15

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 Station
10753 Falls Road, Suite 305
Lutherville, MD 21093
410-583-2820/FAX 410-583-2842
Email: tobrien@jhmi.edu

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 Dr. Dominic Morgan's care, including the recent defense medical exam provided by Dr. Steven Orlin in Philadelphia, Pennsylvania, as well 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-Wallace failed to appropriately screen Dr. 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

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,

Terrence P. O'Brien, M.D.
Director, Refractive Surgery

Declaration of Terrence P. O'Brien, M.D.

I, Terrence P. O'Brien, 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. **When I saw Dominic Morgan 4/24/00, it was after the 12/5/99 note by Dr. Harlan and the 2/14/00 ERG by Dr. Sunness, but before the June 2000 noted by Dr. Guyton. My evaluation was not yet completed.**

2. **Dominic Morgan's history of significant ROP was a contraindication to LASIK, and I told Mr. Morgan that, but I had not then determined if LASIK was the only factor contributing to his problems, and I thus indicated that situation by the phrase "unclear etiology."**

3. **Dr. Guyton felt that, in theory, a lens problem could be part of Mr. Morgan's visual problem, and that to exclude that possibility it would be appropriate to wait two years to see if any lens problem progressed. If there were no progression, then he felt the lens could not be a significant factor contributing to Mr. Morgan's visual problem.**

4. **After two years passed without any progression of Mr. Morgan's minimal nuclear sclerosis, it was quite clear that the lens opacity was minimal and not a significant contributor to Mr. Morgan's problems. It became evident with medical certainty that the LASIK procedure was the principal factor responsible for Mr. Morgan's visual problems.**

5. **I concur with Dr. Saiz's analyses and opinions. Dominic Morgan's history of ROP was a contraindication for the LASIK procedure. He was never a suitable candidate, and the LASIK performed by Dr. Anita Nevyas-Wallace is responsible for his problems.**

6. **I served as an expert against in the earlier Cheryl Fiorelli case, and Dr. Stephen Orlin was Nevyas-Wallace's expert. In that case Nevyas-Wallace performed LASIK when the pre-operative best corrected visual acuity (BCVA) was below 20/40.**

Dated:

Terrence P. O'Brien, M.D.

THE WILMER EYE INSTITUTE AT GREEN SPRING STATION
THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE
THE JOHNS HOPKINS HOSPITAL

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 Station
10753 Falls Road, Suite 305
Lutherville, MD 21093
(410) 614-2020
Fax: (410) 583-2842
Email: tobrien@jhmi.edu

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/Delaware Valley 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. Herbert 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. Wallace 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 neovascularization especially superiorly measuring 2-3 mm x 2-3 mm with overlying punctate keratopathy and an irregular epithelium. Dr. Wallace 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 Deglin including examination of the retinal periphery. Dr. Deglin 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. In 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-Wallace 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 Delaware Valley Laser Surgery Institute and tentatively planned to perform LASIK 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 Shelton, 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 Shelton 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

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 corneal 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

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 LASIK 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

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 Delaware Valley Laser Surgery Institute. In addition, Dr. Anita Nevyas-Wallace reportedly had been certified in Automated Lamellar Keratoplasty and was familiar with the necessity of corneal 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 post-operative 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 corneal 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 haptic 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,

Terrence P. O'Brien, M.D.
Director, Refractive Eye Surgery