



# State Medical Board of Ohio

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November 9, 2005

Vikas Kumar Jain, M.D.  
160 Merywen Circle  
Granville, OH 43023

Dear Doctor Jain:

Please find enclosed certified copies of the Entry of Order; the Report and Recommendation of Sharon W. Murphy, Esq., Hearing Examiner, State Medical Board of Ohio; and an excerpt of draft Minutes of the State Medical Board, meeting in regular session on November 9, 2005, including motions approving and confirming the Report and Recommendation as the Findings and Order of the State Medical Board of Ohio.

Section 119.12, Ohio Revised Code, may authorize an appeal from this Order. Such an appeal must be taken to the Franklin County Court of Common Pleas.

Such an appeal setting forth the Order appealed from and the grounds of the appeal must be commenced by the filing of an original Notice of Appeal with the State Medical Board of Ohio and a copy of the Notice of Appeal with the Franklin County Court of Common Pleas. Any such appeal must be filed within fifteen (15) days after the mailing of this notice and in accordance with the requirements of Section 119.12, Ohio Revised Code.

THE STATE MEDICAL BOARD OF OHIO

Lance A. Talmage, M.D.  
Secretary

LAT:jam  
Enclosures

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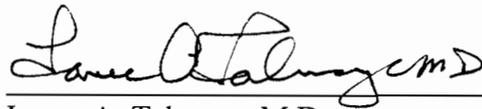
Cc: Brian M. Kneafsey, Jr., Esq.  
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CERTIFICATION

I hereby certify that the attached copy of the Entry of Order of the State Medical Board of Ohio; Report and Recommendation of Sharon W. Murphy, State Medical Board Attorney Hearing Examiner; and excerpt of draft Minutes of the State Medical Board, meeting in regular session on November 9, 2005, including motions approving and confirming the Findings of Fact, Conclusions and Proposed Order of the Hearing Examiner as the Findings and Order of the State Medical Board of Ohio; constitute a true and complete copy of the Findings and Order of the State Medical Board in the matter of Vikas Kumar Jain, M.D., as it appears in the Journal of the State Medical Board of Ohio.

This certification is made by authority of the State Medical Board of Ohio and in its behalf.



Lance A. Talmage, M.D.  
Secretary

(SEAL)

November 9, 2005  
Date

BEFORE THE STATE MEDICAL BOARD OF OHIO

IN THE MATTER OF

\*

\*

VIKAS KUMAR JAIN, M.D.

\*

ENTRY OF ORDER

This matter came on for consideration before the State Medical Board of Ohio on November 9, 2005.

Upon the Report and Recommendation of Sharon W. Murphy, State Medical Board Attorney Hearing Examiner, designated in this Matter pursuant to R.C. 4731.23, a true copy of which Report and Recommendation is attached hereto and incorporated herein, and upon the approval and confirmation by vote of the Board on the above date, the following Order is hereby entered on the Journal of the State Medical Board of Ohio for the above date.

It is hereby ORDERED that:

The certificate of Vikas Kumar Jain, M.D., to practice medicine and surgery in the State of Ohio shall be PERMANENTLY REVOKED.

This Order shall become effective immediately upon the mailing of notification of approval by the Board.

(SEAL)



Lance A. Talmage, M.D.  
Secretary

November 9, 2005

Date

2005 OCT 13 P 6 24

**REPORT AND RECOMMENDATION  
IN THE MATTER OF VIKAS KUMAR JAIN, M.D.**

The Matter of Vikas Kumar Jain, M.D., was heard by Sharon W. Murphy, Esq., Hearing Examiner for the State Medical Board of Ohio, on January 10, 11, 13, 17 through 20, 24, and 25, 2005.

**INTRODUCTION**

**I. Basis for Hearing**

- A. By letter dated June 9, 2004, the State Medical Board of Ohio [Board] notified Vikas Kumar Jain, M.D., that it had proposed to take disciplinary action against his certificate to practice medicine and surgery in Ohio based on his treatment of twenty-two patients. The Board alleged that Dr. Jain’s treatment of those patients constitutes “[a] departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established,” as that clause is used in Section 4731.22(B)(6), Ohio Revised Code.” Accordingly, the Board advised Dr. Jain of his right to request a hearing in this matter. (State’s Exhibit 23A)
- B. On July 7, 2004, the Board received a written hearing request submitted by Kris M. Dawley, Esq., on behalf of Dr. Jain. (State’s Exhibit 23C)

**II. Appearances**

- A. On behalf of the State of Ohio: Jim Petro, Attorney General, by Rebecca J. Albers and Kyle C. Wilcox, Assistant Attorneys General.
- B. On behalf of the Respondent: Brian M. Kneafsey, Jr., Esq.

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## **EVIDENCE EXAMINED**

### **I. Testimony Heard**

#### **A. Presented by the State**

1. Vikas Kumar Jain, M.D., as upon cross-examination
2. Douglas P. Webb, M.D.
3. Michael G. Gressel, M.D.

B. Presented by the Respondent

1. Vikas Kumar Jain, M.D.
2. Richard N. Whitney, M.D.
3. Stan Sateren, M.D.

II. Exhibits Examined

A. Presented by the State

1. State's Exhibits 1A through 1C; 2A, 2B; 3; 4 through 9; 10A, 10B, 11A through 11D; 12A through 12C; 13; 14A, 14B; 15; 16; 17A, 17B; 17C; 18; 19; 20A, 20B; 21; and 22: Patient records for Patients 1 through 22, respectively. (Note: There are additional sub-exhibits contained within the patient medical records that are not reproducible with available computer technology. A copy of each of these sub-exhibits will be maintained in the Board offices for Board member viewing. These sub-exhibits include the following:
  - a. State's Exhibits 1D, 2C, 3A, 4A, 5A, 6A, 7A, 8A, 9A, 10C, 11E, 12D, 14C, 15A, 16A; and 17D: Colorized images derived from computerized corneal topography.
  - b. State's Exhibit 10D: Photographic slide images of Patient 10's eyes.
  - c. State's Exhibit 10E: Color retina tomography of Patient 10's eyes.
  - d. State's Exhibit 15B: Colorized images of Patient 15's eyes derived from GDx nerve fiber analysis.
  - e. State's Exhibit 18A: Photographic slide and filmstrip images of Patient 18's eyes.
  - f. State's Exhibit 19A: Colorized images of pathology reports of biopsies performed on Patient 19.
  - g. State's Exhibit 19B: Colorized images of Patient 19's eyes derived from GDx nerve fiber analysis.
  - h. State's Exhibit 19C: Photographic slide and filmstrip images of Patient 19's eyes.
  - i. State's Exhibit 20C: Colorized images of Patient 20's eyes derived from GDx nerve fiber analysis.

- j. State's Exhibit 20D: Photographic slide images of Patient 20's eyes.
- k. State's Exhibit 20E: A videotape of a procedure performed by a subsequent treating physician on Patient 20's eyes.
- l. State's Exhibit 21A: Photographic slide and filmstrip images of Patient 21's eyes.
- m. State's Exhibit 22A: Colorized images derived from GDx nerve fiber analysis of Patient 22's eyes.
- n. State's Exhibit 22B: Photographic slide and filmstrip images of Patient 22's eyes.

(Note: State's Exhibits 1 through 22 and all subparts are sealed to protect patient confidentiality)

- 2. State's Exhibits 23A through 23M: Procedural exhibits. [Note: State's Exhibit 23B is a patient key and is sealed to protect patient confidentiality.]
- 3. State's Exhibit 24: Curriculum vitae of Michael G. Gressel, M.D.
- 4. State's Exhibit 25: Expert reports prepared by Dr. Gressel.
- 5. State's Exhibit 26: Curriculum vitae of Douglas P. Webb, M.D.
- 6. State's Exhibit 27: Expert reports prepared by Dr. Webb.
- 7. State's Exhibit 29: Certified copies of documents pertaining to Dr. Jain as maintained by the Board.
- 8. State's Exhibits 30 through 33: Diagrams of the eye created during the course of the hearing. [Note: these exhibits will be held in the Board's offices.]
- 9. State's Exhibit 34: State's Closing Argument.
- 10. State's Exhibit 35: State's Reply to Respondent's Closing Argument.

B. Presented by the Respondent

- 1. Respondent's Exhibit A: Curriculum vitae of Vikas K. Jain, M.D.
- 2. Respondent's Exhibit B: Copy of a Nidek EC-5000 LASIK Nomogram Lookup Table.

3. Respondent's Exhibit C: Respondent's Closing Argument.

C. Presented by the Hearing Examiner, sua sponte

Board Exhibit A: A paper entitled "Refractive Errors," published on the website of the American Academy of Ophthalmology. [Note: this document was used to describe very basic ophthalmology concepts; it was not used to address any issue in controversy in this matter.]

### PROCEDURAL MATTERS

1. When the Respondent rested in this matter, the State asked for additional time to evaluate whether it would be appropriate to provide rebuttal evidence. The request was granted. Nevertheless, after the last day of hearing, the State advised that they would not present any rebuttal evidence. (See Hearing Transcript at 1786-1798)
2. At the close of the hearing, the parties agreed to submit written closing arguments. Pursuant to a schedule set forth by the Hearing Examiner, the final written argument was filed on April 29, 2005. The hearing record closed at that time. (See Hearing Transcript at 1797-1798)

### SUMMARY OF THE EVIDENCE

All exhibits and transcripts of testimony, even if not specifically mentioned, were thoroughly reviewed and considered by the Hearing Examiner prior to preparing this Report and Recommendation.

#### I. Background of Physician Witnesses

##### *Vikas Kumar Jain, M.D.*

1. Vikas Kumar Jain, M.D., testified that he had been born in Delhi, India, and raised in India, Scotland, London, New York City, and Fort Myers, Florida. Dr. Jain completed his undergraduate education at Johns Hopkins University. Thereafter, he went to the University of Florida College of Medicine and, in 1990, graduated first in his class of 117 students. Dr. Jain testified that he had received numerous awards during medical school. (Hearing Transcript [Tr.] at 15-16, 1429-1431; Respondent's Exhibit [Resp. Ex.] A)

Thereafter, Dr. Jain participated in an internal medicine internship at Faulkner Hospital, which is an affiliate of Harvard Medical School and Tufts Medical School. He completed a residency at the Massachusetts Eye and Ear Infirmary, which is Harvard Medical School's ophthalmology residency. Dr. Jain testified that, "It was a particularly strong residency program, considered one of the best in the nation, with a lot of exposure to some of the

aspects of ophthalmology that sometimes aren't necessarily considered parts of ophthalmology, like plastics and things of that nature." Finally, Dr. Jain completed a fellowship in corneal and refractive surgery at Harvard Medical School and Cornea Consultants in Boston, Massachusetts. (Tr. at 15-16, 1431-1433; Resp. Ex. A)

Dr. Jain testified that he is certified in ophthalmology by the American Board of Ophthalmology. He is also a member of the Alpha Omega Alpha Honor Medical Society; the American College of Surgeons; and the American Society of Cataract and Refractive Surgery. Dr. Jain added that he is not currently a member of the American Academy of Ophthalmology, although he had been at one time. Dr. Jain testified that he had participated in research during his education, and has been published in peer-reviewed journals and authoritative texts. (Tr. at 20, 1434-1437; Resp. Ex. A)

After finishing his fellowship, Dr. Jain practiced in Fort Myers, Florida, from 1995 through 1999. In 1999, Dr. Jain started practicing at the Bloomberg Eye Center in Newark, Ohio. Dr. Jain practiced in Newark until his license was suspended in November 2002 pursuant to a Step I Consent Agreement. Dr. Jain's license was reinstated in May 2004, pursuant to the terms of the Step II Consent Agreement. Dr. Jain testified that he had practiced for several weeks after reinstatement of his license, but has not practiced since. Dr. Jain added that his work now at the Bloomberg Eye Center is administrative only. Dr. Jain is currently subject to the terms of the Step II Consent Agreement with the Board. He testified that he devotes his time to his recovery program. (Tr. at 16-17, 20-21, 1429, 1939)

Dr. Jain testified that he is licensed to practice in Ohio, Florida, New York, Indiana, and Illinois, but that he is under the terms of a Consent Agreement in each of those states. Previously, he had been licensed in Massachusetts. Dr. Jain is married, and his wife is also a physician. They have four children, ages six through thirteen. (Tr. at 1438-1429)

2. Dr. Jain testified that he has been the owner of the Bloomberg Eye Center since 1999. Dr. Jain further testified that he had relocated to Ohio in 1999 after learning that the Bloomberg Eye Center was available for purchase. Dr. Jain explained that Dr. Bloomberg had owned the practice for thirty years. Dr. Jain further testified that the Bloomberg Eye Center operates in Newark; Columbus; and Logan, Ohio. Dr. Jain added that, during the time at issue, he had practiced for a short time in New York and Chicago, in addition to his practice at the Bloomberg Eye Center. (Tr. at 18-20, 1440)

Dr. Jain stated that, initially, the practice at Bloomberg Eye Center had consisted primarily of medical ophthalmology, such as cataracts and glaucoma, and general ophthalmic pathology. Laser Assisted *In Situ* Keratomileusis [LASIK] was also performed, but did not comprise a significant portion of the practice. As LASIK became more popular, however, it had consumed greater proportions of the practice. Dr. Jain testified that, at the time at issue in this matter, his practice had been mainly refractive surgery, or LASIK, and related surgeries. Thirty percent of the practice was general ophthalmology including diagnosis and treatment of common ocular disorders, such as glaucoma and cataracts. He added that, "in 2001 and

2002, at Bloomberg Eye Center, we did one percent of all the LASIK in America. So it was quite a busy place.” (Tr. at 16-18, 1441)

Dr. Jain testified that LASIK, or refractive surgery, was first approved by the FDA in 1998, and that he had studied it during his training at Harvard. Dr. Jain stated that LASIK refers to a surgical procedure in which the shape of the cornea is changed utilizing a laser. It is surgery designed to decrease or eliminate a person’s dependence on contact lenses or glasses. Dr. Jain testified that, when he last practiced, he had been performing approximately sixteen to twenty LASIK procedures per day. (Tr. at 18-19, 1439-1440)

***Michael G. Gressel, M.D.***

3. Michael G. Gressel, M.D., testified that he had received his medical degree in 1978 from the University of Cincinnati College of Medicine. Dr. Gressel completed an internship in internal medicine in 1978 and a residency in ophthalmology in 1982, both at the Cleveland Clinic Foundation. He also completed a glaucoma fellowship in 1984. Dr. Gressel was certified by the American Board of Ophthalmology in 1985. (Tr. at 720-721; State’s Exhibit [St. Ex.] 24)

Dr. Gressel practices general ophthalmology in Lorain, Ohio. He has a group practice with three other ophthalmologists and a number of optometrists. Dr. Gressel testified that he performs laser vision correction surgery and treats glaucoma and cataracts. Dr. Gressel testified that his practice, Lakeland Eye Surgeons and Consultants, was acquired by the Cleveland Clinic Foundation in 2002. Dr. Gressel holds privileges at the Cleveland Clinic Family Healthcare Center and Community Health Partners in Lorain, Ohio; at the Hospital for Orthopedics and Specialty Services formerly known as the Amherst Hospital in Amherst, Ohio; at the Allen Medical Center in Oberlin, Ohio; and at the Elyria Memorial Hospital in Elyria, Ohio. (Tr. at 722-724)

Dr. Gressel testified that he had performed 150 LASIK procedures each year from 2000 through 2002. He added that LASIK had consisted of approximately fifteen to twenty percent of his practice. (Tr. at 1127-1128, 1155-1157)

***Douglas P. Webb, M.D.***

4. Douglas P. Webb, M.D., testified that he had received his medical degree in 1982 from the Ohio State University College of Medicine. Dr. Webb completed an internship at the Cleveland Clinic Foundation and a residency in ophthalmology at University hospitals Case Western Reserve University in Cleveland in 1986. (Tr. at 538-539; St. Ex. 26)

Dr. Webb stated that he is an assistant clinical professor in ophthalmology at Case Western Reserve University, and has been affiliated with that institution since completing his residency in 1986. He is board certified by the American Board of Ophthalmology. Dr. Webb testified that his practice is primarily general ophthalmology, with a focus on anterior segment work. Therefore, he does a lot of work with glaucoma and surgical

procedures involving the front of the eye. He stated that he also does retinal work and laser treatment of the retina. (Tr. at 539-542; St. Ex. 26)

Dr. Webb testified that he had performed approximately one hundred LASIK procedures in his career, with the last being in 2001. Dr. Webb acknowledged that LASIK surgery has changed over the past four years. Dr. Webb further testified that he has performed approximately 150 corneal transplants. Most recently he performed the procedure two months ago. Finally, Dr. Webb testified that his testimony at this hearing constitutes the first time he had ever testified in a legal proceeding. (Tr. at 544-545)

## II. The Eye, in General

### *The Cornea*

5. The cornea is the curved portion, the clear window, in the front of the eye. The cornea works with the lens of the eye to bend or refract the light coming into the eye so that the light focuses on the retina or nerve layer that lines the back of the eye. The retina then sends images to the brain through the optic nerve. For clear vision to occur, the cornea must have the correct shape and power to focus the light rays precisely on the retina at the back of the eye. If the cornea is too steep, too flat, or irregular in shape, there will be a refractive error such that the eye cannot bend light at the angle needed to focus on the retina. Common refractive errors include myopia or nearsightedness, hyperopia or farsightedness, astigmatism or distorted vision, and presbyopia or aging eyes. Refractive errors can be temporarily corrected through the use of spectacle eyeglasses or contact lenses. Alternatively, refractive errors can be more permanently corrected through surgical procedures, including: laser in situ keratomileusis [LASIK], astigmatic keratotomy [AK], or photorefractive keratectomy [PRK]. (Tr. at 57-58, 728; Board Exhibit [Bd. Ex.] A)

### *LASIK, in General*

6. LASIK is a microsurgical procedure involving the use of a laser to correct refractive errors. In LASIK, a microkeratome blade is used to cut a thin flap in the cornea. The flap is folded back, and a laser scapes the exposed corneal tissue to reshape it. The flap is then replaced and allowed to heal. No stitches are used during this procedure. (Bd. Ex. A)

Prior to performing a LASIK procedure, a variety of tests or procedures may be performed in the examination of the eye. These include: assessment of visual acuity with and without correction, manifest refraction, cycloplegic refraction, manual keratometry, corneal topography, simulated keratometry, and corneal pachymetry. (St. Exs. 1 through 16)

### *Manifest Refraction*

7. Manifest refraction of the eye in its natural, non-dilated state and is used to determine the optical prescription that will provide optimal vision. (Tr. at 749-751)

### ***Cycloplegic Refraction***

8. Cycloplegic refraction measures the eye after it has been dilated. With cycloplegic refraction, the ciliary muscle in the eye is relaxed. This is important because the eye muscles are so strong that they frequently obscure the true state of the eyes. Cycloplegic refraction provides a more accurate picture and, in most cases, it provides the information that will be programmed into the laser during a LASIK procedure. (Tr. at 1457-1458)

### ***Keratometry***

9. Keratometry is the measurement of the curvature of the cornea, and can be obtained through a manual method or through a computerized method during corneal topography [see below]. In the manual method, an instrument called a keratometer is used. During the manual method, light is directed on to the cornea, which is used as a mirror. By the way the light configures on the surface of the cornea, the curvature of the cornea can be determined. Typically, two measurements are taken: the first in one axis; and the second, 90 degrees away from the first. The results will be reported with decimals that are multiples of one-eighth or one-quarter or one-half of the diopter. (Tr. at 28, 757, 1143-1150)

Alternatively, simulated keratometry is derived from computerized corneal topography. (Tr. at 349) (See below).

### ***Corneal Topography***

10. Corneal topography is an assessment of the surface of the cornea. A corneal topographer measures thousands of points of light on the surface of the cornea. It maps the curvature and shape of the cornea and helps in correlating the shape of the cornea to errors in focusing and detects disease states that may be contraindications to LASIK surgery. A corneal topographer provides pictorial images of the topography of the cornea. (1491-1492)

Dr. Gressel described the procedure for corneal topography as follows:

[It] involves having a patient put their chin into a chin rest and look into a lighted white bowl, and inside the lighted white bowl are a series of concentric rings, white illuminated rings that reflect off of the surface of the cornea. There's a detector device that detects the reflections coming off the surface of the cornea, and the separation between those rings is mathematically analyzed in such a way as to derive an estimate of what the curvature of the cornea or the steepness of the cornea is like. Different topographers use different mathematical algorithms and different techniques for trying to establish what the curvature of the cornea is, but it's an approximation based upon reflected light. \* \* \* Manual keratometry gives you a quantitative number for the steepness of the cornea right in the center; whereas, corneal topography gives you not just quantitative information but qualitative information about a much larger surface of the area of the cornea.

(Tr. at 747-749)

### ***Corneal Pachymetry***

11. Pachymetry is a measurement of the thickness of the central cornea using an ultrasonic pachymeter. (Tr. at 411-412, 735-736)

### **III. The LASIK Process at Bloomberg Eye Center**

12. Dr. Jain testified that, when a prospective patient called the Bloomberg Eye Center to inquire about LASIK, the patient was directed to a patient counselor who described the indications for the procedure, the pricing schedule, and the process involved. If the patient was still interested, the patient received a brochure regarding the procedure, and questionnaires and informed consent forms that the patient was to complete and return to Bloomberg Eye Center. Then the patient presented for a thorough eye examination. (Tr. at 1444-1449, 1450-1452)

Dr. Jain testified that, during the time period at issue in this matter, there were two ophthalmologists working at Bloomberg Eye Center, Dr. Jain and Shahin Shahinfar, M.D., a retinal specialist. There were also two to four optometrists at any given time, including Steven Blausey, O.D., Denise Bell, O.D., and Anupama Kumar, O.D. There were also a number of technicians. Dr. Jain testified that the optometrists had helped to care for patients with primary ocular disorders, checked eyes for glasses, and gave appropriate contacts or glasses prescriptions. Dr. Jain added that the optometrists also had conducted routine eye examinations for children and adults, and had been helpful in the preoperative and postoperative management of patients. (1441)

Dr. Jain testified that Dr. Blausey, an optometrist, had been the director of the Bloomberg Eye Center and also had shared some administrative duties. Dr. Jain described Dr. Blausey as an “outstanding optometrist” who was “better able to diagnose certain diseases or post-LASIK issues than a lot of ophthalmologists because of the sheer number that he sees.” Dr. Jain added that Dr. Blausey had participated in a one-year surgical fellowship after his optometric training, and that he had been competent to follow post-surgical patients at Bloomberg Eye Center. (Tr. at 21-23, 1442-1443)

Dr. Jain testified that, when a patient presented for surgery, the patient was greeted at the front desk, and escorted to the pre-LASIK reception area. The patient was seen by a counselor who reviewed the informed consent and any questions the patient may have had. Dr. Jain testified that, at that point, the physician saw the patient. The physician reviewed the eye examination with the patient, and discussed the risks, benefits and alternatives of LASIK surgery. Dr. Jain testified that Bloomberg Eye Center used a form with a preprinted checklist so that the physician would remember to discuss each important factor with the patient. Finally, Dr. Jain testified that the physician provided a “generic disclaimer” stating that the physician cannot discuss all the potential complications and that

LASIK is a relatively new procedure; therefore, long-term consequences are not yet known. (Tr. at 1458-1459, 1478-1483)

Dr. Jain testified that the complications that are discussed with patients include the fact that LASIK is not a perfect procedure and may not result in the elimination of glasses. He stated that statistically, “98 percent of the people see 20/40 or better after LASIK, and about 80 percent of people see 20/20 or better after LASIK. With the latest technology, actually with a custom technique, 80 percent of patients see 20/15 or better.” Dr. Jain testified that he also discusses the enhancement rate, or the likelihood that the patient will require a second procedure. Dr. Jain stated that five to ten percent of patients would need an enhancement. (Tr. at 1459-1463)

After the informed consent discussion, the patient was given oral Valium to allow the patient to sleep after the LASIK procedure. While the patient was waiting, technicians calibrated and programmed the laser. The technicians programmed the laser based on a cycloplegic refraction obtained during the evaluation. (Tr. at 1478-1483)

Dr. Jain testified that, during the LASIK surgery, the patient sat in a reclining chair. Dr. Jain discussed any additional questions the patient may have had, and explained the procedure to the patient. Dr. Jain placed drops in the eye for numbing, and then placed a spring into the eye to hold the lids apart. Dr. Jain testified that he spoke soothingly and calmly to the patient, explaining the steps of the procedure as he proceeded. He then placed a microkeratome on the eye to make a flap in the cornea. After the flap was made, Dr. Jain performed the laser treatment, which lasted from ten to sixty seconds. Afterwards, the corneal flap was replaced and the eye was irrigated with a cannula. The procedure was often repeated for the other eye. After the procedure, antibiotic, anti-inflammatory, and steroid eye drops were administered, and the eyes were covered by transparent plastic shields. The patient was given discharge instructions, and told to return the next day. (Tr. at 1483-1489)

At the follow-up appointment, the eye shield was removed, uncorrected vision was measured, and the patient was questioned about his or her status. Dr. Jain testified that ocular pressures and refractions were not measured at this visit, due to the possibility of disturbing the flaps. (Tr. at 1489-1490)

#### **IV. The Patients**

##### ***Patient 1***

##### **Medical Records for Patient 1**

13. On February 13, 2001, Patient 1, a forty-one year old female, presented to the Bloomberg Eye Center with complaints of myopia in both eyes. (St. Ex. 1A at 2) Patient 1 provided

Bloomberg Eye Center with a copy of her most recent prescription for eyeglasses. That prescription was:

Right eye:	sphere, plano [0];	cylinder, -2.25;	axis, 110
Left eye:	sphere, plano;	cylinder, -2.00;	axis, 90

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On the same piece of paper was included the most recent prescription for Patient 1's boyfriend. That prescription was:

Right eye:	sphere, -2.25;	cylinder, -0.75;	axis, 93
Left eye:	sphere, -1.75;	cylinder, -1.50;	axis, 98

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(St. Ex. 1B at 9, 14, 17)

14. That same day, Dr. Jain performed a Pre-Procedure Evaluation for LASIK. A number of tests were performed with the following results:

Visual Acuity	Right Eye	20/100
without Correction	Left eye	20/80
Current Prescription	Right eye: sphere, -2.25; cylinder, -0.75; axis, 093;	20/20
	Left eye: sphere, -1.75; cylinder, -1.50; axis, 090;	20/20
Manifest Refraction	Right eye: no change in refraction;	20/20
	Left eye: no change in refraction;	20/20
Cycloplegic Refraction	Right eye: sphere, -1.75; cylinder, -1.00; axis, 110;	20/20
	Left eye: sphere, -1.25 cylinder, -1.75; axis, 085;	20/20
Simulated Keratometry	Right eye: 44.93@040; 43.42@120	
[recorded as "K's"]	Left eye: 43.07@170; 42.11@90	
Desired Correction	Right eye: sphere, -1.09; cylinder, -1.09; axis, 110	
	Left eye: sphere, -0.59 cylinder, -1.858; axis, 085	

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Manual keratometry was not performed on either eye. Furthermore, in a section entitled "Topics Discussed," the following boxes were checked: no guarantee, presbyopia/reading glasses, healing period, infection, enhancement/cost, realistic expectations, long-term results, photophobia/glare, and reduced vision. Finally, Dr. Jain wrote, "May need readers." (St. Ex. 1A at 29)

15. In a later summary prepared by Patient 1 regarding the care she had received at Bloomberg Eye Center, Patient 1 reported that technicians had performed all testing on her initial evaluation. She further noted that,

During and after being dilated and again afterwards I brought it to their attention that I could not see and read what was on the screen to my satisfaction. I said that I was 'seeing triple' and everything was very blurry. Technicians said I must be really sensitive to the dilation drops.

(St. Ex. 1B at 25)

16. On March 2, 2001, Dr. Jain performed LASIK surgery on both eyes. Patient 1 signed a twelve-page informed consent form. Cost for the procedure was \$978.00. (St. Ex. 1A at 8a-13b, 25-28)
17. On March 3, 2001, Dr. Jain saw Patient 1. Patient 1 stated that her visual acuity in both eyes had improved but was still blurry. She stated that she had been taking Ocuflax and FML eye drops as prescribed. Examination of her eyes revealed the following:

Visual Acuity	Right Eye	20/60
without Correction	Left eye	20/100
Visual Acuity	Right Eye	20/20
Pinhole	Left eye	20/20

(St. Ex. 1A at 24)

18. On March 26, 2001, Dr. Blausey saw Patient 1. Patient 1 complained that her vision in both eyes was “still somewhat blurry,” and the left eye was “sensitive to touch at times.” Examination of her eyes revealed the following:

Visual Acuity	Right Eye	20/60
without Correction	Left eye	20/50
Visual Acuity	Right Eye	20/30
Pinhole	Left eye	20/30
Manifest Refraction	Right eye: sphere, +0.75; cylinder, -1.50; axis, 120;	20/30
	Left eye: sphere, +1.50; cylinder, -0.75; axis, 090;	20/25

Dr. Blausey gave Patient 1 a prescription for glasses and recommended that she be seen by Dr. Jain in two months (St. Ex. 1A at 23)

19. On May 25, 2001, Dr. Blausey saw Patient 1 again. Examination of her eyes revealed the following:

Visual Acuity	Right Eye	20/20
with Correction	Left eye	20/20
Manifest Refraction	Right eye: sphere, +1.00; cylinder, -2.00; axis, 105;	20/20
	Left eye: sphere, +1.75; cylinder, -1.50; axis, 095;	20/20

Dr. Blausey noted that Patient 1 had been overcorrected with mixed astigmatism and recommended a second LASIK procedure with a Visx laser. Dr. Blausey prescribed Acular eye drops. Furthermore, Dr. Blausey recommended that Patient 1 be seen by Dr. Jain in one month. (St. Ex. 1A at 22)

20. On June 25, 2001, Patient 1 saw Dr. Jain. Corneal topography of both eyes was performed. Nevertheless, the images produced by the topographer were inverted on the vertical axis. Therefore, the inferior portion of the eye appeared at the top of the diagram, and the superior part of the eye appeared at the bottom of the diagram. (St. Ex. 1A at 4-5) Examination of Patient 1's eyes revealed the following:

Visual Acuity	Right Eye 20/20
with Correction	Left eye 20/20
Manifest Refraction	Right eye: sphere, +0.75; cylinder, -2.00; axis, 105; 20/20
	Left eye: sphere, +1.75; cylinder, -1.75; axis, 095; 20/20
Simulated Keratometry	Right eye: 44.45@010; 41.59@110
	Left eye: 42.55@010; 41.85@090
Pachymetry	Right eye: 495
	Left eye: 488
Desired Correction	Right eye: sphere, -4.159; cylinder, -0.50; axis, 120
	Left eye: sphere, -3.499 cylinder, -0.79; axis, 80

Dr. Jain noted that he planned to perform astigmatic keratotomy for the right eye and LASIK enhancement for the left eye. He noted a cost of \$220.00. (St. Ex. 1A at 21)

21. On June 29, 2001, Patient 1 obtained a second opinion from Carl Minning, M.D., of Eye Surgery Associates of Zanesville. (St. Ex. 1B at 26)

On July 11, 2001, Patient 1 called the Bloomberg Eye Center. She stated that she had concerns about the LASIK and AK [astigmatic keratotomy enhancement] she was supposed to have done on July 17 and 18, 2001. She asked to see Dr. Jain again prior to having these procedures done and stated that she may postpone the procedures because of the negative results she had had so far after the previous procedure. (St. Ex. 1A at 19)

On July 12, 2001, Patient 1 presented to Bloomberg Eye Center and stated that she wanted to discuss the AK and LASIK scheduled for the following week. The record noted that the procedures had been postponed. Dr. Jain wrote, "recheck after second opinion." (St. Ex. 1A at 18)

22. By letter dated August 17, 2001, Dr. Minning wrote to Curtin G. Kelley, M.D., regarding Patient 1. Dr. Minning advised that, since Dr. Jain's LASIK procedure, Patient 1 had been experiencing a significant refractive error and had seen Dr. Minning for a second opinion. Dr. Minning continued,

In looking at her preoperative and postoperative refractions, I was really quite puzzled as to how this had occurred with her LASIK. After looking through a copy of Dr. Jain's office notes, I was quite surprised to find that upon presentation they had listed [Patient 1's] present glasses as being the

prescription of that of her boyfriend. She had taken both prescriptions with her on the same piece of paper and apparently they started off with this refraction.

Even though she apparently underwent some type of refraction at the Bloomberg Eye Center, there was only limited change noted from her boyfriend's prescription and she apparently was treated for this resulting in an unusual postoperative refractive error.

(St. Ex. 1B at 9) Dr. Minning referred Patient 1 to Dr. Kelley, a corneal specialist, due to the nature of the problem. (St. Ex. 1B at 9)

On April 22, 2002, Dr. Kelley advised Dr. Minning that, after the LASIK procedures performed by Dr. Jain, Patient 1 had been left with a mixed astigmatism of the right eye and a hyperopic astigmatism in the left eye. On March 1, 2002, Dr. Kelley performed a secondary LASIK procedure on each of Patient 1's eyes. At her five-week postoperative checkup, Patient 1's visual acuity was 20/20-1 in both eyes. [Note: visual acuity of 20/20-1 indicates that the patient could read the line the on the eye chart for 20/20 vision but for one object.] (St. Ex. 1B at 6)

23. At some point, Patient 1 initiated a lawsuit against Dr. Jain. (St. Ex. 1B at 51)

#### **Testimony of Dr. Gressel regarding Patient 1**

24. Dr. Gressel provided expert testimony for the State regarding Patients 1 through 17. Regarding Patient 1, Dr. Gressel testified that Dr. Jain's care and treatment of Patient 1 had fallen below the minimal standards of care for the following reasons:

- a. Dr. Jain failed to ensure that Patient 1's refraction was accurate before performing LASIK. Dr. Gressel testified that, as a result this failure, Dr. Jain had caused Patient 1's eyes to be treated for her boyfriend's refractive error. Dr. Gressel noted that the desired correction entered into the laser by Dr. Jain was consistent with Patient 1's current prescription only in the astigmatism axis of the left eye. Dr. Gressel further stated that the sphere and cylinder powers were radically different from Patient 1's prescription but were remarkably similar to her boyfriend's prescription. Dr. Gressel stated: "It's pretty clear that what was entered into the laser corresponds very, very, very closely with her boyfriend's prescription." Dr. Gressel concluded that, "This reflects inadequate supervision of the Bloomberg Eye Center staff by Dr. Jain, as well as a careless failure on his part to recheck such an important determinant of the ultimate treatment etched into the patient's cornea." (Tr. at 762, 765-766, 769-776, 1182-1183; St. Ex. 25)

Furthermore, Dr. Gressel testified that a cycloplegic examination had been performed preoperatively. He explained that a cycloplegic examination allows the prescription for distance vision to be ascertained without the influence of the ciliary muscle of the

eye affecting the outcome. In that state, it is possible to determine the best corrected vision. Dr. Gressel noted, however, that, in this case, although the record indicates that Patient 1's corrected vision was reported to be 20/20, Patient 1 had reported seeing triple vision. Dr. Gressel concluded that a skilled practitioner would have recognized that Patient 1's correction was not appropriate, despite the fact that she could read the chart at 20/20. (Tr. at 1183-1185; St. Ex. 1B at 25)

Dr. Gressel explained that the refractive outcome demonstrated a marked overcorrection of the spherical component for each eye, which created a moderate degree of farsightedness in the left eye, and a milder degree of overcorrection in the right eye. Dr. Gressel further explained that this outcome would not be expected had the desired correction programmed into the laser been based on Patient 1's true cycloplegic refraction. Moreover, the degree of astigmatism in both eyes would be an unexpected outcome had the cycloplegic refraction actually been correct. On the other hand, Dr. Gressel noted that this outcome was "perfectly consistent" with the desired correction having been based on her boyfriend's prescription. (Tr. at 1190-1194)

- b. Dr. Jain failed to perform manual keratometry prior to performing LASIK. Dr. Gressel testified that it is important to perform manual keratometry prior to performing LASIK surgery because those readings will be necessary should the patient later develop cataracts. Dr. Gressel explained that the pre-LASIK manual keratometry readings would help the surgeon determine the appropriate power of the intraocular lens implant. He stated that this has been the gold standard for many years. (Tr. at 728-729, 755-756)

Moreover, Dr. Gressel testified noted that, in this case, there had been indicators that something was wrong in the astigmatism portion of the refraction, such that a prudent surgeon might have used manual keratometry as a cross-check before etching a new shape into the cornea based on that refraction. (Tr. at 756- 757, 759-762, 763-764; St. Ex. 25)

Dr. Gressel acknowledged that there is a newer technology for measuring the curvature of the cornea: corneal topography. Nevertheless, Dr. Gressel noted that there are many differences between manual keratometry and corneal topography. He explained that both measure the curvature and contour of the cornea but, due to the quality of the topography machines available at the time at issue in this case, simulated keratometry measurements derived from corneal topography were not as reliable as manual keratometry measurements. Dr. Gressel added that his criticism of the use of simulated keratometry is limited to the specific application of determining the curvature of the very center-most part of the cornea because that is the part of the cornea that is most important for later picking an intraocular lens implant should that patient eventually need cataract surgery. He explained that there is a significant amount of other information provided by corneal topography, which is quite valuable. Therefore, Dr. Gressel testified that, during the time at issue, it had been important to

measure both corneal topography and manual keratometry. Dr. Gressel concluded that, during the time at issue, failure to obtain manual keratometry was a violation of the standard of care. (Tr. at 730-735, 1143-1150)

- c. Dr. Jain failed to conform to the minimal standard of care because he failed to perform corneal pachymetry prior to LASIK. Dr. Gressel testified that failure to do so had put Patient 1 at unconscionable and preventable risk of developing ectasia after LASIK. (Tr. at 756-759; St. Ex. 25)

Dr. Gressel testified that it was a significant violation of the standard of care for Dr. Jain to fail to perform pachymetry prior to perform a laser vision correction. Dr. Gressel testified that pachymetry, a measurement of the thickness of the central cornea using an ultrasonic pachymeter, takes ten to fifteen seconds per eye to perform. Moreover, it requires nothing more than putting a numbing drop in the eye then gently touching the surface of the eye with an ultrasonic probe. Dr. Gressel testified that this is important to do because laser vision correction can destabilize the cornea. (Tr. at 735-736)

Dr. Gressel explained that there is pressure inside the eye pushing out against the cornea. If the cornea is thin or unstable, the pressure may cause the cornea to bulge outwards. Dr. Gressel testified that this is a disease state referred to as ectasia. Dr. Gressel testified that, without performing pachymetry, it is impossible to determine whether a patient is an appropriate candidate for LASIK surgery. (Tr. at 735-738, 1179-1180)

In discussing the importance of performing pachymetry, Dr. Gressel described the procedure in LASIK, as follows:

One thing that we do is to make a flap. The first step of LASIK is to create a partial thickness separation of the layers of the cornea with a device referred to as a keratome or microkeratome. The microkeratome goes down approximately a fourth of the way into the thickness of the cornea and separates the layers of the cornea, leaving a small area of attachment between the outer part, which we call the flap, and the remainder of the cornea. That connection we call the hinge. And in making this separation, it allows the surgeon to peel back the outer third or so, or fourth or so, of the cornea, just like opening the pages of a book. And then the laser vision correction procedure, using the excimer laser, is used to reshape the tissue underneath. The tissue underneath is called the bed, and it reshapes it by removing tissue. So in two ways we have destabilized the cornea. We have destabilized it by making the flap, which weakens the dome, and we've destabilized it by removing tissue from it with the laser. Pachymetry tells us whether there's enough corneal thickness to be able to safely operate on the cornea with LASIK

without producing an unsafe destabilization. And without knowledge of pachymetry prior to doing LASIK surgery, one doesn't know that there is not going to be a destabilization of the cornea sufficient to cause ectasia.

(Tr. at 739-740)

Dr. Gressel testified that it is very important to protect the patient from ectasia. He explained that ectasia of the cornea results in "horrible visual symptoms that are extremely difficult, if not impossible, to visually rehabilitate." He stated that, when a cornea bulges and thins, it does so in an irregular way that causes distortion of vision, with no rhyme or reason to the contour. Therefore the vision cannot be corrected with spectacle lenses. One option for improving vision is a soft contact lens, but that does not always work because the soft contact lenses will conform itself to the irregular shape of the cornea. Therefore the best hope is a rigid gas permeable contact lens that will flatten the steeper parts of the cornea and even it out. Nevertheless, many people cannot tolerate gas permeable lenses. In others, the corrected vision is very disappointing. Many people eventually require a corneal transplant operation, which takes the better part of the year for visual rehabilitation. Even then, the patient is left with irregular visual astigmatism and it is difficult to visually rehabilitate that patient. He concluded that ectasia is a very negative outcome. (Tr. at 743-745)

Dr. Gressel noted that Dr. Jain, in his responses to Dr. Gressel's expert reports, had stated that it was his practice not to perform pachymetry as long as the correction being performed is seven diopters or less. Dr. Gressel testified that he strongly disagrees with Dr. Jain's reasoning. Dr. Gressel testified that an average cornea for the general population is approximately 540 microns thick, but there is a wide variation from the low 400s to the low 700s. Dr. Gressel added that it is not possible to predict where a particular patient will fall in the range of corneal thicknesses. He further testified that, during the time period at issue in this matter, it was generally accepted that after a LASIK procedure there should be at least 250 microns remaining in the corneal bed. More recently, the estimate has been raised to at least 300 microns. (Tr. at 1133-1135)

Dr. Gressel acknowledged that a correction of 7 diopters or less of astigmatism removes approximately 70 microns or less of corneal tissue. Nevertheless, Dr. Gressel testified that Dr. Jain's reasoning is flawed because it fails to take into consideration the thickness of the flap. Dr. Gressel stated that a flap, once healed, is never as stable as uncut cornea. Therefore, the thickness of the flap must be subtracted from the residual thickness of the cornea in determining the residual strength of the cornea. Dr. Gressel noted that Dr. Jain had used a microkeratome in his LASIK procedures that created a flap of 160 microns. Dr. Gressel noted that, when Dr. Jain asserted that it was not necessary to do pachymetry because the amount of correction being performed was seven diopters or less, he had overlooked the more significant factor, the thickness of the flap. (Tr. at 740-747, 1141-1142)

- d. Dr. Jain failed to recognize that the image produced by his corneal topographer was inverted on the vertical axis, or upside-down. Dr. Gressel explained that, by optical convention, 90° should appear at the top of the diagram and 270° should appear at the bottom. In this case, 90° appears at the bottom of the diagram and 270° appears at the top. He stated that this would not have been a problem had Dr. Jain been aware that the diagram was inverted. (Tr. at 768-769)
- e. Dr. Gressel stated, as a result of the treatment provided by Dr. Jain, Patient 1 suffered complications that should have been preventable and which required her to have additional need for surgery. Moreover, in the end, Patient 1 was forced to wear glasses or contact lenses that she otherwise would not have needed. (Tr. at 1197-1198)
- f. Dr. Gressel stated that, in his care and treatment of Patient 1, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section B6, which states: “The ophthalmologist must evaluate the patient and assure that the evaluation accurately documents the ophthalmic findings and the indications for treatment.” Dr. Gressel added that Dr. Jain also violated Section B7 of the same Code, which states: “When other aspects of eye care for which the ophthalmologist is responsible are delegated to an auxiliary, the auxiliary must be qualified and adequately supervised.” (St. Ex. 25)

### **Testimony of Dr. Jain regarding Patient 1**

25. Dr. Jain acknowledged that, at some point after performing the LASIK procedure on Patient 1, he had learned that Patient 1’s boyfriend’s prescription had been programmed into the laser used on Patient 1’s eyes. Dr. Jain testified that Patient 1 must have provided the technicians with her boyfriend’s glasses rather than her own. Dr. Jain testified that it is not unusual for a patient to present with someone else’s glasses or prescription. He explained that patients often lose their own eyeglasses and borrow someone else’s glasses rather than purchase new ones. Then, when the patient comes for an appointment, they present with the other person’s eyeglasses. Alternatively, Dr. Jain surmised that Patient 1 had come to the clinic with her boyfriend, that both Patient 1 and the boyfriend had put their glasses on the counter, and that the technician had picked out the boyfriend’s glasses rather than Patient 1’s to determine Patient 1’s current prescription. (Tr. at 43-45, 50-51, 1524-1527)

Later, however, Dr. Jain testified that he disagreed with Dr. Gressel’s criticism that Dr. Jain had failed to make certain that Patient 1’s refraction was correct before he performed LASIK. Dr. Jain testified that the cycloplegic refraction had been determined by one of Bloomberg Eye Center’s most senior technicians. Dr. Jain stated that this technician had worked at Bloomberg Eye Center for twenty years, and that that technician had been fully aware that patients did not always bring their own that glasses. Dr. Jain further testified that, even though Patient 1 later claimed that she had seen triple on the initial visit, Dr. Jain did not believe that she had divulged this information to the technician or to Dr. Jain at any

time during that first visit. Dr. Jain testified that, if Patient 1 had indicated that she had triple vision, it would have been documented in the chart. (Tr. at 1521-1522)

26. Dr. Jain testified that Patient 1's preoperative evaluation had been conducted by a variety of people, including technicians and optometrists, before the physician had seen the patient. Technicians obtain the patient's current prescription either through eyeglasses that the patient provides or through a written prescription. (Tr. at 25-27)

Dr. Jain stated that he "[v]ery, very rarely" double-checked the prescription before it was entered into the laser. Instead, he checked the settings to assure that they were consistent with the manifest refraction and the cycloplegic refraction in the patient's chart. Dr. Jain testified that that is all that most ophthalmologists would do. (Tr. at 1480-1483)

27. Dr. Jain noted that Patient 1's uncorrected vision one day after surgery was 20/60 and the right eye and 20/100 in the left eye. He stated that one would normally expect a better result one day after surgery. Nevertheless, he said it was reassuring that the pinhole, or potential vision, was 20/20 and 20/20=. Dr. Jain explained that the pinhole visual acuity is determined by a placing a shade, filled with pinholes, in front of the patient's eye. Then, based on how the patient performs reading the eye chart, the pinhole vision or potential vision can be determined. Dr. Jain acknowledged that pinhole vision is not actual vision. (Tr. at 37-39)

28. Dr. Jain testified that manual keratometry had been performed on Patient 1. He added that the results, 4493@40, could be found on the line the labeled "Cyclo." Dr. Jain explained that there is no printout in manual keratometry because the procedure is so rudimentary. (Tr. at 28-29, 54-55)

29. Dr. Jain explained that pachymetry is a means of determining corneal thickness. He stated that it is important to know corneal thickness if there is a possibility that the practitioner might remove too much corneal tissue during a LASIK procedure. Dr. Jain stated that, when the cornea is too thin, there is a possibility it will bulge forward and poor vision will result. Nevertheless, in this case, Dr. Jain testified that he had not measured corneal pachymetry prior to performing LASIK on Patient 1 because the dilated refraction was less than minus seven diopters of myopia, or nearsightedness. (Tr. at 29-31)

Dr. Jain testified that, in this time period 2000 to 2002, his office had not routinely performed pachymetry in patients who had less than 7 diopters of myopia. He stated that a bed of 250 microns is the generally accepted norm for how much contiguous corneal tissue should remain after a LASIK procedure. Moreover, he stated that the flap that is created in a LASIK procedure is generally about 130 microns. In addition, for each diopter of correction, 12 microns of corneal tissue is removed. Therefore, for seven diopters, at 12 microns per diopter, 84 microns of tissue would be ablated or removed. Thus, 250 microns, plus 130 microns for the flap, plus 84 microns ablated would equal 464 microns. Dr. Jain stated that "the vast majority of the population" has a corneal thickness that

exceeds 465 microns. Therefore, he concluded, there is little chance that the cornea would be too thin after a LASIK procedure if the dilated refraction is less than minus seven diopters of myopia prior to the procedure being performed. (Tr. at 31-32, 1500-1502)

Responding to Dr. Gressel's testimony that the thickness of the corneal flap should not be included in calculating the thickness of the post-LASIK cornea because it does not contribute to the integrity of the cornea, Dr. Jain testified that Dr. Gressel was "blatantly wrong." Dr. Jain explained that the corneal flap attaches to the cornea after the procedure. He continued that, despite the fact that the flap can be lifted even years after the LASIK procedure, it nevertheless gives support to the cornea, although not necessarily to the extent it did pre-LASIK. (Tr. at 1502-1503)

Dr. Jain testified that, currently, corneal pachymetry is approved and reimbursable by most insurance companies. Six months ago, however, it was not. He added that, since early 2003, it has been standard procedure to perform both corneal topography and pachymetry on all LASIK patients. (Tr. at 1446-1447, 1454-1455)

## ***Patient 2***

### **Medical Records for Patient 2**

30. On February 5, 2001, Patient 2, a thirty-year-old male, presented to Bloomberg Eye Center for a LASIK evaluation. A number of tests were performed with the following results:

Visual Acuity with Correction	Right Eye 20/20-3 Left eye 20/20-1
Visual Acuity without Correction	Right Eye 20/400 Left eye 20/400
1997 Prescription	Right eye: sphere, -4.50; cylinder, -0.50; axis, 120 Left eye: sphere, -4.25; cylinder, -0.75; axis, 080
Manifest Refraction	Right eye: sphere, -5.00; cylinder, -0.50; axis, 120; 20/20 Left eye: sphere, -4.50; cylinder, -0.75; axis, 075; 20/20
Cycloplegic Refraction	Right eye: sphere, -4.75; cylinder, -0.50; axis, 120; 20/20 Left eye: sphere, -4.25; cylinder, -0.75; axis, 075; 20/20
Simulated Keratometry [recorded as "K's"]	Right eye: 44.82@146; 43.43@056 Left eye: 45.18@032; 43.88@122
Desired Correction	Right eye: sphere, -4.159; cylinder, -0.50; axis, 120 Left eye: sphere, -3.499; cylinder, -0.79; axis, 080

Corneal topography was performed with an EYESIS topographer, which demonstrated an atypical inferior corneal steepening in both eyes. Dr. Jain wrote, "no keratoconus" (St. Ex. 2B at 22, 29, 74)

31. On February 8, 2001, Dr. Jain performed a LASIK procedure on both eyes of Patient 2. The cost of the procedure was \$978.00. The following day, Patient 2's visual acuity

without correction was 20/100 in the right eye and 20/60+2 in the left eye. Dr. Jain's impression was, "Doing well!" (St. Ex. 2B at 68-71, 73)

32. On March 2, 2001, Patient 2 complained that he could see better if he tilted his head backwards and that, when looking directly at an object, it appeared blurry. He also complained of glare. Manifest refraction was performed with the following results:

Manifest Refraction	Right eye: sphere, +0.50; cylinder, -0.75; axis, 105;	20/20-
	Left eye: sphere, -0.25; cylinder, -1.00; axis, 120;	20/25+

Dr. Jain noted, "Doing well!" He planned to see Patient 2 in three months. (St. Ex. 2B at 66)

33. On April 2, 2001, Patient 2 saw Dr. Bell, an optometrist. Patient 2 denied improvement in his vision and complained of seeing halos. An examination of his eyes revealed the following:

Visual Acuity	Right Eye 20/30
<u>without Correction</u>	<u>Left eye 20/30</u>
Manifest Refraction	Right eye: sphere, + 0.50; cylinder, -1.00; axis, 110; 20/20-2
	Left eye: sphere, plano; cylinder, -1.25; axis, 115; 20/25
Simulated Keratometry	Right eye: 40.66@158; 37.50@060
	Left eye: 42.13@029; 39.84@119

Dr. Bell noted "residual astigmatism," and that Patient 2 was seeing double even with correction. In her plan, Dr. Bell suggested an astigmatic keratotomy enhancement or a laser astigmatism correction. (St. Ex. 2B at 21, 22, 62)

34. On April 5, 2001, corneal topography was performed with an Alcon topographer. The topography image was inverted and appeared to have corneal steepening superiorly. However, if viewed properly, the actual corneal steepness is in the inferior portion of the cornea. Despite this, Dr. Jain noted "no keratoconus." (St. Ex. 2B at 22)
35. Patient 2 saw Dr. Jain on April 5, 2001. Patient 2 complained that he was frustrated with his poor vision, glare, and halo. He also complained of diplopia, or double vision. Visual acuity without correction was 20/40-1 in the right eye and 20/30-1 in the left eye. Dr. Jain noted that Patient 2 would need enhancement and eyeglasses in the future. (St. Ex. 2B at 61)
36. Patient 2 saw Dr. Jain on May 15, 2001. An examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/20
<u>with Correction</u>	<u>Left eye: 20/20</u>
Visual Acuity	Right eye: 20/40
<u>without Correction</u>	<u>Left eye 20/30+</u>

Visual Acuity	Right eye: 20/25
Pinhole	Left eye: 20/25+
Current Prescription	Right eye: sphere, +1.25; cylinder, -1.50; axis, 120 Left eye: sphere, +1.00; cylinder, -1.75; axis, 115
Manifest Refraction	Right eye: sphere, + 2.75; cylinder, -2.50; axis, 092; 20/20 Left eye: sphere, +1.75; cylinder, -2.75; axis, 118; 20/20
Manual Keratometry	Right eye: 43.00@170; 39.50@080 Left eye: 43.00@020; 40.25@110
Pachymetry	Right eye: 495 Left eye: 488

Dr. Jain wrote, "Mild overcorrection," and "Doing well!" Dr. Jain prescribed Acular eye drops. (St. Ex. 2B at 60)

37. On April 5, 2001, Patient 2 had corneal topography performed. Dr. Jain labeled the records, "no keratoconus." (St. Ex. 2B at 20-21)
38. Patient 2 called the Bloomberg Eye Center on two occasions in June 2001. He advised that he had gotten a second opinion, because his eyes were "messed up." He further stated that he had been advised that an autonomous laser procedure could be used to correct the problem with his eyes. Dr. Jain agreed with this opinion. He recommended that Patient 2 continue with Acular eye drops. (St. Ex. 2B at 53, 58)
39. Patient 2 saw Dr. Jain on July 3, 2001. He complained of glare and stated that he was unhappy with his vision. An examination of his eyes revealed the following:

Current Prescription	Right eye: sphere, +1.00; cylinder, -1.50; axis, 122 Left eye: sphere, +0.75; cylinder, -1.75; axis, 106
Manifest Refraction	Right eye: sphere, +4.50; cylinder, -5.25; axis, 092; 20/20+ Left eye: sphere, +1.25; cylinder, -2.75; axis, 110; 20/20
Manual Keratometry	Right eye: 44.00@165; 39.00@075 Left eye: 43.50@025; 40.00@115
Simulated Keratometry	Right eye: 44.68@160; 37.41@070 Left eye: 43.52@030; 39.76@110

Upon corneal topography, Dr. Jain noted that there was inferior steepening in both eyes. (St. Ex. 2B at 16-17, 52)

40. On July 17, 2001, Patient 2 stated that he was unhappy with his vision. An examination of his eyes revealed the following:

Current Prescription	Right eye: sphere, +1.00; cylinder, -1.50; axis, 122 Left eye: sphere, +0.75; cylinder, -1.75; axis, 106
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Manifest Refraction	Right eye: sphere, + 5.50; cylinder, -5.50; axis, 090; 20/20+ Left eye: sphere, +1.75; cylinder, -2.75; axis, 112; 20/20
Manual Keratometry	Right eye: 43.25@160; 38.75@070 Left eye: 43.75@020; 40.25@115
Simulated Keratometry	Right eye: 45.13@160; 37.77@070 Left eye: 43.55@030; 39.54@110
Pachymetry	Right eye: 498 Left eye: 491

Dr. Jain noted that there was steepening superiorly in both eyes. He failed to notice that the image was inverted, with 270° appearing superiorly and 90° appearing inferiorly. Moreover, he failed to address the fact that, on the previous topography, he had acknowledged the inferior steepening. (St. Ex. 2B at 18-19, 50-51)

41. On September 13, 2001, Dr. Blausey wrote a letter on behalf of Patient 2 regarding Patient 2's upcoming jury duty. Dr. Blausey wrote, in part:

[Patient 2] underwent LASIK vision correction surgery on February 8, 2001. He has experienced some radical vision fluctuations in each eye from that procedure, which was an unpredicted result. His last visit was on July 31, 2001. At that time, his vision with current correction was a hard pressed 20/25 in each eye. Eyeglasses were prescribed for him at that time in hopes to improve his vision. [Patient 2's] subjective vision is definitely subnormal.

(St. Ex. 2B at 10)

42. On September 25, 2001, Patient 2 underwent corneal topography. The images are rotated appropriately with 90° appearing at the top. Corneal steepening is noted in the inferior portions of both eyes. (St. Ex. 2B at 14)
43. On October 16, 2001, Patient 2 complained that his vision in both eyes was "terrible." His eye examination revealed the following:

Visual Acuity with Correction	Right Eye 20/60 Left eye 20/25=
Visual Acuity without Correction	Right Eye 20/100+ Left eye 20/40=
Current Prescription	Right eye: sphere, +1.25; cylinder, -1.50; axis, 120 Left eye: sphere, +1.00; cylinder, -1.75; axis, 115
Manifest Refraction	Right eye: sphere, +5.00; cylinder, -1.50; axis, 120; 20/20 Left eye: sphere, +2.25; cylinder, -4.50; axis, 116; 20/20+
Manual Keratometry	Right eye: 45.00@160; 39.25@070 Left eye: 44.25@020; 40.00@110

Simulated Keratometry	Right eye: 39.50@066;	45.75@056
	Left eye: 39.75@117;	44.25@027

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Dr. Jain wrote, "Will need customized ablation!" On the corneal topography diagram, Dr. Jain noted "no keratoconus." (St. Ex. 2B at 13, 45)

44. On November 11, 2001, Patient 2 requested copies of his medical records to be sent to his attorney. He also requested that Dr. Jain pay for the contact lenses that Patient 2 would need in the future. (St. Ex. 2B at 42)
45. Thereafter, Patient 2 was fitted with rigid gas permeable contact lens that was unsuccessful because he had "too much edge lift" in his flap. He returned repeatedly for other contact lens fittings. His visual acuity without correction was 20/80 in the right eye and 20/50 in the left eye. It was noted that he had "edge lift" in both eyes and increased "flange steepness." (St. Ex. 2B at 4, 78, 80) Subsequently, he complained of worsening vision, and it was noted that the flap was lifting in both eyes. (St. Ex. 2B at 37-38)
46. On July 16, 2002, Patient 2 reported that he could not see highway signs clearly. He also complained of glare and letters that appeared double and triple. He stated that his soft contact lenses were not fitting well. Visual acuity with contact lenses was 20/25 in the right eye and 20/25= in the left eye. In the right eye, it was noted that the edge of the flap had lifted, and stippling was noted in the left eye. (St. Ex. 2B at 35)
47. On October 14, 2002, Dr. Blausey saw Patient 2 for a recheck of his rigid gas permeable contact lenses. Patient 2's visual acuity with the lenses was 20/30- in the right eye and 20/25= in the left eye. (St. Ex. 2B at 32)

### **Testimony of Dr. Gressel regarding Patient 2**

48. Dr. Gressel testified that, in his care and treatment of Patient 2, Dr. Jain had failed to conform to the minimal standard of care. (Tr. at 777-778; St. Ex. 25) In support of his opinion, Dr. Gressel cited the following reasons:
  - a. Dr. Jain failed to obtain corneal pachymetry prior to the performance of LASIK. Dr. Gressel stated that a preoperative pachymetry measurement would have revealed that Patient 2's corneas were too thin to safely undergo a LASIK procedure. It also would have revealed that Patient 2 had atypical corneal steepening as evidenced on corneal topography performed February 5, 2001. Dr. Gressel explained that atypical corneal steepening is a sign of ectasia or bulging of the cornea. Dr. Gressel opined that, had Dr. Jain performed corneal pachymetry prior to surgery, it likely would have revealed the ectasia, a contraindication to LASIK surgery. (Tr. at 777-778; St. Ex. 2B at 22; St. Ex. 25)

- b. Dr. Jain did not perform manual keratometry prior to performing LASIK. Dr. Gressel reiterated that manual keratometry is important should the patient require cataract surgery in the future. Additionally, in this case, manual keratometry might have demonstrated the pre-existing distortion in the corneas. Dr. Gressel concluded that, had Dr. Jain performed corneal pachymetry and manual keratometry prior to the LASIK procedure, he would have discovered that Patient 2 had problems with his corneas that contraindicated LASIK surgery. (Tr. at 778-779; St. Ex. 25)
- c. Dr. Jain failed to document the LASIK procedure properly. Dr. Gressel noted that the medical record contains printouts from the laser machines, but no other information regarding the LASIK procedure. Dr. Gressel testified that these printouts do not provide information regarding the creation of the flaps, the thickness of the flaps, or the microkeratomes used during the procedure. Dr. Gressel testified that this information might be important to the patient in the future. (Tr. at 786-787; St. Ex. 2B at 69-71)
- d. Dr. Jain inappropriately performed LASIK surgery despite atypical corneal steepening that had been evident on preoperative topography and which is a contraindication for the performance of LASIK. Dr. Gressel explained that corneal topography images are based on a scale that depicts the steepest parts of the cornea by color designations of yellow and orange and the flatter areas by color designations of green and blue. Dr. Gressel continued that a normal cornea has its steepest portion centrally, and its flatter portion peripherally. In Patient 2's preoperative image, however, there is a yellow area at the bottom of the image, which indicates peripheral steepening and is abnormal. Dr. Gressel concluded that, by performing LASIK on a cornea with atypical corneal steepening, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section A7, which states: "It is the responsibility of an ophthalmologist to act in the best interest of the patient." (Tr. at 781-782; St. Ex. 2B at 22; St. Ex. 25)

Dr. Gressel further noted that, despite the fact that Patient 2 had had only a minimal amount of correction during his LASIK procedure, the following day his uncorrected visual acuity had been 20/100 in the right eye and 20/60 in the left eye. Dr. Gressel stated that this is not the quality of vision one would expect for someone who had had a minimal amount of treatment one day earlier. Nevertheless, Dr. Jain inappropriately documented his impression as, "Doing well!" (Tr. at 787-788; St. Ex. 2B at 68, 69)

- e. Despite Patient 2's continuing refractive instability and visual dissatisfaction, Dr. Jain failed to recognize obvious ectasia in Patient 2's corneas. Dr. Gressel noted that Patient 2 had complained that he was able to see better by tilting his head back and that, when he looked straight at an object, the object appeared blurry. Dr. Gressel testified that this complaint was indication that, when Patient 2 had looked through the central part of his cornea, he experienced optical aberrations. In order to see more clearly, Patient 2 had been forced tilt his head so that he was looking at objects through the peripheral portion of his cornea. Dr. Gressel concluded that this was a

sign of problems in the central cornea, which Dr. Jain should have readily recognized. (Tr. at 788-789; St. Ex. 2B at 66)

Moreover, Dr. Gressel testified that Dr. Jain should have recognized the ectasia because the corneal topography performed on April 5, 2001, showed abnormal corneal steepening inferiorly. Nevertheless, Dr. Jain wrote, “no keratoconus,” which is a statement that Dr. Jain found no indication of ectasia. Dr. Gressel testified that the topography image is inverted so that the steepening appears to be superior, and that Dr. Jain’s writing, “no keratoconus,” was an indication that Dr. Jain had failed to appreciate that the image was inverted. Dr. Gressel testified that, even in Dr. Jain’s prehearing expert report, he stated that he had believed the steepening to be in the superior portion of the cornea. Dr. Gressel stated that the inversion of the image should have been readily apparent to Dr. Jain because steepening in the superior portion of the cornea rarely, if ever, occurs. Finally, Dr. Gressel testified that a topographic image of inferior steepening is so striking, that to see one inverted would be as obvious an inversion as an upside-down Christmas tree. Dr. Gressel concluded that any competent ophthalmologist would have recognized this image as upside-down keratoconus. (Tr. at 781-786; 791-792)

In addition, Dr. Gressel testified that the steepening was skewed rather than symmetrical which is referred to as an irregular astigmatism. He explained that irregular astigmatism cannot be corrected with a spectacle lens, as opposed to a contact lens, which explains why Patient 2 was seeing double even with the best spectacle lens correction possible. (Tr. at 781-782, 783-786, 791-792; St. Ex. 2B at 20, 21)

Finally, Dr. Gressel also stated that the topography shows an extremely large degree of astigmatism, five diopters in the right eye, which one would not expect if the LASIK operation had been performed on a normal cornea. Dr. Gressel concluded that an abnormal astigmatism or ectasia had existed prior to the LASIK procedure, and that it had been highly inappropriate to perform LASIK on this cornea. He concluded that, performing LASIK on such a cornea likely cause further destabilization and progressive and dramatic bulging of the cornea. In fact, Dr. Gressel testified that Patient 2 had demonstrated an eleven-fold increase in astigmatism between his pre- and post-surgical refractions. (Tr. at 793-797; St. Ex. 2B at 20)

- f. Instead of recognizing that the surgery had destabilized both corneas, Dr. Jain suggested additional laser surgery in the form of astigmatic keratotomy or laser astigmatism correction, which “undoubtedly” would have made things worse. (Tr. at 797-798; St. Ex. 25)
- g. Dr. Jain performed corneal topography on July 3, 2001. He recognized that the images were inverted and that the steepening was inferior. Nevertheless, in a topography obtained two weeks later, Dr. Jain again identified the steepening as superior. Dr. Gressel concluded that Dr. Jain had still not realized that his corneal

topographer was printing images upside down. Therefore, Dr. Jain continued to be unable to interpret his own tests properly. Dr. Gressel added that the astigmatism had been increasing in size because, by July, the topographer was reading seven diopters of astigmatism in the right eye. (Tr. at 798-799; St. Ex. 2B at 16-19)

- h. Dr. Jain failed to make appropriate referrals despite the fact that Patient 2's condition was deteriorating under his care. Dr. Gressel acknowledged that Patient 2 had seen another physician, but noted that Patient 2 had done this on his own initiative and not through a referral by Dr. Jain. Dr. Gressel concluded that, by failing to refer Patient 2 for a second opinion, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section B4, which states: "Consultation(s) shall be obtained if required by the condition." (Tr. at 800-801; St. Ex. 25)

When asked if it is the physician's responsibility or the patient's responsibility to seek referral to another physician when the patient is not doing well, Dr. Gressel testified that it is the physician's responsibility to act in the best interest of the patient. He explained that, if the physician is not successful in improving the patient's condition, especially if the patient is deteriorating under that physician's care, it is in the best interest of that patient to be seen by another physician who may be able to help the patient. Dr. Gressel testified that this would be true even if the physician thought that other physicians in the area didn't like him. Dr. Gressel explained:

If a physician believed that \* \* \* the other practitioners around him were out to get him or that they would, instead of trying to help the patient, use the referral to try to cast him in a negative light, that doctor might be entirely on the wrong track to be thinking about himself rather than thinking about the benefit of the patient.

(Tr. at 1122-1123) Dr. Gressel noted that many patients traveled great distances to see Dr. Jain; therefore, it is difficult to understand why Dr. Jain could not encourage these patients "to travel similar distances to go outside of whatever the sphere of influence he felt that this out-to-get-him conspiracy existed in." Dr. Gressel concluded that it appeared that Dr. Jain had been acting in his own best interest rather than in the interests of his patients. (Tr. at 1123-1124)

- i. Dr. Jain's plan to perform customized ablation violated the minimal standards of care because it was an indication of Dr. Jain's continued failure to recognize that doing additional surgery, other than a corneal transplant, was unconscionable, harmful, and absolutely contraindicated. Another problem, according to Dr. Gressel, was that Dr. Jain was exhibiting "tremendous naiveté" in assuming the customized ablation could correct this magnitude of astigmatism with such a large amount of irregularity. Dr. Gressel opined that customized ablation should not even have been considered, for fear of further destabilizing the corneas in Patient 2's eyes. Finally, Dr. Gressel testified that, at the time Patient 2 had been treated, there was no FDA approved

treatment for asymmetrical astigmatism such as this. It was only later that the FDA approved the Excimer laser for customized ablation on asymmetrical astigmatisms. (Tr. at 802-804; St. Ex. 2B at 45)

- j. Dr. Jain made a number of mistakes in his treatment of Patient 2 and failed to disclose these errors to Patient 2. Dr. Gressel testified that, when a physician makes a mistake in treating a patient, the physician should inform the patient as to what the problem is and should make every possible effort to repair it. Dr. Jain's failure to advise Patient 2 of the mistakes made in his care had deprived Patient 2 of an opportunity to seek help for the problem. (Tr. at 804)

### **Testimony of Dr. Jain regarding Patient 2**

49. Dr. Jain disagreed with Dr. Gressel's opinion that, for pre-LASIK patients, manual keratometry is necessary to provide information regarding the presurgical condition of the eye, which might be necessary in the event that a subsequent surgery was needed. Dr. Jain stated that there are many ways to calculate intraocular lens powers for a patient who has had LASIK, should they later need cataract surgery. The most commonly accepted way is through corneal topography. Dr. Jain concluded that his decision to forego manual keratometry in his pre-LASIK patients did not constitute a departure from accepted standards of care. Dr. Jain added that "there is nothing that manual keratometry provides that is not found in computerized corneal topography." (Tr. at 1446-1447, 1454-1455, 1491-1494, 1499)
50. Dr. Jain testified that his performing LASIK surgery on Patient 2's eyes had not been a violation of the standard of care because he had relied upon an EYESIS topography that had shown the eyes to be normal preoperatively. Therefore, Dr. Jain testified that he had rightfully concluded that Patient 2 was an appropriate candidate for LASIK. Dr. Jain provided this testimony despite his acknowledgment that the medical record at hearing contains only one preoperative corneal topography, and that it reveals corneal steepening inferiorly. (Tr. at 58, 88-90, 1529)
51. Regarding his postoperative care for Patient 2, Dr. Jain testified that he had seen Patient 2 frequently. Dr. Jain further testified that he had recognized that Patient 2 was not having a normal recovery from his LASIK procedure and had followed him carefully. Moreover, Dr. Jain testified that he had told Patient 2 that the outcome was not optimal. Dr. Jain testified that he had referred Patient 2 to Dr. Blausey for the fitting of various types of contact lenses, and that rigid gas-permeable lenses contact lenses had been successful eventually. (Tr. at 1529 -1531)
52. Regarding Patient 2's complaint that to see objects clearly he must tilt his head back, Dr. Jain testified that it was a very nonspecific complaint. He added, "I've probably had hundreds of patients in my career tell me they can see better if they tilt their head one way or the other or back or forward. And it's really so nonspecific \* \* \*." (Tr. at 65-66)

53. Dr. Jain acknowledged that, in his report, he had admitted that he had failed to notice that the axis on the corneal topography had been transposed. Dr. Jain explained that a topography image appears as a circle. There are numbers around the circle. The numbering starts at “00 degrees” on the left, and as you move clockwise around the circle, “90 degrees” appears at the top, “180 degrees” appears at the right, and “270 degrees” appears at the bottom. Dr. Jain further explained that one of the technicians at Bloomberg Eye Center had set up the topographer incorrectly so that the scale was reversed. Nevertheless, Dr. Jain stated that, as an ophthalmologist, he had become accustomed to seeing topographic images with 90 degrees at the top and, in this case, he had failed to notice the inversion. (Tr. at 76-78, 1556-5057)

Dr. Jain acknowledged that his failure to realize that the image was inverted had caused him to miss clinically important information regarding Patient 2’s condition. Dr. Jain further acknowledged that, viewed properly, the image had shown inferior steepening, an indication that the cornea is bulging outward, which is a sign of keratoconus. Finally, Dr. Jain acknowledged that, had he realized that the image was inverted, he would have recognized that Patient 2 was experiencing ectasia. (Tr. at 78-79, 85-86)

54. Dr. Jain disagreed with Dr. Gressel’s criticism that Dr. Jain had failed to refer Patient 2 for a second opinion because Patient 2 *had* seen another physician. Dr. Jain acknowledged that he had not specifically referred Patient 2 to see the other physician. Nevertheless, Dr. Jain testified that Patient 2 had seen the other physician and that that physician had called Dr. Jain with concerns about Patient 2’s care. Dr. Jain testified that he had told the other physician, “I did the best that I could in my care of this patient.” Therefore, Dr. Jain concluded that his care of Patient 2 had not fallen below the minimal standard of care in that regard. (Tr. at 80-83, 1529-1530)

Moreover, Dr. Jain testified that he routinely maintained close communication with his patients after LASIK. Dr. Jain testified that he had discussed complications very openly with his patients. He stated that, if there was a complication, either Dr. Blausey, Dr. Shahinfar, or Dr. Jain would see the patient as often as was needed after the surgery. (Tr. at 1519-1520)

55. Dr. Jain testified that he had not advised Patient 2 of the mistakes Dr. Jain had made in his care of Patient 2 because Patient 2 was “a very, very anxious patient.” Dr. Jain testified that he had feared that telling Patient 2 of the errors would have “set him off.” Nevertheless, Dr. Jain acknowledged that, “presumably,” Patient 2 had had a right to know. (Tr. at 95)
56. Regarding his plan for customized ablation, Dr. Jain testified that it had not been clear to him that customized ablation would have been absolutely contraindicated because he had not yet “internalized the fact that the abnormal topography was consistent with ectasia.” Nevertheless, Dr. Jain acknowledged that his failure to appreciate the seriousness of the corneal topography had been a problem. Dr. Jain further acknowledged that, at some point in July 2001, he had realized that the topographies were inverted and that Patient 2 had ectasia.

Dr. Jain could not explain why, three months later, he had forgotten that Patient 2 had ectasia. Dr. Jain testified that he could not specifically recall his thinking at that time. (Tr. at 99-101)

### **Patient 3**

#### **Medical Records for Patient 3**

57. On September 28, 2002, Patient 3, a 52-year-old male, presented to the Bloomberg Eye Center to be evaluated for LASIK surgery. Corneal topography was performed on both eyes. Further examination of Patient 3's eyes revealed the following:

Visual Acuity	Right eye: 20/25
with Correction	Left eye: 20/30-
Visual Acuity	Right eye: 20/40-
without Correction	Left eye: 20/70
Current Prescription	Right eye: sphere, +0.75; cylinder, -0.25; axis, 150
	Left eye: sphere, +2.00; cylinder, +0.75; axis, 175
Manifest Refraction	Right eye: sphere, +0.75; cylinder, -0.50; axis, 150; 20/25+
	Left eye: sphere, +2.75; cylinder, -1.00; axis, 175; 20/30-
Cycloplegic Refraction	Right eye: sphere, +1.00; cylinder, -0.50; axis, 150; 20/25+
	Left eye: sphere, +2.75; cylinder, -1.00; axis, 175; 20/30-
Simulated Keratometry	Right eye: 41.29
	Left eye: 41.04
Pachymetry	Right eye: 626
	Left eye: 634
Desired Correction	Right eye: sphere, +1.59; cylinder, -0.50; axis, 150
	Left eye: sphere, +4.10; cylinder, -1.00; axis, 175

The corneas were marked as "clear." Amblyopia of the left eye was noted. Dr. Jain wrote, "Will need readers!" Dr. Jain quoted a price of \$1598.00 for bilateral LASIK surgery. Moreover, Patient 3 accepted the Bloomberg Eye Center's Lifetime Assurance Plan, which covered all enhancements and all non-dilated examinations for life. For that, Patient 3 paid an extra \$69.00 per eye. (St. Ex. 3 at 13, 65)

58. On October 11, 2002, Patient 3's previous medical records were faxed to the Bloomberg Eye Center. (St. Ex. 3 at 67-81) The previous medical records contained the results of a corneal topography that had been performed on March 1, 2000. Handwritten on that record, it states, "irregular astigmatism—central steepening 2° Cogan's Dystrophy [anterior basement membrane dystrophy]." The record also contains an operative note for a superficial keratectomy, or mechanical debridement of the corneal epithelium, that had been performed on the right eye on March 21, 2000. The diagnosis was anterior basement membrane dystrophy of the right eye. (St. Ex. 3 at 73, 81; Tr. at 1215)

59. On October 15, 2002, Dr. Jain performed LASIK surgery bilaterally on Patient 3. Dr. Jain made no record of the type of microkeratome or the microkeratome settings used for the procedure. (St. Ex. 3 at 55, 57, 61)
60. On a LASIK follow-up visit, Dr. Jain noted that Patient 3 had a PRK [photorefractive keratectomy] scar in the right cornea. (St. Ex. 3 at 53)
61. Patient 3 had corneal topography performed on both eyes on December 30, 2002. (St. Ex. 3 at 9, 15) Examination of Patient 3's eyes revealed the following:

Visual Acuity	Right eye: 20/40+
without Correction	Left eye: 20/50+
Current Prescription	Right eye: sphere, +0.75; cylinder, -1.75; axis, 130; 20/20- Left eye: not noted
Manifest Refraction	Right eye: sphere, -0.75; cylinder, -0.75; axis, 130; 20/30 Left eye: sphere, -0.25; cylinder, -0.75; axis, 129; 20/25-
Cycloplegic Refraction	Right eye: sphere, -4.75; cylinder, -0.50; axis, 120; 20/20 Left eye: sphere, -4.25; cylinder, -0.75; axis, 075; 20/20

Haze was noted in both eyes. (St. Ex. 3 at 9, 1541)

### **Testimony of Dr. Gressel regarding Patient 3**

62. Dr. Gressel testified that Dr. Jain had failed to conform to minimal standards of care in his care and treatment of Patient 3. In support of his opinion, Dr. Gressel cited the following:
- a. Dr. Jain failed to properly ascertain the nature of Patient 3's prior surgery before had repeatedly stated that Patient 3's prior surgery had been a PRK, which is a laser vision correction operation to reshape the cornea. Dr. Gressel testified that PRK would have been expected to provide lasting relief from irregular astigmatism and recurrent erosion caused by Patient 2's corneal dystrophy. Nevertheless, the prior procedure that had actually been performed was simply a removal of the superficial layers of the epithelium, in hopes that they would grow back more smoothly and with a better adhesion to the underlying tissue. Dr. Gressel testified that this procedure would not be reasonably expected to provide lasting relief from irregular astigmatism and recurrent erosions caused by the corneal dystrophy. Therefore, Dr. Gressel opined that Dr. Jain might have been lulled into a false sense of security based on his belief that PRK had been performed. Dr. Gressel stated that Dr. Jain's failure to properly ascertain that nature of the prior surgery violated the Code of Ethics of the American Academy of Ophthalmology, Section B6, which states: "The ophthalmologist must evaluate the patient and assure that the evaluation accurately documents the ophthalmic findings and the indications for treatment." (Tr. at 805-806, 809, 811-813; St. Ex. 25)

- b. Dr. Jain failed to record the type of microkeratome or microkeratome settings used during the LASIK procedure. Dr. Gressel explained that the microkeratome determines the depth of the flap created during the LASIK procedure. He added that Dr. Jain had used a Nidek laser and that it is not uncommon for doctors who use the Nidek microkeratome to use a setting designed to get, on average, a 160-micron flap. Nevertheless, knowing the average is misleading because there is a large variability from one eye to the other, so that many flaps are substantially thicker than the average. Dr. Gressel added that, the thicker the flap, the more reduction in the residual strength of the cornea. Therefore, without the pertinent data being recorded, a subsequent treating physician would not know the depth of a flap created during a LASIK procedure. (Tr. at 1115, 1136-1139)
- c. Dr. Jain inappropriately performed LASIK in an eye with anterior basement membrane dystrophy. Dr. Gressel explained that PRK or combined PRK/PTK would have been the accepted treatment. Moreover, anterior basement membrane dystrophy is now, and was then, a contraindication for performing LASIK. Dr. Gressel concluded that, in this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section A7, which states: "It is the responsibility of an ophthalmologist to act in the best interest of the patient." (Tr. at 806-807; St. Ex. 25)

Dr. Gressel noted that, in his expert report, Dr. Jain had used the phrase "active" anterior basement membrane dystrophy, as if to imply that, because the disease was not active, performing LASIK surgery on Patient 3 had not posed a risk. Dr. Gressel concluded that, whether symptomatic or not, anterior basement membrane dystrophy greatly increases the risk of developing a sloughing of the corneal epithelium. Dr. Gressel explained that, in anterior basement membrane dystrophy, there is an excessive production of material between the surface layer cells, called the epithelium cells, and the underlying tissue. That excessive material prevents the epithelium from sticking properly to the underlying tissue. Then, when the keratome cuts across the cornea in making a LASIK flap, it "roughs up" the cornea. It is possible, in a patient with anterior basement membrane dystrophy, the whole epithelium in the central part of the cornea will fall off, resulting in "tremendous problems" with pain, decreased vision, and a prolonged period of visual rehabilitation. Moreover, people who have anterior basement membrane dystrophy frequently have an irregular astigmatism caused by the production of that abnormal material; therefore, these people have an increased chance of having dissatisfaction with of the results of LASIK surgery. Dr. Gressel concluded that, for all these reasons, LASIK surgery is contraindicated in a patient with anterior basement membrane dystrophy. (Tr. at 806-809)

- d. Dr. Jain failed to inform Patient 3 that the presence of anterior basement membrane dystrophy greatly increases the risk of sloughing of the corneal epithelium at the time of LASIK, followed by wound healing problems, scarring, and irregular astigmatism. Dr. Gressel concluded that, in this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, section B2, which states: "The

performance of medical or surgical procedures shall be preceded by appropriate informed consent.” (Tr. at 809-810; St. Ex. 25)

### **Testimony of Dr. Jain regarding Patient 3**

63. Dr. Jain acknowledged that the prior treating physician had diagnosed anterior basement membrane dystrophy. Dr. Jain described anterior basement membrane dystrophy as a common disorder, which occurs in 10% of the population. He stated that it is not a serious disorder, but people with anterior basement membrane dystrophy tend to have a high risk of their epithelium sloughing during LASIK surgery. (Tr. at 107-108)

Nevertheless, Dr. Jain testified that Patient 3 had not had “active” anterior basement membrane dystrophy at the time Dr. Jain treated him. Dr. Jain explained that the disease waxes and wanes, and may not be clinically evident or symptomatic at times. He added that patients with the disease generally experience an epithelial sloughing or a large corneal abrasion after LASIK, but Patient 3 did not. Therefore, Dr. Jain concluded that Patient 3 had not had active anterior basement membrane dystrophy at the time of his LASIK surgery. (Tr. at 1534-1535, 1765-1766)

Finally, Dr. Jain testified that, even if there had been epithelial sloughing, it is “not that much of a problem” although it does increase the risk of inflammation after LASIK. Therefore, Dr. Jain concluded that, even if Patient 3 had had the active disease, anterior basement membrane dystrophy or Cogan’s dystrophy is not an absolute contraindication to LASIK surgery. (Tr. at 118-119, 124-125)

64. Dr. Jain testified that he had not contacted the prior treating physician to determine how or why he had diagnosed anterior basement membrane dystrophy because that physician did not like Dr. Jain. Dr. Jain testified as follows:

Dr. Schumer was really not a good—he didn’t like me a lot. And he didn’t—he was pretty vocal about it in the community. And, you know, he used to charge quite a bit for LASIK, and I don’t think he had good feelings toward me for charging less—significantly less than his center did. So I don’t think—I mean, that’s one of the reasons I didn’t call him. Because calling some of these doctors when I first came into the practice was very difficult and they would be very snide and negative towards me. So that was just the reality of it.

(Tr. at 109-110)

65. Dr. Jain testified that he had documented that Patient 3 had had a prior PRK because he had noticed some opacity in the cornea that appeared to be a scar. Dr. Jain testified as follows:

A. [by Dr. Jain] At first—There was some thinking that he had [a PRK procedure].

- Q. [by Ms. Albers] Where do you see the thinking that he had?
- A. Well, let me see if it's in the chart. Maybe in his input. Yeah, here it is on Page 3. \* \* \*
- Q. And did the patient write that?
- A. No. I wrote that. The patient reported, apparently, corneal scratches OD and 4-00 above that, and under that I wrote, "History of PRK OD.
- Q. And how did you get that?
- A. By talking to him.
- Q. And he told you he had had PRK surgery on his eye?
- A. Well, I don't recall, but he could have told me that he had a procedure and he described what it was. And I put kind of what my best, you know, guesstimate as to what it would have been down. Now, the records from Dr. Schumer's office, just to clarify—I didn't get those for—until about two weeks after my initial visit with the patient. They are dated 10-11 and I saw the patient first on September 28th.
- Q. But you did the LASIK on October 15th, correct?
- A. Right. After I got the records. But—But I didn't have the records at the time –
- Q. So you waited to do the LASIK until you got the records?
- A. Yes.
- Q. And is there a history of PRK in –
- A. No.
- Q. — his records?
- A. No. Once I got the records, then I was able to tell that he had, in fact, not had a PRK. PRK would have been a treatment for anterior membrane— anterior basement membrane dystrophy.
- Q. Then apparently on Page 53, on the follow-up, you had forgotten that he hadn't had PRK?

A. Yes. I mean, I don't remember, but basically, my indication—my intent was to indicate that there was an opacity that I noticed there, not necessarily what caused the opacity. So—

Q. But then again on Page 45 of your record, what is this?

A. This appears to be—I spoke to \* \* \* an [insurance] adjuster from Guardian, regarding LASIK being treatment for anterior membrane—anterior basement membrane dystrophy. I think he was asking—to see if we could bill it through the insurance. So his insurance called. And, you know, I explained that it is not. [Patient No. 3] did undergo a PRK procedure with Dr. Schumer, which was a treatment for anterior basement membrane dystrophy. She was satisfied with the information and will call me back.

Q. So, again, you actually relayed something that wasn't accurate to the insurance company?

A. Well, the fact that he had gone—undergone PRK?

Q. Uh-huh.

A. Yeah, that—that was probably an error. But the fact that, you know, LASIK is not a treatment for anterior basement membrane dystrophy, that's true. And that he, you know, had undergone some kind of treatment, presumably, for this—this dystrophy with Dr. Schumer.

(Tr. at 115-118)

Later, Dr. Jain testified that he had determined that Patient 3 had had a PRK procedure by a previous physician because Patient 3 had specifically told him so. Nevertheless Dr. Jain did not recall specifically what Patient 3 had said. (Tr. at 1532-1533)

66. Dr. Jain acknowledged that Patient 3 had had greater astigmatism after the LASIK procedure than he had had before. Dr. Jain explained, however, that the astigmatism would likely improve as Patient 3 recovered from the LASIK surgery. (Tr. at 118)

67. Regarding Dr. Gressel's criticism that Dr. Jain had failed to inform Patient 3 that the presence of anterior basement membrane dystrophy greatly increases the risk of sloughing, Dr. Jain testified that he had had no reason to inform the patient of the complication since the patient did not have that condition. Dr. Jain concluded that his care and treatment of Patient 3 had not departed from the minimal standard of care. (Tr. at 1535-1536)

68. Dr. Jain acknowledged that he had not recorded microkeratome data for Patient 3's LASIK surgery. Dr. Jain testified that, at the time this procedure was performed, he had not

routinely recorded which microkeratome had been used in each LASIK procedure. Dr. Jain testified that he had not thought it necessary to record microkeratome data because whenever he used a Nidek laser, he used the same Nidek microkeratome with a 160-micron blade. When asked how a subsequent treating physician would be able to determine which keratome had been used, Dr. Jain testified that the subsequent treating physician would be able to view the flap upon examination of the cornea. Dr. Jain testified that the subsequent treating physician could also contact the Bloomberg Eye Center and staff would be able to say that they had always used the Nidek microkeratome with the 160-micron blade. Dr. Jain acknowledged, however, that even the records at the Bloomberg Eye Center contain the only the Nidek printout which does not contain the microkeratome information. (Tr. at 61-62, 114, 1751-1752)

Later, however, Dr. Jain testified that a subsequent treating physician would not be able to determine the microkeratome data simply by examining the patient's eye. Instead, Dr. Jain testified that the subsequent treating physician could obtain that information as follows:

In the chart there would be information regarding the Nidek laser use. And even though the—the printout specifically doesn't say that a Nidek microkeratome was used, typically, in that time period when Nidek lasers were sold, they were sold with the microkeratomers. They came with a number of—two—usually two Nidek microkeratomers. So that inference could be made.

(Tr. at 1752-1753) When asked how a subsequent treating physician would know this if that physician was not familiar with Nidek lasers, Dr. Jain responded: "Once again, it would have to, you know, be based on the—the foreknowledge that we just talked about. So if you're, you know, saying that fifteen years from now a physician would not necessarily know that a Nidek was used, then I suppose you're correct." Finally, Dr. Jain concluded that a subsequent treating physician could refer to the Nidek web site. (Tr. at 1753-1754, 1781-1782)

#### ***Patient 4***

##### **Medical Records for Patient 4**

69. On March 12, 2002, Patient 4, a forty-four year old female, presented to the Bloomberg Eye Center for evaluation for LASIK surgery on the left eye. It was noted that the optic nerve in her right eye had not formed at birth, and that she had never had good vision in that eye. A dense cataract was noted in the right eye, and intraocular pressure in that eye was listed as three. Corneal topography was performed in both eyes and Dr. Jain noted that there was no keratoconus. (St. Ex. 4 at 3, 7, 83) Examination of her eyes revealed the following:

Visual Acuity	Right eye: 20/NLP [no light perception]	
without Correction	Left eye 20/100	
Current Prescription	Right eye: sphere, -2.25;	20/NLP
	Left eye: sphere, -2.25; cylinder, -0.25; axis, 140;	20/25

Manifest Refraction	Right eye: no improvement Left eye: sphere, -2.75; cylinder, -0.50; axis, 005; 20/20-
Cycloplegic Refraction	Right eye: none recorded Left eye: sphere, -2.25; cylinder, -1.00; axis, 005; 20/20-1
Simulated Keratometry	Right eye: none recorded Left eye: 43.89
Pachymetry	Right eye: none recorded Left eye: 595
Desired Correction	Right eye: none recorded Left eye: sphere, -1.11 cylinder, -1.11; axis, 005

Dr. Jain quoted a price of \$499.00, and Patient 4 accepted the Bloomberg Eye Center Lifetime Assurance Plan for an additional \$69.00. Dr. Jain performed LASIK on Patient 4's left eye on March 13, 2002. Dr. Jain did not document the type of microkeratome or microkeratome settings used. (St. Ex. 4 at 75, 79, 83)

Dr. Jain examined Patient 4 the following day. Visual acuity without correction was listed as: right eye, 20/ NLP; and left eye, 20/40+. (St. Ex. 4 at 71) Dr. Jain dictated a consultation note. In it, he stated:

Patient presents for mature cataract formation in her right eye. She has had the cataract for approximately 20 years but it has become manifest more significantly at this juncture.

On examination today, motility is unremarkable. Pupillary exam is likewise unremarkable. Confrontation visual fields are normal in the left eye. The right eye has a dense cataract and therefore visual fields cannot be performed. Slit lamp exam is remarkable for 1+ corneal guttata of the right eye and no guttata in the left eye. There is a white cataract of the right eye. It is potentially Morgagnian but it is difficult to ascertain this through the cloudy cortical material. There is no view of the posterior pole in the right eye.

After a lengthy discussion, it was decided to proceed with cataract extraction (with placement of IOL if possible) in the right eye. Because the condition of the posterior segment is not known, the guarded nature of this procedure has been explained to the patient. In addition, it is important to note that the patient reports optic nerve hyperplasia of the right eye. Therefore, another reason exists for poor visual prognosis. It is important to remove the cataract so that visualization of the posterior pole can be obtained sometime in the future. The corneal view is very clear. I will also be checking speculum microscopy.

(St. Ex. 4 at 67)

70. On April 10, 2002, Dr. Jain performed phacoemulsification with removal of traumatic white cataract, anterior vitrectomy, anterior and posterior synechiolysis, and iridoplasty on Patient 4's right eye. He listed the preoperative diagnoses as traumatic cataract, vitreous prolapse, extensive anterior and posterior synechia, zonular dehiscence, and iris irregularities. The operative note states, in part:

There was obvious endophthalmodonesis, signifying zonular weakness. Cataract extraction proceeded without difficulty following a can opener type anterior capsulotomy, extensive anterior and posterior synechiolysis. Inferiorly, there was a vitreous prolapse from the zonular dehiscence. After the cataract was removed, a limited anterior vitrectomy was performed. Likewise, an iridoplasty was conducted to regularize the iris. The patient was left aphakic [without a lens]. The patient tolerated the procedure well and left the operating room in satisfactory condition.

(St. Ex. 4 at 63-65)

71. The following day, Patient 4 complained of pain in her right eye. Dr. Jain noted 2+ stromal edema, which indicates swelling in the middle of the cornea. (St. Ex. 4 at 61)

On April 14, 2002, Patient 4 complained that her eye felt "scratchy." Dr. Jain noted, "severe inflammation," and planned to consider a vitrectomy by Dr. Shahinfar. (St. Ex. 4 at 57, 61) In a referral note to Dr. Shahinfar, Dr. Jain wrote, in part:

[Patient 4] underwent a difficult cataract extraction approximately eight days ago. Her history is significant for traumatic cataract formation at a young age and haptic nerve hypoplasia. Her cataract extraction was complicated as it was pre-existing zonular laxity.

(St. Ex. 4 at 53)

72. Dr. Shahinfar saw Patient 4 on April 18, 2002. Dr. Shahinfar noted edema, wound leak, and choroidal effusions of the right eye. Later that day, Dr. Shahinfar performed a wound revision and removed cataract fragments from the right eye. He also repaired the wound leak that had resulted from the surgery performed by Dr. Jain. (St. Ex. 4 at 51, 55) In his operative note, Dr. Shahinfar wrote, in part, as follows:

A vitrectomy was performed. The visualization was limited due to corneal edema. There were choroidal detachments present as well. Care was taken not to inject the choroidal detachment. The vitreous was pulled from the incision and cleared from the anterior chamber. A core vitrectomy was performed as well. Cataract fragments were noted in the peripheral capsule behind the iris. This was removed during the vitrectomy. \* \* \* Additional 10-0 Nylon sutures

were required to close the incision and make the eye watertight. Subconjunctival antibiotics were given. There were no complications.

(St. Ex. 4 at 49)

In a letter dated April 18, 2002, Dr. Shahinfar advised Dr. Jain and that he had performed cataract surgery on Patient 4. Dr. Shahinfar noted that the surgery had been complicated by vitreous incarceration, wound leak, and corneal edema. He also noted that Patient 4 had developed choroidals as a result of hypotony. Dr. Shahinfar opined that the choroidals would resolve as well as the corneal edema. He added, however, that, because of her history of optic neuropathy, her vision would not improve substantially. (St. Ex. 4 at 45)

73. Following Dr. Shahinfar's wound revision, Patient 4 continued to complain of pain, itching, and sensitivity to light in her right eye. Visual acuity was noted to be 20/HM [hand movement] in the right eye and 20/40 in the left. Her right pupil was fixed and dilated. Manifest refraction, listed for the right eye only was: sphere, +11.50; cylinder, -1.65; axis, 140; 20/400. (St. Ex. 4 at 41-43)

#### **Testimony of Dr. Gressel regarding Patient 4**

74. Dr. Gressel testified that Dr. Jain's care and treatment of Patient 4 had constituted a departure from and a failure to conform to minimal standards of care. In support of his opinion, Dr. Gressel relied on the following:
- a. Dr. Jain failed to act in Patient 4's best interest when he performed LASIK in Patient 4's left eye. He stated that Dr. Jain's "[i]nappropriate and unscrupulous performance of LASIK on Patient 4's only-seeing left eye [had] exposed Patient 4 to an unconscionable risk of potential harm." He added that, had complications occurred after the left eye's surgery, Patient 4 would have had no vision at all. He stated that LASIK is "as elective a procedure as any procedure can be," and that no harm will come from failing to perform LASIK. Dr. Gressel concluded that Dr. Jain's failure to act in Patient 4's best interest was a violation of the Code of Ethics of the American Academy of Ophthalmology, section A7, which states: "It is the responsibility of an ophthalmologist to act in the best interest of the patient." (Tr. at 818-819; St. Ex. 25)

Furthermore, Dr. Gressel noted that Dr. Jain, in his expert report, had stated that it had been ethically acceptable for him to perform LASIK on Patient 4's left eye, despite the fact that it was not in her best interest, because Patient 4 had agreed to the surgery. Dr. Gressel opined that Dr. Jain's adherence to this opinion was of "gravest ethical concern." He added that:

A physician has a responsibility to the patient, because of the physician's greater understanding and knowledge of what can happen as

a result of an operation, to exercise prudence and restraint and not behave like a profiteer in dealing with a person who has so much to lose. And this [is], in my opinion, the gravest departure from the standard of care contained in these seventeen cases.

(Tr. at 819-821; 1218-1221)

- b. With regard to Patient 4's right eye, Dr. Jain performed unnecessary cataract surgery and may have falsified the medical record in an attempt to justify the operation. Dr. Gressel opined that an eye that has had lifelong poor vision due to an optic nerve abnormality, that has no light perception, and that has an intraocular pressure of 3 mmHg, would have been expected to exhibit an afferent pupillary defect. Dr. Gressel stated that there was no indication in the medical record that Dr. Jain had evaluated Patient 4 for afferent pupillary defect at any time prior to the cataract surgery. He explained that the presence of an afferent pupillary defect is regarded as an indication of a poor prognosis for visual improvement. He continued that, if there is little chance of visual improvement, then there is no benefit to the patient in removing a cataract. Dr. Gressel concluded: "The only benefit is the fee paid to doctor." (Tr. at 822-828; St. Ex. 25; St. Ex. 4 at 67, 71, 83)
- c. Dr. Gressel testified that there are other examples in the medical record that suggest that Dr. Jain did not accurately record his care and treatment of Patient 4. Dr. Gressel provided the following examples:
  - i. Dr. Jain's claim that the pupillary exam was "unremarkable" suggested that the potential for visual improvement was far greater than was actually the case. Dr. Gressel reiterated that there was no indication in the record that Dr. Jain had performed a pupillary exam at any time prior to surgery. Moreover, he stated that, "It is beyond any reasonable explanation that an eye like this would not have abnormal pupils. It's just not within the realm of medical possibility that a person with these findings in the right eye would have unremarkable pupils. It just isn't possible." Therefore, Dr. Gressel concluded that Dr. Jain's statement that the pupillary exam had been unremarkable was either inaccurate or contrived. By that, Dr. Gressel meant that Dr. Jain had either not done a pupillary exam, or that Dr. Jain had done a pupillary exam that demonstrated an afferent pupillary defect, but had not accurately recorded it. (Tr. at 822-829, 1221-1222)

Dr. Gressel concluded that Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, section B6, which states: "The ophthalmologist must evaluate the patient and assure that the evaluation accurately documents the ophthalmic findings and the indications for treatment. Recommendations of unnecessary treatment or withholding of necessary treatment is unethical." (Tr. at 822-828; St. Ex. 25)

- ii. Dr. Jain failed to document the presence of “obvious endophthalmodonesis, signifying zonular weakness” prior to surgery. Dr. Gressel opined that, if endophthalmodonesis had been “obvious” at surgery, it should have been detected in the preoperative examination. Dr. Gressel explained that this finding is significant because it would have “further deterred a prudent ophthalmologist from embarking on such a surgical misadventure in the right eye.” (Tr. at 835; St. Ex. 25)
  - iii. After operating on the cataract in the right eye, Dr. Jain wrote, “Inferiorly, there was vitreous prolapse from the zonular dehiscence,” implying that the vitreous prolapse was a pre-existing condition. Nevertheless, Dr. Jain had not documented vitreous prolapse in any of his preoperative examinations. (Tr. at 829)
  - iv. In the letter of referral to Dr. Shahinfar, Dr. Jain described “traumatic cataract formation at a young age,” whereas no corroboration of a history of trauma appears anywhere else in the medical record. Dr. Gressel testified that Dr. Jain would have benefited by a preoperative history of traumatic cataract because a traumatic cataract would likely be accompanied by damage to zonules and a lens that falls out of position more easily than usual, making it less likely that these problems had originated during Dr. Jain’s surgery. (Tr. at 839-841)
  - v. Dr. Jain made an inaccurate statement when he listed “iris irregularities” as a preoperative diagnosis and wrote that “an iridoplasty was conducted to regularize the iris.” Dr. Gressel noted that Dr. Jain had not documented any abnormalities of the iris prior to surgery. Therefore, it appeared likely that the iridoplasty had actually been performed to address damage to the iris caused by Dr. Jain during the cataract surgery. (Tr. at 829; St. Ex. 25)
- d. Dr. Jain failed to provide adequate documentation, as follows:
- i. Dr. Jain failed to document the presence or absence of an afferent pupillary defect, as noted above.
  - ii. Dr. Jain failed to record keratometry in the left eye prior to LASIK. Instead, he documented only a mean simulated keratometry reading derived from corneal topography. Dr. Gressel explained that the importance of keratometry lies in the fact that any future cataract surgery would entail a need for keratometry measurements taken prior to LASIK to facilitate the proper selection of intraocular lens implant power. (Tr. at 821-822; St. Ex. 25)
  - iii. Dr. Jain failed to record the type of microkeratome and microkeratome settings he had used during the LASIK surgery. Dr. Gressel explained that, if the left eye were to need additional corneal surgery in the future, knowledge of the type of

microkeratome and settings used could assist in estimation of the LASIK flap thickness, which could influence surgical decision-making. (Tr. at 822; St. Ex. 25)

- e. Dr. Jain performed cataract surgery on the right eye in an incompetent fashion. Dr. Gressel provided the following examples:

- i. Phacoemulsification was a poor choice for removing such a dense cataract, especially in light of the frail zonules. Dr. Gressel reiterated his opinion that no surgery should have been performed in this eye. Nevertheless, he added that, if removal of a cataract in this condition had been necessary, Dr. Jain should have performed an intracapsular cataract extraction. (Tr. at 830-832; St. Ex. 25)

Dr. Gressel stated that phacoemulsification on a normal cataract is a procedure in which the cataract is emulsified into a slurry material and then suctioned from the eye through a small opening. Nevertheless, in this case, the cataract was very dense and would have had the consistency of concrete. Phacoemulsification on this cataract “would have been like chipping away at concrete.” Dr. Gressel stated that the situation was even more difficult, which Dr. Jain should have realized, because with obvious endophthalmodonesis, the zonules that held the cataract in place were weak. When zonules are too weak prior to surgery, it is very easy to knock the whole human lens back into the posterior cavity. Dr. Gressel stated that intracapsular cataract extraction, an older but still necessary procedure, would have been less likely to fragment the cataract and disperse the fragments into the vitreous. Dr. Gressel added that the fragmentation and dispersal of pieces of the cataract was in all likelihood the cause of Patient 4’s postoperative discomfort, pain, light sensitivity, and “severe inflammation.” (Tr. at 831-835; 1236-1237)

- ii. Dr. Jain allegedly observed “obvious endophthalmodonesis, signifying zonular weakness” prior to making the first incision in the eye. Nevertheless, Dr. Jain took no measures to support the cataract from behind to prevent lens fragments from falling into the vitreous. Dr. Gressel testified that this is a complication that should not occur if a cataract is removed properly. (Tr. at 830, 834-835; St. Ex. 25)
- iii. Dr. Jain failed to clear the wound of vitreous and failed to close the wound in a watertight fashion. Because of this, Patient 4 experienced high pressure and fluid buildup in the back of the eye called choroidal effusions. Dr. Gressel concluded that these problems had forced Patient 4 to undergo another operation. (Tr. at 830; St. Ex. 25)
- iv. Dr. Jain failed to diagnose the wound leak and choroidal effusions that had occurred as a complication of his surgery. Dr. Gressel testified that the wound

leak would have been present at the time of surgery, yet Dr. Jain had failed to notice it. (Tr. at 1226-1227: St. Ex. 25)

Dr. Jain also missed an opportunity to discover the wound leak when, on the first postoperative day, an intraocular pressure could not be obtained. Dr. Gressel testified that one of the causes of low or unobtainable intraocular pressure readings is a wound leak. Nevertheless, Dr. Jain failed to investigate although he should have. (Tr. at 923-925, 1226-1227: St. Ex. 25)

Dr. Gressel further testified that more than a week passed before Dr. Jain referred Patient 4 to Dr. Shahinfar. Moreover, even in his referral note to Dr. Shahinfar, Dr. Jain had not yet diagnosed the cause of Patient 4's problems. (Tr. at 1226-1227: St. Ex. 25)

Finally, Dr. Gressel testified that the failure to diagnose the wound leak had probably led to increased discomfort and pain for Patient 4. This occurred because the longer the lens fragments remain in the vitreous, the more pain and inflammation there will be. (Tr. at 1226-1227: St. Ex. 25)

- v. Dr. Gressel testified that, despite Dr. Jain's notes, which imply that both the vitreous prolapse and the iris irregularities had existed preoperatively, "it's very difficult to escape the conclusion that the manner in which the cataract was removed caused both the problem with the iris and the vitreous prolapse." (Tr. at 829)
- f. Dr. Jain failed to insert an intraocular lens; thus, no visual rehabilitation of the eye had been provided. Dr. Gressel testified that he believes it had been inappropriate for Dr. Jain to perform cataract surgery on Patient 4's right eye despite the fact that her postoperative visual acuity was recorded to be 20/400. Dr. Gressel explained that a vision of 20/400 does not carry with it any implications for improved quality of life; having a vision of 20/400 in both eyes would qualify someone as being legally blind. Moreover, Dr. Gressel testified that the risks of the procedure that was performed far outweigh the benefit of an end result of 20/400. (Tr. at 830, 842, 1223-1224; St. Ex. 25)
- g. By operating on a cataract that was undoubtedly rock-hard and that had poor zonular support, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section B1, which states: "An ophthalmologist should perform only those procedures in which the ophthalmologist is competent by virtue of specific training or experience or is assisted by one who is." (St. Ex. 25)

#### **Testimony of Dr. Jain regarding Patient 4**

- 75. Dr. Jain testified that he had been justified in performing the LASIK surgery on Patient 4's left eye. Dr. Jain acknowledged that LASIK is an elective procedure. Nevertheless,

Dr. Jain testified that he had explained to Patient 4 all of the risks and benefits of the surgery and the alternatives “in the context of her functional monocular status.” He further stated that, after that discussion, it had been Patient 4’s decision to have the surgery. (Tr. at 133-135, 1537-1541, 1757-1759)

Dr. Jain acknowledged, however, that a patient’s desire to have a procedure performed is not the only consideration. Dr. Jain explained that:

It doesn’t absolve me of responsibility. But in terms of, you know, what—what is my view of the doctor-patient relationship, it’s not as paternalistic as I suppose it—some physicians would take. Some experts would take the approach that it should be extremely paternalistic; and if there’s any risk, not just significant risk, that certain things shouldn’t be done. However, I believe that the relationship should be more of an open relationship where the risks and benefits are discussed openly with the patient. And as long as the patient is of sound mind, it’s ultimately up to the patient to decide whether or not that risk is reasonable.

(Tr. at 135-136)

76. Dr. Jain acknowledged that he had not performed manual keratometry on Patient 4. Dr. Jain opined that his decision to forego manual keratometry in his pre-LASIK patients had not constituted a departure from accepted standards of care. Dr. Jain added that “there is nothing that manual keratometry provides that is not found in computerized corneal topography.” (Tr. at 133, 1499)
77. Dr. Jain acknowledged that he had not documented microkeratome settings for Patient 4’s LASIK surgery, but added that it had not been necessary to document them because “they were the standard microkeratome settings.” (Tr. at 136)
78. Dr. Jain testified that he had been justified in performing the cataract surgery on Patient 4’s right eye. Dr. Jain acknowledged that, when Patient 4 first presented to Bloomberg Eye Center, the visual acuity in her right eye had been documented as no light perception. Nevertheless, Dr. Jain testified that he had later examined Patient 4’s right eye with an indirect ophthalmoscope and found that she did have light perception in that eye. When asked where he had documented that finding, Dr. Jain testified: “I don’t know—don’t see that I noted it in that note. I remember checking it, but I see it’s not written in that—or, been transcribed, either, in that note.” Dr. Jain admitted that he had not corrected the medical record to indicate that the original assessment of no light perception had been inaccurate. (Tr. at 134, 137-139, 1543)

Dr. Jain further testified that he disagreed with Dr. Gressel’s testimony that Dr. Jain had failed to evaluate Patient 4 for afferent pupillary defect. Dr. Jain testified that he had examined the eye and found Patient 4 to have a reverse afferent pupillary defect. Dr. Jain

explained that reverse afferent pupillary defect is a very complex concept about which he learned when he trained under “one of the most amazing neuro-ophthalmologists in the country.” In fact, Dr. Jain testified that this most amazing neuro-ophthalmologist had taught him to not document findings regarding afferent pupillary defect. (Tr. at 1541-1542)  
Dr. Jain explained:

He always used to tell us, ‘If the pupil exam is normal, write that the pupil exam is normal. Don’t write all those little 5 to 3, negative afferent pupillary defects.’ He was very, very against jargon and mumbo jumbo. He said ophthalmologists can understand each other’s jargon, but other doctors can’t. So if your pupillary exam is normal, you write it as normal.

(Tr. at 1542)

Dr. Jain stated that it is quite possible to have a normal pupillary examination in a non-seeing eye. He explained that if a light were shone into the good eye of a person with a bad eye, the pupil in the bad eye would constrict as well. Dr. Jain testified that, when he shined a light into the right eye, both of Patient 4’s pupils had constricted. Therefore, the pupillary exam had been normal. (Tr. at 1541-1543)

Despite testifying earlier that he had examined Patient 4’s right eye with an indirect ophthalmoscope and discovered that she had been able to perceive light, Dr. Jain later testified that, as a result of his care, Patient 4’s vision had improved from 20/NLP to 20/400. He stated that with a visual acuity of 20/400, you are able to see the big “E” on the eye chart. He added that that is “a pretty significant improvement,” enough that a person would be able to get out of a burning building. (Tr. at 151-153, 1549-1550)

Dr. Jain further testified that he had decided to perform surgery in Patient 4’s right eye because he believed that there had been a potential for improving the vision in that eye. He stated that, before surgery, there had essentially been no useful vision. Moreover, after discussing the risks, benefits, and alternatives, Patient 4 had understood that there was a potential for improvement despite the fact that she would not be able to read the eye chart. Therefore, Patient 4 had chosen to have the surgery. Dr. Jain concluded that he had been perfectly justified in performing the cataract surgery on Patient 4’s right eye.  
(Tr. at 131-133, 1536-1537, 1549-1550)

79. Dr. Jain testified that the phacoemulsification had been the appropriate procedure to be performed on Patient 4’s right eye. Dr. Jain testified that intraocular cataract extraction is a very old procedure, and that complications of the procedure include retinal detachment and evisceration of the eye. Dr. Jain concluded that intraocular cataract extraction is a procedure that was abandoned many years ago. (Tr. at 1548-1549)
80. Dr. Jain testified that the surgery on Patient 4’s right eye had been complicated. He stated that there had been significant endophthalmodonesis or zonular weakness. Dr. Jain

explained that the zonules are very thin cables that support the lens inside the eye. He added that, because the zonules were weak, a portion of the lens had fallen back into the vitreous gel. Therefore, he had been unable to remove the lens completely. (Tr. at 139-140)

Dr. Jain explained that, in endophthalmodonesis, the zonules are not properly supporting the intraocular structures. He stated that it presents as a generalized quivering of the internal structures of the eye. He added that it is more pronounced when the patient is supine, due to the effects of gravity on the lens. For that reason, he explained, endophthalmodonesis may not be apparent when the patient is sitting. (Tr. at 141-142)

Later, Dr. Jain testified that, to a trained ophthalmologist, the quivering of the internal structures of the eye with endophthalmodonesis is easily observed. At the same time, Dr. Jain justified his failure to observe the quivering when Patient 4 was sitting because the quivering is easier to observe when the patient is supine. (Tr. at 1546-1547)

81. Dr. Jain testified that he had been aware of the complications that occurred at the time he performed the surgery. He stated that he had not been aware, however, that pieces of the lens had fallen back into the vitreous. He stated that his view of the posterior portion of the eye had been blocked by the stromal edema. Therefore, he had not seen that pieces of the lens had fallen back into the eye. (Tr. at 144-146)
82. Dr. Jain testified that other complications of the surgery included vitreous prolapse, meaning that the vitreous gel in the back of the eye was pushing through the wound into the aqueous in the front part of the eye, causing edema of the cornea. Moreover, the aqueous was leaking out of the eye through the wound hole. Dr. Jain testified that that this result was, "clearly not desirable." (Tr. at 146-148)
83. In addition, Dr. Jain testified that there had been formation of choroidals or choroidal effusions in the back of the eye, which indicates "a moving forward of the vascular tunic of the eye." He explained that there are three layers in the eye, the retina, the choroid, and the sclera. With the formation of choroidals, the choroid moves forward due to the low pressure in the anterior portion of the eye caused by the leakage. Dr. Jain stated that this is not a "catastrophic complication," because it resolves as the eye pressure normalizes. He acknowledged, however, that it is a complication that came about as a result of the cataract surgery he had performed. (Tr. at 146-148)
84. Dr. Jain disagreed with Dr. Gressel's criticism that his notation of iris irregularities in the operative note was not consistent with the previous medical record. Dr. Jain explained that he may not have found the iris irregularities until initiation of surgery, because the dilation that is done at the time of cataract surgery is more aggressive than that done preoperatively. Therefore, when Dr. Jain examined the eye at the time of Patient 4's cataract surgery, he noticed that the lens did not completely dilate and that the iris was irregular. Dr. Jain testified that this had been caused by extensive posterior adhesions, or synechiae, from the iris to the lens, or cataract. In addition, there were extensive anterior synechiae to the

cornea. Dr. Jain testified that these problems had not been apparent preoperatively. (Tr. at 139-141; 1551-1554)

85. Despite his earlier testimony that the pupil was “unremarkable,” Dr. Jain testified that, due to the iris irregularities, the shape of the pupil was irregular when dilated. (Tr. at 1553-1554)
86. Initially, Dr. Jain testified that the wound leak and choroidal effusions had not been discovered until Dr. Shahinfar operated on Patient 4. (Tr. at 146-147)

Later, however, Dr. Jain testified that he had discovered the wound leak himself and that that had been the reason he referred Patient 4 to Dr. Shahinfar. Dr. Jain stated that, at the conclusion of the surgery, there had not been a wound leak and that the wound leak had developed postoperatively. When Dr. Jain diagnosed the wound leak, he referred Patient 4 to Dr. Shahinfar. Dr. Jain stated that Dr. Shahinfar had provided the appropriate treatment immediately. (Tr. at 1551, 1554-1555)

When asked if the wound leak had been caused by his failure to secure the eye properly, Dr. Jain stated, “no.” He explained that cataract wounds are meant to be self-sealing, and that the leak had been caused by the vitreous prolapsing into the wound. He stated that it is a complication of surgery that occurs in three to four of every 100 cataract surgeries. Dr. Jain concluded that he had not departed from the minimal standards of care in his care and treatment of Patient 4. (Tr. at 150-151, 1555)

87. Dr. Jain acknowledged that a technician at Bloomberg Eye Center had entered erroneous information into Patient 4’s medical record. Moreover, despite knowing of the erroneous information, Dr. Jain had not corrected the medical record. (Tr. at 149-150)
88. Dr. Jain acknowledged that Patient 4 had had a complicated postoperative course. Nevertheless, Dr. Jain denied that he had performed the surgery incompetently. Dr. Jain concluded that he had not violated or departed from the minimal standards of care. (Tr. at 1549-1550)

### ***Patient 5***

#### **Medical Records for Patient 5**

89. Patient 5, a 51 year-old male, presented to the Bloomberg Eye Center to be evaluated for LASIK on April 19, 2001. (St. Ex. 5 at 163) Examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/FC [finger counting]
without Correction	Left eye: 20/400
Current Prescription	Right eye: sphere, -0.50; cylinder, -3.00; axis, 085; 20/25-
	Left eye: sphere, -2.50; cylinder, -0.75; axis, 083; 20/25

Manifest Refraction	Right eye: sphere, -0.50; cylinder, -3.00; axis, 085; 20/25- Left eye: sphere, -2.50; cylinder, -1.00; axis, 080; 20/20
Cycloplegic Refraction	Right eye: sphere, -0.25; cylinder, -2.75; axis, 190; 20/20-1 Left eye: sphere, -1.75; cylinder, -1.00; axis, 069; 20/20
Manual Keratometry	Right eye: none documented Left eye: none documented
Simulated Keratometry	Right eye: none documented Left eye: 43.04
Pachymetry	Right eye: 495 Left eye: 488
Desired Correction	Right eye: sphere, plano; cylinder, -2.75; axis, 090 Left eye: sphere, -1.05; cylinder, -1.10; axis, 069

Corneal topography was performed for both eyes, and the left eye appeared normal. The image for the right eye, however, was inverted and it appeared that there was superior steepening. Nevertheless, someone had hand-written 270° at the top and 90° at the bottom. LASIK was recommended for both eyes at a cost of \$1578.00. (St. Ex. 5 at 9, 11, 161, 163)

90. On May 29, 2001, Dr. Jain performed LASIK on both eyes of Patient 5. (St. Ex. 5 at 57-68, 149, 153, 155)
91. On June 21, 2001, Patient 5 complained that he was seeing halos, ghost images, and shadows on objects. He also stated that his vision was deteriorating. Examination of his eyes revealed the following:

Visual Acuity without Correction	Right eye: 20/30+ Left eye: 20/25
Visual Acuity Pinhole	Right eye: 20/20 Left eye: 20/20+
Manifest Refraction	Right eye: sphere, 0.00; cylinder, -0.50; axis, 030; 20/20 Left eye: sphere, -0.25; cylinder, -0.50; axis, 075; 20/20

(St. Ex. 5 at 147)

92. On July 10, 2001, corneal topography was performed. Marked irregularity of the inferior medial section of the right cornea was circled in ink, but no diagnosis was documented. (St. Ex. 5 at 19)
93. On August 1, 2001, another corneal topography was performed. Dr. Jain noted that there was inferior steepening. He saw Patient 5 the following day. Patient 5 complained that he had been seeing double vertically since the LASIK procedure, with the right eye being worse than the left. (St. Ex. 5 at 13, 143)

94. Dr. Blausey saw Patient 5 on October 4, 2001. Patient 5 complained of having a ghost image in the right eye for the past two months. Dr. Blausey noted that Patient 5's vision was not stable and that he had a residual astigmatism. Dr. Blausey recommended corneal topography to be done in one month. (St. Ex. 5 at 141)
95. Dr. Blausey saw Patient 5 again on November 9, 2001. At that time, Patient 5 reported no improvement in his vision and double vision in the right eye. Dr. Blausey noted an impression of irregular astigmatism versus off-center ablation. He recommended that Dr. Jain see Patient 5 in one month. (St. Ex. 5 at 137)
96. Despite the recommendation that Dr. Jain see Patient 5 in one month, Dr. Blausey saw Patient 5 on December 14, 2001. Patient 5 continued to have blurred and double vision in the right eye. Evaluation of Patient 5's eyes revealed the following:

Visual Acuity	Right eye: 20/30
without Correction	Left eye: 20/25-
Manifest Refraction	Right eye: sphere, plano; cylinder, -0.50; axis, 040; 20/20
	Left eye: sphere, +0.25; cylinder, -0.25; axis, 104; 20/20

Dr. Blausey ordered consultation with Dr. Jain in January 2002 to evaluate Patient 5's right eye. (St. Ex. 5 at 135)

97. On January 21, 2002, Dr. Jain saw Patient 5. Patient 5 complained that his vision was still blurry with a ghost image, and that blurriness in the right eye was greater than that in the left eye. Corneal topography was performed; Dr. Jain noted that there was no keratoconus. Dr. Jain wrote that he would consider astigmatic keratotomy enhancement of the right eye. (St. Ex. 5 at 23, 145)

In a letter to Dr. Blausey, Dr. Jain noted that he had seen Patient 5. Dr. Jain also stated that: "I have discussed the options with [Patient 5] and he prefers to wait and be rechecked in three months. I believe that he would make a good candidate for wave front ablation." (St. Ex. 5 at 131)

98. Dr. Jain saw Patient 5 on April 29, 2002. Patient 5 stated that the double vision in his right eye had been increasing. Patient 5 signed an informed surgical consent to have astigmatic keratotomy in the right eye due to the residual astigmatism in that eye. Nevertheless, the medical record contains no operative note to indicate that the procedure was done. Dr. Jain saw Patient 5 the following day. (St. Ex. 5 at 51-53, 125)
99. On June 3, 2002, Patient 5 called the Bloomberg Eye Center to report that the vision in his right eye was still blurry after the astigmatic keratotomy enhancement. He called again on June 26, 2002, and stated that he could barely see out of his right eye. (St. Ex. 5 at 123)

100. On June 27, 2002, it was noted that Patient 5 had had an astigmatic keratotomy enhancement on April 29, 2002. Patient 5 continued to complain that the vision in his right eye was deteriorating. Examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/50	
without Correction	Left eye: 20/20	
Current Prescription	Right eye: sphere, +3.25; cylinder, -3.75; axis, 093;	20/20
	Left eye: none recorded	
Manifest Refraction	Right eye: sphere, plano	20/60
	Left eye: none recorded	

Corneal topography was performed, and inferior steepening of the right eye was noted. (St. Ex. 5 at 25, 27, 121)

101. On July 16, 2002, Dr. Blausey saw Patient 5. Examination of Patient 5's eyes revealed the following:

Visual Acuity	Right eye: 20/400	
without Correction	Left eye: none recorded	
Manifest Refraction	Right eye: sphere, +3.50; cylinder, -3.75; axis, 100;	20/20-1
	Left eye: none recorded	
Pachymetry	Right eye: 530	
	Left eye: none recorded	

Corneal topography revealed significant inferior steepening of the right eye. Dr. Blausey noted that there was inferior steepening, but added that there was no thinning of the cornea. He suggested a consultation with Dr. Jain due to his concerns about the inferior steepening throughout the eye, and recommended suture placement in the right eye. Nevertheless, the medical record contains no operative note pertaining to suture placement in the right eye. (St. Ex. 5 at 31, 121)

102. Patient 5 presented to the Bloomberg Eye Center on an illegible date in August 2002. The note indicates that he was being evaluated status-post suture placement in the right eye on July 16, 2002. Patient 5 complained that his right eye felt like it had "a log in it." He also stated that he could only see if he tilted his head "way back." He complained of pain, tearing, and a film over his eye. Examination of his eyes revealed the following:

Manifest Refraction	Right eye: sphere, +2.75; cylinder, -4.50; axis, 100	20/25+2
	Left eye: sphere, -0.25	20/20-1

Dr. Jain noted that the sutures were loose, and he removed them. (St. Ex. 5 at 117)

Patient 5 continued to complain of poor vision in his right eye over the next several months. (St. Ex. 5 at 113-115) On December 6, 2002, corneal topography revealed significant

inferior steepening of the right eye. Dr. Blausey diagnosed ectasia. He ordered a trial of soft contact lenses. Patient 5 continued to have difficulty with his vision, despite eventually resorting to the use of rigid gas permeable contact lenses. (St. Ex. 5 at 39, 43, 47, 93-113)

### **Testimony of Dr. Gressel regarding Patient 5**

103. Dr. Gressel testified that Dr. Jain's care and treatment of Patient 5 had fallen below the minimal standards of care. In support of his opinion, Dr. Gressel cited the following:

- a. Dr. Jain failed to diagnose corneal ectasia that was present in Patient 5's right eye prior to Dr. Jain's performing LASIK in that eye. Dr. Gressel testified that corneal topographies performed prior to the LASIK surgery clearly demonstrated inferior steepening or ectasia in the right eye. He added that the failure to diagnose ectasia was significant because ectasia is a contraindication for the performance of LASIK. (Tr. at 843, 844, 845, 856-857; St. Ex. 25)

Dr. Gressel testified that, although Dr. Jain had ordered corneal topographies on this patient, the topography images were inverted. Moreover, the topography machine did not automatically print the numbers around the axis. Dr. Gressel noted that the numbers had been written in by hand. Whoever added the numbers had not done so in such a manner that it would indicate that the corneal steepening was in the inferior portion of the eye, rather than the superior portion of the eye, which the image would otherwise reflect. Nevertheless, Dr. Jain noted negative keratoconus, to indicate that there was no ectasia. (Tr. at 847-850; St. Ex. 5 at 11)

Dr. Gressel noted that it was not until Dr. Blausey diagnosed ectasia in December 2002 that the diagnosis was mentioned in the medical record. (St. Ex. 25)

- b. Dr. Jain failed to perform measurements of corneal thickness, or pachymetry, prior to performing LASIK for Patient 5. Dr. Gressel testified that, in this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, section B10, which states: "Ordering unnecessary procedures or materials or withholding necessary procedures or materials is unethical." (Tr. at 843, 844; St. Ex. 25)

Dr. Gressel noted that Dr. Jain had had a formula to determine when it is safe to perform LASIK without first performing pachymetry. Dr. Gressel further noted that the formula was based on the range of normal corneal thicknesses and number of diopters of required correction. Dr. Gressel acknowledged that such a formula might be effective in most patients, but not all. Moreover, the formula would not prevent significantly negative outcomes in eyes that fall into the normal range of corneal thickness but which have abnormally shaped corneas. (Tr. at 1231-1233)

- c. Dr. Jain failed to perform and/or properly document the performance of keratometry prior to performing LASIK for Patient 5. Dr. Gressel reiterated his earlier testimony

that the importance of keratometry lies in the fact that any future cataract surgery would entail a need for keratometry measurements taken prior to LASIK to facilitate the proper selection of intraocular lens implant power. In addition, Dr. Gressel testified that, because the corneal steepening in Patient 5's right eye extended as far as the central portion of the cornea, there is a good chance that manual keratometry would have revealed to Dr. Jain the significant inferior steepening. (Tr. at 843-846, 858; St. Ex. 25)

- d. Dr. Jain inappropriately performed LASIK on Patient 5's right eye despite obvious ectasia. Dr. Gressel concluded that, in this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section A7, which states: "It is the responsibility of an ophthalmologist to act in the best interest of the patient." (Tr. at 843; St. Ex. 25)

Dr. Gressel noted that Patient 5 had continued to have problems including vertically separated double vision, and ghost images. (Tr. at 843; St. Ex. 25)

- e. Dr. Jain failed to document the type of microkeratome or the microkeratome settings utilized. Dr. Gressel reiterated his earlier testimony that, if the left eye were to need additional corneal surgery in the future, knowledge of the type of microkeratome and settings used could assist in estimation of the LASIK flap thickness, which could influence surgical decision-making. (Tr. at 843, 846-847; St. Ex. 25)
- f. On January 21, 2002, Dr. Jain recommended wave front ablation, failing to note postoperatively the abnormal corneal contour. Dr. Gressel testified that wave front ablation is an additional type of laser treatment that allows removal of corneal tissue in an asymmetric pattern as opposed to a symmetrical pattern. Dr. Gressel further testified that the magnitude of aberrations involved was far too great to justify any expectation that the problems could be fixed with wave front ablation. Moreover, Dr. Gressel stated that removal of additional tissue from the cornea of an eye in that condition likely would have increased the corneal problems. Dr. Gressel stated that, by proposing wave front ablation, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section A7, which states: "It is the responsibility of an ophthalmologist to act in the best interest of the patient." (Tr. at 843, 852; St. Ex. 25)
- g. Dr. Jain failed to properly diagnose corneal ectasia present in Patient 5's right eye prior to the astigmatic keratotomy procedure. Dr. Gressel testified that it is significant to note that, after performing the astigmatic keratotomy, there was dramatically greater astigmatism present than there had been prior. He explained that the condition of the eye worsened as would have been expected by performing astigmatic keratotomy on an eye in that condition. (Tr. at 843, 854-855, 858; St. Ex. 25)

- h. Dr. Jain failed to perform measurements of corneal thickness, or pachymetry, prior to performing astigmatic keratotomy. Dr. Gressel concluded that, in this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, section B10, which states: “Ordering unnecessary procedures or materials or withholding necessary procedures or materials is unethical.” (Tr. at 843, 844; St. Ex. 25)
- i.. Dr. Jain provided inappropriate treatment by placing an astigmatic keratotomy incision in the part of the cornea most affected by ectasia. Dr. Gressel testified that performing an astigmatic keratotomy in a patient who has ectasia is contraindicated because the incision is made in a part of the cornea that is the steepest in an attempt to flatten or minimize the steepness. In this patient, the incision in that area further weakened and worsened the condition. Therefore, Dr. Gressel concluded that, by performing the astigmatic keratotomy, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section A7, which states: “It is the responsibility of an ophthalmologist to act in the best interest of the patient.” (Tr. at 843-844, 857; St. Ex. 25)
- j. Dr. Jain failed to appropriately document his performance of the astigmatic keratotomy. Dr. Gressel testified that it would appear that Dr. Jain had sutured the astigmatic keratotomy incisions in an attempt to reduce the amount of astigmatism in Patient 5’s right eye. Nevertheless, Dr. Gressel testified that he could not accurately determine Dr. Jain’s intention because Dr. Jain had not created an operative note. Dr. Gressel testified that it is important to create an operative note for each procedure performed because, should something happened to Dr. Jain, without an operative note, there is no mechanism to transfer information regarding the patient to a subsequent treating physician. (Tr. at 853-855; St. Ex. 25)
- k. Dr. Jain failed to document the type of microkeratome or the microkeratome settings he had used. Dr. Gressel explained that, if the eye were to need additional corneal surgery in the future, knowledge of the type of microkeratome and settings used could assist in estimation of the LASIK flap thickness, which could influence surgical decision-making. (Tr. at 843-844, 1229-1231; St. Ex. 25)
- l. Dr. Jain failed to refer Patient 5 to another physician when it became apparent that he was not improving under Dr. Jain’s care. Subsequent medical records for Patient 5 demonstrate unsuccessful attempts at visual rehabilitation with contact lenses. Dr. Gressel testified that Patient 5’s visual acuity continued to fluctuate and to be unstable. Dr. Gressel concluded that the failure to refer Patient 5 had constituted a violation of the Code of Ethics of the American Academy of Ophthalmology, Section B4, which states: “Consultation(s) shall be obtained if required by the condition.” (Tr. at 843-844, 858-859, 1235-1236, 1401-1406, 1409-1411; St. Ex. 25)

**Testimony of Dr. Jain regarding Patient 5**

104. Dr. Jain testified that the main reason he reviews corneal topography is to look for signs of corneal steepening. He noted, however, that it was his practice to review topographies with the understanding that 90° is at the top of the diagram and 270° is at the bottom. He stated that he had simply assumed that the diagrams were accurate. Moreover, he admitted that it had not been until “significantly later” that he had realized that the topographies were inverted. (Tr. at 154-155, 1556-1557, 1560-1561)
105. Dr. Jain acknowledged that he might have discovered the inferior steepening had he performed manual keratometry prior to performing the astigmatic keratotomy. (Tr. at 159-160)
106. Dr. Jain acknowledged that Patient 5’s medical record does not contain an operative note for the astigmatic keratotomy. He stated that he did not know why it was not in the record. (Tr. at 164-165)
107. Dr. Jain objected to the criticism that he had inappropriately failed to refer Patient 5 to another physician. Dr. Jain stated that he had been trying to do his best and had believed that Patient 5 was satisfied with his care. Dr. Jain acknowledged that Patient 5 had not had complete information about his surgery, and that there had been an oversight on his part regarding the issue of inverted topography. Dr. Jain testified that he had informed the patient of that oversight. (Tr. at 1759-1760)

In other testimony, however, Dr. Jain testified that he could not remember if he had advised Patient 5 of the inverted topographies. Dr. Jain acknowledged that he had not documented anywhere in the medical record that he had advised Patient 5 of the inverted topographies. (Tr. at 158-159)

Furthermore, Dr. Jain acknowledged that it was Dr. Blausey, and optometrist, who had diagnosed Patient 5’s ectasia. (Tr. at 159)

***Patient 6***

**Medical Records for Patient 6**

108. Patient 6, a 52-year-old male, presented to the Bloomberg Eye Center on July 11, 2002, to be evaluated for LASIK. Examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/20
with Correction	Left eye: 20/20
Visual Acuity	Right eye: 20/40
without Correction	Left eye: 20/60
Current Prescription	Right eye: sphere, +1.50; cylinder, -0.25; axis, 150
	Left eye: sphere, +1.25; cylinder, -0.25; axis, 002

Manifest Refraction	Right eye: sphere, +1.00; cylinder, -0.25; axis, 140; 20/20 Left eye: sphere, +1.25 20/20
Cycloplegic Refraction	Right eye: sphere, +1.50; cylinder, -0.25; axis, 140; 20/20 Left eye: sphere, +1.75 20/20
Simulated Keratometry	Right eye: 45.27 Left eye: 45.09
Pachymetry	Right eye: 614 Left eye: 607
Desired Correction	Right eye: sphere, +3.90; cylinder, -0.25; axis, 140 Left eye: sphere, +2.60;

In addition, it was noted that Patient 6's left eye was dominant. Patient 6 was scheduled for LASIK correction on both eyes, with correction for astigmatism, hyperopia, and monovision. It was noted that, to achieve monovision, the right eye would be corrected for near vision and the left eye would be corrected for distance. The cost was noted to be \$1598.00. Patient 6 accepted the Lifetime Assurance Plan for an additional \$69.00 per eye. (St. Ex. 6 at 33)

109. On July 16, 2002, Dr. Jain performed LASIK on both eyes. For the right eye, he entered a correction for hyperopia and astigmatism; for the left eye, he entered a correction for hyperopia. The desired correction was noted to be:

Right eye: sphere, +3.90; cylinder, -0.25; axis, 140  
Left eye: sphere, +2.69; cylinder, -0.00; axis, 002

The medical record contains no signed informed consent form for the LASIK performed on July 16, 2002. (St. Ex. 6 at 28-29)

110. Dr. Jain saw Patient 6 the following day. Patient 6 complained that his distance vision was very blurred, but his near vision was good. Visual acuity without correction for the right eye was noted to be 20/CF, and for the left eye 20/70. Dr. Jain recommended follow-up in eight weeks. (St. Ex. 6 at 27)
111. On July 23, 2002, Patient 6 called the Bloomberg Eye Center complaining that his vision was blurry in both eyes and that he was not comfortable driving a car. An appointment was scheduled for two days later, but Patient 6 did not appear. On July 29, 2002, a woman called on his behalf and stated that his vision was not better and that he needed to be seen. An appointment was scheduled for July 30, 2002. (St. Ex. 6 at 26)
112. Dr. Jain saw Patient 6 on July 30, 2002. He complained that the vision in his right eye was "much worse," and he was squinting to see. Visual acuity without correction for the right eye was noted to be 20/400J7, and for the left eye 20/50. Manifest refraction was recorded as follows:

Right eye: sphere, -3.50; cylinder, -0.25; axis, 140; 20/20  
Left eye: sphere, +1.25 20/20

Dr. Jain prescribed eyeglasses and eye drops. He recommended that Patient 6 return in eight weeks. (St. Ex. 6 at 25)

113. On August 2, 2002, Patient 6's employer called requesting something in writing regarding Patient 6's vision because Patient 6 had been unable to work since July 29, 2002. Dr. Jain sent a letter to the employer in which he stated:

[Patient 6] is experiencing an initial over-correction, which is not unusual. He is still correctable to 20/20. The initial over-correction accounts for why [Patient 6] is experiencing difficulty working. He will need to be off work from July 29, 2002, until further notice.

(St. Ex. 6 at 23, 24)

114. A telephone contact sheet in the medical record dated September 4, 2002, states as follows:

[Patient 6's] girlfriend called and is wanting to know what he is supposed to do with his eyes. We gave him a prescription back in July. He is telling his girlfriend that his glasses are worse than his eyes. I explained to her that for him being farsighted that it usually takes more than one time to correct his vision. She stated that they were never told that when he came in for the consultation that he would need an enhancement. I tried to get him to come in for an appt. tomorrow. She is going to check with him. She also told me that they were getting a 2<sup>nd</sup> opinion but nobody will do anything for him.

(St. Ex. 6 at 22)

115. In a note for an undated visit, it is documented that Patient 6 was very upset and displeased with the outcome of his surgery. He stated that he was unable to see far away, that he was not able to function, and that he could not see to drive. Moreover, he had been unable to wear his glasses. Visual acuity without correction for the right eye was noted to be 20/400, and for the left eye 20/200. Manifest refraction was recorded as follows:

Right eye: sphere, -3.25; cylinder, -0.75; axis, 030; 20/25  
Left eye: sphere, -1.25 cylinder, -0.50; axis, 095; 20/20

Dr. Jain planned to enhance both eyes, maintaining monovision in the right eye. His enhancement plan was as follows:

Right eye: sphere, - 0.50; cylinder, - 0.50; axis, 030  
Left eye: sphere, - 0.50 cylinder, -0.50; axis, 095

(St. Ex. 6 at 21)

116. Corneal topography was performed on September 17, 2002. Dr. Jain noted no keratoconus. (St. Ex. 6 at 8)
117. In a LASIK scheduling order dated October 14, 2002, it is noted that Patient 6's right eye was dominant. That notation was underlined three times. Also highlighted is the statement, "May still want mono." A treatment plan for the right eye is recorded as: sphere, -2.0; cylinder, -0.6; and axis, 035. (St. Ex. 6 at 20)
118. On October 17, 2002, Dr. Jain performed LASIK on Patient 6's right eye. Dr. Jain saw Patient 6 the following day and noted no problems. He planned to see Patient 6 in eight to twelve weeks. Patient 6 was unable to work following that procedure for several weeks due to blurred vision. The medical record contains no informed consent for the LASIK performed on October 17, 2002. (St. Ex. 6 at 5, 16-17)
119. Dr. Blausey saw Patient 6 on November 15, 2002. At that time Patient 6 complained that his distance vision was decreasing although his near vision seemed "good." Examination of his eyes revealed the following:

Visual Acuity	Right eye: <del>20/30</del> <sup>SB</sup> 20/20-
without Correction	Left eye: 20/40
Manifest Refraction	Right eye: sphere, 0.00; cylinder, -0.50; axis, 082; 20/20
	Left eye: sphere, -0.75; cylinder, -0.50; axis, 074; 20/20

(St. Ex. 6 at 14)

120. On February 3, 2003, Patient 6's girlfriend called to schedule an appointment for Patient 6. She stated that Patient 6 wanted to see Dr. Shahinfar. Dr. Shahinfar saw Patient 6 on February 11, 2003. At that time, Patient 6 stated that his eyes were not working together, that both eyes hurt, that he had headaches all day, and that his eyes were dry. Examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/20
without Correction	Left eye: 20/100
Manifest Refraction	Right eye: sphere, -0.25 20/20
	Left eye: sphere, -0.75; cylinder, -0.50; axis, 090; 20/20
Visual Acuity	Both eyes: 20/50+

Corneal topography was performed on February 11, 2003. Dr. Jain noted no keratoconus. Dr. Shahinfar recommended enhancement of the left eye, but specifically stated, "Do not enhance" the right eye. He also noted that Patient 6 tended to squint. (St. Ex. 6 at 4, 12)

### Testimony of Dr. Gressel regarding Patient 6

121. Dr. Gressel testified that Dr. Jain's care and treatment of Patient 6 had fallen below the minimal standards of care. In support of his opinion, Dr. Gressel cited the following:

- a. Dr. Jain failed to determine if Patient 6 would be able to adapt to monovision. Dr. Gressel testified that many people are unable to adjust to monovision. He added that it is very simple to test by using disposable soft contact lenses to simulate a visual experience similar to surgically-induced monovision before committing to such an extensive correction. Dr. Gressel stated that it is important to test for monovision, and that doing so might have eliminated much of the confusion and difficulty that Patient 6 had encountered after the surgery. He further stated that Patient 6 had almost no astigmatism, which makes an ideal case for trying soft contact lenses to simulate monovision. He added that, by using soft contact lenses to test for monovision, it is possible to test one eye for near vision and the other for distance vision, and then test the opposite eyes for near vision and distance vision to see which correction is better for the patient. (Tr. at 860-862, 1250-12521; St. Ex. 25)

Dr. Gressel concluded that there had been a strong possibility that Patient 6 would have been unable to adjust to monovision in any form and that, in failing to test before performing LASIK, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section A7, which states: "It is the responsibility of an ophthalmologist to act in the best interest of the patient." (Tr. at 859-860; St. Ex. 25)

- b. On July 16, 2002, Dr. Jain had entered an excessively large treatment for hyperopia for both eyes, which resulted in overcorrections that greatly impaired Patient 6's visual functioning. Dr. Gressel testified that, in coming to that conclusion, he had reasoned as follows:

I used the information recorded on p. 33 [of State's Exhibit 6] to calculate the amount of treatment I would program into a Visx laser for a 52 year-old to accomplish modified monovision (i.e. a postoperative refraction of -1.00 for the right eye and no distance correction for the left eye). This set of calculations yielded for the right eye a programmed treatment of +2.53 +0.25 X 050 (spherical equivalent +2.65) and for the left eye +2.09 sph. Comparison with the treatments documented on pp. 28 and 29 reveals that Dr. Jain used 43% more treatment for the right eye and 24% more treatment for the left eye than I would have done then or would do now. It is my opinion to a reasonable degree of medical probability that this difference is too large to be accounted for by differences between the Visx laser Dr. Jain used and the one I use, and/or the environmental differences between the Bloomberg Eye Center in Newark and the Cleveland Clinic Lorain Ambulatory Surgery Center. I believe Dr. Jain's hyperopia nomogram for the Visx laser was in error, which might explain

the impression among Bloomberg Eye Center staff that ‘...being farsighted...it usually takes more than one time to correct his vision.’

(Tr. at 859-860; St. Ex. 25)

Dr. Gressel noted that, seven days after LASIK, Patient 6 had called to report that his vision was too blurred to allow him to be comfortable driving. Shortly thereafter, Patient 6 reported that his vision was deteriorating. Upon examination, it was found that the uncorrected near acuity was J7 in the right eye and uncorrected distance acuity was 20/50 in the left eye. Dr. Gressel added that the manifest refraction revealed more of an overcorrection than should have been expected at this stage. Dr. Gressel acknowledged that a small overcorrection in the first postoperative weeks is acceptable as the overcorrection tends to regress as the farsightedness corrects. Nevertheless, he stated that, at this stage, there was much more of an overcorrection than would be expected. (Tr. at 859-860, 865-868, 1242-1249; St. Ex. 25)

Dr. Gressel explained as follows:

The significance of the overcorrections for [Patient] 6’s visual functioning can only be understood if one considers both the good and bad effects of even a well-executed laser procedure (LASIK or enhancement). The good part is the ability to help visual function by changing the refractive state of the eye (i.e. nearsightedness, farsightedness, and regular astigmatism). The bad part is that there is always at least some optical aberration induced (this could be thought as being like a ripple in the glass of a windowpane). The larger is the degree of treatment and the greater is the number of treatments, the more aberrations. Hyperopic treatments tend to induce more optical aberrations than myopic treatments. At first glance, one might look at the final visit of [Patient] 6 (p.12) and think ‘Unaided distance acuity in the right eye of 20/20 and a refraction of  $-0.25$  sph – that’s an excellent result!’ However, a review of everything that happened to the right eye reveals that it underwent a relatively large hyperopic treatment that changed its refractive state by 4.75 diopters (and induced at least some optical aberrations), followed by a myopic treatment that changed the refractive state by 3.25 diopters in the opposite direction (inducing still more optical aberrations). In other words, [Patient] 6’s right eye on 02-11-03 was very different from the eye of a person born with natural 20/20 unaided vision and a refractive error of  $-0.25$  sph. Unfortunately, a person with optical aberrations may be capable of 20/20 vision under the ideal, high-contrast conditions of viewing an ophthalmologist’s bright chart in a dimmed room, but may have very real and sometimes incapacitating visual problems under ‘real-world’ viewing conditions.

(Tr. at 859-860; St. Ex. 25)

- c. The day after the first LASIK surgery, Dr. Jain failed to provide and/or document suggestions to assist Patient 6 with his visual functioning, and provided inadequate postoperative care. Dr. Gressel noted that, the first day postoperatively, Patient 6 had complained that his vision was blurry at a distance but that his near vision was good. The distance vision was only 20/70, which makes it very difficult for people to drive. He explained that, when eyes are corrected for monovision, the patient is forced to rely on the eye that has been corrected for far vision because the eye that has been corrected for near vision is of no help when driving. Therefore, when the vision in the distance eye is less than ideal, there is a significant impact on the patient's ability to function. Nevertheless, Dr. Gressel noted that Dr. Jain's only comment was to schedule Patient 6 for a return visit in eight weeks. (Tr. at 862-863)

Dr. Gressel testified that scheduling the patient's next visit so far in the future was inappropriate under the circumstances. Patient 6 complained that he was having difficulty functioning, yet Dr. Jain made no attempt to assist him with eyeglasses or contact lenses. Thereafter, Patient 6's vision continued to deteriorate. (Tr. at 863-865)

Dr. Gressel testified that the fact that Dr. Jain had attempted to "keep [Patient 6] at bay" for eight weeks at a time without attempting to alleviate his postoperative problems was a violation of the Code of Ethics of the American Academy of Ophthalmology, section B8, which states:

The providing of postoperative eye care until the patient has recovered is integral to patient management. The operating ophthalmologist should provide those aspects of postoperative eye care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries). Otherwise, the operating ophthalmologist must make arrangements before surgery for referral of the patient to another ophthalmologist, with the patient's approval and that of the other ophthalmologist.

(Tr. at 859-860; St. Ex. 25)

Dr. Gressel testified that the fact that Patient 6 lived in West Virginia and traveled some distance to see Dr. Jain did not relieve Dr. Jain of his responsibility to provide adequate postoperative care. (Tr. at 1253-1255)

- d. In the second LASIK surgery, Dr. Jain eliminated right eye near vision, forcing Patient 6 to rely on his nondominant right eye for distance vision. Dr. Gressel noted that, prior to the enhancement surgery, Dr. Jain had recorded a plan for enhancement by which the right eye was to be corrected for near vision. It was also documented that the right eye was dominant, and that notation was underlined three times. Dr. Gressel stated that, if the right eye was dominant, it was a direct contraindication

to the ocular dominance determination and treatment plan recorded earlier in the patient record. (Tr. at 859-860; St. Ex. 25)

Moreover, there is a notation in the record that Patient 6 “may still want mono.” In addition, Dr. Jain documented a plan for the right eye’s correction as: “-2.0 -0.6 x 035.” Dr. Gressel concluded that this amount of laser treatment would have been expected to eliminate all of Patient 6’s myopia in the right eye, not preserve some of it as had been planned. Finally, Dr. Gressel testified that the postoperative record confirms that Dr. Jain had in fact eliminated essentially all of the right eye’s myopia. (Tr. at 859-860; St. Ex. 25; St. Ex. 6 at 16, 20, 21, 33)

Dr. Gressel stated that people have a better chance of adjusting to monovision if the dominant eye is used for distance. Dr. Gressel noted that, prior to the first LASIK procedure, a notation in the medical record had indicated that Patient 6’s left eye was the dominant eye. Prior to the enhancement, however, there is a notation that the right eye was the dominant eye. Dr. Gressel suggested that Dr. Jain had made an error in eliminating all of the right eye’s nearsightedness when the enhancement was done, due in part to the confusion about which eye was in fact dominant. In the first LASIK procedure, when the medical record indicated that the left eye was dominant, Dr. Jain corrected the right eye for near vision and the left eye for distance. Nevertheless, during the enhancement procedure, when the medical record indicated that the right eye was dominant, Dr. Jain essentially eliminated all of the right eye’s nearsightedness. Dr. Gressel testified that the trouble with Patient 6’s visual adaptation after the enhancement would be explainable if the left eye had in fact been the dominant eye as noted prior to the first LASIK procedure. (Tr. at 859-860, 868-874; St. Ex. 25; St. Ex. 6 at 21, 33)

Dr. Gressel further noted that Dr. Jain had documented no plan for management of the left eye, which, originally, had been intended for distance vision, but which now had a distance vision of 20/100. He further noted that, at Patient 6’s last visit to Bloomberg Eye Center, it was Dr. Shahinfar who recognized the need for enhancement of the left eye. (Tr. at 874-876)

- e. Dr. Jain failed to obtain or document informed consent before performing either the first LASIK surgery or the enhancement procedure. Dr. Gressel testified that the medical record contained no signed informed consent forms for either procedure. He stated that this was particularly perplexing given the fact that Patient 6’s girlfriend had called to specifically complain about the lack of informed consent being given. Dr. Gressel testified that, “Ordinarily, one would think, if a person complains about something, that the next time around you would be particularly cautious and vigilant about that issue that had been raised. No sign of such vigilance here.” Dr. Gressel testified that he is more inclined to believe that no informed consent was given, in light of the girlfriend’s complaint, since, even after her complaint, there is no signed

informed consent form for the enhancement procedure. (Tr. at 859-860, 876-877, 1238-1240; St. Ex. 25)

Dr. Gressel concluded that Dr. Jain's failure to record proper documentation of informed consent for the LASIK procedures in both eyes and the enhancement procedure in the right eye violated the Code of Ethics of the American Academy of Ophthalmology, section B2, which states: "The performance of medical or surgical procedures shall be preceded by appropriate informed consent." (Tr. at 859-860; St. Ex. 25)

- f. Dr. Jain failed to provide adequate postoperative care for Patient 6. Dr. Gressel noted that, on the first postoperative day after the enhancement, there was no subjective appraisal of Patient 6's visual functioning from his own perspective. Moreover, Patient 6 was instructed to return in eight to 12 weeks which, in Dr. Gressel's opinion, is an extended period of time considering the level of difficulty Patient 6 had been experiencing. In addition, on November 15, 2002, Patient 6 complained that his distance vision was decreasing, yet he was told to return in two months. (Tr. at 859-860, 1253-1255; St. Ex. 25; St. Ex. 6 at 16)

#### **Testimony of Dr. Jain regarding Patient 6**

122. Dr. Jain testified that, prior to the first LASIK procedure, he had carefully reviewed the procedure with Patient 6. Dr. Jain further testified that he had made it clear to Patient 6 that approximately 20% of people who have monovision are not able to tolerate it. In those cases, the eye that had been corrected for near vision will be redone and the patient will wear reading glasses. (Tr. at 166-167)

Dr. Jain testified that any attempt to determine whether Patient 6 could adjust to monovision through the use of contact lenses would likely have been ineffective because, more often than not, patients are unable to tolerate contacts. Moreover, unless the contact lens can also correct whatever astigmatism the patient might have, it is not an actual simulation of what would happen with LASIK. For these reasons, Dr. Jain stated that he does not attempt to simulate monovision through the use of contact lenses. Therefore, Dr. Jain concluded that his failure to test Patient 6's ability to tolerate monovision with the use of contact lenses was not a departure from the minimal standards of care. (Tr. at 167-168, 1569-1571)

123. Dr. Jain testified that the overcorrection had been purposeful and intended. Dr. Jain stated that there is always regression of the initial hyperopic result. Moreover, Dr. Jain testified that postoperatively Patient 6's vision had been corrected to 20/20. Dr. Jain acknowledged that Patient 6 had complained that his vision was "much worse." Nevertheless, Dr. Jain testified that, when correcting hyperopia to monovision, "you have to overcorrect them a lot." He also stated that these patients complain of difficulty with their vision until the vision in the distance eye resolves. Dr. Jain testified that it is even more complicated with

hyperopic vision because correcting for hyperopia requires removal of tissue, and cannot be undone. He explained that it is easier to “overshoot them to myopia” and repair with additional correction at a later date. Nonetheless, Dr. Jain acknowledged that Patient 6 had ended up with more correction than expected, but added that it was not much more than expected and was not “way out of line.” (Tr. at 175-177; 1564-1565)

Dr. Jain concluded that his initial LASIK treatment for hyperopia had been within the standards of care. He stated that the correction was intentional and within the generally accepted norms for the treatment of hyperopia, especially since the patient had been counseled to expect the overcorrection. He further testified that the later enhancement procedure on the right eye had conformed to the minimal standards of care. He added that, by February 12, 2002, Patient 6’s uncorrected vision in both eyes was 20/20; therefore, Dr. Jain concluded, what he had originally intended is what eventually occurred. (Tr. at 1567-1569)

124. Dr. Jain stated that patients who have farsighted vision face a different LASIK procedure than the LASIK procedure used for nearsighted patients. (Tr. at 1463) Dr. Jain testified that, in farsighted LASIK, he routinely overcorrected the patient’s vision thirty to forty percent because the regression rate was thirty to forty percent. He explained that,

If a person was a plus-2 hyperope and you didn’t at least overcorrect them thirty percent to plus-2.6, they would fall back into the hyperopic zone and they would be very, very unhappy. However, if you did overcorrect them thirty percent and you explain to them very, very clearly that, ‘You’re just going to have terrible distance vision for about two months of every diopter we attempt to correct, and you – and that’s part of the deal,’ then they understand and expect that. And the next day when they can’t see anything far away, but when they look at the paper they can read everything, and since you’ve told them that that’s what’s going to happen, they’re usually fine with it. You know, once again, it’s always about managing expectations. As long as the patients know what to expect, they’re fine with it.

(Tr. at 1464-1465)

Dr. Jain testified that, in farsighted LASIK, tissue is removed from the peripheral cornea, not the central cornea and that the peripheral cornea is significantly thicker than the central cornea. He added that,

In tissue removal in the peripheral cornea essentially is a non-issue because to the degree of farsightedness that is FDA approved, you can’t correct more than that. You can never thin the cornea enough to create a problem because of how far out in the periphery the farsighted correction occurs. And studies have shown that it’s much better to overcorrect people into myopia and then

enhance them back to plano [because] the predictability of farsighted LASIK is very, very poor compared to nearsighted LASIK.

(Tr. at 1467-1468)

125. Regarding Dr. Gressel's criticism of Dr. Jain for failing to provide adequate postoperative care, Dr. Jain testified that he had counseled Patient 6 that he would have to make frequent postoperative visits. Dr. Jain added that, considering the distance between his office and Patient 6's home in West Virginia, Patient 6 had said that he "would do the best he could."  
(Tr. at 174-175)

Dr. Jain also testified that he had told Patient 6 that it would take several months to reach the optimal improvement in his vision. Dr. Jain explained that he had told Patient 6 that his vision would continue to improve postoperatively for approximately two months per diopter of attempted correction. Moreover, Dr. Jain testified that, with hyperopic LASIK, it would take at least eight weeks for any significant change to occur. Therefore, a visit every eight weeks is appropriate. Dr. Jain explained that he had also told Patient 6 that Patient 6 could come to the office whenever he felt necessary. Dr. Jain concluded that his postoperative care of Patient 6 had met the minimal standards of care. (Tr. at 179-180; 1571-1573)

126. Dr. Jain discussed Dr. Gressel's criticism that, during the second LASIK surgery, Dr. Jain had eliminated Patient 6's right eye near vision, forcing Patient 6 to rely on the nondominant right eye for distance. Dr. Jain acknowledged that, initially, the medical record indicates that the left eye was dominant, while later it indicates that the right eye was dominant. Dr. Jain testified that ocular dominance is not a critically important determination, given that 20% of the general population does not have any ocular dominance. He added that, in his experience, patients do well when either the dominant eye or the non-dominant eye is corrected for distance. Therefore, he had not considered it to be a problem when the dominance between the eyes switched. Moreover, Dr. Jain testified that, when he did the enhancement, he determined that the left eye was pretty perfect for near vision; therefore, he corrected the dominant right eye for distance.  
(Tr. at 169-171, 1565-1567)

127. Dr. Jain testified that he had provided and obtained informed consent from Patient 6. Dr. Jain testified that with hyperopes who have monovision, he had spent a great deal of time explaining to them what they would be experiencing. For example, Dr. Jain might say:

You're going to be amazed how well you're going to be able to read even the tiny, tiny stock—stock quotes in the newspaper up-close. And you might have to look really up-close. And your other eye will be wonderful for normal-level reading—because you have to overcorrect them—but your distance will be just horrible. And it will take—and the rule of thumb I use is two months for every diopter of intended correction—for you to get to the

point where you expect to not really be dependent on glasses. So it is a prolonged recovery period.

(Tr. at 171-172) Dr. Jain testified that he had reviewed these details with Patient 6. He stated that he also told Patient 6 that, since he had corrected almost four diopters of hyperopia in the right eye, he would expect eight months of recovery time for the right eye. And since he had corrected 2.6 diopters in the left eye, he should expect five months recovery for the left eye. Dr. Jain concluded that Patient 6 had been left with 20/20 vision in both eyes and that Patient 6 had been happy with his monovision. Nevertheless, Dr. Jain acknowledged that there is no signed informed consent form, and no documentation of this discussion, in the medical record. (Tr. at 172-174)

### ***Patient 7***

#### **Medical Records for Patient 7**

128. Patient 7, a 50 year-old male, presented to the Bloomberg Eye Center to be evaluated for LASIK on July 9, 2001. Examination of his eyes revealed the following:

Visual Acuity with Correction	Right eye: 20/40 Left eye: 20/30-2
Visual Acuity without Correction	Right eye: 20/CF Left eye: 20/CF
Current Prescription	Right eye: sphere, -6.75; cylinder, -0.75; axis, 098 Left eye: sphere, -5.50; cylinder, -1.00; axis, 082
Manifest Refraction	Right eye: sphere, -7.25; cylinder, -0.75; axis, 090; 20/20-1 Left eye: sphere, -5.75; cylinder, -1.00; axis, 090; 20/20
Cycloplegic Refraction	Right eye: sphere, -7.25; cylinder, -0.75; axis, 090; 20/20 Left eye: sphere, -5.75; cylinder, -1.00; axis, 090; 20/20
Simulated Keratometry	Right eye: 40.56 Left eye: 40.34
Pachymetry	Right eye: 563 Left eye: 570
Intraocular Pressure	Right eye: 16 mmHg Left eye: 18 mmHg
Desired Correction	Right eye: sphere, -5.60; cylinder, -0.85; axis, 090 Left eye: sphere, -4.30; cylinder, -1.10; axis, 090

129. In addition, it was noted that the left eye was the dominant eye. It was also noted that corneal topography had been within normal limits for both eyes; however, it was also noted that there was inferior steepening. A plan was documented for LASIK correction in both eyes. Myopia and astigmatism were circled; correction for monovision was not. Prices were quoted of \$978.00 for one eye and \$1076.00 for the other. Patient 7 accepted the Lifetime Assurance Plan at \$98.00. (St. Ex. 7 at 139, 141, 143)

130. On July 12, 2001, Dr. Jain performed LASIK [first LASIK procedure] on both eyes. There is no indication that corneal topography was performed on the day of surgery. Moreover, the microkeratome settings were not documented. Patient 7 did sign an informed consent form for bilateral LASIK surgery. (St. Ex. 7 at 33-34, 131-135)

The following day, Dr. Shah, an optometrist at Bloomberg Eye Center, saw Patient 7. Patient 7 denied pain or discomfort. Dr. Shah noted "Grade 2+ DLK" [diffuse lamellar keratitis] in the right eye and "Grade 2 DLK" in the left eye. She prescribed eye drops. Dr. Shah did not document an intraocular pressure. (St. Ex. 7 at 129; Tr. at 192)

131. On July 16, 2001, Dr. Bell, another optometrist at Bloomberg Eye Center, saw Patient 7. Patient 7 complained that his vision was deteriorating. Examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/200
without Correction	Left eye: 20/25-
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Visual Acuity	Right eye: 20/40-1
Pinhole	Left eye: 20/25+1
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Dr. Bell noted Grade 2+ DLK in the right eye and Grade 2- DLK in the left eye. She prescribed eye drops with prednisone forte 1%, a steroid, to be applied hourly to each eye. Dr. Bell did not document an intraocular pressure. (St. Ex. 7 at 127)

132. The next day, Dr. Bell saw Patient 7 again. Dr. Bell noted that the right eye was clearing peripherally but that it was becoming more dense centrally. She also noted that the DLK was not responding to steroids, and she planned an irrigation of the right eye. Dr. Bell did not document an intraocular pressure. She continued the steroid eye drops. (St. Ex. 7 at 125)
133. On July 19, 2001, Patient 7 signed an informed consent form for flap irrigation of the right eye. There is no operative note corresponding to that informed consent form. (St. Ex. 7 at 31-32)
134. On July 20, 2001, Dr. Shah saw Patient 7. She noted that Patient 7 had had a flap irrigation of the right eye the previous day. She also documented that there was an epithelial defect with surrounding edema in the right eye. She increased the prednisone forte to every thirty minutes in the right eye, but continued the prednisone forte hourly in the left eye. She also noted a plan to replace the soft contact lens. Dr. Shah did not document an intraocular pressure. (St. Ex. 7 at 121)
135. Dr. Bell saw Patient 7 on July 23, 2001. Patient 7 reported that he had not removed the contact lens since the flap irrigation except during his eye examination on July 20, 2001. Dr. Bell removed the soft contact lens. She noted central scarring of the right eye with increased striae and a fold/wrinkle in the flap. Dr. Bell prescribed eye drops including prednisone forte 1% hourly to the right eye and Maxitrol for the left eye. She did not document an intraocular pressure. (St. Ex. 7 at 117)

136. Dr. Kumar, another optometrist, saw Patient 7 on July 26, 2001. Patient 7 reported that vision in his right eye was not improving, and he had the sensation that there was a foreign body in that eye. Dr. Kumar noted striae and a scar in the right eye. She continued steroid eye drops, but did not document an intraocular pressure. (St. Ex. 7 at 115)
137. Dr. Kumar saw Patient 7 again on August 2, 2001. Patient 7 reported some improvement in his vision. Dr. Kumar decreased the prednisone forte eye drops to every three hours. Dr. Kumar advised that Patient 7 see Dr. Jain in one week, and that notation was double underlined. No intraocular pressure was documented. (St. Ex. 7 at 113)
138. Dr. Jain saw Patient 7 on August 9, 2001, fifteen days after the flap irrigation. Dr. Jain recommended epithelial debridement and irrigation with sterile water to be performed the following day. No intraocular pressure was documented. (St. Ex. 111)
139. On August 10, 2001, Dr. Jain performed a flap irrigation and debridement of the right eye. The preoperative diagnoses were listed as striae with debris and epithelial plaque of the right eye. (St. Ex. 7 at 101, 109) In his operative note, Dr. Jain wrote, in part, as follows:

The flap was lifted and an alcohol soaked Q-tip was used to scrap [sic] off the epithelium plaque from the underside of the flap. The flap was replaced and irrigated with sterile water. One drop of Ocuflax was placed. A bandage contact lens was placed.

(St. Ex. 7 at 101)

140. Dr. Blausey saw Patient 7 on August 11, 2001. Patient 7 complained of discomfort, and stated that the vision in his right eye was still blurred. Examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/300
without Correction	Left eye: 20/25-2
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Visual Acuity	Right eye: 20/200
Pinhole	Left eye: 20/—
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Dr. Blausey noted two epithelial defects, haze, residual striae, and central thinning. He suggested that Patient 7 see Dr. Jain if he had no improvement in his vision within one week. (St. Ex. 7 at 107)

141. Dr. Bell saw Patient 7 on August 13, 2001, and again on August 15, 2001. Dr. Bell noted faint scarring centrally, striae and wrinkles in the flap, and an epithelial defect of the right eye. She further noted that the flap was still not secure due to the prednisone forte, but added that the prednisone forte could not be discontinued due to the scarring. (St. Ex. 7 at 103, 105)

142. Dr. Bell saw Patient 7 again on August 20, 2001. Examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/200
without Correction	Left eye: 20/20-2
Manifest Refraction	Right eye: sphere, +5.75; cylinder, -1.50; axis, 043; 20/70-1
	Left eye: sphere, plano; cylinder, -0.75; axis, 019; 20/20+2

Dr. Bell noted many striae, wrinkles, and folds in the flap; scarring centrally; flap more secure; epithelium healing well. She continued the prednisone forte. (St. Ex. 7 at 99)

143. Dr. Bell saw Patient 7 again on September 10, 2001. Patient 7 stated that his vision “may be a little better than last visit.” Dr. Bell noted many wrinkles, and “faint scar much improved.” She discontinued the prednisone forte. (St. Ex. 7 at 97)

144. Dr. Shah saw Patient 7 on October 15, 2001, and December 3, 2001. Dr. Shah found trace haze centrally and no epithelial defects. She recommended that Patient 7 see Dr. Jain in early January. (St. Ex. 7 at 93)

145. Dr. Kumar saw Patient 7 on January 8, 2002. Dr. Kumar considered the need for enhancement of the right eye. She also suggested that Dr. Jain see Patient 7 in one month, and double underlined that notation. (St. Ex. 7 at 91)

146. Dr. Jain saw Patient 7 on February 11, 2002. Patient 7 complained that his vision continued to be blurry. Visual acuity without correction in the right eye was 20/100 and in the left eye 20/50. Dr. Jain recommended enhancement of the left eye first and of the right eye thereafter. (St. Ex. 7 at 91)

147. Dr. Jain performed a LASIK enhancement on the left eye on March 14, 2002. Dr. Jain did not perform topography or pachymetry prior to the surgery. Moreover, there is no operative note describing the surgery or any indication of the microkeratomes used. Dr. Jain saw Patient 7 again the following day. He noted Stage 1 DLK [diffuse lamellar keratitis] of the left eye. He prescribed prednisone forte and Maxitrol eye drops for the left eye, and prescribed oral Prednisone over the next five days. (St. Ex. 7 at 21-30, 77, 79, 81, 83)

Dr. Blausey saw Patient 7 on March 16, 2002. Dr. Blausey noted striae of the right eye and Stage 2 DLK of the left eye. He recommended that Dr. Jain see Patient 7 within a few days. (St. Ex. 7 at 77)

148. Dr. Jain saw Patient 7 on March 18, 2002. He noted striae of the right eye and Stage 1 DLK of the left eye. He recommended a flap removal with enhancement of the right eye. Dr. Jain saw Patient 7 again three days later. (St. Ex. 7 at 75)

149. On March 27, 2002, Dr. Jain performed the enhancement of the right eye. Patient 7 signed an informed consent form for LASIK. (St. Ex. 7 at 11-20, 67-75)

Thereafter, Patient 7 continued to complain of blurred vision in that eye. On May 29, 2002, Patient 7's visual acuity was 20/200+ in the right eye and 20/20 in the left. Dr. Blausey noted that there was haze in the right eye. He wrote that Patient 7 had requested increased distance vision in his right eye and that PRK might be appropriate in the future. (St. Ex. 7 at 63-65)

150. On June 24, 2002, Dr. Jain saw Patient 7. Patient 7 continued to complain of blurred vision in the right eye. Visual acuity was 20/80- in the right eye and 20/20 in the left eye. Manifest refraction was recorded for the right eye only, as follows: sphere, -2.00; cylinder, -0.50; axis, 165; visual acuity, 20/25+1. Pachymetry was recorded for the right eye as 499, and for the left eye as 609. Corneal topography was also performed. Dr. Jain recommended enhancement of the right eye, and noted a 1 to 2% chance of ectasia and scarring. (St. Ex. 7 at 7, 61)

151. On July 25, 2002, Dr. Jain performed a LASIK enhancement on the right eye. The medical record contains the last page of an informed consent form. (St. Ex. 7 at 9, 53-59)

Dr. Jain saw Patient 7 the next day, and Patient 7 continued to complain of blurred and fluctuating vision. Dr. Jain recommended that the next appointment be in eight weeks. (St. Ex. 7 at 9, 51)

Dr. Jain saw Patient 7 again on September 19, 2002. At that point, Patient 7 complained that his vision was not improving. Visual acuity for the right eye was 20/60, and for the left eye 20/20. Dr. Jain suggested a radial keratotomy of the right eye at no charge. (St. Ex. 7 at 51)

152. On January 16, 2003, Patient 7 requested release of his medical records. (St. Ex. 7 at 49)

#### **Testimony of Dr. Gressel regarding Patient 7**

153. Dr. Gressel testified that Dr. Jain's care and treatment of Patient 7 had constituted a departure from and a failure to conform to minimal standards of care. In support of his opinion, Dr. Gressel relied on the following:

- a. Prior to performing the first LASIK procedure for Patient 7, Dr. Jain failed to perform manual keratometry. Dr. Gressel noted that Dr. Jain had claimed that 40.56 and 40.34 were the manual keratometry readings. Nevertheless, Dr. Gressel explained that results from manual keratometry will only appear with decimal multiples of 1/8, for example, .00, .125, .25, or .50. He further explained that readings that end in any other decimal numbers, such as those found in this record, 40.56 and 40.34, could only be obtained from simulated keratometry obtained through corneal topography.

- Therefore, Dr. Gressel concluded that these numbers had been derived from corneal topography and not manual keratometry, although the medical record contains no report of corneal topography. (Tr. at 877-880; St. Ex. 25)
- b. Although the medical record refers to topography conducted prior to the first LASIK procedure, there is no topographic image in the medical record. Moreover, although there was a plan to repeat topography on the day of surgery, it does not appear that that was done. Dr. Gressel noted that, on the pre-LASIK evaluation sheet, someone had written, “slight inferior steepening,” which may have been an indication that there was a problem with the cornea. Dr. Gressel continued that he could not make that determination without having the topographic image to review. Dr. Gressel testified that simply documenting the simulated keratometry measurements does a disservice because the topographic image provides much qualitative information about the steepening, including where the steepening is located. Therefore, Dr. Gressel concluded, without the image to review, it is impossible to know whether this was a truly abnormal cornea or simply an unusually flat cornea. (Tr. at 877-879, 912, 913; St. Ex. 25)
  - c. The topography referenced in the medical record indicates that Patient 7 had exhibited inferior steeping of the corneas; however, the simulated keratometry measurements derived from the referenced topography indicate that Patient 7’s were extremely flat. Dr. Gressel testified that this was significant because the numbers derived from corneal topography, 40.56 and 40.34, indicate unusually flat corneas such that less than 10% of the population would have corneas so flat. He added that Dr. Jain had attempted to correct a large degree of myopia in addition to myopic astigmatism, which required that he flatten the corneas even further. Dr. Gressel testified that, in such cases, even when patients can see the eye chart clearly, their vision remains distorted and they are very dissatisfied with the outcome. He concluded that surgeons should be aware of conditions that predispose a patient to negative outcomes. (Tr. at 877-879, 910-912, 1255-1256; St. Ex. 25)
  - d. Dr. Jain failed to provide adequate postoperative care and/or supervision of care for Patient 7 while Patient 7 was being treated with steroids for approximately 3 weeks. Dr. Gressel stated that Patient 7 had developed DLK postoperatively. He explained that DLK is a non-infectious inflammation in the interface between the flap and the underlying corneal bed. If the inflammation is left unchecked or inadequately treated, it can result in severe scarring of the cornea and visual disability. Dr. Gressel testified that, in the lesser stages of DLK, intensive corticosteroid treatment is appropriate. If, however, the cornea does not clear rapidly in response to the steroid treatment, then it is necessary to irrigate underneath the flap to remove whatever material is causing the inflammatory response. (Tr. at 877-879, 882-888, 1265-1266; St. Ex. 25)

Dr. Gressel testified that, in this case, the inadequately controlled DLK had been the main cause of the wrinkling of the flap. He stated that, between July 13 and July 16,

2001, the DLK had not improved despite topical steroid therapy. Dr. Gressel stated that Dr. Jain should have seen the patient and flap should have been irrigated immediately. Moreover, Dr. Gressel testified that a postoperative complication this serious needs to be evaluated by an ophthalmologist daily, "at the very least." Finally, Dr. Gressel testified that, although the medical record indicates that the DLK never progressed higher than a Grade 2, it is unlikely that the "tremendous and unusual scarring" had resulted from only a Grade 2 DLK. (Tr. at 887, 897-898, 1266-1267)

- e. Dr. Gressel testified that Dr. Jain should have seen the patient himself rather than delegating his care to optometrists. (Tr. at 887, 897-898, 1266-1267)

Dr. Gressel testified regarding the scope of practice of optometrists in the state of Ohio. He stated that optometrists are licensed to examine eyes and to treat with certain medications from a formulary. There are certain medications that they are not legally entitled to prescribe. They are capable of taking care of some types of disease states, but they are not qualified to manage serious postoperative complications. They do not perform surgery. They do not perform invasive procedures. This is true regardless of whether the optometrist has completed a fellowship. (Tr. at 751-753, 887, 897-898, 1266-1267)

- f. On July 19, 2001, Dr. Jain conducted flap irrigation for Patient 7, but failed to document the details of this procedure in the medical record. (Tr. at 877-879; St. Ex. 25)
- g. On August 10, 2001, Dr. Jain used poor judgment in performing a second flap irrigation and a debridement on the right eye, utilizing alcohol to decimate epithelial cells. Dr. Gressel testified that alcohol may be toxic to stromal and endothelial cells in the cornea, not just epithelial cells. Moreover, Dr. Gressel stated that the use of alcohol might have damaged the stromal cells in the flap, which would have contributed to the continued wrinkling and scarring in a flap that was probably abnormally thin. (Tr. at 877-879; 891; St. Ex. 25)

Dr. Gressel testified that, in this procedure, Dr. Jain had used a Q-tip soaked with alcohol to scrape off epithelial plaque from the underside of the flap. He stated that what would have been appropriate is to use the alcohol to remove the epithelium, the outside surface of the cornea. That would have allowed sterile water to penetrate into the cornea to make it swell, thereby eliminating the folds and wrinkles. (Tr. at 891)

Dr. Gressel noted that what Dr. Jain did, however, was to use an alcohol soaked Q-tip to scrape off the epithelium from the underside of the flap. Dr. Gressel testified that he does not understand the rationale for putting alcohol underneath the flap at that stage of treating Patient 7. He noted that alcohol has both good and bad properties. If there is persistent epithelium underneath the flap that continues to regrow after other attempts to remove it, some doctors use alcohol to try to keep the cells from coming back. However, the downside of alcohol is that it is a toxic chemical that can harm

the cornea. Dr. Gressel stated that a prudent surgeon would not have resorted to the use of alcohol without first attempting to remove the epithelium by other means, such as suturing the edge of the flap to eliminate the pathway by which the epithelium gains access to the underside of the flap. Dr. Gressel concluded that the use of alcohol as the first intervention was extremely aggressive and demonstrated poor judgment. (Tr. at 891-893, 1257-1258)

- h. Patient 7 underwent approximately four weeks of steroid therapy before an intraocular pressure was measured. Dr. Gressel testified that, any time corticosteroid therapy is administered directly to the surface of the eye, there is a chance that glaucoma will develop. Dr. Gressel testified that there have been a number of cases in which patients underwent LASIK surgery and were treated with corticosteroids topically, but who did not have intraocular pressure measured during that treatment. Those patients developed glaucoma that was not diagnosed, resulting in blindness. He added that glaucoma could develop in less than five days when applying corticosteroids directly to the eye. (Tr. at 877-879, 883-885; St. Ex. 25)

Dr. Gressel testified that it is not difficult to measure intraocular pressure, even if there are problems with the flap, by using the Tono-Pen. He explained that the Tono-Pen is a hand-held device used in an anesthetized eye. He added that use of the Tono-Pen does not disturb the flap in any way. (Tr. at 884)

- i. Dr. Jain failed to personally provide adequate care to Patient 7 or to adequately supervise the activities of others involved in Patient 7's care. Dr. Gressel testified that Dr. Jain's failure to do so had resulted in Patient 7 being subjected to the risks of steroid-induced glaucoma without intraocular pressure checks, caregivers relying on erroneous measurements of corneal thickness without re-checking, and epithelium regrowing on the underside of the flap for an inordinate period of time. Moreover, during this time, Patient 7 had been seen only by non-ophthalmologists who may not have recognized these problems as they developed. Dr. Gressel added that Dr. Jain's meager involvement in Patient 7's postoperative care would probably have been even less without insistent prompting by the other examiners repeatedly requesting that Dr. Jain see Patient 7. Dr. Gressel concluded that:

Dr. Jain's conduct stands in stark contrast with the conduct of a conscientious, prudent, and compassionate surgeon. Such a surgeon becomes more closely involved and makes decisions in a more cautious fashion when a patient on whom he has operated is not doing well. Dr. Jain became more detached the worse things got, except for proposing and executing an increasingly desperate series of risky procedures.

(Tr. at 877-879; St. Ex. 25)

Dr. Gressel opined that, for these reasons, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, section B8, which states:

The providing of postoperative eye care until the patient has recovered is integral to patient management. The operating ophthalmologist should provide those aspects of postoperative eye care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries). Otherwise, the operating ophthalmologist must make arrangements before surgery for referral of the patient to another ophthalmologist, with the patient's approval and that of the other ophthalmologist.

(Tr. at 877-879; St. Ex. 25) Dr. Gressel further opined that Dr Jain's conduct had violated Section B7 of the same Code, which states: "When other aspects of eye care for which the ophthalmologist is responsible are delegated to an auxiliary, the auxiliary must be qualified and adequately supervised." (Tr. at 877-879; St. Ex. 25)

- j. On March 14, 2002, Dr. Jain failed to recheck corneal thickness with pachymetry or corneal contour with topography before he performed the LASIK enhancement procedure. Moreover, Dr. Jain did not create an operative note describing that procedure. (Tr. at 877-879, 889; St. Ex. 25)
- k. On March 27, 2002, Dr. Jain performed a LASIK procedure on Patient 7's right eye, the third LASIK procedure, whereby Dr. Jain inappropriately removed the flap from Patient 7's right eye. Dr. Gressel stated that Dr. Jain had resorted to removing the flap because it had become so scarred that it was an impediment to vision. Dr. Gressel added that removing and discarding the flap was an extreme and highly unusual recourse, especially because Dr. Jain had not first sutured the flap or obtained a second opinion from another ophthalmologist. Dr. Gressel testified that it was even more inappropriate in this case due to the already extremely thin cornea. Therefore, removal of the flap had had a high risk of causing corneal perforation, with potentially disastrous results. (Tr. at 877-879, 902-903, 925-926, 1260-1265; St. Ex. 25)

Later, however, Dr. Gressel testified that, by the time of the flap removal, the cornea was in such dire condition that flap removal was probably the best option available, other than a corneal transplant. (Tr. at 1267)

- l. Dr. Jain did not record an operative note for the third LASIK procedure, which included removal of the flap from the right eye. Moreover, the record does not indicate when the procedure was done; the only indications are Dr. Jain's notation that he planned to perform the procedure and, two months later, a notation that the procedure had been performed. (Tr. at 903-905)

- m. Dr. Jain did not obtain and/or document an appropriate informed consent for the third LASIK procedure, which included removal of the flap from the right eye, a procedure that differs in risk from the first LASIK procedure performed on Patient 7. (Tr. at 887-879; St. Ex. 25)
- n. On July 25, 2002, Dr. Jain performed a surface ablation procedure on the right eye of Patient 7, which caused further thinning of the right cornea. Thereafter, Patient 7 continued to experience blurred, fluctuating vision. (Tr. at 887-879; St. Ex. 25)
- o. Dr. Jain inappropriately proposed performing a radial keratotomy. Dr. Gressel noted that, by the time Dr. Jain proposed performing the radial keratotomy, Dr. Jain had already performed a series of inappropriate treatments on the right eye, which had further flattened a cornea that had been unusually flat at the outset. Dr. Gressel suggested that Dr. Jain would have caused even more flattening if Patient 7 had allowed him to perform radial keratotomy, which likely would have caused poor optical performance and visual result that most people would find unsatisfactory. Dr. Gressel concluded that the right eye had not been a good candidate for LASIK in the first place, and that each new procedure had worsened Patient 7's visual problems. (Tr. at 877-879; St. Ex. 25)
- p. Dr. Jain failed to maintain an record of the total amount of tissue removed from Patient 7's eye. (Tr. at 877-879; St. Ex. 25)
- q. Dr. Jain failed to adequately monitor the measurement of corneal pachymetry performed by Bloomberg Eye Center staff. For example, Dr. Gressel explained that the initial pachymetry measurement for the left eye had been 570 microns. During the LASIK procedures, approximately 90 microns of tissue had been removed. Nevertheless, after the LASIK procedures, the pachymetry was recorded as 609 microns. Such readings would imply that after removal of 90 microns of corneal tissue, the cornea was 39 microns thicker. Dr. Gressel concluded that significant errors had been made in measuring corneal thickness, but Dr. Jain failed to notice or correct them. (Tr. at 877-879, 907-908; St. Ex. 25)
- r. Dr. Jain failed to refer Patient 7 to another physician when it became apparent that Patient 7's condition was deteriorating under Dr. Jain's care. Dr. Gressel concluded that, in this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section B4, which states: "Consultation(s) shall be obtained if required by the condition." (Tr. at 877-879; St. Ex. 25)

#### **Testimony of Dr. Jain regarding Patient 7**

154. Dr. Jain reiterated his prior testimony that manual keratometry is neither necessary nor mandated by the standard of care prior to the performance of LASIK. Nevertheless, Dr. Jain testified that manual keratometry had been performed in this case because some of

the technicians automatically do manual keratometry. Dr. Jain stated that that would be why “sometimes you see them sometimes you don’t.” (Tr. at 181-182)

When asked where the manual keratometry had been recorded, Dr. Jain referred to the numbers listed under pachymetry, 40.61@062 and 40.51@152, and stated that they were manual keratometry readings. Dr. Jain did not address Dr. Gressel’s testimony that, when performing manual keratometry, the results will always be reported as multiples of 1/8, and that 40.61 and 40.51 would have been derived from simulated keratometry rather than manual keratometry. (Tr. at 181-182)

155. Dr. Jain acknowledged that Patient 7’s medical record does not contain a topographic image taken prior to the first LASIK surgery. He explained that, at about that time, the printer on his topographer had not been working; therefore, it was not unusual for a medical record to contain a notation regarding topography results without also containing a corresponding image. (Tr. at 185-186)

Dr. Jain further acknowledged that the medical record contains no indication that topography was redone on the day of surgery. Nevertheless, Dr. Jain testified that, even if he had redone topography on the day of surgery, it would not have prevented him from performing the LASIK on Patient 7’s right eye because, “after all is said and done,” the postoperative topography was normal. (Tr. at 186, 217-218)

156. Dr. Jain testified that Patient 7’s right eye had not been too flat preoperatively such that LASIK was contraindicated. (Tr. at 1574-1575)

157. Dr. Jain acknowledged that the medical record did not contain an operative note regarding the flap irrigation he had performed on July 19, 2001. Nevertheless, Dr. Jain explained as follows:

I was very compulsive about getting op notes. I always kept a Dictaphone in my pocket and dictated it right then, and then sent it down to the transcriptionist downstairs. But I have to tell you, when I first came to Bloomberg, it took me about a year to get one of the girls at the office, transcriptionists, to get the notes consistently in the charts there. Every time after surgery I looked in the charts, there would be no—the op note would be missing. “Where are they?” “I haven’t filed them yet,” and she would be bringing the file to me. So there was a problem. By this time, I thought I had them fixed, 90 percent of the problem. But there was this kind of problem with getting the op notes in the chart. But I was very, very compulsive about doing them. I’ve always been compulsive about doing things right then just so they get done. I don’t know why it’s not in here. But it was done.

(Tr. at 190-191)

158. Dr. Jain subsequently explained why he had not created an operative note describing the second LASIK procedure performed on March 14, 2002. Dr. Jain stated that he does not believe that an operative note is mandated by the standards of care unless there are complications during the surgery. Nevertheless, Dr. Jain testified that, after receiving the Board's notice of opportunity for hearing, Bloomberg Eye Center has been creating operative notes on all procedures in order to comply with the wishes of the Board. (Tr. at 207-209)
159. Dr. Jain testified that using alcohol to debride epithelium from underneath the flap of Patient 7's right eye had been within the standard of care. Moreover, Dr. Jain testified that his use of alcohol had not caused damage to the cornea or the flap itself. Dr. Jain testified that epithelium under the flap causes permanent scarring and will cause "a melt of the cornea"; thus, it is vitally important to remove the epithelium. He added that using alcohol to remove the epithelium is commonly performed. Moreover, Dr. Jain testified that there is no evidence to suggest that alcohol causes long-term damage to the cornea. Dr. Jain concluded that Dr. Gressel's failure to appreciate this "shows a disparity in the experience in dealing with LASIK complications." (Tr. at 201, 1575-1577)
160. Dr. Jain testified that it is important to measure intraocular pressure when treating a patient with steroids on a long-term basis, not in an acute situation. He added that an increase in intraocular pressure would not occur for two to three weeks after the initiation of steroids. Moreover, Dr. Jain testified that, when there is active inflammation in the flap, it is inappropriate to measure intraocular pressure early in the treatment because doing so will disturb the ocular surface or the flap. (Tr. at 187-189)
161. Dr. Jain testified that removal of a flap might be considered a serious complication, depending on how many cases the surgeon has done and what kind of complications the surgeon has seen. Dr. Jain testified that he has had much experience in these areas. (Tr. at 213-214)
162. Dr. Jain testified that he had not sent Patient 7 to another ophthalmologist for a second opinion prior to removing the flap. Dr. Jain explained as follows:
- A. No. I mean, to—for me to refer a patient at this—with that kind of a flap to an ophthalmologist, it's a lawsuit. You know, all ophthalmologists in this area do is say, "Look what this doctor has done to your eye." I mean, it really is—I know it's a practical matter, but it's really kind of the truth. I mean, you know, you take a patient – I personally don't think it would be in the best interest of the patient.

THE EXAMINER: Why not?

THE WITNESS: You know. Because the patient was with us. We—I mean, you know, we spent—I spent and the optometrists spent – we developed a very

good relationship with that patient. If the patient was indicating to us, “Doc, I really have problems. What’s going on? I’d really like to get a second opinion,” or we sense that, then we would refer him, you know. But to preemptively send him at this, when he’s already in—you know, very difficult emotionally because of all of the stuff has happened, to send him to an ophthalmologist that might incite him, I just didn’t think was in the best interest of the patient.

THE EXAMINER: That might incite him to what?

THE WITNESS: To, you know, to just—just, I mean, completely get him riled like, you know, I mean, I—I had so many patients—a few patients that went out and other ophthalmologists stirred up against us. It really had become an issue.

THE EXAMINER: Stirred them up against you?

THE WITNESS: Uh-huh.

THE EXAMINER: The other ophthalmologists stirred the patients up against you?

THE WITNESS: Yes.

THE EXAMINER: And it had become an issue for you?

THE WITNESS: Yes.

THE EXAMINER: Go on.

THE WITNESS: Well, I mean, and I—That’s the thing I think I have to—without telling you that, I don’t think I can give you a full picture of, you know, of what’s—what’s happening. Dr. Davidoff down the street, I mean, he was just out of control. I mean, he was just—every patient that by any chance happened to go to him would tell me, “You wouldn’t believe what he’s saying about you.” I mean, it was unbelievable. And his group, too. I mean, I think I have to share that and tell you that in the context of all of this so—you know. So I didn’t feel—Because in this particular case, we were in very clear communication with the patient, telling him exactly what was going on, telling him what had happened, communicating that, “We’re going to enhance the other eye. Here are the precautions we are going to take. If we see this happening, here’s what we are going to do.” I really was trying to do my best to keep him informed of everything that was happening.

BY MS. ALBERS: So you feel that the criticisms these other ophthalmologists had of you were unjustified?

A. Well, no, not—not completely—not necessarily completely. But I think that there was a tendency for them to incite the patients. Like, you know, there's—there's ways of talking about things to patients. And there's the inflammatory way. And, unfortunately, that seemed to have become more the norm. And—And then there's the—the kind of the nurturing way. And I think there was, you know, that issue.

(Tr. at 214-217)

163. Dr. Jain testified that he had obtained informed consent for all of the procedures he performed on Patient 7. He explained that he had had a very regimented way of mandating that informed consent be done prior to any procedure. Moreover, on the initial evaluation form, there is a list of topics that Dr. Jain always discussed with the patient. Dr. Jain further testified that it was his standard practice to explain to the patient what he was going to do. And if the patient had any questions, Dr. Jain answered them. (Tr. at 1580-1583)
164. Dr. Jain testified that Dr. Gressel's opinion that Dr. Jain had not addressed the DLK in a timely manner was "a little bit dubious." Dr. Jain stated that, in three to five out of every one hundred cases, DLK will develop to some degree. Dr. Jain testified that he had had only four occurrences of DLK out of 6000 cases. Dr. Jain also took issue with Dr. Gressel's suggestion that Patient 7's DLK had progressed past Grade 2 and that staff at the Bloomberg Eye Center had failed to document it. Dr. Jain stated that it is clear that the DLK did not progress past Grade 2 because, postoperatively, the patient's vision was 20/20 in each eye. Moreover, Dr. Jain added, by Dr. Gressel's own testimony, Stage 3 or 4 DLK induces scarring and there was no such scarring in this cornea. Dr. Jain concluded that his treatment of Patient 7's DLK had been within the standard of care. (Tr. at 1583-1585)
165. Dr. Jain testified that it had been appropriate for the optometrists to follow Patient 7 postoperatively. Dr. Jain testified that the optometrists at Bloomberg Eye Center had seen many LASIK patients in the course of their practice and that they routinely treated Dr. Jain's postoperative patients. Furthermore, Dr. Jain testified that it is not unusual for optometrists to participate in the preoperative and postoperative care of LASIK patients. Finally, Dr. Jain testified that Dr. Blausey had been instructed to immediately report any complications to one of the two ophthalmologists. Therefore, Dr. Jain concluded that his postoperative care of Patient 7 had not been below the minimal standards of care. (Tr. at 192-194, 1578-1580)

**Patient 8**

**Medical Records for Patient 8**

166. On March 3, 2001, Patient 8, a 21-year-old male, presented to the Bloomberg Eye Center for evaluation for LASIK. Examination of his eyes revealed the following:

Visual Acuity with Correction	Right eye: 20/20- Left eye: 20/30
Visual Acuity without Correction	Right eye: 20/400 Left eye: 20/400
Visual Acuity Pinhole	Right eye: 20/20 Left eye: 20/20
Current Prescription	Right eye: sphere, -2.25 Left eye: sphere, -2.00
Manifest Refraction	Right eye: sphere, -2.50; 20/20 Left eye: sphere, -2.50; 20/20
Cycloplegic Refraction	Right eye: sphere, -2.75; 20/20 Left eye: sphere, -2.75; 20/20
Manual Keratometry	Right eye: 42.00@180; 43.00@090 Left eye: 42.00@180; 43.00@090
Desired Correction	Right eye: Plano Left eye: Plano

There was no record of pachymetry or topography being performed. (St. Ex. 8 at 3, 51)

167. Dr. Jain performed LASIK on both eyes on April 21, 2001. The laser printout does not reveal the type of microkeratome or the microkeratome settings utilized for Patient 8. Moreover, there is no record of any postoperative care being provided to Patient 8 (St. Ex. 8 at 13-24, 45, 47)

168. Patient 8 returned to the Bloomberg Eye Center on June 4, 2002, to be evaluated for a LASIK enhancement for both eyes. Examination of his eyes revealed the following:

Visual Acuity without Correction	Right eye: 20/40- Left eye: 20/40-
Manifest Refraction	Right eye: sphere, -0.75; cylinder, -1.00; axis, 065; 20/25 Left eye: sphere, -0.50; cylinder, -0.75; axis, 130; 20/20
Cycloplegic Refraction	Right eye: sphere, -0.75; cylinder, -1.00; axis, 065; 20/25 Left eye: sphere, -0.50; cylinder, -0.75; axis, 130; 20/20
Manual Keratometry	Right eye: 40.25@180; 41.25@090 Left eye: 40.25@180; 41.25@090

In addition, distorted mires were found in the right eye. That notation was highlighted with two stars and an arrow. (St. Ex. 8 at 43)

169. Dr. Jain performed the enhancement surgery on both eyes on June 29, 2002. There is a notation that Patient 8 should obtain postoperative care with Steve Gordon, O.D. The record contains neither information regarding the microkeratome or microkeratome settings utilized nor any documentation regarding the postoperative care that was provided to Patient 8, if any. (St. Ex. 8 at 9-11, 25, 33, 37, 41)
170. On February 25, 2003, Dr. Shahinfar saw Patient 8 upon referral from Dr. Gordon. Dr. Gordon requested that Dr. Shahinfar “perform a thorough corneal evaluation with corneal mapping/topography to assess the potential for further improvement” in the right eye. Patient 8 complained that his vision was distorted and terrible, and that he could see shapes only. Manual keratometry was attempted; however, it was noted that the vision in the right eye was too distorted. Corneal topography revealed inferior steepening in the right eye. Dr. Shahinfar noted a decentralized flap and thinning of the cornea. (St. Ex. 8 at 9, 27, 31)

In a referral letter to Dr. Gordon, Dr. Shahinfar wrote, in part, as follows:

[Patient 8’s] vision has improved in the left eye but in the right eye the vision is not optimal. His topography shows significant steepening of the cornea inferiorly. This corresponds with the slit lamp exam that shows some bulging inferiorly as well as thinning of the cornea. The pachymetry centrally was 489. This will probably be thinner inferior to the central cornea.

In summary, I do not believe this gentleman is a candidate for surgical correction. I have recommended that he follow-up with you for possible fitting of gas permeable contact lenses for visual rehabilitation in the right eye. Unfortunately, I do not have any preoperative topography or pachymetry but this may have been a case of a pellucid marginal degeneration or keratoconus.

(St. Ex. 8 at 7)

### **Testimony of Dr. Gressel regarding Patient 8**

171. Dr. Gressel testified that Dr. Jain’s care and treatment of Patient 8 had fallen below the minimal standards of care for the following reasons:
- a. On March 3, 2001, Dr. Jain evaluated Patient 8 for LASIK, but did not perform preoperative pachymetry and topography. Dr. Gressel testified that, had these measurements been done, there would have existed enough evidence of ectasia or predisposition to ectasia to deter a prudent ophthalmologist from performing either procedure on the right eye. Dr. Gressel concluded that, in this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, section B10,

which states: "Ordering unnecessary procedures or materials or withholding necessary procedures or materials is unethical." (Tr. at 927-929, 932-933, 939-942, 1270-1271; St. Ex. 25)

Dr. Gressel further noted that, when corneal topography was eventually done, it revealed marked irregularity of the contour and dramatic inferior steepening of the cornea of the right eye. Moreover, the simulated keratometry measurements suggested that there was 11½ diopters of astigmatism, which is enormous. Dr. Gressel explained that this level of astigmatism would be expected to cause very severe visual disability, which cannot be corrected with eyeglasses. (Tr. at 937-940)

- b. Dr. Jain failed to document and/or diagnose the presence of ectasia in the right eye of Patient 8 prior to the LASIK enhancement procedure of June 29, 2002. Dr. Gressel stated that Dr. Jain's failure to diagnose ectasia was significant because ectasia is a contraindication to LASIK. Moreover, distorted keratometry mires are an indication of ectasia and had been found in Patient 8's right eye, a finding that was flagged by an arrow and two stars in Patient 8's medical records. (Tr. at 927-928, 935-936; St. Ex. 25)
- c. Dr. Jain performed LASIK enhancements for residual myopic astigmatism in both eyes, once again proceeding without prior pachymetry or topography. This was done despite the distorted keratometry mires in the right eye. Dr. Gressel testified that distorted mires can be discovered by manual keratometry and occur when the surface of the cornea is irregular. He added that this is one of the reasons why manual keratometry is so helpful in evaluating people before LASIK. Moreover, when distorted mires are present, it is absolutely mandatory that the surgeon perform corneal topography under these circumstances. (Tr. at 935-936)

Dr. Gressel stated that, although the ultimate visual outcome for the right eye is not evident from the medical record, it is unlikely that adequate visual rehabilitation in the presence of 11.50 diopters of astigmatism can be accomplished without further surgery, such as a corneal transplant. Dr. Gressel concluded that significant harm had occurred to Patient 8 as a result of Dr. Jain performing inappropriate surgery. In this regard, Dr. Gressel concluded, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section A7, which states: "It is the responsibility of an ophthalmologist to act in the best interest of the patient." (Tr. at 927-928 St. Ex. 25)

- d. Dr. Jain failed to document the type of microkeratome or the microkeratome settings utilized in either the LASIK procedure or the subsequent enhancement procedure for Patient 8. Dr. Gressel noted that knowledge of the type of microkeratome and settings used could assist in estimation of the LASIK flap thickness, which could help determine whether the ectasia in the right eye antedated the original LASIK procedure or had been caused by the original LASIK procedure. (Tr. at 927-929; St. Ex. 25)

- e. There is no record of Dr. Jain providing postoperative care or arranging for care to be provided by a co-managing doctor after the initial LASIK procedure, although, Dr. Gressel acknowledged there was some evidence of such an arrangement with Dr. Gordon when the enhancement was performed over a year later. Nevertheless, Dr. Gressel testified that that, even if Dr. Gordon had assumed the postoperative care of Patient 8, that alone would not be sufficient because Dr. Jain's medical record did not indicate what Dr. Gordon would be responsible for or how the patient would be managed. Moreover, there is no documentation regarding the ultimate outcome of either surgery. Dr. Gressel concluded that Dr. Jain has a responsibility to maintain an accurate record of his patient's postoperative course. (Tr. at 927-929, 943-944, 1269-1270)

### **Testimony of Dr. Jain regarding Patient 8**

172. Dr. Jain acknowledged that he had not seen Patient 8 at any time prior to the day he performed the first LASIK procedure. He stated that Dr. Gordon, the optometrist, had determined that Patient 8 was an appropriate patient for LASIK. Dr. Jain argued that it was appropriate for an optometrist to make that decision. Dr. Jain testified that he had reviewed the risks, benefits, and alternatives with Patient 8 prior to performing the procedure. (Tr. at 220-222)
173. Dr. Jain further acknowledged that he had not performed pachymetry measurements prior to performing LASIK. Dr. Jain testified that, even if he had performed pachymetry measurements prior to the LASIK procedure, it probably would not have revealed any problems. Dr. Jain stated that Patient 8's corneas measured 489 microns after the LASIK treatment and the enhancement. He explained that, since the average corneal thickness is 520 microns, and approximately 48 microns of tissue had been removed from Patient 8's eye during the procedures, it is likely that Patient 8 had had 549 microns corneas prior to the first procedure. Therefore, performance of pachymetry would not have provided any information that could not be determined postoperatively. (Tr. at 234-235)
174. Regarding Dr. Gressel's criticism of Dr. Jain for failing to document the microkeratomes used, Dr. Jain testified that he had used the same microkeratome in this procedure as he had in every other. When it was brought to his attention that he had not used a Nidek laser in this case he, as he had in other patients, Dr. Jain stated that he had used a 160-micron microkeratome nonetheless. Moreover, Dr. Jain testified that, by examining the cornea with a slit lamp, a subsequent treating physician could "tell the depth, to a large extent, and the thickness of the flap." (Tr. at 222-223)
175. Dr. Jain testified that, in Patient 8's case, the finding of distorted mires had not been a contraindication for performing the enhancement procedure. Dr. Jain stated that he had performed a very small amount of enhancement in a very young patient. Moreover, he stated that distorted mires are not really significant as they will sometimes appear when the patient has dry eyes and will disappear when the patient blinks. Dr. Jain concluded that the

presence of distorted mires is a nonspecific finding; thus, the presence of distorted mires alone is not an indication of ectasia. (Tr. at 226-227, 1586-1587)

Dr. Jain acknowledged, however, that if he had done topography prior to performing the enhancement it is possible that he would have discovered ectasia. Nevertheless, Dr. Jain testified that it is unlikely that Patient 8 had had ectasia preoperatively since manual keratometry performed in Dr. Gordon's office had indicated symmetric corneas, and symmetric corneas argue against ectasia. Dr. Jain concluded that his performance of both the LASIK procedure and the enhancement procedure in this patient had been consistent with the minimal standards of care. (Tr. at 229-230, 234-235, 1587-1590)

Nevertheless, Dr. Jain acknowledged that, as stated in the last notation in the medical record, Patient 8 had required gas permeable contact lenses to see. Dr. Jain acknowledged that this was not "an optimal outcome." (Tr. at 230-231)

176. Regarding Dr. Gressel's criticism that Dr. Jain had failed to provide or document adequate postoperative care of Patient 8, Dr. Jain testified that he had co-managed this patient with Dr. Gordon, the optometrist. Dr. Jain testified that he had had an arrangement with Dr. Gordon whereby Dr. Gordon would perform the majority of the preoperative and postoperative care. Dr. Jain acknowledged that the co-management plan had not been documented in Patient 8's medical record and that he had not reviewed Dr. Gordon's medical records for Patient 8. (Tr. at 1590-1591)

### ***Patient 9***

#### **Medical Records for Patient 9**

177. Patient 9, a 49 year old female, presented to the Bloomberg Eye Center to be evaluated for bilateral LASIK on February 12, 2001. Examination of her eyes revealed the following:

Visual Acuity	Right eye: 20/20
with Correction	Left eye: 20/20=
Visual Acuity	Right eye: 20/400
without Correction	Left eye: 20/FC
Current Prescription	Right eye: sphere, -3.00; cylinder, -0.50; axis, 008
	Left eye: sphere, -2.75; cylinder, -0.50; axis, 016
Manifest Refraction	Right eye: sphere, -3.00; cylinder, -0.50; axis, 010; 20/20
	Left eye: sphere, -3.00; cylinder, -0.50; axis, 025; 20/20
Cycloplegic Refraction	Right eye: sphere, -3.25; cylinder, -0.25; axis, 180; 20/20
	Left eye: sphere, -2.50; cylinder, -0.50; axis, 180; 20/20
Simulated Keratometry	Right eye: 43.54@090; 39.50@080
(recorded as Ks)	Left eye: 44.41@100; 43.62@010
Desired Correction	Right eye: sphere, -2.50
	Left eye: sphere, -1.99; cylinder, -0.595; axis, 180

Intraocular Pressure	Right eye: 17 mmHg
	Left eye: 15 mmHg

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Corneal topography was performed and Dr. Jain noted no keratoconus. Dr. Jain recommended bilateral LASIK surgery, and noted “will need readers.” A price was quoted of \$978.00. Patient 9 signed an informed consent form. (St. Ex. 9 at 10a-17, 63, 64)

On February 13, 2001, Dr. Jain performed LASIK on both eyes of Patient 9. Dr. Jain failed to document microkeratome data. Patient 9 called the office later that day and complained of pain and “excessive watering” in both eyes. Dr. Jain prescribed Vicodin and Voltaren. (St. Ex. 9 at 60, 61)

178. Dr. Mancini, an optometrist, saw Patient 9 on February 14, 2001. Patient 9 complained of discomfort in both eyes. Visual acuity in the both eyes was 20/25. Dr. Mancini noted a fiber in the right eye. Dr. Mancini also noted that the left eye was clear and that there was no DLK in either eye. Moreover, Dr. Mancini noted that the flap was in place in both eyes. Dr. Mancini instructed Patient 9 to return in two to three weeks. (St. Ex. 9 at 59; Tr. at 238)

179. Dr. Blausey saw Patient 9 on March 9, 2001. Patient 9 reported poor vision and haziness especially in the right eye. She also complained that her eyes were “foggy all the time” and that the eye drops were not helping. Examination of her eyes revealed the following:

Visual Acuity	Right eye: 20/50-1
without Correction	Left eye: 20/30-2
Visual Acuity	Right eye: 20/20-3
without Correction	Left eye: 20/25+3
Manifest Refraction	Right eye: sphere, -0.75; cylinder, -0.50; axis, 165; 20/20-3
	Left eye: sphere, -0.75 20/20

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Dr. Blausey noted that there was a fiber in the right eye. He noted also that there had been regression in her vision and suggested that she see Dr. Jain in two months. (St. Ex. 9 at 58)

180. Dr. Jain saw Patient 9 on May 18, 2001. Patient 9 reported that her vision had continued to decline and that the right eye was worse than the left. She also stated that both eyes were sore and dry. Examination of her eyes revealed the following:

Visual Acuity	Right eye: 20/50-
without Correction	Left eye: 20/30
Manifest Refraction	Right eye: sphere, -1.00; cylinder, -0.50; axis, 165; 20/20
	Left eye: sphere, -0.50 20/20

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Dr. Jain noted that both eyes were clear; he did not mention the fiber observed by other examiners. He recommended enhancement of both eyes and quoted a price of \$110.00 per

eye. The surgery was planned for June 29, 2001, but was canceled because Patient 9 had conjunctivitis. (St. Ex. 9 at 55, 57)

181. Corneal topography was performed on July 10, 2001. Dr. Jain noted no keratoconus. (St. Ex. 9 at 53-54)
182. Dr. Jain performed LASIK on both eyes on November 9, 2001. He did not document information regarding the microkeratomes used. Moreover, no pachymetry measurement is recorded as being performed prior to the surgery. Patient 9 signed an informed consent form. (St. Ex. 9 at 49-50)

Dr. Shah saw Patient 9 the following day. Patient 9 complained of pain and light sensitivity in both eyes. Visual acuity without correction was 20/100 in both eyes. Dr. Shah noted abrasions and Stage 2 DLK bilaterally. She prescribed prednisone forte hourly for both eyes and bandage contact lenses. Dr. Shah did not measure intraocular pressure. (St. Ex. 9 at 48)

Dr. Blausey saw Patient 9 on November 12, 2001. Patient 9 stated that the pain was “not as bad” but that her vision was still blurry. Visual acuity was 20/70 in the right eye and 20/200 in the left eye. Dr. Blausey noted Stage 2 DLK bilaterally. He did not measure intraocular pressure. (St. Ex. 9 at 47)

183. When Patient 9 presented to the Bloomberg Eye Center on November 13, 2001, she demanded to see Dr. Jain. Patient 9 reported that her visual acuity was “very bad.” She stated that she had difficulty keeping her eyes open, and complained of excessive watering and pain. Dr. Jain noted Stage 2 DLK with epithelial defects [corneal abrasions] in both eyes. Dr. Jain continued the prednisone forte eye drops, and prescribed prednisone, Xanax, and Zantac orally. The oral prednisone was ordered at 80 mg daily. He did not measure intraocular pressure. (St. Ex. 9 at 46; Tr. at 962-963)
184. Dr. Jain saw Patient 9 again on November 14, 2001. Patient 9 reported that her eyes were improving. Dr. Jain noted Stage 2 DLK and bandage contact lenses. He increased the prednisone forte eye drops to every 30 minutes, and increase the oral prednisone to 80 mg every 12 hours. (St. Ex. 9 at 45)
185. Dr. Jain saw Patient 9 on November 15, 16, 19, and 21, 2001. Patient 9 reported that her vision remained blurry and that she continued to have some discomfort and photophobia. Uncorrected visual acuity ranged from 20/60- to 20/100 in the right eye and 20/70 to 20/200 in the left. Dr. Jain noted that the DLK was decreasing, and considered removal of the bandage contact lenses. He continued Prednisone orally and by eye drops. Dr. Jain did not record intraocular pressures. (St. Ex. 9 at 41-44)

186. On November 26, 2001, intraocular pressure was recorded as 15 mmHg in the right eye and 14 mmHg in the left. Dr. Jain ordered that the oral Prednisone be discontinued in five days. He continued the prednisone forte eyedrops. (St. Ex. 9 at 40)
187. Dr. Jain saw Patient 9 on December 6, 2001. Patient 7 stated that her visual acuity was improving. Dr. Jain noted epithelial nests in the left eye but stated that the flaps were clear. He decreased the prednisone forte to once daily and instructed Patient 9 to return in one month. (St. Ex. 9 at 39)
188. Dr. Jain next saw Patient 9 on January 18, 2002. Patient 9 reported that her left eye felt irritated and as if there was a film over it. She also complained of headache due to strain. Visual acuity was 20/25 in the right eye and 20/50 in the left. Dr. Jain noted trivial cells in the right eye, and epithelial cells in the left eye. He described the right eye as clear and the left eye as quiescent. His impression was fluctuation of the left eye with ingrowth of epithelial cells. Patient 9 continued to use prednisone forte in both eyes, but Dr. Jain did not measure intraocular pressures. He instructed her to return in six weeks. (St. Ex. 9 at 37)
189. Dr. Jain saw Patient 9 on February 6, 2002. He noted trivial cells, quiescent, in the right eye, and quiescent cell nests in the left eye. His impression was “stable ingrowth.” Dr. Jain prescribed FML for the right eye four times daily. He did not measure intraocular pressure, and instructed Patient 9 to return in four weeks. (St. Ex. 9 at 34)
190. On April 1, 2002, Dr. Jain noted quiescent cells in the right eye and a “slightly worse ingrowth patch” in the left eye. Dr. Jain instructed Patient 9 to call in immediately if her visual acuity diminished or if her pain increased. He prescribed prednisone forte for both eyes, and instructed her to return in two weeks. He noted that long-term use of prednisone forte might cause cataracts or glaucoma. Dr. Jain did not record intraocular pressures. Instead, he considered removing the flap. (St. Ex. 9 at 32)
191. Dr. Jain saw Patient 9 again on April 12 and June 14, 2002. On June 14, 2002, he noted that the right eye was clearer but that there was epithelial ingrowth in the left eye. He recommended flap debridement. Dr. Jain did not record intraocular pressures. (St. Ex. 9 at 28, 30)
192. On June 17, 2002, Dr. Jain performed a flap debridement in Patient 9’s left eye, but he did not create an operative note describing this procedure. The following day Patient 9 complained that her left eye was “very painful.” Patient 9’s last visit to the Bloomberg Eye Center was on June 22, 2002. At that time she stated that her visual acuity had improved but still fluctuated. She also complained of burning and aching in the left eye. Visual acuity was 20/25 in both eyes. Dr. Jain noted that the corneas were clear. (St. Ex. 9 at 23-27)
193. On January 17, 2003, Patient 9 requested copies of her medical records. (St. Ex. 9 at 22)

### **Testimony of Dr. Gressel regarding Patient 9**

194. Dr. Gressel testified that Dr. Jain's care and treatment of Patient 9 had fallen below the minimal standards of care for the following reasons:

- a. Prior to performing the first LASIK procedure on February 13, 2001, Dr. Jain failed to perform keratometry, failed to measure corneal pachymetry, and failed to document microkeratome data. Moreover, Dr. Jain failed to measure corneal pachymetry before the second LASIK procedure, and failed to document microkeratome data. (Tr. at 947-950; St. Ex. 25)
  
- b. Dr. Jain failed to promptly and appropriately treat Patient 9 after the diagnosis of DLK, and failed to recognize the progression of DLK. Dr. Gressel testified that DLK has the potential to be visually threatening because it progresses rapidly from one stage to another. Therefore, it needs to be closely monitored and aggressively treated to keep it from getting worse. Furthermore, if the DLK does not respond to intensive therapy with steroid eyedrops, the flap must be lifted and irrigated to remove any of the inflammatory cells, debris, or chemical substances that are inciting the inflammatory response. Dr. Gressel opined that, due to the severity of Patient 9's DLK, Dr. Jain should have intervened within the first week of diagnosing DLK by irrigating under the flaps, to remove particles and inflammatory cells. He stated that this would have greatly diminished the duration of Patient 9's pain, visual disability, and exposure to the risks of steroid therapy. He added that it might have also prevented the epithelial ingrowth under the flap in the left eye that was diagnosed later. Finally, Dr. Gressel testified that it was his opinion that Dr. Jain had failed to recognize that the DLK had deteriorated beyond Stage 2. (Tr. at 947-948, 958-960, 972-973, 1282-1297; St. Ex. 25)
  
- c. Dr. Jain failed to timely measure intraocular pressure during steroid therapy for DLK, and failed to adequately monitor for cataracts and glaucoma that could result from long-term use of steroids. Dr. Gressel noted that, at one point, Patient 9 had received steroids for forty-one days without having had her intraocular pressure checked, despite Dr. Jain's noting that long-term use of steroids may cause cataracts and glaucoma. Moreover, Dr. Jain should have examined the crystalline lens to monitor for the development of cataracts, but he did not do so. Dr. Gressel concluded that Dr. Jain's failure to monitor intraocular pressure while prescribing "whopping doses" of steroid therapy violated the Code of Ethics of the American Academy of Ophthalmology, Section A7, which states: "It is the responsibility of an ophthalmologist to act in the best interest of the patient." (Tr. at 947-948, 965-966; St. Ex. 25)

Dr. Gressel noted that Dr. Jain had argued that intraocular pressure cannot be monitored while the patient is wearing bandage contact lenses. Dr. Gressel disagreed with that argument and stated that glaucoma can result in blindness in a patient being treated with high-dose steroids. He added that the risks involved in failing to monitor intraocular pressure are much more significant than to remove the contact lens and

- delay epithelial healing. Moreover, Dr. Gressel testified that it is not difficult to remove the contact lens, measure eye pressure with a Tono pen, and then reapply the contact lens. Dr. Gressel concluded that, after a patient has been on high-dose steroids such as this for five days, intraocular pressure needs to be monitored due to the risk of steroid induced glaucoma. (Tr. at 966-968, 1298-1302)
- d. On June 17, 2002, Dr. Jain performed a flap debridement in Patient 9's left eye, but no operative note was entered describing this procedure. (Tr. at 947-948, 981; St. Ex. 25)
- e. Dr. Jain exhibited extremely poor judgment by even considering removal of the flap in the left eye, which Dr. Gressel described as "a highly unusual and desperate measure generally reserved for recalcitrant infections beneath the flap." Dr. Gressel stated that Dr. Jain should have first attempted to irrigate under the flap. Dr. Gressel testified that removing the flap would have been inappropriate since the flap itself was not damaged or diseased in any way. He added that the problem had resulted from growth of epithelial cells under the flap and not from any problem inherent in the flap itself. (Tr. at 947-948, 979-980, 1301-1302; St. Ex. 25)
195. Dr. Gressel testified that Dr. Jain's failure to document the presence of a fiber under the flap of Patient 9's right eye had not been a violation of the minimal standards of care. Dr. Gressel testified that the fiber, which would have been left under the flap during the LASIK procedure, would not be likely to cause visual complications, and would not need to be removed unless complications arose. Moreover, Dr. Gressel testified that Dr. Jain's failure to document the existence of the fiber had not constituted a departure from the standard of care because its existence had already been documented in the record and repeated documentation is not necessary. (Tr. at 947-948, 950-951; St. Ex. 25)

#### **Testimony of Dr. Jain regarding Patient 9**

196. Dr. Jain testified that it was his opinion that, to a reasonable degree of medical probability, his decision to forego manual keratometry in his pre-LASIK patients did not constitute a departure from accepted standards of care. Dr. Jain added that "there is nothing that manual keratometry provides that is not found in computerized corneal topography." (Tr. at 236-237, 1499)
197. Dr. Jain testified that the finding of a fiber under the flap was clinically insignificant, as it causes no harm to the patient. Therefore, he concluded that documenting the existence of the fiber had not been mandated by the standard of care. (Tr. at 238-241)
198. Dr. Jain testified that, after diagnosing DLK, he had responded aggressively by treating Patient 9 with high-dose topical and oral steroids. Dr. Jain testified that, when he performed the enhancement procedure, he found that Patient 9 had a very friable epithelium. He stated that when he lifted the flap, "it was just like pasty glue [and] the epithelium came off." He

explained that it is a rare condition and is difficult to manage when it occurs. Moreover, he stated that it is very difficult to irrigate under a flap when the epithelium is so friable. Finally, Dr. Jain explained that the biggest risk factor for the development of DLK is an epithelial defect. Therefore, had he lifted the flap to irrigate, the whole epithelium would have sloughed and Patient 9 would have had an even more explosive case of DLK. Dr. Jain stated that irrigating under the flap would have been the worst treatment he could have chosen. Dr. Jain concluded that his treatment of DLK in Patient 9 had been consistent with the standards of care. (Tr. at 246-247, 1592-1594, 1598-1600)

199. Dr. Jain acknowledged that the development of cataracts and glaucoma are risks when using steroids to treat DLK. Dr. Jain testified, however, that cataracts develop over a period of years and are not a threat with the short-term use of steroids. Moreover, elevated intraocular pressure develops over a period of weeks to months when using topical or oral steroids. Therefore, he explained, there is little risk of immediate harm to the patient in failing to monitor the intraocular pressure. On the other hand, he argued that removing the bandage contact lenses could lead to breakdown of the epithelium. Dr. Jain testified that the surgeon's main objective at that point is "to get the epithelium healed," or risk development of a corneal ulcer, which may result in permanent scarring. Dr. Jain concluded that his treatment of DLK for this patient had been consistent with the standards of care. (Tr. at 251, 1594-1598)
200. Dr. Jain testified that he had created an operative note for the flap debridement procedure, but acknowledged that there was no operative note in the medical record. (Tr. at 237)

### ***Patient 10***

#### **Medical Records for Patient 10**

201. Patient 10, a 25-year-old male, first presented to the Bloomberg Eye Center on December 18, 1986. Patient 10 reported having had a history of traumatic injury to his left eye with subsequent increased intraocular pressure. Patient 10 continued to be treated at the Bloomberg Eye Center for the next several years. (St. Ex. 10a at 2a-4b, 21-39,73)
202. On April 14, 2000, when Patient 10 was 38 years old, Dr. Jain evaluated him for LASIK. Examination of Patient 10's eyes revealed the following:

Visual Acuity	Right eye: 20/25+
with Correction	Left eye: 20/25+
Visual Acuity	Right eye: 20/CF
without Correction	Left eye: 20/CF
Current Prescription	Right eye: sphere, -5.00; cylinder, -1.00; axis, 165
	Left eye: sphere, -4.75; cylinder, -1.75; axis, 040
Manifest Refraction	Right eye: sphere, -4.50; cylinder, -1.00; axis, 165; 20/20
	Left eye: sphere, -4.75; cylinder, -1.50; axis, 040; 20/20

Cycloplegic Refraction	Right eye: sphere, -4.50; cylinder, -1.00; axis, 165; 20/20 Left eye: sphere, -4.50; cylinder, -1.50; axis, 040; 20/20
Intraocular Pressure	Right eye: 22 mmHg Left eye: 22 mmHg
Desired Correction	Right eye: sphere, -3.8; cylinder, -1.00; axis, 165 Left eye: sphere, -3.8; cylinder, -1.50; axis, 040

Dr. Jain noted K-spindles bilaterally and pigment dispersion syndrome [PDS]; otherwise, the eyes were clear. Corneal topography revealed regular astigmatism. Dr. Jain wrote that Patient 10 was an excellent candidate for bilateral LASIK. A price was quoted of \$2500.00. There is no indication that Dr. Jain performed corneal pachymetry or keratometry. (St. Ex. 10a at 20, 69-72)

203. Dr. Jain performed bilateral LASIK surgery on May 30, 2000. Prior to the procedure, Patient 10 signed an informed consent and Dr. Jain gave him Valium 10 mg. During the procedure, Dr. Jain was unable to complete the flap, and converted the procedure to a PRK [photorefractive keratectomy]. The record contains no operative report regarding these procedures, or an informed consent pertaining to the PRK. The record does not indicate the microkeratomes used. (St. Ex. 10a at 14-19, 66-68)
204. Dr. Jain saw Patient 10 the following day. At that time, Patient 10 complained of blurry vision, discomfort, excessive watering, and occasional sharp pain in his left eye. Visual acuity without correction in the right eye was 20/25; in the left eye it was 20/100-. Dr. Jain noted epithelial defects in the left eye. Intraocular pressure was noted to be "less than 20" bilaterally. Dr. Jain wrote, "Doing well." Thereafter, Patient 10 continued to complain of poor and unbalanced vision, shadows around letters, haziness, and irritation in the left eye. Dr. Jain prescribed a bandage soft contact lens for the left eye, and continued to write, "Doing well." (St. Ex. 10a at 62-65)

On June 26, 2000, Dr. Jain noted dense K-spindles bilaterally. Intraocular pressure was noted to be 17 and the right eye and 20 in the left eye. Dr. Jain recommended that Patient 10 return in four months. (St. Ex. 10a at 62)

205. On June 30, 2000, Patient 10 submitted a "Refund Request" for one half of the \$2,500.00 he had paid for LASIK surgery. As basis for the request, Patient 10 advised that, during the procedure on his left eye, Dr. Jain had advised him that the microkeratome had stopped at slightly halfway through the cornea. Moreover, Dr. Jain had started and stopped the microkeratome five times during the procedure. Patient 10 opined that each additional unnecessary pass of the microkeratome had caused additional scar tissue as it widened the cut into his cornea. In addition, Patient 10 stated that, during the procedure, Dr. Jain had given him two choices: one, to come back in three months; or, two, to allow PRK to be performed immediately. Patient 10 expressed great dissatisfaction with the care he had received from Dr. Jain. (St. Ex. 10a at 49)

Furthermore, Patient 10 listed the following recommendations to improve the LASIK patient's experience. These were as follows:

1. Test eyes prior to beginning flap procedure to ensure complete numbing has occurred.
2. Change consent forms, informing the patient of options prior to surgery when incomplete flap occurs.
3. Video the surgery to insure documented procedures [are] being followed.
4. Test numbing the patient's eyes during evaluation testing to eliminate unknowns during surgery.
5. Have technician review consent forms with patients in advance of surgery.
6. Dr. Jain needs to slow down, use extra caution as you are dealing with one's complete life. [An office administrator] stated on June 6, 2000, that Dr. Jain is more hurried than Dr. Shahinfar.
7. Take responsibility for your errors.

Finally, Patient 10 requested a complete copy of his file including the names of each person who was present during his surgery. (St. Ex. 10a at 49)

206. On October 5, 2000, Dr. Blausey saw Patient 10. Patient 10 continued to complain of blurry vision in the left eye. Visual acuity without correction in the right eye was 20/30; in the left eye it was 20/60. Dr. Blausey noted that there was significant haze in the left eye and recommended treatment. Dr. Blausey prescribed FML eye drops, a mild steroid treatment. He also recommended that Dr. Jain see Patient 10 in two to three weeks. (St. Ex. 10a at 60)
207. Dr. Jain saw Patient 10 on October 19, 2000. He noted PDS [pigment dispersal syndrome] bilaterally and 2+ haze in the left eye. Pachymetry was noted to be 607 in the right eye and 618 in the left. Intraocular pressure was "less than 20" bilaterally. Dr. Jain prescribed prednisone forte eye drops for the left eye, and wrote, "Doing well!" Corneal topography was performed the following day. (St. Ex. 10a at 13, 59)
208. On October 23, 2000, Patient 10 saw another physician in order to obtain a second opinion on his "botched LASIK/PRK eye." Patient 10 complained of blurry vision, color vision problems, distorted vision, halos, dryness, pain, fluctuating vision, starbursts, light sensitivity at night, and difficulty driving at night. (St. Ex. 10b at 22-24)

209. Over the next several months, Patient 10 continued to complain of poor vision. He reported seeing halos and starbursts, and was having increasing difficulty driving at night. Intraocular pressures ranged from 13 to 22 in the right eye and from 18 to 25 in the left eye. Dr. Jain continued to note haze in the left eye, and continued to write, "Doing well!" (St. Ex. 10a at 54-58)

On March 20, 2001, Dr. Jain prescribed Alphagan eye drops bilaterally. There is discussion in the record noting that Alphagan can be used to treat glaucoma or to regulate pupil size. (St. Ex. 10a at 51-54)

210. On May 24, 2001, Patient 10 stated that he was not pleased with his vision, and that he felt he should be compensated for all that he has been through at Bloomberg Eye Center. Visual acuity without correction was 20/25 bilaterally. Dr. Jain wrote, "Doing well," and instructed Patient 10 to return as needed. (St. Ex. 10a at 50)

#### **Testimony of Dr. Gressel regarding Patient 10**

211. Dr. Gressel testified that Dr. Jain's care and treatment of Patient 10 had fallen below the minimal standards of care for the following reasons:

- a. Prior to performing LASIK on May 30, 2000, Dr. Jain failed to perform keratometry for Patient 10. Dr. Gressel testified that the importance of keratometry lies in the fact that any future cataract surgery would entail a need for keratometry measurements taken prior to LASIK. (Tr. at 983-985; St. Ex. 25)
- b. Dr. Jain failed to measure corneal pachymetry preoperatively, thus creating an unacceptable level of preventable risk that Patient 10 would develop postoperative corneal ectasia. Dr. Gressel acknowledged that, postoperatively, pachymetry measurements were 607 and 618. Nevertheless, Dr. Gressel testified that these numbers could reflect epithelial hypertrophy that had occurred as a result of the LASIK rather than the actual corneal thickness. Moreover, Dr. Gressel testified that, even if those numbers had been a true reflection of the thickness of Patient 10's corneas, that would not have justified Dr. Jain's failure to obtain a pachymetry measurement prior to surgery. (Tr. at 983-985, 1303-1305; St. Ex. 25)
- c. During the LASIK procedure, Dr. Jain experienced problems which resulted in the creation of an incomplete flap in the left eye; therefore, and the operation was converted to PRK. Dr. Gressel testified that Dr. Jain had conducted PRK over a LASIK flap, which is an inappropriate procedure. (Tr. at 983-985, 991-992; St. Ex. 25)

Dr. Gressel testified that PRK stands for photorefractive keratectomy, and involves using the excimer laser on the surface of the eye after the epithelium has been removed. It differs from the LASIK because the work is done on the surface of the eye rather than under a flap in the cornea. (Tr. at 986-987)

Dr. Gressel further testified that an incomplete flap is created when the microkeratome starts to cut a flap, but then jams or stops for some reason. The microkeratome cuts into the cornea, but the cut is not of sufficient size to make a flap under which LASIK can be performed. Dr. Gressel stated, however, that it is difficult to tell exactly what happened in this case since there is no operative note, no diagram to indicate how far the keratome cut into the cornea, and no discussion as to how much of the surface of the cornea was affected. (Tr. at 987-988)

Dr. Gressel testified that, at the time this happened in 2001, the appropriate way to manage this type of complication was to stop the procedure after the keratome had been removed from the eye, to put the flap back, and to allow the flap to heal for a minimum of three months before considering any further surgery. Dr. Gressel added that, had Dr. Jain allowed the eye to heal for three months, it would have been appropriate for him to create a new flap and proceed with the LASIK procedure. (Tr. at 988-989)

Dr. Gressel explained that the standard of care has changed to some extent since Dr. Jain treated Patient 10 in 2002. He added, however, that, even if the current standard of care had been the standard of care at that time, Dr. Jain's treatment of Patient 10 would not have conformed to the minimal standards of care. Dr. Gressel explained that, in May 2002, the standard of care had been to never perform PRK over a LASIK flap because of the high incidence of corneal haze and consequent visual loss that would result. In 2004, however, there had been some acceptance for this kind of treatment for one type of problematic LASIK flap, a "buttonholed" flap. Nevertheless, Dr. Gressel explained, to safely use this procedure, two precautions must be taken. The first is removal of the epithelium with phototherapeutic keratectomy (PTK) prior to PRK; the second is the use of mitomycin-C 0.02% which should be applied to the cornea after PRK to prevent haze. He noted, however, that Dr. Jain had done neither of these. Moreover, Dr. Gressel added that, even in 2005, performing PRK immediately after creating an incomplete flap would not be appropriate. (Tr. at 983-985, 989-990, 1309-1310; St. Ex. 25)

Dr. Gressel concluded that Dr. Jain's performance of PRK under the circumstances had not been in the Patient 10's best interest. Dr. Gressel explained:

[I]t's the doctor's interest. Because when a person has a flap complication, if you put the flap down, don't use the laser, and just let the patient go on their way, they might not come back to see the same doctor. They might go somewhere else. A bird in the hand is worth two in the bush. That's the motivation for proceeding here. It's the doctor's motivation; not the patient's interest.

(Tr. at 990-992)

- d. Dr. Jain failed to document an operative report adequately describing Patient 10's left eye surgery. Moreover, Dr. Gressel testified that Dr. Jain had not even documented performance of the procedure other than in very limited postoperative references to the procedure having been done. (Tr. at 983-985, 987-988, 993-994; St. Ex. 25)
- e. Dr. Jain failed to obtain valid informed consent from Patient 10 before converting the left eye surgery to PRK. Dr. Gressel explained that, although the medical record contains a signed informed consent form for LASIK, there is no consent form for PRK. Moreover, at the time Dr. Jain decided to perform PRK, Patient 10 had already received Valium 10 mg. Dr. Gressel explained that Valium renders a patient incompetent to give informed consent due to the influence of the medication on the decision-making process of the brain. Furthermore, Dr. Gressel stated that Dr. Jain's performing PRK without appropriate informed consent was not justifiable because no harm or lost opportunity would have occurred as a result of simply repositioning the flap and not using the laser. Dr. Jain could have discussed the options with Patient 10 the next day and offered him the opportunity to obtain other opinions. Dr. Gressel concluded that, in this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, section B2, which states: "The performance of medical or surgical procedures shall be preceded by appropriate informed consent." In addition, Dr. Jain violated section A7 of the same Code, which states: "It is the responsibility of an ophthalmologist to act in the best interest of the patient." (Tr. at 983-985, 986, 1305-1306; St. Ex. 25)
- f. Dr. Jain failed to provide appropriate postoperative treatment for Patient 10. Dr. Gressel testified that Dr. Jain had failed to examine Patient 10 frequently enough after Patient 10 started complaining of multiple visual problems. Dr. Gressel explained that most people who have PRK require more frequent postoperative visits than patients who have LASIK because patients who have LASIK have an intact epithelium where the surface layer is reestablished rather quickly. With PRK, however, the surface layer cells are removed in order to allow the laser resurfacing to be done. Those surface layer cells must grow back; therefore, the patient must be watched more closely and for a longer period of time to assure that the patient does not develop infection, haze, or a variety of other problems. Dr. Gressel further noted that Dr. Jain's postoperative care had been inappropriate because, despite the topography revealing pronounced irregular astigmatism in Patient 10's left eye, despite an increase in intraocular pressure, and despite the patient's multiple complaints, Dr. Jain had repeatedly declared in the patient records that Patient 10 was "Doing well." (Tr. at 983-985, 995-1004, 1310-1312; St. Ex. 25)

#### **Testimony of Dr. Jain regarding Patient 10**

212. Dr. Jain testified that his decision to forego manual keratometry in Patient 10 had not constituted a departure from the accepted standards of care. Dr. Jain added that "there is

nothing that manual keratometry provides that is not found in computerized corneal topography.” (Tr. at 1499)

213. Dr. Jain testified that his performance of a PRK procedure over an incomplete LASIK flap had been within the standard of care at the time he performed that procedure. Dr. Jain testified that it had been within the standard of care to perform PRK over LASIK in 2000 as it was in 2004. He added that the standard had not been as clearly defined in 2000 as it was in 2004. (Tr. at 262-263, 266-267, 1607-1608, 1760-1761, 1780-1781)

Dr. Jain further testified that the alternative proposed by Dr. Gressel, allowing the eye to heal and then performing LASIK at a later time, is “by no means innocuous.” Dr. Jain explained that repeating a LASIK procedure after the creation of an incomplete flap is dangerous because the new flap will be created in a different plane. That creates the risk of creating slivers of corneal tissue, which is one of the biggest nightmares of refractive surgery. Moreover, the resulting irregular astigmatism is nearly impossible to treat. Dr. Jain concluded that Dr. Gressel’s proposed alternative is just as problematic as performing PRK over LASIK. (Tr. at 1608-1609)

214. Dr. Jain acknowledged that the medical record does not contain an operative report describing the LASIK/PRK procedure. Nevertheless, Dr. Jain testified that he had documented at the bottom of the Visx operative report that there had been an incomplete flap created which, in his opinion, was adequate documentation regarding that procedure. Moreover, Dr. Jain testified that a subsequent treating physician would be able to see that the flap had been incomplete by examining the eye. (Tr. at 263-269, 1601-1602)
215. Dr. Jain acknowledged that he had not discussed the possibility of performing PRK prior to the LASIK procedure. Nevertheless, Dr. Jain testified that, after creation of the incomplete flap, he had explained the options to Patient 10 and Patient 10 had chosen to proceed with the PRK. Dr. Jain further testified that his explanation had not been an attempt to obtain informed consent because, he explained, after the administration of Valium, Patient 10 had not been able to give informed consent. (Tr. at 264-266) Later, however, Dr. Jain testified that he had obtained valid informed consent from Patient 10 prior to converting the procedure to a PRK. (Tr. at 1604-1605)
216. In response to Dr. Gressel’s criticism that Dr. Jain had not examined Patient 10 frequently enough after the LASIK procedure, Dr. Jain testified that, postoperatively, Patient 10 had been seeing 20/20 in the right eye and 20/20- in the left eye without correction. Dr. Jain concluded that, “arguably, [that had been] a very good outcome given the issue of the incomplete LASIK.” Dr. Jain further testified that Dr. Gressel’s criticism was not appropriate because Dr. Jain had told Patient 10 to call the office “if there was an issue.” Dr. Jain added that, if haze had developed and was a problem for Patient 10, Patient 10 would have called. Dr. Jain concluded that his postoperative care of Patient 10 had been within the standards of care. (Tr. at 1605-1608)

**Patient 11**

**Medical Records for Patient 11**

217. Patient 11, a 47 year-old female, presented to the Bloomberg Eye Center to be evaluated for LASIK on August 7, 2000. Patient 11 stated that she wanted to see without glasses, and stated that she had been unable to wear contact lenses “due to the solution.” (St. Ex. 11a at 29) Examination of her eyes revealed the following:

Visual Acuity with Correction	Right eye: 20/25- Left eye: 20/20-
Visual Acuity without Correction	Right eye: 20/30- Left eye: 20/100
Current Prescription	Right eye: sphere, -0.50; cylinder, -0.25; axis, 180 Left eye: sphere, -1.75; cylinder -1.25; axis, 055
Manifest Refraction	Right eye: sphere, -0.25; cylinder, -0.25; axis, 180; 20/25 Left eye: sphere, -1.25; cylinder, -1.25; axis, 055; 20/20
Cycloplegic Refraction	Right eye: sphere, plano; cylinder, -0.25; axis, 180; 20/20-2 Left eye: sphere, -1.50; cylinder, -1.25; axis, 055; 20/20
Intraocular Pressure	Right eye: 12 mmHg Left eye: 12 mmHg
Desired Correction	Right eye: sphere, -0.40; cylinder, -0.20; axis, 180 Left eye: sphere, -1.25; cylinder, -1.25; axis, 055

The medical record contained numbers that appear to be derived from corneal topography, but does not contain manual keratometry or corneal pachymetry measurements. Dr. Jain noted trace PSC [posterior subcapsular cataract] in the right eye. Dr. Jain noted that he planned to correct both eyes for distance. Moreover, Dr. Jain wrote, “excellent candidate for bilateral LASIK.” He did not discuss the visual consequences of this plan, other than to write, “Will need readers.” He quoted a price of \$699.00 per eye. (St. Ex. 11a at 27-29)

218. Dr. Jain performed bilateral LASIK on Patient 11 on October 3, 2000. Two days later, Patient 11 called the office “extremely disturbed about loss of near acuity.” She reported that she had been led to believe that her near vision would be the same as it had been preoperatively, but stated that her vision was blurry even with reading glasses. Patient 11 further stated that she was sorry she had had the procedure performed. On October 8, 2000, Patient 11 called again and complained that her vision had been deteriorating. She stated that she had been unable to work due to poor vision and requested to be seen by Dr. Jain the following day. (St. Ex. 11A at 22-26)

On October 9, 2000, Patient 11 complained that her vision had worsened, that she saw occasional dark shadows in her left eye, that she had a sensation of a foreign body in her left eye, and that both eyes had been burning. She was not happy with the outcome of the procedure. Examination of her eyes revealed the following:

Visual Acuity	Right eye: 20/60
without Correction	Left eye: 20/25
Current Prescription	Right eye: sphere, +1.75; cylinder, -0.50; axis, 180
	Left eye: sphere, +1.00; cylinder, -1.00; axis, 121
Manifest Refraction	Right eye: sphere, +1.50; cylinder, -0.25; axis, 160; 20/30
	Left eye: sphere, +0.75; cylinder, -0.75; axis, 180; 20/20

Dr. Jain found KP [keratotic precipitates] in the right eye, and noted “slight overcorrection.” Dr. Jain prescribed pilocarpine 1% eye drops and instructed Patient 11 to return in one week. (St. Ex. 11A at 20-21)

219. On October 11, 2000, Patient 11 called to state that she could not tolerate the eye drops. She also requested that a copy of her preoperative eye examination be sent to her. Dr. Bell saw Patient 11 on October 16, 2000. Patient 11 continued to complain about problems with her vision, and stated that she was unhappy about the results of the procedure. Dr. Bell noted KPs in the right eye. On October 18, 2000, Dr. Blausey spoke with Patient 11 by telephone. He noted that Patient 11 seemed “emotionally disturbed from LASIK results.” (St. Ex. 11A at 16-19)
220. Dr. Shahinfar saw Patient 11 on October 20, 2000. He noted that Patient 11 had dry eyes and recommended the use of artificial tears. He also noted that she had been overcorrected in both eyes and that she might need enhancement. (St. Ex. 11A at 15)
221. On November 11, 2000, Patient 11 canceled her scheduled appointment and advised that she did not wish to reschedule. She also requested a release of her medical records. (St. Ex. 11A at 3, of 13-14)
222. Another physician saw Patient 11 on March 4, 2002. At that time, she reported having had LASIK by Dr. Jain, and that she had been left with “shadowing” vision. She also reported that she had seen another physician shortly after the LASIK procedure, and that that physician had told her that she had not been a good candidate for LASIK because her preoperative visual acuity had been 20/25. Moreover, he told her that she had not been a good candidate for LASIK because she had an early cataract. Finally, Patient 11 reported that she had suffered postoperative eye infections for one year after surgery. (St. Ex. 11B at 17)

### **Testimony of Dr. Gressel regarding Patient 11**

223. Dr. Gressel testified that Dr. Jain’s care and treatment of Patient 11 had fallen below the minimal standards of care for the following reasons:
- Dr. Jain failed to conduct keratometry or a corneal pachymetry prior to LASIK, and no topographic image was documented prior to LASIK. Dr. Gressel testified that, by failing to perform these preoperative procedures, Dr. Jain had violated the Code of

Ethics of the American Academy of Ophthalmology, section B10, which states: “Ordering unnecessary procedures or materials or withholding necessary procedures or materials is unethical.” (Tr. at 1004-1007; St. Ex. 25)

Dr. Gressel acknowledged that the preoperative medical record contains numbers that appear to have been derived from corneal topography. He added, however, that there were no images to accompany those numbers. Dr. Gressel testified that those numbers are not sufficient documentation of the information corneal topography provides. (Tr. at 1312-1313)

- b. Dr. Jain provided inappropriate treatment because he failed to determine whether Patient 11’s contact lens intolerance was due, at least in part, to dry eyes. Dr. Gressel acknowledged that the medical record does not state that Patient 11 had dry eyes, other than Dr. Shahinfar’s reference postoperatively. Nevertheless, Dr. Gressel testified that many people are unable to tolerate contact lenses due to dry eyes. Therefore, whenever a patient complains that they do not tolerate contact lenses, the physician should determine whether dry eyes is the cause of the intolerance. Moreover, Dr. Gressel testified that a test for dry eyes is very simple to perform. Dr. Gressel acknowledged that dry eyes are not a contraindication to the performance of LASIK; however, dry eyes complicate LASIK recovery and should be treated prior to surgery. In this case, it was even more important to determine why Patient 11 could not wear contact lenses because she had such a trivial refractive error that performing LASIK had not been appropriate in the first place. Therefore, the better approach would have been to treat her with contact lenses rather than to perform LASIK. (Tr. at 1004-1006, 1011-1013, 1322-1323, 1326-1328; St. Ex. 25)
- c. Dr. Jain provided inappropriate treatment because he declared Patient 11 to be an excellent candidate for LASIK in both eyes, despite the fact that the right eye exhibited a trivial refractive error. (Tr. at 1004-1006; St. Ex. 25)
- d. Dr. Jain did not discuss or document the manner in which Patient 11 had used her eyes in her daily life, and did not explain the visual consequences of eliminating her left eye myopia. Dr. Gressel testified that this had been a violation of the Code of Ethics of the American Academy of Ophthalmology, Section A7, which states: “It is the responsibility of an ophthalmologist to act in the best interest of the patient.” (Tr. at 1004-1006; St. Ex. 25)

Dr. Gressel explained that it is important to discuss how the patient uses her eyes in her daily life to determine whether the patient will adjust well to monovision. In some cases, failure to adjust to monovision renders the person unable to continue in their profession. When asked if the informed consent form signed by Patient 11 addressed this issue, Dr. Gressel stated that it did not as it was a generic form that did not address Patient 11’s specific needs. Moreover, even though the medical records states “both for distance,” and “will need readers,” Dr. Gressel testified that the documentation was not

- adequate to assure that this information was conveyed to the patient and that the patient understood the consequences. (Tr. at 1022-1024, 1313-1321)
- e. Dr. Jain provided inappropriate treatment because he performed LASIK surgery on the right eye despite a finding that Patient 11 had PSC, or posterior subcapsular cataract, which is a contraindication for doing LASIK. Dr. Gressel explained that, in young patients who develop the PSC, the cataract is likely to develop at a much more rapid pace. Moreover, if the cataract develops rapidly, the patient should not have to pay out-of-pocket for a needless operation when a soon-to-be-necessary cataract operation would provide the same benefit and would be covered by insurance. Finally, avoiding unnecessary LASIK at that point would have prevented future problems in determining the appropriate lens implant power, especially since Dr. Jain had not performed preoperative manual keratometry. (Tr. at 1004-1007, 1324-1326; St. Ex. 25)
  - f. Dr. Jain failed to perform appropriate LASIK surgery because he programmed the laser for excessive treatment resulting in overcorrection in Patient 11's right eye. Dr. Gressel testified that the desired correction programmed into the laser had not been justified by the preoperative manifest or cycloplegic refractions. Dr. Gressel concluded that the overcorrection had resulted in Patient 11's extreme dissatisfaction with the outcome of the LASIK procedure. (Tr. at 1004-1006, 1013-1016; St. Ex. 25)
  - g. Dr. Jain provided inappropriate treatment by prescribing pilocarpine postoperatively. Dr. Gressel testified that it was likely that the pilocarpine had precipitated or worsened the inflammation in Patient 11's right eye as evidenced by the KPs. Dr. Gressel explained that KPs stands for keratotic precipitates or clumps of inflammatory cells within the eye. (Tr. at 1004-1006, 1016-1017; St. Ex. 25)

Dr. Gressel further testified that pilocarpine is a medicine that has several indications. One indication is to constrict the pupil in an attempt to correct farsightedness and, in this case, it may have been used to improve Patient 11's near vision. Dr. Gressel continued, however, that, in an eye with inflammation, pilocarpine has a side effect of breaking down the blood-aqueous barrier and allowing chemicals from the bloodstream to pass into the aqueous humor. He stated that that causes increased pain in the eye, sensitivity to light, and aching around the eye. Therefore, pilocarpine is contraindicated in an inflamed eye and is not an appropriate way of managing an overcorrection caused by laser vision correction. (Tr. at 1017-1020)

- h. Dr. Jain performed unnecessary surgery on the right eye. Dr. Gressel explained that, by looking at the preoperative manifest refraction and cycloplegic refraction, it was apparent that the adjustment necessary was only as great as "the smallest incremental change ever made in a contact lens or spectacle lens." Dr. Gressel concluded that the trivial refractive error in the right eye had been too small and insignificant to justify LASIK correction. He concluded that, by performing the surgery, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section B6,

which states: “Recommendation of unnecessary treatment or withholding of necessary treatment is unethical.” Moreover, by performing the surgery, Patient 11 had been left with a loss of her best spectacle-corrected visual acuity. Moreover, Dr. Gressel testified that, prior to surgery, Patient 11 had had a regular astigmatism in her right eye which had not required any treatment whatsoever. He concluded that the chance of improving her vision by performing LASIK had been outweighed by the very likely possibility that she would be more unhappy with the outcome. (Tr. at 1004-1006, 1007-1008, 1024-1025, 1322, 1328-1329; St. Ex. 25)

### **Testimony of Dr. Jain regarding Patient 11**

224. Dr. Jain testified that his decision to forego manual keratometry in his pre-LASIK patients did not constitute a departure from accepted standards of care. (Tr. at 1499)
225. Dr. Jain testified that Patient 11 had not had a dry eye condition that needed to be treated prior to LASIK. Dr. Jain explained that dry eyes are “almost never” a contraindication for LASIK. Moreover, Dr. Jain testified that Patient 11 had not had dry eyes; instead, Patient 11 had had an intolerance to contact lens solution. Dr. Jain acknowledged that Patient 11 had complained of having “scratchy” eyes postoperatively, but Dr. Jain testified that that is a frequent complaint after LASIK. (Tr. at 301-302, 1614-1617)
226. Dr. Jain testified that he had carefully evaluated how Patient 11 used her eyes in daily life, and had reviewed the consequences of performing LASIK prior to the surgery. Moreover, Dr. Jain testified that the informed consent form signed by Patient 11 advises that she might need to wear glasses for reading postoperatively. Dr. Jain concluded that he had properly evaluated Patient 11 prior to surgery and had adequately explained the visual consequences of eliminating her left eye myopia. (Tr. at 313-316, 1610-1614)
227. Dr. Jain acknowledged that he had caused an overcorrection in Patient 11’s right eye, but stated that he had not done so intentionally. Dr. Jain explained that he had used the Visx nomograms to program the laser and, at that time, the nomograms had not been as accurate as they are today. Dr. Jain testified that this was not an excuse for overcorrecting Patient 11’s right eye, but noted that overcorrection is a risk of LASIK. Moreover, he stated that overcorrection is easily corrected when it occurs. Dr. Jain concluded that his performance of LASIK on Patient 11’s right eye had been within the standards of care. (Tr. at 318-320, 1618-1619)
228. Dr. Jain testified that he had used pilocarpine in this case as an accommodative agent. He stated that pilocarpine contracts the ciliary muscle, which has a result of improving near vision. Dr. Jain acknowledged that pilocarpine can induce inflammation, but testified that this is not complication in a LASIK procedure but only in penetrating ocular surgery, which requires an incision into the wall of the eye. Dr. Jain testified that pilocarpine is an acceptable treatment, even in the early postoperative period of LASIK, as an

accommodative agent. He concluded that the use of pilocarpine in this case had been within the standards of care. (Tr. at 313-318, 1619-1622)

229. Dr. Jain testified that performing LASIK surgery on Patient 11's right eye, despite the minimal refractive error, had been in conformance with the standards of care. Dr. Jain explained that, "While it's true that this patient had a low degree of nearsightedness and astigmatism, she did have a treatable error. And that's evidenced by the fact that her vision with her present glasses was improvable to 20/25 from 20/30-. And even though that's a marginal improvement, it is treatable." (Tr. at 1617)

### ***Patient 12***

#### **Medical Records for Patient 12**

230. Patient 12, a 46-year-old female, was evaluated at the Bloomberg Eye Center for LASIK on April 2, 2001. Patient 12 advised that she had used rigid gas permeable contact lenses, but that she had stopped wearing them one month earlier. (St. Ex. 12A at 83) Examination of her eyes revealed the following:

Current Prescription	Right eye: sphere, -4.25; cylinder, -1.50; axis, 080
	Left eye: sphere, -3.25; cylinder, -2.75; axis, 135
Manual Keratometry	Right eye: 47.20@150; 43.81@070
	Left eye: 48.50@035; 43.50@125
Simulated Keratometry	Right eye: 40.66@158; 37.50@060
	Left eye: 48.19@030; 42.71@120

Corneal topography was performed and revealed inferior steepening bilaterally; nevertheless, Dr. Jain noted no keratoconus. It should be noted that the images were inverted with 270 degrees at the top of the diagram. The medical record contains no pachymetry measurements. Patient 12 was advised that she would need to wait one additional month without her gas permeable contact lenses before having LASIK. (St. Ex. 12A at 24-25, 83)

231. Patient 12 returned for a second LASIK evaluation on May 7, 2001. Her eye examination provided the following information:

Visual Acuity with Correction	Right eye: 20/40-
	Left eye: 20/200
Visual Acuity without Correction	Right eye: 20/200
	Left eye: 20/CF
Current Prescription	Right eye: sphere, -4.25; cylinder, -1.50; axis, 080
	Left eye: sphere, -3.25; cylinder, -2.75; axis, 135
Manifest Refraction	Right eye: sphere, -3.50; cylinder, -3.00; axis, 075; 20/20-1
	Left eye: sphere, -2.75; cylinder, -5.00; axis, 110; 20/20-1
Cycloplegic Refraction	Right eye: sphere, -3.25; cylinder, -3.00; axis, 075; 20/20
	Left eye: sphere, -2.25; cylinder, -4.50; axis, 110; 20/25

Manual Keratometry	Right eye: 46.00@150; 43.75@060 Left eye: 47.75@030; 43.25@120
Simulated Keratometry	Right eye: 46.87@150; 43.54@060 Left eye: 47.75@030; 43.25@120
Desired Correction	Right eye: sphere, -1.09; cylinder, -3.30; axis, 175 Left eye: sphere, plano; cylinder, -4.60; axis, 110

Patient 12 reported that her eyeglasses were “useless.” There is no explanation documented regarding that statement. Dr. Jain found that Patient 12’s eyes were very dry, with the left eye being worse than the right eye. The medical record contains no pachymetry measurements or any topographic images corresponding to the simulated keratometry results. Dr. Jain noted that he would correct her eyes for myopia and astigmatism. Dr. Jain quoted a price of \$978.00. Patient 12 accepted the Lifetime Assurance Plan for \$98.00. (St. Ex. 12A at 79, 82)

Dr. Jain performed LASIK bilaterally on May 11, 2001. Dr. Jain failed to record the microkeratome data for the LASIK procedure. In addition, despite the fact that the astigmatism axis for the right eye that had been determined by refraction was 075, Dr. Jain entered an astigmatism axis of 175. (St. Ex. 12A at 76-78)

232. Dr. Jain saw Patient 12 on May 21, 2001. Patient 12 complained that it felt as if she were still wearing contacts and stated that she could see neither near nor far with her right eye. Examination of her eyes revealed the following:

Manifest Refraction	Right eye: sphere, -2.50	20/40+2
	Left eye: sphere, +0.75; cylinder, -2.50; axis, 105;	20/40
Cycloplegic Refraction	Right eye: sphere, +0.25; cylinder, -2.50; axis, 060;	20/40-
	Left eye: sphere, +0.75; cylinder, -2.50; axis, 118;	20/30+

Someone other than Dr. Jain noted “mild debris,” but Dr. Jain stated that both corneas were clear. Dr. Jain noted that Patient 12 was “not correctable to 20/40,” and recommended a consultation with Dr. Shahinfar to evaluate the macula. There is no evidence, however, that that consultation was ever completed. Corneal topography was performed, although the images were inverted with 270 degrees still appearing at the top. Viewed properly, the images reveal inferior steepening bilaterally; nevertheless, Dr. Jain found “no keratoconus.” (St. Ex. 12A at 22-23, 74)

233. Dr. Jain saw Patient 12 on June 25, 2001. Patient 12 complained that her vision had been fluctuating unexpectedly, and that she had been having double vision. Under manifest refraction, it stated, “difficult refraction” and “no change in refraction.” Dr. Jain noted macrostriae bilaterally. He prescribed Alphagan eye drops bilaterally. (St. Ex. 12A at 73)
234. On June 27, 2001, Dr. Jain performed a bilateral flap irrigation procedure utilizing an alcohol-soaked Q-tip to scrape epithelium plaque from the underside of the flaps. The

preoperative diagnosis was macrostriae, both eyes. Postoperatively, Dr. Jain applied a bandage contact lens each eye. (St. Ex. 12A at 71-72) The following day, Patient 12 complained that her eyes were very irritated and burned "like crazy." Dr. Jain noted moderate periorbital swelling. He also ordered that the Alphagan be replaced with Acular eye drops. (St. Ex. 12A at 70)

235. On August 27, 2001, Patient 12 complained of very blurred vision, glare, double vision, and difficulty with depth perception. Manifest refraction was as follows:

Right eye:	sphere, +0.50;	cylinder, -3.75;	axis, 066;	20/30
Left eye:	sphere, plano;	cylinder, -3.00;	axis, 130;	20/40

Dr. Jain noted that he would consider astigmatic keratotomy in the future, and instructed her to return in six weeks. Corneal topography revealed inferior steepening bilaterally, more significant on the left. Dr. Jain noted inferior steepening of the right eye. These images were not inverted. (St. Ex. 12A at 20-21, 64)

236. On October 9, 2001, Patient 12 continued to complain of poor vision. Examination of her eyes revealed the following:

Visual Acuity	Right eye: 20/60
with Correction	Left eye: 20/80
Visual Acuity	Right eye: 20/200
without Correction	Left eye: 20/200
Visual Acuity	Right eye: 20/50
Pinhole	Left eye: 20/70
Manual Keratometry	Right eye: 44.25; 40.12@075
	Left eye: 41.25; 45.62@057
Simulated Keratometry	Right eye: 44.25@165; 40.12@075
	Left eye: 41.25@147; 45.62@057
Pachymetry	Right eye: 438
	Left eye: 431

Dr. Jain ordered rigid gas permeable contact lenses. The following day, corneal topography revealed significant inferior corneal steepening bilaterally. (St. Ex. 12A at 17a, 63)

Thereafter, Patient 12 continued to complain of poor vision, including difficulty driving due to triple and double vision and reflections on the road that were not where they appeared to be. She also complained of discomfort with her contact lenses. On November 27, 2001, Patient 12 requested release of her medical records. She continued to be seen frequently at Bloomberg Eye Center through October 2002 for contact lens fitting due to discomfort and poor vision. (St. Ex. 12A at 36-62)

Another physician diagnosed Patient 12's condition as compound myopic astigmatism and noted "significant loss of best corrected visual acuity." (St. Ex. 12C at 37b)

### **Testimony of Dr. Gressel regarding Patient 12**

237. Dr. Gressel testified that Dr. Jain's care and treatment of Patient 12 had fallen below the minimal standards of care for the following reasons:
- a. Although the corneal topography images taken of Patient 12's eyes demonstrated ectasia in both corneas, Dr. Jain indicated "no keratoconus" in the medical record. Dr. Gressel noted that, even though the images were inverted, the inferior steepening was quite obvious and was extensive enough to reach the center of the eye. He further noted that, in the steep meridian, the right eye had 47 diopters of curvature towards the center, and the left eye had 48 diopters, which, in his opinion, was "quite steep." (Tr. at 1027-1029, 1032-1033; St. Ex. 25)
  - b. On May 7, 2001, Patient 12 was re-evaluated for LASIK [second evaluation], at which time she reported that her eyeglasses were useless, but Dr. Jain failed to document an explanation of this complaint or the difference between the measurement of her glasses and the refraction reported. (Tr. at 1027-1029; St. Ex. 25)
  - c. A different set of simulated K measurements derived from topography was recorded during the second evaluation, but no topographic images were taken and/or documented for the second evaluation. (Tr. at 1027-1029; St. Ex. 25)
  - d. Dr. Jain failed to determine whether the corneal topography had returned to normal with discontinuation of contact lens wear before proceeding with surgery. (Tr. at 1027-1029; St. Ex. 25)
  - e. Dr. Jain failed to measure corneal pachymetry preoperatively. Dr. Gressel acknowledged that postoperative pachymetry measurements were 438 and 426, but stated that postoperative measurements do not guarantee that the corneas were thick enough for LASIK preoperatively. (Tr. at 1027-1029, 1329-1331; St. Ex. 25)
  - f. Dr. Jain's performance of LASIK was inappropriate for both eyes because preoperative topography clearly demonstrated ectasia. Dr. Gressel testified that the significant bilateral inferior corneal steepening rendered Patient 12 an inappropriate candidate for LASIK. (Tr. at 1027-1029, 1032-1033; St. Ex. 25)
  - g. Dr. Jain failed to record the microkeratome data for the LASIK procedure. (Tr. at 1027-1029, 1033-1034; St. Ex. 25)
  - h. In performing LASIK on Patient 12's right eye, Dr. Jain failed to enter an astigmatism axis into the laser that corresponded with the axis determined by

refraction. Instead, Dr. Jain prescribed an astigmatism correction that was 100 degrees different from the axis determined by the refraction recorded during the second evaluation. Dr. Gressel explained that the laser printout indicates that the minus axis for the LASIK treatment for the right eye was programmed to be 175; however, both the preoperative cycloplegic refraction and manifest refraction show a minus axis of 075. He further explained that a discrepancy of 100 degrees is very significant due to the magnitude of the cylinder. He added that Patient 12's astigmatism had nearly doubled, going from 3.3 diopters to somewhere close to 6 diopters. Dr. Gressel stated that this would cause virtually unmanageable visual impairment and great disparity between the two eyes, which is visually disabling. Finally, Dr. Gressel testified that it is a problem that most likely cannot be fixed. (Tr. at 1027-1029, 1033-1036; St. Ex. 25)

Dr. Gressel was asked why, if the astigmatism axis entered into the laser had been so damaging, the resulting vision in the right eye appeared to be better, at times, than the resulting vision in the left eye. Dr. Gressel explained that, in addition to the error entering the astigmatism axis into the laser, Dr. Jain also performed LASIK on eyes with significant ectasia. Therefore, it is possible that the vision in the left eye had been destabilized by the surgery even more than in the right due to the extent of the pre-existing ectasia. Dr. Gressel noted that the vision in both eyes continued to fluctuate and deteriorate. He concluded that it had been inappropriate for Dr. Jain to perform LASIK on either of Patient 12's eyes. (Tr. at 1331-1334, 1341-1342)

- i. Following the LASIK procedure, Patient 12 reported that she could see neither near nor far with her right eye. Dr. Gressel testified that Dr. Jain had failed to discern the true cause of Patient 12's problems and inappropriately determined that the problem was related to Patient 12's macula. Dr. Jain recorded a plan to consult another physician concerning Patient 12's macula, although no record of such consult was entered in the medical records. Nevertheless, the medical record did not support even a differential diagnosis of problems with the macula. Dr. Gressel testified that Dr. Jain should have realized the true state of Patient 12's eyes and, if not, he should have undertaken a review of all the measurements that had been obtained prior to and during the surgery. Moreover, Dr. Jain should have realized that the corneal topography had revealed abnormal corneas even before LASIK was performed. (Tr. at 1027-1029, 1036-1040, 1334-1335; St. Ex. 25)
- j. During a flap irrigation, Dr. Jain scraped the underside of the flap with alcohol. Dr. Gressel testified that, not only does alcohol have a toxic effect on epithelial cells, but it may also have a similar effect on corneal stromal and endothelial cells. Dr. Gressel explained that the accepted treatment would have been to remove the surface epithelium from the outside of the eye in order to allow sterile water to penetrate into the stroma of the cornea and into the flap, which would swell the flap and smooth the wrinkles. What Dr. Jain did, however, was to lift up the flap and scrape the underside of the flap with an alcohol-soaked Q-tip. He did so despite the

fact that there had not been any documentation prior to this that epithelium had been viewed under the flap. Dr. Gressel concluded that using alcohol as the initial intervention to try to remove epithelium from the underside of the flap is “way too aggressive and too risky.” He stated that such a procedure should only be used after repeated failures to eliminate epithelium from under the flap. (Tr. at 1027-1029, 1042-1045; St. Ex. 25)

- k. On June 25, 2001, as Patient 12 reported fluctuating vision, Dr. Jain noted macrostriae in both eyes, and Dr. Jain recommended Alphagan eye drops. Nevertheless, Dr. Jain did not document a rationale supporting the use of such eye drops. Dr. Gressel testified that Alphagan is generally used as a treatment for optic nerve damage related to glaucoma, which was not present in this case. He acknowledged, however, noted that Alphagan can be used to constrict the pupil, thereby reducing night vision problems in a post-LASIK patient. (Tr. at 1027-1029, 1041-1042, 1336; St. Ex. 25)
- l. On August 27, 2001, the refraction for Patient 12 indicated considerable astigmatism in both eyes, yet Dr. Jain’s plan was to consider astigmatic keratotomy. Dr. Gressel testified that this plan was inappropriate due to the postoperative topographic images, which demonstrated obvious ectasia. Dr. Gressel testified that, rather than recommending more inappropriate surgery, Dr. Jain should have acknowledged that that “surgery never should have been done in the first place.” (Tr. at 1027-1029, 1046-1051; St. Ex. 25)

Dr. Gressel explained that an astigmatic keratotomy involves a deep incision being cut into the steepest meridian of the cornea for the purpose of flattening that meridian. Dr. Gressel testified that it would have been very inappropriate to perform astigmatic keratotomy in this patient due the significant ectasia in the steeper part of the cornea. He stated that a deep incision in that area would have further destabilized the cornea and caused worsening ectasia. Moreover, Dr. Gressel testified that Dr. Jain’s consideration of astigmatic keratotomy was further evidence that he “totally and utterly fail[ed] to recognize what the problem [was] or to understand how to manage it.” Dr. Gressel noted that topographies continued to be inverted, and Dr. Jain continued to ignore that fact. (Tr. at 1046-1051)

- m. Although Patient 12 failed to improve and continued to deteriorate under Dr. Jain’s care, Dr. Jain failed to consult with or make a referral to another physician. Dr. Gressel noted that Dr. Jain had ordered a consultation with Dr. Shahinfar, although the reason stated was inappropriate and the consultation was never done. Moreover, Dr. Gressel testified referral to another physician had been necessary simply to obtain an appropriate diagnosis. Dr. Gressel concluded that, by failing to refer Patient 12 to another physician when it was clear that his care was not helping her, Dr. Jain had violated the Code of Ethics of the American Academy of

Ophthalmology, Section B4, which states: “Consultation(s) shall be obtained if required by the condition.” (Tr. at 1027-1029, 1049, 1337-1340; St. Ex. 25)

- n. Dr. Jain failed to tell Patient 12 that he had made errors in the course of her care. Dr. Gressel testified that Dr. Jain had failed to inform Patient 12 that he had inappropriately performed LASIK on diseased corneas or that he had entered the wrong astigmatism axis into the laser during the procedure for the right eye. Dr. Gressel testified that, when a physician makes a medical error, the standard of care requires that the physician acknowledge that error to the patient, and then offer any and all possible assistance in attempting to resolve the problems that had resulted from the error. (Tr. at 1052)

### **Testimony of Dr. Jain regarding Patient 12**

238. Dr. Jain testified that he had assumed that, when Patient 12 complained that her eyeglasses were useless, she had been referring to a set of eyeglasses that she had obtained when she removed her rigid gas permeable contact lenses in preparation for LASIK. He acknowledged, however, that there is no reference in the medical record to Patient 12 having obtained such eyeglasses. Moreover, Dr. Jain acknowledged that he had not even considered the possibility that the eyeglasses that she referred to as useless were, in fact, the eyeglasses from which he had derived the “current prescription.” (Tr. at 324-328)
239. Dr. Jain acknowledged that there had been inferior steepening in the corneal topography obtained preoperatively. In fact, Dr. Jain admitted that the inferior steepening might have been consistent with keratoconus; however, he testified that the image did not portray the steepening in red, which is more consistent with keratoconus. Nevertheless, Dr. Jain explained that inferior steepening, in and of itself, is not a contraindication for LASIK. He noted, however, that keratoconus *is* a contraindication for LASIK. Moreover, Dr. Jain testified that he had not realized that the topographic images were inverted because no one had alerted him to that fact. He stated that he had put a lot of trust in his technicians. Nevertheless, he acknowledged that his failure to recognize the inverted images had been “definitely an oversight.” (Tr. at 330-332)
240. Dr. Jain testified that he had not recorded the microkeratome data because, “It was the same that we used before.” (Tr. at 333)
241. Dr. Jain acknowledged that he had made a transcription error when he programmed the astigmatism axis into the laser. He further acknowledged that it had been a significant error. (Tr. at 332-333)
242. Dr. Jain testified that, at the time he requested Dr. Shahinfar to evaluate the macula, he had not yet realized that the topographies were inverted. Dr. Jain testified that, because the topography appeared to be the same as the preoperative topography and her vision was not

correctable to 20/20, he had thought it appropriate to check the macula because it was possible that she had had a problem with the retina. (Tr. at 336-338)

243. Dr. Jain testified that he had decided to irrigate the flap because he had found macrostriae, or wrinkles, in the flap. Once the flap was lifted, he noted epithelial plaque on the underside of the flap. Dr. Jain testified that alcohol is an accepted way of treating epithelial ingrowth. (Tr. at 338-340)
244. Dr. Jain testified that he had used Alphagan to improve Patient 12's vision in circumstances of dim illumination. (Tr. at 338)
245. When asked if he had advised Patient 12 of the errors he had made during the course of her care, Dr. Jain reviewed the medical record to look for documentation of his disclosure. Dr. Jain did not find any such documentation. Dr. Jain testified, however, that when he had recommended rigid gas permeable lenses in October 2001, it was a sign that he had finally recognized his errors. He testified that, at least, he had recognized that there was a problem. Nevertheless, he admitted that he had not documented that an error had occurred or that he had advised Patient 12 of that error. (Tr. at 334, 344-347)

### ***Patient 13***

#### **Medical Records for Patient 13**

246. Patient 13, a 53-year-old female, presented to the Bloomberg Eye Center on June 12, 2002, to be evaluated for LASIK. The medical record contains a one-page record regarding treatment Patient 13 had obtained from South Holland Vision in November 2001, January 2002, and April 2002. That record indicates that Patient 13 had LASIK surgery in early November 2001. Nevertheless, the record contains no information regarding preoperative refraction, preoperative or postoperative keratometry, pachymetry, topography, or treatment goals. Moreover, the record contains no information about the amount of laser treatment provided, or the microkeratome and settings used. (St. Ex. 13 at 2, 3, 12, 13)

The medical record contains a manifest refraction obtained on April 16, 2002. Examination of her eyes revealed the following:

Visual Acuity	Right eye: 20/100
without Correction	Left eye: 20/50
Manifest Refraction	Right eye: sphere, -2.00; cylinder, -2.50; axis, 162; 20/30
	Left eye: sphere, plano; cylinder, -2.00; axis, 022; 20/30

Moreover, the right eye revealed opacities, while the left eye was clear. (St. Ex. 13 at 13)

247. The Bloomberg Eye Center medical record contains a telephone contact sheet dated April 30, 2002, which states that "any enhancement, AK, etc., will be free of charge per Dr. Jain." (St. Ex. 13 at 12)

248. On June 12, 2002, during Patient 13's first visit to the Bloomberg Eye Center, her eye examination revealed the following:

Visual Acuity	Right eye: 20/400
without Correction	Left eye: 20/40
Manifest Refraction	Right eye: sphere, -2.00; cylinder, -2.75; axis, 162; 20/30+2
	Left eye: sphere, -0.50; cylinder, -2.00; axis, 115; 20/25
Desired Correction	Right eye: sphere, plano; cylinder, -3.10; axis, 162
	Left eye: sphere, plano; cylinder, -1.45; axis, 015

Dr. Jain noted that her corneas were clear. (St. Ex. 13 at 11)

249. Dr. Jain performed LASIK later that day on both eyes. Prior to performing LASIK, Dr. Jain did not measure corneal pachymetry or perform corneal topography. There is no informed consent in the medical record. (St. Ex. 13 at 7-9)
250. The following day, Dr. Jain saw Patient 13. He noted simply that the corneas were clear and recommended follow-up "PRN." There are no further entries in the medical record. (St. Ex. 13 at 6)

### Testimony of Dr. Gressel regarding Patient 13

251. Dr. Gressel testified that Dr. Jain's care and treatment of Patient 13 had fallen below the minimal standards of care for the following reasons:
- Dr. Jain failed to measure corneal pachymetry, keratometry, and topography prior to performing the LASIK enhancement. Dr. Gressel stated that pachymetry is important, in general, to make sure that there is enough corneal tissue to avoid excessive thinning of the cornea by removing still more tissue with the laser. He added that keratometry is important, in general, to provide information necessary for any future cataract surgery, as noted above. Finally, topography is important, in general, to demonstrate that the cornea is not so diseased that it will be destabilized or made worse by further surgery. (Tr. at 1053-1054, 1057-1058; St. Ex. 25)

Dr. Gressel further testified that, in this case, these omissions were even more significant. He explained that Patient 13's vision had not been correctable to 20/20 with refraction, and that Patient 13 had had 2.0 and 2.75 diopters of astigmatism remaining, both of which raise a "particularly high concern that there might be some disease state of the cornea." Moreover, there is no evidence regarding the measurements of Patient 13's eyes prior to the original LASIK or information of what laser treatment was given. Dr. Gressel opined that this had not been a simple routine enhancement for slight under- or over-correction. He added that there had been something "substantially different going on" that Dr. Jain should have evaluated more

carefully. Dr. Gressel concluded that, for these reasons, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section B6, which states: “The ophthalmologist must evaluate the patient and assure that the evaluation accurately documents the ophthalmic findings and the indications for treatment.” (Tr. at 1053-1054, 1057-1058; St. Ex. 25)

Dr. Gressel added that his opinion would not change even if Dr. Jain had been the physician who performed the original LASIK procedure. In explaining why his opinion would not change, Dr. Gressel testified:

Dr. Jain has established a pattern of not doing topography or pachymetry before an initial LASIK operation. So I’m not very much reassured, knowing that he was—that if I knew that he was the original surgeon, because that does not in any way assure that—that those things were done in Chicago. [Moreover,] we have no reason to believe that adequate testing has been done to establish that there is not a disease state of the cornea. We don’t have an explanation for why the patient has so much astigmatism or for why the vision is not correctable to 20/20.

(Tr. at 1058-1059)

- b. The Bloomberg Eye Center’s medical record for Patient 13 contained no information regarding the first LASIK procedure performed at South Holland Vision. For example, there was no information concerning her preoperative refraction, preoperative or postoperative keratometry, pachymetry, topography, or treatment goals. (Tr. at 1053-1054; St. Ex. 25)

Dr. Gressel noted that the information provided regarding the first LASIK procedure revealed that, one week after surgery, Patient 13 had had 2.0 diopters of astigmatism in both eyes. In addition, the right eye had 2.25 diopters of myopic sphere, and the left eye had 0.5 diopters of myopic sphere. Moreover, the postoperative visual acuity was only 20/40 in the right and 20/30 in the left. Dr. Gressel testified that there was no explanation regarding these complications in the medical record. (Tr. at 1053-1054, 1055-1056; St. Ex. 25)

Dr. Gressel testified that complete information regarding Patient 13’s treatment and condition after the first LASIK procedure should have been made a part of the Bloomberg Eye Center medical record. Nevertheless, Dr. Gressel testified that there is ample evidence to show that Dr. Jain’s care of this patient had fallen below the minimal standard of care even without having access to the full medical records regarding the first LASIK procedure. (Tr. at 1344-1345; St. Ex. 25)

- c. In conducting the LASIK enhancement, Dr. Jain inappropriately programmed the astigmatism treatment for the right eye to be 13% greater than the astigmatism

measured by refraction, and programmed the astigmatism treatment for the left eye to be 28% less than the astigmatism measured by refraction. Dr. Gressel testified that Dr. Jain failed to record any explanation for this divergence from the refractions. Moreover, Dr. Gressel testified that Dr. Jain had failed to record any explanation for the discrepancy between his management of the astigmatism in the two eyes, leading to the inescapable conclusion that he made an error in, at least, one of them. (Tr. at 1053-1054, 1059-1061, 1355-1358; St. Ex. 25)

Dr. Gressel testified that he had reached this conclusion by comparing what had been programmed into the laser to the astigmatism measured by refraction. He noted that, for the right eye, Dr. Jain had programmed the laser to correct 3.10 diopters of astigmatism, while the refraction had indicated 2.75. In the left eye, Dr. Jain programmed to -1.45 diopters of astigmatism, while the refraction said -2.00. Dr. Gressel explained that Dr. Jain had used totally different strategies in treating the astigmatism in the two eyes, which was difficult to comprehend. Dr. Gressel opined that Dr. Jain might have been trying to create monovision, with the right eye corrected for near vision and the left eye corrected for distance vision. He added that he could not be sure if that was Dr. Jain's intention since Dr. Jain did not document his plan. (Tr. at 1059-1061, 1355)

Dr. Gressel further testified that the fact that both eyes had exhibited a relatively symmetrical degree of astigmatism had also supported his conclusion that Dr. Jain had made an error in programming the laser. Dr. Gressel noted that, preoperatively, the right eye had had 2.75 diopters and the left eye had had 2.0 diopters of astigmatism. Dr. Jain's plan for the enhancement procedure was to treat 3.10 diopters of astigmatism in the right eye, which is more than what was contained in the refraction, and only treat 1.45 diopters of astigmatism in the left eye, which is less than what was contained in the manifest refraction. Dr. Gressel continued that, unless Dr. Jain had been using a different strategy to manage the astigmatism in each eye, which would have been of no advantage to the patient and would not have been a reasonable plan, Dr. Jain must have made an error in his calculations. Dr. Gressel testified that his opinion would not change even considering the coupling phenomenon created by using the Nidek laser. (Tr. at 1354-1358)

- d. The medical record contains no informed consent forms signed by Patient 13 pertaining to the enhancement procedure. Dr. Gressel testified that this failure constitutes a violation of the Code of Ethics of the American Academy of Ophthalmology, section B2, which states: "The performance of medical or surgical procedures shall be preceded by appropriate informed consent." (Tr. at 1053-1054, 1063, 1354; St. Ex. 25)
- e. Dr. Jain failed to provide and/or document an appropriate postoperative plan of care for Patient 13, other than to return "prn," or "as needed." Dr. Gressel testified that, in

this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, section B8, which states:

The providing of postoperative eye care until the patient has recovered is integral to patient management. The operating ophthalmologist should provide those aspects of postoperative eye care within the unique competence of the ophthalmologist (which do not include those permitted by law to be performed by auxiliaries). Otherwise, the operating ophthalmologist must make arrangements before surgery for referral of the patient to another ophthalmologist, with the patient's approval and that of the other ophthalmologist.

(Tr. at 1053-1054, 1061; St. Ex. 25)

Dr. Gressel testified that advising the patient to return as needed is inadequate. He noted that, even if the patient had returned to Hammond, Indiana, for postoperative care, there should have been some indication in the Bloomberg Eye Center medical record. He further noted that, on the first postoperative day, which was the only postoperative visit with Dr. Jain, Patient 13 was taking steroid and antibiotic eye drops, but there is no indication regarding how long she was to continue using those eye drops. Moreover, Dr. Gressel testified that Patient 13's vision was "not particularly good" the day after surgery, but there is no indication in the medical record regarding her final outcome. (Tr. at 1061-1063, 1345-1352)

### **Testimony of Dr. Jain regarding Patient 13**

252. Dr. Jain testified that he had been in Chicago and had performed Patient 13's first LASIK procedure. Therefore, when she needed an enhancement procedure, she had gone to the Bloomberg Eye Center to see Dr. Jain. Dr. Jain explained that he had co-managed the care of Patient 13 for both procedures with an optometrist at South Holland Vision, which is in the Chicago area. (Tr. at 347-350)

Dr. Jain testified that, during the first surgery, he had planned to provide monovision, which explained why she had had more residual myopia in one eye than the other. Later however, Patient 13 requested that both eyes be corrected for distance. When asked how he knew these things, Dr. Jain acknowledged that he had not documented the information, but testified that he could make that determination based on the prescription he had entered into the laser. Dr. Jain further testified that his intention during the enhancement procedure had been to provide visual acuity "as close to 20/20 as possible." (Tr. at 350-352)

Dr. Jain acknowledged that the manifest refraction obtained at the Bloomberg Eye Center on June 12, 2002, was different from the manifest refraction obtained at South Holland Vision on April 16, 2002, but added that the difference was not significant. He also acknowledged that Patient 13's visual acuity in the right eye had decreased from 20/100 to

20/400. Regarding that difference, Dr. Jain testified that he remembers the technician who checked Patient 13's eyes on that first visit at Bloomberg Eye Center, and stated that the technician was someone who "didn't push patients to go down the chart much." Therefore, the visual acuity obtained by that technician often appeared to be less optimal than the patient's actual vision. (Tr. at 352-355; St. Ex. 13 at 11, 13)

Dr. Jain further acknowledged that the only information he had had regarding the first laser treatment had been the page faxed to him by South Holland Vision. Moreover, he stated that, when he did the enhancement procedure, he had not really known what he had done during the first LASIK procedure, other than what he might have been told by the optometrist at South Holland Vision. Dr. Jain stated that he had had a telephone conversation with that optometrist; however, he acknowledged that there is no documentation in the record regarding that conversation. (Tr. at 360-361)

253. Dr. Jain testified that he had programmed a 13% greater astigmatism in the right eye and a 28% lesser astigmatism in the left eye than that which was indicated by the refraction. He stated he had done so due to the nomograms for the Nidek laser that, because of a coupling effect, require that you "over-program the astigmatism in order to get the desired result." Dr. Jain explained that the Nidek laser tends to undercorrect the astigmatism and that, the higher the degree of astigmatism, the more the Nidek laser undercorrects. Therefore, Dr. Jain concluded that he had programmed the laser appropriately according to the Nidek nomograms in order to achieve the correction he had desired. (Tr. at 358-360, 1473-1474, 1724-1725, 1782-1785; Resp. Ex. B)

Dr. Jain testified that, simply because there are disparities between the residual refractive errors, it does not mean that there had been an error programming the laser. Dr. Jain further testified that, because the Nidek nomograms are so complicated, and because Dr. Gressel has not worked with the Nidek laser, Dr. Gressel had not understood that Dr. Jain's programming had been appropriate. Dr. Jain concluded that his management of Patient 13's astigmatism had been within the minimal standards of care. (Tr. at 359-360, 1623-1629)

Later however, Dr. Jain acknowledged that, in his expert report, he had not raised the issue of coupling when responding to allegations regarding his correction for Patient 13's astigmatism. Instead, Dr. Jain had stated: "I disagree with Dr. Gressel's assessment. Just because there is an asymmetry in the degree of myopia between two eyes does not lead to the \* \* \* 'inescapable conclusion' that I made an error on correcting one of them. Sometimes one eye responds differently to LASIK surgery than the other eye." (Tr. at 1763-1764)

254. Dr. Jain testified that he had obtained informed consent from Patient 13 for the enhancement procedure. Dr. Jain explained that, at Bloomberg Eye Center, every patient must sign an informed consent form prior to having a procedure performed. (Tr. at 355)
255. Dr. Jain testified that he had arranged for the care of Patient 13 after the enhancement to be managed by Dr. Park, an optometrist at South Holland Vision. Dr. Jain testified that he had

arranged to see Patient 13 on her first postoperative day, and that she then be seen in four to six weeks and then four to six months. He testified that there had not been a written aftercare plan other than to follow-up with the optometrist in Chicago. Dr. Jain testified that it had been within the minimal standards of care to use out-of-town optometrists to provide pre-and postoperative care to his surgical patients. (Tr. at 1624, 1629-1630)

Later, it was noted that Patient 13 had stated that the name of her optometrist in the Chicago area was Dr. Williams. Dr. Jain testified that the name did not “ring a bell, but it could be.” Dr. Jain did not explain his testimony regarding Dr. Park after being confronted with the fact that Patient 13 had claimed that her optometrist was Dr. Williams. (Tr. at 1630)

### ***Patient 14***

#### **Medical Records for Patient 14**

256. Patient 14, a 33-year-old female who resided in Columbus, Ohio, presented to the Bloomberg Eye Center for LASIK evaluation on January 25, 2001. Examination of her eyes revealed the following:

Visual Acuity	Right eye: 20/20
with Correction	Left eye: 20/20
Visual Acuity	Right eye: 20/400
without Correction	Left eye: 20/400
Current Prescription	Right eye: sphere, -2.00; cylinder, -1.00; axis, 085
	Left eye: sphere, -2.00; cylinder, -1.00; axis, 087
Manifest Refraction	Right eye: sphere, -2.00; cylinder, -1.25; axis, 085; 20/20
	Left eye: sphere, -2.50; cylinder, -1.00; axis, 097; 20/20
Cycloplegic Refraction	Right eye: sphere, -2.00; cylinder, -1.25; axis, 085; 20/20
	Left eye: sphere, -2.25; cylinder, -0.75; axis, 097; 20/20
Manual Keratometry	Right eye: not recorded
	Left eye: not recorded
Simulated Keratometry	Right eye: 44.58@086; 44.17@176
	Left eye: 44.64@076; 44.11@166
Pachymetry	Right eye: not recorded
	Left eye: not recorded
Desired Correction	Right eye: sphere, -1.438; cylinder, -1.227; axis, 085
	Left eye: sphere, -1.79; cylinder, -0.75; axis, 097

Dr. Jain planned to correct her eyes for myopia and astigmatism. He quoted a price of \$978.00. Corneal topography was performed the following day. Dr. Jain noted no keratoconus. (St. Ex. 14A at 9, 20)

257. Dr. Jain performed LASIK surgery bilaterally on January 31, 2001. (St. Ex. 14A at 15-17) Dr. Blausey saw Patient 14 the following day. Patient 14’s visual acuity without correction

was 20/25 in the right eye and 20/25+1 in the left. Dr. Blausey prescribed Ocuflax and FML eye drops. (St. Ex. 14A at 14)

Three weeks later, Dr. Kumar saw Patient 14. Her visual acuity without correction was 20/20 bilaterally, and she was no longer using eye drops. Dr. Kumar noted that she was doing well and suggested that she return in one year or as needed. There are no additional visits recorded in the medical record. (St. Ex. 14A at 13)

258. On September 4, 2002, another local physician evaluated Patient 14. She complained of problems with distance vision, and difficulty seeing with glare at night. Visual acuity without correction was 20/40 in the right eye and 20/20 in the left eye. That physician prescribed eyeglasses. (St. Ex. 14B at 1a-3)

#### **Testimony of Dr. Gressel regarding Patient 14**

259. Dr. Gressel testified that Dr. Jain's care and treatment of Patient 14 had fallen below the minimal standards of care for the following reasons:

- a. Dr. Jain failed to measure corneal pachymetry preoperatively, which placed Patient 14 at an unacceptable risk of postoperative ectasia. (Tr. at 1065-1066, 1359-1360; St. Ex. 25)
- b. Dr. Jain failed to measure keratometry prior to LASIK. Dr. Gressel reiterated his earlier testimony that the importance of keratometry lies in the fact that any future cataract surgery would entail a need for keratometry measurements taken prior to LASIK to facilitate the proper selection of intraocular lens implant power. (Tr. at 1065-1066, 1359-1360; St. Ex. 25)
- c. There is no documentation that Dr. Jain examined Patient 14 postoperatively. (Tr. at 1065-1066, 1361-1363; St. Ex. 25)

#### **Testimony of Dr. Jain regarding Patient 14**

260. Dr. Jain testified that, in 2001, the standard of care did not require preoperative pachymetry if the desired correction was less than 7 diopters. Dr. Jain acknowledged that, since 2002, the standard of care has required preoperative pachymetry for all LASIK patients. (Tr. at 366-368)

261. Dr. Jain continued to maintain that manual keratometry is not mandated by the standard of care. Nevertheless, Dr. Jain testified that manual keratometry would be required if simulated keratometry readings were not available. (Tr. at 368-371, 1499)

262. Dr. Jain acknowledged that, postoperatively, Patient 14 had been seen only by optometrists at the Bloomberg Eye Center. (Tr. at 371-372)

**Patient 15**

**Medical Records for Patient 15**

263. Patient 15, a 51-year-old male, presented to the Bloomberg Eye Center on April 29, 2002. Patient 15 complained of having had a film over his left eye for the past month, and difficulty reading fine print. Examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/200
without Correction	Left eye: 20/40=
Visual Acuity	Right eye: 20/40=
Pinhole	Left eye: 20/30=
Visual Acuity	Right eye: 20/J400
NVA	Left eye: 20/J200
Manifest Refraction	Right eye: sphere, +3.00; cylinder, -1.75; axis, 170; 20/40
	Left eye: sphere, +0.25; cylinder, -0.75; axis, 163; 20/40+
Simulated Keratometry	Right eye: 43.87@170; 45.25@080
	Left eye: 43.66@170; 44.75@080
Intraocular Pressure	Right eye: 13 mmHg
	Left eye: 15 mmHg
Glare	Right eye: 20/200
	Left eye: 20/400-

Dr. Jain noted "G.S. (D.A.)," a 2+ nuclear sclerotic cataract in the right eye and a 3+ posterior subcapsular cataract in the left eye. He also noted amblyopia of the right eye. The optic disc and retina were unremarkable. Dr. Jain scheduled Patient 15 for cataract extraction with intraocular lens implant for the left eye. The intraocular lens choices available for the left eye were the Amo model in a 21.00-diopter strength, a Staar model in a 22.50-diopter strength, or a Chiron model in a 23.00-diopter strength, with the plan of achieving a postoperative refraction of plano. Dr. Jain also noted that he would perform a GDx examination, a nerve fiber analysis used to test for glaucoma, on the day of surgery. (St. Ex. 15 at 65, 66, 68)

264. On May 1, 2002, Dr. Jain performed a phacoemulsification of the cataract with an intraocular lens implantation on Patient 15's left eye. He also performed a GDx nerve fiber analysis, and noted that it was negative. (St. Ex. 15 at 4, 27a-37, 63-64)

265. Dr. Jain saw Patient 15 the following day. Patient 15 complained of blurred vision and the sensation of a foreign body in his left eye. Examination of his eyes revealed the following:

Visual Acuity	Right eye: not recorded
without Correction	Left eye: 20/70
Visual Acuity	Right eye: not recorded
Pinhole	Left eye: 20/40

Pachymetry	Right eye: 575 Left eye: 614
Intraocular Pressure	Right eye: 13 mmHg Left eye: 14 mmHg

Dr. Jain noted that he had found a cortical remnant in the left eye, which he deemed to be secondary to open angle glaucoma. (St. Ex. 15 at 62)

That same day, Dr. Jain performed an anterior chamber paracentesis for the left eye. He listed diagnoses of secondary glaucoma and increased intraocular pressure. Nevertheless, there is no clinical indication of increased ocular pressure anywhere in the record. (St. Ex. 15 at 61)

266. On May 9, 2002, Patient 9 complained that his vision remained blurry and that he had difficulty seeing the television. Examination of his eyes revealed the following:

Visual Acuity without Correction	Right eye: 20/200 Left eye: 20/80
Visual Acuity Pinhole	Right eye: not recorded Left eye: 20/40
Manifest Refraction	Right eye: not recorded Left eye: sphere, -1.75; cylinder, -1.00; axis, 175; 20/20
Pachymetry	Right eye: 578 Left eye: 592
Intraocular Pressure	Right eye: 18 mmHg Left eye: 17 mmHg

Dr. Jain planned to perform cataract surgery with an intraocular lens implant in the right eye. The intraocular lens choices were noted to be an Amo model in a 20.00-diopter strength, a Starr model in a 21.50-diopter strength, or a Chiron model implant in a 22.00-diopter strength, with the desired postoperative refraction of "emmetropia." Dr. Jain did not mention his previous diagnosis of amblyopia in the right eye. (St. Ex. 15 at 59, 60)

267. Dr. Jain performed a phacoemulsification of the cataract with an intraocular lens implantation in Patient 15's right eye on May 22, 2002. (St. Ex. 15 at 16-22, 56, 57)
268. The following day, Patient 15 complained of having a film over his right eye. Examination of his eyes revealed the following:

Visual Acuity without Correction	Right eye: 20/50 Left eye: 20/50+
Visual Acuity Pinhole	Right eye: 20/25 Left eye: 20/25+
Manifest Refraction	Right eye: sphere, +1.50; cylinder, -1.50; axis, 172; 20/30 Left eye: sphere, -1.50; cylinder, -0.50; axis, 175; 20/20

Pachymetry	Right eye: 596 Left eye: 595
Intraocular Pressure	Right eye: 19 mmHg Left eye: 16 mmHg

Dr. Jain noted trace stromal edema in the right eye. (St. Ex. 15 at 55)

269. On June 6, 2002, Patient 15 stated that he was disappointed that he was unable to see distance and complained that his vision was still blurry. He also stated that he had believed that he had been going to have LASIK on his right eye rather than cataract surgery. Examination of his eyes revealed the following:

Visual Acuity without Correction	Right eye: 20/60 Left eye: 20/70
Manifest Refraction	Right eye: sphere, +1.50; cylinder, -1.00; axis, 175; 20/50 Left eye: sphere, -1.25; cylinder, -1.25; axis, 180; 20/25
Pachymetry	Right eye: 598 Left eye: 591
Intraocular Pressure	Right eye: 14 mmHg Left eye: 18 mmHg

Dr. Jain noted early posterior capsule opacity [PCO], or clouding of the capsule behind the implants. The PCO was +½ in the right eye and +1 in the left. (St. Ex. 15 at 53)

270. On July 3, 2002, Patient 15 contacted the Bloomberg Eye Center by telephone. Dr. Blausey documented the conversation as follows:

[Patient 15] was concerned about the cost of LASIK. He notes he was told he would see near and distance [after the intraocular lens implant]. He wished to have mono[vision] with [the right eye seeing near and the left eye seeing distance]. I explained LASIK was an option better than [intraocular lens] exchange. He wishes for LASIK without additional charge as he feels it is an inclusive cost with the [intraocular lens] surgery. He has been given an appointment with [Dr. Jain] to discuss options and finances.

(St. Ex. 15 at 51)

271. Dr. Jain saw Patient 15 on July 9, 2002. Examination of his eyes provided the following:

Visual Acuity without Correction	Right eye: 20/50 Left eye: 20/70
Visual Acuity Pinhole	Right eye: 20/40 Left eye: 20/30

Manifest Refraction	Right eye: sphere, +1.00; cylinder, -0.50; axis, 155; 20/40
	Left eye: sphere, -2.50; cylinder, -0.50; axis, 170; 20/30
Pachymetry	Right eye: 583
	Left eye: 598

Dr. Jain noted early PCO +1 bilaterally. He scheduled Patient 15 for LASIK with a plan to correct the right eye for near vision with the Visx laser and the left eye for distance with the Nidek laser. (St. Ex. 15 at 48, 53)

272. On a "LASIK Patient Scheduling" sheet dated July 9, 2002, the following was recorded:

Manifest Refraction	Right eye: sphere, +1.00; cylinder, -0.75; axis, 160; 20/40+2
	Left eye: sphere, -1.00; cylinder, -0.50; axis, 178; 20/20-3
Desired Correction	Right eye: sphere, +3.25; cylinder, -0.75; axis, 160
	Left eye: sphere, -0.60; cylinder, -0.50; axis, 174

In addition, "K's" are noted to be 44.56 for the right eye and 44.20 for the left eye. Dr. Jain noted that the LASIK procedure would be performed free of cost. (St. Ex. 15 at 48)

273. On August 19, 2002, Patient 15 called the office to state that he would not pay his bill until he was happy with his visual acuity. He also stated that Dr. Jain did not spend enough time with him, and repeated his earlier allegation that he had been told that he would be able to see near and far without glasses. (St. Ex. 15 at 47)

274. Dr. Jain performed LASIK surgery on September 17, 2002. The Visx laser printout for the right eye states, "This treatment exceeds the limits approved for refractive use." (St. Ex. 15 at 43-46)

275. Dr. Blausey saw Patient 15 on September 18 and October 10, 2002. Evaluation of Patient 15's eyes revealed the following:

Visual Acuity	Right eye: 20/60
without Correction	Left eye: 20/30
Manifest Refraction	Right eye: sphere, +0.25; cylinder, -0.50; axis, 155; 20/30
	Left eye: sphere, -0.75; cylinder, -0.30; axis, 135; 20/20

(St. Ex. 15 at 42)

276. Dr. Blausey saw Patient 15 again on November 19, 2002. Patient 15 complained that his vision was "bad up close and far away." Corneal topography was performed on November 19, 2002. Evaluation of Patient 15's eyes revealed the following:

Visual Acuity	Right eye: 20/40
without Correction	Left eye: 20/30-1

Manifest Refraction	Right eye: sphere, +0.75; cylinder, -0.75; axis, 180; 20/40+
	Left eye: sphere, -0.75; cylinder, -0.25; axis, 165; 20/25+2

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Dr. Blausey noted, “difficult refraction.” Corneal topography was performed that day. There are no additional visits in the record. Dr. Jain did not see Patient 15 at any time after the LASIK procedures. (St. Ex. 15 at 39)

### Testimony of Dr. Gressel regarding Patient 15

277. Dr. Gressel testified that Dr. Jain’s care and treatment of Patient 15 had fallen below the minimal standards of care for the following reasons:

- a. On May 1, 2002, Dr. Jain performed a GDx examination, employing a device that measures the thickness of the retinal nerve fiber layer used for the diagnosis of glaucoma, despite the absence of any documentation of the risk factors associated with glaucoma, optic nerve disorder, or retinal disorder. Dr. Gressel suggested that Dr. Jain had ordered the test as a means to enrich himself rather than to serve the patient’s interests. Dr. Gressel concluded that, in this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, section B10. (Tr. at 1066-1071, 1371-1372; St. Ex. 25)

Dr. Gressel testified that disk asymmetry might be a reason to order a GDx examination. He added, however, that in this case Dr. Jain had described the cup to disk ratio as being 0.3 in both eyes which is an indication of symmetry rather than asymmetry. Dr. Gressel noted that patients who develop glaucoma generally develop asymmetry of the optic nerves. (Tr. at 1070-1071, 1374-1376)

In reviewing the image from the GDx, Dr. Gressel noted:

My impression from this is that both optic nerves were smaller than average in diameter and had correspondingly small cups. The retinal nerve fiber layer analysis contained on the far right side of the images shows that there is a very slightly \* \* \* thicker inferior retinal nerve fiber layer in the left eye compared to the right. It’s a relatively small degree of asymmetry. The nerve fiber analysis at the bottom of the page shows several of their indices that are slightly unusual from a statistical standpoint, but nothing that is extremely strongly suggestive of glaucoma.

(Tr. at 1372-1373) Dr. Gressel concluded that there was minimal asymmetry in the nerve fiber layer thickness between the two eyes. (Tr. at 1373)

- b. Dr. Jain failed to adequately inform Patient 15 that, due the significant astigmatism present in the left eye, cataract surgery in the left eye would not provide satisfactory unaided vision. Dr. Gressel concluded that, in this regard, Dr. Jain had violated the

Code of Ethics of the American Academy of Ophthalmology, Section A7.  
(Tr. at 1066-1069; St. Ex. 25)

- c. When performing cataract surgery in the left eye, Dr. Jain chose an intraocular lens model that was not intended for correction of astigmatism. Dr. Gressel testified that, by choosing a lens that could not correct astigmatism in Patient 15's left eye, Dr. Jain would have had to perform an astigmatic keratotomy to ensure good vision postoperatively. Instead, postoperatively, the left eye exhibited compound myopic astigmatism, with a spherical equivalent -2.75, which was quite different from Dr. Jain's stated goal of "plano." (Tr. at 1066-1069, 1081-1082, 1384-1385, 1388; St. Ex. 25)
- d. Dr. Jain inappropriately diagnosed glaucoma when, one day after the left-eye cataract surgery, Patient 15's left eye exhibited a cortical remnant in the anterior chamber. Dr. Jain repeated the diagnosis of glaucoma in his operative note for anterior chamber paracentesis. Dr. Gressel opined that the diagnosis of glaucoma had been inappropriate because there was no evidence of inflammation, there was no intraocular pressure elevation, and the cortical remnant was "quite small." Therefore, there had been no evidence of glaucoma. (Tr. at 1066-1069; St. Ex. 25)
- e. Dr. Jain performed unnecessary surgery by executing an anterior chamber paracentesis on Patient 15's left eye for a diagnosis of secondary glaucoma. Dr. Gressel testified that anterior chamber paracentesis is an appropriate treatment for glaucoma, as it removes fluid from the anterior chamber. Dr. Gressel further noted, however, that, in this case, there had been no evidence of intraocular pressure elevation or evidence of an unusual anterior chamber inflammation to represent indications for that procedure. He noted that the intraocular pressure in the left eye had been 14, which is lower than the average of 15½. Dr. Gressel concluded that, in this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section B6. (Tr. at 1066-1069, 1075-1076; St. Ex. 25)

Dr. Gressel acknowledged that anterior chamber paracentesis can be used to remove cortical remnants. He stated that cortical remnants are pieces of cataract tissue trapped behind the iris during phacoemulsification of the cataract, which, after surgery, appear in the anterior chamber. He stated that removing the cortical remnant with anterior chamber paracentesis is appropriate if the cortical remnant is causing elevation of intraocular pressure, corneal edema, or intraocular inflammation, or if the cortical remnant is extremely large. Dr. Gressel noted that none of these conditions had been documented in Patient 15's record. (1076-1077, 1368)

- f. Instead of addressing the compound myopic astigmatism evident in the left eye, Dr. Jain proposed to remove the cataract from Patient 15's right eye, making no reference to his prior diagnosis of amblyopia of the right eye. In doing so, Dr. Jain failed to record any evidence that Patient 15 had been compromised by the vision in the right eye. (Tr. at 1066-1069, 1377-1378; St. Ex. 25)

Dr. Gressel explained that amblyopia is “an eye-and-brain condition that can only develop during childhood and can only be successfully treated during childhood, whereby the part of the brain responsible for recognizing vision coming from the eye \* \* \* never fully develops.” (Tr. at 1071-1072)

- g. Dr. Jain performed unnecessary surgery by removing the cataract from the right eye without evidence that the right eye’s cataract had any appreciable effect on Patient 15’s quality of life. Dr. Gressel concluded that, in this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section B6. (Tr. at 1066-1069; St. Ex. 25)

Dr. Gressel was referred to the results of the glare test performed on April 29, 2002, which revealed right eye visual acuity of 20/200 and left eye visual acuity of 20/400. He was also referred to Patient 15’s complaints of difficulty driving during the daytime, driving at night, and driving towards the sun or oncoming headlights. When asked if these problems would indicate that the cataract in the right eye had substantially diminished Patient 15’s vision, Dr. Gressel testified that he would attribute those problems to the condition of the left eye. Dr. Gressel explained that a posterior subcapsular cataract, as found in the left eye, creates significantly more visual impairment than a nuclear sclerotic cataract, as found in the right eye. Moreover, the type of cataract found in the left eye is much more likely to cause glare disability than the type of cataract in the right eye. Dr. Gressel noted that Dr. Jain could have tested to evaluate the impact of the right eye’s cataract by performing a second glare test after the left eye cataract had been removed, but had failed to do so. (Tr. at 1364-1371)

- h. Dr. Jain failed to adequately counsel Patient 15 about realistic expectations for visual results after surgery on an amblyopic eye. (Tr. at 1066-1069, 1081; St. Ex. 25)
- i. When performing cataract surgery on the right eye, Dr. Jain entered the plan of selecting an intraocular lens implant of such power to “aim for emmetropia.” Nevertheless, Dr. Jain chose a model of intraocular lens implant which was incapable of correcting the 1.75 diopters of astigmatism that had been present in that eye. Dr. Gressel testified that, in order to ensure good vision, the astigmatism would have had to be corrected with astigmatic keratotomy, which was not done. He noted that Patient 15’s right eye had been left with a compound hyperopic astigmatism, with a spherical equivalent of +0.75. (Tr. at 1066-1069, 1078, 1081-1082, 1388; St. Ex. 25)
- j. Dr. Jain failed to perform potential acuity meter testing [PAM] prior to surgery for removal of the right-eye cataract. Dr. Gressel testified that potential acuity meter testing helps to predict what kind of vision a patient will have after removal of the cataract. He stated that it would have been imperative to perform this test in the right eye due to the amblyopia, because it is important to know how much of the visual

- abnormality is due to the cataract versus how much is due to the amblyopia. (Tr. at 1066-1069, 1079-1080; St. Ex. 25)
- k. Dr. Jain failed to perform corneal topography prior to the LASIK surgery. Dr. Gressel testified that this failure placed Patient 15 at unconscionable and preventable risk of developing corneal ectasia and other unsatisfactory visual conditions after LASIK. (Tr. at 1066-1069; St. Ex. 25)
  - l. Dr. Jain performed an inappropriate LASIK operation on the left eye. Dr. Gressel testified that, because of the amblyopic condition of the right eye, Patient 15 would not have had a reasonable expectation of reliance on the right eye if the left eye had developed a complication as a result of LASIK. Dr. Gressel concluded that, in this regard, Dr. Jain had violated the Code of Ethics of the American Academy of Ophthalmology, Section A7. (Tr. at 1066-1069, 1366-1367; St. Ex. 25)
  - m. Prior to surgery, Dr. Jain failed to counsel and/or document the counseling of Patient 15 as to realistic expectations for visual results after surgery on an amblyopic eye. (Tr. at 1066-1069, 1377-1379; St. Ex. 25)
  - n. During the LASIK procedure, Dr. Jain incorrectly entered an erroneous astigmatism axis. Dr. Gressel explained that the refraction performed on July 2, 2002, had revealed an axis with the refraction of 178 degrees, where a second refraction performed on July 9, 2002, had revealed an axis with the refraction of 170 degrees. Dr. Gressel testified that these are remarkably different, particularly in the spherical component. He concluded that the magnitude of difference between the refractions suggests a less-than-competent performance of one of the refractions. In addition, Dr. Gressel noted that Dr. Jain had entered an axis of 174 degrees when he programmed the laser for the LASIK procedure, which further suggests that Dr. Jain made an error when he programmed the laser. Dr. Gressel rejected the notion that Dr. Jain had simply taken the average astigmatism axes of the two refractions because he had not done so regarding discrepancies in other aspects of the two refractions. Dr. Gressel concluded that this was a sloppy practice that has the potential to harm patients and, in many of these cases, did harm patients. (Tr. at 1066-1069, 1090-1093, 1379-1385; St. Ex. 25)
  - o. Dr. Jain performed LASIK in the right eye in an incompetent fashion when he used a hyperopic ablation zone diameter different from that found to give optimal results by the manufacturer. Dr. Gressel testified that Dr. Jain had specified a smaller diameter (8 mm) for the outer limit of the ablation pattern than recommended by the manufacturer (9 mm). Moreover, the Visx laser printout had stated, "This treatment exceeds the limits approved for refractive use." Dr. Gressel testified that Dr. Jain had documented no competent reason for reducing the hyperopic ablation zone. Moreover, postoperative topography showed a substantial inferior decentration of the laser treatment in the right eye. (Tr. at 1066-1069, 1087-1090, 1387; St. Ex. 25)

Dr. Gressel further testified that one might justifiably use a smaller diameter for the outer limit of the ablation zone is when a patient needs a very small flap due to having a very flat cornea. Dr. Gressel noted that Patient 15 did not have an unusually flat cornea. Another reason to use a smaller diameter for the outer limit of the ablation zone would be if the patient had a smaller than average cornea. However, there is no indication in this record that Patient 15 had a smaller than average cornea. Dr. Gressel acknowledged that the axial length of the eye is a little bit shorter than average but stated that axial length does not have a bearing on ablation diameter. Finally, Dr. Gressel testified that there is nothing in the medical record to indicate that Patient 15 had had a smaller than average eye. (Tr. at 1088-1090, 1385-1387)

### **Testimony of Dr. Jain regarding Patient 15**

278. Dr. Jain testified that he had been justified in ordering a GDx examination for Patient 15 because he had documented a suspicion of glaucoma with the notation of, “G.S.,” on Patient 15’s first visit. Moreover, Dr. Jain testified that the GDx examination had been warranted because Dr. Jain had found disk asymmetry as indicated by the diagrams on page 68 of the medical record. [Note, however, that the images drawn by Dr. Jain on page 68 of the medical record do not appear to be significantly asymmetrical.] Dr. Jain concluded that his ordering of the GDx examination had been consistent with the minimal standards of care. (Tr. at 376-380, 1633-1635, 1764-1765)

Regarding Dr. Gressel’s criticism for ordering the GDx examination, Dr. Jain testified that the criticism was “in the general vein of Dr. Gressel’s hypercritical comments. Here, instead of faulting me for not doing enough testing, he’s accused me of committing fraud for doing testing.” (Tr. at 1634-1635)

279. Dr. Jain testified that he had appropriately performed anterior chamber paracentesis. He explained that paracentesis is a simple, quick procedure used to remove a cortical remnant. He stated that, by removing the aqueous humor, the cortical remnant easily passes out of the eye. Dr. Jain did not address the fact that the medical record indicates that he had performed this procedure for a diagnosis of glaucoma and not for the removal of a cortical remnant. (Tr. at 385-386, 1632-1633)

280. Dr. Jain testified that, prior to removing the cataract from the right eye, he had ascertained that Patient 15’s vision would improve by removing the cataract. Dr. Jain testified that, in making that determination, he had relied on the glare test, Patient 15’s visual function status, the finding of a nuclear sclerotic cataract, and a finding of medial opacity due to the aging cataract. Dr. Jain concluded that his removal of the cataract from the right eye had been within the minimal standards of care and that Patient 15 had significantly improved as result of that surgery. (Tr. at 390-391, 1632)

281. Dr. Jain testified that he had provided adequate preoperative counseling to Patient 15 regarding the potential effect of removing the cataract from his right, amblyopic eye. (Tr. at 1631-1632)
282. Dr. Jain testified that he had done sufficient testing prior to performing LASIK. He noted that he had obtained manual keratometry in preparation for the cataract surgery and, on another occasion, he had performed postoperative corneal pachymetry. Therefore, Dr. Jain concluded, his preoperative testing had been within the minimal standards of care. (Tr. at 6035-1637)
283. Dr. Jain testified that he had counseled Patient 15 regarding the risks of operating on the left eye in light of the amblyopia in the right eye. Dr. Jain noted, however, that the amblyopia in the right eye had been minimal. Moreover, Dr. Jain testified that, if the patient understands the risks and benefits and chooses nonetheless to have surgery, it is reasonable for a surgeon to proceed with a procedure. Dr. Jain concluded that he had complied with the minimal standards of care in this regard. (Tr. at 6031-1632, 1639-1640)
284. Initially, Dr. Jain acknowledged that he had made an error in programming the astigmatism angle in the left eye of Patient 15. Later, however, Dr. Jain testified that he had not made an error but, instead, had intentionally picked an axis of 174 because it was the average of the two axes determined by refraction, 170 and 178. Dr. Jain also acknowledged that there had also been a significant disparity between the refractions, one that was -2.50 and another that was -0.50. Nevertheless, Dr. Jain testified that he had been aware that one of the refractionists employed at Bloomberg Eye Center tended to be less than accurate; therefore, Dr. Jain had chosen the refraction of the refractionist who was more likely to be accurate. (Tr. at 392-395, 1637-1638)
285. Dr. Jain testified that he had used a smaller hyperopic ablation zone because Patient 15's eye had been smaller than normal, which had required that he use a smaller ring. Dr. Jain testified that the manufacturer had designed the machine to be capable of adjusting to smaller eye sizes. When asked if he had documented that Patient 15 had had eyes smaller than average, Dr. Jain testified that he had documented that Patient 15's eye had had a relatively small axial length; therefore, one could conclude that his eye had been smaller than average. Dr. Jain concluded that his off-label use of a smaller-than-usual hyperopic ablation zone diameter had been consistent with the minimal standards of care. (Tr. at 396-400, 1640-1642)

### ***Patient 16***

#### **Medical Records for Patient 16**

286. On July 17, 2000, Patient 16, a 46-year-old female, presented to the Bloomberg Eye Center, stating she wished to see without eyeglasses or contact lenses. Examination of her eyes revealed the following:

Visual Acuity with Correction	Right eye: 20/20+ Left eye: 20/20+
Visual Acuity without Correction	Right eye: 20/FC Left eye: 20/FC
Current Prescription	Right eye: sphere, -4.50; cylinder, -2.00; axis, 010 Left eye: sphere, -4.75; cylinder, -2.00; axis, 170
Manifest Refraction	Right eye: sphere, -4.50; cylinder, -2.00; axis, 010; 20/20 Left eye: sphere, -4.75; cylinder, -2.00; axis, 170; 20/20
Cycloplegic Refraction	Right eye: sphere, -4.00; cylinder, -2.25; axis, 180; 20/20 Left eye: sphere, -3.50; cylinder, -2.25; axis, 170; 20/20
Desired Correction	Right eye: sphere, -3.90; cylinder, -2.25; axis, 180 Left eye: sphere, -4.00; cylinder, -2.25; axis, 170
Intraocular Pressure	Right eye: 16 mmHg Left eye: 18 mmHg

Dr. Jain noted that she would be excellent candidate for bilateral LASIK, and planned to correct both eyes for distance. He quoted a price of \$1198.00. Corneal topography was performed; Dr. Jain noted no keratoconus. Dr. Jain did not perform corneal pachymetry or keratometry. (St. Ex. 16 at 5, 22-25)

287. Dr. Jain performed bilateral LASIK on September 5, 2000. Dr. Blausey saw her the following day. (St. Ex. 16 at 19-21; Tr. at 405-406)

288. Dr. Jain saw Patient 16 on September 22, 2000. Examination of her eyes revealed the following:

Visual Acuity without Correction	Right eye: 20/30 Left eye: 20/70
Visual Acuity pinhole	Right eye: not recorded Left eye: 20/40
Manifest Refraction	Right eye: sphere, +1.25; cylinder, -0.50; axis, 165; 20/30 Left eye: sphere, +1.75; 20/40

Dr. Jain noted, "Slightly overcorrected. Doing well!" He prescribed pilocarpine 1% in both eyes and instructed her to return in six months. (St. Ex. 16 at 18)

289. Patient 16 returned on March 22, 2001, and saw Dr. Blausey. Examination of her eyes revealed the following:

Visual Acuity without Correction	Right eye: 20/25-2 Left eye: 20/40
Visual Acuity pinhole	Right eye: not recorded Left eye: 20/25+3

Manifest Refraction	Right eye: sphere, +0.25; cylinder, -0.50; axis, 013; 20/20
	Left eye: sphere, +1.25; cylinder, -0.25; axis, 010; 20/20

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Dr. Blausey noted an overcorrection of the left eye and suggested an enhancement.  
(St. Ex. 16 at 17)

290. Dr. Jain saw Patient 16 on September 20, 2001. Patient 16 stated that there had been no change in her visual acuity. Examination of her eyes revealed the following:

Visual Acuity	Right eye: 20/40
without Correction	Left eye: 20/50
Visual Acuity	Right eye: 20/30
pinhole	Left eye: 20/30
Manifest Refraction	Right eye: sphere, +0.50; cylinder, -1.00; axis, 010; 20/30-
	Left eye: sphere, +1.25; cylinder, -0.25; axis, 105; 20/25-2
Pachymetry	Right eye: 549
	Left eye: 550

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Dr. Jain planned an astigmatic keratotomy for the right eye and an enhancement for the left eye. He quoted a price of \$110.00 per eye. Corneal topography was performed. Nevertheless, Patient 16 did not return. (St. Ex. 16 at 4, 15-16)

### **Testimony of Dr. Gressel regarding Patient 16**

291. Dr. Gressel testified that Dr. Jain's care and treatment of Patient 16 had fallen below the minimal standards of care for the following reasons:
- Dr. Jain failed to do appropriate testing when he performed LASIK. Dr. Jain did not obtain corneal pachymetry, thus placing Patient 16 at an unconscionable and preventable risk of developing corneal ectasia after LASIK. (Tr. at 1094-1095; St. Ex. 25)
  - Dr. Jain failed to perform keratometry prior to LASIK. Dr. Gressel stated that failure to perform keratometry prior to surgery leaves any surgeon who may need to remove cataracts from Patient 16 in the future with the less accurate simulated keratometry values derived from topography as a basis for attempting to select the correct intraocular lens power. (Tr. at 1094-1095; St. Ex. 25)
  - On July 5, 2000, Dr. Jain performed LASIK for compound myopic astigmatism on both eyes of Patient 16. Dr. Gressel testified that, during the procedure, Dr. Jain had caused an overcorrection in Patient 16's left eye by inappropriately programming into the laser an excessive correction for the myopic sphere. (Tr. at 1094-1096; St. Ex. 25) Dr. Gressel stated that he had reached this conclusion as follows:

I used the information under “MYD Refraction” (cycloplegic refraction) in the left eye on page 25 in conjunction with my nomograms for the Visx laser and found that Dr. Jain had designated the left eye for 30% more correction of myopic sphere than I would have then or would now. In my opinion, this is too large a discrepancy to explain on the basis of differences between our lasers or operating environments. Moreover, such an attempted explanation would fail to account for Dr. Jain’s decision to program **more** myopic sphere for the left eye than contained in the cycloplegic refraction, yet program **less** myopic sphere for the right than contained in the cycloplegic refraction. \* \* \* As a result, it is no surprise to me that the left eye ended up with a greater overcorrection than the right, despite the stated goal of correcting ‘both eyes for distance.’

(St. Ex. 25) (emphasis in original) He concluded that Dr. Jain had made an error in programming the laser for the left eye that had caused the overcorrection.  
(Tr. at 1097-1098) Dr. Gressel added:

I would go further and say that the use of a VISX laser to correct the myopic sphere in a LASIK procedure generally requires that you reduce the amount of spherical myopia treatment compared to what’s in the cycloplegic refraction in order to get the desired result. And it is inexplicable to me, based upon that knowledge, that as much as four diopters of myopic sphere correction would have been programmed into the left eye.

(Tr. at 1391-1392)

When asked if it would have been reasonable for Dr. Jain to “split the difference” between the cycloplegic refraction and the manifest refraction, Dr. Gressel testified that splitting the difference would have predisposed the patient to an overcorrection. He stated that the main reason one performs cycloplegic refraction is to eliminate the unintended participation of the focusing muscle of the eye while doing the refraction. He explained that, when the patient uses the focusing muscle of the eye during the refraction, there will be more myopia than truly exists. Dr. Gressel stated that, in this case, the left eye had been accommodating significantly during the manifest refraction. This was the reason that there was so much difference between the manifest refraction and the cycloplegic refraction in the left eye. For that reason, it is imperative that surgeons not rely on the manifest refraction in planning the laser treatment. Finally, Dr. Gressel testified that, despite the improvement in Patient 16’s vision, Dr. Jain’s notation of, “Doing well,” had not been appropriate under the circumstances. (Tr. at 1098-1100, 1390-1393)

- d. Dr. Jain inappropriately prescribed pilocarpine eyedrops for treatment of hyperopia. Dr. Gressel reiterated his earlier testimony that pilocarpine is an inappropriate

medicine to use in a recent postoperative eye in general, and to use for the treatment of an overcorrection after laser vision correction in particular. He explained that it tends to cause brow ache and dimming of vision. Finally, Dr. Gressel testified that pilocarpine would not be expected to cause any lasting effects or improvement upon the refractive state of the eye that would remain after the medication had been discontinued. He concluded that the use of pilocarpine had not been an appropriate approach for managing this situation. (Tr. at 1100, 1394)

### **Testimony of Dr. Jain regarding Patient 16**

292. Dr. Jain testified that, when programming the laser for the left eye, he had split the difference between the cycloplegic and manifest refractions, erring towards overcorrection. He stated that Patient 16's manifest refraction had been: sphere 4.75, cylinder -2.00, and axis 170; while her cycloplegic refraction had been: sphere -3.50, cylinder -2.25, and axis 170. Later, he clarified that he had not "literally split the average," but had erred one-quarter diopter towards overcorrection rather than under correction, which, he stated, is prudent in myopia. Dr. Jain further testified that this case had occurred early in his LASIK career. He explained that the Visx system had been relatively new. Moreover, he had been "still working out some of the nomogram issues," which had required "a little bit of trial and error." Finally, Dr. Jain testified that one must realize that an enhancement is part of the system. He concluded that his programming of the laser had been consistent with the standards of care. (Tr. at 403-404, 1642-1646)
293. Dr. Jain testified that the use of pilocarpine in a postoperative patient is not contraindicated. Dr. Jain concluded that his use of pilocarpine had met the standards of care. (Tr. at 408, 1646-1647)

### ***Patient 17***

#### **Medical Records for Patient 17**

294. Patient 17, a 52-year-old female, presented to the Bloomberg Eye Center for LASIK evaluation on March 30, 2002. Patient 17 reported that she had tried monovision with soft contact lenses but had not liked it. Evaluation of her eyes revealed the following:

Visual Acuity	Right eye: 20/20
with Correction	Left eye: 20/20
Visual Acuity	Right eye: 20/40
without Correction	Left eye: 20/40
Current Prescription	Right eye: sphere, +1.00; cylinder, -1.00; axis, 090
	Left eye: sphere, +1.00; cylinder, -0.75; axis, 083
Manifest Refraction	Right eye: sphere, +1.50; cylinder, -1.00; axis, 077; 20/20
	Left eye: sphere, +1.50; cylinder, -0.75; axis, 085; 20/20
Cycloplegic Refraction	Right eye: sphere, +1.25; cylinder, -1.00; axis, 080; 20/20+3
	Left eye: sphere, +1.00; cylinder, -0.75; axis, 085; 20/20

Automated Keratometry	Right eye: 42.75@106; 43.25@016 Left eye: 43.00@086; 43.50@176
Pachymetry	Right eye: 655 Left eye: 588
Desired Correction	Right eye: sphere, +2.67; cylinder, -1.00; axis, 077 Left eye: sphere, +2.57; cylinder, -0.75; axis, 085
Intraocular Pressure	Right eye: 12 mmHg Left eye: 12 mmHg

Dr. Jain noted that he planned to correct for myopia and astigmatism. Corneal topography was not performed. A price was quoted of \$1,598.00, and Patient 17 accepted the Lifetime Assurance Plan for \$69.00 per eye. (St. Ex. 17A at 52, 55, 56)

295. Dr. Jain performed LASIK on April 16, 2002. He did not record the microkeratomes or the settings used. (St. Ex. 17A at 47-48)
296. Dr. Jain saw Patient 17 the following day. Patient 17 complained that her vision was blurred. Visual acuity without correction was 20/70-1 in the right eye and 20/200 in the left. Dr. Jain advised her to return in eight weeks. (St. Ex. 17A at 54)
297. On April 25, 2002, Dr. Blausey saw Patient 17. Patient 17 complained of having had blurred vision and severe headaches since surgery. Examination of her eyes revealed the following:

Visual Acuity	Right eye: 20/50=
without Correction	Left eye: 20/200=
Manifest Refraction	Right eye: sphere, -1.00; cylinder, -0.25; axis, 134; 20/25 Left eye: sphere, -1.50; cylinder, -0.25; axis, 046; 20/25

Dr. Blausey prescribed contact lenses. One month later, he changed the prescription of her contact lenses. Corneal topography was performed on June 1, 2002. On July 20, 2002, Dr. Blausey noted debris in both eyes and “stable overcorrection.” (St. Ex. 17A at 11, 42, 53)

298. Dr. Jain performed enhancement surgery on the right eye on September 3, 2002. He did not perform topography, keratometry, or pachymetry prior to the enhancement surgery. Corneal topography was performed the following day. Dr. Jain instructed Patient 17 to return in 12 weeks. (St. Ex. 17A at 34-36, 39)
299. Patient 17 was seen at a Wal-Mart Vision Center on October 15, 2002. She complained of throbbing in her left eye and feeling as if it had been on fire for several days. She also complained of blurred vision and redness. She was diagnosed with mild iritis and treated with FML eye drops. (St. Ex. 17A at 32)

300. On November 18, 2002, Dr. Shahinfar performed an enhancement of Patient 17's left eye. Dr. Blausey saw Patient 17 the same day, although it is not clear whether he saw her before or after the surgery. Examination of her eyes revealed the following:

Visual Acuity	Right eye: 20/25	
without Correction	Left eye: 20/60	
Manifest Refraction	Right eye: sphere, -0.50;	20/20
	Left eye: sphere, -0.75; cylinder, -0.75; axis, 055	
Desired Correction	Right eye: none	
	Left eye: sphere, -0.50; cylinder, -0.60; axis, 055	

Haze was noted in the left eye. The plan was to correct the left eye for distance vision. Dr. Shahinfar performed the surgery at some point that day, but it is not clear whether the surgery occurred before or after the examination. Corneal topography was performed prior to the surgery. (St. Ex. 17A at 4, 25-28, 33)

301. Dr. Blausey examined Patient 17 on November 19 and December 9, 2002. Neither Dr. Jain nor Dr. Shahinfar saw Patient 17 after the enhancement. Her final visual acuity without correction was 20/30- in the right eye, and 20/30 in the left eye. On January 30, 2003, Patient 17 requested release of her medical records. (St. Ex. 17A at 22, 23)
302. Patient 17 was seen by another physician on January 31, 2003. Patient 17 complained of headaches and pressure behind both eyes, with the left being worse than the right. She also complained that her vision was "not very good," with the right being worse than the left. She added that she had to use eyeglasses for computer work and reading. Visual acuity without correction was 20/30+2 in both eyes. Manifest refraction for the right eye was: sphere, plano; cylinder, -0.50; axis, 010; visual acuity, 20/20. The examiner noted that there was a good result without loss of best spectacle-corrected visual acuity. (St. Ex. 17B at 5a-5b)

### **Testimony of Dr. Gressel regarding Patient 17**

303. Dr. Gressel testified that Dr. Jain's care and treatment of Patient 17 had fallen below the minimal standards of care for the following reasons:
- Dr. Jain failed to perform corneal topography prior to conducting LASIK in both eyes of Patient 17, and again prior to the enhancement procedure in the right eye. Dr. Gressel testified that this failure had put Patient 17 at increased risk of harm from surgery because there was inadequate assurance that there existed no corneal ectasia or predisposition to ectasia. Moreover, Dr. Gressel noted that preoperative pachymetry readings were 655 and 588, which he described as "substantially more asymmetry" than one normally finds. He stated that it was a possible indication of corneal dystrophy, which causes swelling of the cornea and which is a contraindication to LASIK. (Tr. at 1102-1103, 1108, 1397-1398; St. Ex. 25)

b. Dr. Jain did not record the type of microkeratome or the microkeratome settings utilized. (Tr. at 1102, 1104; St. Ex. 25)

304. No evidence was presented to support the allegation that Dr. Jain had departed from the standards of care when he programmed the laser with values different from the automated keratometry results obtained prior to surgery. (Tr. at 1104-1105)

### **Testimony of Dr. Jain regarding Patient 17**

305. Dr. Jain testified that preoperative corneal topography had not been necessary in this case because Patient 17 had had no evidence of ectasia. Moreover, her preoperative corneal measurements were normal. Automated keratometry had also been normal. She had a normal postoperative course and normal enhancements. Finally, Dr. Jain testified that her final outcome was good. Therefore, he concluded that his failure to obtain corneal topographies had not constituted violations of the standards of care. (Tr. at 416-422, 1647-1648)

### ***Patient 18***

#### **Medical Records for Patient 18**

306. Patient 18, a 68-year-old male, presented to the Bloomberg Eye Center on November 27, 2000. He reported that he had had a corneal transplant two years earlier which had not been successful and that he was still unable to see. He also stated that his left eye's vision was worsening, that his left eye was frequently irritated, and that he had to tilt his head to see. He also reported that he had had a recent episode of intraocular pressure, which had been treated with eye drops. Examination of Patient 18's eyes revealed the following:

Visual Acuity without Correction	Right eye: 20/20 Left eye: 20/200
Visual Acuity Pinhole	Right eye: not recorded Left eye: no improvement
Pachymetry	Right eye: 566 Left eye: 564
Intraocular Pressure	Right eye: 16 mmHg Left eye: 29 mmHg

Dr. Shahinfar noted an impression of corneal graft edema and possible graft failure. (St. Ex. 18 at 89-90) On November 30, 2000, a fluorescein angiography was performed. (St. Ex. 18 at 87)

307. Dr. Jain saw Patient 18 on December 15, 2000. Dr. Jain noted that Patient 18 had exhibited corneal edema and vitreous in the corneal wound of the left eye. In a letter to Dr. Shahinfar, Dr. Jain stated that Patient 18 had "some vitreous to the wound temporally at the graft host junction" and diffuse Descemet's membrane folds. Dr. Jain further stated

that he agreed with Dr. Shahinfar that the cornea, not the macula, was the primary limiting factor in Patient 18's vision. (St. Ex. 18 at 84-85)

Later that day, Dr. Jain performed a YAG vitreolysis to lyse the vitreous adhesion from the graft host interface. He noted that he planned to perform a penetrating keratoplasty soon thereafter. (St. Ex. 18 at 38, 83-85)

308. On December 27, 2000, Dr. Jain performed a penetrating keratoplasty [a corneal transplant]. The preoperative diagnosis was pseudophakic bullous keratopathy, or swelling in the eye, with anterior vitreous choroidal detachment in the left eye. The choroidal detachment was caused by hemorrhage, during which the interior contents of the eye protruded. Dr. Jain also performed an anterior vitrectomy, or removal of the anterior gel. During the course of the surgery, the previously implanted lens had to be removed, and Dr. Jain was unable to replace the lens. (St. Ex. 18 at 29-36b, 80-82; Tr. at 549-550, 1674)

The next day, Patient 18 complained of discomfort in his left eye. Dr. Blausey noted choroidal detachments with overlying retinal detachment. Dr. Blausey recommended a consult with Dr. Shahinfar to evaluate Patient 18 for retinal detachment. Intraocular pressures were not measured. There is no indication that Dr. Jain saw Patient 18 that day. (St. Ex. 18 at 80-81)

Nevertheless, that same day, Dr. Jain wrote to Dr. Shahinfar regarding Patient 18. He wrote, in part:

This is a gentleman who had a corneal transplant yesterday. He presents with a choroidal detachment in the left eye, which may have been intraoperative from hypotony. The choroidal is extended into the macula. There [are] some retinal folds overlying but I do not think there is an actual retinal detachment. The choroidals should resolve. I have added Homatropine to his eye drops but because the macula is involved, his vision may be affected somewhat. We are not going to know for sure until the macula is entirely flat. The corneal graft appears to be clear otherwise.

(St. Ex. 18 at 80)

Later that day, Dr. Shahinfar evaluated Patient 18 on referral from Dr. Blausey. Dr. Shahinfar noted that retinal detachment was unlikely. He scheduled Patient 18 to be seen by Dr. Jain the following week and by himself in three weeks. (St. Ex. 18 at 79)

Following the corneal transplant, Patient 18 continued to complain of pain in his left eye. He was prescribed Vicodin. Intraocular pressures were not measured. (St. Ex. 18 at 77-78)

309. Dr. Jain saw Patient 18 on January 2, 2001. Patient 18 complained of "terrible" pain in his left eye. He was using Ocuflax and prednisone forte eyedrops at that time. Dr. Jain noted

hemorrhagic choroidals in the left eye and scheduled Patient 18 for “drainage, trabeculectomy if needed.” (St. Ex. 18 at 76)

310. On January 3, 2001, Dr. Jain performed the following procedures on the left eye: trabeculectomy, drainage of suprachoroidal heme, drainage of hyphema, anterior vitrectomy, peripheral retinal cryotherapy, and pars plana vitrectomy (dry). He listed preoperative diagnoses as follows: high intraocular pressure, severe choroidal detachment, hyphema, vitreous in anterior chamber, and peripheral retinal tear. (St. Ex. 18 at 20-28b, 75)
311. Over the next several days, Patient 18 continued to complain of pain. Dr. Jain prescribed Ocuflax, Homatropine, prednisone forte, Voltaren, Cosopt, Ocupress, and Azopt eye drops. On January 5, 2001, examination of his eyes revealed the following:

Visual Acuity	Right eye: not recorded
without Correction	Left eye: hand movements
Pachymetry	Right eye: 590
	Left eye: 1000
Intraocular Pressure	Right eye: 16 mmHg
	Left eye: 24 mmHg

Dr. Jain noted 2+ stromal edema, flat macula, and elevated intraocular pressure in the left eye. His plan was to “follow pachymetries.” He noted, “doing well,” “stable,” and “reasonable.” (St. Ex. 18 at 72-73)

312. Dr. Jain examined Patient 18 on January 8, 2001. Patient 18 complained of less discomfort, but added photophobia as a complaint. Examination of Patient 18’s eyes revealed the following:

Visual Acuity	Right eye: 20/20
without Correction	Left eye: 20/400 with +10 lens
Pachymetry	Right eye: 578
	Left eye: 563
Intraocular Pressure	Right eye: 16 mmHg
	Left eye: 38 mmHg

Dr. Jain noted, “Doing well,” and scheduled Patient 18 for a paracentesis. Later that day, Dr. Jain performed an anterior chamber paracentesis of the left eye. The diagnosis was: high intraocular pressure, status post cataract extraction, left eye. On January 8, 2001, Patient 18 reported that he was also taking Diamox 500 mg twice daily in addition to his eye drops. (St. Ex. 18 at 70-71)

313. A few days later, Patient 18’s daughter called the office stating that Patient 18 was in “extreme pain.” An appointment was scheduled to rule out endophthalmitis. On

January 12, 2001, Dr. Jain evaluated Patient 18. He noted a heavy injection in the sclera of the left eye with possible necrosis. Other notations are illegible. (St. Ex. 18 at 64-68)

On January 15, 2001, Patient 18 stated that his eye was not hurting as much but that it was puffy. Intraocular pressure in the left eye was 42 mmHg. The following day, it was 52 mmHg. Later that day, Dr. Jain performed an Arson laser suture release to relieve elevated intraocular pressure. Nevertheless, a few days later, the intraocular pressure was 36 mmHg in the left eye. Dr. Jain prescribed Percocet for pain. (St. Ex. 18 at 58-65)

314. On January 23, 2001, Dr. Jain evaluated Patient 18. Examination of his eyes revealed the following:

Visual Acuity without Correction	Right eye: 20/not recorded Left eye: 20/400
Visual Acuity Pinhole	Right eye: 20/not recorded Left eye: 20/300
Manifest Refraction	Right eye: not recorded Left eye: sphere, +14.00; cylinder, -2.50; axis, 030; 20/80
Intraocular Pressure	Right eye: not recorded Left eye: 24 mmHg

(St. Ex. 18 at 56)

315. On March 30, 2001, Dr. Jain advised Dr. Shahinfar that he would be happy to insert a secondary intraocular lens if Dr. Shahinfar thought it appropriate. On April 2, 2001, Dr. Shahinfar replied that he had discussed the possibility of a secondary lens implant with Patient 18. Dr. Shahinfar added, in part,

I explained that his vision may not be functional to be able to read things with as a result of the choroidals. His best, corrected vision has been in the 20/200 range. The graft looks good. The risk of recurrent choroidals is a possibility but it has been three months since his last surgery and secondary lens implant may be done since the surgery is fairly quick.

(St. Ex. 18 at 47, 49)

316. On April 5, 2001, Patient 18 requested release of his medical records. Patient 18 did not return to the Bloomberg Eye Center. (St. Ex. 18 at 3)

### **Testimony of Dr. Webb regarding Patient 18**

317. Dr. Webb provided expert testimony for the State regarding Patients 18 through 22. Regarding Patient 18, Dr. Webb testified that Dr. Jain's care and treatment of Patient 18 had fallen below the minimal standard of care for the following reasons:

- a. The YAG vitreolysis performed on December 20, 2000, was unnecessary given that a penetrating keratoplasty was scheduled to be performed shortly thereafter. Dr. Webb testified that the vitreous adhesions could have been addressed during the later procedure. (Tr. at 548)

Dr. Webb testified that Dr. Jain had performed a YAG vitreolysis in preparation for a second corneal transplant. Dr. Webb testified that a YAG vitreolysis is performed when the vitreous gel, which fills the chamber behind the lens and in front of the retina, protrudes forward and becomes incarcerated in the wound that was created during the original corneal transplant. During the YAG vitreolysis, a laser is used to lyse the adhesions between the gel and the cornea. (Tr. at 549, 553-555)

Dr. Webb testified that there had been no clear indication for performing the YAG vitreolysis independently from the corneal transplant. He stated that, if the YAG vitreolysis had been done in an attempt to alleviate the adhesions between the vitreous and the cornea, it could easily have been done during the procedure to replace the corneal transplant. Therefore, if this had been Dr. Jain's intention, the YAG vitreolysis had been an unnecessary procedure. (Tr. at 551-552, 570, 688-689)

Dr. Webb further testified that, on the other hand, if the YAG vitreolysis had been done to relieve corneal edema in an attempt to avoid the corneal transplant, Dr. Jain should have waited longer before performing the corneal transplant. Dr. Webb concluded that waiting only seven days before performing the corneal transplant had not provided sufficient time to determine whether the YAG vitreolysis would relieve the problem. (Tr. at 552, 689-690)

- b. On December 27, 2000, Dr. Jain performed a penetrating keratoplasty or corneal transplant. Despite the complicated nature of the penetrating keratoplasty, Dr. Jain did not personally examine or treat Patient 18 postoperatively for five days, failing to provide adequate postoperative care. (Tr. at 548)

Dr. Webb testified that he had been "shocked" to find that Dr. Blausey, the optometrist, had seen Patient 18 on his first postoperative day. Dr. Webb testified that this had been a very complicated case that should have been followed by a surgically trained ophthalmologist. Dr. Webb testified that the American Academy of Ophthalmology does not recognize optometrists as competent to provide postoperative care, and doing so had been a violation of the standard of care. (Tr. at 552, 558, 560-561, 698-700)

- c. Dr. Jain failed to measure and/or document measurement of the intraocular pressure of Patient 18 until five days following penetrating keratoplasty. (Tr. at 548)

Dr. Webb testified that one of the reasons he felt that Dr. Jain's management of this case had been substandard is that, if there had been choroidal hemorrhages that were as significant as they were at the time of surgery, they should have been dealt with at the time of surgery. Dr. Webb testified that suturing the eye closed and inviting the possibility of increasing intraocular pressure could have resulted in blindness for Patient 18. Dr. Webb testified that it is well established that drainage of choroidal hemorrhages should be done at the time the problem is first recognized. (Tr. at 551-552 570-571, 691-693, 697-698)

Dr. Webb disagreed with the statements that it is nearly impossible to measure intraocular pressure after a corneal transplant and that, even if measuring intraocular pressure is attempted, the measurement will be inaccurate. Dr. Webb testified that, at a minimum, a gross estimation should be obtained. Moreover, he testified that there are instruments available, including a Schiottz tonometer, which is capable of obtaining general intraocular pressures. Dr. Webb concluded that it had been a violation of the minimal standards of care regardless of whether Dr. Jain failed to monitor intraocular pressure or if he had simply failed to document intraocular pressure. Dr. Webb testified that failure to monitor intraocular pressure was even more significant in this case since Dr. Jain was aware that there were choroidals and the patient was complaining of severe pain in his eye. (Tr. at 563-564, 570-571, 691-693, 697-698)

### **Testimony of Dr. Jain regarding Patient 18**

318. Dr. Jain testified that he had performed the YAG vitreolysis in an attempt to relieve the patient's symptoms prior to performing the corneal transplant. Dr. Jain testified that he had done so because there is a small chance that corneal edema can be relieved to simply by performing the YAG vitreolysis, therefore rendering the corneal transplant unnecessary. Dr. Jain acknowledged that the YAG vitreolysis had not resolved the problem in this case. (Tr. at 433-435, 437, 1685-1688)

Dr. Jain disagreed with Dr. Webb's criticism that he should have waited more than seven days after the YAG vitreolysis to see if the corneal edema would recede prior to performing the corneal transplant. He testified that he had managed many patients this way during his training at Harvard. Dr. Jain suggested that Dr. Webb has not done much corneal transplant surgery and had not experienced a similar problem involving the cornea and the vitreous. Dr. Jain concluded that his treatment in performing the YAG vitreolysis had been within the standards of care. (Tr. at 1685-1688)

319. Dr. Jain testified that Patient 18 had not been very cooperative during the corneal transplant surgery. Dr. Jain testified that Patient 18 had been "bearing down," or exerting a positive Valsalva effect, during the procedure. Dr. Jain explained that, because Patient 18 had been bearing down when Dr. Jain removed the cornea, Patient 18 had caused the intraocular contents including the iris and the vitreous gel to push forward out of the eye. Dr. Jain

concluded that this had caused the choroidal hemorrhages. Nevertheless, Dr. Jain acknowledged that he had not documented the fact that Patient 18 had been bearing down during the surgery. (Tr. at 1673-1674, 1767-1772)

Dr. Jain testified that Patient 18 had been awake during the surgery and that Dr. Jain had told him many times to relax and stop bearing down. Dr. Jain added that Patient 18 had not been able to heed that advice. (Tr. at 1675-1676)

Dr. Jain testified that, during the surgery, he had recognized that the intraocular contents were extruding. Therefore, he did what was the most vital thing to do, which was to replace the cornea very quickly. He testified that, in doing so, the surgeon cannot “pay too much attention to detail.” (Tr. at 1674-1675)

Dr. Jain testified that he disagreed with Dr. Webb’s opinion that Dr. Jain should have drained the choroidal hemorrhages during the surgery. Dr. Jain explained that it had been a very complicated surgery, and once the cornea is in place “you really want to leave well enough alone.” He added that, “You do not want to embark on yet another really heroic measure which is fraught with peril.” Dr. Jain concluded that it would have been completely inappropriate for him to address the choroidal hemorrhages at the time. Dr. Jain testified that the appropriate procedure is to treat the choroidal hemorrhages five days postoperatively, at the earliest. (Tr. at 1676-1678)

320. Dr. Jain testified that Dr. Blausey had been perfectly competent to treat postoperative patients such as Patient 18, and that allowing Dr. Blausey to do so had not violated the minimal standards of care. Dr. Jain testified that Dr. Blausey had worked at Bloomberg Eye Center for quite some time and was familiar with postoperative corneal transplant patients. (Tr. at 1678-1679)
321. Dr. Jain testified that, after a corneal transplant, it is nearly impossible to obtain intraocular pressure measurements. Moreover, immediately after a corneal transplant, the cornea should not be touched. In addition, any intraocular pressure measurement that you do obtain is generally inaccurate. Dr. Jain testified that, postoperatively, he had attempted to obtain intraocular pressure measurements using tactile tensions. He stated that Patient 18’s eye had been so painful that he would retract his head whenever Dr. Jain approached his eye. Nevertheless, Dr. Jain testified that he had soothed Patient 18 had been allowed to gently palpate Patient 18’s eye. Dr. Jain testified that the eye had been “rock hard,” which clearly had been due to elevated intraocular pressure. Dr. Jain acknowledged that he had not documented this in the medical record, but stated that he could remember palpating the eye. (Tr. at 446-447, 450-453, 456-457 1680, 1771-1772)

Dr. Jain testified that in a patient like this with elevated intraocular pressure, the appropriate treatment is topical medication such as Azopt, Ocupress, and Diamox, which is what Dr. Jain employed. Dr. Jain concluded that it would not have made any difference in the treatment to have known the exact intraocular pressure measurement. Nevertheless,

Dr. Jain testified that there is a point when intraocular pressure is so high that the surgeon must intervene or it will cut off the blood supply to the central retinal artery, resulting in blindness. (Tr. at 447-448, 453-454, 1680-1681, 1682-1683-1685)

### ***Patient 19***

#### **Medical Records for Patient 19**

322. Patient 19, a 62-year-old female, started treating with the Bloomberg Eye Center in March 1985. Over the years, Patient 19 underwent a variety of procedures performed at the Bloomberg Eye Center, including: bilateral cataract extractions with intraocular lens implants, a secondary intraocular lens implant, a corneal transplant, three YAG vitreolyses, superficial keratectomy, a repair of wound dehiscence with vitreous iris prolapse, removal of cortical remnants, repositioning of intraocular lens, an AK, an anterior vitrectomy, retrobulbar steroid injections, and an iridoplasty. (St. Ex. 19 at 3, 109, 43)

323. On March 21, 2001, Dr. Jain performed an excisional biopsy of a large basal cell carcinoma on the nasal bridge with complex repair of the wound. In his operative note, Dr. Jain wrote, "The large basal cell was grasped and excised at the base, taking care to remove the entire depth of the lesion down to the muscularis." Moreover, he stated that he had performed a complex wound repair. (St. Ex. 19 at 125-146)

Subsequently, the pathology report provided a diagnosis of basal cell carcinoma, and noted: "The lesion had extended to the inked lateral (peripheral) and deep (base) edges of the specimen." (St. Ex. 19 at 127-129)

324. On March 27, 2002, Dr. Jain performed a second excisional biopsy on the nasal bridge of Patient 19. In his operative report, Dr. Jain described the procedure as "excision of recurrent tumor with wide margins," and "excision of skin overlying central nasal bridge." The preoperative diagnosis was recurrent basal cell carcinoma at periphery of large nasal lesion. Dr. Jain noted that he had excised tissue of approximately 5.0 cm x 3.0 cm. (St. Ex. 19 at 61-81, 309)

The pathology report indicated a diagnosis of basal cell carcinoma, with a lesion that extended "to the deep edge (base) of the specimen and close to the lateral (peripheral) edge of the specimen." (St. Ex. 19 at 59)

325. On April 10, 2002, Dr. Jain referred Patient 19 to Melinda J. Woofter, M.D., a dermatologist. (St. Ex. 19 at 9) On April 22, 2002, Dr. Woofter wrote to Dr. Jain regarding Patient 19. Dr. Woofter wrote, in part, as follows:

She has had a basal cell carcinoma that was primarily biopsied 3/23/01. She later had the lesion we excised on 3/27/02, which was quite large and the deep margins were positive as well as the lesion extending close to the lateral margin from three to six o'clock \* \* \*. There is a pink, moist wound over the

nasal bridge extending onto the nasal tip measuring 2.5 x 2.2 cm. There is a depression noted at the juncture of the nasal tip with the bridge. The entire lesion measures 2.5 x 2.2 cm with surrounding erythema and telangiectasia.

(St. Ex. 19 at 7) Dr. Woofter noted that she had discussed options with Patient 19, which included performing a simple excision versus radiation therapy versus Mohs micrographic surgery. Patient 19 chose to proceed with the Mohs micrographic surgery. (St. Ex. 19 at 7)

On May 1, 2002, Dr. Woofter advised Dr. Jain that she had excised “a very large basal cell carcinoma.” She noted that the tumor had been excised with two stages of Mohs micrographic surgery, which had left “a defect of 3.5 x 3.0 x 0.06 cm down to the cartilage.” She further advised that another physician would perform and monitor reconstruction. Patient 19 was 80 years old at that time. (St. Ex. 19 at 295)

326. On May 29, 2002, Howard L. Rivas, D.O., advised Dr. Jain that he had seen Patient 19 after having performed a skin graft to the excised cancer site on her nose. Dr. Reeves noted that the skin graft was completely viable and that Patient 19 was doing well. (St. Ex. 19 at 293)

#### **Testimony of Dr. Webb regarding Patient 19**

327. Dr. Webb testified that Dr. Jain had excised a basal cell carcinoma from the bridge of Patient 19’s nose on March 21, 2001. The pathology report indicated that there was extension of the skin cancer to the wound margin of the specimen, which would indicate that, most likely, there had been residual cancer cells left in the patient after that procedure. Dr. Webb testified that Dr. Jain had failed to document any discussion with Patient 19 regarding the biopsy results and the available options for treating or following the residual cancer cells. Dr. Webb noted that, subsequently, Patient 19 had a recurrent tumor at that site which required a second excision. Again, the margins were not clear on that excision either. (Tr. at 573-578)

Dr. Webb testified that the standard of care mandates that the physician discuss with the patient the fact that there is residual tumor. Moreover, management of the residual tumor is a decision that must be made with the patient’s informed consent. Dr. Webb explained that it had not been necessary for Dr. Jain to perform additional surgery immediately after the March 21, 2001, excision. He explained that basal cell carcinomas are generally locally growing tumors that do not metastasize. Therefore, it is not unreasonable to observe the surgical site so long as the patient is aware that there is a possibility of recurrence of the tumor. Nevertheless, Dr. Webb testified that it would be below the standard of care to fail to document this discussion in the record. (Tr. at 578-580, 583, 674-687)

**Testimony of Dr. Jain regarding Patient 19**

328. Dr. Jain testified that, during his training, he had had extensive training in facial plastic surgery. Dr. Jain stated that he had performed approximately ten facial plastic surgeries per year. (Tr. at 465, 473, 1689-1690)
329. Jain further testified that, when he had received the March 21, 2001, pathology report, he had discussed the options for management with Patient 19. Dr. Jain stated that he had adequately documented his conversation with Patient 19 when he noted as follows: “Status post excision BCCA with tumor to margin. Follow.” Dr. Jain concluded that his treatment of Patient 19 had been consistent with the standards of care. (Tr. at 470, 1693, 1695-1696)

**Patient 20**

**Medical Records for Patient 20**

330. Patient 20, a 61-year-old male, presented to the Bloomberg Eye Center on June 28, 2001, to be evaluated for cataract surgery. Examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/20 -1
with Correction	Left eye: 20/20 -2
Current Prescription	Right eye: sphere, -4.50; cylinder, -0.25; axis, 085
	Left eye: sphere, -3.25; cylinder, -0.50; axis, 095
Glare	Right eye: 20/60
	Left eye: 20/70

Dr. Jain noted 2+ nuclear sclerotic cataracts and 2+ posterior sub capsular cataracts bilaterally. He also noted intermittent strabismus. In his plan, Dr. Jain noted that he would consider a cataract workup. (St. Ex. 20A at 3, 153)

331. On April 18, 2002, Patient 20 took a Visual Function Status test. He noted that, with glasses, he had “quite a lot” of difficulty driving at night and reading labels on medicine bottles. He also reported that he had some difficulty reading traffic signs, driving during the daytime, seeing steps, and doing household chores. In addition, Patient 20 reported that glare caused “quite a lot” of difficulty for him when performing normal daily activities and driving towards the sun or oncoming headlights, and some difficulty walking outside on a sunny day. (St. Ex. 20A at 149) Examination of Patient 20’s eyes revealed the following:

Visual Acuity	Right eye: 20/20 -
with Correction	Left eye: 20/20
Current Prescription	Right eye: sphere, -4.50; cylinder, -0.25; axis 085
	Left eye: sphere, -3.25; cylinder, -0.50; axis, 195
Manifest Refraction	Right eye: sphere, -4.00; cylinder, -0.25; axis, 075; 20/20 -
	Left eye: sphere, -2.75; cylinder, -0.50; axis, 080; 20/20 -

Manual Keratometry	Right eye: 43.50@165; 43.75@075 Left eye: 43.25@165; 43.50@075
Intraocular Pressure	Right eye: 10 mmHg Left eye: 10 mmHg
Glare	Right eye: 20/50 - Left eye: 20/50 -
Desired Correction	Right eye: plano Left eye: not recorded

Dr. Jain diagrammed 2.5+ nuclear sclerotic cataracts and 2+ posterior sub capsular cataracts bilaterally, but also noted that the cataracts in the right eye were greater than in the left eye. He also diagrammed 4+ MH [media haze] bilaterally. He also noted suspicion of glaucoma. Dr. Jain performed a GDx, and planned cataract extraction with intraocular lens implant for the right eye and then the left. (St. Ex. 20A at 25-39, 145, 147) (See State’s Exhibit 20C, in the Board’s offices, for colorized copies of the GDx images.)

332. On May 1, 2002, Dr. Jain performed a cataract extraction with an intraocular lens implant in the right eye. He inserted a Bausch & Lomb model C11UB 15.0 diopter lens. (St. Ex. 20A at the 77 -98, 141, 143) Dr. Jain saw Patient 20 the following day. Examination of his eyes revealed the following:

Visual Acuity without Correction	Right eye: 20/200 Left eye: not recorded
Visual Acuity Pinhole	Right eye: 20/60 Left eye: not recorded
Manual Keratometry	Right eye: 43.50@165; 43.75@075 Left eye: 43.25@165; 43.50@075
Pachymetry	Right eye: 518 Left eye: 495
Intraocular Pressure	Right eye: 19 mmHg Left eye: 19 mmHg
Glare	Right eye: not recorded Left eye: 20/50=
Desired Correction	Right eye: not recorded Left eye: plano

Dr. Jain noted trace scleral edema and a cortical remnant in the right eye. Dr. Jain performed a paracentesis on the right eye for a diagnosis of “secondary glaucoma, increased intraocular pressure.” Subsequently, intraocular pressure in the right eye was 8 mmHg. (St. Ex. 20A at 135, 137, 139)

333. On May 8, 2002, Dr. Jain performed a cataract extraction with an intraocular lens implant on the left eye. As in the right eye, he inserted a Bausch & Lomb model C11UB 15.0 diopter lens. (St. Ex. 20A at 53 -75, 129, 131)

334. On May 9, 2002, Dr. Jain saw Patient 20. Patient 20 complained that he was seeing double and having ghost images in both eyes. He stated that his vision fluctuated and that his right eye's vision was fuzzy. Evaluation of his eyes revealed the following:

Visual Acuity	Right eye: 20/200
without Correction	Left eye: 20/100
Manifest Refraction	Right eye: sphere, -2.75; cylinder, -0.50; axis, 180; 20/20
	Left eye: sphere, -2.75; cylinder, -0.50; axis, 180; 20/20
Pachymetry	Right eye: 518
	Left eye: 600
Intraocular Pressure	Right eye: 10 mmHg
	Left eye: 14 mmHg

Dr. Jain noted that Patient 20 was stable and that he would follow the pachymetries. (St. Ex. 20A at 133)

335. On May 24, 2002, Patient 20 complained of extreme light sensitivity, redness of his eyes, and blurred vision. Examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/200
without Correction	Left eye: 20/200
Manifest Refraction	Right eye: sphere, -3.00; cylinder, -0.75; axis, 180; 20/25
	Left eye: sphere, -2.75; cylinder, -0.75; axis, 180; 20/20
Pachymetry	Right eye: 539
	Left eye: 554
Intraocular Pressure	Right eye: 17 mmHg
	Left eye: 16 mmHg

Dr. Jain prescribed glasses and FML eye drops. His plan was to perform LASIK on the right eye. (St. Ex. 20A at 123, 127)

336. Dr. Jain saw Patient 20 again on June 6, 2002. Patient 20 complained of redness, itching, watering and burning with extreme light sensitivity and ghost images. Examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/25
with Correction	Left eye: 20/25
Pachymetry	Right eye: 526
	Left eye: 570
Intraocular Pressure	Right eye: <20 mmHg
	Left eye: <20 mmHg

Dr. Jain noted bilateral scleral edema and phimosis of the left eye. He prescribed oral doxycycline. (St. Ex. 20A at 121)

337. On June 27, 2002, Patient 20 complained of having difficulty with bright light and ghost images. Patient 20 requested to have his eye muscles checked due to his history of “lazy eye.” Examination of his eyes revealed the following:

Visual Acuity	Right eye: 20/20 -3
with Correction	Left eye: 20/20 -3
Visual Acuity	Right eye: 20/200
without Correction	Left eye: 20/200
Visual Acuity	Right eye: J2
NVA	Left eye: J1
Pachymetry	Right eye: 515
	Left eye: 502
Desired Correction	Right eye: sphere, -1.78; cylinder, -0.80; axis, 180
	Left eye: N/A
Intraocular Pressure	Right eye: 15 mmHg
	Left eye: 17 mmHg

Dr. Jain noted bilateral scleral edema, with 2+ opacification of the right posterior capsule, and 1+ opacification of the left posterior capsule. Dr. Jain further noted that Patient 20 was stable. He scheduled LASIK for the right eye. (St. Ex. 20A at 111, 117)

338. On August 26, 2002, Dr. Jain performed LASIK surgery on the right eye. Thereafter, Patient 20 continued to complain of glare at night. He also complained that he was unable to drive comfortably. (St. Ex. 20A at 5-23, 103)

339. On July 25, 2003, Patient 20 requested release of his medical records. He did not return to the Bloomberg Eye Center. (St. Ex. 20A at 101)

340. On July 25, 2003, another physician examined Patient 20. Patient 20 complained of blurred vision in both eyes. He also reported that another physician had told him that his intraocular lens implant had “slipped.” Patient 20 reported that he had been told that the LASIK surgery had been performed because Dr. Jain had inserted the wrong intraocular lens implants. Upon examination, the new physician found Patient 20 to have bilateral subluxated intraocular lenses with posterior capsule opacification bilaterally. The new physician scheduled an intraocular lens exchange. (St. Ex. 20A at 111, 117) (Note: the subsequent treating physician maintained photographic slides of Patient 20’s eyes and a videotape of the performance of a lens removal. See State’s Exhibits 20D and 20E, in the Board’s offices.)

#### **Testimony of Dr. Webb regarding Patient 20**

341. Dr. Webb testified that Dr. Jain’s care and treatment of Patient 20 had fallen below the minimal standards of care because he had failed to document that he had explained to Patient 20 his rationale for performing the LASIK procedure. (Tr. at 619 -620)

Dr. Webb testified that, initially, he had believed Dr. Jain had implanted a lens for which the implant power had been incorrectly calculated. Dr. Webb added that he had included this criticism in his report to the Board. Dr. Webb further testified, however, that, after finding additional calculations in the medical record, he had later changed his mind. With the new information, Dr. Webb concluded that Dr. Jain had properly calculated his choice of the lens implant. Nevertheless, the implant had been unsuccessful due to the way Patient 20's eye reacted to it. Dr. Webb testified that this was not a failure on the part of Dr. Jain and that this is something that occasionally happens. (Tr. at 621 -622, 623 -624, 646 -649)

Dr. Webb further testified that LASIK had not been an inappropriate treatment in this case. He added that his only criticism was that Dr. Jain had not documented Patient 20's understanding as to whether the LASIK procedure had been performed to correct nearsightedness or to address his primary complaint, which was glare. Dr. Webb testified that it is the standard of care to be sure that the patient understands why a procedure is being performed and to document that understanding in the medical record. (Tr. at 620, 625-626, 649 -652)

### **Testimony of Dr. Jain regarding Patient 20**

342. Dr. Jain testified that he had performed the LASIK procedure to treat the myopia that had resulted from the cataract surgery. Dr. Jain testified that he had discussed with Patient 20 the indications for, the risks and benefits of, and the alternatives to the LASIK procedure. Dr. Jain concluded that his care and treatment of Patient 20 had been consistent with the minimal standards of care. (Tr. at 1697 -1698, 1701 -1702)

Dr. Jain further testified that much of the problem in this case had been caused by the subsequent treating physician. He explained that the subsequent treating physician had originally been a partner of Dr. Bloomberg, who had left Dr. Bloomberg and set up his own practice in the same neighborhood. Dr. Jain further testified that, when Dr. Jain arrived in town, the subsequent treating physician had treated him very negatively simply because he was associated with the Bloomberg Eye Center. Moreover, Dr. Jain testified that, whenever a patient left the Bloomberg Eye Center to be treated by this physician, the physician "bad mouthed" Dr. Jain, and said things such as, "Oh, my gosh, what have they done to you?" (Tr. at 1699 -1700)

### ***Patient 21***

#### **Medical Records for Patient 21**

343. Patient 21, a 60-year-old male, presented to the Bloomberg Eye Center on May 31, 2000, for a cataract evaluation. He complained of experiencing glare at night and with oncoming traffic. He also complains of difficulty focusing. Examination of his eyes revealed the following:

Visual Acuity with Correction	Right eye: 20/30 Left eye: 20/25
Current Prescription	Right eye: sphere, +1.00; cylinder, -1.00; axis, 078 Left eye: sphere, +1.00; cylinder, -0.25; axis, 078
Manual Keratometry	Right eye: 43.75@010; 44.50@100 Left eye: 44.50@010; 44.00@100
Intraocular Pressure	Right eye: 13 mmHg Left eye: 13 mmHg
Glare	Right eye: 20/40- Left eye: 20/30-
Desired Correction	Right eye: sphere, plano Left eye: N/A

Dr. Jain documented 2+ nuclear sclerotic cataracts and 2+ posterior subcapsular cataracts bilaterally, but also noted that the right eye was worse than the left. He also diagrammed 3+ MH bilaterally. Dr. Jain planned to perform a cataract extraction with an intraocular lens implant, first on the right eye, and then on the left. (St. Ex. 21 at 9-15b, 84, 85)

344. On June 27, 2000, Dr. Jain performed phacoemulsification with posterior intraocular lens implantation on Patient 21 for a visually significant cataract. This procedure was notable for lack of pupillary dilation, which required stretch pupilloplasty. He also performed lysis of posterior synechiae and an iridoplasty. Finally, Dr. Jain noted that an intraoperative hyphema [intraocular bleeding] had occurred for which he employed irrigation and aspiration to evacuate. (St. Ex. 21 at an 75-76, 81-83)
345. Dr. Jain saw Patient 21 on June 28, 2000. Patient 21 complained that his vision was blurred, that his eyes hurt, and that he felt nauseated. Examination of his eyes revealed the following:

Visual Acuity without Correction	Right eye: 20/80- Left eye: not recorded
Visual Acuity Pinhole	Right eye: 20/80+ Left eye: not recorded
Pachymetry	Right eye: 805 Left eye: 596
Intraocular Pressure	Right eye: 36 mmHg Left eye: 18 mmHg

Dr. Jain diagnosed elevated intraocular pressure secondary to glaucoma, and he performed a paracentesis. He also prescribed Ocuflax, prednisone forte, and Diamox. Dr. Jain noted that he would follow the pachymetries, and instructed Patient 21 to return 14 days later. Nevertheless, Patient 21 called the office on June 30 and July 1, 2000, complaining of nausea, pain, and decreased vision. He spoke with a technician who contacted Dr. Jain.

Dr. Jain prescribed Diamox and Timoptic eye drops, and an appointment was scheduled for July 5, 2000. (St. Ex. 21 at 2, 74, 77)

346. On July 5, 2000, Dr. Jain saw Patient 21. Patient 21 complained of a “gel-like substance in the central field of his vision.” He also stated that he “was sick of the symptoms” his eye was causing him. Examination of his eyes revealed the following:

Visual Acuity without Correction	Right eye: LP [light perception] Left eye: 20/80
Visual Acuity Pinhole	Right eye: 20/NP [no light perception] Left eye: not recorded
Pachymetry	Right eye: 966 Left eye: not recorded
Intraocular Pressure	Right eye: 8 mmHg Left eye: 10 mmHg

Dr. Jain noted a large ovoid fibrin plaque in the pupil, and 2+ scleral edema in the anterior chamber of the right eye. He diagnosed acute “postoperative inflammation vs. endophthalmitis,” although Dr. Jain doubted it would turn out to be endophthalmitis. Dr. Jain prescribed atropine eye drops and requested a consultation with Dr. Shahinfar. (St. Ex. 21 at 72-73)

347. Dr. Shahinfar saw Patient 21 on July 6, 2000. Patient 21 stated that his pain had resolved, but that his vision remained poor, he felt lousy, and he had no appetite. Dr. Shahinfar performed a pars plana vitrectomy, a membranectomy, removal of the anterior chamber fibrin clot, release of posterior synechiae, injection of antibiotics, and culture of the right eye. The culture revealed Staphylococcus, and Dr. Shahinfar diagnosed endophthalmitis. (St. Ex. 21 at 63-71)

Patient 21 continued to have problems with recurrent inflammation through at least April 2002. During this time, he was treated by Dr. Shahinfar. (St. Ex. 21 at 3, 4, 33-62) (Please note: the medical record contains slides and photographic strips of Patient 21’s eyes. See State’s Exhibit 21B.)

### **Testimony of Dr. Webb regarding Patient 21**

348. Dr. Webb testified that Dr. Jain’s care and treatment of Patient 21 had fallen below the minimal standard of care because Dr. Jain had failed to treat Patient 21’s condition appropriately. Moreover, Dr. Webb testified that Dr. Jain had failed to provide adequate postoperative care. In support of that opinion, Dr. Webb testified that the cataract extraction surgery performed by Dr. Jain had not been a routine case. Dr. Webb stated that the pupil had not dilated, which makes the surgery more difficult because it obscures the view of the cataract. Therefore, Dr. Jain had been forced to stretch or dilate the pupil in order to obtain a better view of the cataract. During the stretching, however, a hyphema

occurred which, Dr. Webb testified, is an indication of bleeding in the anterior chamber of the eye. Dr. Webb added that a hyphema is not an unusual complication under the circumstances. Nevertheless, Dr. Webb testified that Dr. Jain had not provided appropriate postoperative care in light of the complicated nature of this procedure. (Tr. at 584-586)

Dr. Webb continued that Patient 21 had had a significantly elevated intraocular pressure on the first postoperative day. Dr. Jain performed paracentesis and prescribed medication to lower the pressure. Nevertheless, Dr. Jain did not schedule a follow-up appointment until fourteen days later. Dr. Webb testified that this was poor postoperative care and a violation of the minimal standard of care due to the elevated intraocular pressure. Dr. Webb explained that untreated elevated intraocular pressure could damage the optic nerve, which is not repairable. (Tr. at 586-587, 590-593, 600-601)

Dr. Webb further noted that, in the interim, Patient 21 had called Bloomberg Eye Center on more than one occasion to complain of pain and nausea. Dr. Webb testified that pain and nausea frequently accompany elevated intraocular pressure. Dr. Webb also noted that Patient 21's phone calls had been managed by an optometrist, which was inappropriate and below the minimal standard of care. Even then, Dr. Webb noted, Dr. Jain did not see Patient 21 for another four days, a week after performing the paracentesis for an intraocular pressure of 36 mmHg. By the time Patient 21 was finally seen by an ophthalmologist, he was still nauseated and there was a significant amount of inflammatory activity inside the eye. Dr. Webb testified that Dr. Jain should have seen Patient 21 much sooner than he did. (Tr. at 587-588, 594-596, 657-662, 670-674)

### **Testimony of Dr. Jain regarding Patient 21**

349. Dr. Jain testified that he had been concerned about the increased intraocular pressure and increased corneal swelling as noted by the pachymetry of 966. Dr. Jain testified that he would have preferred that Dr. Shahinfar had seen Patient 21 the same day, but Dr. Shahinfar had not been available. Dr. Jain acknowledged that there are other retinal specialists in Columbus. Nonetheless, Dr. Jain testified that he had had a feeling that Patient 21 would not want to travel to Columbus from Logan, where he lived. Dr. Jain further acknowledged that he had not documented any discussion with Patient 21 regarding the seriousness of his condition and the options available for treatment. Dr. Jain added that he had not thought that Patient 21 would go blind in 24 hours. Moreover, Dr. Jain testified that elevated intraocular pressure usually occurs in the first 24 to 48 hours postoperatively. Therefore, Dr. Jain had concluded that it was unlikely that the intraocular pressure would "spike" again. Finally, Dr. Jain testified that Patient 21 had had a good outcome. Dr. Jain concluded that his postoperative care of Patient 21 had been consistent with the minimal standards of care. (Tr. at 504-510, 1706-1713)

***Patient 22***

**Medical Records for Patient 22**

350. Patient 22, a female born in 1929, had been seen at the Bloomberg Eye Center since at least 1990. She had been treated by other physicians until 1999, when she started seeing Dr. Jain. Over the years she had had many procedures performed to including bilateral cataract extractions with intraocular lens implants, penetrating keratoplasties, superficial keratectomies, Argon green laser treatments, YAG laser posterior capsulotomy, intraocular lens repositionings, panretinal photocoagulations, pars plana vitrectomy, permanent punctal cauteries, and FML. Patient 22 had been diagnosed with age-related macular degeneration, proliferative diabetic retinopathy, vitreous hemorrhage, subretinal scarring, and a large macular scar related to subfoveal subretinal neovascularization or macular degeneration caused by blood vessels growing into and damaging the retina of the left eye. (St. Ex. 22A at 3, 81, 285, 289, 301-30; Tr. at 604)
351. Dr. Jain started treating Patient 22 in 1999. Dr. Jain performed panretinal photocoagulation on both eyes in early 2000. Her visual acuity with correction at that time was 20/hand movements in the right eye and 20/400 in the left. Dr. Jain performed a fluorescein angiogram in June 2000. In August 2000, he performed a penetrating keratoplasty, intraocular lens repositioning, vitrectomy, and synechiolysis on the right eye. (St. Ex. 22A at 231, 235-243)
352. On August 23, 2000, Dr. Jain performed a corneal transplant, intraocular lens repositioning, vitrectomy, and synechiolysis on the right eye. The next day, intraocular pressure in the right eye was 30 mmHg; Dr. Jain performed an anterior chamber paracentesis, after which the intraocular pressure was 10 mmHg. (St. Ex. 22A 223, 225)
353. On October 4, 2000, Dr. Jain performed a corneal transplant, intraocular lens repositioning, posterior synechiolysis, superficial keratectomy, and anterior stromal micropuncture on the left eye. Diagnoses were listed as pseudophakos bullous keratopathy, cortical cataract disreminants, posterior synechia, dislocated pseudophakos, superficial corneal pannus, and recurrent erosion syndrome. (St. Ex. 22A at 511-513)

The next day, intraocular pressures were not measured; instead, it was noted, “too distorted.” On October 6, 2000, Patient 22 went to the emergency room with complaints of pain, headache, nausea and vomiting. Her daughter called the office and asked for an appointment with Dr. Jain. Upon examination, the intraocular pressure in Patient 22’s left eye was 35 mmHg. Dr. Jain performed an anterior chamber paracentesis, after which the intraocular pressure was 8 mmHg. (St. Ex. 22A at 35-47, 203, 211-217)

Thereafter, Patient 22 continued to complain of discomfort and a sensation of having a foreign body in her left eye. Patient 22 saw Dr. Blausey on December 12, 2000, at which time he diagnosed her as having filamentary keratitis in the left eye. Dr. Blausey noted that

there was a “filament without exposure” in the left eye. He prescribed a bandage soft contact lens for the left eye. (St. Ex. 22A at 197)

354. On January 23, 2001, Dr. Jain saw Patient 22. Her visual acuity without correction was 20/hand movements in the right eye and 20/figure counting in the left. Dr. Jain noted “NV fibrosis” in the left eye, and “heavy” panretinal photocoagulation bilaterally. His impression was insulin dependent diabetes mellitus, peripheral diabetic retinopathy with macular edema, dry eye syndrome, OAG [open-angle glaucoma], and blepharitis. Dr. Jain performed a focal macular laser procedure on the right eye. On January 31, 2001, he performed the same procedure in the left eye. (St. Ex. 22A at 183-191)
355. On February 7, 2001, Dr. Jain performed panretinal photocoagulation of the right eye. One week later, he performed the same procedure on the left eye. (St. Ex. 22A at 175-181)
356. On March 8, 2001, Dr. Jain performed temporary punctal cautery of the lower lid of the left eye for a diagnosis of dry eye syndrome. On March 15, 2001, he performed the same procedure on the right eye. (St. Ex. 22A at 167, 171)
357. On March 21, 2001, Dr. Jain performed a superficial keratectomy, anterior stromal micropuncture, repositioning of intraocular lens, anterior vitrectomy, and posterior synechiolysis on the left eye. (St. Ex. 22A at 165, 493-510)
358. On April 4, 2001, Dr. Jain performed a superficial keratectomy, anterior stromal micropuncture, repositioning of intraocular lens, anterior vitrectomy, and posterior synechiolysis of the right eye. Preoperative diagnoses were listed as superficial vascular pannus, recurrent erosion syndrome, posterior synechia, subluxed pseudophakos, and vitreous prolapse. Over the next year and a half, Patient 22’s visual acuity continued to be 20/finger counting, hand movements, or light perception in each eye. (St. Ex. 22A at 157, 475-492, 765-793)
359. On July 6, 2001, Dr. Jain performed a permanent punctal cautery of the lower lid of the left eye, for a diagnosis of severe dry eye syndrome. On July 23, 2001, he performed the same procedure on the right eye. (St. Ex. 22A at 773, 777)
360. On September 5, 2001, examination of Patient 22’s eyes revealed the following:

Visual Acuity without Correction	Right eye: 20/hand movements Left eye: 20/finger counting
Visual Acuity Pinhole	Right eye: 20/25 Left eye: 20/25+
Manifest Refraction	Right eye: sphere, -3.50; cylinder, -5.00; axis, 005; 20/HM Left eye: sphere, -1.75; cylinder, -2.50; axis, 095; 20/CF
Intraocular Pressure	Right eye: <20 mmHg Left eye: <20 mmHg

Dr. Jain performed a GDx on the left eye, and wrote “Good” on the image. He noted that he would consider a superficial keratectomy. (St. Ex. 22A at 115, 765)

361. On October 31, 2001, Dr. Jain performed a superficial keratectomy, anterior stromal micropuncture, debridement of epithelial filaments, removal of corneal sutures, and placement of bandage contact lens on the left eye. Diagnoses were listed as superficial vascular pannus, recurrent erosion syndrome, epithelial filaments, and residual corneal sutures. (St. Ex. 22A at 461-474, 753-755)
362. On February 15, 2002, Dr. Jain performed a removal of filaments and loose sutures with debridement of the left eye. (St. Ex. 22A at 369, 745) In a letter to Dr. Shahinfar, Dr. Jain wrote as follows:

The purpose of this letter is to get your opinion regarding [Patient 22’s] eyes. [Patient 22] has undergone uneventful bilateral penetrating keratoplasty. At this juncture, she has a good view of the posterior pole. She has burned out proliferative diabetic retinopathy with dense periretinal membranes in both eyes. Please evaluate [Patient 22] and see if you would recommend a vitrectomy with epi-retinal membrane removal.

(St. Ex. 22A at 369)

Dr. Shahinfar saw Patient 22 on March 13, 2002. Dr. Shahinfar advised that Patient 22 had a history of PKP in both eyes, proliferative diabetic retinopathy, and subretinal fibrosis in the right eye. He added that she had had extensive laser in both eyes. Dr. Shahinfar concluded: “I do not believe any additional treatment would help her.” (St. Ex. 22A at 737)

363. On September 3, 2002, Dr. Jain performed removal of a loose suture with filaments from the left eye. The following day, pachymetry in the right eye was 516, and in the left eye it was 707. On the diagram for the left eye, Dr. Jain wrote positive ectasia, and 2+ anterior stromal scarring. Diagnoses included iriditis and “Fuchs.” (St. Ex. 22A at 727, 729)
364. On September 9, 2002, Dr. Jain performed a superficial keratectomy, anterior stromal micropuncture, removal of epithelial filaments, removal of residual corneal sutures, and placement of bandage contact lens on the left eye. Diagnoses were listed as superficial corneal scarring with corneal ectasia, residual corneal sutures, corneal filaments, and recurrent erosion syndrome. One week later, Dr. Jain noted an epithelial defect in the left eye and bilateral irregular mires. (St. Ex. 22A at 447-460, 719, 725)
365. On September 21, 2002, Dr. Jain removed corneal sutures and filament from the left eye. (St. Ex. 22A at 369)

366. On October 3, 2002, Dr. Jain performed a superficial keratectomy with a Nidek microkeratome, anterior stromal micropuncture, removal of residual corneal sutures, removal of epithelial filaments, and placement of a soft bandage contact lens on the right eye. Preoperative diagnoses were superficial corneal scarring, residual corneal sutures, epithelial filaments, and recurrent erosion syndrome. (St. Ex. 22A at 435-446, 701, 717)

On October 4, 2002, Dr. Jain diagnosed a low intraocular pressure in the right eye. Nevertheless, the intraocular pressure was documented to be <20 mmHg. The following day, however, it was documented to be <5 mmHg; and on October 7, 2002, the right eye was noted to be "soft." No intraocular pressure was recorded. On October 8, 2002, a relative of Patient 22 called to state that Patient 22 was experiencing severe pain in her right eye. Dr. Jain saw Patient 22 and diagnosed a wound leak in the right eye. He planned to repeat the corneal transplant. (St. Ex. 22A at 707-715)

367. On October 10, 2002, Dr. Jain performed a corneal transplant, removal of residual cortical remnants, posterior synechiolysis, drainage of hyphema, and repair of an anterior segment wound on the right eye. The preoperative diagnoses were listed as wound dehiscence, flat anterior chamber, vitreous prolapse, subluxed pseudophakos, severe corneal edema, residual cortical cataract, posterior synechiae, and hyphema. (St. Ex. 22A at 373, 417-434, 697-699)

On October 11, 2002, intraocular pressure in the right eye was 30 mmHg. Dr. Jain performed an anterior chamber paracentesis on the right eye with a resulting intraocular pressure of 4 mmHg. Moreover, postoperatively, Patient 22 complained of severe pain in her right eye. Dr. Jain noted 2+ DMF [Descemet's membrane folds]. He questioned possible hemorrhagic choroidals, and requested a consultation with Dr. Shahinfar. (St. Ex. 22A at 369, 695, 687-689)

By letter dated October 15, 2002, Dr. Shahinfar advised Dr. Jain said he had seen Patient 22. Dr. Shahinfar continued as follows:

She continues to have poor vision. She is uncomfortable. The view of the posterior pole is difficult because of vitreous hemorrhage and possible choroidals. I did ultrasound, which may be revealing choroidals, although I cannot rule out [retinal detachment] with PVR. Unfortunately, because of the poor view and poor prognosis, there is not much that can be done at this point. I recommend that she use some homatropine for comfort. I will see her again next week. I will have a better view of the retina as the blood clears.

(St. Ex. 22A at 681)

368. Thereafter, Patient 22 continued to complain of severe pain. On October 21, 2002, Dr. Jain performed paracentesis for an of "28 to 30," mmHg, with a resulting intraocular pressure of five. Dr. Jain diagnosed increased intraocular pressure secondary to hyphema. (St. Ex. 22A at 679)

369. Patient 22's visual acuity remained 20/finger counting, hand movements, or light perception in each eye. On January 2, 2003, pachymetry in the right eye was 705 and in the left 535. On January 16, 2003, Dr. Shahinfar performed a pars plana vitrectomy on the right eye, for a diagnosis of non-clearing vitreous hemorrhage. Thereafter, Patient 22 continued to complain of pain in her right eye and headaches. (St. Ex. 22A at 401-416, 638-661)

#### **Testimony of Dr. Webb regarding Patient 22**

370. Dr. Webb testified that Dr. Jain had failed to conform to the minimal standards of care in his treatment of Patient 22 because he performed unnecessary and excessive surgery. In support of that opinion, Dr. Webb testified that, in January 2001, Dr. Jain had applied focal macular laser therapy to both eyes on two separate days for what was described as macular edema. Dr. Webb testified that macular edema is an indication of swelling in the retina, usually due to diabetes, and laser treatment is designed to reduce the swelling in the retina. Nevertheless, Dr. Webb testified that Patient 22's preoperative vision had been very poor, and there had been no improvement after the treatment. Dr. Webb explained that visual acuity of 20/hand movements, 20/finger counting, or 20/light perception is a designation of legal blindness. He added that the only vision worse than these is to have no light perception. Therefore, Dr. Webb concluded that the focal laser procedures had been unnecessary and had not been likely to provide any improvement in Patient 22's vision, given her pre-existing severe macular degenerative changes and poor vision. (Tr. at 602-604, 607-611, 705-711)

371. Dr. Webb further testified that Dr. Jain had unnecessarily performed a superficial keratectomy on Patient 22's right eye on October 31, 2002. Dr. Webb explained that Patient 22 had not exhibited significant corneal ectasia as documented by pachymetry, and that she had an extremely poor visual prognosis due to the severe retinal disease. Dr. Webb concluded that Dr. Jain's performance of the superficial keratectomy had been unnecessary. Moreover, performance of the procedure had resulted in a dehiscence of her previous corneal transplant, necessitating another corneal transplantation procedure one week later. Dr. Webb further concluded Dr. Jain's performance of this procedure had violated the minimal standard of care. (Tr. at 612-615)

#### **Testimony of Dr. Jain regarding Patient 22**

372. Dr. Jain testified that, at the time he had treated Patient 22, she had been a 75-year-old woman with long-standing diabetes and many related complications. Those complications included diabetic retinopathy, which is an indication of excessive blood vessel growth on the retina, and various corneal complications. Dr. Jain acknowledged that he had performed numerous procedures, but stated that all of the procedures had been necessary. Moreover, Dr. Jain stated that he had done each procedure in the best interests of the patient and in the hopes of improving her vision. (Tr. at 530, 1714, 1715-1716)

Dr. Jain testified that he strongly disagreed with Dr. Webb's impression that there had been no hope of improving her vision. Dr. Jain further testified that hand motions and counting fingers is actually "not bad vision." He added that, even though Patient 22 would not have been able to drive or read a newspaper, she would have been able to perform activities of daily living, get around the house, and escape a burning building. (Tr. at 518-519, 530, 1715)

373. Dr. Jain stated that he had performed the focal macular laser treatments to seal the key blood vessels in the macula. Dr. Jain testified that he had applied a very specific form of laser treatment, which is the gold standard for treatment of macular edema in early diabetic retinopathy. He explained that the purpose of the laser treatment was to decrease the incidence of further visual loss, rather than to improve her vision. Dr. Jain testified that he had studied this procedure during his training at Harvard. (Tr. at 520, 1715-1719)

374. Dr. Jain testified that he had performed the superficial keratectomies to treat anterior stromal scarring and recurrent erosion syndrome. He explained that a superficial keratectomy removes the superficial layer of the cornea. (Tr. at 521, 523)

Dr. Jain further testified that performing superficial keratectomy with a microkeratome is well documented in medical literature. He stated that it is a very good way to perform a superficial keratectomy because it automates the procedure and does not require the surgeon to do a free-hand dissection. Dr. Jain testified that, any time the surgeon can do corneal work in an automated fashion, it is preferable because the hand is not as precise as the laser. Dr. Jain testified that it was unfortunate that there had been a wound dehiscence, which required a repeat corneal transplant. He concluded, however, that he had performed the procedure appropriately. (Tr. at 1719-1720)

375. Dr. Jain concluded that the surgeries he performed in this case had been necessary and that his care and treatment of Patient 22 had been consistent with the standards of care. (Tr. at 1722-1723)

## V. Dr. Jain's Impairment

### *Richard N. Whitney, M.D.*

376. Richard N. Whitney, M.D., testified at hearing on behalf of Dr. Jain. Dr. Whitney testified that he had completed medical school at the University of Texas in Dallas, Texas. Thereafter, he completed an emergency medicine residency at Truman Medical Center in Kansas City, Missouri. Finally, Dr. Whitney completed a fellowship in addiction medicine at Charter Hospital in Dallas, Texas. He stated that he is certified by the American Society of Addiction Medicine and is currently employed as the Medical Director of Shepherd Hill, a chemical dependency treatment program associated with Licking Memorial Hospital. (Tr. at 1653-1655)

377. Dr. Whitney testified that he is familiar with Dr. Jain because, on November 11, 2002, Dr. Jain had been admitted to Shepherd Hill with a diagnosis of alcohol dependence. Dr. Jain remained as an inpatient in that program until January 24, 2003. Dr. Whitney testified that he had been Dr. Jain's attending physician through the residential treatment program and during the subsequent two-month extended residential treatment program called Central Ohio Recovery Residence [CORR]. Dr. Whitney testified that Dr. Jain had successfully completed the recommended course of treatment. (Tr. at 1655-1656, 1659-1660)

After completion of the CORR program, Dr. Jain participated in an aftercare program, which included weekly counselor-facilitated meetings for a two-year period. He also participated in Caduceus meetings on a weekly basis, submitted to random urine screening for drugs and alcohol, and participated in a twelve-step recovery program. Dr. Jain also signed a contract with the Ohio Physicians Effectiveness Program [OPEP]. Dr. Whitney testified that Dr. Jain had fully complied with the program. (Tr. at 1661-1663)

Dr. Whitney further testified that, in a recent meeting with Dr. Jain, Dr. Jain had indicated that, despite the tremendous stress in his life, he has continued to work an excellent recovery program. Dr. Whitney concluded the Dr. Jain's attitude has been exemplary, and that Dr. Jain is doing as well as could possibly be expected. Finally, Dr. Whitney testified that Dr. Jain's chances of continued recovery are as high as any physician Dr. Whitney has ever treated. (1663-1669)

***Stan Sateren, M.D.***

378. Stan Sateren, M.D., testified at hearing on behalf of Dr. Jain. Dr. Sateren testified that he completed medical school at Northwestern University Medical School, followed by a residency in internal medicine and thereafter. Dr. Sateren was board certified in internal medicine. After practicing for several years, Dr. Sateren was certified by the American Society of Addiction Medicine in 1988, and received the award of Fellow from the American Society of Addiction Medicine in 1998. (Tr. at 39-1940)

Dr. Sateren testified that he is currently the President and Medical Director of the Ohio Physicians Health Program, formerly OPEP. Dr. Sateren testified that the mission of the Ohio Physicians Health Program is to support the health and wellness of health care professionals, most often as it relates to chemical impairment. (Tr. at 1738-1739)

Dr. Sateren testified that he had met Dr. Jain as Dr. Jain was coming out of treatment at Shepherd Hill. Dr. Sateren testified that Dr. Jain had entered into a standard OPEP contract and that his compliance with that contract has been "excellent." Dr. Sateren continued that, with two years of documented solid recovery, Dr. Jain's prognosis is "very, very good." He added that, because there have been absolutely no issues of noncompliance, Dr. Jain is at a higher level of probability for success in long-term recovery. (Tr. at 1740-7045)

***Dr. Jain***

379. Dr. Jain testified that he had received a letter from the Board in October 2002 ordering him to go to Shepherd Hill for evaluation for chemical dependency. Dr. Jain testified that, at that time, there had been no publicity surrounding his impairment or his treatment of any patients. Nevertheless, Dr. Jain testified that he had gone for the evaluation and entered Shepherd Hill for treatment. The following month, his Step I Consent Agreement was presented to the Board. That evening, every major news organization on both the local and the national level, both television and print, carried a story about him. (Tr. at 1725-1726)

Dr. Jain further testified:

And that was the onset of the deluge of the publicity in December of '02. \* \* \* Both patient complaints and lawsuits started pouring in. I must have received, over the period of the next six months, dozens and dozens of lawsuits. It was clear that it was triggered by the publicity. And it was clear by some of the—the complaints alleged that—that it was in the context of the litigious nature of our society that, you know, there are a lot of people out there, I have done thousands upon thousands of surgeries, and there were a lot of people wanting to capitalize on my misfortune and/or my disease. But it was definitely the publicity that started the barrage of problems.

(Tr. at 1726-1727)

380. Dr. Jain testified that the terms of his initial Step I Consent Agreement with the Board suspended his medical license. In addition, the Step I Consent Agreement required him to complete treatment at Shepherd Hill and comply with an aftercare program. He was also required to comply with an OPEP contract, attend seven Alcoholics Anonymous [AA] meetings per week, attend a three-hour Caduceus session weekly, undergo random weekly urine screens, see a psychologist weekly, and comply with any other conditions and recommendations imposed by Shepherd Hill. (Tr. at 1728; St. Ex. 29)

Moreover, Dr. Jain testified that the Step I Consent Agreement had set forth conditions with which he must comply in order to have his medical license reinstated. These included a requirement that two Board-approved addictionologists would agree that Dr. Jain was not a threat to the public and that he was in solid recovery. The Step I Consent Agreement also required that he be assessed by a psychiatrist who would recommend to the Board that Dr. Jain could practice medicine without presenting a threat to the public. Dr. Jain was also required to sign a Step II Consent Agreement which set forth very specific probationary terms. Dr. Jain testified that he had complied with all of the requirements, and his license had been reinstated in May 2004. Finally, Dr. Jain testified that, shortly after he had returned to practice upon reinstatement of this license, he had received the June 2004 notice of opportunity for hearing in this matter. (Tr. at 1728-1732; St. Ex. 29)

Dr. Jain testified that he had practiced for only six weeks before he decided to cease practicing. Dr. Jain testified that he had had a legal dispute with Dr. Shahinfar in which Dr. Shahinfar had “legally attacked” Dr. Jain while Dr. Jain was in treatment. Dr. Jain further testified that the culmination of that battle had forced him to stop practicing. Dr. Jain testified that he has not practiced since that time. (Tr. at 1732)

381. Dr. Jain testified that he is committed to a lifelong recovery. (Tr. at 1732-1734)
382. Dr. Jain testified that he believes he could return to the practice of ophthalmology at a higher level of competence and effectiveness than that at which he had practiced between 2000 and 2002. In making that statement, Dr. Jain acknowledged that, despite arguing throughout the hearing that his practice had been appropriate, he has accepted that he had practiced during this time with some “oversights.” (Tr. at 1734-1735)

### **FINDINGS OF FACT**

- I. In the routine course of his medical practice, Vikas Kumar Jain, M.D., undertook the care and treatment of Patients 1 through 22. The evidence presented at hearing supports the following findings regarding Dr. Jain’s care and treatment of Patients 1 through 22:
- A. Dr. Jain failed to perform and/or document the performance of appropriate testing and measurements. Examples of this include the following:
1. Dr. Jain failed to perform manual keratometry on the eyes of Patient 1, Patient 2, Patient 5, Patient 9, Patient 10, Patient 11, Patient 14, and Patient 16. Dr. Gressel was convincing when he testified that manual keratometry is beneficial in the event that cataract surgery is necessary at some point in the future. Moreover, manual keratometry is relatively simple to perform, and some of the Bloomberg Eye Center technicians performed it in their routine practice anyway. In addition, there was convincing evidence that, had Dr. Jain monitored manual keratometry, it may have prevented him from subsequent errors in his treatment of these patients, such as his failure to recognize the incorrect refraction in programming the laser for Patient 1’s LASIK surgery.
  2. Dr. Jain failed to perform pachymetry prior to performing LASIK in Patient 1, Patient 2, Patient 4, Patient 8, Patient 9, Patient 10, Patient 11, Patient 12, Patient 13, Patient 14, and Patient 16. Pachymetry is a measurement of corneal thickness. Corneal thickness is an issue in LASIK surgery because there is pressure inside the eye pushing out against the cornea. If the cornea is too thin or unstable, the pressure may cause the cornea to bulge outwards, a disease state referred to as ectasia. Pachymetry is vital prior to LASIK surgery in order to ensure that there is sufficient corneal tissue so that the cornea will not become too thin and destabilized by the removal of corneal tissue and creation of the flap during LASIK. Therefore, without pachymetry it is impossible to

determine whether a patient is an appropriate candidate for LASIK surgery. Moreover, pachymetry takes ten to fifteen seconds to perform.

Dr. Jain testified that, unless more than 7 diopters of corneal tissue will be removed during LASIK surgery, it is not necessary to perform pachymetry because only a small percentage of people have corneas so thin that stabilization would be likely to occur with the removal of just 7 diopters of tissue. This rationale is shocking in light of the disastrous results that could befall that “small” percentage of people.

3. Dr. Jain failed to recheck the refractions for Patient 1’s eyes, despite markedly inconsistent testing results.
4. Dr. Jain failed to monitor intraocular pressure in Patient 7’s eyes despite four weeks of intense corticosteroid treatment. Dr. Gressel convincingly testified that it is important to measure intraocular pressure during the use of corticosteroids because corticosteroids can cause glaucoma as soon as five days after initiation of such treatment.
5. Dr. Jain failed to perform corneal topography prior to LASIK enhancement in Patient 8, despite the presence of distorted mires. Distorted mires may be an indication of corneal ectasia. Therefore, in the presence of distorted mires, topography is mandatory prior to LASIK surgery. Dr. Jain’s failure to perform topography in this case is even more egregious because, in Patient 8’s medical record, someone had highlighted the distorted mires with an arrow and two stars.
6. Dr. Jain failed to timely measure intraocular pressure in Patient 9 during steroid therapy for DLK, and failed to adequately monitor for cataracts and glaucoma that could result from long-term use of steroids.
7. Dr. Jain failed to perform corneal topography prior to LASIK surgery and/or LASIK enhancement in Patient 17. Dr. Jain failed to perform corneal topography despite his testimony that corneal topography is necessary prior to the performance of LASIK.
8. When Dr. Jain did perform corneal topography, he failed to recognize that a Bloomberg Eye Center staff member had programmed the topographer so that the vertical axis on the image produced was inverted.
9. Dr. Jain failed to measure and/or document measurement of the intraocular pressure of Patient 18’s eyes until five days following Dr. Jain’s performance of a penetrating keratoplasty [corneal transplant]. It was especially important in this case because choroidal hemorrhages had been apparent during the surgery, but Dr. Jain had not addressed them. Closing the wound despite the

hemorrhages could have caused severely elevated intraocular pressure resulting in blindness for Patient 18. Dr. Jain's testimony that it is nearly impossible to obtain intraocular pressure measurements after a corneal transplant is not persuasive.

- B. Dr. Jain failed to appropriately ascertain, evaluate, and/or document the medical histories and/or visual needs of patients prior to treatment. Examples of this include the following:
1. Dr. Jain failed to properly ascertain the nature of Patient 3's prior surgery, falsely documenting that he had undergone a photorefractive keratectomy [PRK].
  2. Dr. Jain failed to evaluate whether Patient 6 would tolerate monovision prior to correcting his eyes for monovision.
  3. Dr. Jain did not discuss or document the manner in which Patient 11 used her eyes in her daily life, and did not explain the visual consequences of eliminating her left eye myopia, prior to performing LASIK.
- C. Dr. Jain failed to render and/or document appropriate diagnoses. Examples of this include the following:
1. Dr. Jain failed to recognize abnormal inferior corneal steepening in both of Patient 2's eyes prior to performing LASIK. Inferior corneal steepening is an indication of ectasia, which is a contraindication for LASIK surgery. Dr. Jain testified that he had failed to appreciate inferior corneal steepening because one of his technicians had inappropriately programmed the topographer so that the images appeared inverted, and no one had advised him of that fact. This does not in any way excuse Dr. Jain's failure to recognize the inferior corneal steepening. This failure is even more significant because superior corneal steepening is rare, and yet it occurred with so many of Dr. Jain's patients and over such a long period of time. As Dr. Gressel noted, any reasonable ophthalmologist would have recognized that something was very wrong. Nevertheless, Dr. Jain simply dismissed his failure to recognize the inverted topographies as an "oversight."
  2. Despite Patient 2's continuing operative refractive instability and visual dissatisfaction, which should have been a sign that something was seriously wrong, Dr. Jain still failed to recognize the obvious ectasia in Patient 2's corneas.
  3. Dr. Jain failed to diagnose Patient 4's post-surgical wound leak and choroidal effusions.
  4. Despite his noting of the presence of "obvious endophthalmodonesis, signifying zonular weakness" in his operative note for surgery on Patient 4's right eye,

Dr. Jain failed to document that diagnosis at any time presence prior to surgery. Dr. Gressel explained that, if Patient 4 had actually had endophthalmodonesis, it would have “further deterred a prudent ophthalmologist from embarking on such a surgical misadventure in the right eye.”

5. Dr. Jain failed to diagnose ectasia in Patient 5’s eyes prior to performing LASIK. As noted above, Dr. Jain’s justification that no one had told him that the corneal topography images were inverted is not compelling.
  6. Dr. Jain failed to diagnose ectasia in Patient 8’s eyes prior to performing LASIK.
  7. Dr. Jain failed to diagnose ectasia in Patient 12’s eyes prior to performing LASIK.
- D. Dr. Jain failed to properly obtain and/or document appropriate informed consent. Examples of this include the following:
1. The medical records for a number of these patients contained no signed informed consent forms for surgeries performed by Dr. Jain. For example, in Patient 6’s medical record, there is no informed consent form for either the LASIK surgery or the subsequent enhancement procedure. This was particularly striking since, after the first LASIK procedure, Patient 6’s girlfriend complained that there had been no informed consent prior to the surgery. Nevertheless, even after that complaint was registered, the record contains no informed consent form for the subsequent enhancement surgery.
  2. When Dr. Jain performed LASIK on Patient 3, in an eye that had been diagnosed previously with anterior basement membrane dystrophy, Dr. Jain failed to advise Patient 3 that LASIK is contraindicated in an eye with anterior basement membrane dystrophy. Moreover, Dr. Jain failed to inform Patient 3 that when performing LASIK in an eye with anterior basement membrane dystrophy, there is a greatly increased risk of sloughing of the corneal epithelium, in addition to wound healing problems, scarring, and irregular astigmatism. Even if Dr. Jain had been convincing when he testified that Patient 3’s anterior basement membrane dystrophy had not been active at that time, it would not relieve him of the responsibility to discuss the issue with Patient 3.
  3. Dr. Jain did not obtain and/or document an appropriate informed consent for the third LASIK procedure he performed on Patient 7, which included removal of the flap from the right eye, a procedure that differs in risk from the first LASIK procedure performed on Patient 7.
  4. Without prior consent, Dr. Jain converted a LASIK procedure to a PRK despite having administered Valium to Patient 10. Informed consent cannot be obtained after the administration of drugs that affect cognition. Furthermore,

Dr. Gressel noted that it had not been necessary to perform a PRK emergently; in fact, performing PRK on top of a newly created a flap frequently causes additional complications.

5. Dr. Jain failed to advise or document that he had advised Patient 12 of his failure to diagnose to ectasia prior to performing LASIK or astigmatic keratotomy, both contraindicated by ectasia.
6. Dr. Jain failed to adequately inform Patient 15 that, due the significant astigmatism present in the left eye, cataract surgery in the left eye would not provide satisfactory unaided vision.
7. After Dr. Jain removed a basal cell carcinoma from the bridge of Patient 19's nose, the pathology report indicated that there was extension of the cancer to the wound margin of the specimen. Cancer cells in the margin of the specimen were an indication that, most likely, residual cancer cells had been left in the bridge of Patient 19's nose. Nevertheless, Dr. Jain failed to advise and/or document his discussion with Patient 19 regarding the available options for treating the residual cancer cells. On his own, Dr. Jain decided to simply do nothing.
8. Patient 20 presented to the Bloomberg Eye Center with complaints of glare. Dr. Jain performed LASIK, but failed to advise and/or document that he had advised Patient 20 that he was performing LASIK to treat nearsightedness rather than glare.
9. Most egregiously, Dr. Jain's errors in conduct and omission had caused harm to a number of these patients, yet Dr. Jain did not admit his errors to the patients. Instead, Dr. Jain continued to treat these patients in attempts to repair those errors without providing the patients an opportunity to make educated choices regarding their treatment.

Examples include Dr. Jain's failure to advise Patient 2 that he had performed LASIK despite obvious, but missed, ectasia in both eyes. Dr. Jain justified his failure to advise Patient 2 by stating that Patient 2 was an anxious person and that Dr. Jain was afraid that telling him might "set him off." Dr. Jain's reasoning is simply outrageous.

- E. In addition to ordering unnecessary surgeries, Dr. Jain ordered unnecessary procedures. Examples of this include the following:
  1. Dr. Jain performed GDx without reasonable suspicion of glaucoma in Patient 15.

2. Dr. Jain performed YAG vitreolysis to sever adhesions in Patient 18, despite the fact that Dr. Jain intended to perform a corneal transplant one week later, during which the adhesions could have been severed.
  3. Dr. Jain performed focal laser procedures in the eyes of Patient 22, despite the fact that she had no potential for improved vision given her pre-existing severe macular degenerative changes and poor vision.
- F. Dr. Jain performed unnecessary surgeries. Examples of this include the following:
1. The LASIK Dr. Jain performed on Patient 11's right eye was unnecessary because the trivial refractive error had been too small and insignificant to justify LASIK correction.
  2. Dr. Jain inappropriately performed a LASIK surgery on Patient 11's right eye despite a finding that Patient 11 had a posterior subcapsular cataract, which is a contraindication for LASIK.
  3. Dr. Jain removed a cataract from Patient 15's right eye, which had been previously diagnosed with amblyopia. Therefore, Dr. Jain had performed the surgery without assurance that removal of the cataract would improve vision in that eye.
  4. The superficial keratectomy Dr. Jain performed on Patient 22's right eye was unnecessary because Patient 22 had not exhibited significant corneal ectasia. In addition, she had had an extremely poor visual prognosis due to the severe retinal disease. Moreover, performance of the unnecessary procedure had resulted in a dehiscence of her previous corneal transplant, necessitating another corneal transplantation procedure one week later.
- G. Dr. Jain performed inappropriate or inadequate treatment. Examples of this include the following:
1. Dr. Jain performed LASIK in Patient 3 despite previous diagnosis of anterior basement membrane dystrophy, a contraindication for LASIK.
  2. Dr. Jain performed LASIK surgery on Patient 4's left eye, her only visually functioning eye, placing her at an unreasonable risk of loss of vision. Dr. Gressel's testimony that Dr. Jain had not performed the surgery with Patient 4's best interest in mind was convincing. Moreover, Dr. Jain's testimony that he had been justified in performing the surgery despite the extreme risk because it had been Patient 4's decision was, as noted by Dr. Gressel, of "greatest ethical concern."

3. The phacoemulsification Dr. Jain performed on the cataract in Patient 4's right eye had been a poor choice for removing such a dense cataract, especially in light of the frail zonules in that eye.
4. Dr. Jain performed surgery incompetently in Patient 4's right eye. His incompetence included failing to take measures to prevent lens fragments from falling into the vitreous, and failing to make the wound watertight. Because of this, Patient 4 experienced choroidal effusions, which had forced her to undergo another operation.
5. Dr. Jain failed to investigate the reason why a postoperative intraocular pressure could not be obtained in Patient 4's right eye. Had Dr. Jain investigated the problem, he may have discovered the wound leak in that eye, because one of the causes of low or unobtainable intraocular pressure readings is a wound leak.
6. Dr. Jain failed to find or correct Patient 4's post-surgical wound leak and choroidal effusions.
7. Dr. Jain caused excessive overcorrection in the eyes of Patient 6, Patient 11, and Patient 16.
8. Dr. Jain inappropriately proposed performing a radial keratotomy on Patient 7's right eye. Moreover, by the time Dr. Jain proposed performing the radial keratotomy, Dr. Jain had already performed a series of inappropriate treatments that had further flattened a cornea that had been unusually flat at the outset. Had Patient 7 allowed Dr. Jain to perform radial keratotomy, it likely would have caused even more flattening, resulting in even poorer optical performance, in an eye that had not been a good candidate for LASIK in the first place.
9. In performing LASIK on Patient 12's right eye, Dr. Jain failed to enter an astigmatism axis into the laser that corresponded with the axis determined by refraction. Instead, Dr. Jain prescribed an astigmatism correction that was 100 degrees different from the axis determined by refraction.
10. In conducting the LASIK enhancement for Patient 13, Dr. Jain inappropriately programmed the astigmatism treatment for the right eye to be 13% greater than the astigmatism measured by refraction, and programmed the astigmatism treatment for the left eye to be 28% less than the astigmatism measured by refraction. Dr. Jain's testimony at hearing that he had programmed the laser in this manner due to the coupling phenomenon associated with the Nidek laser is not convincing, especially since Dr. Jain did not document this reasoning in the medical record or in the expert report he had created prior to hearing.

11. Dr. Jain performed cataract surgery in Patient 15's left eye, with an intention to provide a spherical equivalent of plano. Nevertheless, despite Patient 15's considerable astigmatism, Dr. Jain chose an intraocular lens model that was not intended for correction of such astigmatism. Therefore, in order to obtain good postoperative vision, Patient 15 would have to undergo a subsequent astigmatic keratectomy.
  12. Dr. Jain performed LASIK on Patient 15's left eye that was inappropriate. Due to the amblyopic condition of the right eye, Patient 15 would not have had a reasonable expectation of reliance on the right eye if the left eye developed a complication as a result of LASIK.
  13. During the LASIK procedure on Patient 15's left eye, Dr. Jain incorrectly entered an erroneous astigmatism axis.
  14. In treating Patient 16, Dr. Jain programmed the laser with less correction of the myopic sphere for the right eye than was contained in the cycloplegic refraction, and more correction of the myopic sphere for the left eye than was contained in the cycloplegic refraction, resulting in overcorrection for the left eye.
  15. Dr. Jain failed to treat intraoperative choroidal detachments in Patient 18.
- H. Dr. Jain failed to provide adequate postoperative care and/or supervision of care for patients. Examples of this include the following:
1. Dr. Jain allowed optometrists to follow Patient 7 after serious surgery, in spite of complications with DLK. Moreover, when Patient 7's condition did not improve through corticosteroid treatment, Dr. Jain did not irrigate the flap in a timely manner.
  2. Dr. Jain failed to provide appropriate postoperative treatment for Patient 10 after performing a LASIK surgery and converting it to a PRK. Dr. Jain's testimony was ridiculous when he stated that, because he had told Patient 10 to call the office if there was a problem, Dr. Jain had rendered sufficient postoperative care.
  3. Dr. Jain performed LASIK on Patient 13, but kept no records of any preoperative or postoperative care rendered to that patient.
  4. Dr. Jain performed LASIK on Patient 14, but did not see the patient postoperatively. Only optometrists and technicians at Bloomberg Eye Center saw Patient 14 after Dr. Jain's surgery.

5. Dr. Jain failed to see Patient 18 for five days after a corneal transplant complicated by choroidal detachments that had caused the contents of the eye to come forward.
  6. The day after a complicated surgery, Dr. Jain performed a paracentesis in Patient 21's eye due to elevated intraocular pressure. Nevertheless, Dr. Jain did not advise Patient 21 to return for follow-up until fifteen days later.
- I. Dr. Jain failed to appropriately document his care. Examples of this include the following:
1. In many of the patient records, Dr. Jain failed to document LASIK procedures properly. The medical records contain printouts from the laser machines, but no operative notes or other information regarding the LASIK procedure. Moreover, the laser printouts do not provide information regarding the creation of the flaps, the thickness of the flaps, despite the fact that this information might be important to the patients in the future.
  2. Dr. Jain failed to record microkeratome data in Patient 2, Patient 3, Patient 4, Patient 5, Patient 7, Patient 8, Patient 9, Patient 10 and Patient 12. Dr. Jain was unconvincing when he testified that his failure to record microkeratome data was not a problem because subsequent treating physicians could call his office to discover that the Bloomberg Eye Center had always used in Nidek 160-micron microkeratome.
  3. Despite clear evidence that the patients were not doing well, Dr. Jain frequently documented his impression as, "Doing well!"
  4. Dr. Jain repeatedly documented that Patient 2 was "Doing well!" Nevertheless, at hearing, Dr. Jain testified that he had recognized that Patient 2 was not having a normal recovery from his LASIK procedure and had followed him carefully.
  5. Dr. Jain inaccurately documented in Patient 3's medical record that Patient 3 had had a photorefractive keratectomy [PRK] procedure performed by a prior physician. When asked why he had documented a procedure that had not been performed, Dr. Jain testified that he had asked Patient 3 to describe what the prior physician had done and Dr. Jain had "guesstimate[d]" what that procedure might have been. Dr. Jain further explained that he had not contacted the prior treating physician because the prior treating physician did not like Dr. Jain and had made negative remarks in the community regarding Dr. Jain. Clearly, Dr. Jain's rationale for not contacting the prior treating physician reveals that Dr. Jain did not have this patient's best interest in mind.

6. In his operative note, Dr. Jain documented “iris irregularities” as a preoperative diagnosis, when iris irregularities had not been mentioned in any preoperative notes. Dr. Jain’s recording of the diagnosis for the first time after the surgery is significant because “iris irregularities” is a diagnosis that, if true, might have led to the complications and negative outcome that occurred in this case. Alternatively, if not true, it might have been an attempt on Dr. Jain’s part to hide his incompetent surgery.
7. Similarly, Dr. Jain documented in an operative note for Patient 4 that she had had “vitreous prolapse from the zonular dehiscence,” implying that the vitreous prolapse had been a pre-existing condition, which led to complications during the surgery. Nevertheless, Dr. Jain had not documented vitreous prolapse in any of his preoperative examinations.
8. Again, although Dr. Jain documented in an operative note and a postoperative referral letter that Patient 4 had had “traumatic cataract formation at a young age,” there is no indication of a history of traumatic cataract formation anywhere else in the medical record. This is significant because, if Patient 4 had truly had a preoperative history of traumatic cataract, it could account for many of the problems that occurred during Dr. Jain’s surgery, rather than wrongdoing on Dr. Jain’s part.
9. Dr. Jain documented in a consultation note for Patient 4 that pupillary examination was unremarkable, when no pupillary examination had been mentioned in any preoperative notes.
10. Patient 5’s medical record does not contain an operative note for the astigmatic keratotomy.
11. Dr. Jain conducted flap irrigation for Patient 7, but failed to document any details of this procedure in the medical record.
12. Dr. Jain did not record an operative note for the third LASIK procedure performed on Patient 7, which included removal of the flap from the right eye. Moreover, the record does not indicate when the procedure was done. The only indications are Dr. Jain’s notation that he planned to perform the procedure and, two months later, a notation that the procedure had been performed.
13. Dr. Jain did not record an operative note for a flap debridement in Patient 9’s left eye.
14. Dr. Jain had not documented the LASIK procedure which he converted to a PRK in Patient 10’s left eye, other than in very limited postoperative references to the procedure having been done. Dr. Jain’s testimony that he had sufficiently

documented the incomplete flap and conversion to a PRK by hand-writing a note on the bottom of the Visx printout that there had been an incomplete flap is not convincing. Moreover, Dr. Jain's testimony that a subsequent treating physician would be able to see that the flap had been incomplete by examining the eye, even if true, does not excuse his failure to document performance of the procedure.

- J. Dr. Jain failed to make appropriate referrals. For example, Dr. Jain failed to refer Patient 2 for a consulting opinion despite Patient 2's deteriorating condition after Dr. Jain performed LASIK on an eye with ectasia. Similarly, Dr. Jain failed to refer Patient 7 for a consulting opinion despite the patient's deteriorating condition under his care.

Most appalling, however, is Dr. Jain's reasoning for failing to refer patients who were not doing well under his care. Dr. Jain believed that it was in the patients' best interest to continue under his care because other ophthalmologists did not like him and incited the patients against him. This logic is outrageous.

- II. The State failed to provide sufficient evidence to support the following allegations:
  - A. Dr. Jain inappropriately failed to discern and/or document the presence of a fiber under the flap of Patient 9's right eye.
  - B. In his treatment of Patient 20, Dr. Jain failed to insert the correct size intraocular lenses.

### CONCLUSIONS OF LAW

The conduct of Vikas Kumar Jain, M.D., as set forth in Findings of Fact I, individually and/or collectively, constitutes "[a] departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in Section 4731.22(B)(6), Ohio Revised Code.

\* \* \* \* \*

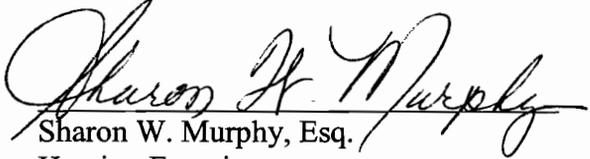
Dr. Gressel was accurate when he testified that, in review of Dr. Jain's treatment of these patients, he had found "a pattern of incompetence, negligence, and utter disregard for acting in the best interest of the patients" and a pattern of "very sloppy, shoddy, slash-and-dash, irresponsible style of taking care of people." Moreover, as noted by the State in its closing argument, Dr. Jain's failure to take responsibility for the disastrous outcomes in some of these cases, coupled with his failure to admit that his own errors had caused the disastrous outcomes, is sufficient reason alone to permanently revoke Dr. Jain's certificate to practice medicine and surgery in this State.

**PROPOSED ORDER**

It is hereby ORDERED that:

The certificate of Vikas Kumar Jain, M.D., to practice medicine and surgery in the State of Ohio shall be PERMANENTLY REVOKED.

This Order shall become effective immediately upon the mailing of notification of approval by the Board.

  
Sharon W. Murphy, Esq.  
Hearing Examiner



# State Medical Board of Ohio

77 S. High St., 17th Floor • Columbus, OH 43215-6127 • (614) 466-3954 • Website: [www.med.ohio.gov](http://www.med.ohio.gov)

## EXCERPT FROM THE DRAFT MINUTES OF NOVEMBER 9, 2005

### REPORTS AND RECOMMENDATIONS

Dr. Davidson announced that the Board would now consider the findings and order appearing on the Board's agenda. She asked whether each member of the Board had received, read, and considered the hearing records, the proposed findings, conclusions, and orders, and any objections filed in the matters of: Lynne Ellen Zegiob Check, M.D.; Vikas Kumar Jain, M.D.; and Barry Joseph Politi, M.D. A roll call was taken:

ROLL CALL:	Mr. Albert	- aye
	Dr. Egner	- aye
	Dr. Talmage	- aye
	Dr. Varyani	- aye
	Mr. Browning	- aye
	Dr. Robbins	- aye
	Dr. Saxena	- aye
	Dr. Steinbergh	- aye
	Dr. Davidson	- aye

Dr. Davidson asked whether each member of the Board understands that the disciplinary guidelines do not limit any sanction to be imposed, and that the range of sanctions available in each matter runs from dismissal to permanent revocation. A roll call was taken:

ROLL CALL:	Mr. Albert	- aye
	Dr. Egner	- aye
	Dr. Talmage	- aye
	Dr. Varyani	- aye
	Mr. Browning	- aye
	Dr. Robbins	- aye
	Dr. Saxena	- aye
	Dr. Steinbergh	- aye
	Dr. Davidson	- aye

Dr. Davidson noted that, in accordance with the provision in Section 4731.22(F)(2), Revised Code, specifying that no member of the Board who supervises the investigation of a case shall participate in further adjudication of the case, the Secretary and Supervising Member must abstain from further participation in the adjudication of these matters. In the matters before the Board today, Dr. Talmage

served as Secretary and Mr. Albert served as Supervising Member.

Dr. Davidson stated that, if there were no objections, the Chair would dispense with the reading of the proposed findings of fact, conclusions and orders in the above matters. No objections were voiced by Board members present.

The original Reports and Recommendations shall be maintained in the exhibits section of this Journal.

.....  
VIKAS KUMAR JAIN, M.D.

.....  
**MR. BROWNING MOVED TO APPROVE AND CONFIRM MS. MURPHY'S PROPOSED FINDINGS OF FACT, CONCLUSIONS, AND ORDER IN THE MATTER OF VIKAS KUMAR JAIN, M.D. DR. STEINBERGH SECONDED THE MOTION.**

.....  
A vote was taken on Mr. Browning's motion to approve and confirm:

Vote:	Mr. Albert	- abstain
	Dr. Egner	- aye
	Dr. Talmage	- abstain
	Dr. Varyani	- aye
	Mr. Browning	- aye
	Dr. Robbins	- aye
	Dr. Saxena	- aye
	Dr. Steinbergh	- aye
	Dr. Davidson	- aye

.  
The motion carried.



# State Medical Board of Ohio

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## CORRECTION TO NOTICE OF OPPORTUNITY FOR HEARING

September 3, 2004

Vikas Kumar Jain, M.D.  
160 Merywen Circle  
Granville, Ohio 43023

Dear Doctor Jain:

It has been brought to my attention that the June 9, 2004, notice of opportunity for hearing issued to you by the State Medical Board of Ohio contained a number of non-substantive clerical and/or typographical errors. Please note the following corrections to the June 9, 2004 notice, a copy of which is attached for your reference:

- In paragraph (1)(C), 1<sup>st</sup> sentence, substitute “**September 28 or 30, 2002**” for “September 30, 2002;”
- In paragraph (1)(E), 3<sup>rd</sup> sentence, substitute “**May 29, 2001**” for “April 29, 2001;”
- In paragraph (1)(N), 1<sup>st</sup> sentence, substitute “**January 25 or 26, 2001**” for “January 25, 2001;”
- In paragraph (1)(P), 3<sup>rd</sup> sentence, substitute “**September 5, 2000**” for “July 5, 2000;”
- In paragraph (1)(V), 4<sup>th</sup> sentence, substitute “**October 31, 2001**” for “October 31, 2002.”

Pursuant to Rule 4731-13-17(H), Ohio Administrative Code, these corrections to the notice of opportunity for hearing do not necessitate the issuance of an amended cite, and this letter does not supersede the original notice of opportunity for hearing. Accordingly, a new request for hearing is not necessary and this matter will proceed as currently scheduled.

Very truly yours,

A handwritten signature in black ink that reads "Lance A. Talmage, M.D.". The signature is written in a cursive, flowing style.

Lance A. Talmage, M.D.  
Secretary

Vikas Kumar Jain, M.D.  
Page 2

LAT/blt

CERTIFIED MAIL # 7000 0600 0024 5143 8411  
RETURN RECEIPT REQUESTED

cc: Kris Dawley, Esq.  
Schottenstein, Zox and Dunn  
250 West Street  
Columbus, Ohio 43215-2538

CERTIFIED MAIL # 7000 0600 0024 5143 8428  
RETURN RECEIPT REQUESTED



# State Medical Board of Ohio

77 S. High St., 17th Floor • Columbus, OH 43215-6127 • (614) 466-3934 • Website: [www.med.ohio.gov](http://www.med.ohio.gov)

June 9, 2004

Vikas Kumar Jain, M.D.  
160 Merywen Circle  
Granville, Ohio 43023

Dear Doctor Jain:

In accordance with Chapter 119., Ohio Revised Code, you are hereby notified that the State Medical Board of Ohio [Board] intends to determine whether or not to limit, revoke, permanently revoke, suspend, refuse to register or reinstate your certificate to practice medicine and surgery, or to reprimand you or place you on probation for one or more of the following reasons:

- (1) In the routine course of your medical practice, you undertook the care of Patients 1 through 22, as identified in the attached Patient Key. The Patient Key is confidential, and shall be withheld from public disclosure.

As demonstrated in your patients' records, you failed to perform and/or document the performance of appropriate testing and/or measurements; and/or you failed to appropriately ascertain, evaluate, and/or document the medical histories and/or visual needs activity of daily living of patients prior to treatment; and/or you failed to render and/or document appropriate diagnoses; and/or you failed to provide appropriate and/or adequate treatment and/or failed to document such treatment; and/or you failed to make appropriate referrals and/or document making such referrals; and/or you performed unnecessary surgeries; and/or you ordered unnecessary procedures; and/or you failed to properly obtain and/or document appropriate informed consent; and/or you failed to provide adequate post-operative care and/or supervision of care for patients and/or failed to properly document such care. Examples of such conduct include the following:

- (A) On or about February 13, 2001, you evaluated Patient 1 for Laser Assisted *In Situ* Keratomileusis [LASIK], subsequently performing LASIK for this patient on or about March 2, 2001. Prior to performing LASIK, you failed to perform keratometry and corneal pachymetry for Patient 1. Prior to performing LASIK, when Patient 1 was checked for

*Mailed 6/10/04*

the refraction, she reported that that lens refraction did not give her clear vision, but rather triple vision; nevertheless, you programmed that refraction into the laser. You failed to make certain that Patient 1's refraction was accurate and/or failed to adequately supervise this pre-surgical test, consequently treating Patient 1 for the wrong refractive error. After you performed LASIK on Patient 1, she eventually underwent a corrective LASIK procedure in both eyes by another physician.

- (B) On or about February 5, 2001, you evaluated Patient 2 for the LASIK procedure, subsequently performing LASIK on this patient on or about February 8, 2001. You failed to perform keratometry prior to performing LASIK for Patient 2; you failed to obtain Patient 2's corneal pachymetry; and you failed to recognize Patient 2's atypical corneal steepening, a contraindication for the LASIK procedure, that was evident on Patient 2's pre-LASIK topography. During examinations following his LASIK procedure, Patient 2 reported that he had to tilt his head back to see better, an indication of possible corneal asymmetry; reported seeing halos; and denied improvement. Patient 2's records indicate that on or about April 2, 2001, he was seeing double even with strong spectacle correction. Although topographies conducted on or about April 5, 2001, indicate ectasia in both of Patient 2's eyes, you failed to acknowledge and/or record the ectasia, labeling the records "no keratoconus." Further, you failed to recognize possible destabilization of both corneas, considering instead further laser surgery. On or about July 17, 2001, you recognized that part of the topography of both eyes was "steep" but you failed to notice the inversion of the image. During a follow up examination on or about October 16, 2001, you opined that a customized ablation would be needed, despite Patient 2's refractive instability, large amounts of mixed astigmatism, and reported "terrible" vision. On or about October 14, 2002, Patient 2's records indicate that he was required to wear rigid gas permeable contact lenses in both eyes.
- (C) On or about September 30, 2002, you evaluated Patient 3 for LASIK, subsequently performing LASIK for this patient on or about October 15, 2002. Prior to consulting you for the LASIK procedure, Patient 3 had been diagnosed with anterior membrane corneal dystrophy and had undergone mechanical debridement of the corneal epithelium [superficial keratectomy] by another physician. Although the records of Patient 3's previous surgery had been faxed to you on or about October 11, 2002, you failed to properly ascertain and/or document the nature of Patient 3's surgery, incorrectly recording in Patient 3's medical records that he had undergone a prior photorefractive keratectomy [PRK]. Further, you failed to record the type of microkeratome or the microkeratome settings

used for the LASIK procedure. Further, you inappropriately treated Patient 3 by performing LASIK on Patient 3's right eye, which was afflicted with anterior membrane corneal dystrophy, a contraindication for LASIK. Further, you failed to inform and/or document that you informed Patient 3 of the possible risks associated with performing LASIK upon an eye afflicted with anterior membrane corneal dystrophy.

- (D) On or about March 13, 2002, you examined Patient 4, and found Patient 4 to have a right eye with no light perception (i.e., no visual functioning) and with an intraocular pressure of 3. Your medical records indicate that Patient 4 reported having life-long poor vision in the right eye due to optic nerve abnormality. You also noted that Patient 4 had developed a dense cataract of the right eye, which prevented visualization of the fundus. No pupillary examination or description of the iris of the right eye was recorded. Patient 4's left eye examination revealed a myopic astigmatism, and you performed LASIK on Patient 4's left eye, her only visually functioning eye, on or about March 13, 2002. On or about April 10, 2002, you performed cataract extraction surgery on Patient 4's right eye, and noted obvious endophthalmodonesis. The surgery for Patient 4's right eye resulted in vitreous loss, no intraocular lens was implanted, and no visual rehabilitation of the eye was provided. After surgery, Patient 4's right eye was painful and exhibited severe inflammation, and you referred Patient 4 to another surgeon in your practice, who found complications from your surgery including wound leak and choroidal effusions. The referral surgeon performed a second surgery to remove cataract fragments left behind by your surgery, and closed the wound you failed to make watertight. In your referral letter to the second surgeon, you describe Patient 4 as having "traumatic cataract formation at a young age," when no corroboration of a history of trauma appears anywhere else in the record.

You inappropriately performed surgery on Patient 4's left eye, her only visually functioning eye, placing her at an unreasonable risk for loss of vision.

Further, although Patient 4's preoperative conditions for her right eye were indicative of an afferent pupillary defect, regarded as an indication of a poor prognosis for visual improvement in a non-seeing eye, you performed unnecessary surgery on Patient 4's right eye. Further, you performed surgery on Patient 4's right eye incompetently, including failing to take measures to prevent lens fragments from falling into the vitreous, failing to make the wound watertight, and making a poor choice of surgical methodology. Further, you failed to diagnose and correct Patient 4's right eye post-surgical wound leak and choroidal effusions.

Further, although your clinical consultation note dated on or about March 14, 2002, indicates that the pupillary examination was “unremarkable,” your hand-written medical records dated on or about March 12, 2002, and on or about March 14, 2002, fail to corroborate the claim that the pupil of the right eye was ever examined prior to surgery.

You failed to discern and/or document the presence or absence of an afferent pupillary affect, you failed to perform keratometry and/or document the performance of keratometry in Patient 4’s left eye prior to conducting LASIK, you failed to document the type of microkeratome and microkeratome settings used for LASIK, and you failed to discern and/or document the presence of endophthalmodonesis prior to surgery. On or about April 10, 2002, you recorded a pre-operative diagnosis of “iris irregularities” for Patient 4’s right eye, when none of your previous descriptions of Patient 4’s examinations support iris abnormalities.

During her care at the eye clinic where you conducted surgery, Patient 4 did not gain useful vision in her right eye, reporting discomfort and sensitivity to light. The patient records reveal that the physician who subsequently treated Patient 4 did not expect visual improvement for the right eye based upon that eye’s optic nerve condition, which was present prior to your surgery.

- (E) On or about April 19, 2001, you evaluated Patient 5 for LASIK, and subsequently performed LASIK on both eyes of this patient on or about May 29, 2001, and an astigmatic keratotomy for Patient 5’s left eye on or about April 29, 2002. A corneal topography taken prior to the LASIK procedure for Patient 5 showed pronounced asymmetric steepening of the cornea, indicative of ectasia. Following the LASIK procedure conducted on or about April 29, 2001, Patient 5 reported double vision and seeing a ghost image in the right eye. On or about January 21, 2002, you opined that Patient 5 was a good candidate for wave front ablation, failing to note the abnormal corneal contour present postoperatively. Following your performance of the astigmatic keratotomy for Patient 5, he reported that his right eye vision was getting worse, and refraction revealed more astigmatism in the right eye than before the LASIK procedure. On or about July 16, 2002, you sutured the astigmatic keratotomy incisions, but, when following this procedure Patient 5 reported development of pain and exhibited worsening astigmatism, the sutures were removed. On or about December 6, 2002, the diagnosis of ectasia was entered for Patient 5 following examination by an optometrist. Subsequent medical records for Patient 5 demonstrate unsuccessful attempts at visual rehabilitation with contact lenses.

You failed to properly diagnose corneal ectasia present in Patient 5's right eye prior to the LASIK procedure of on or about May 29, 2001, and that continued to be present prior to the astigmatic keratotomy conducted on or about April 29, 2002. Further, you inappropriately performed LASIK on Patient 5's right eye, which exhibited ectasia, and inappropriately placed an astigmatic keratotomy incision in the part of the cornea most affected by ectasia. Further, you failed to document the type of microkeratome utilized or the microkeratome settings used, and you failed to appropriately document the operative procedures conducted on or about April 29, 2002, and on or about July 16, 2002. Further, you failed to perform and/or properly document the performance of pachymetry and/or keratometry prior to performing LASIK for Patient 5, and further failed to perform and/or document the performance of pachymetry prior to performing the astigmatic keratometry for Patient 5. Further, you failed to refer Patient 5 to another physician when it became apparent that he was not improving under your care.

- (F) On or about July 11, 2002, you evaluated Patient 6 for LASIK, at that time noting in the patient records that his left eye was dominant. Prior to performing the LASIK procedure for Patient 6, you failed to test this patient to determine whether he would be able to adapt to monovision; nevertheless, on or about July 16, 2002, you performed LASIK on this patient, creating modified monovision by correcting the right eye for near vision and the left eye for distance vision. Further, you entered a large treatment for hyperopia into the laser, which resulted in overcorrections of Patient 6's eyes. The day following his LASIK surgery, Patient 6 reported that his distance vision was blurred, yet you failed to provide and/or document suggestions to assist Patient 6 with his visual functioning, instructing him to return in eight weeks. On or about July 23, 2002, Patient 6 reported that his distance vision was so blurred that he was not comfortable driving. On or about July 30, 2002, Patient 6 reported that his right eye was worse, and you prescribed glasses and eye drops. At a subsequent follow-up examination, Patient 6 reported that he could not function with his glasses, he could not see at a distance, he could not see well enough to drive, and he was upset and displeased with the outcome of the surgery.

On or about October 17, 2002, you performed a second LASIK procedure on Patient 6. Although you had previously noted in this patient's records that his left eye was dominant, and had previously entered treatment plans to correct his right eye for near vision, you eliminated all of Patient 6's right eye near vision, forcing Patient 6 to rely on his nondominant right eye for distance. During follow-up examinations subsequent to the second LASIK procedure, Patient 6

reported that his distance vision was decreasing, reported symptoms of dry eye syndrome, and reported a sense of noncooperation between the eyes.

Further, you failed to obtain and/or document informed consent from Patient 6 prior to performing the LASIK procedure on or about July 16, 2002, and prior to performing the second procedure on or about October 17, 2002. Further, you failed to provide adequate post-operative care for Patient 6.

- (G) On or about July 9, 2001, you evaluated Patient 7 for LASIK, subsequently performing the LASIK procedure on both eyes of Patient 7 on or about July 12, 2001 [first LASIK procedure]. Prior to performing the first LASIK procedure for Patient 7, you failed to perform keratometry. Although the medical records refer to topography conducted for this patient, there is no topographic image for Patient 7 in the records, and there is no indication that the plan to repeat the topography on the day of surgery was conducted. However, the topography referenced in the medical records indicate that this patient exhibited inferior steeping of the corneas, and simulated K measurements derived from the referenced topography indicated flat corneas.

Following the first LASIK procedure, Patient 7 exhibited diffuse lamellar keratitis [DLK], and Patient 7's records indicate that he exhibited striae, haze, wrinkles, scarring, and epithelial plaque in his right eye. Patient 7 was treated with steroids for approximately three weeks following the first LASIK procedure, but you failed to provide adequate post-operative care and/or supervision of care for Patient 7.

On or about July 19, 2001, you conducted flap irrigation for Patient 7, but you failed to document the details of this procedure in Patient 7's medical record. On or about August 10, 2001, you performed a second flap irrigation and a debridement on the right eye of Patient 7, utilizing alcohol to decimate epithelial cells. Following the second flap irrigation, Patient 7 underwent approximately four weeks of steroid therapy before an intraocular pressure was measured.

You saw Patient 7 again on or about February 11, 2002, and Patient 7 reported that his vision was still blurred in both eyes, in the right eye more so than the left. On or about March 14, 2002, you performed a LASIK enhancement procedure of Patient 7's left eye [second LASIK procedure] for correction of residual myopic astigmatism, but you failed to recheck the corneal thickness with pachymetry and failed to check the corneal contour with topography. Further, there is no operative note

describing the second LASIK procedure. On or about March 15, 2002, the day following the second LASIK procedure, Patient 7 again exhibited symptoms of DLK.

On or about March 27, 2002, you performed a LASIK procedure on Patient 7's right eye [third LASIK procedure], whereby you inappropriately removed the flap from Patient 7's right eye without first having sutured the flap and without first having obtained a second opinion from another ophthalmologist. Further, you failed to obtain and/or document an appropriate informed consent for this third LASIK procedure, which included removal of the flap from the right eye, a procedure that differs in risk from the first LASIK procedure performed on Patient 7.

Following the third LASIK procedure, Patient 7 continued to report blurred vision. On or about July 25, 2002, you performed a surface ablation procedure on the right eye of Patient 7, which caused further thinning of the right cornea, and Patient 7 continued to experience blurred, fluctuating vision. Further, you inappropriately proposed performing a radial keratotomy.

Further, you inappropriately performed LASIK procedures on Patient 7's right eye. Further, you failed to maintain an accurate total of the amount of tissue removed from Patient 7's eye, failed to adequately supervise the pachymetry, and failed to appropriately document operative notes. Further, you failed to provide adequate post-operative care and/or supervision of care for Patient 7 and failed to provide appropriate care and/or supervision of care during steroid therapy. Further, you failed to refer Patient 7 to another physician when it became apparent that he was not improving under your care. Further, you failed to perform keratometry prior to surgery and failed to record the type of microkeratome or the microkeratome settings used.

- (H) On or about March 3, 2001, you evaluated Patient 8 for LASIK, subsequently performing LASIK on both eyes of Patient 8 on or about April 21, 2001. On or about June 29, 2002, you performed a second LASIK procedure on both eyes of Patient 8. Prior to both of the LASIK procedures, you failed to perform preoperative tests and/or measurements including pachymetry and topography. You failed to document the type of microkeratome or the microkeratome settings utilized for Patient 8. In or about January 2003, Patient 8 was referred to another ophthalmologist in your clinic because of blurred vision in the patient's right eye. On or about February 25, 2003, Patient 8 was examined in your clinic, and it was determined that Patient 8 presented with symptoms consistent with

corneal ectasia, a decentered flap, thin cornea, and 11.50 diopters of astigmatism. Patient 8 was referred back to the optometrist for possible fitting of gas permeable contact lenses for visual rehabilitation.

You failed to document and/or diagnose the presence of ectasia in the right eye of Patient 8 prior to the LASIK enhancement procedure of on or about June 29, 2002, despite the presence of distorted keratometry mires in Patient 8's right eye, an observation flagged by an arrow and two stars in Patient 8's medical records. Further, you inappropriately performed LASIK on the right eye of Patient 8, who presented with ectasia in that eye. Further, you failed to document and/or provide adequate postoperative care and/or postoperative care arrangements for Patient 8.

- (I) You evaluated Patient 9 for LASIK on or about February 12, 2001, and performed LASIK on both eyes of Patient 9 on or about February 13, 2001 [first LASIK procedure]. On or about November 9, 2001, you performed a second LASIK procedure for Patient 9 [second LASIK procedure]. Prior to performing the first LASIK procedure, you failed to perform keratometry, and simulated K measurements were derived from topography. Further, you failed to measure corneal pachymetry before either the first or second LASIK procedure and failed to document microkeratome data.

During examinations following the first LASIK procedure, Patient 9 reported declining acuity in both eyes and hazy vision in her right eye. Although a fiber was noted under the flap of Patient 9's right eye by another examiner on or about February 14, 2001, and again noted by an optometrist on or about March 9, 2001, your examination of Patient 9 on or about May 18, 2001, describes Patient 9's right cornea as "clear."

Following the second LASIK procedure, Patient 9 developed Diffuse Lamellar Keratitis [DLK] and corneal epithelial defects in both eyes, causing long-term pain and visual disability for Patient 9. You treated Patient 9 with intensive topical and oral steroid therapy, and the DLK and corneal epithelial defects generally resolved, although some degree of persistent discomfort remained in Patient 9's left eye. However, you failed to timely measure intraocular pressures during steroid therapy, failing to adequately monitor for cataracts and glaucoma that could result from long-term use of steroids. On or about June 17, 2002, you performed a flap debridement in Patient 9's left eye, but no operative note was entered describing this procedure. Following the June 17, 2002, procedure, Patient 9 reported that her left eye burned and was painful.

You failed to promptly and appropriately treat Patient 9 after the diagnosis of DLK, and failed to recognize the progression of DLK. Further, you failed to discern and/or document the presence of a fiber under the flap of Patient 9's right eye, and failed to document an operative note describing the procedure you conducted on Patient 9's left eye on or about June 17, 2002.

- (J) On or about April 14, 2000, you evaluated Patient 10 for LASIK, subsequently performing surgery for Patient 10 on or about May 30, 2000. Prior to performing LASIK for Patient 10, you failed to perform a corneal pachymetry or keratometry for Patient 10. During the LASIK procedure, problems developed with an incomplete flap of the left eye, and the operation was converted to photorefractive keratectomy [PRK.] Following surgery, Patient 10 was found to have reduced vision. Further, your records indicate that following the procedure, Patient 10 reported blurry vision, starbursts, and halos, and had difficulty driving at night. Despite the topography revealing pronounced irregular astigmatism in Patient 10's left eye, despite an increase in intraocular pressure, and despite the patient's complaints, you declared in the patient records that Patient 10 was doing well.

You failed to document an operative report adequately describing Patient 10's left eye surgery; you failed to obtain and/or document an appropriate informed consent for converting Patient 10's left eye surgery from LASIK to PRK; you failed to adequately perform surgery for Patient 10; you conducted PRK over a LASIK flap, an inappropriate procedure; and you failed to provide appropriate post-operative treatment for Patient 10.

- (K) On or about August 7, 2000, you evaluated Patient 11 for LASIK, subsequently performing the LASIK procedure on Patient 11 on or about October 3, 2000. At the time of her evaluation, you did not perform keratometry or a corneal pachymetry, and no topographic image of this patient's eyes was taken and/or documented prior to the first LASIK procedure. At the time of her evaluation, you declared Patient 11 to be an excellent candidate for LASIK in both eyes, despite the fact that the right eye exhibited a trivial refractive error, and that the right eye exhibited trace posterior subcapsular cataract. Further, at the time of surgery, you programmed an excessive treatment for Patient 11's right eye, causing overcorrection. Further, you did not discuss and/or document the manner in which Patient 11 used her eyes in her daily life, and did not explain the visual consequences of eliminating her left eye myopia.

Following her surgery, Patient 11 reported blurred vision, the need for reading glasses, dry eye syndrome, and uveitis in the form of KP. Patient 11 was left with loss of best spectacle-corrected visual acuity and irregular astigmatism.

In treating Patient 11, you failed to conduct appropriate testing; failed to provide appropriate treatment; failed to perform appropriate surgery; failed to adequately discuss and/or document the discussion of the consequences of the surgery; and performed unnecessary surgery.

- (L) On or about April 2, 2001, you evaluated Patient 12 for LASIK [first evaluation], advising her that she would have to do without her rigid gas permeable contact lenses for another month before the evaluation could be completed. Although the corneal topography images taken of Patient 12's eyes demonstrated ectasia in both eyes, you indicated "no keratoconus" in the medical record. On or about May 7, 2001, Patient 12 was re-evaluated for LASIK [second evaluation], at which time she reported that her glasses were useless, but you failed to document an explanation of this complaint or the difference between the measurement of her glasses and the refraction reported. A different set of simulated K measurements derived from topography was recorded during the second evaluation, but no topographic images were taken and/or documented for the second evaluation. No pachymetry was performed during either evaluation.

On or about May 11, 2001, you performed LASIK for Patient 12, despite the preoperative demonstration of ectasia. You failed to record the microkeratome data for the LASIK procedure, and you failed to enter an astigmatism axis into the laser that corresponded with the axis determined to be the refraction of the right eye, prescribing instead an astigmatism correction that was 100 degrees different from the axis determined by the refraction recorded during the second evaluation. Following the LASIK procedure, Patient 12 reported that she could see neither near nor far with her right eye, and you inappropriately concluded the concern to be related to Patient 12's macula, and entered a plan to consult another physician concerning Patient 12's macula, although no record of such consult was entered in the medical records. On or about June 25, 2001, as Patient 12 reported fluctuating vision, you noted macrostriae in both eyes, and you recommended Alphagan eye drops, but did not document a rationale supporting the use of such eye drops. On or about June 27, 2001, you performed a flap irrigation procedure utilizing an alcohol-soaked Q-tip to scrape the epithelium plaque from the underside of the flap. On or about August 27, 2001, the refraction for Patient 12 indicated considerable astigmatism in both eyes, yet your plan

was to consider astigmatic keratotomy despite postoperative topographic images demonstrating obvious ectasia. On or about October 9, 2001, the magnitude of the refractive astigmatism in Patient 12 had greatly increased, and rigid gas permeable contact lens fitting was attempted. The medical records for Patient 12 after this date document that Patient 12 continued to experience significant impairment due to fluctuating vision, and she reported that when she drove at night, she saw triple and double images and the reflections on the roads were not where they appeared to be to her. Although Patient 12 failed to improve and/or continued to deteriorate under your care, you failed to consult with and/or make a referral to another physician.

- (M) On or about June 12, 2002, you performed a LASIK enhancement procedure for Patient 13, who exhibited an unexplained high degree of astigmatism and best spectacle-corrected visual acuity of less than 20/20 following her original LASIK procedure. You failed to measure corneal pachymetry and topography prior to performing the enhancement, and although you received faxed medical record information from another vision facility concerning Patient 13, there was no documentation of the LASIK treatments previously provided to Patient 13, and no information in the patient record concerning her preoperative refraction, preoperative or postoperative keratometry, pachymetry, topography, or treatment goals. In conducting the LASIK enhancement and without documenting your explanation, you inappropriately programmed the astigmatism treatment for the right eye at 13% greater than the astigmatism measured by refraction, and programmed the astigmatism treatment for the left eye at 28% less than the astigmatism measured by refraction. Prior to performing the enhancement, you failed to obtain and/or document an informed consent of any kind for Patient 13, and postoperatively, you failed to provide and/or document an appropriate plan of care for Patient 13, other than "prn."
- (N) On or about January 25, 2001, you evaluated Patient 14 for LASIK, and performed LASIK for this patient on both eyes on or about January 31, 2001. Preoperatively, you failed to measure corneal pachymetry and failed to measure keratometry, relying instead upon simulated K measurement derived from topography. There is no documentation that you examined Patient 14 postoperatively.
- (O) On or about April 29, 2002, you examined Patient 15, who came to you with the complaints that his vision tended to film over in his left eye, and that he had difficulty reading fine print. At the time of his initial consultation with you, Patient 15 did not indicate a problem with his right eye. You rendered diagnoses for Patient 15 of nuclear cataracts,

more so in the left eye than the right, and amblyopia in the right eye. On or about May 1, 2002, you performed cataract surgery for the left eye of Patient 15. On the day of surgery, despite the absence of documentation of risk factors for or suspicions of glaucoma or optic nerve or retinal disorder, you unnecessarily performed a glaucoma test on Patient 15. The day following left-eye cataract surgery, Patient 15's left eye exhibited a cortical remnant in the anterior chamber, but there was no evidence of inflammation, and despite the absence of an intraocular pressure elevation, you rendered a diagnosis of "cortical remnant (secondary open angle glaucoma)." On or about May 2, 2002, you performed unnecessary surgery by executing an anterior chamber paracentesis on Patient 15's left eye. On the operative note you entered for paracentesis, you again entered a diagnosis of secondary glaucoma, despite the absence of an intraocular pressure elevation. On or about May 9, 2002, Patient 15 reported difficulty with blurred vision and difficulty seeing the television, and instead of addressing the compound myopic astigmatism evident in the left eye, you proposed to remove the cataract from Patient 15's right eye, making no reference to your prior diagnosis of amblyopia for this eye. You failed to perform potential acuity meter testing prior to surgery for removal of the right-eye cataract, and failed to discuss and /or document the discussion of the inherent limitations of improving vision in an amblyopic eye by removing a cataract. Following the right eye cataract surgery for Patient 15, his right eye exhibited compound hyperopic astigmatism, while his left eye exhibited compound myopic astigmatism.

Following the surgeries, when Patient 15 complained that he was not experiencing promised unaided monovision, he was scheduled to undergo LASIK to correct the problem. You failed to perform corneal topographies prior to the LASIK procedures. On or about September 17, 2002, you performed LASIK on the left eye of Patient 15, an inappropriate procedure because, due to the amblyopic condition of Patient 15's right eye, he would not have had a reasonable expectation of reliance on the right eye if the left eye developed a complication as a result of LASIK. Further, for the LASIK procedure, you incorrectly entered and caused to be treated an erroneous astigmatism axis for Patient 15.

Further, prior to surgery, you failed to counsel and/or document the counseling of Patient 15 as to realistic expectations for visual results after surgery on an amblyopic eye.

- (P) On or about July 17, 2000, you evaluated Patient 16 for LASIK and found this patient to have compound myopic astigmatism. Prior to the

LASIK procedure, you failed to perform corneal pachymetry and keratometry. On or about July 5, 2000, you performed LASIK on both eyes of Patient 16, causing an overcorrection in Patient 16's left eye by inappropriately programming an excessive correction for the myopic sphere. Further, you inappropriately prescribed pilocarpine 1% eye drops for hyperopia. Approximately one year following the LASIK procedure, Patient 16 exhibited mixed astigmatism in the right eye and compound hyperopic astigmatism in the left eye, but refused further treatment.

- (Q) On or about March 30, 2002, you evaluated Patient 17 for LASIK, recommending LASIK for compound hyperopic astigmatism. Prior to conducting LASIK for Patient 17, you failed to perform corneal topography. You performed LASIK for both eyes of Patient 17 on or about April 16, 2002, and, although you performed automated keratometry prior to the surgery, the values obtained were different than those you entered into the laser at the time of the surgery. Further, there is no record of the type of microkeratome or the microkeratome settings utilized. Approximately one week following the surgery, Patient 17 reported she was experiencing blurred vision and headaches. On or about September 3, 2002, you performed a LASIK enhancement to adjust the overcorrection to Patient 17's right eye, but again you failed to perform corneal topography prior to the enhancement.
- (R) On or about December 15, 2000, you evaluated Patient 18 for a failed corneal graft of his left eye, which had been performed by another physician. You noted that Patient 18 exhibited corneal edema and vitreous was present in the corneal wound. On or about December 20, 2000 [December 20<sup>th</sup> procedure], you performed YAG vitreolysis on Patient 18's left eye to remove vitreous adhesions prior to performing a penetrating keratoplasty. On or about December 27, 2000 [December 27<sup>th</sup> procedure], you performed a penetrating keratoplasty in Patient 18's left eye, which was complicated by choroidal detachments and apparent forward movement of the intraocular contents, necessitating removal of the posterior chamber lens implant and an anterior vitrectomy; you were unable to replace the lens implant during that procedure. Following the December 27<sup>th</sup> procedure, Patient 18 complained of pain, and was examined by others at the clinic where you worked, but you did not examine the patient until five days postoperatively, at which time you noted that Patient 18 had an elevated intraocular pressure. Patient 18 underwent two further procedures to address complications. Your last documented examination of this patient noted that he remained aphakic with mildly elevated intraocular pressure.

Despite the complicated nature of the December 27<sup>th</sup> procedure, you did not examine or treat this patient yourself postoperatively for five days, failing to provide adequate postoperative care. Further, you failed to measure and/or document measurement of the intraocular pressure of Patient 18 until five days following the December 27<sup>th</sup> procedure. Further, the December 20<sup>th</sup> procedure was unnecessary given that a penetrating keratoplasty was scheduled to be performed shortly thereafter, at which time the vitreous adhesions could have been addressed.

- (S) On or about March 21, 2001, you performed an excisional biopsy of a large basal cell carcinoma on the nasal bridge of Patient 19. Although the pathology report dated on or about March 27, 2001, indicated that the lesion extended to the wound margin on the peripheral and deep (base) edges of the specimen, you took no action in response to this report, failing to appropriately treat Patient 19's condition. Approximately one year later, on or about March 27, 2002, you performed another excisional biopsy on the nasal bridge of Patient 19 for "recurrent tumor." The pathology report for the March 27, 2002, biopsy indicated that the lesion extended to the deep edge (base) of the specimen and close to the lateral (peripheral) edge of the specimen. Subsequently, Patient 19 was referred to a dermatologist who performed Mohs micrographic surgery to remove the residual tumor; reconstruction was performed thereafter by a general surgeon.
  
- (T) On or about April 18, 2002, you evaluated Patient 20, noting that he exhibited posterior subcapsular cataracts bilaterally and that he complained of glare symptoms. On or about May 1, 2002, you performed a cataract extraction with lens implantation on Patient 20's right eye, and on or about May 8, 2002, you performed a similar procedure on Patient 20's left eye. Although the lens implantation measurements were intended to correct Patient 20 for emmetropia, both eyes were approximately 3 diopters myopic postoperatively.

Patient 20 continued to complain of glare postoperatively and was noted to have 1 to 2 plus opacification of the posterior capsule. On or about August 26, 2002, you performed LASIK on Patient 20's right eye. Following this operation, Patient 20 continued to complain of glare. On or about July 25, 2003, Patient 20 was examined by another physician, and found to have bilateral subluxated intraocular lenses with posterior capsule opacification bilaterally.

In your treatment of Patient 20, you failed to insert the correct size intraocular lenses, and failed to adequately address Patient 20's symptoms of glare.

- (U) On or about June 27, 2000, you performed phakoemulsification with posterior chamber lens implantation on Patient 21 for a visually significant cataract. This procedure was notable for lack of pupillary dilation and posterior synachia which required pupil stretching and lysis of posterior synachia, resulting in an intraoperative hyphema during the stretching. Although on the day immediately following surgery, Patient 21 complained of nausea and registered an elevated intraocular pressure, you recommended a follow up in 15 days. Patient 21 continued to register complaints, including nausea, pain, and decreased vision, with your medical office. On or about July 5, 2000, you examined Patient 21, who was still complaining of feeling sick, finding him to have a large fibrin plaque obscuring the pupil. You rendered a diagnosis of acute postoperative inflammation, and you noted that you doubted endophthalmitis. You prescribed atropine drops and referred Patient 21 to another ophthalmologist in your practice group, who did not see the patient until the following day. Upon examination by this second ophthalmologist, Patient 21 was confirmed to have staphylococcal endophthalmitis.

You failed to appropriately diagnose, treat, and refer Patient 21, and failed to render appropriate postoperative care for Patient 21.

- (V) Patient 22 had an extensive past ocular medical history that included cataract extraction and lens implantation conducted by another physician, and a diagnosis of macular degeneration. In order to treat documented macular edema in Patient 22, you applied focal macular laser therapy to Patient 22's right eye on or about January 23, 2001, and to her left eye on or about January 31, 2001. These focal laser procedures were unnecessary given Patient 22's pre-existing severe macular degenerative changes. Although the right eye of Patient 22 did not exhibit significant corneal ectasia documented by pachymetry, and despite her poor visual prognosis because of severe retinal disease, on or about October 31, 2002, you unnecessarily performed superficial keratectomy on Patient 22's right eye, which ultimately resulted in a dehiscence of her previous penetrating keratoplasty, necessitating another corneal transplantation procedure one week later.

Your acts, conduct, and/or omissions as alleged in paragraph 1 above, individually and/or collectively, constitute "[a] departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances,

whether or not actual injury to a patient is established,” as that clause is used in Section 4731.22(B)(6), Ohio Revised Code.

Pursuant to Chapter 119., Ohio Revised Code, you are hereby advised that you are entitled to a hearing in this matter. If you wish to request such hearing, the request must be made in writing and must be received in the offices of the State Medical Board within thirty days of the time of mailing of this notice.

You are further advised that, if you timely request a hearing, you are entitled to appear at such hearing in person, or by your attorney, or by such other representative as is permitted to practice before this agency, or you may present your position, arguments, or contentions in writing, and that at the hearing you may present evidence and examine witnesses appearing for or against you.

In the event that there is no request for such hearing received within thirty days of the time of mailing of this notice, the State Medical Board may, in your absence and upon consideration of this matter, determine whether or not to limit, revoke, permanently revoke, suspend, refuse to register or reinstate your certificate to practice medicine and surgery or to reprimand you or place you on probation.

Please note that, whether or not you request a hearing, Section 4731.22(L), Ohio Revised Code, provides that “[w]hen the board refuses to grant a certificate to an applicant, revokes an individual’s certificate to practice, refuses to register an applicant, or refuses to reinstate an individual’s certificate to practice, the board may specify that its action is permanent. An individual subject to a permanent action taken by the board is forever thereafter ineligible to hold a certificate to practice and the board shall not accept an application for reinstatement of the certificate or for issuance of a new certificate.”

Copies of the applicable sections are enclosed for your information.

Very truly yours,



Lance A. Talmage, M.D.  
Secretary

LAT/blt

CERTIFIED MAIL # 7000 0600 0024 5144 8298  
RETURN RECEIPT REQUESTED

Vikas Kumar Jain, M.D.  
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CC: Kris Dawley, Esq.  
Schottenstein, Zox and Dunn  
250 West Street  
Columbus, Ohio 43215-2538

CERTIFIED MAIL # 7000 0600 0024 5144 8328  
RETURN RECEIPT REQUESTED

**STEP II  
CONSENT AGREEMENT  
WITH CONTINUING SUSPENSION  
BETWEEN  
VIKAS KUMAR JAIN, M.D.  
AND  
THE STATE MEDICAL BOARD OF OHIO**

This Consent Agreement is entered into by and between Vikas Kumar Jain, M.D. [Dr. Jain], and the State Medical Board of Ohio [Board], a state agency charged with enforcing Chapter 4731., Ohio Revised Code.

Dr. Jain enters into this Consent Agreement being fully informed of his rights under Chapter 119., Ohio Revised Code, including the right to representation by counsel and the right to a formal adjudicative hearing on the issues considered herein.

**BASIS FOR ACTION**

This Consent Agreement is entered into on the basis of the following stipulations, admissions and understandings:

- A. The Board is empowered by Section 4731.22(B), Ohio Revised Code, to limit, revoke, suspend a certificate, refuse to register or reinstate an applicant, or reprimand or place on probation the holder of a certificate for violations of Section 4731.22(B)(26), Ohio Revised Code, "impairment of ability to practice according to acceptable and prevailing standards of care because of habitual or excessive use or abuse of drugs, alcohol, or other substances that impair ability to practice;" Section 4731.22(B)(5), Ohio Revised Code, "[m]aking a false, fraudulent, deceptive, or misleading statement;" and/or Section 4731.22(B)(13), Ohio Revised Code, "[a] plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction for, a misdemeanor involving moral turpitude." Further the Board is empowered by Section 4731.22(A), Ohio Revised Code, to revoke a certificate for "fraud, misrepresentation, or deception in applying for or securing any" license or certificate issued by the Board.
- B. The Board enters into this Consent Agreement in lieu of formal proceedings based upon the violations of Sections 4731.22(A), (B)(5), and (B)(26), Ohio Revised Code, as set forth in Paragraphs E through G of the Step I Consent Agreement Between Vikas Kumar Jain, M.D., and the State Medical Board of Ohio, effective December 11, 2002 [December 2002 Step I Consent Agreement], a copy of which is attached hereto and incorporated fully herein, and as set forth in Paragraphs E through G, below; and the violation of Section 4731.22(B)(13), Ohio Revised Code, to wit,

Section 2903.13, Ohio Revised Code, Assault, as set forth in Paragraph H, below. The Board expressly reserves the right to institute formal proceedings based upon any other violations of Chapter 4731. of the Revised Code, whether occurring before or after the effective date of this Consent Agreement, including, but not limited to, the right to institute formal proceedings based upon any violations related to patient care or involving criminal acts, regardless of whether the acts underlying such additional violations are fully or partially set forth herein or are otherwise related to the violations of Sections 4731.22(A), (B)(5), (B)(26) and/or (B)(13), Ohio Revised Code, as set forth in this section.

Additionally, Dr. Jain states and acknowledges that he understands that the Board may pursue by separate action any violations beyond the violations of Sections 4731.22(A), (B)(5), (B)(26) and/or (B)(13), Ohio Revised Code, as set forth in the December 2002 Step I Consent Agreement and/or Paragraphs E through H, below, even if such violations arise from the same common nucleus of operative facts outlined within this Consent Agreement. Dr. Jain further states and acknowledges that subsequent Board Orders and/or Consent Agreements may supercede this Step II Consent Agreement and may result in further discipline, up to and including permanent revocation of his license to practice medicine and surgery in Ohio.

- C. Dr. Jain's license to practice medicine and surgery in the State of Ohio, License # 35-076297, was suspended for an indefinite period of time, but not less than 270 days, pursuant to the terms of the December 2002 Step I Consent Agreement, and remains suspended to date.
- D. Dr. Jain states that he is also licensed to practice medicine and surgery in the States of Florida, Indiana, Illinois, and New York.
- E. Dr. Jain admits that after entering residential treatment on November 11, 2002, at Shepherd Hill Hospital [Shepherd Hill], a Board-approved treatment provider in Newark, Ohio, he was discharged on January 24, 2003, treatment complete.
- F. Dr. Jain states, and the Board acknowledges receipt of information to support, that since his discharge from treatment at Shepherd Hill, he has remained compliant with his recovery plan/aftercare contract with Shepherd Hill, including participating in at least six AA/NA/Caduceus meetings per week and attending weekly continuing care sessions. In addition, Dr. Jain states, and the Board has information to support, that he has remained fully compliant with the terms of the advocacy contract into which he entered with the Ohio Physicians Effectiveness Program on February 3, 2003, including participating in at least three AA/CA/NA/ Caduceus meetings per week and submitting to random weekly urine screens. Dr. Jain states that such recovery plan/aftercare contract and advocacy contract remain in effect to date. Further, Dr. Jain admits that he has been in treatment with Azaria Akashi, Ph.D., a psychologist

practicing in Granville, Ohio, since December 2002, and states that such treatment has been beneficial to him in preventing relapse.

- G. Dr. Jain states, and the Board acknowledges, that Richard N. Whitney, M.D., of Shepherd Hill, and Edna Jones, M.D., of Parkside Behavioral Healthcare, a Board-approved treatment provider in Columbus, Ohio, have provided written reports indicating that Dr. Jain's ability to practice has been assessed and that he has been found capable of practicing medicine and surgery according to acceptable and prevailing standards of care, so long as certain treatment and monitoring conditions are in place, to include participation in at least four AA meetings and one Caduceus meeting weekly, with a gradual return to practice and work hours conducive to recovery. Further, Dr. Jain admits that it has been recommended that prior to performing surgery, he submit to saliva testing for detection of alcohol consumption.
- H. Dr. Jain admits that on April 5, 2002, while being transported by taxicab from Columbus International Airport at a speed of approximately 60 to 65 miles per hour, he assaulted the cab driver, impeding the cab driver's ability to maintain control of the vehicle. Dr. Jain further admits that on June 9, 2003, in the Court of Common Pleas of Franklin County, Ohio, Case Number 02CR-3232, he pled guilty to and was subsequently found guilty of one misdemeanor count of Assault, in violation of Section 2903.13, Ohio Revised Code.

### **AGREED CONDITIONS**

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of any formal proceedings at this time, Dr. Jain knowingly and voluntarily agrees with the Board to the following terms, conditions and limitations:

### **CONTINUED SUSPENSION OF CERTIFICATE**

- 1. For violation of Section 4731.22(B)(13), Ohio Revised Code, the certificate of Dr. Jain to practice medicine and surgery shall remain suspended for an indefinite period of time, but not less than 150 days from the effective date of this Consent Agreement.

### **INTERIM MONITORING**

- 2. During the period that Dr. Jain's certificate to practice medicine and surgery in the State of Ohio is suspended, Dr. Jain shall comply with the following terms, conditions, and limitations:
  - A. Dr. Jain shall obey all federal, state and local laws; all rules governing the practice of medicine in Ohio; and all terms of probation imposed by the Franklin County Court of Common Pleas in criminal case number 02CR-3232 by Entry dated June 10, 2003, a copy of which is attached hereto and incorporated herein.

- B. Dr. Jain shall submit quarterly declarations under penalty of Board disciplinary action and/or criminal prosecution, stating whether there has been compliance with all the conditions of this Consent Agreement. The first quarterly declaration must be received in the Board's offices on the date his quarterly declaration would have been due pursuant to his December 2002 Consent Agreement with the Board. Subsequent quarterly declarations must be received in the Board's offices on or before the first day of every third month.
- C. Dr. Jain shall appear in person for an interview before the full Board or its designated representative. The first such appearance shall take place on the date his appearance would have been scheduled pursuant to his December 2002 Consent Agreement with the Board. Subsequent personal appearances must occur every three months thereafter, and/or as otherwise requested by the Board. If an appearance is missed or is rescheduled for any reason, ensuing appearances shall be scheduled based on the appearance date as originally scheduled.

### **Sobriety**

- D. Dr. Jain shall abstain completely from the personal use or possession of drugs, except those prescribed, dispensed or administered to him by another so authorized by law who has full knowledge of Dr. Jain's history of chemical dependency.
- E. Dr. Jain shall abstain completely from the use of alcohol.

### **Drug and Alcohol Screens/Supervising Physician**

- F. Dr. Jain shall submit to random urine screenings for drugs and alcohol on a weekly basis or as otherwise directed by the Board. Dr. Jain shall ensure that all screening reports are forwarded directly to the Board on a quarterly basis. The drug testing panel utilized must be acceptable to the Secretary of the Board.

Within thirty days of the effective date of this Consent Agreement, Dr. Jain shall submit to the Board for its prior approval the name and curriculum vitae of a supervising physician to whom Dr. Jain shall submit the required urine specimens. In approving an individual to serve in this capacity, the Board will give preference to a physician who practices in the same locale as Dr. Jain. Dr. Jain and the supervising physician shall ensure that the urine specimens are obtained on a random basis and that the giving of the specimen is witnessed by a reliable person. In addition, the supervising physician shall assure that appropriate control over the specimen is maintained and shall immediately inform the Board of any positive screening results.

Dr. Jain shall ensure that the supervising physician provides quarterly reports to

the Board, in a format acceptable to the Board, as set forth in the materials provided by the Board to the supervising physician, verifying whether all urine screens have been conducted in compliance with this Consent Agreement, whether all urine screens have been negative, and whether the supervising physician remains willing and able to continue in his or her responsibilities.

In the event that the designated supervising physician becomes unable or unwilling to so serve, Dr. Jain must immediately notify the Board in writing, and make arrangements acceptable to the Board for another supervising physician as soon as practicable. Dr. Jain shall further ensure that the previously designated supervising physician also notifies the Board directly of his or her inability to continue to serve and the reasons therefore.

All screening reports and supervising physician reports required under this paragraph must be received in the Board's offices no later than the due date for Dr. Jain's quarterly declaration. It is Dr. Jain's responsibility to ensure that reports are timely submitted.

#### **Drug and Alcohol Screens Upon Board Request**

- G. The Board retains the right to require, and Dr. Jain agrees to submit, blood or urine specimens for analysis at Dr. Jain's expense upon the Board's request and without prior notice. Dr. Jain's refusal to submit a blood or urine specimen upon request of the Board shall result in a minimum of one year of actual license suspension.

#### **Rehabilitation Program**

- H. Within thirty days of the effective date of this Consent Agreement, Dr. Jain shall undertake and maintain participation in an alcohol and drug rehabilitation program, such as AA, NA, CA, or Caduceus, no less than five times per week. Substitution of any other specific program must receive prior Board approval.

Dr. Jain shall submit acceptable documentary evidence of continuing compliance with this program which must be received in the Board's offices no later than the due date for Dr. Jain's quarterly declarations.

#### **Aftercare/ Physician Health Program**

- I. Dr. Jain shall maintain continued compliance with the terms of the recovery plan/aftercare contract entered into with his treatment provider, and with the advocacy contract with the Ohio Physicians Effectiveness Program, or, if approved in advance by the Board, another physician health program, provided that, where terms of the recovery plan/aftercare contract or advocacy contract

conflict with terms of this Consent Agreement, the terms of this Consent Agreement shall control.

### **Releases**

- J. Dr. Jain shall provide continuing authorization, through appropriate written consent forms, for disclosure by his treatment provider to the Board, to treating and monitoring physicians, and to others involved in the monitoring process, of information necessary for them to fulfill their respective duties and obligations.

### **Psychological Treatment**

- K. Within thirty days of the effective date of this consent agreement, Dr. Jain shall continue to undergo psychological treatment with Azaria Akashi, Ph.D., weekly, or as otherwise directed by the Board. Dr. Jain shall comply with his psychological treatment plan and shall ensure that psychological reports are forwarded by his treating psychologist to the Board on a quarterly basis, or as otherwise directed by the Board. The psychological reports shall contain information describing Dr. Jain's current treatment plan and any changes that have been made to the treatment plan since the prior report; Dr. Jain's compliance with his treatment plan; Dr. Jain's mental status; Dr. Jain's progress in treatment; and results of any testing or laboratory studies that have been conducted since the prior report. Dr. Jain shall ensure that his treating psychologist immediately notifies the Board of his failure to comply with his treatment plan and/or any determination that Dr. Jain is unable to practice due to his psychological condition. It is Dr. Jain's responsibility to ensure that quarterly reports are received in the Board's offices no later than the due date for Dr. Jain's quarterly declaration.

In the event that the designated treating psychologist becomes unable or unwilling to serve in this capacity, Dr. Jain must immediately so notify the Board in writing. In addition, Dr. Jain shall make arrangements acceptable to the Board for another treating psychologist within thirty days after the previously designated treating psychologist becomes unable or unwilling to serve, unless otherwise determined by the Board. Furthermore, Dr. Jain shall ensure that the previously designated treating psychologist also notifies the Board directly of his or her inability to continue to serve and the reasons therefore.

### **CONDITIONS FOR REINSTATEMENT**

3. The Board shall not consider reinstatement of Dr. Jain's certificate to practice medicine and surgery until all of the following conditions are met:

- A. Dr. Jain shall submit an application for reinstatement, accompanied by appropriate fees, if any.
- B. Dr. Jain shall demonstrate to the satisfaction of the Board that he can resume practice in compliance with acceptable and prevailing standards of care under the provisions of his certificate. Such demonstration shall include but shall not be limited to the following:
  - i. Evidence of continuing full compliance with this Consent Agreement.
  - ii. Acceptable documentation of successful completion of a course or courses dealing with personal ethics, anger management or other topics addressing the violations set forth in Paragraph H, above. The exact number of hours and the specific content of the course or courses shall be subject to the prior approval by the Board or its designees, but in no event shall be less than ten hours. Any courses taken in compliance with this provision shall be in addition to the Continuing Medical Education requirements for relicensure for the Continuing Medical Education acquisition period(s) in which they are complete.
  - iii. At the time Dr. Jain submits his application for reinstatement, Dr. Jain shall provide the Board with a written report of evaluation by a psychiatrist acceptable to the Board indicating that Dr. Jain's ability to practice has been assessed and that he has been found capable of practicing in accordance with acceptable and prevailing standards of care. Such evaluation shall have been performed within sixty days prior to Dr. Jain's application for reinstatement. Prior to the examination, Dr. Jain shall provide the psychiatrist with copies of patient records from any prior evaluations and/or treatment that he has received, including his treatment at Shepherd Hill, and a copy of this Consent Agreement. The report from the evaluating psychiatrist shall include the psychiatrist's diagnoses and conclusions; any recommendations for care, counseling, and treatment for the psychiatric diagnoses; any conditions, restrictions, or limitations that should be imposed on Dr. Jain's practice; and the basis for the psychiatrist's determinations.
  - iv. At the time Dr. Jain submits his application for reinstatement, Dr. Jain shall submit a plan for the administration of saliva screening for detection of alcohol consumption to be conducted in accordance with the provisions of Paragraph 4(F), below. Such plan shall include, at a minimum, detailed information as to the type of testing device and testing ranges to be utilized, as well as the name of the individual(s) who will administer such screenings. The Secretary and Supervising Member of the Board shall approve or disapprove of such plan, and shall consider, among other

factors, whether the proposed testing device and testing ranges are adequate for public protection.

- C. In the event the report of the psychiatrist referenced in Paragraph 3(B)(iii) above includes recommendations for care, counseling, or treatment for Dr. Jain, or includes conditions, restrictions, or limitations that should be imposed on Dr. Jain's practice, then Dr. Jain shall enter into a written addendum to this Consent Agreement, which shall include additional probationary terms, conditions or limitations based upon the psychiatrist's report, as determined by the Board, or, if the Board and Dr. Jain are unable to agree on the terms of a written addendum to this Consent Agreement, then Dr. Jain further agrees to abide by any terms, conditions and limitations imposed by the Board Order after a hearing conducted pursuant to Chapter 119. of the Ohio Revised Code.

#### **Absence from Practice in Excess of Two Years**

- D. In the event that Dr. Jain has not been engaged in the active practice of medicine and surgery for a period in excess of two years prior to application for reinstatement, the Board may exercise its discretion under Section 4731.222, Ohio Revised Code, to require additional evidence of Dr. Jain's fitness to resume practice.

#### **PROBATIONARY CONDITIONS**

4. Upon reinstatement, Dr. Jain's certificate to practice medicine and surgery in the State of Ohio shall be subject to the following probationary terms, conditions and limitations for a minimum of five years:
- A. Dr. Jain shall continue to be subject to the terms, conditions and limitations specified in subparagraphs A through K of Paragraph 2 of this Consent Agreement.

#### **Drug Associated Restrictions**

- B. Dr. Jain shall keep a log of all controlled substances prescribed. Such log shall be submitted, in the format approved by the Board, thirty days prior to Dr. Jain's personal appearance before the Board or its designated representative, or as otherwise directed by the Board. Further, Dr. Jain shall make his patient records with regard to such prescribing available for review by an agent of the Board upon request.
- C. Dr. Jain shall not, without prior Board approval, administer, personally furnish, or possess, except as allowed under Paragraph 2(D), above, any controlled substances as defined by state or federal law. In the event that the Board agrees at a future date to modify this Consent Agreement to allow Dr. Jain to administer or personally furnish controlled substances, Dr. Jain shall keep a log of all controlled substances

prescribed, administered or personally furnished. Such log shall be submitted in the format approved by the Board thirty days prior to Dr. Jain's personal appearance before the Board or its designated representative, or as otherwise directed by the Board. Further, Dr. Jain shall make his patient records with regard to such prescribing, administering, or personally furnishing available for review by an agent of the Board upon request.

### **Monitoring Physician**

- D. Before engaging in any medical practice, Dr. Jain shall submit the name and curriculum vitae of a monitoring physician for prior written approval by the Secretary or Supervising Member of the Board. In approving an individual to serve in this capacity, the Secretary and Supervising Member will give preference to a physician who practices in the same locale as Dr. Jain and who is engaged in the same or similar practice specialty.

The monitoring physician shall monitor Dr. Jain and his medical practice, and shall review Dr. Jain's patient charts. The chart review may be done on a random basis, with the frequency and number of charts reviewed to be determined by the Board.

Further, the monitoring physician shall provide the Board with reports on the monitoring of Dr. Jain and his medical practice, and on the review of Dr. Jain's patient charts. Dr. Jain shall ensure that the reports are forwarded to the Board on a quarterly basis and are received in the Board's offices no later than the due date for Dr. Jain's quarterly declaration.

In the event that the designated monitoring physician becomes unable or unwilling to serve in this capacity, Dr. Jain must immediately so notify the Board in writing. In addition, Dr. Jain shall make arrangements acceptable to the Board for another monitoring physician within thirty days after the previously designated monitoring physician becomes unable or unwilling to serve, unless otherwise determined by the Board. Furthermore, Dr. Jain shall ensure that the previously designated monitoring physician also notifies the Board directly of his or her inability to continue to serve and the reasons therefore.

### **Work Hour Limitation**

- E. Dr. Jain shall limit his work hours to no more than forty hours of work per week, until otherwise approved by the Board. Dr. Jain shall keep a log reflecting the dates, times, and facilities and/or locations at which he works. Dr. Jain shall submit his work logs for receipt in the Board's offices no later than the due date for Dr. Jain's quarterly declarations.

Any request by Dr. Jain for modification of the limitation on work hours set forth in this paragraph shall be accompanied by documentation from a physician affiliated with a Board approved treatment provider, or other physician approved by the Board for this purpose, who has evaluated Dr. Jain, indicating that such physician supports Dr. Jain's request for modification.

### **Work Period Saliva Screenings**

- F. Prior to the commencement of each work period during which Dr. Jain may be required to exercise medical judgment, including but not limited to conducting surgery, examining patients, examining medical records, or engaging in medical record keeping, or as otherwise directed by the Board, Dr. Jain shall submit to saliva screening in accordance with a plan approved by the Secretary and Supervising Member. In the event that the saliva screening indicates the presence of alcohol, Dr. Jain shall immediately submit a blood specimen for analysis, at his expense, and shall refrain from work during that work period.

Dr. Jain shall immediately notify the Board of any positive saliva results and all blood screening results. Such notice shall be through telephone communication to the Board at the earliest opportunity, and shall be followed by written communication to the Board. In addition, Dr. Jain shall ensure that all blood screening reports are immediately forwarded directly to the Board.

Further, Dr. Jain shall submit a copy of his work schedule together with acceptable documentary evidence of continuing compliance with this provision, which must be received in the Board's offices no later than the due date for Dr. Jain's quarterly declarations.

Any request by Dr. Jain for modification of the requirement that he submit to saliva screenings prior to commencement of each work period as set forth in this paragraph shall be accompanied by documentation from a physician affiliated with a Board approved treatment provider and approved in advance by the Board for this purpose, who has evaluated Dr. Jain, indicating that such physician supports Dr. Jain's request for modification.

### **Tolling Provisions**

- G. In the event that Dr. Jain should leave Ohio for three continuous months, or reside or practice outside the State, Dr. Jain must notify the Board in writing of the dates of departure and return. Periods of time spent outside Ohio will not apply to the reduction of the probationary period under this Consent Agreement, unless otherwise determined by motion of the Board in instances where the Board can be assured that probationary monitoring is otherwise being performed.

- H. In the event Dr. Jain is found by the Secretary of the Board to have failed to comply with any provision of this Consent Agreement, and is so notified of that deficiency in writing, such period(s) of noncompliance will not apply to the reduction of the probationary period under this Consent Agreement.

### **REQUIRED REPORTING**

Within thirty days of the effective date of this Consent Agreement, Dr. Jain shall provide a copy of this Consent Agreement to all employers or entities with which he is under contract to provide health care services or is receiving training; and the Chief of Staff at each hospital where he has privileges or appointments. Further, Dr. Jain shall provide a copy of this Consent Agreement to all employers or entities with which he contracts to provide health care services, or applies for or receives training, and the Chief of Staff at each hospital where he applies for or obtains privileges or appointments.

Within thirty days of the effective date of this Consent Agreement, Dr. Jain shall provide a copy of this Consent Agreement by certified mail, return receipt requested, to the proper licensing authority of any state or jurisdiction in which he currently holds any professional license. Dr. Jain further agrees to provide a copy of this Consent Agreement by certified mail, return receipt requested, at time of application to the proper licensing authority of any state in which he applies for any professional license or for reinstatement of any professional license. Further, Dr. Jain shall provide this Board with a copy of the return receipt as proof of notification within thirty days of receiving that return receipt.

### **FAILURE TO COMPLY**

If, in the discretion of the Secretary and Supervising Member of the Board, Dr. Jain appears to have violated or breached any term or condition of this Consent Agreement, the Board reserves the right to institute formal disciplinary proceedings for any and all possible violations or breaches, including, but not limited to, alleged violations of the laws of Ohio occurring before the effective date of this Consent Agreement.

If the Secretary and Supervising Member of the Board determine that there is clear and convincing evidence that Dr. Jain has violated any term, condition or limitation of this Consent Agreement, Dr. Jain agrees that the violation, as alleged, also constitutes clear and convincing evidence that his continued practice presents a danger of immediate and serious harm to the public for purposes of initiating a summary suspension pursuant to Section 4731.22(G), Ohio Revised Code.

### **DURATION/MODIFICATION OF TERMS**

Dr. Jain shall not request termination of this Consent Agreement for a minimum of five years from the effective date of reinstatement of his certificate to practice medicine and surgery. In addition, Dr. Jain shall not request modification to the probationary terms, limitations, and conditions contained herein, with the exception of the limitation included in Paragraph 4(E)

STEP II CONSENT AGREEMENT

Vikas Kumar Jain, M.D.

PAGE 12

requiring that he limit his work hours to no more than forty hours per week, for at least one year following reinstatement. Otherwise, the above-described terms, limitations and conditions may be amended or terminated in writing at any time upon the agreement of both parties.

**ACKNOWLEDGMENTS/LIABILITY RELEASE**

Dr. Jain acknowledges that he has had an opportunity to ask questions concerning the terms of this Consent Agreement and that all questions asked have been answered in a satisfactory manner.

Any action initiated by the Board based on alleged violations of this Consent Agreement shall comply with the Administrative Procedure Act, Chapter 119., Ohio Revised Code.

Dr. Jain hereby releases the Board, its members, employees, agents, officers and representatives jointly and severally from any and all liability arising from the within matter.

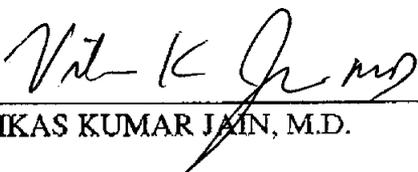
This Consent Agreement shall be considered a public record as that term is used in Section 149.43, Ohio Revised Code, and may be reported to appropriate organizations, data banks, and governmental bodies. Dr. Jain agrees to provide his social security number to the Board and hereby authorizes the Board to utilize that number in conjunction with that reporting.

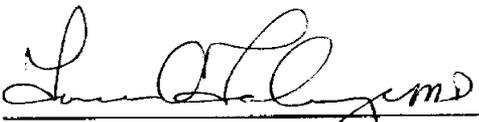
**EFFECTIVE DATE**

It is expressly understood that this Consent Agreement is subject to ratification by the Board prior to signature by the Secretary and Supervising Member and shall become effective upon the last date of signature below.

**TERMINATION OF PRIOR CONSENT AGREEMENT**

The December 2002 Consent Agreement between Dr. Jain and the Board shall be terminated upon the last date of the signature below, concurrent with this Consent Agreement becoming effective.

  
\_\_\_\_\_  
VIKAS KUMAR JAIN, M.D.

  
\_\_\_\_\_  
LANCE A. TALMAGE, M.D.  
Secretary

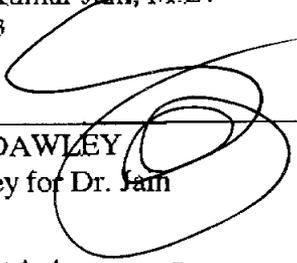
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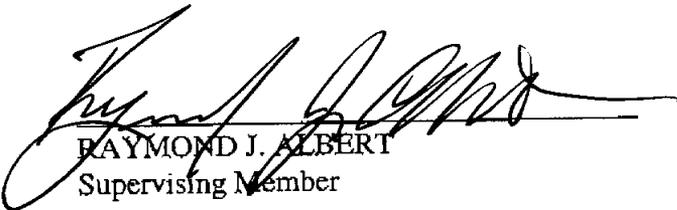
STEP II CONSENT AGREEMENT

Vikas Kumar Jain, M.D.

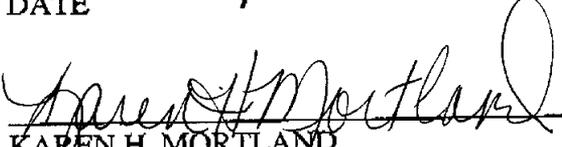
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\_\_\_\_\_  
KRIS DAWLEY  
Attorney for Dr. Jain

11/12/03  
DATE

  
\_\_\_\_\_  
RAYMOND J. ALBERT  
Supervising Member

11/12/03  
DATE

  
\_\_\_\_\_  
KAREN H. MORTLAND  
Enforcement Attorney

11/12/03  
DATE

Rev. 5 08/08/01

**STEP I**  
**CONSENT AGREEMENT**  
**BETWEEN**  
**VIKAS KUMAR JAIN, M.D.**  
**AND**  
**THE STATE MEDICAL BOARD OF OHIO**

This Consent Agreement is entered into by and between Vikas Kumar Jain, M.D., [Dr. Jain] and the State Medical Board of Ohio [the Board], a state agency charged with enforcing Chapter 4731., Ohio Revised Code.

Dr. Jain enters into this Consent Agreement being fully informed of his rights under Chapter 119., Ohio Revised Code, including the right to representation by counsel and the right to a formal adjudicative hearing on the issues considered herein.

**BASIS FOR ACTION**

This Consent Agreement is entered into on the basis of the following stipulations, admissions and understandings:

- A. The Board is empowered by Section 4731.22(B), Ohio Revised Code, to limit, revoke, suspend a certificate, refuse to register or reinstate an applicant, or reprimand or place on probation the holder of a certificate for violation of Section 4731.22(B)(26), “[i]mpairment of ability to practice according to acceptable and prevailing standards of care because of habitual or excessive use or abuse of drugs, alcohol, or other substances that impair ability to practice,” or Section 4731.22(B)(5), making “a false, fraudulent, deceptive, or misleading statement.” Further the Board is empowered by Section 4731.22(A), Ohio Revised Code, to revoke a certificate for “fraud, misrepresentation, or deception in applying for or securing any” license or certificate issued by the Board.
- B. The Board enters into this Consent Agreement in lieu of formal proceedings based upon the violations of Sections 4731.22(A), (B)(5), and (B)(26), Ohio Revised Code, as set forth in Paragraphs E, F, and G below, and expressly reserves the right to institute formal proceedings based upon any other violations of Chapter 4731. of the Revised Code, whether occurring before or after the effective date of this Agreement. Such express reservation includes, but is not limited to, the right to institute formal proceedings based upon any violations related to patient care or involving criminal acts, regardless of whether the acts underlying such additional violations are fully or partially set forth herein or are otherwise related to the violations of Sections 4731.22(A), (B)(5), and/or (B)(26), Ohio Revised Code, as set forth herein.

Additionally, Dr. Jain states and acknowledges he understands that the Board intends to pursue by separate action any violations beyond the violations of Sections 4731.22(A), (B)(5), and (B)(26), Ohio Revised Code, as set forth in Paragraphs E, F, and G below, including but not limited to, Sections 4731.22(B)(2), (B)(6), (B)(9), (B)(10) and (B)(20), Ohio Revised Code, even if such violations arise from the same common nucleus of operative facts as outlined within this Consent Agreement primarily addressing the issue of Dr. Jain's alcohol dependence. Dr. Jain further states and acknowledges that he understands that subsequent Board Orders and/or Consent Agreements may supercede this Step I Consent Agreement and may result in further discipline, up to and including permanent revocation of his license to practice medicine and surgery in Ohio.

- C. Dr. Jain is licensed to practice medicine and surgery in the State of Ohio, License # 35-076297.
- D. Dr. Jain states that he is also licensed to practice medicine and surgery in the State(s) of FLORIDA, INDIANA, ILLINOIS, NEW YORK.
- E. Dr. Jain admits that on February 2, 2000, as he was operating his motor vehicle in Licking County, Ohio, he was stopped by the Ohio State Highway Patrol for weaving out of his lane of traffic and was subsequently arrested for Driving Under the Influence. Dr. Jain admits that he refused to submit to the breathalyzer test. Dr. Jain admits that on June 6, 2000, he pled guilty to Driving Under the Influence, a violation of Section 4511.19(A), Ohio Revised Code, a misdemeanor of the first degree, and Rules for Driving in Marked Lanes, a minor misdemeanor.

Dr. Jain further admits that on November 3, 2001, he performed Lasik eye surgery at a surgery center in Chicago, Illinois. Dr. Jain admits that after performing one procedure, the staff of the surgery center cancelled the remaining procedures scheduled for him out of concern that he was intoxicated.

Dr. Jain further admits that on August 4, 2001, at Port Columbus Airport, Columbus, Ohio, he was denied transport on America West Airlines due to his level of intoxication and disruptive behavior.

- F. Dr. Jain admits that on November 4, 2002, pursuant to Board order, he entered Shepherd Hill Hospital, a Board-approved treatment provider, for the purpose of undergoing a three-day inpatient evaluation for determining whether he is in violation of Section 4731.22(B)(26), Ohio Revised Code. Dr. Jain further admits that as a result of this evaluation, he was diagnosed with alcohol dependence, and that inpatient level of care was recommended. Dr. Jain further admits that he thereafter entered residential treatment for alcoholism at Shepherd Hill Hospital on November 11, 2002, and that such treatment continues to date.

- G. Dr. Jain admits that in April 2002, in completing his application card for renewal of his certificate to practice medicine or surgery in Ohio, he answered "No" to Question 1, which inquired whether he had been found guilty of, or pled guilty or no contest to, a misdemeanor or felony at any time since signing his last application for renewal of his certificate. Dr. Jain admits that he signed such application card certifying that the information provided on the application of renewal was true and correct in every respect, when in fact he knew that his answer to Question 1 was false, as he had pled guilty to Driving Under the Influence, a violation of Section 4511.19(A), Ohio Revised Code, a misdemeanor of the first degree, and Rules for Driving in Marked Lanes, a minor misdemeanor, as set forth in Paragraph F, above.

### **AGREED CONDITIONS**

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of any formal proceedings at this time, Dr. Jain knowingly and voluntarily agrees with the Board to the following terms, conditions and limitations:

#### **SUSPENSION OF CERTIFICATE**

1. The certificate of Dr. Jain to practice medicine and surgery in the State of Ohio shall be **SUSPENDED** for an indefinite period of time, but not less than 270 days.

#### **INTERIM MONITORING**

##### Sobriety

2. Dr. Jain shall abstain completely from the personal use or possession of drugs, except those prescribed, dispensed or administered to him by another so authorized by law who has full knowledge of Dr. Jain's history of chemical dependency.
3. Dr. Jain shall abstain completely from the use of alcohol.

##### Releases; Quarterly Declarations and Appearances

4. Dr. Jain shall provide authorization, through appropriate written consent forms, for disclosure of evaluative reports, summaries, and records, of whatever nature, by any and all parties that provide treatment or evaluation for Dr. Jain's chemical dependency or related conditions, or for purposes of complying with this Consent Agreement, whether such treatment or evaluation occurred before or after the effective date of this Consent Agreement. The above-mentioned evaluative reports, summaries, and records are considered medical records for purposes of Section 149.43 of the Ohio Revised Code and are confidential pursuant to statute. Dr. Jain further agrees to provide the Board written consent permitting any treatment provider from whom he obtains treatment to notify the Board in the event he fails to agree to or

- comply with any treatment contract or aftercare contract. Failure to provide such consent, or revocation of such consent, shall constitute a violation of this Consent Agreement.
5. Dr. Jain shall submit quarterly declarations under penalty of Board disciplinary action and/or criminal prosecution, stating whether there has been compliance with all the conditions of this Consent Agreement. The first quarterly declaration must be received in the Board's offices on the first day of the third month following the month in which this Consent Agreement becomes effective, provided that if the effective date is on or after the sixteenth day of the month, the first quarterly declaration must be received in the Board's offices on the first day of the fourth month following. Subsequent quarterly declarations must be received in the Board's offices on or before the first day of every third month.
  6. Dr. Jain shall appear in person for an interview before the full Board or its designated representative during the third month following the effective date of this Consent Agreement. Subsequent personal appearances must occur every three months thereafter, and/or as otherwise requested by the Board. If an appearance is missed or is rescheduled for any reason, ensuing appearances shall be scheduled based on the appearance date as originally scheduled.

Drug & Alcohol Screens; Supervising Physician

7. Dr. Jain shall submit to random urine screenings for drugs and alcohol on a weekly basis or as otherwise directed by the Board. Dr. Jain shall ensure that all screening reports are forwarded directly to the Board on a quarterly basis. The drug testing panel utilized must be acceptable to the Secretary of the Board.

Within thirty days of the effective date of this Consent Agreement, Dr. Jain shall submit to the Board for its prior approval the name of a supervising physician to whom Dr. Jain shall submit the required urine specimens. In approving an individual to serve in this capacity, the Board will give preference to a physician who practices in the same locale as Dr. Jain. Dr. Jain and the supervising physician shall ensure that the urine specimens are obtained on a random basis and that the giving of the specimen is witnessed by a reliable person. In addition, the supervising physician shall assure that appropriate control over the specimen is maintained and shall immediately inform the Board of any positive screening results.

Dr. Jain shall ensure that the supervising physician provides quarterly reports to the Board, in a format acceptable to the Board, as set forth in the materials provided by the Board to the supervising physician, verifying whether all urine screens have been conducted in compliance with this Consent Agreement, whether all urine screens have been negative, and whether the supervising physician remains willing and able to continue in his or her responsibilities.

In the event that the designated supervising physician becomes unable or unwilling to so serve, Dr. Jain must immediately notify the Board in writing, and make arrangements acceptable to the Board for another supervising physician as soon as practicable. Dr. Jain shall further ensure that the previously designated supervising physician also notifies the Board directly of his or her inability to continue to serve and the reasons therefore.

All screening reports and supervising physician reports required under this paragraph must be received in the Board's offices no later than the due date for Dr. Jain's quarterly declaration. It is Dr. Jain's responsibility to ensure that reports are timely submitted.

#### Rehabilitation Program

8. Within thirty days of the effective date of this Consent Agreement, Dr. Jain shall undertake and maintain participation in an alcohol and drug rehabilitation program, such as A.A., N.A., C.A., or Caduceus, no less than three times per week. Substitution of any other specific program must receive prior Board approval.

Dr. Jain shall submit acceptable documentary evidence of continuing compliance with this program which must be received in the Board's offices no later than the due date for Dr. Jain's quarterly declarations.

#### **CONDITIONS FOR REINSTATEMENT**

9. The Board shall not consider reinstatement of Dr. Jain's certificate to practice medicine and surgery until all of the following conditions are met:
  - a. Dr. Jain shall submit an application for reinstatement, accompanied by appropriate fees, if any.
  - b. Dr. Jain shall demonstrate to the satisfaction of the Board that he can resume practice in compliance with acceptable and prevailing standards of care under the provisions of his certificate. Such demonstration shall include but shall not be limited to the following:
    - i. Certification from a treatment provider approved under Section 4731.25 of the Revised Code that Dr. Jain has successfully completed any required inpatient treatment.
    - ii. Evidence of continuing full compliance with a post-discharge aftercare contract with a treatment provider approved under Section 4731.25 of the Revised Code. Such evidence shall include, but not be limited to, a copy

of the signed aftercare contract. The aftercare contract must comply with rule 4731-16-10 of the Administrative Code.

- iii. Evidence of continuing full compliance with this Consent Agreement.
- iv. Two written reports indicating that Dr. Jain's ability to practice has been assessed and that he has been found capable of practicing according to acceptable and prevailing standards of care. These reports shall be made by individuals or providers approved by the Board under Section 4731.25, Ohio Revised Code, or otherwise approved in advance by the Board for making such assessments. Prior to the assessments, Dr. Jain shall provide the evaluators with copies of patient records from any evaluations and/or treatment that he has received, and a copy of this Consent Agreement. The reports from the evaluators shall include any recommendations for treatment, monitoring, or supervision of Dr. Jain, and any conditions, restrictions, or limitations that should be imposed on Dr. Jain's practice. The reports shall also describe the basis for the evaluator's determinations.

All reports required pursuant to this paragraph shall be based upon evaluations occurring within the three months immediately preceding any application for reinstatement.

- c. Dr. Jain shall enter into a written consent agreement including probationary terms, conditions and limitations as determined by the Board or, if the Board and Dr. Jain are unable to agree on the terms of a written Consent Agreement, then Dr. Jain further agrees to abide by any terms, conditions and limitations imposed by Board Order after a hearing conducted pursuant to Chapter 119. of the Ohio Revised Code.

Further, upon reinstatement of Dr. Jain's certificate to practice medicine and surgery in this state, the Board shall require continued monitoring which shall include, but not be limited to, compliance with the written consent agreement entered into before reinstatement or with conditions imposed by Board Order after a hearing conducted pursuant to Chapter 119. of the Revised Code. Moreover, upon termination of the consent agreement or Board Order, Dr. Jain shall submit to the Board for at least two years annual progress reports made under penalty of Board disciplinary action or criminal prosecution stating whether Dr. Jain has maintained sobriety.

- 10. In the event that Dr. Jain has not been engaged in the active practice of medicine and surgery for a period in excess of two years prior to application for reinstatement, the Board may exercise its discretion under Section 4731.222, Ohio Revised Code, to require additional evidence of Dr. Jain's fitness to resume practice.

## **REQUIRED REPORTING BY LICENSEE**

11. Within thirty days of the effective date of this Consent Agreement, Dr. Jain shall provide a copy of this Consent Agreement by certified mail, return receipt requested, to the proper licensing authority of any state or jurisdiction in which he currently holds any professional license. Dr. Jain further agrees to provide a copy of this Consent Agreement by certified mail, return receipt requested, at time of application to the proper licensing authority of any state in which he applies for any professional license or reinstatement of any professional license. Further, Dr. Jain shall provide this Board with a copy of the return receipt as proof of notification within thirty days of receiving that return receipt.
12. Within thirty days of the effective date of this Consent Agreement, Dr. Jain shall provide a copy of this Consent Agreement to all employers or entities with which he is under contract to provide health care services or is receiving training; and the Chief of Staff at each hospital where he has privileges or appointments. Further, Dr. Jain shall provide a copy of this Consent Agreement to all employers or entities with which he contracts to provide health care services, or applies for or receives training, and the Chief of Staff at each hospital where he applies for or obtains privileges or appointments.

The above-described terms, conditions and limitations may be amended or terminated in writing at any time upon the agreement of both parties.

## **FAILURE TO COMPLY**

If, in the discretion of the Secretary and Supervising Member of the Board, Dr. Jain appears to have violated or breached any term or condition of this Consent Agreement, the Board reserves the right to institute formal disciplinary proceedings for any and all possible violations or breaches, including but not limited to, alleged violations of the laws of Ohio occurring before the effective date of this Consent Agreement.

## **ACKNOWLEDGMENTS/LIABILITY RELEASE**

Dr. Jain acknowledges that he has had an opportunity to ask questions concerning the terms of this Consent Agreement and that all questions asked have been answered in a satisfactory manner.

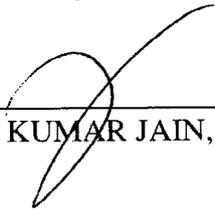
Any action initiated by the Board based on alleged violations of this Consent Agreement shall comply with the Administrative Procedure Act, Chapter 119., Ohio Revised Code.

Dr. Jain hereby releases the Board, its members, employees, agents, officers and representatives jointly and severally from any and all liability arising from the within matter.

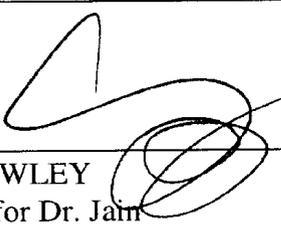
This Consent Agreement shall be considered a public record as that term is used in Section 149.43, Ohio Revised Code, and may be reported to appropriate organizations, data banks, and governmental bodies. Dr. Jain agrees to provide his social security number to the Board and hereby authorizes the Board to utilize that number in conjunction with that reporting.

**EFFECTIVE DATE**

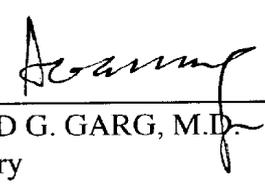
It is expressly understood that this Consent Agreement is subject to ratification by the Board prior to signature by the Secretary and Supervising Member and shall become effective upon the last date of signature below.

  
\_\_\_\_\_  
VIKAS KUMAR JAIN, M.D.

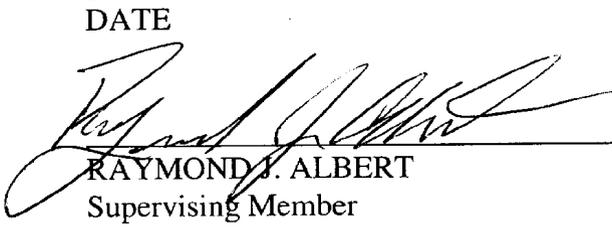
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\_\_\_\_\_  
KRIS DAWLEY  
Attorney for Dr. Jain

12-10-02  
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\_\_\_\_\_  
ANAND G. GARG, M.D.  
Secretary

12/11/02  
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RAYMOND J. ALBERT  
Supervising Member

12/11/02  
\_\_\_\_\_  
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REBECCA J. ALBERS  
Assistant Attorney General

12/11/02  
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