's work is so important.

11 Quality of life consists of two
12 overall components, physical and
13 psychological. We know that around 20 million
14 people in the U.S. have depression in any one-
15 year period, and many of them do not seek
16 mental health treatment.

17 Psychological well-being is an
18 equally important part of quality of life, and
19 depression is a central and widespread cause
20 of diminished quality of life.

21 The vast body of scientific
22 literature and research on depression and

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1 suicide, as well as my own clinical
2 experience, shows that the cause of these
3 events is extremely unlikely to be a single
4 event or factor. Rather, these events occur
5 due to multiple factors, and this continues to
6 be a complex area of study.

7 There have been many attempts in
8 the past in other settings and situations to
9 try to establish a direct link between these
10 events and a single cause, but here's the
11 problem. These attempts don't work, because
12 depression and suicide are complex and have
13 multiple causes.

14 In examining the origins and course
15 of depressive illness, you must take into
16 account a person's background, personality,
17 environment, coping skills, outlook on life,
18 and even genetic predisposition.

19 Depression is a complex mental
20 illness, and while one factor may play a role,
21 it isn't simply a matter of cause and effect.

22 There is no scientific evidence of any direct

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1 link between LASIK and the development of
2 depression or suicide. However, there are
3 studies from some other elective surgeries,
4 such as back surgery or cosmetic surgery, that
5 have found associations between pre-operative
6 psychological factors such as depression,
7 anxiety and life satisfaction, and patients'
8 perceptions of surgical outcome and level of
9 functioning.

10 As a psychiatrist, I fully support
11 increased research focused on psychological
12 factors and their bearings on quality of life.

13 In the case of LASIK, our current knowledge
14 tells us quality of life after refractive
15 surgery is similar to that of patients who
16 have never had refractive error, and better
17 than that, of eyeglass wearers and contact
18 lens users.

19 In fact, in a study published in
20 2007, the glasses and contact lens users had
21 lower quality of life scores than those
22 patients treated with LASIK or those who

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1 naturally see 20/20.

2 A statistically higher percentage
3 of glasses and contact lens users had concerns
4 about injury, difficulty coping with demands
5 in life, difficulty fulfilling roles, and less
6 confidence in everyday activities.

7 Today, 10 years after its FDA
8 approval, LASIK has a 95 percent satisfaction
9 rate in the large population. However, there
10 are a small number of dissatisfied
11 individuals. To me, this indicates that we
12 need to take post-LASIK quality of life
13 complaints seriously, but at the same time, we
14 need to make sure we understand the real
15 causes of these complaints in all their
16 complexity.

17 The result of this study will be a
18 new base of knowledge that may help us provide
19 additional screening and pre- and post-LASIK
20 counseling that addresses these factors,
21 steers some people away from LASIK, guides
22 others through the procedure in a different

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1 way based on their level of psychological
2 risk, and in the end leads to better
3 experiences, which is, after all, our ultimate
4 goal. Thank you for your time.

5 CHAIRPERSON WEISS: Thank you. Dr.
6 Schallhorn.

7 DR. SCHALLHORN: Thank you. My
8 name is Dr. Steve Schallhorn, and I am here to
9 represent the American Academy of
10 Ophthalmology.

11 I appreciate the opportunity to
12 address this Panel.

13 I currently practice at a private
14 clinic in San Diego and serve on a number of
15 committees with the Academy. I retired from
16 the Navy last year after almost 30 years of
17 service. While in the Navy, I founded the
18 Department of Defense Refractive Surgery
19 Program and directed the Navy program since
20 its inception in 1993.

21 I have performed thousands of
22 procedures on members of the military and

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1 conducted numerous clinical trials to explore
2 laser vision correction.

3 For disclosures, I currently as a
4 consultant to AMO, a company that markets an
5 excimer laser.

6 The American Academy of
7 Ophthalmology was founded in 1896, and is the
8 world's largest association of eye physicians,
9 with more than 27,000 members worldwide. Our
10 members are committed to responding
11 compassionately and ethically to patients'
12 needs and advancing the highest standards of
13 eye care.

14 On behalf of the Academy, I wish to
15 bring the following information to the
16 attention of the FDA and the Panel.

17 LASIK is safe and effective. This
18 has been documented in studies enrolling
19 thousands of patients conducted over the last
20 15 years. Patient satisfaction after LASIK is
21 excellent, higher than that reported for other
22 forms of elective surgery. The satisfaction

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1 rates in Navy LASIK studies I conducted were
2 very similar.

3 LASIK has benefitted millions of
4 patients. Quality of life is the next area
5 where we need to focus. It is important to
6 appreciate that quality of life is not the
7 same as safety and effectiveness.

8 Published studies demonstrate an
9 overall improvement in the quality of life
10 after LASIK. However, because satisfaction is
11 so high after LASIK, these previous studies
12 could not fully assess the quality of life in
13 those patients who were dissatisfied.

14 In addition, there are still a
15 small number of patients whose outcomes are
16 not reflected in their level of satisfaction.

17 While we can identify several reasons for
18 dissatisfaction, sometimes we can't, which
19 points to other factors.

20 That is why, together with the FDA,
21 the National Eye Institute and ASCRS, the
22 Academy is committed to participating in,

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1 managing, operating and co-funding a study to
2 further evaluate underlying factors that
3 impact satisfaction and quality of life after
4 LASIK.

5 The study will be a clinically
6 robust evaluation of quality of life after
7 LASIK. We will enroll a large number of
8 patients, because of the need to have
9 statistical validity, given the low percentage
10 of dissatisfied patients.

11 Our objectives are to determine the
12 change in quality of life after LASIK and to
13 understand the factors associated with
14 satisfaction and dissatisfaction. As
15 physicians, we are dedicated to doing
16 everything in our power to make the LASIK
17 procedure even better for all our patients.

18 The Academy believes that knowledge
19 gained from the study will benefit both
20 patients and physicians, providing an
21 opportunity to understand, anticipate, and
22 eliminate issues related to patient

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1 dissatisfaction.

2 In summary, the Academy agrees that
3 LASIK is a safe and effective procedure that
4 has benefitted millions of patients. As we
5 have done for every surgical procedure, we
6 will continue to refine and improve LASIK for
7 our patients.

8 Let me close with a story that
9 describes what LASIK means for many patients.

10 It is from a patient that requested laser
11 vision correction many years ago. He was a
12 firefighter on a ship and a successful contact
13 lens wearer.

14 A fire broke out on the ship which
15 killed several people. After hours of
16 battling the out of control blaze, he went to
17 a safe area to replace his breathing
18 apparatus. Upon taking off his mask, smoke
19 and fumes caused intense contact lens
20 discomfort. He had to remove the lens, but
21 did not have time to retrieve another pair.

22 He then donned another mask and

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1 went on to fight the fire, eventually putting
2 it out. He subsequently received a
3 Presidential medal for his heroism for
4 fighting the fire while in a legally blind
5 state.

6 He sent me a letter requesting
7 laser vision correction, because he was sure
8 it would be a life saver. Soon afterwards, he
9 underwent the procedure, and is how
10 exceptionally happy.

11 This illustrates the very real
12 benefit that LASIK can provide for our
13 patients. The goal of this study is to ensure
14 that those significant benefits are preserved
15 and quality of life issues are effectively
16 addressed.

17 Thank you very much.

18 CHAIRPERSON WEISS: Thank you. Our
19 next speaker will be Terylyn F. Bankes, Dr.
20 Terylyn F. Bankes.

21 DR. BANKES: I am Dr. Terylyn F.
22 Bankes, and I have no conflict of interest

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1 with LASIK surgery.

2 I am going to present my part, and
3 then I have been requested by a patient, Kim
4 Harringer, to report on her story as well.

5 I have heard about the problems --

6 CHAIRPERSON WEISS: As long as you
7 do it in five minutes.

8 DR. BANKES: I will. I have heard
9 about the problems that patients with poor
10 visual outcomes have been experiencing since
11 2000. I volunteered to be the physician
12 counselor for several LASIK patient support
13 group meetings held throughout the Tampa Bay
14 area from 2001 through 2004.

15 Meetings consisted of from 10 to 30
16 various members, all of whom had visual
17 problems following refractive surgery.
18 Members described a variety of emotional
19 responses, including depression, anxiety,
20 difficulty sleeping, and panic attacks. Many
21 had self-anger, taking responsibility for
22 their poor outcomes upon themselves.

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1 They bitterly complained of the
2 expense of trying to find visual solutions.
3 Some called LASIK the "stupidest thing I ever
4 did." They bemoaned their loss of autonomy,
5 especially their decreased night vision and
6 visual aberrations that kept them from
7 recognizing people when in dim light
8 situations, made night driving an
9 impossibility, reduced their ability to read,
10 and threatened their job security.

11 Many became obsessed with their
12 vision and reported that they felt estranged
13 from family and friends who did not want to
14 talk to them anymore about their continuing
15 insolvable problems.

16 The ophthalmologic surgeons
17 routinely discounted their symptoms or were
18 unable to deal with them as patients. I heard
19 stories of true depression, suicidal ideation
20 and rage.

21 Ophthalmologists I currently work
22 with on a daily basis have expressed the

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1 concern of what LASIK will do for cataract
2 surgery.

3 The method to calculate the power
4 of the intraocular lens required for cataract
5 surgery is unknown, and the community
6 ophthalmologists have no way to assess the
7 intraocular lens requirements. Therefore,
8 they are unwilling to treat these patients.

9 As our LASIK patients age, the lens
10 calculations will be a growing problem.

11 Another recent question involves
12 the increasing number of LASIK flap MRSA
13 infections. Optometrists have expressed to me
14 the concern that this might become an
15 epidemic. What does the future hold for these
16 LASIK patients?

17 The problems with LASIK are a open
18 secret among ophthalmologists, many of whom
19 have patients in their practices with poor
20 outcomes. I fail to understand how the
21 ophthalmologic community can defend the
22 continuing production of life altering

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1 complications, and I view it as a true
2 disgrace of modern medicine.

3 I challenge this FDA Panel to take
4 the necessary action to protect our patients
5 in the United States. Thank you.

6 Now I am going to report on Kim
7 Harringer's story. Kim Harringer is a 44-
8 year-old woman who had -- is married, was a
9 Registered Nurse and has rheumatoid arthritis.

10 She had RK surgery in -- 14 years
11 ago, and then her vision regressed. So back
12 in 2006 she saw a surgeon who did LASIK
13 surgery on top of her previous surgery.

14 He told her that he could do the
15 LASIK surgery with no problem. Immediately
16 following the surgery, there was a problem.
17 What ensued was a nightmare of increasing
18 frustration, despair, depression, Kim sought
19 to find out what happened to her vision.

20 She was aided in her research for
21 relief by family members who sought to
22 understand what was going on with her. She

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1 was having constant problems with depression.

2 She was depressed and suicidal. She was
3 admitted to a mental hospital five times.

4 On her fifth admission, she was
5 diagnosed as having hysterical blindness.
6 Finally, recently, she found an optometrist
7 who was able to fit her with some hard
8 contacts which, while still she has problems,
9 have improved her vision somewhat.

10 She asks -- When asked what people
11 would like to learn from her experience, she
12 is very clear. The whole health field in
13 general needs to be aware and reconsider. Not
14 everyone fits into some textbook diagnosis.

15 Medical remedies trail medical
16 advances in the light of LASIK surgery, and
17 for patients like Kim, we have a lot of
18 catching up to do when it comes to
19 understanding and treating poor outcomes.

20 Thank you.

21 (Applause.)

22 CHAIRPERSON WEISS: Thank you. The

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1 next -- I would ask the audience if we could
2 restrain from applause, because then it
3 becomes a little bit of a popularity contest.

4 So we are listening to everyone. Trust me,
5 the Panel is hearing everyone.

6 The next speaker will be Dr.
7 Michael Mullery.

8 DR. MULLERY: My name is Michael
9 Mullery, M.D., MBA. I am a graduate of the
10 University of Notre Dame and the Pennsylvania
11 State University College of Medicine. I am a
12 Board certified medical specialist with a
13 secondary interest in psychiatrist.

14 The refractive surgery industry has
15 known since its inception that LASIK surgery
16 carriers a risk of depression and suicide.
17 Bad outcomes are not rare, and these outcomes
18 can result in serious qualitative and
19 quantitative vision losses, including
20 blindness.

21 Now the FDA is allowing the very
22 entities that have publicly engaged in

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1 minimizing these risks to conduct studies
2 looking at LASIK and its effect on quality of
3 life. This is an overt conflict of interest
4 that defies both common sense and the
5 scientific method.

6 There can be no objectivity when
7 the bottom lien is the very survival of one's
8 multi-billion dollar cash cow. It is time to
9 leave the study of the psychological
10 consequences of vision loss after LASIK to
11 mental health professionals that are better
12 trained to study this and lack any financial
13 interest in the outcome.

14 In 1999, the Journal of
15 Psychosomatics, July/August, researchers from
16 Griffith University in Australia, in
17 conjunction with the World Health
18 Organization's Center for Suicide Research,
19 reported on a study that compared suicide
20 secondary to vision loss to suicide secondary
21 to hearing loss.

22 The study found that 63 percent of

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1 hearing impaired suicides had a history of
2 mental illness, compared to only eight percent
3 of the sight impaired suicides. In this
4 study, fear of sight loss and the uncertainty
5 about future vision emerged as greater risk
6 factors for suicide than complete blindness.

7 Most importantly, however, sight
8 loss itself was identified as the main causal
9 factor for vision suicides, whereas hearing
10 suicides were coupled with several other
11 causal factors.

12 I would estimate that I have
13 interviewed close to 75 people who have
14 developed suicidal ideation as a result of
15 LASIK. What I've found is that very few of
16 these patients have a history of depression or
17 other psychiatric problems.

18 This finding is consistent with the
19 Griffith University-WHO study of vision loss
20 and suicide, and inconsistent with the
21 industry's claims that preexisting
22 psychopathology is responsible.

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1 If vision loss is causal, as the
2 Griffith University-WHO study claimed, then
3 better screening for preexisting psychological
4 problems is not the answer. Stopping the
5 vision loss is.

6 How many totally preventable deaths
7 can the FDA allow when there is absolutely no
8 medical need for a procedure? In the
9 following case LASIK itself is undoubtedly the
10 sole causal factor in this man's suicidal
11 ideation.

12 A.J. underwent LASIK and ended up
13 with a result that his surgeon could not
14 explain, severely over-corrected with
15 irregular astigmatism, A.J. could not even
16 read the big E after his surgery.

17 In A.J.'s own words, "My life and
18 world changed beyond description the next days
19 following my surgery. First, fear set in, as
20 I felt alone and helpless, as my life became
21 an endless routine. I was sitting in front of
22 slit lamps, with no improvement in my vision.

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1 I was constantly nauseous from the vision
2 imbalance and resulting headaches. Then out
3 of the blue, panic set in. I began to cry all
4 the time.

5 "There seemed no easy way out of
6 the situation I had created for myself. The
7 simple solution to eliminate glasses had
8 become my first ever experience with
9 depression, deep, deep depression, which I
10 tried to hide from my wife.

11 "My business was suffering and I
12 became obsessed with my vision, to the point
13 that I was becoming unglued. I had always
14 been a very stable person. I had no history
15 of mental illness, depression or drug
16 addiction, nor had I ever been prone to
17 violence. But now for the first time in my
18 life, I was suicidal and full of rage.

19 "How could I stop this from
20 happening to someone else, and how could I
21 make my own pain go away?"

22 In another case a dental student

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1 without any history of psychological problems
2 reports himself becoming suicidal after his
3 LASIK left him with constant headaches, blur,
4 and vision that could not be corrected with
5 glasses.

6 "I shutter to think how close I was
7 to ending my life," he says. "Taking eight
8 courses and studying for a national license
9 exam with one semi-functional eye was a
10 hellish nightmare."

11 This patient reached the point
12 where he found himself with a half-drunk
13 bottle of vodka in one hand and a loaded gun
14 in the other. Incidentally, his surgeon
15 considered him a success.

16 Another patient, S.D., with no
17 prior psychological history reports becoming
18 suicidal when LASIK surgery to correct for
19 myopia produced finger-only vision in one eye
20 and 20/200 vision in the other. She is now
21 awaiting bilateral corneal transplantations.

22 She reports that collusion by local

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1 refractive surgeons added to her sense of
2 despair, as none of the local refractive
3 surgeons who saw her for second opinions even
4 mentioned to her that she had ectasia.

5 In conclusion, patients are killing
6 themselves as a result of failed LASIK. A
7 risk of death is not an acceptable risk for a
8 totally unnecessary procedure with no medical
9 benefit.

10 Research on this issue remains
11 virtually nil, and thus the full extent of
12 this catastrophic complication remains
13 unknown. Public safety is best served by a
14 moratorium on these procedures so that these
15 previously unstudied risks can be evaluated
16 and understood.

17 Studies looking at the effects of
18 unsuccessful LASIK with depression and
19 suicidal ideations should be done by mental
20 health professionals and suicidologists who
21 are better able to assess mental health issues
22 and who lack the financial conflict of

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1 interest that LASIK surgeons and co-managing
2 optometrists obviously have.

3 If a moratorium is not immediately
4 instituted, the labeling of the excimer lasers
5 for the surgical correction of myopia,
6 hyperopia and astigmatism should be altered to
7 include risk of suicide and depression, even
8 in the absence of any preexisting psychiatric
9 history. Thank you.

10 CHAIRPERSON WEISS: Thank you. Our
11 next speaker will be Courtney Henrichs.

12 MS. HENRICHS: Hi. My name is
13 Courtney Henrichs, and my travel here is paid
14 for by ASCRS, but I am here on my own accord
15 to tell you about the positive experience of
16 LASIK surgery.

17 Two years ago I had LASIK surgery
18 performed by Dr. Maloney in L.A. through the
19 Focus on Independence Program. It has been a
20 positive, life changing experience for me.

21 In 2002 I broke my neck in a
22 downhill skiing accident, leaving me

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1 quadriplegic. Prior to my accident, I had
2 worn contact lenses.

3 Because of the very limited use of
4 my hands and fingers, I had to make the switch
5 to glasses, but wearing glasses as a
6 quadriplegic also had its drawbacks. If they
7 smudged, someone had to clean them for me. In
8 the rain, someone had to dry them for me.

9 In Wisconsin where I live, it is
10 cold, and when I came in from the outside,
11 they would often fog up, and I would either
12 have to wait for them to clear or someone
13 would have to wipe them again for me.

14 Also, when I would wake up in the
15 middle of the night, I wouldn't be able to
16 see, and I would have to wake someone else up
17 to bring me my glasses. I also had issues
18 with the glasses sliding down my nose while
19 trying to work on homework. I would be able
20 to push them back up, but in the process I
21 would once again smudge them, and someone else
22 had to clean them for me.

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1 It was an exciting day when I
2 finally had my LASIK. I was fairly confident,
3 because I had two pre-operative appointments,
4 one with Dr. Sprik in Wausau, Wisconsin, and
5 the other done by Dr. Maloney himself when I
6 reached L.A.

7 I sat up a few minutes afterwards,
8 and I looked around and was thrilled at how
9 clearly I could see. I could even read the
10 clock, which beforehand was something that
11 would have been impossible for me to do.

12 By the end of that day, I already
13 had 20/15 vision. After having so much of my
14 independence taken away, I felt like I was
15 given something back. It was like my own
16 little miracle.

17 I didn't need the help of others
18 with my glasses any longer. This may not seem
19 like much for those of you that don't require
20 assistance of others, but for me it is one
21 more step toward independence, and I don't
22 take it for granted.

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1 I am a college student now, and I
2 am grateful every day for the gift of LASIK,
3 and I hope LASIK can continue to give others
4 that same gift of independence as it has given
5 me.

6 CHAIRPERSON WEISS: Thank you very
7 much. Our next speaker will be Amanda
8 Campbell.

9 MR. KROUNER: Good morning again.
10 I am here on behalf of Amanda Campbell. My
11 name is Todd Krouner. I was recently retained
12 by her. She is a widow now in Brentwood,
13 Tennessee, whose husband, Lawrence Campbell, a
14 police officer with that police force, shot
15 himself with his service revolver last month
16 on March 16, 2008.

17 Ms. Campbell regrets that, given
18 her current circumstances, she is not able to
19 afford the trip here to Maryland today.

20 In a March 25, 2008, article
21 reported in the OSN supersite, Dr. Richard
22 Lindstrom, who you know as President of ASCRS

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1 and OSN Chief Medical Editor, is quoted as
2 asserting that there is no correlation
3 whatsoever between adverse LASIK outcomes and
4 suicide.

5 Presumably, Dr. Lindstrom did not
6 have the benefit of reading police officer
7 Campbell's suicide note.

8 In my April 15, 2008, written
9 submission to the FDA, I referred to Dr.
10 Lindstrom's assertion, but in my letter I also
11 questioned the integrity of certain Titans in
12 the LASIK industry, and I want to be clear
13 that none of those comments are meant to cast
14 any such aspersion on Dr. Lindstrom. However,
15 I respectfully disagree with his absolute
16 position based on the explicit statements in
17 police officer Campbell's suicide note from
18 just last month.

19 He states: "No one knows what I am
20 feeling, constant pain, blurred vision, stress
21 that I never had before. If only Dr. Robert
22 P. Selkin had done a pre-op and knew I was not

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1 a candidate for LASIK surgery.

2 "No one understands truly my burden
3 I carry, dry eyes, cannot light a fire, cannot
4 stand in front of air conditioning, cannot
5 cook without opening a window, cannot spray
6 deodorant. The list goes on and on.

7 "I just cannot burden my family for
8 a poor decision, eye surgery, which Selkin
9 knew was wrong but only wanted money, and I
10 will not live on drugs, Xanax. I never used
11 that drug wrong, a half a milligram at night
12 and sparingly in the afternoon on a bad day.
13 I am not a drug user. Never could I do this,
14 as it has ruined so many lives."

15 He goes on to state, "Do not have
16 LASIK surgery. Tell the media."

17 On behalf of the Campbell family,
18 that is why I am here on their behalf today.
19 If there were any question about the cause of
20 police officer Campbell's suicide, he states
21 explicitly: "To blame for this, Selkin eye
22 surgery. Eye surgery has taken my life out of

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1 me. The pain, distorted vision, chronic dry
2 eye is not bearable" -- emphasis in original.

3 Out of fairness to Dr. Robert P.
4 Selkin, I do not know today if he committed
5 medical malpractice in the tragic Campbell
6 case. However, out of fairness to Lawrence
7 Campbell's widow and two children, to date
8 inexplicably they have been denied access to
9 eye records.

10 What is clear in this case -- and I
11 emphasize this one case -- is that LASIK
12 surgery clearly constituted a material
13 contributing factor, if not the sole factor,
14 to police officer Campbell's suicide.

15 To Mrs. Campbell's knowledge,
16 prior to his LASIK surgery she reports that
17 her husband suffered from no mental illness
18 whatsoever.

19 Now you have heard today and
20 certainly recognize that LASIK surgery helps
21 the vast majority of patients who have it.
22 For a small minority, their regret is

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1 profound.

2 For a smaller minority of patients
3 still, depression associated with their visual
4 disability is real. The association with
5 suicide and bad LASIK outcomes, however rare,
6 cannot be dismissed, and warrants further
7 investigation.

8 As a final point, I would just like
9 to call the FDA's attention to its reporting
10 obligations. The FDA's work should be
11 transparent and readily available to the
12 public. It is not always.

13 Nine months ago, my law firm served
14 a Freedom of Information request to obtain
15 information concerning the Administration's
16 recall of the Alcon LADARVision 6000. To
17 date, we have still received no substantive
18 response.

19 Vindication of injured patients'
20 rights depends on timely disclosure of such
21 information. Thank you.

22 CHAIRPERSON WEISS: Thank you. Our

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1 next speaker will be Dr. Roger Davis.

2 DR. DAVIS: Panel members, my name
3 is Roger Davis. I have a PhD in clinical
4 psychology with perhaps 20 publications,
5 including several co-authored books and
6 psychological tests.

7 Back in 2000 I served as Director
8 of Research for the Surgical Eyes Foundation,
9 now VRSN. I have communicated with about 300
10 patients with LASIK complications. Over 100
11 have told me that they have considered
12 suicide because of their LASIK. Perhaps 90
13 percent indicates some element of deception,
14 which then drives the development of post-
15 traumatic stress, depression and suicidal
16 ideation.

17 While Director of Research, we
18 submitted a study on depression and suicidal
19 thoughts to a major refractive surgery
20 journal. Among 58 patients admitting suicidal
21 ideation, 83 percent stated they were told
22 they were a success by their surgeon.

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1 In 115 patients who were severely
2 depressed, the number was 76 percent.
3 Interestingly, the single complication most
4 strongly associated with suicidal ideation was
5 dry eye syndrome, considered a side effect or
6 symptom.

7 My most important point here today
8 is that patients respond emotionally to their
9 total situation, not simply to their eyes.
10 With minor complications, they develop various
11 adjustment disorders. With severe
12 complications, however, they develop what I
13 have termed refractive surgery shock syndrome,
14 which includes major depression, suicidal
15 ideation and post-traumatic stress.

16 Suicidal patients pass through
17 several stages of inquiry. First, they ask
18 such questions as "Will I ever get my vision
19 and my life back? Why didn't they tell me
20 this could happen? Why didn't my informed
21 consent mention this? Why didn't my surgeon
22 tell me I could have more than one

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1 complication?"

2 Eventually patients move on to ask
3 questions about their surgeon: "Why is my
4 surgeon telling me nothing is wrong with my
5 eyes? Why are my complaints not being
6 recorded in my medical chart? Is my surgeon
7 really as good as he was presented? What if
8 my surgeon really does not understand what is
9 wrong with my eyes? If my doctor doesn't
10 understand, will anyone understand?"

11 Eventually, patients find others
12 like themselves on the Internet, and now they
13 begin asking questions about the industry
14 itself: If LASIK is so safe, why are so many
15 other patients out there with complications?
16 Why are so many patients telling the same
17 story? How are they getting away with this?
18 Why doesn't the FDA step in and stop this?
19 Why don't honest doctors speak up about this?
20 Is it really all about money? Am I the
21 victim of a medical cover-up?

22 Obviously, every patient who thinks

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1 about suicide following LASIK wants to get
2 away from their eyes. Beyond this, however,
3 there are individual differences.

4 Some individuals have traveled
5 widely looking for solutions. Since they have
6 done everything they could possibly do, for
7 them suicide seems like a rational option.
8 Here, suicidal thoughts express the desire to
9 be done with the journey.

10 Many individuals see themselves as
11 victims of a corrupt industry. They feel
12 powerless to help themselves or others. Here,
13 suicidal wishes express the desire not to be a
14 victim, simply to return to a world of
15 integrity, compassion and purity.

16 Some patients vacillate between
17 periods of crisis and exhaustion, living on
18 the bring, constantly in fear that their
19 vision is getting worse. They have no time
20 for anti-LASIK activism. Here, suicidal
21 wishes express the desire to escape the
22 anxiety and unpredictability of complications.

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1 Some patients feel that no one
2 understands their situation, not their doctor,
3 not their family, not even other patients.
4 Suicidal wishes express the desire to have the
5 severity of their vision issues finally
6 appreciated. If I kill myself, someone will
7 finally understand how bad it was.

8 Some patients feel that they paid
9 to have their vision destroyed. Here,
10 suicidal thoughts express guilt at having
11 wasted one's potential as a human being.

12 In my experience, no pre-existing
13 psychopathology is necessary for patients to
14 develop suicidal ideation post-LASIK. Decades
15 of psychological research has shown that
16 catastrophic injuries of all kinds produce a
17 period of prolonged psychological crisis and
18 adjustment. Why should catastrophic LASIK
19 injuries be any different?

20 I have not known perfectionism or
21 body dysmorphic disorder to play a role in
22 post-LASIK depression or suicide.

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1 I ask that the upcoming FDA study
2 address psychological construct such as
3 deception and adequacy of informed consent in
4 existing patients, in a prospective study that
5 could decide the future of the industry.
6 Patients may have different experiences and a
7 higher standard of care.

8 Also, I suggest to the Panel that,
9 if the FDA wants to understand depression and
10 suicide post-LASIK, forget about satisfaction
11 surveys. If you want to understand suicidal
12 patients, study suicidal patients. You can
13 find as many as you want.

14 Finally, I ask the Panel to declare
15 a moratorium on the use of the excimer laser
16 for refractive surgery. Research connecting
17 complications to quality of life problems
18 provides the ethical basis for informed
19 consent. That research should have been done
20 10 years ago.

21 Because this research does not yet
22 exist, refractive surgery cannot be performed

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1 ethically, whatever its satisfaction or
2 complication rate. Thank you.

3 CHAIRPERSON WEISS: Our next
4 speaker will be Jo Ann Wills.

5 MS. WILLS: I don't know whether
6 being the first or the last is more unnerving
7 for the speaker.

8 My name is Jo Wills. I am here to
9 speak about my husband, Keith Wills. I had a
10 long presentation that I was going to give
11 you, but I think I have changed my ways here.

12 My husband had LASIK surgery in
13 1997 in October. He spent almost 11 years.
14 He went to a doctor who was under an IDE study
15 who didn't tell us that it was an IDE study.
16 We had no information that this was a study
17 until we went to our lawyer to sue this
18 doctor.

19 The doctor performed seven
20 surgeries on my husband, or enhancements to
21 correct the initial problems. He under-
22 corrected my husband, so he could over-correct

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1 later.

2 The doctor was deceitful. He even
3 tried to convince me to have LASIK surgery
4 that day. He definitely wanted to make money.

5 Prior to his surgery, he didn't get
6 the form that was approved by the SAIRB.
7 Apparently it wasn't even approved until just
8 weeks before my husband had surgery.

9 My husband has all the same
10 problems the other people that have had
11 problems. He has ghosting, starbursts,
12 multiple visions. He sees seven of me in one
13 eye and four of -- or three of me in one eye,
14 four of me in another. He's got seven wives.

15 I have been listening today, and I
16 noticed that there is a lot of people that
17 have come forward that are in the industry.
18 They have something to benefit from. The
19 military, it seems, has had a high success,
20 but they police themselves.

21 I don't see FDA actually policing
22 these doctors. Unfortunately, it seems that

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1 most of these people here that are having
2 problems are having problems because they went
3 to the wrong doctor, one that didn't do the
4 proper work that they were supposed to do
5 before in evaluating these people for their
6 surgery.

7 In closing, I want to mention that
8 I noticed that none of you up here wear
9 glasses. Is there any reason why?

10 Thank you for letting me speak
11 today.

12 CHAIRPERSON WEISS: We will answer
13 that one during Panel.

14 Next, we have a few speakers who
15 were not on the initial list. Rebecca Petris,
16 please.

17 AUDIENCE MEMBER: May I make a
18 point of order?

19 CHAIRPERSON WEISS: No, you may
20 not. This is not the time for point of order.
21 What we are going to do is follow
22 proceedings, just because we have such an

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1 unusually large number of speakers today.

2 Mr. Edward Bosnick. Sir, you can
3 begin next, and if that -- We can go out of
4 order. No, if you are ready, you can begin.
5 Thank you.

6 DR. BOSHNICK: I am Dr. Edward
7 Boshnick. I am an optometrist in Miami,
8 Florida, in private practice for over 37
9 years.

10 Over the years, I have devoted the
11 major portion of my practice to the non-
12 surgical treatment of patients who have lost
13 quality vision due to ocular trauma, disease,
14 and refractive eye surgery, including LASIK.

15 Over these years, I have taken care
16 of several hundred post-refractive surgical
17 patients. The great majority of these
18 patients had LASIK. Many had two or more
19 procedures in each eye.

20 Please bear in mind that I don't
21 get to see happy post-LASIK patients. Some of
22 the patients I have seen have lost their jobs

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1 and families as a result of their vision loss.

2 Two of my patients have attempted suicide on
3 multiple occasions. Three of my patients have
4 spoken to me about suicidal thoughts.

5 The complications I have seen
6 include severely disordered corneas resulting
7 in loss of best corrected visual acuity,
8 visual distortions known as higher order
9 aberrations, under-correction and over-
10 correction of their visual errors, nighttime
11 and indoor vision disorders including halos,
12 glare, ghosting and multiple vision, and also
13 severe dry eye, of course, which is fairly
14 common; loss of contrast sensitivity, which is
15 the ability to distinguish between different
16 shades of light and gray; corneal ectasia,
17 which is a gradual protrusion of the corneal
18 surface; depression and its consequences. I
19 would say that most of my patients are
20 depressed, and many are on anti-depressant
21 medications.

22 From what I have seen and witnessed

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1 in my many patients, I feel at the present
2 time LASIK presents a significant public
3 health crisis.

4 CHAIRPERSON WEISS: Thank you.

5 DR. BOSHNIK: Thank you very much.

6 CHAIRPERSON WEISS: Rebecca Petris.

7 MS. PETRIS: Thank you very much
8 for the opportunity to speak.

9 I used to be a commercial jet
10 finance specialist. I left that career a few
11 year ago because of problems I suffered from
12 LASIK, chronic pain from dry eye and reduced
13 vision.

14 I started several years ago a small
15 nonprofit organization for people with
16 complications of laser eye surgery. It is
17 called Laser My Eye.

18 Dry eye quickly emerged as the
19 leading problem that we were facing from
20 people seeking out help. As a result of that,
21 I went on to start a company called The Dry
22 Eye Company to try and find more resources for

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1 people with dry eye.

2 That company runs a number of
3 informational websites for people with dry eye
4 syndrome. A large percentage, of course, of
5 the people that come there are suffering from
6 severe dry eye after LASIK, seeking out help.

7 One of the things that we do is
8 collect little known products that can help
9 people with dry eye that they are not learning
10 about from their doctors.

11 I missed the deadline to request a
12 speaking slot here, because I was too busy
13 working with these patients that are looking
14 for help after LASIK. I took a Redeye here
15 from Seattle last night, because I could not
16 tear myself off the phone.

17 I spoke yesterday morning with a
18 man in Arkansas for about an hour and a half
19 who was suicidal. He was three months post-op
20 from LASIK, and what he kept telling me was,
21 Rebecca, why didn't anybody tell me this could
22 happen? Why didn't anyone tell me how bad it

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1 could be? They told me I could get dry eye.
2 It was on the form. I understood, but they
3 said we'll give you some drops, we'll give you
4 some plugs; it will be okay, and it will
5 probably go away quickly.

6 I get these kinds of calls every
7 day, all day long. The vast majority of my
8 time is spent speaking with patients who are
9 going through this, not three months after
10 surgery, but six months, 12 months, three
11 years, six years after surgery, people who
12 have done everything and been everywhere.
13 They have traveled to national and
14 international experts, and they have not found
15 remedies, and I don't have answers for them.

16 There's been a lot of talk here
17 today from the industry saying we care, but I
18 am not seeing the compassion. I want to see
19 it.

20 There are a lot of doctors here
21 today. I wish they could be flies on the wall
22 of my office during the day, hearing the

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1 wreckage of the patients' lives and their
2 families' that are just looking for help.

3 I agree with the presenter that
4 said that depression and anxiety and suicide
5 are not -- they don't come from a single
6 factor, not just from the fact that they had
7 LASIK, absolutely not.

8 It is because they did not get
9 proper informed consent. They went through
10 the surgery. They did not get treated
11 properly afterwards. They wandered from
12 doctor to doctor afterwards. No one
13 understood their problems. They haven't had
14 solutions to the problems that they are
15 facing, financial problems.

16 They are facing a host of factors,
17 all related to the LASIK. It is not about the
18 20 minute surgery. It is about what came
19 before and about what has come after it. It
20 is the lack of solutions for them.

21 Few people understand that dry eye
22 pain after LASIK can drive people absolutely

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1 to distraction. I can't tell you how many
2 people I know are on short term or long term
3 disability now because of this kind of pain.
4 They need help.

5 If the industry were interested in
6 helping, if they are interested in helping,
7 they need to rally around the consumer groups
8 that are looking for help. They need to come
9 to us with practical solutions to help. Plugs
10 and drugs are not doing it for us.

11 We've got people we talk to that
12 have been everywhere. They have volunteered
13 for every clinical trial going. They are
14 scrounging together anything they can to just
15 hold it together from day to day.

16 I don't organized notes for
17 presentations for you today. I am simply
18 overwhelmed with the need. I feel like triage
19 nurse with all these people coming, seeking
20 help, for whom I just don't have enough
21 answers, and that is what I am here for today,
22 just to appeal to you for help to prevent more

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1 of this, and to help us get solutions for the
2 people that are facing problems from LASIK.
3 Thank you for giving me the time.

4 CHAIRPERSON WEISS: Thank you. Mr.
5 Roger Barnes.

6 LT. COLONEL BARNES: I am
7 Lieutenant Colonel Scott Barnes. I wasn't
8 sure that I would have an opportunity to speak
9 from the Army's perspective, and so I gave a
10 brief few words when I was speaking on behalf
11 of Doyle Stulting.

12 In my role as the -- I am at Fort
13 Bragg, North Carolina, as I mentioned. I am a
14 cornea and refractive surgery trained
15 specialist, and when I went through -- Prior
16 to understanding what ophthalmology was or
17 knowing anything about -- or becoming an eye
18 surgeon, I was working a different side of the
19 fence with Special Operations arena.

20 That includes the Green Berets, the
21 Army Rangers, Special Operations, Aviation
22 Regiments, which are the people that fly the

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1 helicopters that may have been popularized in
2 Black Hawk Down, and a number of classified
3 units that we don't talk about exist, but they
4 do some significant work.

5 Really since the year 2000, the
6 Army has -- or the Special Operations Command,
7 particularly, said, hey, now that you've gone
8 off and become an eye surgeon, we need you to
9 come back and help us decide if we should have
10 a refractive surgery program for these
11 particular people. I said, well, the Army has
12 decided it's a good thing.

13 They said, we don't care what the
14 Army says; we want to know from one of our
15 guys that used to be out there doing the
16 things that we are doing, jumping out of
17 planes and diving and flying helicopters -- we
18 need to know, is it safe for us, because we
19 don't trust anybody, even the Regular Army.

20 So I said, sure, I'll come up to
21 Fort Bragg, and I'll spend a couple of years
22 doing some work to help decide if this is the

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1 program that we should institute.

2 Now these guys are fairly unique,
3 and to dispel any rumors, they don't just take
4 everything. They complain a lot. If
5 something isn't perfect, they complain. If
6 things don't work out well for them, they
7 complain, and they don't have any qualms in
8 saying you screwed up my life, if we do
9 something wrong.

10 So it behooves us as physicians to
11 make sure that we are going to be giving them
12 something that is going to enhance their
13 quality of life, make them be able to do their
14 job better, and to avoid problems if they are
15 there; and we all know that problems can occur
16 in any surgical procedure. Everyone has said
17 that.

18 The bottom line with most of these
19 guys -- and they were very concerned when I
20 talked to them and said, hey, I'm going to be
21 going up to Washington, D.C., and I may have
22 an opportunity to speak on your behalf. And

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1 they said, doc, whatever you do, tell them
2 that, no matter what happens anywhere else,
3 please don't take this away from us. Please
4 don't take it away from us.

5 When I go out there -- they call it
6 outside of the wire," outside of the protected
7 area -- When I go outside of the wire and I
8 can't see somebody as well as they can see me,
9 that's a significant quality of life issue.

10 If I end up losing my glasses when
11 I jump out of a plane at 25,000 feet, I can't
12 stop on the way to Pearl Vision and get a set
13 of glasses. It affects my quality of life.
14 It affects what I am able to do, what I can do
15 for the guys that are depending on me.

16 So it's a significant issue for
17 these guys. They are not talking about
18 cosmetic needs. They are not talking about it
19 would be nice to not take my pictures in
20 glasses. They are saying, I can't do my job
21 as well in glasses or contacts as I can after
22 refractive surgery.

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1 So it makes -- And when they go off
2 to battle, they end up knowing that if they
3 ever get caught as a prisoner of war, if they
4 are -5, 06 diopter myope, the first thing that
5 is always done is that your glasses are broken
6 and taken from you. They don't even need to
7 put a guard on you. You will not be able to
8 find your way out when you can't see.

9 If they are lost and behind enemy
10 lines, and they are trying to evade and trying
11 to depend on maybe seeing some of their guys
12 come by so they can get rescued, they are not
13 going to jump out of the bushes when they are
14 a 06 myope and say I can't even see who that
15 is. I'm not going to jump up and say are you
16 an insurgent or are you my buddy, because it
17 is a life risk for them to do that.

18 So for them to say, I don't have to
19 wear glasses or contacts, I now can see to see
20 my own guys, I can see to distinguish bad
21 guy/good guy, I can see to safely jump out of
22 a plane, I can see to dive underwater, I can

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1 see safely to fly a helicopter at night -- and
2 we do most of our work at night. Most all of
3 our work in the military is at night. That
4 phrase, "we own the night" -- that's kind of
5 something that we look at.

6 So night glare, halo, those issues
7 -- huge matters for us. So I don't -- I'm not
8 going to belabor the point anymore. I've
9 spoken enough on that, but the word from the
10 guys that are out there standing in harm's way
11 whose lives depend on their ability to see to
12 do their job, are asking you to please not
13 take this away. Thank you.

14 CHAIRPERSON WEISS: Thank you. Our
15 next speaker will be Mr. Joseph Schell.

16 MR. SCHELL: That's Joseph Schnell.

17 I had LASIK performed on myself on both eyes
18 on March 29, 2007, at LASIK-Plus in New Jersey
19 using the Bausch & Lomb 217A Technolas excimer
20 laser. I will be addressing quality of life
21 issues as well as commenting on my experience
22 just with refractive eye surgery and thoughts

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1 about this industry.

2 My overall experience with LASIK
3 has been and continues to be at odds with what
4 the refractive eye surgery industry,
5 specifically LASIK, advertises and promotes
6 for prospective patients. There is no event
7 in my life that has so negatively impacted my
8 physical, emotional, visual and psychological
9 health as my LASIK procedure.

10 This is so, despite having been
11 classified as having a fairly good result by
12 an anti-LASIK optometrist, having received no
13 significant determination of problems from
14 evaluations at Eye Hospital and University of
15 Pennsylvania's Scheie Institute, both located
16 in Philadelphia, PA.

17 I personally have deemed my vision
18 and eye health to be far inferior now than it
19 was before LASIK, and I am amazed at how this
20 elective procedure is pushed and promoted as
21 being so beneficial for the patient.

22 Even if there were no serious

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1 complications or side effects, LASIK's
2 effects, including intended effects, are at
3 odds with what is beneficial for patients. I
4 was shocked after having learned with the
5 passage of time that many of the so called
6 possible side effects are quite universal and
7 far from remote possibilities as the informed
8 consent and doctors, clinics, employees of
9 LASIK would have patients believe.

10 If you talk long enough to almost
11 any LASIK patient, you hear about dry hear in
12 varying degrees, lack of crisp vision compared
13 to glasses, the much worse close vision than
14 with glasses for older patients, worse
15 astigmatism, many times not correctable with
16 ordinary contact lenses or glasses and
17 sometimes not at all.

18 A former union member of mine
19 suggested I consider LASIK, because our health
20 plan covered most of the cost of the
21 procedure. He had recently had the procedure
22 done at the time he told me.

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1 About one and a half years later, I
2 heard from yet another member of the same
3 union tell me of how bitterly the first
4 mentioned member was complaining of night
5 vision disturbances and how miserable he was
6 over the effects of LASIK, and herein lies a
7 very disturbing phenomenon: Many glowing
8 testimonials from LASIK patients, despite the
9 fact their vision has markedly decreased from
10 once what it was.

11 I know of at least one reference
12 suggesting that patients of LASIK and other
13 forms of refractive eye surgery have such poor
14 dim light perception that it would render them
15 unable to obtain a driver's license in
16 Germany.

17 After LASIK, I acquired many
18 problems as a result of the surgery. At
19 night, I experience glare, halos, starbursts,
20 and disturbing astigmatism as I look at the
21 moon, traffic lights and other lights on
22 billboards and such.

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1 My dim light perception is
2 significantly less than what it was before
3 LASIK. Many times when driving, I look into
4 less lit areas of the roadway and see only
5 darkness. I still have memories of what my
6 nighttime vision was before LASIK, and it was
7 excellent. Now it is quite poor.

8 My right eye has significant
9 ghosting, even during the day. It gets
10 considerably worse when I am stressed or sick.

11 It seems as if my eyes never work together as
12 well as they used to before the LASIK
13 procedure. They are often uncomfortable
14 during the day, sometimes feeling dry,
15 sometimes feeling watery and sensitive.

16 I had floaters before LASIK, but
17 they multiplied extensively after LASIK,
18 especially in the right eye. These new
19 floaters make reading and driving more
20 difficult, on top of the other LASIK induced
21 problems I experienced, because many are in
22 the central field of my vision.

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1 Another recent problem that has
2 developed is that, when I look to my extreme
3 left, I see double of everything.

4 My eye and vision problems are not
5 the only result of LASIK. Directly coinciding
6 with the aftermath of my LASIK problems, I
7 have and continue to experience physical and
8 psychological problems as well.

9 Within one or two weeks after
10 LASIK, I began to suffer from suicide ideation
11 and extreme anxiety. Sometimes I felt like my
12 heart would just give out.

13 A clinical psychologist and
14 optometrist have told me that I am most likely
15 suffering from some form of post-traumatic
16 stress disorder. The suicide ideation had
17 mostly resolved itself from the tremendous
18 support I received from fellow LASIK sufferers
19 and doctors who treat post-LASIK problems.

20 For some months, I had daily nausea
21 and gastrointestinal upset. I still
22 experience these symptoms to this day, though

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1 not necessarily every day.

2 I have developed a swallowing
3 reflex that I cannot will away. I sometimes
4 choke on my food. I oftentimes feel as though
5 someone is pressing both of their thumbs on
6 the front of my neck under my Adam's apple.

7 I also oftentimes develop a lump in
8 my throat when driving in the dark, as I know
9 my dim light perception is not what it once
10 was.

11 I wake almost every day with very
12 dry mouth and nasal passages. Even when I am
13 feeling somewhat positive, this feeling of
14 impending dread overtakes me at times. I
15 never had the above symptoms until they
16 shortly developed after my LASIK procedure.

17 No stress or passing of loved ones
18 have come even close to the suffering I have
19 experienced, and still do, as a result of my
20 LASIK procedure and severe regret of buying a
21 package of lies that fooled me into getting
22 the surgery on two of my most precious organs.

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1 The informed consents are
2 structured and legally tweaked to protect the
3 company and the LASIK surgeon. There is a
4 statement at LASIK-Plus informed consent that
5 separates the center and surgeon as separate
6 entities.

7 I only met with my surgeon five
8 minutes before the procedure. He stated that
9 I received the informed consent one week
10 before my LASIK procedure. I told him he was
11 mistaken about that.

12 I was given the informed consent on
13 the day of the surgery, after my eyes had been
14 dilated. I could barely see the print, if at
15 all.

16 CHAIRPERSON WEISS: Would you be
17 able to conclude your comments, please?

18 MR. SCHELL: Yes. In retrospect, I
19 realize I should have exercised better
20 judgment, the way things went down, but I
21 thought LASIK had been around long enough that
22 this is the way things are done.

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1 In the brochure that LASIK --

2 CHAIRPERSON WEISS: Unfortunately,
3 we will have to end at this point. Thank you.

4 We have heard from all the speakers
5 in the public session. What I would like to
6 do before we break for lunch is open up from
7 the Panel questions to any of those who have
8 spoken.

9 Does any members of the Panel have
10 any questions? Yes, please. If you are going
11 to ask a question, for the transcriptionist,
12 if you put on your microphone, identify
13 yourself so that it facilitates their job.
14 yes, please?

15 MS. COFER: Paula Cofer, patient
16 representative. I have a question for Dr.
17 Kerry Solomon.

18 CHAIRPERSON WEISS: Dr. Solomon,
19 can you come up to the podium?

20 MS. COFER: Do I have time for
21 several questions?

22 CHAIRPERSON WEISS: Is Dr. Solomon

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1 in the room? I think Dr. Solomon has left.
2 Is there any of the other LASIK surgeons here
3 that you wanted to address that question to?

4 MS. COFER: Anyone that
5 participated in the 95.4 percent patient
6 satisfaction meta analysis, or can speak to
7 that.

8 CHAIRPERSON WEISS: Dr. Donnenfeld
9 is going to come up to the podium. Can you
10 put on the mic?

11 MS. COFER: Good morning. Thank
12 you for stepping up.

13 Are you familiar with the 95.4
14 percent meta analysis survey that was done of
15 the peer reviewed literature?

16 CHAIRPERSON WEISS: If you could
17 put a microphone on, again.

18 DR. DONNENFELD: I am familiar with
19 the article, certainly not as familiar as Dr.
20 Solomon, however.

21 MS. COFER: Okay. Well, you may
22 not be able to answer my questions, but the

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1 question that I have about it is: Would you
2 agree that the surgeons who publish in the
3 peer reviewed literature are generally
4 surgeons that perform better screening? They
5 are more conservative than the average LASIK
6 surgeon, say someone who operates at a high
7 volume LASIK center?

8 Another way to ask it is: Would
9 you agree that there is no evidence to support
10 that the studies retained in the meta analysis
11 are representative of the standard of care?

12 DR. DONNENFELD: I would suggest
13 that well trained LASIK surgeons can routinely
14 achieve the results that were obtained in the
15 meta analysis, and that the results probably
16 underestimate the quality results, since most
17 of those results were obtained with older
18 technology, using methodology that we no
19 longer use today. And I would suggest that
20 the results we see today are far better than
21 the ones that Dr. Solomon presented.

22 MS. COFER: I don't think you

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1 answered the part of my question about the
2 type of doctors that publish in the peer
3 review literature versus the doctors that do
4 not.

5 DR. DONNENFELD: As far as the
6 quality of doctors performing laser surgery, I
7 would suggest that there are always going to
8 be doctors who are better and doctors who are
9 not as good. I think it is important to
10 suggest that patients who look for laser
11 surgery, look for the best possible doctors to
12 perform their surgery.

13 I can't really comment on doctors
14 who don't publish.

15 MS. COFER: I understand. I'm just
16 interested in your opinion.

17 I have another question. In the
18 meta analysis that was published, do you
19 believe that they are suggesting that the
20 complication rate can be derived by
21 subtracting the percentage of satisfied
22 patients from 100 percent? In other words,

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1 are we looking at a four percent complication
2 rate, based on a 95 percent or 95.4 percent
3 satisfaction rate?

4 DR. DONNENFELD: Absolutely not.
5 It is impossible to suggest that complications
6 and satisfaction have a one to one
7 relationship. It is a very difficult area to
8 evaluate.

9 MS. COFER: Okay. And do you know
10 overall how far out the satisfaction surveys
11 tracked the patients in the meta analysis?

12 DR. DONNENFELD: The meta analysis
13 involved literally hundreds of studies that
14 were evaluated, and some of the studies were
15 as short as three months. Others went out two
16 years of follow-up.

17 MS. COFER: Thank you. One last
18 question. Is it true that the patients that
19 are told that complications of LASIK such as
20 dry eyes, night vision impairment -- these
21 complications will resolve with time?

22 The reason I am wording it that way

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1 is, if a patient was surveyed at six months
2 and this patient had night vision impairment
3 or dry eyes, do you think it is possible that
4 they would answer that they are satisfied with
5 their visual outcome, because they are
6 believing at six months they are expecting
7 these complications to resolve? So do you
8 think that is a factor in these surveys?

9 DR. DONNENFELD: I am not an expert
10 in epidemiology, but I can say from having
11 cared for tens of thousands of patients that
12 patients do not say they are satisfied when
13 they aren't happy, expecting to be satisfied
14 in the future.

15 Patients who are unhappy will
16 generally voice their opinions at every step
17 of the way.

18 MS. COFER: Actually, I did have
19 one more question. I'm sorry. Is that okay?

20 CHAIRPERSON WEISS: Can we make
21 this the last question that you have for Dr.
22 Donnenfeld?

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1 MS. COFER: Just one more question.
2 Did the study -- I have only seen the press
3 release. I haven't actually seen the data,
4 but did the study, the 95.4 percent meta
5 analysis study -- did it report the percentage
6 of patients that were experiencing dry eyes
7 and night vision impairment in the studies?

8 DR. DONNENFELD: I can address the
9 dry eye. I was part of that, and in the meta
10 analysis, I believe it was 35 percent of
11 patients reported dry eye following their
12 LASIK surgery, and 32 percent of patients
13 reported dry eye prior to their surgery.

14 So that dry eye does occur after
15 surgery. It is a very common problem that we
16 see. Probably one in four adult individuals
17 in the United States experiences some form of
18 dry eye. So that it does occur after surgery,
19 as it does occur before surgery as well, and
20 that at times laser surgery can make dry eyes
21 worse.

22 MS. COFER: The information on the

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