EXHIBIT 5

Why I do not recommend Dr. Herbert Nevyas!

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 laser vision correction. In March, 1998, I went for my initial consultation at Nevyas Eye Associates in Bala Cynwyd (Philadelphia area), Pennsylvania. They were advertising 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 better 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 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

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

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

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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

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:

Dates are separated to reduce page load times due to volume. Click date to view date filings in new