http://www.quackwatch.org/00AboutQuackwatch/chd.html
Donations of $1 to $50 to help support Quackwatch can be made through
http://s1.amazon.com/exec/varzea/pay/T1X6GUTTCLU3T4

of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of Part 58, regarding nonclinical laboratory studies. The terms "research," "clinical research," "clinical study," "study," and "clinical investigation" are deemed to be synonymous for purposes of this part.

(d) "Emergency use" means the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

(e) "Human subject" means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

(f) "Institution" means any public or private entity or agency (including Federal, State, and other agencies). The term "facility" as used in section 520(g) of the act is deemed to be synonymous with the term "institution" for purposes of this part.

(g) "Institutional Review Board (IRB)" means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase "institutional review committee" as used in section 520(g) of the act.

(h) "Investigator" means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(i) "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) "Sponsor" means a person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(k) "Sponsor-investigator" means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., it does not include a corporation or agency. The obligations of a sponsor-investigator under this part include both those of a sponsor and those of an investigator.

(l) "Test article" means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act.

§56.103 Circumstances in which IRB review is required.

(a) Except as provided in §§56.104 and 56.105, any clinical investigation which must meet the requirements for prior submission (as required in Parts 312, 812, and 813) to the Food and Drug Administration shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part.

(b) Except as provided in §§56.104 and 56.105, the Food and Drug Administration may decide not to consider in support of an application for a research or marketing permit any data or information that has been derived from a clinical investigation that has not been approved by, and that was not subject to initial and continuing review by, an IRB meeting the requirements of this part. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulations to submit the results of the investigation to the Food and Drug Administration.

(c) Compliance with these regulations will in no way render inapplicable pertinent Federal, State, or local laws or regulations.

§56.104 Exemptions from IRB requirement.

The following categories of clinical investigations are exempt from the requirements of this part for IRB review:

(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

§56.105 Waiver of IRB requirement.

On the application of a sponsor or sponsor-investigator, the Food and Drug Administration may waive any of the requirements contained in these regulations, including the requirements for IRB review, for specific research activities

or for classes of research activities, otherwise covered by these regulations.

Subpart B — Organization and Personnel

§56.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, including but not limited to subjects covered by other parts of this chapter, the IRB should include one or more individuals who are primarily concerned with the welfare of these subjects.

(b) No IRB may consist entirely of men, or entirely of women, or entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Subpart C — IRB Functions and Operations

§56.108 IRB functions and operations.

In order to fulfill the requirements of these regulations, each IRB shall:

(a) Follow written procedures (1) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution, (2) for determining which projects requirereview more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review, (3) for insuring prompt reporting to the IRB of changes in a research activity, (4) for insuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects; and (5) for insuring prompt reporting to the IRB of unanticipated problems involving risks to subjects or others.

(b) Except when an expedited review procedure is used (see §56.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

(c) Be responsible for reporting to the appropriate institutional officials and the Food and Drug Administration any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.

§56.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §50.25. The IRB may require that information, in addition to that specifically mentioned in §50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent in accordance with §50.27, except that the IRB may, for some or all subjects, waive the requirement that the subject or the subject's legally authorized representative sign a written consent form if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§56.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Food and Drug Administration has established, and published in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the FEDERAL REGISTER.

(b) An IRB may review some or all of the research appearing on the list through an expedited review procedure, if the research involves no more than minimal risk. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §56.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Food and Drug Administration may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects.

§56.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by Part 50.

(5) Informed consent will be appropriately documented, in accordance with and to the extent required by §50.27.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§56.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 56.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration.

§56.114 Cooperative research.

In complying with these regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

Subpart D — Records and Reports

§56.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB as required by §56.108(a).

(7) Statements of significant new findings provided to subjects, as required by §50.25.

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

(c) The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section.

Subpart E — Administrative Actions for Noncompliance

§56.120 Lesser administrative actions.

(a) If apparent noncompliance with these regulations in the operation of an IRB is observed by an FDA investigator during an inspection, the inspector will present an oral or written summary of observations to an appropriate representative of the IRB. The Food and Drug Administration may subsequently send a letter describing the noncompliance to the IRB and to the parent institution. The agency will require that the IRB or the parent institution respond to this letter within a time period specified by FDA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

(b) On the basis of the IRB's or the institution's response, FDA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, the agency may:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part;

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or

(4) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, notify relevant State and Federal regulatory agencies and other parties with a direct interest in the agency's action of the deficiencies in the operation of the IRB.

(c) The parent institution is presumed to be responsible for the operation of an IRB, and the Food and Drug Administration will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, the Food and Drug Administration may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

§56.121 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the agency under §56.120(a), and the Commissioner of Food and Drugs determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Commissioner will institute proceedings in accordance with the requirements for a regulatory hearing set forth in Part 16.

(b) The Commissioner may disqualify an IRB or the parent institution if the Commissioner determines that:

1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects in a clinical investigation.

(c) If the Commissioner determines that disqualification is appropriate, the Commissioner will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing clinical research conducted under the review of the IRB. The Food and Drug Administration will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and clinical investigators, may also be sent a notice of the disqualification. In addition, the agency may elect to publish a notice of its action in the FEDERAL REGISTER.

(d) The Food and Drug Administration will not approve an application for a research permit for a clinical investigation that is to be under the review of a disqualified IRB or that is to be conducted at a disqualified institution, and it may refuse to consider in support of a marketing permit the data from a clinical investigation that was reviewed by a disqualified IRB as conducted at a disqualified institution, unless the IRB or the parent institution is reinstated as provided in §56.123.

§56.122 Public disclosure of information regarding revocation.

A determination that the Food and Drug Administration has disqualified an institution and the administrative record

regarding that determination are disclosable to the public under Part 20.

§56.123 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated if the Commissioner determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under §56.121(c).

§56.124 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, through the Department of Justice institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. The agency may also refer pertinentmatters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

Exhibit C

Schulman Associates
Institutional Review Board, Inc.
IRB

John M. Isidor, J.D., Chairman
Alan A. Schulman, J.D., Vice-Chairman
Jonathan Singer, M.D., Vice-Chairman

APPROVED: 08-20-97
EXPIRATION DATE: 08-19-98

August 27, 1997

FROM:	Schulman Associates Institutional Review Board, Inc. (SAIRB)
TO:	Herbert J. Nevyas, M.D./Anita Nevyas-Wallace, M.D. – Bala Cynwyd, PA
SUBJECT:	Protocol and Informed Consent
SPONSOR:	Nevyas Eye Associates
PROTOCOL NO:	NEV-97-001

At a meeting of the Institutional Review Board of August 20, 1997, the Board reviewed the informed consent and protocol entitled:

LASIK with an Excimer Laser in the Surgical Treatment of Refractive Errors: Myopia with or without Astigmatism

This letter is to inform you that the Board has approved the revised protocol dated July 19, 1997, and the enclosed IRB stamped informed consent. You must use only the enclosed "SAIRB Approved" informed consent. We have included a copy of the most current Board membership list to maintain with your study binder.

Under FDA regulations, this approval will last only one year. If the study is expected to last beyond a year, you must request re-approval for the next year at least 4 weeks prior to the expiration date noted above. Please use the enclosed Report Form and indicate if six month, annual, or final report. Your first report to the Board on the status of this study is due six months from the approval date or at the time the study closes, whichever is earlier.

The FDA requires you to notify the IRB of any new advertisements or recruiting material, serious adverse events, amendments or changes in the protocol, significant protocol deviations, patient death or termination of the study. Please note that you must submit all protocol amendments and/or advertisements to the Board for review, and await a response from the Board, prior to implementing the amendments and/or advertisements.

Schulman Associates Institutional Review Board, Inc. is in compliance with the regulations of the Food and Drug Administration as described in 21 CFR parts 50 and 56.

Sincerely,

John M. Isidor, J.D., Chairman
Schulman Associates Institutional Review Board, Inc.

JMI/jab
Enclosures

cc: Dr. Barbara Fant

PLEASE USE OUR IRB #97-1942-0 ON ALL CORRESPONDENCE FOR THIS STUDY.

NYA 000004

Schulman Associates
Institutional Review Board, Inc
IRB

John M. Isidor, J.D., Chairman
Alan A. Schulman, J.D., Vice-Chairman
Julie Waltz Gerlach, B.S.N., M.P.H., Vice-Chairman

July 17, 1998

FROM: Schulman Associates Institutional Review Board, Inc.
TO: Herbert J. Nevyas, M.D.
SUBJECT: **Amendment 1 dated 12-4-97, Protocol Version 1.2 dated July 8, 1998 Consent forms for LASIK retreatment surgery, LASIK fellow eye surgery on different days, LASIK fellow eye surgery on the same day**
SPONSOR: Herbert J. Nevyas, M.D.
PROTOCOL NO.: NEV-97-001

The Board has received Barbara Fant's letter dated July 8, 1998, regarding the above-referenced protocol.

This letter is to inform you that the Board, at its meeting of July 15, 1998, reviewed and approved Amendment 1 dated 12-4-97 and Protocol Version 1.2 dated July 8, 1998. The Board has also approved the consents for the LASIK retreatment surgery and the LASIK fellow eye surgery on different days. The consent form for the LASIK fellow eye surgery on the same day is approved, as revised; the Board felt a more complete consent form was necessary. Enclosed are "SAIRB Approved" copies of the above listed consent forms dated July 17, 1998.

Sincerely,

John M. Isidor, J.D., Chairman
Schulman Associates Institutional Review Board, Inc.

JMI/lh

Enclosure

cc: Barbara Fant, Pharm.D.

PLEASE REFERENCE OUR IRB #97-1942-0 ON ALL CORRESPONDENCE FOR THIS STUDY

NYA 00049

10 Knollcrest Drive, Suite 200 Cincinnati, Ohio 45237 Phone: (513) 761-4100 Fax (513) 761-5546

Nevyas Eye Associates / Delaware Valley Laser Surgery Institute
Ambulatory Surgery Center

Herbert J. Nevyas, M.D.
Refractive, Cataract, and Corneal Surgery

Joann Y. Nevyas, M.D.
Cataract and Glaucoma Surgery and Therapy

Anita Nevyas-Wallace, M.D.
Refractive, Cataract, and Corneal Surgery

Ira B. Wallace, M.D.
Ophthalmic Plastic and Reconstructive Surgery, Cosmetic Surgery

Edward A. Deglin, M.D.
Vitreo-retinal Disease and Surgery

Mitchell E. Stein, M.D.
Retinal Disease, Glaucoma Medical and Surgical Ophthalmology

Rick S. Choe, M.D.
Glaucoma Surgery and Therapy, Cataract Medical and Surgical Ophthalmology

Bari M. Brandt, M.D.
Vitreo-retinal Disease

Richard H. Sterling, O.D.
Interprofessional Relations Refractive Surgery Coordinator

FAX COVER SHEET

DATE: 10-9-98

TO: Barbara Fat, PhD

FAX: 513-751-3773

PHONE:

RE: Conmargo Pr's

FROM: Rich Sterling OD

FAX: [610] 668-1509 BALA CYNWYD OFFICE

PAGES [including cover sheet]: 9

COMMENTS:

☐ URGENT ☑ REVIEW ☐ REPLY

Please note that the information contained in this transmission is confidential in nature. The information is to be used for its intended purpose only and is to be destroyed after the stated need has been fulfilled. This information is not for disclosure. Please deliver immediately to the individual indicated above. If you have received this transmission in error, please notify us immediately by phone and destroy the transmitted documents.

NYA 00074

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Fax 610-668-1509

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☐ Central Square
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215-673-2020
Fax 215-969-6375

☐ 1001-E Lincoln Drive West
Greentree Executive Campus
Marlton, NJ 08053
609-985-9797
Fax 609-985-1191

Dear Barbara:

I simply listed the OD's that have comanaged cases from the list of Post-op visits doctors in the McDonald software:

Frank Angelini, OD	Victor Barouh, OD	Steven Berger, OD
Bruce Block, OD	John Boscia, OD	Jeffrey Brooks, OD
Jeffrey Brosof, OD	Peter Campanella, OD	Leon Candeub, OD
Joan Cirbus, OD	Alan Citrenbaum, OD	Alan Cohen, OD
Paul Cohen, OD	Kevin Corcoran, OD	William Dent, OD
Paul Difiore, OD	William DiMino, OD	Valerie DiPietro-Longo, OD
Peggy Dixon, OD	Peter Dodge, OD	Jeffrey Eidman, OD
Gary Finnegan, OD	Richard Floyd, OD	Stephen Galanter, OD
Joseph Gallagher, OD	Philip Gerson, OD	Robert Ginsburg, OD
Jeffrey Gold, OD	Leroy Goldfarb, OD	Randolph Greber, OD
Donald Hartranft, OD	Jack Hauler, OD	Stephen Hersh, OD
William Jacobson, OD	Martin Kalish, OD	Michelle Kaller, OD
Barry Kanofsky, OD	Michael Karliner, OD	Jerry Kasrel, OD
Martin Kitagawa, OD	Glenn Knezich, OD	Daniel Kramer, OD
Janice Kulba, OD	Roslyn, Kushner, OD	Richard Lawver, OD
Robert Levy, OD	Michael Maizel, OD	Raymond Mancuso, OD
Kimberly McClure, OD	Jonia Mekel, OD	Edward Melman, OD
Morse Michels, OD	Robert Mintz, OD	Benson Olenick, OD
Carl Pecorara, OD	Gary Poole, OD	James Prate, OD
Barry Preiss, OD	Harry Prihar, OD	Raymond Puzio, OD
Louis Reardon, OD	John Renyo, OD	Alan Rosenberg, OD
Jerry Rosenfeld, OD	Harvery Rosenwasser, OD	Alan Roth, OD
Robin Sapossnek, OD	Renny Sardella, OD	Mark Schnitzel, OD
Ronald Shane, OD	Deborah Signorino, OD	Steven Simmerman, OD
Stephen Sinoway, OD	Harry Snyder, OD	Robert Spivack, OD
Mervin Stoltzfus, OD	Joan Storer, MD	Paul Suscavage, OD
Sam Tilonsky, OD	Richard Weiner, OD	Arnold Witkin, OD
Robert Wortman, OD	Samuel Young, OD	

In addition to the above names we have a group of OD's, Delaware Valley Refractive Surgery Partnership that was formed specifically to comanage refractive pts.. In other words they are also "potential" comanaging doctors. As you see I've enclosed names, no addresses, if you need that let me know.

Rich

5-7-98

Drs.:

The enclosed represents all the patients who have had LASIK since the IDE submission. The total is 25 high myopes (as defined by FDA >-6.75D) and 53 low myopes.

As mentioned before as of 5-6-98 Barbara Fant, PhD had not submitted our enhancements to the FDA, she has though put us first on her to do list.

Rich

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

INVESTIGATOR	ID#	EYE	DATE	SPH./CYL	PRIMARY	FELLOW	ENH. PRE-IDE	ENH.-IDE
HJN	63086	OD	8/28/97	-3.25-5.00x26"	X			
HJN	63086	OS	8/28/97	-4.75-3.00x167"		X		
HJN	64118	OS	8/28/97	-2.50-2x175"		X		
HJN	64611	OD	8/28/97	-4.00-0.50x133"		X		
HJN	64611	OS	8/28/97	-3.50-0.75x180	X			
HJN	64712	OS	8/28/97	-6.75-0.75x170		X		
ANW	62658	OS	8/28/97	-2.00-1.25x123			X	
ANW	60816	OD	8/28/97	-1.00-2.50x105"			X	
HJN	64712	OD	9/11/97	-6.75-1.25x180"	X			
HJN	63828	OD	9/11/97	-7.75-1.00x180"		X		
HJN	64070	OS	9/11/97	-12.00-0.75x150		X		
HJN	64973	OS	9/11/97	-2.75-1.00x165	X			
HJN	64118	OD	9/11/97	-0.75-2.50x165"	X			
HJN	58377	OS	9/11/97	-3.50-2.00x154"			X	
HJN	62610	OD	9/11/97	PL-2.00x87			X	
HJN	64969	OS	9/11/97	-6.50-1.00x180"	X			
ANW	57726	OD	9/11/97	-1.50sphere"	X			
HJN	58908	OS	9/25/97	+3.50-1.00x80"			X	
ANW	65180	OS	9/25/97	-3.75-1.25x180"		X		
ANW	62514	OD	9/25/97	-1.25sphere			X	
HJN	64532	OS	10/7/97	-13.00-0.50x135"		X		
HJN	65251	OS	10/9/97	-7.25-0.50x63		X		
HJN	65280	OS	10/9/97	-3.50-0.50x2"		X		

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

HJN	64532	OD	10/9/97	-11.50-1.00x10"	X			
HJN	64657	OS	10/9/97	-8.50-1.00x158"	X			
HJN	64411	OS	10/9/97	-7.75-2.75x170"		X		
ANW	65180	OD	10/9/97	-3.25-2.00x166"	X			
HJN	64657	OD	10/23/97	-8.00-1.25x175"		X		
HJN	64892	OS	10/23/97	-3.75-2.50x10"		X		
HJN	61604	OS	10/23/97	-8.25-2.25x115"		X		
HJN	65251	OD	10/23/97	-7.50 sphere"	X			
HJN	65280	OD	10/23/97	-3.75-0.50x153"	X			
HJN	64941	OS	11/13/97	-6.25-0.50x90"		X		
HJN	64892	OD	11/13/97	-2.75-1.50x170	X			
HJN	65212	OS	11/13/97	-11.00-0.75x165"		X		
HJN	62117	OS	11/13/97	-1.75-0.50x95"			X	
ANW	65607	OD	11/13/97	-2.75-0.25x175"		X		
ANW	65459	OD	11/13/97	-4.00-1.50x110"		X		
HJN	65890	OS	12/4/97	-7.00 sphere"	X			
HJN	65212	OD	12/4/97	-10.75-1.00x180	X			
HJN	65489	OD	12/4/97	-4.50-0.50x180		X		
HJN	64941	OD	12/4/97	-6.00-0.50x93"	X			
HJN	66033	OD	12-4-97	-12.00-3.50x14"		X		
HJN	65701	OD	12/4/97	-3.75-0.25x150"		x		
ANW	65615	OD	12/4/97	-10.00-1.25x170"		X		
ANW	61798	OD	12/4/97	-2.25-1.25x130"		X		

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

ANW	65607	OS	12/4/97	-2.50 sphere"	X			
ANW	57385	OD	12/4/97	-2.00-0.50x91"	X			
ANW	66068	OS	12/4/97	-7.00-1.75x167"		X		
ANW	65724	OS	12/4/97	-4.50-0.25x25		X		
HJN	59885	OD	12/11/97	-2.00-0.50x60"	X			
HJN	65489	OS	12/11/97	-4.25-0.50x180"	X			
ANW	65459	OS	12/11/97	-4.50-0.75x93"	X			
ANW	61798	OS	12/11/97	"-3.25-1.25x100	X			
ANW	65615	OS	12/11/97	-8.00-3.00x175"	X			
ANW	65724	OD	12/11/97	-4.00-0.75x148"	X			
ANW	66068	OD	12/11/97	-7.25-1.00x15"	X			
ANW	65322	OS	01/08/98	"-8.00-1.25x167		X		
HJN	65890	OD	01/08/98	-6.75 sphere	X			
HJN	50547	OS	01/08/98	"-11.00-.50x130		X		
HJN	63622	OD	01/08/98	-1.50-2.50x3	X			
HJN	63828	OS	01/08/98	-1.25-0.75x135			X	
ANW	66350	OS	01/08/98	-3.75-0.75x5		X		
ANW	65408	OS	01/08/98	-10.50-0.75X169		X		
ANW	65408	OD	1/12/98	-10.25-1.25X180	X			
ANW	66591	OS	01/20/98	-9.25-1.25X160		X		
ANW	66350	OD	1/20/98	-4.00-0.50X148	X			
ANW	65322	OD	1/20/98	-7.75-1.25X48	X			
HJN	66746	OS	1/29/98	-3.00-0.75X180		X		

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

HJN	66236	OS	1/29/98	-14.25-2.00X172		X		
HJN	66591	OD	1/29/98	-10.00-1.00X35	X			
HJN	64520	OD	1/29/98	-0.50-1.75X21	X			
HJN	50547	OD	1/29/98	-10.75-0.25X180	X			
HJN	60618	OD	1/29/98	-1.50-0.50X178			X	
HJN	65843	OD	2/19/98	-3.75SPHERE		X		
HJN	66746	OD	2/19/98	-3.00SPHERE	X			
HJN	66346	OS	2/19/98	-8.00-1.00X180		X		
HJN	66236	OD	2/19/98	-13.00-1.50X30	X			
HJN	65481	OS	2/19/98	-4.00-0.25X180		X		
HJN	34389	OD	2/19/98	-3.50-3.25X165		X		
HJN	66385	OS	2/19/98	-9.75-1.75X4		X		
HJN	59885	OS	2/19/98	-2.75-0.25X120		X		
HJN	66940	OS	2/19/98	-5.75 SPHERE		X		
ANW	58377	OS	2/19/98	PL-4.00X162			X	
ANW	66784	OD	2/19/98	-4.50-2.00X80	X			
ANW	66647	OD	2/19/98	-4.50-0.50X113		X		
ANW	66678	OS	2/19/98	-5.50-0.25X165		X		
ANW	66053	OS	2/19/98	-8.00-0.25X6		X		
ANW	66678	OD	2/26/98	-6.00-0.50X13	X			
ANW	66647	OS	2/26/98	-4.25-0.50X60	X			
ANW	66053	OD	2/26/98	-7.00-0.25X30	X			
HJN	65843	OS	2/26/98	-3.75-0.50X180	X			

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

HJN	65481	OD	2/26/98	-4.00 SPHERE	X			
HJN	66385	OD	2/26/98	-10.25-2.50X13	X			
HJN	67025	OS	2/26/98	-8.00-1.00X176		X		
HJN	66884	OS	2/26/98	-6.00-1.00X180		X		
HJN	66940	OD	2/26/98	-6.50SPHERE	X			
HJN	66033	OS	2/26/98	-10.50-2.50X180	X			
HJN	67206	OS	3/12/98	"-7.00-0.50X110		X		
HJN	67025	OD	3/12/98	"-7.75-0.50X160	X			
HJN	66879	OS	3/12/98	"-6.00-4.00X165		X		
HJN	66346	OD	3/12/98	"-7.00-1.75X168	X			
HJN	67230	OS	3/12/98	"-4.00 SPHERE		X		
HJN	67466	OS	3/12/98	"-8.75-0.25X145		X		
HJN	66920	OD	3/12/98	"-3.50-2.25X180		X		
HJN	67429	OS	3/12/98	"-2.50 SPHERE		X		
ANW	66943	OD	3/12/98	"-6.50-1.25X58		X		
ANW	66508	OS	3/12/98	"-5.00-0.50X95		X		
HJN	67206	OD	3/19/98	"-7.25-0.50X40	X			
HJN	67879	OD	3/19/98	"-4.75-5.00X3	X			
HJN	67230	OD	3/19/98	"-4.00 SPHERE	X			
HJN	67429	OD	3/19/98	"-3.00-0.25X177	X			
HJN	64921	OD	3/19/98	"-10.00-1.50X14		X		
HJN	66884	OD	3/19/98	"PL-2.50X50	X			
HJN	66920	OS	3/19/98	"-4.50-1.75X165	X			

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

HJN	62581	OS	3/19/98	"-9.75-0.75X100		X		
HJN	67466	OD	3/19/98	"-9.50-1.25X164	X			
ANW	67608	OS	3/19/98	"-4.25-1.00X164		X		
ANW	66508	OD	3/19/98	"-4.50 SPHERE	X			
ANW	66943	OS	3/19/98	"-9.00-0.75X176	X			
ANW	67608	OD	3/19/98	"-4.00-1.00X180	X			
HJN	65701	OS	4/9/98	"-5.00-0.50X90	X			
HJN	67643	OS	4/9/98	"-3.75-2.25X160		X		
HJN	67520	OD	4/9/98	"-1.50-0.75X90		X		
HJN	62581	OD	4/9/98	"-9.75-0.25X97	X			
HJN	67526	OS	4/9/98	"-4.25-0.25X110		X		
HJN	67946	OS	4/9/98	"-5.25-0.50X180		X		
HJN	67567	OS	4/9/98	"-6.75 SPHERE		X		
HJN	67770	OS	4/9/98	"-1.50-1.25X175		x		
HJN	67946	OD	4/9/98	"-5.00 SPHERE	X			
HJN	67512	OD	4/9/98	"-7.50-0.50X58		X		
ANW	64401	OD	4/9/98	"-4.75-0.50X157		X		
ANW	67310	OS	4/9/98	"-8.50-0.75X151		X		
ANW	64401	OS	4/9/98	"-4.50-0.50X171	X			
ANW	67392	OS	4/9/98	"-5.75 SPHERE		X		
HJN	67849	OS	4/23/98	"-3.25-0.75X75		X		
HJN	66039	OD	4/23/98	"-5.00 SPHERE		X		
HJN	67386	OS	4/23/98	"-7.50-0.25X90		X		
HJN	67971	OD	4/23/98	"-1.00-1.00X150		X		
HJN	64921	OS	4/23/98	"-9.75-1.25X90	X			

REPORT OF LASIK PROCEDURES FOR NEVYAS MODEL SULLIVAN EXCIMER LASER
RE: G970088/S2, S3 AND S4

HJN	67526	OD	4/23/98	"-4.25-0.25X90	X			
HJN	68038	OD	4/23/98	"-6.25-0.25X160		X		
HJN	67643	OD	4/23/98	"-4.00-2.00X40	X			
HJN	67596	OD	4/23/98	"-4.75-0.75X90		X		
HJN	68038	OS	4/23/98	"-6.00-0.50X125	X			
HJN	67567	OD	4/23/98	"-6.75 SPHERE	X			
HJN	67947	OS	4/23/98	"-4.75-0.25X25		X		
ANW	67310	OD	4/23/98	"-8.75-2.00X22	X			
ANW	67530	OD	4/23/98	"-5.00-0.25X164		X		
ANW	67392	OD	4/23/98	"-6.75 SPHERE	X			
ANW	67256	OS	4/23/98	"-4.25-2.00X11		X		
HJN	67947	OD	4/30/98	"-4.25-0.25X135	X			
HJN	67849	OD	4/30/98	"-3.25-0.50X105	X			
HJN	66421	OD	4/30/98	"-2.00-0.75X135		X		
HJN	67386	OD	4/30/98	"-7.50-0.25X90	X			
HJN	66421	OS	4/30/98	"-1.25-0.25X10	X			
HJN	67971	OS	4/30/98	"-1.25-2.00X60	X			
HJN	67770	OD	4/30/98	"-1.50-1.00X15	X			
HJN	67596	OS	4/30/98	"-6.50-1.00X70	X			
HJN	66039	OS	4/30/98	"-4.50-1.25X165	X			
HJN	67981	OS	4/30/98	"-5.50-4.25X5		X		
ANW	67530	OS	4/30/98	"-4.75 SPHERE	X			
ANW	67256	OD	4/30/98	"-4.25-2.00X170	X			

12-12-97

Dr. Nevyas:

This is what I submitted to Barbara Fant, PhD as she requested. The columns marked Primary and Fellow correspond to the number of patients that have had monovision (fellow) or those that had distance eye done since conditional approval (there are a 2 pts. that are distance eyes that had only one eye done). I found that so far we have done **17 eyes over -6.75** sphere with **seven patients being considered primary eyes** over -6.75. Those patients that had surgery on "the other eye" prior to 8-28-97 conditional approval are considered fellow eyes for these purposes.

I spoke with Dr. Ronald Shane (OD in Sunbury who sent Nevin Garrett for LASIK) about the possibility of "marketing" his area for refractive surgery. Sunbury is 52 miles outside of Harrisburg. The doctors in his area send their work to Harrisburg where there are two groups doing LASIK (Chottiner and another). In addition Lancaster ophthalmologists have been marketing the Harrisburg and surrounding area. Dr. Shane told me he just got the letter from Kremer so he is aware of his efforts. He said he will send to you when he can, and he talks up your practice all the time, because of his relationship with your Dad and his impression of you and your philosophy.

Rich

REPORT OF LASIK P[illegible]DURES FOR NEVYAS MOL[illegible]ULLIVAN E[illegible]R LASER
RE: G970088/S2, S3 AND S[illegible]

INVESTIGATOR	ID#	EYE	DATE	SPH./CYL	PRIMARY	FELLOW	ENH. PRE-IDE	ENH.-IDE
HJN	63086	OD	8/28/97	-3.25-5.00x26"	X			
HJN	63086	OS	8/28/97	-4.75-3.00x167"		X		
HJN	64118	OS	8/28/97	-2.50-2x175"		X		
HJN	64611	OD	8/28/97	-4.00-0.50x133"		X		
HJN	64611	OS	8/28/97	-3.50-0.75x180	X			
HJN	64712	OS	8/28/97	-6.75-0.75x170		X		
ANW	62658	OS	8/28/97	-2.00-1.25x123			X	
ANW	60816	OD	8/28/97	-1.00-2.50x105"			X	
HJN	64712	OD	9/11/97	-6.75-1.25x180"	X			
HJN	63828	OD	9/11/97	-7.75-1.00x180"		X		
HJN	64070	OS	9/11/97	-12.00-0.75x150		X		
HJN	64973	OS	9/11/97	-2.75-1.00x165	X			
HJN	64118	OD	9/11/97	-0.75-2.50x165"	X			
HJN	58377	OS	9/11/97	-3.50-2.00x154"			X	
HJN	62610	OD	9/11/97	PL-2.00x87			X	
HJN	64969	OS	9/11/97	-6.50-1.00x180"	X			
ANW	57726	OD	9/11/97	-1.50sphere"	X			
HJN	58908	OS	9/25/97	+3.50-1.00x80"			X	
ANW	65180	OS	9/25/97	-3.75-1.25x180"		X		
ANW	62514	OD	9/25/97	-1.25sphere			X	
HJN	64532	OS	10/7/97	-13.00-0.50x135"		X		
HJN	65251	OS	10/9/97	-7.25-0.50x63		X		
HJN	65280	OS	10/9/97	-3.50-0.50x2"		X		

HJN	64532	OD	10/9/97	-11.50-1.00x10"	X			
HJN	64657	OS	10/9/97	-8.50-1.00x158"	X			
HJN	64411	OS	10/9/97	-7.75-2.75x170"		X		
ANW	65180	OD	10/9/97	-3.25-2.00x166"	X			
HJN	64657	OD	10/23/97	-8.00-1.25x175"		X		
HJN	64892	OS	10/23/97	-3.75-2.50x10"		X		
HJN	61604	OS	10/23/97	-8.25-2.25x115"		X		
HJN	65251	OD	10/23/97	-7.50 sphere"	X			
HJN	65280	OD	10/23/97	-3.75-0.50x153"	X			
HJN	64941	OS	11/13/97	-6.25-0.50x90"		X		
HJN	64892	OD	11/13/97	-2.75-1.50x170	X			
HJN	65212	OS	11/13/97	-11.00-0.75x165"		X		
HJN	62117	OS	11/13/97	-1.75-0.50x95"			X	
ANW	65607	OD	11/13/97	-2.75-0.25x175"		X		
ANW	65459	OD	11/13/97	-4.00-1.50x110"		X		
HJN	65890	OS	12/4/97	-7.00 sphere"	X			
HJN	65212	OD	12/4/97	-10.75-1.00x180	X			
HJN	65489	OD	12/4/97	-4.50-0.50x180		X		
HJN	64941	OD	12/4/97	-6.00-0.50x93"	X			
HJN	66033	OD	12-4-97	-12.00-3.50x14"		X		
HJN	65701	OD	12/4/97	-3.75-0.25x150"	X			
ANW	65615	OD	12/4/97	-10.00-1.25x170"		X		
ANW	61798	OD	12/4/97	-2.25-1.25x130"		X		

REPORT OF LASIK PROC[illegible]RES FOR NEVYAS MODEL [illegible]VAN EXCI[illegible]ASER
RE: G970088/S2, S3 AND S4

ANW	65607	OS	12/4/97	-2.50 sphere"	X			
ANW	57385	OD	12/4/97	-2.00-0.50x91"	X			
ANW	66068	OS	12/4/97	-7.00-1.75x167"		X		
ANW	65724	OS	12/4/97	-4.50-0.25x25		X		
HJN	59885	OD	12/11/97	-2.00-0.50x60"	X			
HJN	65489	OS	12/11/97	-4.25-0.50x180"	X			
ANW	65459	OS	12/11/97	-4.50-0.75x93"	X			
ANW	61798	OS	12/11/97	"-3.25-1.25x100	X			
ANW	65615	OS	12/11/97	-8.00-3.00x175"	X			
ANW	65724	OD	12/11/97	-4.00-0.75x148"	X			
ANW	66068	OD	12/11/97	-7.25-1.00x15"	X			

Subj: **BSCVA Loss Case Summaries**
Date: 8/5/02 1:25:15 PM Eastern Daylight Time
From: BSFant
To: Nevyas

File: Case Summaries 2 or More Lines of BCVA.doc (120832 bytes)
DL Time (TCP/IP): < 1 minute

Rich,
Attached is a Word document that contains the draft case summaries for eyes treated with the Nevyas laser that had a 2 line or more loss in BSCVA at 6 months or greater postop. At the beginning of the document are 2 tables -- the first is an alphabetical listing of the patients and the second is a listing by surgery ID number of the cases included in the summaries. The summaries contain all the pertinent information that is in the database. Please review the charts for each and add (or have Herb/Anita add) any other explanatory information. We should have a conclusion for each regarding the BSCVA loss. I've written some -- please make sure my comments are reflective of your opinion(s). I've also highlighted in yellow some things that need to be checked. I would like to have these back by the end of this week if possible to forward to FDA.

Thanks,

Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
3307 Clifton Avenue
Cincinnati, Ohio 45220

PH: (513)-961-8200 FAX: (513)-961-2858

Dear Barb:
In this e-mail I'll respond to your 8/5/02 e-mail regarding 2 line or more loss in BSCVA. I've reviewed all the charts (except Dominic Morgan and Keith Wills) and I'll summarize for you those that need editing. First of all most of the MR or manifest refractions are written incorrectly (e.g. -7.75x-1.50x7 should be -7.75-1.50x7, no x after sphere).
1. (J-T)261- He was 53 years of age at surgery. His preop UCVA was 20/1000 and his MR was -7.25-1.00x4. At the 1/27/01 visit (~4 years) his BSCVA was 20/30 +3.
2. (J-W)325- The last sentence should read -1.50-1.25x90 but it was actually -1.25-1.00x45 which was BSCVA of 20/25+2 and UCVA 20/40+3.
3. (S-E)347- OD preop was actually -12.00-3.50x14. About the 6th line down should be +1.25-1.00x10 and the next to the last line should be +2.25-1.25x45
4. (L-W) 825/826- The sentence that begins with At 6 months... should be +1.75--1.25x135.
5. (M-N) 928- Preop BSCVA was 20/20-. On the last line it should be -1.00-0.50x110 with UCVA of 20/30+3 and BSCVA of 20/20-.
6. (J-R) 1037- About the 5th line down should be MR of -6.50-0.50x103
7. (R-S)1235- BSCVA at 24 months and the MR was -0.50-1.25x133 which yielded 20/25+ BSCVA
8. (L-A) 1236- 6 month visit MR was PL-1.75x170 and at 9 months MR was +0.50-2.50x175
9. (Y-V) 1288 Patient moved to Minnesota lost to followup
10. (A-B) 1529 Last sentence should be +0.75-0.25x110
11. (H-O) 1544 On the next to the last sentence drop the ..."to reverse the monovision".
12. (E-F) 1599-1600 OD is corrected to 20/25 and OS is now -0.75-1.00x165 which gave him 20/20-BSCVA
13. (P-A) 1714- 3rd line should read -7.75-2.00x180
14. (J-K) 1760/1761- At the 3 month postop visit OU had UCVA of 20/20 with the OD MR being -0.50-0.75x45 and OS PL with BCVA of 20/20
15. (J-H) 1949 Pt. has not returned for followup.

To answer your message that I received today regarding the nomogram it is the sphere that determines 17R or 17H not the spherical equivalent.
Rich

~~A-B 1529~~ last selected +0.75 -0.25 x110

~~H-O 1544~~ Both eyes undercorrect / drop the monovision

~~E-F 1599~~ OD is 20/15
OS is -0.75-1.00 x165 ⇒ 20/20

P-A 1714 - -7.75-2.00 x180

JK 1760/1761 At 3 mos. PO. ~~OD~~ OU had UCVA of 20/20 + MR → OD -0.50-0.75 x45 + OS PL c Bc of

J-H 1949 - Pt. has not returned for followup

* ~~Didn't have ko~~

~~L-W 825-826~~ At 6 mos ⊕ 1.75-1.25

NYA 00134

Alphabetical Patient List

Last	First	
Aaron	Linda	
Albert	Regina	
Angstadt	Patricia	
Bagnoli	Al	
Bogdan	Raymond	
Chung	Suk Ling	12/21/01
DeMauriac	Pierre	
Eng	Soo	9/24/01
Ettinger	Jean	
Forstater	Eleanor	
Harlan	Colette	
Hartshorne	Joanne	
Hoerner	Meghan	
Jenson	Tory	
Koenig	Joerg	
Morgan	Dominic	3/27/00 = CANNOT HAVE.
Nester	Michael	
Onofrio	Helen	
Paige	Daniel	
Pavlin	Teresa	
Ring	Jonathan	
Ryan	Cynthia	
Sawn	Walter	8/17/98.
Soper	Robert	
Tumolo	John	
Yang	Yer	
Waddell	Lois	3/8/00
Welty	John	
Wheeler	Chris	
Wills	Keith	9/12/01 = CANNOT HAV
Yeo	Jacqueline	1/21/02

Patient List Sorted by Surgery ID (order of case summaries)

PatientID	Last	First	SurgeryID	Eye	DateofBirth	SurgeryDate	Age at Surgery	gender
104	Pavlin	Teresa	218	OS	10/1/1953	3/19/1998	44	F
113	Hoerner	Meghan	238	OS	11/7/1969	3/4/1999	29	F
123	Tumolo	John	261	OD	2/12/1944	9/11/1997	54	M
130	Bogdan	Raymond	275	OS	1/24/1950	10/9/1997	48	M
131	Wills	Keith	277	OS	1/26/1958	10/7/1997	40	M
131	Wills	Keith	278	OD	1/26/1958	10/9/1997	40	M

Alphabetical Patient List

Last	First
Aaron	Linda
Albert	Regina
Angstadt	Patricia
Bagnoli	Al
Bogdan	Raymond
Chung	Suk Ling
DeMaurlac	Pierre
Eng	Soo
Ettinger	Jean
Forstater	Eleanor
Harlan	Colette
Hartshorne	Joanne
Hoerner	Meghan
Jenson	Tory
Koenig	Joerg
Morgan	Dominic
Nester	Michael
Onofrio	Helen
Paige	Daniel
Pavlin	Teresa
Ring	Jonathan
Ryan	Cynthia
Sawn	Walter
Soper	Robert
Tumolo	John
Vang	Yer
Waddell	Lois
Welty	John
Wheeler	Chris
Wills	Keith
Yeo	Jacqueline

Patient List Sorted by Surgery ID (order of case summaries)

PatientID	Last	First	SurgeryID	Eye	DateofBirth	SurgeryDate	Age at Surgery	gender
104	Pavlin	Teresa	218	OS	10/1/1953	3/19/1998	44	F
113	Hoerner	Meghan	238	OS	11/7/1969	3/4/1999	29	F
123	Tumolo	John	261	OD	2/12/1944	9/11/1997	54	M
130	Bogdan	Raymond	275	OS	1/24/1950	10/9/1997	48	M
131	Wills	Keith	277	OS	1/26/1958	10/7/1997	40	M
131	Wills	Keith	278	OD	1/26/1958	10/9/1997	40	M

PatientID	Last	First	SurgeryID	Eye	DateofBirth	SurgeryDate	Age at Surgery	gender
149	Welty	John	325	OD	11/5/1948	1/12/1998	49	M
160	Eng	Soo	347	OD	8/30/1961	12/4/1997	36	F
186	Sawn	Walter	407	OS	8/9/1966	4/9/1998	32	M
268	Harlan	Colette	612	OS	3/22/1957	9/10/1998	41	F
361	Waddell	Lois	825	OS	3/4/1959	9/2/1999	40	F
361	Waddell	Lois	826	OD	3/4/1959	9/2/1999	40	F
408	Nester	Michael	928	OS	1/22/1949	5/7/1999	50	M
450	DeMaurlac	Pierre	1019	OS	10/30/1944	8/12/1999	55	M
451	Albert	Regina	1021	OS	6/4/1952	8/12/1999	47	F
451	Albert	Regina	1022	OD	6/4/1952	8/12/1999	47	F
458	Ring	Jonathan	1037	OD	2/27/1977	12/20/1999	23	M
496	Paige	Daniel	1107	OS	12/17/1945	9/17/1999	54	M
496	Paige	Daniel	1108	OD	12/17/1945	9/17/1999	54	M
545	Wheeler	Chris	1191	OS	8/9/1945	12/16/1999	54	M
545	Wheeler	Chris	1192	OD	8/9/1945	12/16/1999	54	M
552	Jenson	Tory	1204	OD	5/29/1961	1/13/2000	39	F
579	Soper	Robert	1235	OS	3/20/1978	2/17/2000	22	M
257	Aaron	Linda	1236	OS	5/2/1949	8/26/1999	50	F
479	Vang	Yer	1284	OD	6/12/1963	3/16/2000	37	M
578	Ettinger	Jean	1288	OS	1/13/1945	3/16/2000	55	F
341	Chung	Suk Ling	1457	OD	9/9/1958	7/7/2000	42	F
650	Yeo	Jacqueline	1499	OD	4/7/1962	7/13/2000	38	F
650	Yeo	Jacqueline	1500	OS	4/7/1962	7/13/2000	38	F
648	Bagnoli	Al	1529	OS	1/20/1953	8/11/2000	48	M
651	Onofrio	Helen	1544	OD	11/12/1955	8/25/2000	45	F
697	Forstater	Eleanor	1599	OD	12/27/1968	10/27/2000	32	F
697	Forstater	Eleanor	1600	OS	12/27/1968	10/27/2000	32	F
744	Angstadt	Patricia	1714	OD	4/24/1947	1/26/2001	54	F
761	Koenig	Joerg	1760	OD	6/10/1968	2/16/2001	33	M
761	Koenig	Joerg	1761	OS	6/10/1968	2/16/2001	33	M
826	Hartshorne	Joanne	1949	OS	11/3/1948	5/18/2001	53	F
828	Ryan	Cynthia	2007	OD	7/12/1948	5/31/2001	53	F
880	Morgan	Dominic	2182	OD	8/8/1960	4/30/1998	38	M
880	Morgan	Dominic	2183	OS	8/8/1960	4/23/1998	38	M

Case Summaries for Eyes that Lost 2 or More Lines of BCVA

(T-P) 218: T-P is a 44 year old female who underwent uneventful unilateral LASIK surgery on the left eye with the Nevyas Excimer Laser on 3/19/1998. Preoperatively, the manifest refraction was –9.75 x-0.75 x 100; UCVA was 20/1000; and, BSCVA was 20/20. An intentional undercorrection for monovision was performed in this eye with a target residual of –1.75 D MRSE. The patient's postoperative course was unremarkable except for the removal of a chalazion at 3 months postoperatively. BSCVA was reported to be 20/40 at this visit and improved to 20/25 at the 6-month visit, fluctuated to 20/30 (a 2 line loss in BSCVA) at 9 months post-LASIK, and remained at 20/25 for all subsequent visits. At the 24-month end of study visit, BSCVA was 20/25 and the patient offered no complaints.

(M-H) 238: M-H is a 29 year old female who underwent uneventful unilateral LASIK surgery on the left eye with the Nevyas Excimer Laser on 3/4/1999. Preoperatively, the manifest refraction was –9.00 x –1.25 x 15; UCVA was 20/1000; and, BSCVA was 20/20. An intentional undercorrection was performed in this highly myopic eye with a target residual of –0.50 D MRSE. At 6 months postoperatively, the eye had a manifest refraction of –2.00 x –0.25 x 45; UCVA 20/60; and, a BSCVA of 20/30, which was a 2 line decrease from the preoperative BSCVA of 20/20. The eye was retreated 1 week later with the Nevyas Excimer Laser to improve the refractive outcome. At the last reported visit, 12 months post-retreatment, the eye had a manifest refraction of 0.25 x 0.00 x 0; UCVA of 20/25; BSCVA of 20/20, and the patient offered no complaints..

(J-T) 261: J-T is a 4 year old male who underwent unilateral LASIK surgery on the right eye with the Nevyas Excimer Laser on 9/11/1997. The LASIK surgery was unremarkable; surgery was performed using the "old" centration technique. Preoperatively, the eye had a manifest refraction of –7.75 x –1.50 x 7; UCVA was 20/100, and BSCVA was 20/20. Target postoperative refraction was plano. The eye's BSCVA has fluctuated between 20/25 and 20/30 since the 6 month postoperative visit. At the 24-month end of study visit, the eye had a manifest refraction of –0.50 x-0.75 x 75 with a UCVA of 20/70 and BSCVA of 20/30. The patient was seen again at ~4 years post-LASIK and the treated eye showed good refractive stability with a manifest refraction of –0.75 x –0.75 x 77, UCVA of 20/50, and BSCVA of 20/30. The patient is pleased with the result and offers no complaints.

(R-B) 275: R-B is a 48 year old male who underwent LASIK surgery on the left eye on 10/9/1997 with the Nevyas Excimer Laser. The eye was intentionally undercorrected with a target of –1.25 D MRSE. Surgery was performed using the "old" centration technique. Preoperatively, the eye had a manifest refraction of -7.75 x –2,75 x170, UCVA of 20/1000 and BSCVA of 20/20. Postoperatively, the eye was noted to overcorrected. At 6 months postoperatively, the eye had a reported manifest refraction of 6.00 x –1.25 x 120, UCVA of 20/200, and BSCVA of 20/30. At 10 months postoperatively, the eye was retreated using a commercially available laser. At 6 months

post-retreatment, the eye had a manifest refraction of 0.00 x-0.75 x 60 with a UCVA of 20/25 and BSCVA of 20/20.

(K-W) 277/278: K-W is a 40 year old male who underwent LASIK surgery on the left eye on10/7/97 and on the right eye on 10/9/97 with the Nevyas Excimer Laser. Preoperatively, the manifest refraction in the left eye was –13.00 x –0.50 x 135 and –11.25 x-1.00x 10 in the right eye. Both eyes had a preoperative UCVA of 20/2000 and BSCVA of 20/20. The target postoperative refraction was –1.50 MRSE in the left eye and plano in the right eye. At 6 months postoperatively, the left eye was undercorrected with a manifest refraction of –1.50 x –1.50 x140 with an UCVA of 20/100 and a BSCVA of 20/30 and the right eye was overcorrectedwith a manifest refraction of 1.25 x –2.00 x 110 with UCVA BSCVA both reported to be 20/40. An astigmatic keratotomy procedure was planned to treat the residual astigmatism in these eyes.
\RESULTS of AK?

(J-W) 325: J-W is a 49 year old male who underwent unilateral LASIK surgery on the right eye with the Nevyas Excimer Laser on 1/12/1998. The eye had a preoperative manifest refraction of –10.25 x-1.25 x 180, UCVA of 20/1000 and BSCVA of 20/20. The right eye was intentionally undercorrected with a target postoperative refraction of –1.00 MRSE, and was treated using the "old" centration technique. At 1month postoperatively, the patient complained of ghost images and a decentration was observed. The decentration was still noted to be present at 3 months post-LASIK. At 6 months postoperatively, patient was unhappy with his distance vision and glasses were prescribed. The manifest refraction was 0.25 x –0.75 x 95 with UCVA and BSCVA both measured to be 20/30. An AK procedure was performed at approximately 8 months post-LASIK to reduce the residual cylinder. At the last reported visit, 6 months after the AK procedure, the eye had a manifest refraction of –1.50 x –1.24 x 90 with a UCVA of 20/40 and BSCVA of 20/20 and the patient had no complaints.

(S-E) 347: S-E is a 36 year old female who underwent unilateral LASIK surgery on the right eye with the Nevyas Excimer Laser on 12/4/1997. Preoperative manifest refraction was-11.25 x-3.00 x 9 with a UCVAof 20/1000 and BSCVA of 20/30. The eye was intentionally undercorrected with a postoperative target refraction of –1.50 D MRSE; and, surgery was performed using the "old" centration technique. At 6 months postoperatively, the eye was slightly overcorrected with a manifest refraction of 1.25 x –1.00 x 10, UCVA of 20/40 and BSCVA of 20/30. The patient complained of decreased near and distance vision in dim light. At 18 months postoperatively, glasses were prescribed for night time driving. At approximately 36 months post-LASIK, a retreatment procedure was performed to improve the refractive outcome. Preoperative refraction at the time of retreatment was –2.50 x-3.50 x 135. At the last reported visit, 6 months after the retreatment, the eye had a manifest refraction of 2.25 x –1.25x 45 with an UCVA of 20/30 and a BSCVA of 20/25.

Check the +/- signs on these refractions.

Herb Nevyas

From: Stephen Barrett, M.D. [sbinfo@quackwatch.org]
Sent: Wednesday, July 30, 2003 8:07 AM
To: Herb Nevyas:
Subject: Links to lasiksucks4u site

You can find the links to lasiksucks4u.com by using this URL http://www.google.com/search?as_lq=www.lasiksucks4u.com&btnG=Search
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Stephen Barrett, M.D.
Board Chairman, Quackwatch, Inc.
NCAHF Vice President and Director of Internet Operations P.O. Box 1747, Allentown, PA 18105
Telephone: (610) 437-1795

http://www.quackwatch.org (health fraud and quackery) http://www.chirobase.org (guide to chiropractic) http://www.dentalwatch.org (guide to dental care) http://www.homeowatch.org (guide to homeopathy) http://www.ihealthpilot.org (under construction) http://www.mlmwatch.org (multi-level marketing) http://www.naturowatch.org (naturopathy) -- under construction http://www.nutriwatch.org (nutrition facts and fallacies) http://www.ncahf.org (National Council Against Health Fraud) http://www.chsourcebook.com (consumer health sourcebook)

Editor, Consumer Health Digest http://www.ncahf.org/digest/chd.html
Publisher, Chiropractic News Digest
http://www.quackwatch.org/00AboutQuackwatch/chd.html
Donations of $1 to $50 to help support Quackwatch can be made through
http://s1.amazon.com/exec/varzea/pay/T1X6GUTTCLU3T4

Herb Nevyas

From: Stephen Barrett, M.D. [sbinfo@quackwatch.org]
Sent: Wednesday, July 30, 2003 6:52 AM
To: Herb Nevyas;
Subject: Fwd: Re: lasik surgery

At 9:57 PM -0400 7/29/03, Stephen Barrett, M.D. wrote:
>I just looked at your site again and am curious about two things:
>
>1. When did you put the information on the site?
>2. I would be interested in receiving copies of additional information
>that people send you.
>
>Thanks for calling this to my attention.

======

Mr. Morgan replied:

>X-Original-To: sbinfo@enter.net
>Delivered-To: sbinfo@enter.net
>Date: Tue, 29 Jul 2003 19:55:45 -0700 (PDT)
>From: DOM MORGAN <djm0860@yahoo.com>
>Subject: Re: lasik surgery
>To: "Stephen Barrett, M.D." <sbinfo@quackwatch.org>
>
>dr barrett,
>
>after litigation i started updating my site with names, etc..
>everything has been there, just not posted, due to confidentialy during
>litigation. i did not intentionally want to post this information yet,
>i was waiting until i had 'everything' i wanted to post.
> i am far from done. there is quite a bit more to do.
>
>i beg to differ as far as their practices in that they should have
>never considered me in the first place.
>also their tactics they used, what they told me, and more importantly
>the other persons that were damaged.
>i'm not a vindictive person, but they ruined my life...
>
>what information are you requesting from me pertaining to others? i
>have been in contact with several of nevyas' other patients who were
>damaged, but they are in litigation now.
>
>a question for you...do you know these people personally? i've had
>over 2 years dealing with these people.
>
>dom

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- - - - - - - - - - - - - - - -
Stephen Barrett, M.D.
Board Chairman, Quackwatch, Inc.
NCAHF Vice President and Director of Internet Operations P.O. Box 1747, Allentown, PA 8105
Telephone: (610) 437-1795