EXHIBIT 3

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Why I do not recommend Nevyas Eye Associates!

After damaging my eyes with Refractive Surgery, Drs. Herbert Nevyas and Anita Nevyas-Wallace sued to silence me. These are my medical and legal experiences with Drs. Herbert Nevyas and Anita Nevyas-Wallace of Nevyas Eye Associates.

My intention with this site is to update and further prove all allegations I brought against Anita Nevyas as documented on my previously owned website LasikSucks4u.com and now LasikDecision.com. I would also like to show how I believe the courts were misled in many of their decisions and/or opinions regarding my med mal lawsuit Morgan v. Nevyas and the current Nevyas v. Morgan lawsuit.

Drs. Herbert Nevyas & Anita Nevyas-Wallace

Bala Cynwyd, PA / Philadelphia, PA / Marlton, NJ

My experience with Drs. Herbert Nevyas and Anita Nevyas-Wallace (Nevyas Eye Associates), information regarding their investigational study, and the legal battle to retain my free speech rights.

My Experience

My Lasik experience started in 1998. I'd been hearing about Lasik surgery for some time, and after wearing thick glasses for thirty years, I decided to look further into las vision correction. In March, 1998, I went for my initial consultation at Nevyas Eye Associates in Bala Cynwyd (Philadelphia area), Pennsylvania. They were advertisi extensively (for Lasik...with a laser under an IDE (Investigational Device Exemption) Please see the Nevyas Eye Associates section of this site). At over four hours, the pre-op exam seemed very long, but was not complete, due to my prior history of 'retinopathy of prematurity' or ROP (I was born two and one-half months early, and received too much oxygen in the incubator, thereby damaging some retinal nerves). Anita Nevyas-Wallace, the doctor (who performed my Lasik surgery) stated she foresaw no problems and thought me to be a good candidate. Two weeks later, my initial evaluation was complete, and I was reassured I was to be a "good candidate" for this Lasik procedure. I was NOT told that a change in prescription gave me bett than the 20/50 Best Corrected Visual Acuity (BCVA) I ever had, and that instead of the Lasik, the new prescription would have worked just as well if not better than wha was seeing (refracted to 20/40 -2 according to their records).

Because of the ROP, Dr Nevyas-Wallace sent me to see a retinal specialist in their own group to determine whether this would cause any problems in connection with Lasik. I was told there would be no contraindications (problems), and again was reassured that it would be okay to have surgery. I did not ever expect to have 20/2(

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better than what I was seeing (refracted to 20/40 -2 according to their records).

Because of the ROP, Dr Nevyas-Wallace sent me to see a retinal specialist in their own group to determine whether this would cause any problems in connection with Lasik. I was told there would be no contraindications (problems), and again was reassured that it would be okay to have surgery. I did not ever expect to have 20/20 vision, and was happy with the 20/50 (or maybe a line better, 20/40) prediction the doctor assured me, since the 20/50 was my best correction with glasses. I was elated at the thought of not having to wear glasses anymore, and with the very promising outcome predicted, and being told several times I was a good candidate, decided to have surgery.

Two weeks later, I had surgery on my left eye, and a week after that, on my right eye. The day after, looking through the plastic shield was probably the best vision I ever had in each eye without glasses, but during the daytime only, and did not last. My night vision was filled with halos, starbursts, glare, and ghosting. My vision was still way off, and fluctuated severely, depending on light levels. I was told that as my corneas healed, my vision should improve, and the severe night problems would stop, usually in about three to six months. Later I was told this could take up to one year. After the first year, the doctor just kept adding on time, finally stating the problems I was experiencing could be permanent. Almost seven years later, I still have these same problems.

At one day post-op and four days post-op, each cornea looked okay according to the doctor, but I was still experiencing problems. About two weeks after surgery, I was fitted for soft contacts to determine whether the problems could be eased while my eyes healed. I went through three different prescriptions in as many months. The third month, I was fitted for gas-permeable hard contact lenses, because of continued problems. Consequently, I decided to see another ophthalmologist for another opinion, as I was getting more and more upset with the way I was seeing and what I was being told.

This is my nineteenth visit since my initial consultation five months ago. These visits have been averaging between two to eight hours, with about 15-20 minutes with the surgeon. Yes, I'm getting more frightened by now, especially after hearing what my second opinion doctor told me, that he could not help me get my vision back to what it was prior to Lasik. After five more visits, the surgeons at Nevyas Eye decided that the problems were retinal due to the ROP.

After three more months and three more visits, the doctors were unable to help me. More gas perms and the same results, So I went to another specialist, this time at Wills Eye Hospital, and they couldn't help me either (and that's number twenty four!).

In July '99, Dr. Herbert Nevyas, the doctor who runs the laser center (Anita's father) I went to told me "Deal with it...People lose their sight every day...I'll see you in 8 months" (as I stated in depositions)...I was livid!

1999 brought even more distressing results. Five more retinal evaluations, three more corneal evaluations.

The following month, I had a low vision evaluation. My prescription was changed again, but not with better results. I then ventured to John Hopkins' Wilmer Eye Institute in Baltimore. After seeing several world renowned specialists, I still could not get any help for my post-Lasik eyes. After another visit to the laser center where I had surgery, and another visit to a low vision specialist, it was decided that glasses and contacts would not work. I was fitted for bioptic and mirage lenses. How fitting it is to have Lasik surgery and not be dependent on glasses (due to the fluctuation of vision and constant focusing of these glasses, they were essentially useless)! How I looked like a freak with these things on, and boy, how people stare at what they do not understand!

Two more visits and I ended the year 1999. How pathetic this is...over eighteen months and thirty four visits to doctors and hospitals, and still nobody was able to help me. I was determined to find somebody who could help my post-Lasik eyes and get my vision back to where it was prior to Lasik. I know that something happened, because I did not have these problems prior to Lasik.

In 2000, things did not get any better. Same problems, no help for my vision. Again I ventured back and forth between doctors still seeking to get my vision back prior to Lasik. Eight more visits to end the year, for a total of forty six visits to different doctors and hospitals. Nobody was able to help me.

I am pretty much done with the doctors now, because NOTHING CAN BE DONE. I've had three visits in 2001, and five in 2002. Of the visits in 2002, I saw Dr. James Salz in California (who afterwards became one of my experts for my medical malpractice lawsuit), one of the (if not THE) foremost authorities in this field. Another top Doctor I saw was Dr Terrence O'Brien at John Hopkins. Bottom line is after reviewing ALL of my records since having had Lasik, I cannot be corrected because some of the damage was due to increased pressure from the suction cups used to lift the corneal flaps. Dr. Salz stated I SHOULD NOT HAVE EVER BEEN CONSIDERED A CANDIDATE FOR LASIK and submitted to my attorney many reports.

Dr. Salz' Website

I can only hope and pray that somebody out there will be able to help us, and if you're still not convinced of the risks:

Other horror stories: www.surgicaleyes.org, www.lasikdisaster.com, lifeafterlasik.com, www.lasiksos.com,www.lasikcourt.com, www.lasikmemorial.com, which are listed at http://www.escrs.org/eurotimes/March2003/primesite.asp also, as well as many others. There are casualties out there who have not posted sites, as well as many others who were offered out of court settlements, and not brought their cases to light due to confidentiality.

Herbert Nevyas 2007 Letter To NJ DMV

Dr. Herbert Nevyas sent the following letter to New Jersey's Motor Vehicle Commission on July 31 2007, ***OVER 7 YEARS SINCE MY LAST APPOINTMENT WITH THE NEVYASES****! I believe that this should have been done at most within either the first 2 years since my surgery, maybe even 2 years after,* ***not 7****!*

To Whom It May Concern:

I have serious concerns about the driving skills of Mr. Dominic Morgan (DOB 8/8/1960) of [redacted] (alternate older address [redacted]).

It is my understanding that Mr. Morgan maintains a valid New Jersey driver's license, even though he is no longer licensed in Pennsylvania. I examined Mr. Morgan from an ophthalmologic standpoint several years ago, and he reported vision as low as 20/200 in each eye when I last saw him. I know that he has been judged legally blind after an examination by Dr. John D Dugan, Jr. in Vorhees, NJ, and that he is presently receiving Social Security Disability payments because of his legal blindness.

I think that Mr. Morgan should be re-evaluated by your impartial examiner and his license revoked if he does not measure up to the appropriate visual standard. I would not want to be responsible for allowing a legally blind driver to be on the highway.

Sincerely,

Herbert J. Nevyas, M.D,

The pdf of this document (redacted) **is available here**.

Before The Nevyas' Study

It started with Ed Sullivan, the guy who built the 'Nevyas Laser', a man already under scrutiny by the FDA...

"Ed Sullivan, doing business as ExSull, Drexel Hill, Pa, has been put on notice by the FDA that the agency regards him "clearly as a manufacturer with multiple manufacturing sites" subject to

FDA rules and regulations and, if he makes another one of these excimer lasers "which are unapproved devices," he will be in violation of the federal Food, Drug and Cosmetics Act and subject to legal penalties, according to top-ranking FDA officials within the national Division of Enforcement." [as written in The Journal of Refractive Surgery - Volume 11 (5) * September/October 1995 * News, which was removed from the url address http://www.slackinc.com/eye/jrs/vol115/news1.htm].

And the FDA knew that! From the affidavit Herbert Nevyas submitted to the FDA, it tells of Ed Sullivan building their laser. However, documents show Mr. Sullivan in teleconferences and meetings with the doctors and their laison with the FDA well **after** this article was written.

After I received inspection reports even less redacted from the FDA regarding inspections of the Nevyas' facility, the FDA promised "to do what they could to help me", but then refused after copies of the inspection reports were returned. In fact Les Weinstein, the CDRH Ombudsman, outright told me (through his secretary) he could no longer have any communication with me. It seems to me (based on my communications with the FDA) that the FDA was more concerned with being sued by the Nevyases for the information released, then by doing the right thing.

The inspection reports of Sullivan's facility below were obtained via the Freedom Of Information Act. Regardless of these reports and the articles written concerning 'Homegrown Lasers", is this what the FDA considers "protecting the public's safety"?

Click PAGE # to open pages in new window

PAGE 1 - *Previous inspection, 5/16/96, was a follow up to a Warning Letter issued on 8/17/95. The Warning Letter informed the firm that the FDA considered ExSull, Inc., to be a manufacturer of a Class III medical device, that was both adulterated and misbranded, in that there were no approved PMA or IDE for any of the devices and that the firm itself was not registered as a medical device manufacturer.*

PAGE 2 - *Mr. Sullivan stated that "he called the FDA and was sent material relating to the building of "custom devices", and that the FDA person he had spoken to over the telephone assured him that it was okay to build them in the Doctor's office".*

PAGE 3 - *Repeated attempts to schedule a subsequent meeting with Mr. Sullivan (via my leaving numerous messages on his voice mail) were unsuccessful. Mr. Sullivan would not commit to a date and time, when he returned my repeated phone calls, and in some instances did not even return my phone calls. Only after inadvertently meeting him at one of his client's (on 6/25/97), did he then agree to see me at his ExSull, Inc.,*

PAGE 4 - *Mr. Sullivan stated that he did not have any standard procedures for assembling the device. He stated that the device components are delivered to each physician's office, where he then assembles the compete excimer laser. He informed me that he will then test the laser,* ***but that he does not have any performance specifications, written assembly instructions or quality control tests.***

PAGE 5 - *and that any involvement by Mr. Sullivan in a sale, would depend on the nature of the sale. He would not elaborate on that statement, but explained that it means that he is not involved in every sale.*

PAGE 6 - *Mr. Sullivan informed me that he has not contracted to build any additional units, since he assembled the device for* [redacted] *in October 1996. On 6/26/97, Mr. Sullivan showed me a copy of an IDE for that same client* [redacted], *Mr. Sullivan explained that he was working on the document, and an examination of the IDE showed that the unit had been used to treat at least* [redacted] *patients, without an approved IDE. Mr. Sullivan would not allow me to copy this document, and stated that the FDA already has this IDE on file.*

PAGE 7 - *Mr. Sullivan did state that he will be publishing an article with a Dr. Herbert Nevyas, regarding the use of the ExSull, Inc., excimer laser for treatment of a patient with an irregular cornea, due to an eye injury.*

PAGE 8 - *According to Mr. Sullivan, this entire process (the exchange of laser beam requirements and the design specifications) is all done via telephone or personal visits, and* ***he does not have any written records of the design specifications****. He stated that each individual physician should have those records. Mr. Sullivan stated that he knew of no injuries with the device.* ***He did say that in theory the laser would have some patients possibly experiencing overcorrection, but that the majority would experience a slight***

undercorrection, which might require additional treatment. *In addition, he explained that there has been no hazing or scaring, with the devices. He stated that the physicians handle all of the complaints from the patients, and that he is not aware of any major complications.*

PAGE 9 - *Mr. Sullivan informed me that he designed the hardware for the "beam shaper" or "beam sculptor", as well as, the software that controls that hardware. He stated that his program was written in [redacted] and that three versions have been made, of that software. He informed me that he had no documentation or procedures for upgrading or changing the program (at the [redacted]. In addition, he could not provide any information regarding which of the software versions are in any of the particular devices, stating that he did not keep any of those records.*

PAGE 10 - *Mr. Sullivan gave his permission for me to observe the calibration procedure. I was allowed to examine the optical compartment, including the "beam shaper" or "beam sculptor", designed by Mr. Sullivan. Mr. Sullivan would not let me photograph this part of the device.*

PAGE 11 - *He informed me that he is only a consultant, and that each device he assembles is considered a "Custom Device". He confirmed that he did not have any medical device manufacturing records, such as Master Device Record or Device History Record. I asked Mr. Sullivan if the firm had a Device Master Record or Device History Record. He responded that he considers himself a consultant, and that he does not keep any records of design specifications, manufacturing specifications or a device History Record. He stated that each of the physicians might have any documentation for the specifications or design, for their device.*

PAGE 12 - *During the inspection, Mr. Sullivan stated that the firm's computer, used to store all of the business records, had experienced a "hard drive crash", in the winter of 1996. He explained that consequently all records from 1994 to December 1996 have been lost.*

PAGE 13 - *He stated that he does not keep any repair or service log books, or a records of any complaints regarding the performance of the laser, by the physicians.*

PAGE 14 - *There are no Exhibits with this EIR, due to the unavailability of records at the firm.*

PAGE 15 - *The observations noted in this FDA-4B3 are not an exhaustive listing of*

objectionable conditions. FDA 483 issued.

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The FDA issued warning letters regarding the lasers Sullivan built, but **STILL** allowed doctors to further modify and use these devices on people considering LASIK!

Warning Letter 1 <> Warning Letter 2

Nevyas' Investigational Study

The following letters are from the FDA to Drs. Herbert Nevyas and Anita Nevyas-Wallace throughout their investigational study, and after their study was terminated. Despite continued deficiencies as noted below, the FDA kept granting the Nevyases Approvals for their study. Based on documents received during my med mal and the current Nevyas v. Morgan lawsuits, **I believe the Nevyases constantly misrepresented themselves and their study to both Schullman Associates (the Nevyases IRB) and the FDA:**

All BLUE font on this page designate links to documents which should open in new window.

May 1997

IDE Disapproval Letter from the FDA to Nevyases dated 05/08/97:

PAGE 1 - *The Food and Drug Administration (FDA) has reviewed your investigational device exemptions (IDE) application. We regret to inform you that your application is disapproved and you may not begin your investigation. Our disapproval is based on the deficiencies listed below.*

PAGE 2 - Deficiencies listed.

PAGE 3 - *Please explain the low effectiveness and safety outcomes achieved in your prior clinical studies and specify what steps you are taking to improve your results. Your refractive and visual outcomes were reported at one month as: MSRE for low myopes, < 57% were within ID and < 35% were within 0.5D; less than 60% achieved BUCVA > 20/40; complication and adverse events occurred in >*

2% of the cases.

PAGE 4 - *Please provide your agreement (or justification for not agreeing) that retreatments done to improve refractive outcome are NOT considered as treatment failures, whereas retreatments done to achieve resolution of an adverse event ARE considered as treatment failures.*

PAGE 5 - *Your description of study procedures, examination conditions and techniques is not adequate. Please provide a detailed description of each procedure, test and instrument to be used in the study.*

PAGE 6 - *For your follow-up visit schedule, the text on page 20 of the protocol appears to be inconsistent with the chart on page 43 of the protocol. In addition, please justify your statement on page 20 that measurement of corneal topography will be at the discretion of the investigator.*

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July 1997

Letter from the FDA to Nevyases dated 07/29/97 to cease using Laser:

PAGE 1 - *FDA is aware that a number of physicians are using lasers for refractive surgery to treat patients even though there is no PMA or IDE in effect for their lasers. Based on the results of our investigations, we believe that you are currently using your laser to treat patients.*

PAGE 2 - *Accordingly, on July 28, 1997, we called you to notify you that use of your excimer laser to treat patients would violate the Act and requested that, if you are presently using the laser to treat patients, you immediately cease doing so.*

Nevertheless, FDA does intend to consider any use of your laser to treat patients after the close of business July 28, 1997 unless and until the agency approves an IDE for your device to be grounds for disapproval of your IDE.

PAGE 3 - *We also want you to know that if FDA approves your IDE application, you would be able to use your laser to perform only specific procedures on a limited number of subjects to demonstrate the safety and effectiveness of your laser for those procedures. Studies conducted under such an IDE would be subject to all IDE regulations. See 21 C.F.R. Part 812. For example,* ***you would be prohibited from***

promoting and commercializing the laser, and from representing that the device is safe and effective.

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August 1997

'Conditional' Approval Letter from the FDA to Nevyases dated 08/07/97:

PAGE 1 - *Your application is conditionally approved because you have not adequately addressed deficiency #2 cited in our May 8, 1997 disapproval letter.*

Also, we are in receipt of your certification (Amendment 4 received August 1, 1997) that you have not used the laser as of the close of business on July 28, 1997, and that you will not use the laser unless and until FDA approves the IDE applic2tion for your device

PAGE 2 - *This approval is being granted on the condition that, within 45 days from the date of this letter, you submit information correcting the following deficiencies.*

PAGE 3 - Deficiencies listed.

PAGE 4 - Deficiencies listed.

PAGE 5 - *We have enclosed the guidance document entitled "Sponsor's Responsibilities for a Significant Risk Device Investigation" to help you understand the functions and duties of a sponsor.*

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October 1997

Letter from the FDA to Nevyases dated 10/03/97:

PAGE 1 - *We acknowledge receipt of your institutional review board (IRB) approval (supplement 3). Supplement 4 responds to our conditional approval letter of August 7, 1997 and requests: an increase crease in treatment range from -6.75 ID to -22 ID; approval to study simultaneous bilateral treatment; and, approval to retreat approximately 125 patients previously treated with this laser prior to IDE approval.*

PAGE 2 - *Requests for additional subjects for enhancements for prior clinical patients will be evaluated as additional data is submitted to support stability of the procedure.*

PAGE 3 - *You agree that you will not perform retreatment procedures for subjects initially treated under this IDE. Retreatment (enhancement) for subjects initially treated under this IDE is appropriate only after your preliminary data demonstrate safety and indicate the time point of stability of the procedure. You may begin retreatment procedures only after FDA has approved your retreatment study plan and data to support stability.*

PAGE 4 - **PAGE 5** - **PAGE 6** - **PAGE 7** - **PAGE 8** - **PAGE 9** - **PAGE 10** - Deficiencies listed.

PAGE 11

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December 1997

Approval Review Letter from the FDA to Nevyases:

PAGE 1 - *The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application. Your application remains conditionally approved because your supplement adequately addressed only deficiency 2 cited in our October 3, 1997 letter.*

This approval is being granted on the condition that, within 45 days from the date of this letter, you submit information correcting the following deficiencies.

PAGE 2 - *You are reminded that prior to a request for expansion beyond 150 subjects, you should provide adequate responses to deficiencies 5 16 in our letter of October 3, 1997.*

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FDA INVESTIGATIONAL STUDY AFFIDAVIT

The following pages are an Investigator Agreement issued by the FDA to a Sponsor/Investigator of an investigational study. Nevyas refused to sign...

PAGE 1 - Investigator agreement signed by Anita Nevyas-Wallace

PAGE 2 - Investigator agreement signed by Herbert Nevyas

PAGE 3 - "*I informed Mr. Kane, that Mr. Sullivan told me that the excimer laser that he would build, is considered a custom device and would not be regulated by the FDA. Mr. Sullivan completed the assembly of the laser in the fall of 1995, and the first patient was treated (using LASIK) in January 1996.*"

PAGE 4 - "*I did not maintain any written records of the design specifications, nor did I receive any written design specifications from Mr. Sullivan.*"

PAGE 5 - "*This patient is not part of the patient population included in my IDE submission. I have treated a total of 252 patients, from January 1996 to the present date (6/30/97),*"

PAGE 6 - "*I affirm that the information on this and the previous pages, is accurate, to the best of my ability.* ***I have read, but would not sign this affidavit.***"

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Nevyases were issued an FDA483:

PAGE 1 - *There was no documentation to show that the CI notified the IRB about all amendments, changes of significant deviations to the protocol [per IRB requirements] prior to implementation. For example, the FDA granted your firm an increase in the number of subjects you could treat with your investigational device on Jan. 20, 1999. IRB. Annual Review dated 7/29/00 does not indicate the IRB knew about population increase. The IRB did not approve the population increase until. August 28, 2000, 20 months later.*

The firm is not complying with the Investigator Agreement which was signed and dated by the Clinical Investigator at the beginning of the Clinical Study.

There was a lapse of IRB approval for the protocol: NEV-97-001 from 8/3/2000 until 8/29/2000 according to IRB, lapse notices and the IRB annual reapproval letter.

January 1998

Approval Review Letter from the FDA to Nevyases:

PAGE 1 - *In your "Substudy for Same-Day Versus Different Day LASIK Treatment for Fellow Eyes": a. Please revise your informed consent document rider for same day surgery to state that the second eye will be rescheduled if there is a complication or an adverse event with the first eye.*

PAGE 2 - *Your statement in the rider to the informed consent document that "...There have been no failures or malfunctions of the Willis Excimer Laser", should be removed or altered. It may unduly influence potential same day fellow eye surgery candidates into believing that the Nevyas Excimer Laser cannot fail. FDA recommends that you remove this statement or alter it to read: "There have been no failures or malfunctions of the Nevyas Excimer Laser to date."*

PAGE 3 -

April 1998

Letter from the FDA to Nevyases dated 04/01/98 Re: Pre Market Approval (PMA):

PAGE 1 - Offers suggestions from the FDA should the Nevyases submit their PMA.

PAGE 2 -

May 1998

Approval Letter from the FDA to Nevyases dated 05/14/98 Re: Contrast Sensitivity & Increased 'Subjects':

PAGE 1 - 'Conditional' approval for substudy and increase of 'subjects'.

PAGE 2 - *We acknowledge your request in your original IDE (dated March 18, 1997) to conduct a study at one site with 400 eyes low myopia and 590 eyes high myopia for each of two investigators (single site total of 1980 eyes or 990 subjects). We believe that adequate safety information has been provided to allow the initiation of your study with a small expansion of an additional 75 subjects (150 eyes). We will allow you to expand to the full number of subjects for this study (990) after you have received approval of*

supplements addressing the following deficiency from our letter of October 3, 1997 (enclosed). No additional expansions of your IDE will be granted until supplements containing the following information are approved:

PAGE 3 - *You should also give serious consideration to the following items which are considered essential for the analysis of your data for the purposes of determining safety and effectiveness for a future PMA application: Deficiencies 5 through 16, excluding deficiency 14, in our letter of October 3, 1997.*

July 1998

"Conditional" Approval Letter from the FDA to Nevyases:

PAGE 1 - *FDA cannot approve your request as proposed because you have not shown stability of manifest refraction, and you have not presented sufficient detail for your hyperopic retreatment. FDA will conditionally approve, however, an expansion to include myopia and myopic astigmatism retreatments at this time.*

PAGE 2 - *This approval is being granted on the condition chat, within 45 days from the date of this letter, you submit your agreement to: 1. conduct the investigation within the modified limit, i.e., retreatment for myopia or myopic astigmatism only; 2. extend the minimum time between the initial operation and the retreatment to 3 months; and, 3. retreat only eyes which are "white and quiet" and in which refractive stability has been documented with two manifest refractions taken at least 30 days apart at less than 1 diopter of—change, confirmed by topography.,*

PAGE 3 -

September 1998

Approval Letter from the FDA to Nevyases:

PAGE 1 -

PAGE 2 -

Nevyases' Co-Investigators (dated 10/01/98)

I started some time ago to contact the doctors on this **LIST** the Nevyases sent to the FDA, as being co-investigators. Three of those contacted who responded have never even heard of the Nevyases.

December 1998

Approval Letter from the FDA to Nevyases:

PAGE 1 -

PAGE 2 -

January 1999

Deviations of Nevyas Eye Associates, As Stated In Letter from the FDA dated 01/07/99:

PAGE 1 - *Our review of the inspection report submitted by the district revealed deviations from Title 21, Code of Federal Regulations, (21 CFR), Part 812 - Investigstional Device Exemptions and Part 50 - Protection of Human Subjects and Section 520(g) of the Act. The deviations noted during the inspection were listed on form FDA-483, "Inspectional Observations," which was presented to and discussed with you at the conclusion of the inspection.*

PAGE 2 - *Use of the Summit laser at your Marlton, New Jersey site for off-label procedures is not included in your IDE protocol. Moreover, enhancements approved under your IDE do not include hyperopic procedures. It is therefore considered a protocol violation to retreat subjects of your IDE study using the Summit laser and performing hyperopic LASIK.*

PAGE 3 - *While your Marlton, New Jersey site has a Summit laser, the advertisement does not specify a location. Future advertisements should specify the location(s) of approved lasers, as the enclosed advertisement would not be appropriate for soliciting subjects for your IDE study. All promotional materials designed to solicit participants or to inform subjects about the IDE study need to be approved by the reviewing IRB.*

Approval Letter from the FDA to Nevyases dated 01/20/99:

PAGE 1 - *Please be aware of the following: In Table 1-1, the data appear to be quite scattered, with some subjects actually increasing in sensitivity during glare (e.g., see BC & CB at 3 cycles per degree (CPD)), while others are severely compromised (see ZM). In order to reduce variability in the data in the contrast sensitivity study, the person administering the test should have experience in this test and the subjects should be well trained prior to testing.*

PAGE 2 - *We continue to be concerned that your ablation is likely to have multifocal properties, which means some light will be out of focus even at the best focal plane.*

November 1999

Request Letter from the FDA to Nevyases:

PAGE 1 - *1. Please separate IDE subjects from pre-IDE subjects in all of your tables, or report only on IDE subjects.*

PAGE 2 -

January 2001

Letter from the FDA to Nevyases Re: Non-Response To Request:

PAGE 1 - *The Food and Drug Administration (FDA) granted approval of your investigational device exemptions (IDE) application on August 7, 1997. As part of your responsibilities as sponsor of a significant risk device investigation, you are required to submit a progress report to FDA and to all reviewing institutional review boards (IRBs) on at least a yearly basis. We have not received a response to FDA's November 10, 1999 request for additional information regarding your August 1998 — August 1999 annual progress report (enclosed).*

PAGE 2 -

April 2001

Request Letter from the FDA to Nevyases:

PAGE 1 - *Please address the following questions/concerns, as well as provide the information requested*

in the tables enclosed with this letter.

PAGE 2 - *8. With regard to your future PMA submission, you have indicated that only subjects treated with the "new centration technique" will be included in the PMA, and that you have selected the eyes treated between 2/19/98 and 11/22/99 as the cohort to support the safety and effectiveness of the device. We would like to clarify that data from all subjects treated. under the IDE should be included in the PMA. The main PMA cohort on which the decision of the safety and effectiveness of the device will mainly rest may be limited to all eyes treated with the new centration technique, but not to only those enrolled during a given period of time, as you appear to have suggested.*

PAGE 3 -

July 2001

Disapproval Letter from the FDA to Nevyases:

PAGE 1 - *The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application proposing two new clinical protocols to evaluate the spherical ablation algorithm. We regret to inform you that your supplement is disapproved and you may not implement the change in your investigation. Our disapproval is based on the following deficiencies which, unless otherwise specified, relate to both protocols:*

PAGE 2 - *3. You have not provided in your protocol the methodology for performing any of the clinical evaluations. For each clinical evaluation, please specify the testing procedures and instruments that will be used, including the lighting conditions and charts you will use to measure distance vision and near vision, etc.*

PAGE 3 - *7. Your protocol states that subjects must have a best spectacle corrected visual acuity (BSCVA) of at least 20/40 in each eye in order to be enrolled in the study. Please be advised that while we find this criteria acceptable for subjects with high myopia (≥7 D MRSE), in order for subjects with low myopia (< 7 D MRSE) to be enrolled, we recommend a BSCVA of at least 20/25 in each eye. Please revise your protocol accordingly, or justify not doing so.*

PAGE 4 - *21. The Conclusion section of the consent form stares, "There is always a possibility of one or*

more late complications That were not known or anticipated at the time of this writing (1997)." It also states, "LASIK is investigational surgery and as such, it has not yet been completely and exhaustively studied by the FDA and medical researchers in this country." Please update the consent form as necessary in keeping with current knowledge including the additions previously mentioned. Please revise the second statement to Improve its accuracy: LASIK is no longer investigational, it has never (page 5) been studied by the FDA, and the FDA does not regulate LASIK, only the devices used for the procedure.

PAGE 5 - *28. There are discrepancies in the way you refer to the protocols throughout the submission. For example, in the Introduction you refer to the new protocols as NEV-97-002 (Myopia/Myopic Astigmatism) and NEV-97-003 (Hyperopia/Hyperopic Astigmatism). However, the myopia protocol itself has been labeled with the protocol number NEV-01-002. To avoid confusion, please make all necessary revisions in any future submission to correct such discrepancies.*

PAGE 6 - *With respect to the profiles of your ablated PMMA samples:*

PAGE 7 - *The deficiencies identified above represent the issues that we believe need to be resolved before your IDE application can be approved. In developing the deficiencies, we carefully considered the relevant statutory criteria for Agency decision-making as well as the burden that may be incurred in your attempt to respond to the deficiencies.*

PAGE 8 - *34. Please be advised that for possible future pre-market approval, although 300 eyes total are needed to support overall safety, data from approximately 125 eyes are needed to support each indication for which approval is being sought.*

August 2001

Supplement Disapproval Letter from the FDA to Nevyases:

PAGE 1 - *We regret to inform you that your supplement is disapproved and you may not implement the change in your investigation. Our disapproval is based on the following deficiencies: 1. An important function of the software in the device is to control the beam delivery hardware (iris size, slot movement, synchronizing iris/slot with laser pulses, etc.) in the creation of an ablation pattern. This area, however, is not discussed at all in the Software Requirement Specifications document.*

PAGE 2 - *The deficiencies identified above represent the issues that we believe need to be resolved before your IDE application can be approved.*

PAGE 3 -

February 2002

Nevyases Deviations and discrepancies continue almost 5 years into their study - Letter from the FDA to Nevyases:

PAGE 1 - *Please address the following, questions and concerns with regard to this submission, which also applied to the previous, delinquent, annual report as outlined in FDA's letter of April 10, 2001, and for which we never received a response:*

PAGE 2 - *5. Please provide tables (similar to those requested for initial treatments) and narrative summarizing the results of the IDE substudy of enhancements for 25 subjects/50 eyes that had undergone treatment prior to implementation of the IDE, and of the data from enhancements performed for eyes enrolled under the IDE. Please provide separate analyses for the first enhancement, second enhancement, etc.*

PAGE 3 - *1. Please note that, based on the stability analyses you have provided in this submission, we do not agree that the time point of stability is at 12 months postoperatively as you have indicated, and, in fact, may be earlier for some of the indications.*

PAGE 4 -

April 2002

IDE Deficiencies Request Letter from the FDA to Nevyases:

PAGE 1 - *1. You must still provide responses to deficiencies 1, 2, 3, and 5 froth our letter of February 6, 2002. 2. You did not provide the requested information in your response to deficiency 4.*

PAGE 2 - *4. In response to deficiency 8, you have indicated how you will verify your current accountability for visits that have already past. After your internal audit is complete and you have more*

insight as to the reasons for any problems with accountability, please directly address the original issue outlined in previous deficiency 8: please describe how you intend to improve subject follow-up and data reporting during the rest of the course of your IDE study.

PAGE 3 - Attachment: *In a reply to Dr. Morris Waxler, FDA's Chief Medical Device Examiner, Dr. Herbert Nevyas states "Since the close of business on July 28, 1997, neither I nor anyone else has used the laser. I certify that, unless and until FDA approves the IDE application for that device, neither I nor anyone else will use the laser to treat patients. I have notified all of my employees, as well as anyone with access to the laser, that the laser may not and will not be used until there is an approved IDE in effect for that laser. I declare that to the best of my knowledge the foregoing is true and correct."*

Nevyas' Investigational Laser

The following documents were submitted to the FDA from 1997 through 2001 regarding the "Nevyas Investigational (Black Box) Laser"

The laser was built by Ed Sullivan who, according to the excerpt below, was already under scrutiny by the FDA.

"Ed Sullivan, doing business as ExSull, Drexel Hill, Pa, has been put on notice by the FDA that the agency regards him "clearly as a manufacturer with multiple manufacturing sites" subject to FDA rules and regulations and, if he makes another one of these excimer lasers "which are unapproved devices," he will be in violation of the federal Food, Drug and Cosmetics Act and subject to legal penalties, according to top-ranking FDA officials within the national Division of Enforcement." [as written in The Journal of Refractive Surgery - Volume 11 (5) * September/October 1995 * News and was found at the url address: http://www.slackinc.com/eye/jrs/vol115/news1.htm">http://www.slackinc.com/eye/jrs/vol115/news1.htm (no longer available).

Click PAGE # to open page in new window

NOTES: Page numbers with an "l" designate the page as landscape. All BLUE font on this page

designate links. ***Some PDF documents may require a decrease in magnification for better clarity.***

PDF Documents (for high speed or download)

To view ALL DOCUMENTS listed below in one PDF (two parts), click HERE.

1997 Reports

PAGE 1 - Prohibition of promotion and other practices. - *21 CFR. § 812.7*

PAGE 2 - Protocol NEV-97-001: Myopia with or without astigmatism - Study Procedures.

PAGE 3 - Protocol NEV-97-001: Inclusion/Exclusion Criteria.

PAGE 4 - IDE Supplement - Question/Response.

PAGE 5 - Protocol NEV-97-001: Ethical and regulatory considerations.

PAGE 6 - Protocol NEV-97-001: Complications, Adverse Events, & Serious/Unanticipated Adverse Device Effects.

PAGE 7 - Protocol NEV-97-001: Inclusion/Exclusion Criteria Revision.

PAGE 8 - Protocol NEV-97-001: Screening for Refractive Surgery Eligibility.

PAGE 9 - **PAGE 10** - Protocol NEV-97-001: Clinical Study Data Submitted to FDA.

1998 Reports

PAGE 1 - **PAGE 2** - **PAGE 3** - **PAGE 4** - **PAGE 5** - **PAGE 6** - **PAGE 7** - **PAGE 8** - **PAGE 9** - **PAGE 10** - **PAGE 11** - **FULL** - Protocol NEV-97-001: Study IDE Supplement Annual Report

PAGE 1 - **PAGE 2** - **PAGE 3** - **FULL** - Protocol NEV-97-001: Study IDE Annual Report Supplement

PAGE 1 - **PAGE 2** - **PAGE 3** - **FULL** - Protocol NEV-97-001: Study Changes, Progress towards PMA Approval, Safety & Efficacy for Study Eyes (*Notice the 100% for cumulative UCVA of 20/40 or better, the 0 counts for the BSCVA worse than 20/40 or better, or for the BSCVA worse than 20/25, 6 months*

after my surgery).

1999 Reports

PAGE 1 - **PAGE 2** - **FULL** - The FDA states "*We continue to be concerned that your ablation is likely to have multifocal properties, which means that some light will be out of focus even at tine best focal plane*".

PAGE 1 - **PAGE 2** - **PAGE 3** - **FULL** - Safety & Efficacy for Study Eyes, Page 1 (*Notice the 100% for cumulative UCVA of 20/40 or better, the 0 counts for the BSCVA worse than 20/40 or better, or for the BSCVA worse than 20/25, 1 1/2 years after my surgery*). The charts on pages 2 and 3 also do not show adverse events or complications.

2001 Reports

PAGE 1 - **PAGE 2** - **FULL** - Protocol Deviations & Summary of Complications and Adverse Events.

PAGE 1 - **PAGE 2** - **PAGE 3** - **FULL** - Nevyas Investigational Study charts submitted to the FDA.

PAGE 1 - The FDA states ***"There was no documentation to show that the CI notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements] prior to implementation"***; ***"The firm is not complying with the Investigator Agreement which was signed and dated by the Clinical Investigator at the beginning of the Clinical Study"***; and ***"There was a lapse of IRB approval for the protocol: NEV-97-001 from 8/3/2000 until 8/29/2000 according to IRB, lapse notices and the IRB annual reapproval letter"***.

Nevyas' Promotion of an Investigational Device

Nevyas' Promotion of An Investigational Device

Guidelines, regulations, and laws were in effect prior to the Nevyases'; investigational study.

Click PAGE # to open page in new window

NOTES: Page numbers with an "l" designate the page as landscape. All BLUE font on this page designate links.

From the Federal Trade Commission:

PAGE1 - **PAGE2** - **FULL** - The FTC enforces the Federal Trade Commission Act (FTC Act), which among other things prohibits deceptive or unfair practices in or affecting commerce. 15 U.S.C. §§ 45, 52-57. An advertisement is deceptive under Section 5 of the FTC Act, and therefore unlawful, if it contains a representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances, and that representation or omission is material, that is, likely to affect a consumer's choice or use of a product or service. It is important to note that advertisers are responsible for claims that are reasonably implied from their advertisements, as well as claims that are expressly stated.

In addition, under the FTC Act, advertisers must have substantiation for all objective claims about a product or service before the claims are disseminated In the context of claims about the safety, efficacy, success or other benefits of RK or PRK, substantiation will usually require competent and reliable scientific evidence' sufficient to support the claim that is made.

From the Food and Drug Administration (FDA):

PAGE1 - **PAGE2** - **FULL** - As you know, the FDA approved applications for premarket approval (PMAs) from Summit Technology, Inc. and from VISX Inc_ for their excimer lasers for the correction of mild to moderate myopia in patients with minimal astigmatism Based on the submitted data, these models were approved for refractive correction only by photorefractive keratectomy (PRK) of the corneal surface. Data were not submitted to support the use of these lasers for laser assisted in-situ keratomileusis (LASIK), laser scrape, astigmatism, hyperopia, or multipass or multizone software algorithms. Currently, these are the only lasers approved by FDA for refractive correction and the only refractive indications for which they are approved. The dioptric ranges indicated in the PMA are based on data submitted by these companies in their applications. Data on higher myopia and astigmatism were not submitted, and therefore the approvals did not provide for their treatment. All other lasers being used for refractive surgery, however manufactured or obtained, should be regarded as investigational devices and patients should have the usual human subject protection of institutional review board (IRB) protection, informed

consent and an IDE approval by FDA.

21 C.F.R. §§ 812.7 Prohibits promotion of an investigational device!

21 C.F.R. §§ 812.7

CODE OF FEDERAL REGULATIONS

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN

SERVICES

SUBCHAPTER H--MEDICAL DEVICES

PART 812--INVESTIGATIONAL DEVICE EXEMPTIONS

SUBPART A--GENERAL PROVISIONS

§§ 812.7 Prohibition of promotion and other practices. A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:

(a) Promote or test market an investigational device, until after FDA has approved the device for commercial distribution.

(b) Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling.

(c) Unduly prolong an investigation. If data developed by the investigation indicate in the case of a class III device that premarket approval cannot be justified or in the case of a class II device that it will not comply with an applicable performance standard or an amendment to that standard, the sponsor shall promptly terminate the investigation.

(d) Represent that an investigational device is safe or effective for the purposes for which it is being

investigated.

However, the Nevyases DID promote:

On radio:

PAGE 1 - **PAGE 2** - **PAGE 3** - **PAGE 4** - **FULL** - Nowhere did the Nevyases state that they were part of an investigational study or that their laser was also an investigational device.

And in an infomercial on MDTV:

PAGE 1 - - **PAGE 3** - **FULL** - The same applied to their infomercial.

FDA Inspection Reports of the Nevyas' Facility

Click PAGE # to open page in new window

NOTES: Page numbers with an "l" designate the page as landscape. All BLUE font on this page designate links.

FDA Issued Inspection Report of Nevyas Eye Associates facility dated 11/02/1998:

PAGE 1 - *There was no documentation to show that the Cl notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements].*

PAGE 2 - *Previous inspection on 6/30/97 of this facility revealed the firm continued to use the laser to perform eye surgery without an approved IDE, planned to use the laser or new treatment procedures not included in the firms disaproved IDE and verified that the firm had received a disapproval letter from CDRH/ODE notifying them that use of the laser to treat patients was a violation of the law.*

PAGE 3 - **PAGE 4** - charts

PAGE 5 - *The current inspection revealed Clinical Investigator currently performs Myopic procedures under an approved IDE however, procedures are being performed on IDE patients prior to approval date, the date is missing on a consent form, consent forms were signed by patients after surgery date and*

procedures were performed on IDE patients which are outside the IDE with an unidentified laser at an unauthorized location.

PAGE 6 - Persons interviewed, individual resposibilities, & operations.

PAGE 7 - [Redacted] *initial IDE submission was disapproved May 8, 1998. He was granted conditional approval on August 7, 1998. As* [Redacted] *addressed various issues presented in letters from FDA CDRH/ODE he was granted more uses of the IDE.*

PAGE 8 - [Redacted] *built the* [Redacted] *for* [Redacted] *however,* [Redacted] *owns it. He was responsible for submitting the information for the IDE, in conjunction with and eventually Pre-Market Approval for the device. He is therefore a Sponsor/Clinical Investigator.*

PAGE 9 - *These procedures were performed well before approval was granted.* [Redacted] *stated he had been doing this procedure previously and no one had told him the procedure couldn't be performed as of 8/28/97.*

PAGE 10 - *Consent form for* [Redacted] *was not signed. There was no way of determining whether consent was obtained before or after surgery to the right eye on 12/4/97, due to lack of a date next to patients' signature.*

PAGE 11 - [Redacted] *had* [Redacted] *enhancements performed which is a condition not indicated in the* [Redacted]. *Additionally, the procedures were performed with a laser that is not indicated in the study and the surgery was performed at a location that is not identified in the protocol.*

PAGE 12 - *There was no evidence of a patient information and consent form in the file for this hyperopic enhancement.*

PAGE 13 - *There was no documentation to show that the CI notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements].*

PAGE 14 - *According to a letter dated August 27, 1997,* ***EXHIBIT #8*** *from the IRB,* [Redacted] *is required, in addition to other items, to report to the IRB any new advertisements, recruiting material, serious adverse events, amendments or changes to the protocol or significant protocol deviations.* ***Observation # 6*** *represents a significant protocol deviation and should have been reported to the IRB for*

approval prior to implementation.

PAGE 15 - **PAGE 16** - **PAGE 17** - **PAGE 18** - **PAGE 19** - Lists exhibits included with inspection report.

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FDA Issued Inspection Report of the Nevyas' facility dated 05/10/2001:

PAGE 1 - *The firm is not complying with the Investigator Agreement which was signed and dated by the Clinical Investigator at the beginning of the Clinical Study.*

PAGE 2 - *An inspection conducted on 12/2/96 revealed the firm had assembled a single excimer laser and was using it to perform* [Redacted] *eye surgery on at least 120 patients without an approved IDE.*

PAGE 3 - Persons interviewed, individual resposibilities, & operations.

PAGE 4 - *According to a letter from the FDA to* [Redacted] *dated 1/20/99* ***EXHIBIT #1****, the investigation is still limited to one location, listed in bold above however, the population has grown to 1015 subjects (2030 eyes)*:

PAGE 5 - *For example, the FDA granted your firm an increase in the number of subjects you could treat with your investigational device on Jan. 20, 1999. IRB Annual Review dated 7/29/00 does not indicate the IRB knew about population increase. The IRB did not approve the population increase until August 28, 2000, 20 months later.*

PAGE 6 - ***EXHIBIT #6*** *is an Investor Agreement which was signed by* [Redacted] *Sponsor/Clinical Investigator and* [Redacted] *Co-Investigator. The agreement indicates, among other things, the clinical investigators agree to promptly report to the IRB all changes in the research activity. The clinical investigators failed to report the increase in the number of study patients, granted by the FDA, to the IRB in a prompt manner.*

PAGE 7 - *I explained to* [Redacted] *that he did not have IRB coverage from 8/3/2000 until 8/29/2000.* [Redacted] *stated his consultant,* [Redacted] *was ill for several months and she normally took care of*

report submittals and updates which is why the firm was tardy with reporting updates.

PAGE 8 - [Redacted] *stated it may appear that patients signed the consent forms one day after surgery however, this is certainly not the case and is not the way things are normally done. He indicated this was a mistake made by someone on his staff.*

PAGE 9 - ***There was no documentation to show that the CI notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements].*** *This observation was carried forth to the current listing of objectionable conditions or practices.* ***See FDA-483 observation #1 listed above on page #4 of this report.***

PAGE 10 - *All changes made to the protocol were documented by the investigator, dated, maintained with the protocol, however all changes were not approved by the IRB* ***(see FDA-483 observation #1 listed on page 4 of this report).***

PAGE 11 - *According to records reviewed, the investigator did submit and obtain IRB approval of the protocol, modifications to the protocol* ***(except as noted in FDA-483 OBSERVATION #1),***

PAGE 12 - Lists exhibits included with inspection report.

PAGE 13 - **PAGE 14** - **PAGE 15** - **PAGE 16** - **PAGE 17** - Nevyases response to inspection.

"All adverse experiences have been reported to the sponsor-investigator, FDA, and IRB in accordance with 21 CFR Part 812", and "*The occurence of all events and complications as defined in Protocol NEV-97-001 have previously been reported to FDA. No serious adverse events related to the Nevyas Excimer Laser have occurred in the study".*

According to **deposition by Anita Wallace**, my visual problems post-lasik was not considered a complication or adverse event (I disagree!), even though she claimed the data regarding my situation was reported to the FDA. The charts submitted to the FDA listing adverse events and complications do NOT show data relevant to the number of medical malpractice claims filed against them during their study.

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The 2nd inspection resulted in an FDA483 issued by the FDA.

Although the records requested via the FDA's Freedom Of Information Act were redacted (edited), the FDA stated:

"There is too much information the general public should not be aware of, not only in the Nevyas' study, but in all studies". - Les Weinstein, CDRH Ombudsman

This second set was obtained from the FDA's Philadelphia Office, and included not only the Nevyas' facility of 05/2001, but that of Ed Sullivan (Exsull), builder of their laser (see above). The inspection was 2 years after the article written in the Journal of Refractive Surgery (Fall Issue - 1995):

Inspection Report of the Nevyas' facility dated 05/2001 (less edited):

PAGE 1 - **PAGE 2** - **PAGE 3** - **PAGE 4** - **PAGE 5** - **PAGE 6** - **PAGE 7** - **PAGE 8** - **PAGE 9** - **PAGE 10** - **PAGE 11** - **PAGE 12** - **ALL PAGES**

Nevyas' Deviation From Standard of Care

As Noted by Drs. James Salz, Terrence O'Brien, & Kenneth Kenyon regarding myself and two other LASIK casualties.

DR. SALZ' REPORTS

The following reports were after seeing Dr James Salz, who afterwards became an expert in my medical malpractice lawsuit against my LASIK doctors. These are his reports, and are filed with the Philadelphia courts:

This was what was determined after waiting for all of the medical reports to come together, as was reported from my attorney to the arbitrator:

1. After LASIK, Mr. Morgan saw Nevyas-Wallace's group for almost 2 years, as well as several other ophthalmologists, seeking to correct his worsened vision. The records confirm that Dominic told Nevyas-Wallace and the other ophthalmologists what each told him, that Dominic obtained some copies of records to take from one to the other, and that sometimes the ophthalmologists wrote or telephoned each other, but no ophthalmologist had copies of all the medical records from all the other ophthalmologists.

2. The only persons to review copies of the entire medical records appear to be Dr. O'Brien (after he became an expert) and Dr. Salz. One cannot be certain what Dr. Orlin and Dr. Willis reviewed.

The early post-LASIK period:

3. Nevyas-Wallace initially told Dominic that all his problems were temporary and would pass with time, first 3 to 6 months, then 6 to 12 months. Meanwhile, Nevyas-Wallace wrote in the records that there were problems in centering the laser ablation during the left eye LASIK procedure (operative note 4/23/98), with resultant temporal decentration in the left eye (medical records 4/27/98, 5/4/98), and nasal decentration in the right eye (medical record 7/6/98).

4. Three other ophthalmologists seeing Dominic Karen Fung, M.D. (medical record 8/3/98), John Dugan, M.D. (medical record 8/25/98), and Michael Belin, M.D. (medical record 1/25/99) told Dominic and wrote that they were concerned with LASIK causing decentration problems. Dr. Dugan sent Dominic to Dr. Laibson. [see telephone call note to Laibson's partner Dr. Rapuano in Laibson records] Dr. Dugan also sent Dominic to Johns Hopkins, [deposition Dugan p. 73] and after Dr. Dugan talked with Dr. Guyton (see below, on 6/19/00) he wrote both that he was uncertain, as well as writing about decentration.

The later post-LASIK period:

5. Peter Laibson, M.D. wrote (letter 2/23/99): "I think it is either a retinal problem (you are familiar with his past history of regressed retinopathy of prematurity with peripheral lattice degeneration) or possibly other factors, which are not obvious on the objective examination."

When deposed, Dr. Laibson would not answer all pertinent questions. Asked by defendants if LASIK was responsible for Dominic's loss of visual acuity, Dr. Laibson said that Dominic*s problems were more than the LASIK flaps [deposition Laibson p. 20-21] and "I can say that the LASIK surgery looked like it was done appropriately; and that as far as visual loss is concerned, I don't know how to answer that question." [deposition Laibson p.24, 25] When asked again by defendants if LASIK was responsible for Dominic's loss of visual acuity, he said, "I don't know."[deposition Laibson p.26] When further pressed by defendants, he rephrased the question to avoid answering what was asked: "I felt it was not likely that if he really did have 20/40 that the LASIK was responsible for the reduction in vision to 20/70." [deposition Laibson p.27, emphasis added] When plaintiff's attorney asked, "Doctor, would you consider the use of the suction cup and the increased intraocular pressure as one of the other factors that you're referring to?" he answered, "I have no comment on that" [deposition Laibson p.38] and later, "I'm not an expert."[deposition Laibson p 43] He explained that the cornea alone could not explain Dominic's problem, so there had to be another problem. [deposition Laibson p 55-56]

6. Nevyas-Wallace wrote (medical record 3/8/99): "Phone call from patient...He says Dr. Michael Belin and Dr. Peter Laibson each said the cornea looks fine and that the problem must be retinal." Thereafter Nevyas-Wallace continued to assure Dominic that his problems would clear up with time, but what was written in Nevyas-Wallace's medical records changed.

7. Sheldon Morris, M.D. when asked specifically if cataracts were present, wrote there were no significant cataracts and Low

VA [visual acuity] related to retinal problems."[medical record 4/17/00] At deposition Dr. Morris said he did not know if the retinal problems were worsened by the LASIK procedure or independent of LASIK. [deposition Morris p. 22]

8. Nevyas-Wallace wrote (medical record 4/26/99): "Impression: Retinal problem. Rule out hysteria."

9. Paul Beer, M.D. wrote (letter 7/21/99): "The explanation that was raised by one of the previous consultants, that his refractive surgery is not aligned with the physical location of his macula, may be very reasonable."

10(A). Nevyas-Wallace wrote (medical record 7/26/99): "Impression: Topography shows central ablation, and no increase (in vision) with contact lens. Therefore, problem is retinal."

10(B). Nevyas-Wallace wrote (medical record 10/11/99): "Impression: Discussed in detail - that as per Drs. Laibson, O'Brien, and Belin, the cornea and topography are excellent and that slight drop in visual acuity is symptomatic with marginal acuity at the onset. Also that retinal factors including retinopathy of prematurity likely to be responsible." This implied that retinal factor other than retinopathy of prematurity were present, and Nevyas-Wallace repeated her implication [deposition Nevyas-Wallace p. 212]: "I discussed matters in detail and I explained to him that I agreed with Dr. Laibson and Dr. O'Brien and Dr. Belin in their assertions that both the appearance of the cornea and the corneal topography are excellent and that slight drop in visual acuity is symptomatic and that retinal factors, including his retinopathy of prematurity, are likely to be responsible."

11. Eugene DeJuan, M.D. wrote for diagnoses: "Question of optical phenomena and retinal degeneration or ischemia secondary to vacuum [cup for LASIK]." (Johns Hopkins medical record 11/29/99)

12. David Fischer, M.D. wrote (letter 3/3/00): "The more insidious causes of diminished vision concern the retina which your LASIK surgeons felt were the culprit. Your fluorescein angiogram was felt to be normal as were your visual fields. The ERG showed mild retinal dysfunction, cause to be determined. During LASIK procedures a suction cup is placed on the eye causing increased intraocular pressures. Could this be a factor as a long-term optic neuropathy which may also be related to your retinopathy of prematurity? I'm afraid these are questions that I cannot answer and I'm hopeful that the doctors at Johns Hopkins can elicit these answers for you."

13. David Guyton, M.D. saw Dominic at Johns Hopkins in June 2000. Dr. Guyton stated, "I could say from that that the refractive surgery wasn't the only thing which was decreasing his vision." [Guyton deposition p. 19] When Dr. Guyton was asked by defendant, "What amount is it would not be related to Lasik then, over from where to where?" he explained that LASIK was responsible for the decrease to 20/70 and postulated cataracts (unrelated to LASIK) for 20/70 to 20/125. [Guyton deposition p. 20-21] Dr. Guyton stated that he deduced cataracts by a process of elimination [Guyton deposition p. 45] since they were barely visible, and suggested waiting [two years] to see if there would be any progression. Absent progression he felt cataracts could not be part of Dominic's visual problem. (letter 6/19/00 and deposition pp. 22, 23, 38, 39).

14. The other two Johns Hopkins doctors, Eugene DeJuan, M.D. (with his fellow, Joseph Harlan, M.D.) and Terrence O'Brien, M.D., did not believe the barely visible cataracts were significant, but did not regard waiting as unreasonable.

15. Defense expert Dr. Orlin examined Dominic 1/30/02 and stated, "over the past two years, these [cataracts] have remained minimal and non-progressive," [Orlin report 6/12/02, p. 2] and neither he nor defense expert Dr. Willis suggested any significant visual loss from cataracts.

16. When plaintiff's expert Dr. Salz examined Dominic 4/27/02, almost 2 years after Dr. Guyton, there still was no cataract progression. Dr. Salz reported no cataract problems, and was then able to conclude with medical certainty that Dominic's problems were causally related to decentered laser ablation, and retinal and optic nerve damage.

17. Terrence O'Brien, M.D., having waited 2 years after Dr. Guyton, agreed with Dr. Salz and became a plaintiff expert. All experts' reports were "set aside" in determining outcome of arbitration.

PAGE 1

Beverly Hills Eye Medical Group, Inc.12561 Promontory RoadLos Angeles, Ca. 90049Phone 323 653-3800 Fax 310 472-4244April 27,2002

Steven A. Friedman, M. D. Physician and Attorney at Law 850 West Chester Pike, 1st Floor Havertown, PA 19083

RE: Dominic Morgan's examination on 4/27/02

Dear Dr. Friedman:

As you requested, I have examined your client and this report will summarize my findings.

History Mr. Morgan stated that his best-corrected visual acuity was never better than 20/50 on numerous previous examinations secondary to his retinopathy of prematurity. The 20/50 visual acuity was confirmed on his driver test examination. He also stated that he went to the Nevyas Eye Center because he heard a radio commercial on KYW. He was told he was a " good candidate" for LASIK despite his ROP. After surgery on his left eye he complained about the quality of his vision and problems with his night vision and was told that it was normal at that stage and would improve with time. These assurances were the reason he consented to surgery on his right eye.

His current complaints include the following: vision fluctuates a great deal, some days worse than others and changes during the same day depending on lighting conditions; cannot see to drive at night; he still has a driver's license but has essentially given up driving; at dusk, everything becomes even more blurry and he sees starbursts around lights; during the day he gets by OK, cannot read road signs but he feels he could drive in familiar areas; all these symptoms are worse in his right eye, especially at night.

Examination:

Uncorrected visual acuity OD 20/100 +2, OS 20/100 -

VA with present glasses OD -1.00 -0.50 x 11 = 20/100, OS -0.75 -0.25 x 26 = 20/80 -1

Refraction OD -0.50 -0.50 x 90 = 20/80 +, OS -1.50 = 20/80 +

Cycloplegic refraction OD -0.50 -0.50 x 90 = 20/100 with triple images of chart letters

OS - 1.25 = 20/100 with triple images of chart letters

PAGE 2

Keratometry OD 41.50/41.75 x 107 clear mires, OS 42.25/42.62 x 90 clear mires Pupil diameter in dark room with pupilscan OD 6.4mm OS 6.5 mm Pachymetry OD .46 mm OS .48 mm

Slit lamp examination—clear corneas with well-healed LASIK flaps OU, normal pupils, no afferent pupil defect, lens shows faint trace nuclear sclerosis in the posterior half of the lens nucleus while the anterior half is clear.

Fundus examination with pupils dilated, both direct and indirect reveals hypoplastic optic nerves with essentially no cup and no obvious pallor OU, prominent temporal peri-papillary atrophy and temporal displacement of macula OU

Humphrey Topography shows relatively small but well centered ablations in both eyes with the lower end of the ablation at the edge of the photopic pupil of about 3 mm. The corneal irregularity measurements are increased to 2.63 OD and 2.49 OS (normal up to 1.5) copy enclosed

Wavescan readings with the Alcon Humphrey System are included. These were performed with normal lighting with pupils of 4.59 mmOD and 4.23mm OS and again with pupils dilated to more closely simulate night conditions when the pupils were 7.6mm OD and 7.4mm OS. The defocus and astigmatism readings with the smaller pupil are quite normal and agree with the minor residual refractive error in both eyes. Both of these values increase with larger pupils because the unablated area of the cornea is measured and this simply reflects the relatively small ablation diameters. The most common aberrations following LASIK are Coma and Spherical Aberration and these values are acceptably low with pupils of about 4.5 mm. For example the spherical aberration for OD is 0.38 OD and 0.16 OS. When the pupils are dilated simulating night conditions, spherical aberration increases to 2.33 OD and 1.72 OS. This represents almost a six-fold increase for OD and a tenfold increase for OS.

Comment: Mr. Morgan has been examined by several highly qualified experts since his LASIK surgery in an attempt to explain the decrease in his best-corrected visual acuity. The possible mechanisms include retinal damage, optic nerve damage, a combination of both; optical problems related to positive angle kappa and an ablation centered over the pupil, and early

cataract changes. Based on my examination, I attribute his loss of vision to a combination of all except the cataract. I do not feel the minimal lens opacity is sufficient to explain his loss of vision. This would not explain why his vision became worse immediately after the surgery in both eyes. Dr. Guyton suggested the minimal cataracts as a possible explanation in June of 2000 and suggested that if the cataracts were at fault we would expect to see progression in the lens changes and further decrease in his visual acuity. It is almost 2 years since that exam and today, his visual acuity was better than the 20/125 recorded by Dr. Guyton and the lens changes are still minimal so this goes against the thought that the cataracts are at fault.

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Mr. Morgan's increased night symptoms are readily explained by the small ablation diameters evident on his topography combined with the fact that his scotopic pupils are about 6.5 mm. The dramatic increase in his spherical aberration in both eyes when his pupils are dilated correlates well with his subjective complaints. The spherical aberration is also higher in the right eye and he has more complaints about his night vision in that eye.

Sincerely,

signature on original scanned document Nevyas v. Morgan

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PAGE 1

Beverly Hills Eye Medical Group, Inc.12561 Promontory RoadLos Angeles, Ca. 90049Phone 323 653-3800 Fax 310 472-4244

April 27, 2002

Steven A. Friedman, M. D. Physician and Attorney at Law 850 West Chester Pike, 1st Floor Havertown, PA 19083

RE: Dominic Morgan v Nevyas Eye Associates-report on standard of care deviations

Dear Dr. Friedman:

As you requested, I have examined your client and reviewed the records you have forwarded to me over the last 3 months. This report will summarize what I believe to be deviations from the standard of care by Nevyas Eye Associates in the treatment of your client, Dominic Morgan. His examination will be summarized in a separate report.

1. Mr. Morgan was not an appropriate candidate for an FDA study where the protocol lists under B, 6 "best corrected visual acuity of 20/40 or better in both eyes". Even without the FDA study criteria, he would not be considered a "good candidate for LASIK". Mr. Morgan stated very clearly in his record and maintains by history that his best-corrected spectacle visual acuity was never better than 20/50. He did have a refraction on March 10, 1998, which showed a best corrected visual acuity of 20/40-2 in each eye. While this is close to 20/40 it is not 20/40. A letter from Dr. Anita Nevyas to Dr. Bellin on 12-18-98 reported his preoperative vision as 20/40-2 to 20/50 and a letter to Dr. DeJuan on March 27, 2000 reports his best-corrected visual acuity as 20/50. A letter from Dr. Herbert Nevyas to Dr. Grace Tammera on 8/20/98 reported that he had 20/50 vision in each eye with full correction before his surgery. This fact combined with his history clearly noted in the record should have disqualified him from an FDA study requiring best corrected visual acuity of 20/40 or better. Rather than emphasizing the likely increased risks of performing LASIK in a patient with already compromised vision secondary to retinopathy of prematurity (ROP), the notes at the Nevyas Eye Center state that he is a "good candidate for LASIK". Exclusion criteria C, 5 of the protocol lists the "Presence of any clinically significant abnormality on physical or ophthalmic examination that would contraindicate outpatient refractive surgery." ROP would be a clinically significant abnormality. I do not know of any surgeon who has performed LASIK on a patient with Mr. Morgan's degree of ROP. He was simply not an appropriate candidate.

There are 3 problems with performing LASIK on eyes with ROP. The first is that the retina is already compromised by the primary disease and the increased pressure in the eye (often 3 to 5 times normal) can by itself damage a normal retina and this risk would be increased in an already compromised retina where the macula has been stretched or dragged temporally. Although exams by retinal specialists has failed to document obvious retinal damage, one cannot rale out hypoxic or pressure induced damage to the macular area during the cutting of the flap which would account for his decreased vision.

He does now have abnormal electroretinograms as documented on April 8, 2002 and February 20, 2000, which indicate abnormal rod and cone function. This is not surprising in a patient with ROP but of course we do not have pre LASIK studies to determine if these abnormalities were increased after his LASIK. If a preoperative ERG was in fact abnormal, that would be an additional reason combined with the clinical appearance and best-corrected vision of 20/50 to exclude him from the study. If a preoperative ERG was normal, we would then have objective evidence that the LASIK surgery caused it to become abnormal.

The second problem with a patient with ROP is that optic nerve and the nerve fiber layer of the retina are more susceptible to damage from the increased intraocular pressure from the application of the suction ring. • Dominic does have abnormal optic nerves, which appear to by hypoplastic in the photos from 4/6/98 at the Nevyas Eye Center and by my exam. The report by Dr. DeJuan at Hopkins also describes "anomalous" optic discs. These small hypoplastic optic nerves are more prone to damage during LASIK. Cases of optic nerve damage have been reported following LASIK have been reported even in normal eyes. The LASIK procedure can cause subclinical ischemic damage to the optic nerve or nerve fiber layer of the retina but not enough to result in obvious optic nerve atrophy or pupil defects. The visual field testing (Goldman) performed at Wilmer shows paracentral scotomas in both eyes and the interpretation by Dr. Zack on 12/6/99 describes, "specific loss including a number of common disorders, most commonly glaucoma." Clearly Dominic does not have glaucoma so these field defects point to damage from the increased intraocular pressure during LASIK in an abnormal optic nerve. The GDX study from March 27, 2000 also shows abnormal nerve fiber layers in both eyes which would usually indicate glaucoma but here is simply an indication of his ROP. If feasible I recommend Patterned Visual Evoked Potential testing to evaluate his optic nerve function. The third problem with an ROP patient involves the controversy of whether to center the excimer ablation over the pupil, as recommended by Guyton Ellis and Hunter, or over the visual axis, as suggested by Wachler and Buzzard. Although this argument is often moot in most normal eyes, the dragged macula in ROP and the significant positive angle Kappa make this a more significant decision in an

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ROP patient. Indeed, the inability of Nevyas to be certain where to properly center the excimer ablation in an ROP patient is another reason why LASIK was inappropriate. The topography following the LASIK appears to be well centered over the pupil. Because Mr. Morgan visual axis or "line of sight" is not looking through the center of the pupil, this may be partially responsible for his visual aberrations and decreased vision. It does not appear that this issue was ever discussed with Mr. Morgan as a potential problem with doing surgery on him as opposed to a truly "good candidate. The Nevyas note of 4/27/98 mentions the "patient was looking nasal to fixation target intraop" and that there was "temp decentration OS." It is possible that Mr. Morgan's line of sight to his temporally pulled macula passes through a peripheral portion of his ablation rather than the central portion and that may explain some of his decreased vision and night symptoms of glare and ghost images. Under these circumstances it may have been more appropriate to center his ablation over the line of sight rather than the pupillary center. This mismatch between the center of the ablation and the temporally displaced macula as a possible explanation for Mr. Morgan's difficulties is also mentioned in the letter from Dr. DeJuan and the letter from Dr. Paul Maurius Bear dated 7/21/99. 2. Violation of FDA and Code of Federal Regulations on promotion and other practices. These regulations state that the investigator shall not: "(a) Promote or test market an investigational device until the FDA has approved the device for commercial distribution and (d) Represent that an investigational device is safe or effective for the purposes for which it is being investigated." Mr. Morgan states and it is confirmed on his patient history dated 3/10/98 that he came to the Nevyas Eye

Associates because he heard a radio commercial on station KYW. I have reviewed the script of radio advertisements, the Nevyas web pages, and a promotional Videotape of a program that was shown on cable television and may have been distributed to patients. I have been told that all of these materials were used during the FDA investigation of the Nevyas Laser. None of these materials included the FDA required warning that the device is limited to investigational use only. The ads also represent that the procedure is safe, and in fact the TV ad shows a simulated blurred 20/200 vision quickly dissolving into a sharp 20/20 vision. There are numerous other representations that the procedure is safe and effective. If patients were responding to these advertisements and then were entered into the FDA study, that would represent a serious deviation from the standard of care and one that I am sure the FDA would be interested in these practices. It would also appear that the poor results obtained by Mr. Morgan with the significant decrease in his best corrected spectacle visual acuity of more than 10

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letters were not properly reported to the FDA and that more patients were recruited for the study than were authorized by the FDA. 3. Performing surgery on the right eye when the left eye sustained a loss of best-corrected visual acuity from 20/40 -2 to 20/70. On 4/27/02 the clinical notes state that the patient "feels vision is weaker since Fri. and night time is a problem." The refraction was -0.25 -0.75 x 80 = 20/70 (the target for this eye was mono vision for the left eye of about -2). Thus the patient had a significant over response to the laser, had complaints about the quality of his vision and his night vision, and had lost at least 2 lines of best-corrected visual acuity. Despite these problems, Dr. Nevyas impression was that he was "doing well" and recommended and performed LASIK surgery on the dominant right eye on 4/30/98. The imbalance between the two eyes that the patient experienced should have been corrected with a contact lens or glasses in the right eye while the situation in the left eye was evaluated. The left eye eventually regressed to about -1.25 so it may actually have been possible for him to continue simply wearing glasses and a contact lens may not have been necessary. This is especially true since the patient had a previous history of strabismus surgery and he may not have had true stereopsis so the anisometropia may have been easily tolerated and surgery on the right eye could have been deferred indefinitely. 4. Comment: Mr. Morgan has been examined by several highly qualified experts since his LASIK surgery in an attempt to explain the decrease in his best-corrected visual acuity. The possible mechanisms include retinal damage, optic nerve damage, a combination of both; optical problems related to positive angle kappa and an ablation centered over the pupil, and early cataract changes. Based on my examination and records review, I attribute his loss of vision and visual complaints to a combination of all except the cataract. I do not feel the minimal lens opacity is sufficient to explain his loss of vision. This would not explain why his vision became worse immediately after the surgery in both eyes. Dr. Guyton suggested the minimal cataracts as a possible explanation in June of 2000 and suggested that if the cataracts were at fault we would expect to see progression in the lens changes and further decrease in his visual acuity. It is almost 2 years since that exam and today, his visual acuity was better than the 20/125 recorded by Dr. Guyton and the lens changes are still minimal so this goes against the thought that the cataracts are at fault. Within a reasonable degree of medical certainty, it is my opinion that LASIK caused all the problems discussed above and in my report to occur. LASIK surgery

usually does not provide a patient with vision better than his or her best corrected vision with spectacles or contact lenses. Although common, this surgery is not without risk, and the practice is not to perform surgery on patients who already have compromised vision secondary to severe eye conditions. By avoiding patients whose vision is already compromised to this degree we leave the patient a "safety net" in case the procedure leaves them with less than

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desirable results. Certainly Mr. Morgan's ROP places him within a category of patients who needed that net, and Dr. Nevyas-Wallace took that net away. Yours truly, James J. Salz, M. D. signature on original scanned document Nevyas v. Morgan

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PAGE 1

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September 16, 2002

Steven A. Friedman, M. D. Physician and Attorney at Law

850 West Chester Pike, 1st Floor Havertown, PA 19083

RE: Reply to defense expert reports

Dear Dr. Friedman:

I have reviewed the additional documents you forwarded to me. These documents include: deposition testimony of Drs. Herbert Nevyas, Anita Nevyas, Joan Nevyas, John Dugan, Sheldon Morris, Ira Wallace, Edward Deglin, Richard Sterling, MRI reports, IME report of Dr. Stephen Orlin, his patient information guide, web page document as well as some FDA documents and appointment documents for Herbert and Anita Nevyas to the Pennsylvania Eye Surgery Institute. The review of these additional records does not change any of the opinions previously expressed in my original report. I have also

reviewed the expert report of Dr. Stephen Orlin and Dr. Amos Willis about your client Dominic Morgan. Dr. Orlin focused on 4 aspects of Mr. Morgan's condition.

1. Progressive cataract formation. I agree with Dr. Orlin that Mr. Morgan's "nuclear sclerotic" cataracts are minimal, not responsible for his visual loss, non- progressive, and not related to his Lasik surgery.

2. Retinal damage. I agree with Dr. Orlin that Mr. Morgan's past ophthalmic history was complicated and significant for Retinopathy of Prematurity (ROP). I would agree that there was no medical reason to evaluate his retina for his retinopathy of pre-maturity (ROP) if surgery was not being contemplated. The term retinopathy in his diagnosis of ROP means the retina is abnormal. Lasik is customarily performed on patients with normal retinas and so there would be no deviation of the standard of care to not perform visual field testing and ERG's on patients with normal retinas undergoing Lasik. This was not the case with Mr. Morgan, however. Since his retina was abnormal, with a pulled macula and decrease in his best corrected visual acuity non invasive testing like visual fields and ERG would have been a valuable way to assess the extent of his damage. Dr. Orlin's patient information guide about laser vision correction states in response to the question How do I know if I am a good candidate for laser vision correction? "Patients who are 21 years of age or older, and have healthy eyes which are free of retinal problems, corneal scars, and any eye disease are suitable."

It is simply not within the standard of care to perform LASIK on patients' with ROP like Dominic. Nevyas's own protocol and criteria are written evidence confirming this standard of care. During the LASIK procedure the intraocular pressure is raised 3 to 4 times the normal value. Optic nerve damage and retinal damage have rarely been described as a complication of LASIK in normal eyes. Since there is no other explanation for his decreased vision, it has to be concluded that the procedure damaged his already abnormal retinas and optic nerves. Mr. Morgan could not give informed consent since his ROP should have excluded him from surgery and he was not given that information. It is clear that Dominic would not have been harmed had he not undergone the LASIK surgery. The fact that Dominic can read 20/40 on a near vision test certainly does not mean he has 20/40 distance vision as Mr. Morgan has residual myopia and is thus receiving a magnified near image. The fact that he voluntarily read 20/40 at near gives evidence that he is giving us an honest examination and is not trying to make his condition appear to be worse than it is. It is not uncommon for nearsighted patients to have better uncorrected near vision than their best corrected distance vision.

3. Ablation centration. Mr. Morgan's postoperative topography merely shows that his ablations are centered over his pupils, not necessarily over his line of sight. . In most patients, the difference between centration over the pupils vs. the line of sight is minimal but in Dominic it was significant because of his ROP and markedly abnormal positive angle kappa. I would agree that the lack of improvement in his vision with a hard contact lens rules out significant irregular astigmatism as a cause. It does not

preclude loss of vision caused by the fact that he is not looking through the optical centers of his ablations, which are centered over his pupils. He is looking through a peripheral area of the ablation, rather than the center of the ablation. The lack of improvement with a hard lens does point to damage to the retina, nerve, or both as the primary cause for most of his impairment.

4. Aberrations. I would agree that the higher order aberrations are not responsible for Mr. Morgan's daytime vision but they do provide objective evidence of his night vision complaints. He most likely would have had the same increase in night aberrations whether or not he had ROP. He was at increased risk of these aberrations because of his large scotopic pupils (6.5mm). In his report dated May 29th, 2002 Dr. Willis states that 20/40 -2 would be considered by most physicians to represent 20/40 visual acuity. Most physicians have not conducted and are not familiar with PDA studies. Mr. Morgan was being enrolled in an PDA study, which specified a minimum requirement of best-corrected vision of 20/40. It did not specify vision of approximately 20/40, around 20/40 or 20/40-2. It is very simple, the 20/40 criteria can be 20/40 or 20/40 +1 but it cannot be 20/40 -2 or -3. I have been involved in 7 PDA studies of laser vision correction as principal investigator so I am very familiar with the PDA requirements. Mr. Morgan should have been disqualified from consideration based on this fact alone.

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Dr. Willis also tries to cloud the issue about what is a clinically significant abnormality and its role as an exclusion criteria. He admits that ROP is a clinically significant abnormality and goes on to say it does not contraindicate refractive surgery because "no one has a significant degree of experience in operating on patients with ROP." That is precisely the point. Mr. Morgan was told he was a "good candidate for LASIK." In fact, Mr. Morgan became a human subject for the study of LASIK in a patient with ROP. The Nevyas FDA study was designed to test their laser in normal myopic eyes. Mr. Morgan did not consent to be in a study of LASIK in patients with ROP to see what would happen. Had he been in such a study, a responsible IRB and the FDA would have had serious concerns about proceeding with such a study, particularly in both eyes of a patient until the preliminary results in at least one eye could have been evaluated. The informed consent would have been much different, as would the discussion of risks and benefits in the informed consent. When we first began investigations in laser vision correction (PRK) in 1990, the FDA required waiting 6 months between eyes and these were normal eyes. Performing Lasik in Dominic Morgan was a violation of the FDA protocol. Even if the protocol never existed, performing LASIK on Dominic Morgan was a serious breach of the ophthalmic community standard of care. Dr. Willis also states that it is not uncommon for Lasik patients to have continued improvements with time. Although that may be true to a minor degree with some patients, in my experience with thousands of patients, a decrease in best corrected vision to the 20/70 to 20/80 level 4 to 5 days after surgery, even in a normal eye, should have been a red flag to not proceed with surgery on the other eye until the outcome was more clearly established. In the vast majority of patients, a 3 to 4 line loss in the best-corrected vision several days after surgery in the absence of obvious causes such as dry eye, striae, or inflammation, is a serious cause for concern and surgery on

the second eye should have been deferred. Mr. Morgan was not informed that surgery on his dominant eye should be deferred until the result in his left eye was well established. In fact, he was misinformed that the initial loss of vision in his left eye was temporary and that it was appropriate to proceed with surgery in his second eye. This represents an additional lack of informed consent and an additional failure to meet the proper standard of care. In summary, the reports by Dr. Orlin and Dr. Willis do not change my opinions about the deviations from the standard of care by Dr. Nevyas and the damages to Mr. Morgan, which resulted from his Lasik surgery. Sincerely, James J. Salz, M. D. signature on original scanned document Nevyas v. Morgan

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PAGE 1

Beverly Hills Eye Medical Group, Inc.12561 Promontory RoadLos Angeles, Ca. 90049Phone 323 653-3800 Fax 310 472-4244DECLARATION OF JAMES J. SALZ, M.D.

I, James J. Salz, M.D. make this declaration subject to the penalties of 18 Pa.C.S.A. Sec. 4904 relating to unsworn falsification to public authorities:

1. I update my curriculum vitae and that of Dr. O'Brien: I am Chair and Dr. O'Brien is Secretary of the International Society of Refractive Surgery/American Academy of Ophthalmology Executive Committee for 2003. Dr. O'Brien and I are both well acquainted with the standards of care regarding the selection of patients for LASIK.

2. Dominic Morgan had (and still has) Retinopathy of Prematurity (ROP), a disease of the retinas caused by premature birth. In other words, Dominic had significant preexisting retinal disease.

3. Everyone agrees Mr. Morgan's ROP was significant. Defense expert Dr. Orlin stated, "His past ophthalmic history was complicated and significant for retinopathy of prematurity." [Orlin report 2/1/02, p.l, emphasis added] Defense expert Dr. Willis stated, "ROP is a clinically-significant abnormality in the sense that it represents a preexisting abnormality in the eye..." [Willis report 5/29/02, p. 1, emphasis added]

4. The patient information brochure distributed by defense expert Dr. Orlin to his patients warns, "Laser vision correction is not for everyone....Patients who are 21 years of age or older, and have healthy eyes which are free of retinal problems, corneal scars, and any eye disease are suitable." [Laser Vision Correction/LASIK brochure of Scheie Eye Institute, pp.1, 13, emphasis added]

5. Defendant Nevyas-Wallace claimed that she "used," " followed," and "adhered to" [Nevyas- Nevyasx deposition p. 103] her

written protocol calling for exclusion of any person who had, "any clinically significant abnormality on physical or ophthalmic examination that would contraindicate outpatient refractive surgery." [Nevyas-Wallace's protocol for LASIK, Exclusion Criteria, emphasis added]

6. LASIK is elective surgery. Because it is elective, the standard of care requires a high degree of predictability of results. People who are candidates for LASIK are those with conditions for which there is adequate experience to predict (not guarantee) a good result. It is not the standard of care to say, as does defense expert Dr. Willis, "The fact that no one has a significant degree of experience in operating on patients with ROP does not suggest that it is inappropriate to perform elective surgery on these patients." [Willis report 5/29/02, p. 1] To the contrary, no one (except Nevyas-Wallace) has any experience performing LASIK on patients with ROP, so no one can predict a good result, and it is below the standard of care to perform the surgery.

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7. Dr. Willis' statement is incorrect and disingenuous; as I previously reported, there are no reports in the literature of anyone ever doing LASIK on a patient with ROP like Dominic. As I previously reported, I am unaware of any ophthalmic surgeon ever having done LASIK on a patient with ROP like Dominic. During the last two years as I have traveled around the country, including Philadelphia, I have asked other ophthalmic surgeons if they were aware of such a thing, or would do such a thing. The answers are uniformly no; everyone believes it is predictable that a poor result would be the likely outcome.

8. Since performing elective LASIK on virtually any significant eye or retinal abnormality or disease is below the standard of care, the ophthalmic community literature does not piecemeal list each significant eye or retinal abnormality or disease "in and of itself." The literature employs more useful generic categorical warnings.

9. As I previously reported, there are multiple reasons why performing LASIK on Mr. Morgan was below the standard of care. These included:

A) doing his dominant right eye one week after getting poor results in the left eye. I previously reported why going ahead with the right eye in the face of poor results in the left was below the standard of care.

B) violating Nevyas-Wallace's own written protocol requiring pre-operative best corrected visual acuity (BCVA) in both eyes of 20/40 or better. I previously reported that it is below the standard of care not to follow one's own protocol.

C) failing to provide a "safety net." I previously reported that the standard of care is to provide a "safety net" in case the procedure produces less than desirable results. By doing LASIK in Mr. Morgan with his significant pre-existing ROP, by violating Nevyas-Wallace's own written protocol requiring pre-operative BCVA in both eyes of 20/40 or better, and by operating when a good result could not be predicted, Nevyas-Wallace took away that safety net.

D) uncertainty how and where to center the laser ablation.

E) barotrauma (i.e. pressure trauma) during application of the suction ring or cutting of the corneal flap, causing further damaging to pre-existing damaged retinas and optic nerves.

10. At the risk of repeating what I previously reported, I address the last two items.

11. Uncertainty how and where to center the laser ablation:

a) As I previously reported, there is an argument in the literature about how and where to center the laser for doing LASIK in normal eyes. Some ophthalmic surgeons prefer to center the laser ablation over the pupil, as recommended by Guyton, Elk's and Hunter. Others prefer to center the laser ablation over the visual axis or "line of sight," as recommended by Wachler and Buzzard. Each claims that its method of centration is better. In normal eyes this argument is of little practical consequence because people with normal retinas essentially see through the pupil center. Thus, either way, the area of laser ablation ends up being virtually identical.

b) In ROP patients this literature argument would be an issue of great importance because nobody knows how or where to properly center the laser ablation.

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c) Unlike people with normal retinas who see through the pupil center, those with ROP see nasally to the pupil center. Because the macula is dragged temporally and has a positive angle kappa, the visual axis or "line of sight" is shifted nasally. In other words, the potential areas of laser ablation would be quite different from each other.

c) Dr. Willis tries to minimize this literature argument and important issue by writing, "Though some controversy exists as to whether centration on the pupil is appropriate, opinions generally favor centration on the visual axis." [Willis report 5/29/02, p. 2]

d) The point is that nobody knows how or where to properly center the laser ablation in patients with ROP. Nobody has adequate experience to predict a good result, and thus nobody can properly say that a ROP patient is a "good candidate for LASIK." For this reason alone, LASIK in ROP is below the standard of care:

12. Barotrauma:

a) As I previously reported, during LASIK a suction ring is placed on the eye to flatten the cornea and keep the eye from moving. The increased pressure on the eye, often 3 to 5 times normal, can damage even a normal retina or optic nerve. From the time the suction ring is put on the eye until it is removed, vision appears dim or goes black.

b) World-wide literature documents barotrauma damage during LASIK even in eyes without any pre-existing retinal or optic nerve abnormality. As examples I refer to Principles and Practice of Refractive Surgery (USA), Lasik Principles and Techniques (USA), Laser in Situ Keratomileusis-induced Optic Neuropathy (USA), Bilateral macular hemorrhage after laser in situ keratomileusis (Argentina), and Macular hemorrhage after laser in situ keratomileusis for high myopia (France).

c) Nevyas-Wallace's own Bilateral Simultaneous Lasik patient information form states that this significantly increased pressure during LASIK can damage even a normal retina.

d) Dominic had "clinically-significant... pre-existing abnormality in the eye..." [Willis report 5/29/02, p. 1] The retinas were clearly damaged with retinopathy. The maculas were dragged temporally, meaning the optic nerves were abnormally stretched, and also dragged temporally. As I previously reported, Dominic had abnormal optic nerves, which appeared to be small and hypoplastic in the pre-operative photos 4/6/98 at the Nevyas Eye Center and by my exam. The report by Dr. DeJuan at Johns Hopkins described "anomalous" optic discs..

e) Pre-existing retinal and optic nerve abnormalities make eyes more susceptible to virtually any kind of trauma, including barotrauma. The ophthalmic community literature does not piecemeal list each significant eye or retinal abnormality or disease "in and of itself," but employs more useful generic categorical warnings. Barotrauma is one of these generic categorical warnings, and is widely written about - somebody is always being punched in the eye, etc.

f) Even if there were nothing in the literature about barotrauma aggravating preexisting retinal and optic nerve abnormalities (and there is), the point remains that nobody has adequate experience to predict a good result, and thus nobody can properly say that a ROP patient is a "good candidate for LASIK." For this reason alone, LASIK in ROP is below the standard of care.

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13. Because nobody could legitimately predict a good result for DM, and he was not a fit candidate for LASIK, DM was a human "guinea pig. Dated: signature on original scanned document Nevyas v. Morgan

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PAGE 1

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DECLARATION OF JAMES J. SALZ, M.D.

I, James J. Salz, M.D. make this declaration subject to the penalties of 18 Pa.C.S.A. Sec. 4904 relating to unsworn falsification to public authorities:

1. I update my curriculum vitae and that of Dr. O'Brien: I am Chair and Dr. O'Brien is Secretary of the International Society of Refractive Surgery/American Academy of Ophthalmology Executive Committee for 2003. Dr. O'Brien and I are both well acquainted with what is meant by "healthy" or "stable" retinas.

2. "Health" means "free from disease." "Healthy" retinas means retinas "free from disease."

3. "Stable" means "staying unchanged." "Stable" retinas means retinas "staying unchanged."

4. Defense expert Dr. Orlin distributes a brochure for patients in his office warning, "Laser vision correction is not for everyone...Patients who are 21 years of age or older, and have healthy eyes which are free of retinal problems, corneal scars, and any eye disease are suitable." [Laser Vision Correction/ LASIK brochure of Scheie Eye Institute, pp. 1,13, emphasis added] The brochure states, "This booklet... is for informational purposes only." [id, p.2]

5. Everyone agrees Dominic Morgan's Retinopathy of Prematurity (ROP) was significant. Dr. Orlin stated, "His past ophthalmic history was complicated and significant for retinopathy of prematurity." [Orlin report 2/1/02, p.l, emphasis added] Defense expert Dr. Willis stated, "ROP is a clinically-significant abnormality in the sense that it represents a pre-existing abnormality in the eye..." [Willis report 5/29/02, p. 1, emphasis added]

6. Dr. Orlin's statement, "Mr. Morgan's retinas were 'healthy' for the purposes described in the brochure" is illogical. Retinas are either healthy or they are not. Dominic's retinas were clearly not healthy "for the purposes described in the brochure" or any other purpose.

7. Dr. Orlin's statement, "The statement made in the brochure does not apply to stable retinas, such as the retinas of the plaintiff at the time he underwent LASIK..." is also illogical. It equates stable retinas with healthy retinas, and that is simply not correct. Stable retinas does not mean healthy retinas.

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8. While knowing if Mr. Morgan's retinas were "stable" at the time he underwent LASIK is useful, it is not the issue at hand. Whether the retinas were stable or not before LASIK, the retinas were certainly not healthy or normal before LASIK, and the real issue is would those abnormal retinas be "stable" after LASIK? They would not, and it was predictable they would not, causing Dominic's visual problems.

9. There are only so many ways I can say it: Doing LASIK in a ROP patient like Dominic is below the standard of care. Dr.

Orlin is, no doubt, embarrassed that his patient brochure contradicts his position in this case, but the fact is the brochure is accurate, and Dr. Orlin is trying to avoid his own contradiction.

Dated: signature on original scanned document Nevyas v. Morgan

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PAGE 1

Beverly Hills Eye Medical Group, Inc.12561 Promontory RoadLos Angeles, Ca. 90049Phone 323 653-3800 Fax 310 472-4244

DECLARATION OF JAMES J. SALZ, M.D.

I, James J. Salz, M.D. make this declaration subject to the penalties of 18 Pa.C.S.A. Sec. 4904 relating to unswom falsification to public authorities:

1. I update my curriculum vitae and that of Dr. O'Brien: I am Chair and Dr. O'Brien is Secretary of the International Society of Refractive Surgery/American Academy of Ophthalmology Executive Committee for 2003. Dr. O'Brien and I are both well acquainted with how medical diagnoses are made by ophthalmologists. For the most accurate diagnoses, the entire medical record should be available.

2. After LASIK, Mr. Morgan saw Nevyas-Wallace's group for almost 2 years, as well as several other ophthalmologists, seeking to correct his worsened vision. The records confirm that Dominic told Nevyas-Wallace and the other ophthalmologists what each told him, that Dominic obtained some copies of records to take from one to the other, and that sometimes the ophthalmologists wrote or telephoned each other, but no ophthalmologist had copies of all the medical records from all the other ophthalmologists,

3. The only persons to review copies of the entire medical records appear to be Dr. O'Brien (after he became an expert) and me. I am not certain what Dr, Orlin and Dr. Willis reviewed. The early post-LASIK period;

4. Nevyas-Wallace initially told Dominic that all his problems were temporary and would pass with time, first 3 to 6 months, then 6 to 12 months. Meanwhile, Nevyas-Wallace wrote in the records that there were problems in centering the laser ablation during the left eye LASIK procedure (operative note 4/23/98), with resultant temporal decentration in the left eye (medical records 4/27/98, 5/4/98), and nasal decentration in the right eye (medical record 7/6/98),

5. Three other ophthalmologists seeing Dominic after LASIK, Karen Fung, M.D. (medical record 8/3/98), John Dugan, M.D.

(medical record 8/25/98), and Michael Belin, M.D. (medical record 1/25/99 told Dominic and wrote that they were concerned with LASIK causing decentration problems. After Dr. Dugan talked with Dr. Guyton (see below, on 6/19/00) he wrote both that he was uncertain, as well as writing about decentration. The later post-LASIK period;

6. Peter Laibson, M.D. wrote (letter 2/23/99): "I think it is either a retinal problem (you are familiar with his past history of regressed retinopathy of prematurity with peripheral

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PAGE 2

lattice degeneration) or possibly other factors, which are not obvious on the objective examination." When deposed. Dr. Laibson would not answer all pertinent questions. Asked by defendants if LASIK was responsible for Dominic's loss of visual acuity, Dr, Laibson said, "1 can say that the LASIK surgery looked like it was done appropriately; and that as for as visual loss is concerned, I don't know how to answer that question." [deposition Laibson p.24, 25] When asked again by defendants if LASIK was responsible for Dominic's Joss of visual acuity, he said, "I don't know."[deposftion Laibson p.26J When further pressed by defendants, he questioned the accuracy of defendant's medical records: "I felt it was not likely that if he really did have 20/40 that the LASIK was responsible for the reduction in vision to 20/70." [deposition Laibson p.27, emphasis added] When plaintiffs attorney asked, "Doctor, would you consider the use of the suction cup and the increased intraocular pressure as one of the other factors that you're referring to?' he answered, "I have no comment on that."[deposition Laibson p.38]

7. Nevyas-Wallace wrote (medical record 3/8/99): ""Phone call from patient...He says Dr. Michael Belin and Dr. Pater Laibson each said the cornea looks fine and that the problem must be retinal." Thereafter Nevyas-Wallace's continued to assure Dominic that his problems would clear up with time, but what was written in Nevyas-Wallace's medical records changed,

8. Sheldon Morris, M.D. wrote (medical record 4/17/00): "Low VA [visual acuity] related to retinal problems." At deposition Dr. Morris said he did not know if the retinal problems were worsened by the LASIK procedure or independent of LASIK. [deposition Morris p. 22]

9. Herbert Nevyas wrote (medical record 4/26/99): 'Impression: Retinal problem Rule out hysteria,"

10. Paul Beer, M.D. wrote (letter 7/21/99): "The explanation that was raised by one of the previous consultants, that his refractive surgery is not aligned with the physical location of his macula, may be very reasonable."

11(A). Herbert Nevyas wrote (medical record 7/26/99): "Impression: Topography shows central ablation, and no increase (in vision) with contact lens. Therefore, problem is retinal."

(B). Nevyas-Wallace wrote (medical record 10/11/99): "Impression: Discussed in detail - that as per Drs, Laibson, O'Brien, and Belin, the cornea and topography are excellent and that slight drop in visual acuity is symptomatic with marginal acuity at

the onset. Also that retinal factors including retinopatby of prematurity likely to be responsible." This implied that retinal factor other than retinopathy of prematurity were present, and Nevyas-Wallace repeated her implication [deposition Nevyas-Nevyasx p. 212]: "I discussed matters in detail and I explained to him that I agreed with Dr. Laibson and Dr. O'Brien and Dr. Bella in their assertions that both the appearance of the cornea and the cornea! topography are excellent and that slight drop in visual acuity is

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symptomatic and that retinal factors, including his retinopathy of prematurity, are likely to be responsible."

12. Eugene DeJuan, M.D. wrote for diagnoses: Question of optical phenomena and retinal degeneration or ischemia secondary to vacuum [cup for LASIK]. (Johns Hopkins medical record 11/29199)

13. David Fischer, M.D. wrote (letter 3/3/00): "The more insidious causes of diminished vision concern the retina which your LASIK surgeons felt were the culprit. Your fluorescein angiogram was felt to be normal as were your visual fields. The ERG showed mild retinal dysfunction, cause to be determined. During LASIK procedures a suction cup is placed on the eye causing increased intraocular pressures. Could this be a factor as a long-term optic neuropathy which may also be related to your retinopathy of prematurity? I'm afraid these are questions that I cannot answer and I'm hopeful that the doctors at Johns Hopkins can elicit these answers for you,"

14. David Guyton, M.D, saw Dominic at Johns Hopkins in June 2000. Dr. Guyton stated, "I could say from that that the refractive surgery wasn't the only thing which was decreasing his vision" [Guyton deposition p. 19] Dr, Guyton stated that the other thing which was decreasing Dominic's vision, which he deduced by a process of elimination [Guyton deposition p. 45] was barely visible cataracts (unrelated to LASIK), and suggested waiting [two yean] to see if there would be any progression. Absent progression he felt cataracts could not be part of Dominic's visual problem, (letter 6/19/00 and deposition pp. 22, 23, 38, 39).

15. The other two Johns Hopkins doctors, Eugene DeJuan, M.D. (with his fellow, Joseph Harlan, M.D.) and Terrence O'Brien, M,D., did not believe there were cataracts, but did not regard waiting as unreasonable.

16. When 1 examined Dominic 4/27/02 it was almost 2 years after Dr. Guyton and there was no progression. As I previously reported, ray opinion is that there are no cataract problems, and Dominic's problems are related to decentered laser ablation, and retinal and optic nerve damage.

17. Terrence O'Brien, M.D., having waited 2 years after Dr. Guyton, agreed with me and became a plaintiff expert.

18. Defense expert Dr. Orlin examined Dominic 1/30/02, 2 1/2 years after Dr. Guyton, and stated, "over the past two years, these have remained minima] and non-progressive," [Orlin report 6/12/02, p. 2] and neither be nor defense expert Dr. Willis

suggested any cataract problems.

Dated: signature on original scanned document Nevyas v. Morgan

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PAGE 1

Beverly Hills Eye Medical Group, Inc.12561 Promontory RoadLos Angeles, Ca. 90049Phone 323 653-3800 Fax 310 472-4244DECLARATION OF JAMES J. SALZ, M.D.

I, James J. Salz, M.D. make this declaration subject to the penalties of 18 Pa.C.S.A. Sec. 4904 relating to unsworn falsification to public authorities:

1. I update my curriculum vitae: I recently wrote a chapter for an ophthalmology text scheduled for publication in the near future, in which I discuss the advantages of performing LASIK in each eye on separate days, and I reviewed the studies and literature on this subject.

2. Two advantages Nevyas-Wallace lists for performing LASIK hi each eye on separate days, are

(1) "The doctor can monitor the hearing process and visual recovery hi the first eye and may be able to make appropriate modifications to the treatment plan for the second eye, increasing the likelihood of a better outcome in the second eye," and

(2) 'You will be given the opportunity to determine whether the LASIK procedure has produced satisfactory visual results without loss of vision..." [Nevyas-Wallace's Bilateral Simultaneous Lasik patient information form, p.2]

3. Nevyas-Wallace misinformed Dominic, despite the initial poor result in his left eye, that he was "doing well," and recommended and performed LASIK surgery on the dominant right eye one week after the left eye.

4. Dominic thus lost the opportunity to "save" his dominant right eye.

5. As I previously reported, this was below the standard of care, and is another example of Nevyas-Wallace taking away the safety net.

Dated: signature on original scanned document Nevyas v. Morgan

DR. TERRENCE O'BRIEN'S REPORTS

The following reports were after seeing Dr Terrence O'Brien, a leading Lasik specialist, who afterwards became an expert in my medical malpractice lawsuit against Herbert Nevyas and Anita Nevyas-Wallace. These are his reports, and are filed with the Philadelphia courts as well as a REPORT CONCERNING A PRIOR PATIENT, ALSO DAMAGED.> DR. O'Brien's SCANNED Reports can be found **HERE**

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DR. TERRENCE O'BRIEN'S REPORTS - RICH TEXT

Terrence P. O'Brien, M.D. Associate Professor of Ophthalmology External Diseases and Cornea Director, Ocular Microbiology Director, Refractive Eye Surgery The Eye Surgery Center at Green Spring Stettin 10753 Falls Road, Suits 305 Lutheivilte, MD 21093 410-S83-2820/FAX 410-583-2842 Email: tobrien@jhmi.«du

June 7, 2002

Steven A. Friedman, M.D., J.D.

850 West Chester Pike, 1st Floor Havertown, PA 19083

RE: MORGAN, DOMINIC JHH: 4-3200368

Dear Dr. Friedman:

I have had the opportunity to carefully review in detail all of the medical records related to Dominic Morgan's care, including the recent defense medical exam provided by Dr. Steven Orlin in Philadelphia, Pennsylvania, as wel! as the comprehensive ocular evaluation conducted by Dr. James Salz in Los Angeles, California. In addition, I reviewed the MD-TV videotape "Infomercial Transcript" that Dr. Anita Nevyas-Wallace used to promote the "Nevyas Excimer Laser" without providing information to viewers regarding the investigational status of the Excimer laser with the FDA.

In review of Dr. Salz' extensive examination and conclusions, I am of the opinion in complete agreement with Dr. Salz to the best degree of medical probability that the care rendered by Dr. Anita Nevyas-

Wallace on behalf of Dominic Morgan fell below standard for LASIK surgery at the time. Indeed, I completely agree with Dr. Salz that Dr. Nevyas-Nevyasx failed to appropriately screen Mr. Morgan and exclude him as a viable candidate for LASIK surgery based on his extensive prior ophthalmologic history which would have predicted a less than optimal result, as he has ultimately experienced with the surgery performed by Dr. Anita Nevyas-Wallace.

Dr. Friedman, your kind attention to this information and awareness of my opinion to the best degree of medical probability which is in complete agreement with Dr. Salz that Dr. Anita Nevyas-Wallace had substandard care

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related to the treatment provided with LASIK surgery on behalf of Dominic Morgan. If you have any questions regarding this deviation from the standard of care in patient selection and treatment, please do not hesitate to contact me directly at 410-847-3508.

Sincerely, signature on original scanned document

Dr. Terrence O'Brien's declaration could not be scanned and converted, but can be found above.

Dr. Terrence O'Brien's report concerning a prior patient, also damaged:

THE WILMER EYE INSTITUTE AT GREEN SPRING STATION The Eye Surgery Center at Green Spring Station 10753 Falls Road, Suits 305 Lutherville, MD 21093 (410) 614-2020 Fax: (410) 583-2842 Email: tobrien@jhrni.edu Terrence P. O'Brien, M.D. Associate Professor of Ophthalmology External Diseases and Cornea Director, Ocular Microbiology Director, Refractive Eye Surgery FACSIMILE:

(215)241-9904

April 6, 2001

Samuel F. Kafrissen, P.C. 1515 Market Street Suite 616

Philadelphia, PA 19102

RE: Cheryl Fiorelli

Dear Mr. Kafrissen:

Thank you very much for your kind inquiry into the ocular conditions and ophthalmologic care provided to Cheryl Fiorelli. I have now had the opportunity to perform a comprehensive review of the medical records of Cheryl Fiorelli from the Nevyas Eye Associates/Nevyasxx Nevyas Laser Surgery Institute from February 4, 1997 through January 4, 1999. In addition, I have reviewed the subsequent records of Cheryl Fiorelli from Richard Tipperman, M.D. from February 3, 1999 through December 16, 1999. Following detailed review of these medical records, I have been provided with a copy of the transcripts from the sworn depositions of Dr. Anita Nevyas-Wallace, Dr. Nevyasx Nevyas and Cheryl Fiorelli and have thoroughly reviewed these documents.

Ms. Cheryl Fiorelli had an ophthalmic history significant for refractive error classified as extreme myopia and high astigmatism. Because of the extremely high myopia and high astigmatism, she had always had reduced visual function that could not be corrected fully with glasses or contact lenses. Because Ms. Fiorelli noted a subjective improvement in the quality and quantity of her vision using contact lenses, she reportedly wore contact lenses from an early age (grade 7). She developed giant papillary conjunctivitis and was treated at the Nevyas Eye Associates in Pennsylvania. She had also received optometric care provided by Dr. Deborah Signorino in Byrn Mawr, Pennsylvania and had worn contact lenses with variable success.

On February 4, 1997 Ms. Fiorelli was evaluated at the Nevyas Eye Associates by Dr. Ira B. Wallace emergently for an ocular foreign body sensation. She removed her contact lens but continued to experience persistent foreign body sensation. Dr. Nevyasx reported that the ocular examination disclosed a measured visual acuity of right eye: 20/70 and left eye: 20/70+ wearing her eye glass prescription. The intraocular pressures were normal measuring right eye: 19 and left eye: 14. The examination was notable for peripheral corneal neovascxilarization especially superiorly measuring 2-3 mm x 2-3 mm with overlying punctate keratopathy and an irregular epithelium. Dr. Nevyasx requested Ms. Fiorelli to abstain from contact lens wear and initiated topical corticosteroid therapy in the form of Flarex 1 drop, 3 times a day. She was scheduled to return to see Dr. Anita Nevyas-Wallace to evaluate her cornea. Of note, pharmacologic dilation was performed and ophthalmoscopy completed by Dr. Edward Nevyas including examination of the retinal periphery. Dr. Nevyas reportedly observed peripheral retinoschisis but no breaks or retinal detachment.

One week following this appointment, a letter was written by Dr. Anita Nevyas-Wallace, M.D. to BlueCross Personal Choice in Philadelphia, Pennsylvania regarding Ms. Cheryl Fiorelli. hi her correspondence to BlueCross Personal Choice dated February 10, 1997, Dr. Anita Nevyas-Wallace pleaded a case for the medical necessity for refractive eye surgery for Ms. Fiorelli. Dr. Nevyas-Nevyasx contended that refractive surgery "should indeed be covered by insurance, as it is necessary in order for her to be able to function in her work".

On March 3, 1997, Dr. Anita Nevyas-Wallace saw Ms. Cheryl Fiorelli back for a follow-up examination. Her assessment was that Ms. Fiorelli's giant papillary conjunctivitis had improved with the giant papillae under the right lid appearing less elevated.

Dr. Anita Nevyas-Wallace then initially planned to perform LASIK refractive surgery on Ms. Fiorelli's left eye on 3/20/97 at the Nevyasxx Nevyas Laser Surgery Institute and tentatively planned to perform LASEK surgery on the right eye on 4/17/97. A bill for professional services was generated on March 12, 1997 payable by Ms. Cheryl Fiorelli in the amount of $2,100 to Nevyas Eye Associates and $400 to Dr. Signorino for optometric referral for the planned LASIK surgery.

On March 20, 1997, Cheryl Fiorelli underwent an initial LASIK procedure actually performed to her

right eye by the surgeon, Dr. Anita Nevyas-Wallace. Apparently, a registered nurse, Deborah Nevyasx, was in control of the foot pedals of the microkeratome that was used to create the LASIK flap. During the procedure, the microkeratome stopped three-quarters of the way on the forward pass and one-quarter of the backward pass. Both times, Nurse Deborah Nevyasx removed her foot off of the pedal and pressed again as the keratome finished its pass. Dr. Anita Nevyas-Wallace, as the surgeon, apparently did not control the foot pedals of the microkeratome device. The Excimer Laser ablation for the extremely high myopia and high astigmatism was

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performed using a non-approved Excimer Laser ("black box laser"). This Excimer Laser was not formally approved by the U.S. Food and Drug Administration, Medical Device Division. From subsequent reports, the laser engine was a Schwind Compex 201, which is not approved for human use in the United States.

The Excimer Laser ablation that was carried out by Dr. Anita Nevyas-Wallace using the unapproved Excimer Laser was subsequently found post-operatively to be significantly decentered based on computer-assisted comeal topographic analysis. In addition, Ms. Cheryl Fiorelli sustained a marked overcorrection with a significant hyperopic astigmatic refractive result. On the fourth day post-operative (3/24/97), Ms. Fiorelli was complaining of subjective and qualitative disturbances in her visual acuity. Her visual acuity without correction in the right eye measured 2100 pinholing to 20/70. The subjective refraction right eye: (+6.75 -2.25: axis 118 equaled 20/70). On follow-up exam, this major over-correction had a slight regression and on 3/31/97 the subjective refraction measured right eye: (+4.75: -2.25: axis 125 equaled 20/80-). The corneal topographic analysis disclosed a significantly decentered Excimer Laser ablation in the right eye.

On May 12, 1997, the visual acuity without correction right eye measured 20/70 pinholing to 20/40 with a significant halo. There was the previously noted supero-nasal decentration of the ablation.

On May 15, 1997, Dr. Anita Nevyas-Wallace attempted a retreatment of Ms. Fiorelli's right eye in an effort to reduce the disturbing subjective qualitative symptoms of halos and decreased vision resulting in

part from the supero-nasal decentration. On 5/19/97, four days status post, the LASIK retreatment in the right eye, the visual acuity without correction in the right eye measured 20/100 pinholing to 20/70. Ms. Fiorelli was still seeing subjective halos in the right eye and complaining of subjectively diminished visual acuity especially at the mid-range distance of about five feet. Her subjective refraction in the right eye: (+4.75 -1.25 x 110 equals 20/60-3).

Ms. Fiorelli's subjective disturbances following the LASIK treatment with the unapproved Excimer Laser with significant decentration persisted through the summer of 1997. On July 7, 1997, the visual acuity without correction measured 20/70 with the hyperopic astigmatic refraction. It was felt that the decreased best corrected visual acuity was in part due to flap striae and due to the decentered ablation as well as the overcorrection. Dr. Anita Nevyas-Wallace then had developed several treatment plans in an effort to improve the poor quality and quantity of vision with yet another laser retreatment. On July 10, 1997, Ms. Fiorelli underwent a third LASIK retreatment to her right eye. On August 25, Ms. Fiorelli was still not driving at night and still complained of subjective halos and poor vision from the right eye. Her visual acuity without

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Measured 20/50 pinholing to 20/50+. The subjective refraction of the right eye disclosed: (+1.75 - 1.25 axis 097 equaling 20/50-).

Despite the initial LASIK surgery and two subsequent surgeries, Ms. Fiorelli continued to have subjective disturbances in her visual function with poor quality of vision and images complicated by significant halo and glare effect with multiple optical images and difficulty driving and carrying out her activities of daily living.

Despite the poor result of the initial surgery in March 1997, Dr. Anita Nevyas-Wallace then elected to proceed with performing a clear lens extraction in Ms. Cheryl Fiorelli's left eye on March 27, 1997, just one week following the initial LAS DC surgery with the initial poor outcome. Despite the high myopia and high astigmatism (left eye: (-14.25: +5.00: axis 010), Dr. Anita Nevyas-Wallace selected a silicone plate haptic intraocular lens, which was inserted into the left eye on March 27, 1997 by Dr. Anita

Nevyas-Wallace. Post-operatively, Ms. Fiorelli had a significant residual myopia of over 3 diopters with significant early posterior capsular opacification. On July 14, 1997, Dr. Anita Nevyas-Wallace performed a YAG Laser Posterior Capsulotomy to Ms. Fiorelli's left eye. A repeat capsulotomy was then required on December 14, 1998. In addition, Ms. Fiorelli sustained a significant elevation in intraocular pressure in the left eye following the cataract surgery.

Because of the anisometropia of the left eye compared with the overcorrected right and the dislocated plate haptic intraocular lens with residual thickened posterior capsulotomy opacity, an intraocular lens exchange was performed by Dr. Richard Tipperman on April 9, 1999. The Chiron silicone plate haptic intraocular lens of incorrect power was exchanged with an Alcon acrylic MA60BM of power +6 diopters inserted in the posterior chamber in the ciliary sulcus. Because of the two previous YAG Laser Capsulotomies, it was not possible to safely place the intraocular lens into the capsular bag due to the radial openings in the posterior capsule and the likelihood of lens subluxation. By May 27, 1999, her visual acuity without correction in the left eye measured 20/40-2 pinholing to 20/30-3. The intraocular lens was well centered in the ciliary sulcus with trace cell and flare. The intraocular pressure was elevated to 30 mmHg possibly in response to the topical steroid use and Ms. Fiorelli was discontinued from the steroid and placed on a non-steroidal anti-inflammatory agent Voltaren along with Alphagan twice a day for the increased pressure.

Because of her continued subjective disturbances in quality and quantity of her vision in the right eye following the LASIK procedure and two enhancements performed by Dr. Anita Nevyas-Wallace, she was referred to the Wills Eye Hospital to Dr. Zoraida Fiol-Silva for an attempt at rigid contact lens fitting. With the fitting of a rigid gas permeable contact lens to her right eye, there was an objective and subjective improvement in visual acuity. This suggests the likelihood

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of irregular astigmatism created by the LASIK procedures including the creation of the LASIK flap and the decentered Excimer Laser ablation.

In summary, Ms. Cheryl Fiorelli has a history of exceptionally high myopia and high astigmatism. She

had been wearing contact lenses since an early age and developed giant papillary conjunctivitis. A short course at attempted therapy was undertaken. Ms. Fiorelli then underwent elective refractive eye surgery for her extremely high myopia and astigmatism. Dr. Anita Nevyas-Wallace selected the LASIK procedure for the right eye. There were no measurements of cornea thickness obtained pre-operatively despite the availability of an ultrasonic pachymeter at the Nevyasxx Nevyas Laser Surgery Institute. In addition, Dr. Anita Nevyas-Wallace reportedly had been certified in Automated Lamellar Keratoplasty and was familiar with the necessity of comeal pachymetry especially in patients with higher myopia and higher intended Excimer Laser ablations.

During the attempted LASIK procedure, there were difficulties with the microkeratome pass both in the forward direction and in the reverse direction. In addition, following the Excimer Laser ablation on March 20, 1997, there was a marked overcorrection with significant hyperopia and astigmatism created by an apparent decentered ablation. Two subsequent retreatments were performed which reduced the overcorrection and astigmatism and improved the decentration yet failed to correct the irregular astigmatism and qualitative disturbances in vision in association with an exceptionally flat cornea following the extensive ablations.

Just one week after the initial LASIK procedure with poor early outcome, Dr. Anita Nevyas-Wallace elected to perform a clear lensectomy on a young, highly myopic patient. A silicone-plate haptic intraocular lens was selected and placed into Ms. Fiorelli's left eye. There was early posterior capsular opacification in association with the silicone-plate haptic intraocular lens. A YAG Laser Capsultomy was performed. A. second YAG Laser Capsultomy was then repeated. The plate haptic intraocular lens was then decentered. There was significant residual postoperative myopia, which created anisometropia given the marked overcorrection with hyperopia and astigmatism in the right eye. A third operative procedure was required on the left eye to exchange the silicone-plate haptic intraocular lens design of sub-optimal power and to enlarge the posterior capsulotomy. This was accomplished by Dr. Tipperman and fortunately, Ms. Fiorelli experienced a return of better visual function in the left eye. Naturally, as a young, high myope patient she continues to carry a significant cumulative risk for retinal detachment following the clear lens extraction procedure, two YAG Laser Capsulotomies and a third intraocular lens exchange and posterior capsulectomy.

It is my opinion, to the best degree of medical probability, that Dr. Anita Nevyas-Wallace deviated from

acceptable standards of care in her surgical judgement in selecting Ms. Cheryl Fiorelli as a candidate for LASIK surgery given her extremely high myopia and astigmatism.

The failure to obtain corneal pachymetry to accurately assess comeal thickness preoperatively even in 1997 was substandard. The creation of the LASIK flap was complicated by microkeratome failure and stoppage both on the forward and reverse passes as documented in the medical record. Actually, a nurse was controlling the foot pedals of the microkeratome and not the operative surgeon. Moreover, an unapproved laser ("black box laser") was used to perform the Excimer Laser ablation. This Excimer Laser ablation resulted in a markedly significant overcorrection and a post-operative topography indicating a significantly decentered ablation. It is my opinion, to the best degree of medical probability, that this marked overcorrection and decentration created by Dr. Anita Nevyas-Wallace's Excimer Laser treatment using the unapproved laser is the direct cause of Ms. Cheryl Fiorelli's irregular astigmatism and continued subjective visual disturbances in the right eye in association with markedly flat keratometry readings.

The decision to perform early clear lens extraction in a young patient with high myopia in her left eye carries a significant cumulative risk for retinal detachment in Ms. Fiorelli's lifetime. This is increased by the necessity for early YAG Capsultomy following placement of a silicone hap tic plate lens in a highly myopic young individual. Finally, a third major operation to exchange the intraocular lens of suboptimal power and extension of the posterior capsultomy can only increase the long term risk of retinal detachment for her left eye.

Mr. Kafrissen, your kind attention to this information regarding the ophthalmologic care provided to Ms. Cheryl Fiorelli by Dr. Anita Nevyas-Wallace, that in my expert medical opinion, falls below acceptable standards by reasonable practitioners is greatly appreciated. Moreover, Ms. Fiorelli's ongoing problems of poor quality of vision with subjective halos are a direct result of the substandard surgeries performed by Dr. Anita Nevyas-Wallace beginning in March 1997.

If you have any questions, please do not hesitate to contact me directly.

Sincerely,

signature on original scanned document

Dr. Kenneth Kenyon's Reports

The following are scanned images of Doctor Kenneth Kenyon's reports regarding Keith Wills, another LASIK casualty, which can be found **HERE**.

The reports of Dr. Kenyon, Dr. Salz, and Dr. O'Brien clearly states the deviation from 'Standard of Care' by Drs. Herbert Nevyas and Anita Nevyas-Wallace.

Dr. Stephen Orlin

Philadelphia, PA

note: Dr. Orlin was expert witness for Drs. Herbert Nevyas and Anita Nevyas-Wallace in several of lawsuits. Below are his opinions in my lawsuit and transcript of video testimony in the Wills v Nevyas lawsuit. Dr. Orlin is not a LASIK doctor.

Affidavit regarding LASIK and Retinopathy of Prematurity (ROP)

AFFIDAVIT OF DR. STEPHEN ORLIN

This affidavit is from Dr. Stephen Orlin, an expert witness of Drs. Herbert Nevyas and Anita Nevyas-Wallace in several lawsuits. He clearly states "Retinopathy of Prematurity, in and of itself, is not a contraindication to LASIK surgery". It also states ***as an expert of the Nevyases****, that my retinas were "healthy" for practical purposes of LASIK.*

Currently, only the rich text format is available.

AFFIDAVIT IN RICH TEXT:

AFFIDAVIT

I, Stephen Orlin, M.D., do affirm the following:

1. I have been made aware of the statements made by plaintiff's counsel that the brochures that I give to patients state that they must have healthy retinas free from disease in order to have LASIK. (See Plaintiff's Reply to Motion in Limine to Preclude Testimony of Plaintiff's Experts (Frye) of Dr. Anita Nevyas-Wallace.)

2. The statement made in that brochure is being taken out of context by plaintiff's counsel.

3. The statement made in that brochure does not apply to stable retinas, such as the retinas of the plaintiff at the time that he underwent LASIK surgery by Dr. Anita Nevyas-Wallace.

4. Mr. Morgan's retinas were "healthy" for the purposes described in the brochure.

5. Retinopathy of prematurity, in and of itself, is not a contraindication to LASIK surgery.

6. There is and was absolutely no literature, either in 1998 up and through to the present, stating that retinopathy of prematurity, in and of itself, is a contraindication to LASIK surgery. Moreover, there have not been any animal studies performed to indicate that retinopathy of prematurity, in and of itself, is a contraindication to LASIK surgery, and no indication in this case that Anita Nevyas-Wallace, M.D. was using the plaintiff as a "guinea pig" as asserted by plaintiff's counsel.

7. I stand by my previously expressed opinions as set forth in my previous reports in this case.

Stephen Orlin, M.D.

Testimony of Dr. Stephen Orlin: Wills v Nevyas

IN THE COURT OF COMMON PLEAS

PHILADELPHIA COUNTY, PENNSYLVANIA

* * *

KEITH AND JO WILLS H/W: JULY TERM, : 2001

-vs- :

:

HERBERT J. NEVYAS, M.D. :

NEVYAS EYE ASSOCIATES:

DELAWARE VALLEY LASER:

SURGERY INSTITUTE: NO. 2866

* * *

Video deposition of STEPHEN E. ORLIN, M.D., held in the law offices of

MARSHALL, DENNEHEY, WARNER, COLEMAN & GOGGIN,

1845 Walnut Street, 19th Floor,

Philadelphia, Pennsylvania 19103, on

Tuesday, December 16, 2003, beginning at 6:43 p.m., before Nancy D. Ronayne, a Court Reporter and Notary Public in and for the Commonwealth of Pennsylvania.

ESQUIRE DEPOSITION SERVICES

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APPEARANCES:

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BY: KATHLEEN M. KRAMER, ESQUIRE

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-- Representing the Defendant

BY MR. EISENBERG:

Q. Doctor Orlin, is this your first time testifying for Doctor Nevyas?

A. Again, I think it is but I'm not a 100 percent sure. I have testified on behalf of his daughter Doctor Anita Nevyas in a lawsuit but I don't think that he was a -- he was named in that suit but I stand to be

corrected on that.

Q. So just so we're clear, you're not sure if you've testified and written reports for Doctor Nevyas in any other cases?

1. That's correct, yes.

Q. Okay.

Q. Doctor Orlin, did you actually testify in the Morgan case for Doctor Anita Wiles Nevyas?

A. Again, I think that I wrote a report but I didn't testify.

Q. And you don't remember ever testifying for Doctor Nevyas; you remember testifying for Anita Nevyas but not for Herbert Nevyas?

A. That's correct. Again, I might be wrong, I'm just telling you I don't know.

Q. Okay. I have a report, Doctor, dated April 6th, 2001 in a Fiarelli case, Fiarelli versus Nevyas; do you remember that case?

A. I remember it now, yes.

Q. Now, is that Doctor Herbert Nevyas?

A. I'd have to see it but I think it is, yes.

Q. Without -- do you remember that case, Doctor?

A. No, I don't remember the details, no.

Q. Did you go in court and testify for him in that case?

A. Again, I honestly don't remember.

Q. Do you remember any of the opinions that you had in that case?

A. I don't remember.

Q. Do you know whether one of your opinions, Doctor, had to do with pupil size?

A. Yes, again, I don't remember.

Q. Do you know that -- or at least I'll represent to you, Doctor, that one of your opinions had to do with pupil size; would you agree with me, Doctor?

A. Again, I don't remember.

Q. Well, it wasn't that long, ago Doctor, it was 2001, it was two years ago that you issued this report. You've only been involved in seven or eight cases and you don't remember this case?

A. I've said I don't remember.

Q. Okay. Do you remember examining Ms. Fiarelli?

A. Again, I don't remember.

Q. Do you -- did you have any conversations with Doctor Nevyas about the Fiarelli case at any point in time?

A. I don't remember.

Q. Your opinion in the Fiarelli case in terms of pupil size, Doctor, you said, pupil size is now known to be a risk factor for postoperative halos particularly in high myopes, however, this too was not clearly recognized in 1997. This too was not clearly recognized in 1997 and was not an absolute contraindication to LASIK surgery. Does that refresh your recollection, Doctor, as to your opinion?

BY MR. EISENBERG:

Q. Does that refresh your recollection, Doctor, as to offering an opinion for Doctor Nevyas in another case?

A. Again, I'm not trying to be difficult but I said in the beginning I don't remember. If you would show me the report maybe I would -- I would remember it but I just -- you ask me isolated questions and I just

don't remember.

Q. Sure, I'll be happy to show you the report that you issued. It's on the same letterhead at the University of Pennsylvania. It's dated April 6th, 2001. It's for another attorney here in Philadelphia, and the case name is Fiarelli versus Nevyas. And this is an expert report that you issued for Doctor Nevyas.

Q. My question, Doctor, is, does this report refresh your recollection that you testified --

A. Yes.

Q. -- for Doctor Nevyas before tonight?

A. Yes, it does.

Q. Is this the only other occasion that you testified for Doctor Nevyas?

A. Again, I don't remember. It might, I didn't anticipate getting tat report so maybe there's another one I just don't know.

Q. Have you ever written a report, Doctor, that's critical of Doctor Nevyas' conduct?

A. No, I haven't.

Q. So we at least know of two reports that you've written defending Doctor Nevyas and we don't know any reports or you've testified there are no reports where you've been critical of him?

A. That's correct, yes.

Q. Now we established that you and Doctor Nevyas know each other professionally?

A. That's correct, yes.

Q. You both work here in Philadelphia, you both are a member of many of the same local organizations and national organizations?

A. That's correct.

Q. And did you both do work at Scheie Eye Institute?

A. Yes, we did.

Q. Is that how you got to know Doctor Nevyas?

A. Probably, he was an attending there part-time attending when I was a resident.

Q. So he's more senior than you?

A. Yes, he is.

Q. Okay. Did you do any work under Doctor Nevyas?

A. No, I didn't.

Q. Now, you said you had attended national conferences with Doctor Nevyas, did I get that right?

A. No. I -- I've been to a conference where he might have been there but we didn't attend them together.

Q. How about New Orleans in 2001, were you two together in New Orleans in 2001, the American Academy of Ophthalmology?

A. Again, I was there and he might have been there too.

Q. But you don't remember?

A. I don't remember, no.

Q. Okay. Why don't I refresh your recollection, Doctor. The American Academy of Ophthalmology Scheie Eye Institute alumni reception at the Windsor Court, New Orleans, November 12th, 2001 And I'd like this to be zoomed in on if you would. In this picture, Doctor Orlin, which I'll show you, I'm showing you for the camera right now, right here is a picture of Doctor Nevyas, can we see that on the camera?

Q. Now, Doctor, taking a look again at your report that you issued in this case. It's fair to say that you reviewed the medical records and – for Mr. Wills before issuing this report?

A. Yes.

Q. What medical records did you review?

A. Certainly remember reviewing Doctor Nevyas' medical records.

Q. Do you have them with you here tonight?

A. No, I don't.

Q. What other medical records did you review?

A. Again, I'd have to see the pile that I was given, I don't remember whether there was a report from I think an optometrist and I don't remember his name. He might have been the person who referred Mr. Wills to Doctor Nevyas in the first place.

Q. Do you know his name, Doctor?

A. I don't remember, no.

Q. You don't remember that either?

A. No.

Q. Do you remember any of the other doctors' names and records that you reviewed?

A. I read the records from Doctor Kenyon and his report but I don't remember any other ophthalmologist medical records.

Q. Okay, Doctor, you don't remember any of what I'll call subsequent treaters, any of the doctors who treated Mr. Wills after he left Doctor Nevyas' care?

A. He -- as I recall, Mr. Wills was referred to Doctor Nevyas by an optometrist. Doctor Nevyas then did the treatments so I reviewed all his records. And then in all likelihood he went back to the optometrist who referred him to Doctor Nevyas in the first place, so I would have reviewed those records as well. But again, I just do not recall the doctor's name and I'm not sure if there was more than one

optometrist involved.

Q. In the medical records you reviewed of Doctor Nevyas, what was his measurement for his pupil size, for Mr. Wills' pupil size?

A. His pupil size in demi-illumination was six and a quarter millimeters in both eyes I think.

Q. And the laser ablation zone you indicated was five millimeters?

A. That's correct, yes.

Q. Do you know what kind of laser Doctor Nevyas was using?

A. No, I don't.

Q. Do you know the status of that laser?

A. No, I don't.

Q. Do you know whether Doctor Nevyas had to submit documents to the FDA in connection with that laser?

A. I think he did, yes.

Q. Do you know whether he reported Mr. Wills to the FDA in connection with that laser?

A. From my recollection and reviewing Doctor Nevyas' deposition he did have to speak to the FDA about Mr. Wills' case, yes.

Q. Have you seen any documents that were sent to the FDA in Mr. Wills' case by Doctor Nevyas?

A. Again, no, I don't think so, no.

Q. We can agree, Doctor, that one of your opinions in this case is that Mr. Wills degree of myopia of nearsightedness was considered to be acceptable for LASIK surgery in 1997?

A. Yes.

Q. In fact, I think you go on to state that this degree of nearsightedness is still acceptable for surgery providing other tests are done including corneal thickness measurements?

A. That's correct, yes.

Q. Is that test an important test, that corneal thickness measurement test?

A. It is, yes.

Q. Is that something you do, Doctor?

A. Yes.

Q. Before you operate on your patients?

A. Yes, it is.

Q. Why do you do that?

A. Well as I alluded to earlier, it's important to know what the thickness of the cornea is because you have to be sure that you leave a certain amount of untreated cornea in the bed before -- I mean after the operation has been done. It's somewhat controversial as to what the amount of cornea is required to prevent weakening or ectasia of the cornea from developing. The standard conventional wisdom is that it should be in the order of 250 microns but again, there's some doctors leave less than that and some doctors who leave more than that. So that's the basic importance of doing pachometry measurements.

Q. And as you said you do it?

A. I do, yes.

Q. And we know your opinion is you don't think that it was important in this case because it didn't have any effect on Mr. Wills' outcome?

A. That's correct, yes.

Q. But, Doctor, are you critical of Doctor Nevyas, just to be fair, that he didn't do this test?

A. Well, again, I think that it's something that I would have done, yes.

Q. So if someone was practicing here at Penn under your supervision, Doctor, and they didn't do this particular pachometry test would you be critical of that, Doctor?

A. Yes.

Q. And the same way you'd be critical of Doctor Nevyas?

A. Yes.

Q. Now, he also didn't do what's called a cycloplegic refraction; do you know what that is, Doctor?

A. Yes.

Q. Why don't you explain that for the members of the jury?

A. Well, basically what a cycloplegic -- what a refraction is it's a measurement of the person's need and strength for eyeglasses. When you have a nearsighted person or a myope as we call it, when light comes into your eye just like when light comes into a camera those rays of light have to be focused on the back of the eye or in the analogy of a camera, have to be focused on the film of the camera in order to get a clear picture. In a nearsighted person the rays of the light coming into focus in front of the retina not because the refractive power of the eye is too strong but because the eye is actually too long. So relative to the length of the eye that focusing is in front of the retina and thereby we call it nearsightedness or shortsightedness. And when you refract somebody you work out with a series of lenses how much lens power that patient needs in order to move that focal point from in front of the retina on to the retina.

And the way we do it is we put different lens of different strengths in front of the patient's eye and when the patient sees the chart clearer, clearer and until it's perfectly clear that end point would be considered to be the refraction. There's two ways of measuring somebody's refraction. One would be with a pupil un-dilated in the normal natural state. And the other way would be with the pupil dilated or as we call it cyclopleged. It's not the dilation of the pupil that's important the cycloplegia paralyzes the ability of the eye to focus, thereby giving a more objective refractive outcome than what you would have if the patient was able to accommodate, because with them accommodating they're refractive error can change.

But the point of it in this particular case is that it is not really relevant firstly because of the patient's age, and secondly, because of his myopia. And the reason for that is if you have a lot of optics involved, so I hope that the jury will understand what I'm saying, but when you have light rays that are in front of the retina, in other words, they come to be focused before the retina, if that patient would accommodate the accommodative process moves that point of refraction further away from the retina. So by means of accommodation a myope would essentially be making their vision blurrier than what it is without the corrections. So myopes really do not accommodate unless they are wearing the refractive corrections. So it is possible to do a non-cycloplegic refraction in a myope and get an accurate measurement of their refraction as opposed to someone who is farsighted where they -- because of their farsightedness they are constantly accommodating so you get a much more unpredictable measurements.

So in my practice again, a measurement, an un-cyclopleg refractive correction in a myope is much more accurate than it would be in a hyperope, in other words, a farsighted person. So I think that the refractive error in a myope is pretty much the same in what you can get with a cycloplegic versus a non-cycloplegic refraction. And the other point is that when people get older they start to lose their ability to accommodate so it's even less of an issue in somebody of Mr. Wills' age who is already starting to lose his accommodative powers so there's no reason necessarily to paralyze his ability or to accommodate. So in a long-winded way I've tried to explain that even though a cycloplegic refraction was not done it probably didn't have much bearing on the outcome of this case.

Q. Would you agree with me, Doctor, that it is a more objective test, that cycloplegic refraction?

A. It is a more objective test particularly in a hyperope not that much so in a myope.

Q. Did you read Doctor Nevyas' testimony that he -- wherein he said that cycloplegic was not as accurate and not as objective?

A. I did read that, yes.

Q. And did you agree with that?

A. Not entirely, no.

Q. Why not? Why don't you explain for the members of the jury where you and Doctor Nevyas differ?

A. Well, one thing he did allude to which might have some bearings when you cycloped somebody one of the so called side effects of the cycloplegia is that you make the pupil bigger. And when the pupil is bigger you can induce small aberrations of distortions in their refraction. So that's the point that he was trying to make in that you do induce, which is in fact probably correct, that you do induce some aberrations in the refraction but I cycloped people when I refract them. I cycloped patients when I refract them and the point that I'm trying to make is that in an older patient my cycloplegic and un-cycloplegical refractions are usually very, very comparable in their measurements.

Q. Again, Doctor, is this one of the tests you would have run on Mr. Wills had you been performing LASIK procedures back in 1997?

A. Yes, it would have been.

Q. So that's the second thing you would have done, you would have done pachometry and you would have done a cycloplegic refraction?

A. Again, I would have but I'm not sure I'm allowed to offer an opinion, I don't think that had any bearing on the outcome of this particular case.

Q. We're going to get to your opinions in a second, Doctor. You have offered an opinion is it true, Doctor, that the diameter of the ablation zone by the laser has a bearing on the subsequent risks for -- for inducing visual aberrations, particularly if the pupil diameter is larger than the ablation zone?

A. That's correct, yes.

Q. Well, I think in plain English we can agree, Doctor, that what you're saying is, if the laser ablation zone is smaller than a patient's pupil diameter the risk of developing glare and halo is increased?

A. Again, that's some of it, we are far more aware of in 2003 than we were in 1997. But I would agree that in today I would state that small ablation zone is an increased risk factor for having halos and glare.

Q. But your opinion is that you didn't really know it back in 1997?

A. Well, again, it's something that was alluded to but a lot of the clinical studies that I reviewed state that those were the reasons why they were doing the clinical trial, to see whether or not the optical zone

diameter had that much bearing on the outcomes.

Q. Well, Doctor, did you look at the literature before you prepared your opinion in this case?

A. Yes, I did.

Q. Did you bring any of that literature with you here tonight?

A. No, I don't have it.

Q. Okay. Doctor Kenyon testified about literature which was before 1997, we'll call it the pre-1997 literature. And some of the articles he referred to, Doctor, came from the American Journal of Ophthalmology, journal you're familiar with?

A. Yes.

Q. You think that's an authoritative journal, Doctor?

A. Yes. Yes.

Q. How about Ophthalmology?

A. Yes, it is.

Q. How about something called Mosby, refractive keratotomy?

A. Well, Mosby is not a journal. Mosby is a textbook probably.

Q. Okay, something you're familiar with though?

A. Mosby is a publisher.

Q. Okay. Sorry about. The article, the title of the article was, Refractive Keratotomy. Let's just stick with the article from Ophthalmology. Many of these articles concern PRK; you're familiar with that?

A. Yes.

Q. Did you ever perform that?

A. Yes.

Q. Okay. And they talk about aberrations usually occurring with scarring or haze, or irregular surface healing, you're familiar with that?

A. Yes.

Q. There's a 1995, it's actually a chapter in Mosby or corneal laser surgery, which talks about aberrations occurring are not due to healing. Are you familiar with that concept?

A. I'm not quite sure what you mean by not due to healing.

Q. Well, what they're showing in these articles, Doctor, is that the corneas can be virtually clear and you can still have these problems of glare and halo?

A. Yes.

Q. Have you read articles like that?

A. Yes.

Q. Doctor, if -- if the problems aren't from the scarring and haze isn't the point of what they're trying to show here that the visual problems are optical? What I'll call multifocal?

A. Well again, the problems are multifactorial. In other words, there different reasons for there being these problems, one of which might be surface irregularity.

Q. If you take out the surface irregularity, Doctor, and you have a clear cornea, a cornea that's virtually clear, have you read the articles which talk about the ghost imaging and halos occurring in PRK surgery where the corneas are clear?

A. Yes.

Q. Well, how can that be?

A. Well, it could be because of the ablation diameter.

Q. And isn't that precisely talking about here, Doctor?

A. Yes.

Q. And is that -- when you say the ablation diameter that's when the pupil is larger than the ablation zone?

A. No. The ablation diameter is independent of the pupil size. You can have ablation zones of varying diameters. And you can have ablation zones which are larger than the diameter of the pupil, the exact opposite scenario to what Mr. Wills had and the patients can still have halos and glare and multifocal and double vision. So the point of that is that it's not only because of the ablation zone diameter or the size of the pupils that predispose patients to these problems.

Q. But wasn't there a considerable amount of literature, Doctor, written before 1997 which talked about glare and halos developing and visual distortions developing because the pupil size was larger than that ablation zone?

A. Again, a lot of the literature that I reviewed alluded to the points that you are bringing up but the pupil size was not a major factor in a lot of those articles. And again, the pupil size is something that is still not quite clear. I mean there has been as I mentioned right at the beginning of this deposition that the pupil size was originally thought to be significant or not thought to be that significant and then thought to be very significant and now again in 2003 thought to be less significant than it was originally anticipated. So again, I think that you're right in that the optical zone size and the pupil size are factors in all of the equations but they are not exclusive. And I would say for sure that not 100 percent of patients who have ablation zones that are smaller than pupil sizes end up with these sorts of problems.

Q. Doctor, we can agree though that when the pupil size is larger than the ablation zone the patient should know that they're at increased risk for developing these problems, isn't that a fair statement, Doctor?

A. I think it is a fair statement and anyone who have refractive surgery should be told that they have the risk for developing halos and glare.

Q. But this is a little bit different, Doctor. I'm not talking about anyone. I'm talking about a patient who comes in that presents with a relatively large pupil and the ablation zone is smaller than that, aren't they at increased risk for developing these problems that we're talking about?

A. I would say they probably are at increased risk.

Q. And don't you think those patients should know about that risk?

A. Yes.

Q. And if that was one of your patients would you tell them?

MS. KRAMER: Objection.

THE VIDEOGRAPHER: Stand by please. Time is 7:54, we are now off the record.

MS. KRAMER: My objection is that I can't tell when you're asking the questions if you're talking about today or you're talking about 1997. If you're talking about today, I object.

MR. EISENBERG: We can go back on the record.

THE VIDEOGRAPHER: Stand by please. The time is 7:55; we are now back on the record.

BY MR. EISENBERG:

Q. I know you weren't doing these procedures in 1997, Doctor, so it's a bit of speculation, but if you were doing them, Doctor, is that something that you would tell your patient about, that is that they were at increased risk because of the relationship between the laser ablation zone and the pupil diameter?

A. Again, I'm not entirely sure that that concept was that clear under those -- at that time. It's something that I would mention to the patients and I'm sure that's something that people do mention to their patients certainly in today's environment. And again, I think that I read the consent form that Mr. Wills signed and halos were mentioned in that consent form.

Q. Excuse me. I'm not talking about whether halos and glare are mentioned in the consent form. Did you see anywhere -- you reviewed the consent form, didn't you?

A. Yes.

Q. Did you review both of them, the right and left eye?

A. Yes.

Q. Okay. I'm not asking you, Doctor, whether glare and halo is mentioned. Did you see anywhere in that consent form that it says that because of the relationship between Mr. Wills' pupil size and the laser ablation zone he was at increased risk for developing these problems?

A. No.

Q. Now, Doctor, you talked a little bit about the problems Mr. Wills is suffering from, this distorted vision.

A. Yes.

Q. Did you run any tests, Doctor, to see if Mr. Wills had this distorted vision?

A. Well, the one test that is a good objective way of measuring that problem was not available to me at the time. And that's called wave front aberrometry. Wave front is a very sophisticated way now of measuring higher order aberrations, those are distortions that a patient might be complaining about that under normal examining conditions we wouldn't necessarily be able to detect. So I didn't do that.

Q. Did you review Doctor Kenyon's reports?

A. Yes.

Q. Did you review his report dated December 3rd, 2003?

A. Yes.

Q. And did you see that he ran contrast sensitivity tests?

A. Yes.

Q. Do you disagree with any of his findings on those testings, Doctor?

A. Again, can I look at that again?

Q. Sure.

A. Which report was this, the 21st of January?

Q. No, December 3rd. Have you been given that report?

MS. KRAMER: It's the new one.

THE WITNESS: Yes, but I don't have it here. You showed it to me.

MS. KRAMER: Yes, the new one.

THE WITNESS: Here it is, I'm sorry. Yes, I saw that and I just reviewed it now.

BY MR. EISENBERG:

Q. Do you disagree with anything he has to say in terms of the contrast sensitivity testing, Doctor?

A. No.

Q. Do you know Doctor Kenyon, Doctor Orlin?

A. Again, I know his -- I know who he is, again, not social friends but I'm scarred to say that in just in case you have a picture of him and I at a meeting together. But I don't know him. I know who he is and certainly would recognize him and I've met him and he's been invited to the Scheie Eye Institute where I worked to give talks. He's – I mean a well-known individual.

Q. Doctor, other than the Fiarelli report which I showed you, concerning your opinions on behalf of Doctor Nevyas, and this report now that you've had a little bit more time to think about it, can you remember any other cases where you testified for Doctor Nevyas where the pupil size has been at issue?

A. I don't remember.

MR. EISENBERG: I have no further questions. Thank you, Doctor.

*note: Dr. Orlin is **not** a LASIK doctor.*

Nevyas' Court Depositions In My Case & Others

Click PAGE # to open page in new window

Excerpt of my deposition in this case:

PAGE 1 - Cover page - My oral deposition in Morgan v. Nevyas.

PAGE 2 - "*he (Dr. Herbert Nevyas) just basically told me to deal **with** it as far as the problems that I'm having with the sight, people lose (page 3) their sight every day, I'll see you in eight months.*"

PAGE 3 - "*Q. Is this the first time that you had a conversation with Dr. Herbert Nevyas that caused you any concern or that you were upset about? A. No.*"

PAGE 4 - "*Q . I believe you were making complaints about your vision. You had mentioned during the prior testimony two indications where you were upset by conversations that you had with Dr. Herbert Nevyas. A. Yes.*"

ALL PAGES

Excerpt of deposition of Anita Nevyas-Wallace in my case:

PAGE 1 - Cover page - Oral deposition of Anita Nevyas-Wallace in Morgan v. Nevyas.

PAGE 2 -

PAGE 3 - "*Q. Did you use that protocol when you operated on Mr. Morgan? A. Yes." "Q. Did you adhere to that protocol when you operated on Mr. Morgan? A. Yes.*"

PAGE 4 - "*Q. Are you saying that a history of retinopathy of prematurity is not a contraindication to LASIK surgery? A. **That is correct.***"

PAGE 5 - "*Q. Did Mr. Morgan have a complication of LASIK surgery in either eye? A. No." "Q. Did Mr. Morgan have an adverse event of LASIK surgery in either eye? A. No.*"

PAGE 6 - "*Q. Doctor, was the outcome of Mr. Morgan's surgery reported to either the Institutional Review Board or the Food and Drug Administration? A. Yes.*"

PAGE 7 - "*Q. Now, do I understand from what you've told me that you reported the outcome **of** the LASIK surgery to the Food and Drug Administration, but that such report did not call it either a complication or an adverse event? **A. Correct.***"

PAGE 8 - "*DR. FRIEDMAN: The reason we're here is because of a lawsuit which he's claiming that he had either a complication or adverse event MS. NEWMAN: I understand that, and she's told you she doesn't believe that it's related to the surgery. DR. FRIEDMAN: It doesn't say that. It says here, "Complications or adverse events that are observed by the investigator or reported by the subject.*"

PAGE 9 - "*A. To let people know that there is a possibility that they might be candidates to be more independent from their glasses and contact lenses. Q. And in that KYW advertisement what were the patients instructed to do to find out that information? A. I think they were instructed to call a phone number for more information.*"

PAGE 10 - "*Q. When you told him that his vision might drop, did you indicate to him how much it might drop? A. Yes. **I told him he could lose one or both eyes or he could die.***"

PAGE 11 - "Q. Doctor, if there is such a thing as focusing and Mr. Morgan focused and when he focused he did 100 percent of his focusing, you said that both the cornea and the lens were important for focusing. And I'm just asking you was the cornea responsible for 50 percent of his focusing, 75 percent, 99 percent? MS. NEWMAN: As compared only to the lens? DR. FRIEDMAN: As compared to the lens. MS. NEWMAN: If you can answer that question, you can do it. If you can't, tell him. A. I can't."

PAGE 12 - "Q. Is it your understanding that Mr. Morgan has developed cataracts in his eyes since his LASIK surgery has occurred? Your understanding and I'm talking to the period up to the last time you saw Mr. Morgan in the Nevyas Eye Associates group, which was about almost two years after the surgery. A. Yes."

PAGE 13 - "Q. During the time that you were seeing Mr. Morgan did you consider that there would be any other explanation other than cataracts? A. Yes. Q. And what did you consider? A. Considered retinal disease, considered optic nerve disease, considered corneal problems."

ALL PAGES

Excerpt of deposition Anita Nevyas-Wallace in another case:

PAGE 1 - Cover page - Oral deposition of Anita Nevyas-Wallace in Fiorelli v. Nevyas.

PAGE 2 - "*Have you ever been involved in a medical malpractice suit before? A. No.*" **(Comment - Deposition dated in this case was 5 months after I filed suit)**

PAGE 3 - "*Q. Have you ever discussed this lawsuit with Herbert Nevyas outside the presence of counsel? A. No.*"

PAGE 4 -

PAGE 5 - "*Q. That you were doing, well, just give me an idea of what you were doing in '97? A. Corneal surgery, conjunctival surgery, refractive surgery, cataract surgery. Q. Refractive surgery, how much of your time was doing refractive procedures? A. About half.*"

PAGE 6 - "*Q. Yes. Well, who were you involved in training with there? Q. Who are her, not your peers, who are your superiors, professors? A. Let's see. Theordore Krupin, William Frayer,* ***Stephen Orlin****, Alexander J. Brucker, James Ketowity, David Schaffer.*"

PAGE 7 - "*Q. I just want to know everybody you can think of right now. And at MCP, the fellowship, Who were you involved with in training at MCP in your fellowship? A. At MCP that was supervised by the department chairman of ophthalmology, at that time, Herbert Nevyas M.D. Q. Herbert Nevyas is that your father? A. Yes.*"

PAGE 8 - "*Q. Now, the presentations that you've given, I did have one quick question on that. You have Nevyas Eye Associates Clinical Lecture Series, what's that? A. Nevyas Eye Associates offers lectures for doctors in the community for educational purposes. Q. Was that in Existence in 1997? A. Yes. Q. Have you lectured regarding the lasik procedure? A. Yes.*"

PAGE 9 - "*Q. What I'd like to talk about is your experience and your training in lasik. When did you receive -- describe for me your training in lasik? A. My training in lasik began with my training in ALK, Automated Lamellar Keratopiasty, a procedure in which the microkeratome is used to raise a thin flap of cornea and then the underlying keratoma is then reshaped using the microkeratome. I began to perform that operation in 1992.* ***That operation was supplanted in our practice by lasik in 1995 and then after the flap was created we instead used, come 1995, a computer guided excimer laser to reshape the stromal bed instead of using the microkeratome to reshape the stromal bed.*** *My training in automated lamellar keratoplasty consisted both of courses taken and time spent with surgeons who were experienced in this technique.*"

PAGE 10 - "*Q. 1995 you started to do lasik, the lasik procedure, did you have any additional training in using the lasik procedure? A. Yes. Q. And tell me about your training that you had in using lasik procedure? A. I had taken at least one course in using the laser, I think I took two.*"

PAGE 11 - "*Q. Did you have any training that involved actually performing the procedure using the laser? A. Perform lasik? Q. Performing lasik, A . I would have to -- there's not a simple answer to that. Q. Why not? A.* ***Because we were performing lasik under IDE with the FDA before there were courses from that.***"

PAGE 12 - "*MS. NEWMAN: Let me object because if you're talking about lasik, unless I'm mistaken, the only lasik procedure was in March of 1997 on Ms. Fiorelli. MR. KAFRISSEN: There are three lasik. MS. NEWMAN: Three lasik? THE WITNESS-:* ***There was one lasik and two enhancements.*** *MR. KAFRISSEN: Right.* ***And my understanding is that those were lasik enhancements, right? THE WITNESS: Lasik enhancements.***"

PAGE 13 - "*Q. So tell me '95 to 97 tell me what do you consider to be postoperative symptoms, you told me postoperative is*

things patient experience, what is that, explain it? A. Postoperative symptoms include loss of best corrective visual acuity. Need I explain what that is? Q. Sure? A. Best corrective visual acuity means the best vision the patient is able to get with glasses or contact lenses. Q. Okay. A. And loss of best corrective visual acuity means that even with glasses or contact lenses the patient can't see as well before -- after surgery, as he did before surgery so that's the loss of best corrective visual acuity. Q.Anything else? A. Sure. Glare, halo symptoms, star burst. Q.Okay. A. Undercorrection, overcorrection. Q. Okay. A. Foreign body sensation. I can't think of any others. ***Q. The post operative symptoms, would you agree with me, that they can be caused by surgical complications? A. They can.***"

PAGE 14 - "*Q. When you perform a lasik procedure and it's on a patient that is referred to you by an optometrist, does the optometrist receive any portion of the fee charged to the patient for the lasik procedure? A. Sometimes.*"

PAGE 15 - "*Q. How did they know that? A. They had her cover one eye and read the eye chart and she could read down to the 20/70 line -- Q. Okay. A. -- with her glasses on. And then we cover the other eye and she was able to get two letters on the next line so it's going to be 70+2.*"

PAGE 16 - "*Q. Did you make any decision as to whether Cheryl could wear contact lenses again at no time, at any point in the future? A. At that visit? Q. At that visit. A. No.*"

PAGE 17 -

PAGE 18 - "*Q. Prior to any of the surgery that you performed, am I correct that the astigmatism Cheryl had in both eyes was correctable with spectacles? A. I'm not sure I can answer that.*"

PAGE 19 - "*Q. How does an irregular astigmatism occur during the lasik procedure, how can it occur? A. Certain flap-complications can result in an irregular astigmatism.*"

PAGE 20 - "*Q. And if you can just explain to me why this vision with correction differs from the vision that you came up with, with the refraction? A. First, I should mention that, that is Dr. Sterling's refraction, not my own.*"

PAGE 21 -

PAGE 22 - "*Q. And what did you tell her? A. I told her that best she could expect is vision as good as she gets with her glasses only without her glasses and that it might not be as good as that, but that was the best she could hope for. And that she might require a thin glass or a contact lens to give her better vision.*"

PAGE 23 - "*Q. Okay. What did you talk about? A... Q. Okay, A. I told her that of the serious and rare complications, the first one to consider is infection. That with any operation anywhere in the body there is a risk of infection and that there's a possibility of getting an infection with an organism for which we have no antibiotic and that the eye could be lost. And she said to me, you mean I could go blind? And I said, yes,* ***but I can't say that's the worst thing that could happen because you***

could die, nobody's died yet, but you could be the first."

"*Q. Okay. So tell me what could she see with her glasses* ***prior to the lasik 3/20 surgery in the right Eye? A. 20/70, Q. And in her left eye what could she see with her glasses? A. 20/70+2.***"

PAGE 24 - "*Q. And there's nothing in here about discussion of the risks, the complications, any of that type of thing, am I correct that there is nothing in your note about that? A. There is a very important phrase in that note. Q. Okay. A. Discussed in detail. Normally, I would only write discussed and that means, I went through risk complications, my entire speech. And then after I got done with that and I had written discussed in detail, if you look in the actual chart the slant of the letters is different after discussed in detail.*"

PAGE 25 - "*A. The only clue in the chart is that I said, reevaluate 10 weeks and then I said return 2/18 that - she had persuaded me to at least -- not insist that she simply spend a month without lenses and that we'd take a look sooner and see whether she could possibly put them in sooner.*"

PAGE 26 - "*Q. Okay. Did you, my question was, document it when she said it? A. No. Q. What we have is your independent recollection of that conversation? A. Yes. Q. And your interpretation of a questionnaire filled out in May 1991; is that accurate? A. My recollection, yes.*" **(Comment - Deposition dated in this case was 2000, 9 years later)**

PAGE 27 - "*Q. Are there any records that you see written by someone at Nevyas Eye Associates that documents a glare problem before you saw her in 1997? A. No. Q. Are there any documents that you see from Nevyas Eye Associates that documents a halo problem prior to your seeing her in 1997? A. No.*"

PAGE 28 - "*Q. Did you document anywhere that the patient said she had problems with glare or halos prior to the surgery? A. No. Q. Okay. Now, did you document anywhere that she had problems with star burst prior to the surgery? A. No. Q. Did she tell you she had problem with star burst before surgery? A. I don't recall.*"

PAGE 29 - "*Q. Let me ask you this then, the bill, were all of the services you rendered throughout the entire course of treatment to Cheryl Fiorelli necessary services? MS. NEWMAN: Did she need them? Were they necessary? THE WITNESS:* ***Is elective surgery -- I don't know what elective surgery falls under.***"

PAGE 30 - "*Q. Tell me what part of it is documented here? A. I have discussed matters in detail with Ms. Fiorelli. Discussed in detail means that in itself, in detail. MS. NEWMAN: Just tell him what you said. THE WITNESS: She is interested in having refractive surgery, and we discussed the lasik procedure.* ***She understands that her best spectacle corrected acuity is in the 20/60 to 20/70 range and that is the expected postoperative best corrected acuity as well.***" **(Comment - The Nevyases' Study protocol stipulates 20/40 or better.)**

PAGE 31 - "*Q. When you say negative 12, I think we had discussed earlier her refraction was around negative 15? A. Minus 14 when she was refracted on March 3rd when I refracted her.*"

PAGE 32 - *"Q. All of your visits up to his point, where were you seeing Cheryl at, physically? A. I'm not sure they were all at the same office. Q. Were you employed at the time? Are you an employee of Nevyas Eye Associates at the time that you were seeing Cheryl? A. Yes. Q. Tell me where are Nevyas Eye Associates offices, where sere they then? A. Actually, I can answer your first question. I was seeing her at our Bala Cynwyd office, that is where all the visits are."*

PAGE 33 - *"Q. The information on this sheet was the programming for the laser, the instructions for the laser's programming, are they made by you, were they made by you for Cheryl Fiorelli? A. The instructions for the laser's programing were made by me. Q. Did you get this sheet at some point before the surgery? A. Yes. Q. And did you review it? A. Yes."*

PAGE 34 - *"Q. Did you consider Cheryl a good candidate for lasik? A.* ***I considered her a good candidate with some – as long as she was aware of the things that I mentioned."***

"MS. NEWMAN: Well, it's clear that she's got a best corrected visual acuity of 20/70. She said that she considered herself -- Dr. Nevyas-Wallace said that the plaintiff considered herself a high handicap with glasses other than what's already been discussed."

PAGE 35 - *"Q. Okay. My question was, was there any standard within the medical community that you were aware of in 1997? Is it your testimony that the standard was to negative 24 or is it your testimony that some doctors were out there doing it? A. Standard worldwide at that time was in the 20 to 22 diopter range."* **(Comment - See the Nevyases' Study protocol.)**

"Q. No, what? A. ***No. I didn't measure cornea thickness.*** *Q. Okay. A. Prior to that surgery. Q. Prior to the lasik on 3/20? A. Correct. Q . Why not? A.* ***That was not standard of care in 1997.*** *Q. You just said that it wasn't standard of care to measure cornea thickness in 1997, is it your testimony that regardless of what the vision of the patient you were dealing with was, you would have to measure corneal thickness?"*

PAGE 36 - *"Q. Ultrasonic pachymetry. Did you have the capacity to perform ultrasonic pachymetry in your office? A. Yes. Q. Did you have that capacity prior to February of 1997? A. Yes. Q. For how long prior to 1997 did you have that capacity in your office? A. We had optical pachymetry since the 1960's and ultrasonic pachymetry since 1990."*

ALL PAGES

Excerpt of deposition of Herbert Nevyas in my case:

PAGE 1 - Cover page - Oral deposition of Herbert Nevyas in Morgan v. Nevyas

PAGE 2 - *"Q: As far as the KYW information that was broadcast on the air, what time frame did that run from? A: I don't remember-There was very little. We had a few — I think we had some advertising on KYW to let people know what we were doing as far back as '93 or '94 and I'm not sure what was done in the next couple of years. I really don't recall. I'm not even sure there was much around that time, if any, I think — if I think back to '94 or '95, we had some advertising at that time. I*

don't think there was later."

PAGE 3 - *"Q: How did you get approved for laser surgery if they didn't have a laser? A: By taking courses that they gave. They may have been using a laser at a laser center. I'm not sure. This was some years ago. to be certain, I'm referring to formal hospital privileges and not — A: I'm not sure. I don't recall whether it was formal hospital privileges or whether it was their approval for using the Summit laser at that time. I do not recall. I had no intention of using it, so I don't remember."*

PAGE 4 - *"Q: Do you know if Dr. Nevyas-Wallace has performed LASIK at any hospital?" "A: I don't know. Not as far as I know, let's put it that way. Not as far as I know."*

PAGE 5 - *"**Q:** In all of the meetings and courses that you've attended, has there been any mention of any patient who had LASIK who had a similar condition to Mr, Morgan?" "MS. KRAMER: I'm going to object to the form and ask if you can define "similar condition." "Q. A similar condition would be a history of retinopathy of prematurity with a large positive angled kappa." "A: Not to my recollection."*

PAGE 6 - *"Q: Doctor, do you have any income earned as an ophthalmologist that comes to you other than via Nevyas Eye Associates or Nevyas Eye Associates of New Jersey? MR. LAPAT: Objection. MS. NEWMAN: Objection. MS. KRAMER: You can answer it. A: Income earned as an ophthalmologist that comes to me? That is assuming that I have income earned as an ophthalmologist that comes to me from the corporation. The answer is no. Q: Doctor, do you have income from the Nevyas Eye Associates or Nevyas Eye Associates of New Jersey? MR. LAPAT: Objection. Again, that has no bearing on this litigation. A: Probably not, no. **Q:** They don't pay you? A: No."*

PAGE 7 - *"Q: What was the purpose of working with MDTV?" "A: They were going to make a video which we could use to show our patients, give them some idea of the refractive surgery we do, and they were going to put it on some public access channels to show people what we were doing."*

PAGE 8 - "Q: Are you familiar with the requirements for driving a car, the requirements I am talking as far as vision for driving a car in Pennsylvania, what they are? A: Pretty much."

"Did you ever tell Mr. Morgan that he should not drive? A: I don't think so. I don't recall that." **(Comment - 7 years after this deposition Herbert wrote a letter to NJ DMV (I believe as an act of vindication) to make sure my license was revoked.)**

PAGE 9 - *"Q: Did you consider the possible diagnoses of malingering, hysteria, nuclear sclerosis or a physical problem that is retinal as being a complication of LASIK surgery? A: No. Q: Did you consider malingering, a physical problem that is retinal, hysteria or nuclear sclerosis as being an adverse event following LASIK surgery? MR. LAPAT: Objection. MS. KRAMER: Go ahead.You can answer. A: Absolutely not."*

PAGE 10 - *"Q: If the patient, when examined preoperatively, doesn't show any evidence of nuclear sclerosis — I' m not sure I understood your answer. Does that mean you could anticipate nuclear sclerosis? A: No, we would anticipate it by examining him, and if we saw it developing, not operate him. Q: I take it since he was operated that it wasn't seen? A: It was not. It*

seemed to be developing now afterwards. It has been several years."

PAGE 11 - *"Q: Doctor, do you see that, "No change in ghost image with hard contact lenses"? **A:** Yes. Q: Are you able to identify who wrote that note? **A:** That is Dr. Anita Wallace.That is the first mention I see of a ghost image.There is no complaint of a ghost image. She just said that there is no change in any. I don't even know that there were any."*

ALL PAGES

Excerpt of deposition of Herbert Nevyas in another case:

PAGE 1 - Cover page - Oral deposition of Herbert Nevyas in Fiorelli v. Nevyas

PAGE 2 -

PAGE 3 - *"Q. And my understanding, from Anita's deposition, is that Anita is your daughter?" "A. Anita's my daughter. Other than to say it's a pity that this woman has resorted to lawsuits, that's all. We haven't discussed the facts of the case at all."*

PAGE 4 -

PAGE 5 - *"Q. Was corneal thickness a factor in planning the Lasik surgery prior to March of 1997?" "**A. I really don't know if it was a factor or not.** Obviously, the gross appearance of the cornea was. I do not have in the record here -- perhaps you have it; I'm not sure, since I didn't see the patient initially --"*

PAGE 6 -

PAGE 7 - *MS. POST: Objection to the form. If you know." "A THE WITNESS: The purpose of the procedure was the same as any of myopic Lasik procedure: to relieve the patient of the myopia, which made her dependent upon glasses or contact lenses, and in her case made her absolutely blind and helpless without an optical prosthesis."*

PAGE 8 - *"Q. Okay. There is a note on the operative form about the laser keratome stopping on its forward and its backward pass." "A. Yes."*

PAGE 9 - *"Q. Can you tell me what significance, if any, the fact that the keratome is recorded as having stopped three-quarters of the way on forward and one-quarter of the way on the backward pass?" "THE WITNESS: The significance is that the microkeratome that was in use at that time, and is still in use pretty widely, had a gear system which could sometimes hang up momentarily, and if the laser hesitates, it could create some unevenness in the cut making the corneal flap. The significance here is that it stopped toward -- I don't know -- the three-quarters was recorded either by the nurse or the optometrist who was assisting, who obviously couldn't be looking in the microscrope, -but it looked to them as if it hesitated when it was pretty well through the pass and, therefore it would have no significance really except to, you know, we note everything that happens in the procedure. No clinical significance."*

PAGE 10 - *"Q. Is there any indication in the record or in the notes that Cheryl was not looking at the light?" "A. There's no way we could know. We have to tell her what to do and then we can only tell by the topography whether her optical axis was indeed lined up with the laser beam center."*

PAGE 11 - *"Q Okay. Do you know why the lensectomy on the left eye was done seven days after the Lasik on the right eye?" "A. Well, from the record, I gather the patient was unhappy with the imbalance now and wanted to get something done on the other eye, and why it was done as a lensectorny rather than as a Lasik, I could give you my assumptions but I don't recall discussing it."*

PAGE 12 - *"MR. KAFRISSEN: What he testified to is that he couldn't recall exactly what he did during this surgery but here are the things that the doctor normally does as an assistant." "THE WITNESS: I must take exception. These are things I might have done as an assistant. Other people might have done them too."*

PAGE 13 - *"**Had you ever discussed her between the previous** surgery and May I5 surgery with Doctor Nevyas Wallace?" "A. Probably there was some discussion but I don't recall. Most likely, Doctor Nevyas-Wallace told me what the situation was and what she had planned, but I don't recall that specifically. She may have mentioned it to me, but she is quite expert on her own and I do not monitor each thing she does. In fact, she's got a national and international reputation particularly in the interpretation of elevation topographies."*

PAGE 14 - *"Q. Okay. With regard to the left eye, as of May 21 27, 1997, what was your assessment?" "A. I have nothing there except that it looked normal. I didn't note any abnormalities. I would have noted abnormalities."*

PAGE 15 - *"Q. Okay. Did the second enhancement have the desired effect as of 7/11/1997?" "A. I haven't testified what the desired effect was. I think you should ask Doctor Wallace exactly what she was hoping to accomplish. It looks like, from her record, that the vision was much better and refractive error was reduced. She had very little astigmatism and essentially no refractive error. If that's what she was aiming to accomplish, then she was successful."*

PAGE 16 - *"Q. Let me get -- I'll get to that in one minute. Did you note that the lens was decentered prior to the July 14 surgery?" "A. No." "MS. POST: Did he make any notation that it was?" "MR. KAFRISSEN: Yes."*

PAGE 17 - *"Q. And what was her overall assessment?" "A. She had very strange complaints. I have vague complaints, Estonopia(ph) is a term that we use for somatic complaints being expressed visually." "Q. Meaning?" "A. That is, complaints that may not be based in physical problems but perhaps in mental problems. It was my impression that she had a lot of complaints beyond what I could see a base for, and some people express their anxieties in terms of physical complaints, and I felt that hers was perhaps somewhat that."*

PAGE 18 - *"Q. Do you have any recollection of any discussions between you and Cheryl Fiorelli at any time, either the specific discussion or just generally?" "A. I'm sure I talked to -her when I saw her. I don't recall much except that she appeared to be an anxious person who seemed to have complaints in excess of what I could find physically. She was always*

complaining. I do remember that, but we tried our best to try to remedy her complaints."

PAGE 19 - *"MR. KAFRISSEN: I'm asking from his review of the record that was from his office that he produced, did he have any reason to suspect or believe or any information that there were erroneous entries or misstatements of fact in the records." "THE WITNESS: Absolutely not."*

ALL PAGES

Nevyas' Threats of Lawsuit and Intimidation to Shut Down My Websites

(The dates are links to the referenced documents provided)

In April, 2000 I filed a medical malpractice lawsuit against Herbert Nevyas and his daughter Anita Nevyas-Wallace, two Philadelphia area LASIK doctors and their practice, Nevyas Eye Associates.

I found out I was not alone. At the time I started this website, there had been multiple cases of medical malpractice (including mine) filed against these doctors and their business, as listed in the **Philadelphia Civil Docket Access System.**

000402621 or **031100946**

In response to posting this website, and including the Nevyases names, I have been sued. Through threats of lawsuit, intimidation, and (I believe) violation of my First Amendment rights, my website was shut down three times previously, the 2nd time after a temporary restraining order was sought, and denied (by the courts). Because of the way my medical malpractice lawsuit was handled through the courts, I believe it necessary to document this case in its entirety.

Below is a chronology of my latest litigation with the Drs. Herbert Nevyas, Anita Nevyas-Wallace, and Nevyas Eye Associates (Nevyases), Bala Cynwyd, PA (I could not name them previously due to litigation). All of the documents are filed with the courts, and are public record:

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window:

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LASIK Gone Wrong - What happened to Keith Wills

LASIK Gone Wrong

What happened to Keith Wills

When EYES, Windows To The Soul, are broken

By Jo Wills

My husband, Keith R. Wills went to Dr. Herbert Nevyas of Bala Cynwyd, PA, for an evaluation to determine if he was a candidate for LASIK surgery on July 26, 1997. Dr. Robert Levy of Burlington, NJ, recommended Dr. Nevyas, a doctor that was performing LASIK in the area, evaluate Keith for LASIK surgery.

LASIK surgery was scheduled to be performed on my husband's first eye on August 28, 1997, and the second was scheduled for September 11, 1997. Dr. Nevyas and Dr. Sterling were both present when Keith and I discussed his need to see in detail since he was an amateur astronomer and worked with small parts and wires in computers. Keith discussed his new purchase of a telescope and how his job duties required clear vision. He was told that his vision would be "crystal clear". Dr. Nevyas even patted my husband on the back and speaking to me said we'll "take care of this big guy". Dr. Nevyas followed up with a letter dated July 26, 1997 to Dr. Robert Levy; stating that Keith was an "excellent candidate for LASIK surgery."

Dr. Nevyas did not inform us that he was using laser that did not have FDA approval. None of the information that he provided prior to the day of the surgery indicated that my husband was going to be a "guinea pig" for the Doctor's own financial advancement. Apparently he wanted his invention approved by the FDA and then he could market the device as he had done with his other inventions.

One day we got a call and a representative from the doctors office told us that the surgery was going to be delayed because the FDA "had to approve" Keith's surgery since he had a high degree of myopia. The

first surgery was initially scheduled for August 8, 1997 and was pushed back to October 7, 1997. When he was informed that the delay continued, Keith became extremely concerned and had a "gut" feeling that the delays were an indication that he shouldn't have the surgery. He was concerned about the possible problems that could result from this surgery so he told them he was canceling the surgery. Dr. Nevyas was so concerned over Keith canceling his surgery that he called and went over Keith's concerns at length. He told my husband that since he was an "excellent candidate" and he had virtually no chance of having any of the problems that he was concerned over. The doctor was aggressive in his attempt to "save" his business and assured my husband that he was not going to have complications so that he would agree to continue with the scheduled surgery. Before the doctor would perform any surgery, we had to submit $5,000.

On the day of surgery, my husband was picked up at our home by a van that was provided by one of Doctor Nevyas' holdings, The Delaware Valley Laser Institute. The doctor now had a captive audience.

Dr. Nevyas had told Keith that he was not to be concerned about the adverse conditions listed in the "Informed Consent" document that the doctor had Keith sign. [How can a patient have informed consent when a doctor makes verbal representations that differ from the document that he requires his patient to sign before he will perform surgery?]

On October 7, 1997, my husband was seated in the operatory chair and the laser was set in front of him. He was told to look at the red light in the laser, but he told Dr. Nevyas that he could not see the red light. There was some whispering but Keith could not determine what was being said and then the Dr. Nevyas asked him if he could see the red light again and Keith responded "no". Then Dr. Nevyas told Keith to look straight ahead and not move his eyes. He told the doctor that he couldn't see so he wasn't sure if he was looking straight ahead. Dr. Nevyas proceeded with the surgery anyway. AN ADVERSE EVENT!

The same happened during the surgery on his other eye on October 9, 1997. He again could not see the red light but Dr. Nevyas performed the LASIK any way. ANOTHER ADVERSE EVENT!

When the LASIK surgery did not turn out as was expected and Keith was not able to see clearly, Dr. Nevyas performed additional procedures to correct the problems that were created by the LASIK surgery. Each succeeding surgery was called an "enhancement" where the doctor told Keith he would "fine tune" his sight. Enhancements created new problems. When my husband would ask at each visit why he was

not seeing any better, Dr. Nevyas would tell Keith to "be patient, it takes time". The doctor would see Keith at specific intervals, having him wait until each procedure healed.

When another doctor told Keith that his eyes would not get better, and that there was virtually no cornea left to correct, Keith sought the advice of an attorney. A lawsuit was filed in Philadelphia, PA. We were told that the doctor's malpractice insurance company was bankrupt and that the State's insurance fund would cover the liability up to a certain limit. If we did get a settlement, no matter how high, it was limited by the State fund's maximum coverage.

We got our day in court in December 2003, the trial started off with Dr. Levy, Keith's treating eye doctor testifying against Dr. Nevyas. Dr. Kenyon, an expert witness, from Boston, MA, followed explaining that Keith was injured by the LASIK surgery. Both Keith and I testified. Dr. Nevyas' expert witness testified at night and the video taped testimony was presented to the jurors the next day. The main point that I got from his testimony was that even Dr. Nevyas' own defense expert did not agree with Dr. Nevyas and that this expert was confused on pertinent matters.

Then it was Dr. Nevyas turn to defend himself, and he testified that he didn't have to report my husband's failed surgery as an adverse event. His reasoning was that he had to perform additional surgery on Keith to correct his eyes so he took Keith off the "investigational device study" and did not report his adverse events. He didn't report Keith's surgery to the FDA at all.

The purpose of the FDA "investigational device study" is to see if the FDA should approve the equipment for use. He should have noted on the report that Keith, a patient entered into the study had an adverse event and required further surgery which would preclude him from being reported in follow up reports for the study. Keith should not have been dropped off the report, which hid the fact that there was a problem with the laser. The FDA does require that all "adverse events" be reported, not excluded/covered up as had happened in this matter. [I wonder how many other adverse events weren't reported because Dr. Nevyas had his "own" interpretation of the study requirements.]

I made numerous contacts with the FDA regarding this matter, but have been unable to get anything from them. The FDA has stated that it has previously investigated the Nevyas Laser and will not investigate unless new information is presented. I informed the FDA that we have new information that they did not have previously, the failure of the doctor to include "Adverse Events" on my husband and why. I am

disturbed that an agency that is supposed to protect the public from injury by medical equipment, will not address our concerns.

Keith was not able to see the red light in the laser. He was not a candidate for the surgery. He did not give his informed consent.

The FDA requires many documents to be signed before a doctor can enter into an "investigational study" and use equipment that has not been FDA approved. The documents I have seen do not have the required signatures, but the Doctor continued to use his invention, refusing to sign a document that was to be part of an agreement. The FDA should have reviewed Dr.'s files, reports and agreements to determine if he was following the rules, regulations and laws set forth to protect the public.

Since my husband's surgeries were never reported as adverse events, Dr. Nevyas failed to report as required by law and his agreement, which included parts that he refused to sign. He covered up the problems of his laser by reporting to the FDA that there were NO ADVERSE events on all his reports to them.

Documents that Dr. Nevyas filed the following year indicated that he made a change from the red light in his laser to a green light; he didn't just make this modification without a reason. The red light was difficult for some patients to see so he made a modification to his laser, my husband was one of those people and now his eyes are permanently damaged.

Is there a pattern here? Dr. Nevyas lied to my husband about "informed consent issues" to convince him to have the surgery. When the Doctor submitted reports to the FDA that omitted required information, he covered up a severe disabling event. It doesn't even stop here, in Civil Court, Dr. Nevyas lied under oath about the fact that he was not required to report my husband as an adverse event to the FDA. Lies, Lies, Lies.

Just one month before our trial, a Louisiana doctor was found guilty of violations of the same federal laws. The FDA publication, P03-92, dated November 5, 2003 states that a Louisiana Doctor was violating federal laws related to the conduct of clinical studies. FDA Commissioner Mark B. McClellan, M.D., Ph.D. made this statement: "This penalty sends a clear message that FDA will not tolerate conduct that can put patients at risk and erode the trust between research subjects and the medical research

community." For example, studies of high risk devices such as ophthalmic lasers must be conducted according to an investigational plan reviewed and approved by FDA and an investigator must obtain informed consent from each participant. In addition, the device cannot be used on patients before the study begins. The Louisiana Doctor's violations are listed below and almost mirror what happened to my husband when he went to Dr. Nevyas.

· Used an unapproved laser on patients before the study began;
· Treated more subjects than allowed under the study plan that was approved by FDA;
· Ignored parameters of the study by treating nearsightedness beyond the permitted range and by treating astigmatism and both eyes of some patients;
· Failed to submit complete, accurate, and timely reports to FDA about the ongoing study; and
· Misrepresented that he was using an FDA-approved laser to treat patients when, in fact, the procedures were performed with an unapproved, experimental laser.

The Nevyas Excimer Laser's ablation [removal of tissue from the body by surgical or other means] zone was 5 mm, and my husband pupils were 6.25 mm, which is considered relatively large. Using a laser on a patient with pupils larger than the laser's ablation zone was known to cause the same problems that my husband suffers from. Clearly Dr. Nevyas should have informed my husband that this almost guaranteed that he would have an adverse result. Due to the fact that Keith had large pupils, Dr. Nevyas should never have considered Keith a candidate for LASIK let alone report that he was an "EXCELLENT CANDIDATE" as in the letter to Dr. Levy.

Dr. Nevyas did not perform the Pachemetry test, it has been indicated by experts that this test would have shown that my husband was not a candidate. My husband's cornea is now too thin to perform further corrections to his eyes.

On 7/21//97, we visited a website "QuackWatch", where Dr. Herbert J. Nevyas, MD, authored a page on Refractive Surgery. It stated: "Laser-in-situ keratomileusis (LASIK): The first corneal flap is made as in ALK, and an extremely precise underlying cut is made with an Excimer Laser. LASIK techniques can be used to correct astigmatism and farsightedness as well as myopia. The results are nearly always predictable, there is no postoperative discomfort, and glare is uncommon. The operation is preferred by eye surgeons throughout the world who have sufficient experience and have access to the necessary

equipment. Several eye-surgery centers in the United States have FDA approval to perform LASIK, and some individual ophthalmologists have acquired unapproved but high-quality devices through foreign channels."

"About the Author:
Dr. Nevyas, who specializes in refractive surgery, is Clinical Professor of Ophthalmology at the Medical College of Pennsylvania. His main office and ambulatory surgical center is located in the Philadelphia area at Two Bala Plaza, Bala Cynwyd, PA 19004. Telephone: (610) 668-2777."

Only recently when I searched the "QuackWatch" website I discovered it is operated by Dr. Stephen Barrett who married Judith Nevyas and they live in a suburb outside of Philadelphia. When the above article was published on the website, it appeared to be an official site endorsing Dr. Nevyas by allowing him to publish with them since they had investigated Dr. Nevyas as an authority on the matter. It appears that I was misled and this was only a "health promotional" site for a family member.

On 2/13/2003 that same website included a revision dated 4/24/1999, which included an expanded list of complications. [This may have been a result of lawsuits filed against Dr. Nevyas and his associates.]

I would like to know why we were not protected against this doctor and why the FDA failed us in this matter. We tried to obtain copies of the official documents to use in our medical malpractice lawsuit, but the FDA, stated they were confidential and they would not be released.

Those documents could have been presented to the jury showing that this was not an approved laser, and that the doctor had even misled the government by providing inaccurate reports, documents and representations.

After the civil court trial was over, jury members stated that if they had known this information it would have changed their decision. The documents were requested from the doctor but he refused to present them in court. They were requested as part of the pre-trial discovery, but not submitted by either the doctor or the FDA. Just prior to the doctor's testimony, my attorney informed his attorney to bring the documents to court but they were never provided.

I have contacted numerous local agencies; the Attorney General's of NJ and PA, the Court System, even the local authorities. Each has told me that the FDA is the agency responsible in this matter. The FDA

claims no responsibility; they oversee equipment, not the doctor's use or practice.

We are a family of 4, two teenage girls who have not been able to spend time with their daddy doing things they enjoy. I have a husband that is no longer the man I married, he cannot enjoy his hobbies and interests and it interferes with the way my husband performs his job duties. I am concerned that we have had to radically change our way of life, not because of an accident, or the aging process, but because someone willfully misled my husband changing the way we all live.

After seeing what happened to Martha Stewart for lying to investigators, I cannot understand why this doctor gets away with his actions, ones that caused actual physical pain and permanent disability to other human beings.

Any assistance in helping us understand why the "system" failed us along with any recommendations as to a direction we may take would be appreciated.

You can visit the Wills' webpage Here

Mr. & Mrs. Wills were also threatend with a lawsuit by the Nevyases attorneys.

Your essay above referred to is replete with false and defamatory statements maliciously designated to injure Dr. Nevyas and Nevyas Eye Associates. Initially you falsely state that Dr. Nevyas stated that your husband's vision would be "crystal clear" and further stated that Dr. Nevyas said "we'll take care of this big guy". Both of the statements are false.

Dr. Nevyas never made any such statements.

You further state that "Dr. Nevyas did not inform us that he was using [sic] laser that did not have the FDA approval."

This statement is false and defamatory because Dr. Nevyas did have FDA approval to use his laser under an investigational device exemption. You know this to be true and therefore falsifying the statement in your essay can only be malicious.

You further state that Dr. Nevyas wanted FDA approval for his laser or because "then he could market the device as he had done with his other inventions."

This statement is false and defamatory. Dr. Nevyas requested an investigational device exemption only for use in his own practice. He did not seek approval to commercially market his laser. Your husband was part of the study which was fully and completely explained to him in writing and nothing that Dr. Nevyas did treated your husband as a "guinea pig" which you falsely and maliciously assert. The study was fully approved by the FDA. In addition, Dr. Nevyas did not call either you or your husband to try to persuade either you or your husband to have the Lasik Surgery. Sending a van to pick up your husband for Surgery was a service provided by Dr. Nevyas for your husband's benefit. He was not required to use the services of a van, nor was he at any time or in any way prevented from leaving Dr. Nevyas' office or the surgical center or notifying Dr. Nevyas that he had changed his mind about the surgery.

You falsely and maliciously state your husband's treatment was not reported to the FDA.

On the contrary your husband's treatment was reported to the FDA.

You falsely state that Dr. Nevyas "lied to my husband about' informed consent issues'...."

Your husband signed a detailed consent form and then passed a true and false test to make sure he understood what he was signing. You fail to report that the court completely rejected any claim that your husband did not receive informed consent.

You falsely and maliciously state that Dr. Nevyas treated more subjects than allowed under the study plan that was approved by the FDA. You falsely and maliciously state that Dr. Nevyas "ignored parameters of the study by treating nearsightedness beyond the permitted range and by treating astigmatism and both eyes of some patients."

All of Dr. Nevyas' treatment was reviewed by the FDA and the study was at no time halted. You falsely state that Dr. Nevyas failed to submit complete accurate and timely reports to the FDA about the on going study."

You falsely state that Dr. Nevyas "Misrepresented that he was using an FDA approved laser to treat patients when, in fact, the procedures were performed with an unapproved experimental laser."

Dr Nevyas received FDA approval to use a laser which he used on your husband and you know that as does your husband. The FDA approved the laser for use by Dr. Nevyas under an investigational device exemption.

You falsely state that Dr. Nevyas should have never have considered Keith as a candidate for LASIK..."

This statement is false and you know it to be false.

You have many other half-truths false statements and malicious innuendo in your essay. The truth is that the FDA approved Dr. Nevyas' study and that your husband went from being virtually blind without assistance of corrective lenses to being 20/20 without any correction at all.

Finally, you include in your 'Guest Book the statement that "Dr. Herbert Nevyas and Dr. Anita Nevyas accused of submitting fraudulent reports to the FDA" which is false and defamatory.

The statement implies that the FDA accused both Dr. Nevyas and Dr. Anita Nevyas of submitting fraudulent reports to the FDA" which is false and defamatory. The statement implies that the FDA accused both Dr. Herbert Nevyas and Dr. Anita Nevyas of submitting fraudulent reports to the FDA. You know this to be false.

You also state "Dr. Anita Nevyas Target of FDA Criminal Complaint". This is false, defamatory and maliciously published by you when you know this to be a falsehood. Dr. Anita Nevyas was never a target of an FDA criminal complaint, but in fact has an unblemished record with the FDA.

You must either remove all of these lies from your essay and "Guest Book" or remove the entire document. Your conduct is inexcusable. Your husband has his day in court you presented all of your evidence and the jury found against you as well as they should have. If you wish to avoid litigation remove this filth from the Web by July 5, 2006.

Very truly yours,
Leon W. Silverman

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