

LAW OFFICES

*Stein & Silverman, P.C.*

230 SO. BROAD STREET  
PHILADELPHIA, PA. 19102

ELIAS H. STEIN  
LEON W. SILVERMAN  
ALLISON S. LAPAT  
ANDREW J LAPAT

(AREA CODE 215)  
985-0255  
TELECOPIER (215) 985-0342

January 18, 2005

Jeffrey Albert, Esquire  
McKissock & Hoffman, P.C.  
1818 Market Street, Suite 13<sup>th</sup> floor  
Philadelphia, PA 19103

Steven Friedman, Esq.  
850 West Chester Pike  
Havertown, PA 19083

Dominic Morgan,  
3360 Chichester Avenue, #M-11,  
Boothwyn, PA 19061

**RE: Nevyas v. Morgan**  
**Philadelphia County CCP, November Term 2003; No.: 946**

Dear Messrs. Albert, Friedman and Morgan:

Enclosed are copies of Plaintiffs' Opposition to Defendant Morgan's and Friedman's Preliminary Objections which were filed with the court today.

Very truly yours,

**STEIN & SILVERMAN, P.C.**

Andrew Lapat

AL/vpl  
Enclosures

PHILADELPHIA COURT OF COMMON PLEAS  
**PETITION/MOTION COVER SHEET**

CONTROL NUMBER:  
 121916  
 (RESPONDING PARTIES MUST INCLUDE THIS NUMBER ON ALL FILINGS)

FOR COURT USE ONLY	
ASSIGNED TO JUDGE:	ANSWER/RESPONSE DATE:
Do not send Judge courtesy copy of Petition/Motion/Answer/Response. Status may be obtained online at <a href="http://courts.phila.gov">http://courts.phila.gov</a>	

November \_\_\_\_\_ Term, 2003  
Month Year  
 No. 0946

Herbert Nevyas, MD, et al  
 \_\_\_\_\_  
 vs.  
 Dominic Morgan, et al  
 \_\_\_\_\_

Name of Filing Party:  
 Herbert Nevyas, MD, et al  
 \_\_\_\_\_  
 (Check one)  Plaintiff  Defendant  
 (Check one)  Movant  Respondent

INDICATE NATURE OF DOCUMENT FILED:  
 Petition (Attach Rule to Show Cause)  Motion  
 Answer to Petition  Response to Motion

Has another petition/motion been decided in this case?  Yes  No  
 Is another petition/motion pending?  Yes  No  
 If the answer to either question is yes, you must identify the judge(s):

TYPE OF PETITION/MOTION (see list on reverse side)  
 Opposition to Defendant Morgan's Preliminary Objs.  
 PETITION/MOTION CODE (see list on reverse side)

<p><b>I. CASE PROGRAM</b></p> <p>Is this case in the (answer all questions):</p> <p><b>A. COMMERCE PROGRAM</b>                  Name of Judicial Team Leader: _____                  Applicable Petition/Motion Deadline: _____                  Has deadline been previously extended by the Court?  <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><b>B. DAY FORWARD/MAJOR JURY PROGRAM</b> — Year _____                  Name of Judicial Team Leader: _____                  Applicable Petition/Motion Deadline: _____                  Has deadline been previously extended by the Court?  <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><b>C. NON JURY PROGRAM</b>                  Date Listed: _____</p> <p><b>D. ARBITRATION PROGRAM</b>                  Arbitration Date: _____</p> <p><b>E. ARBITRATION APPEAL PROGRAM</b>                  Date Listed: _____</p> <p><b>F. OTHER PROGRAM:</b> _____                  Date Listed: _____</p>	<p><b>II. PARTIES</b>                  (Name, address and telephone number of all counsel of record and unrepresented parties. Attach a stamped addressed envelope for each attorney of record and unrepresented party.)</p> <p>Jeffrey Albert, Esq.                  McKissock &amp; Hoffman, PC                  1818 Market St., 13th Flr.                  Phila., PA 19103                  215-246-2100</p> <p>Steven A. Friedman, Esq.                  850 West Chester Pike                  Havertown, PA 19083                  610-789-0568</p> <p>Dominic Morgan                  3350 Chichester Ave, M11                  Boothwyn, PA 19060                  610-859-8595</p> <p>Andrew Lapat, Esq.                  Stein &amp; Silverman, PC                  230 S. Broad St., 18th Flr.                  Phila., PA 19102                  215-985-0255</p>
<p><b>III. OTHER</b></p>	

By filing this document and signing below, the moving party certifies that this motion, petition, answer or response along with all documents filed, will be served upon all counsel and unrepresented parties as required by rules of Court (see PA. R.C.P. 206.6, Note to 208.2(a), and 440). Furthermore, moving party verifies that the answers made herein are true and correct and understands that sanctions may be imposed for inaccurate or incomplete answers.

\_\_\_\_\_  
 (Attorney Signature/Unrepresented Party)      Jan. 18, 2005      Andrew Lapat, Esq.      55673  
(Date) (Print Name) (Attorney I.D. No.)

The Petition, Motion and Answer or Response, if any, will be forwarded to the Court after the Answer/Response Date. No extension of the Answer/Response Date will be granted even if the parties so stipulate.



HERBERT J. NEVYAS, M.D.,  
ANITA NEVYAS-WALLACE, M.D.,  
and  
NEVYAS EYE ASSOCIATES, P.C.,  
Plaintiffs  
vs.  
DOMINIC MORGAN  
STEVEN FRIEDMAN  
Defendant.

---

: COURT OF COMMON PLEAS  
: Philadelphia County  
:  
: NOVEMBER TERM, 2003  
: NO.: 946  
:  
:  
:  
:  
:  
:

**ORDER**

AND NOW, this \_\_\_\_ day of \_\_\_\_\_, 2005, upon consideration of Plaintiffs' Opposition to Preliminary Objections and Memorandum In Support, it is hereby ORDERED and DECREED:

1. Defendant's preliminary objections are OVERRULED; and
2. Defendant Morgan is ordered to file an Answer to the Amended Complaint within twenty (20) days.

By the Court:

\_\_\_\_\_. J.

STEIN & SILVERMAN, P.C.  
BY: Andrew Lapat, Esquire  
Attorney Identification No. 55673  
230 South Broad Street, 18<sup>TH</sup> Floor  
Philadelphia, PA. 19102  
(215) 985-0255

Attorney for Plaintiffs Dr. Herbert Nevyas  
And Dr. Anita Nevyas-Wallace

HERBERT J. NEVYAS, M.D.,	:	COURT OF COMMON PLEAS
ANITA NEVYAS-WALLACE, M.D.,	:	Philadelphia County
and	:	
NEVYAS EYE ASSOCIATES, P.C.,	:	NOVEMBER TERM, 2003
Plaintiffs	:	NO.: 946
vs.	:	
DOMINIC MORGAN	:	
STEVEN FRIEDMAN	:	
Defendant.	:	

**ORDER**

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BY: Andrew Lapat, Esquire  
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Attorney for Plaintiffs Dr. Herbert Nevyas  
And Dr. Anita Nevyas-Wallace

HERBERT J. NEVYAS, M.D.,	:	COURT OF COMMON PLEAS
ANITA NEVYAS-WALLACE, M.D.,	:	Philadelphia County
and	:	
NEVYAS EYE ASSOCIATES, P.C.,	:	NOVEMBER TERM, 2003
Plaintiffs	:	NO.: 946
vs.	:	
DOMINIC MORGAN,	:	
STEVEN FRIEDMAN	:	
Defendants.	:	

**OPPOSITION TO DEFENDANT MORGAN'S PRELIMINARY OBJECTIONS**

Plaintiffs Herbert J. Nevyas, M.D., Anita Nevyas-Wallace, M.D., and Nevyas Eye Associates, P.C. respond to Defendant Friedman's preliminary objections as follows:

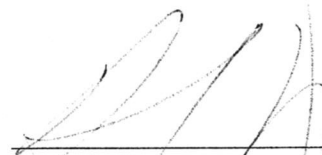
The entirety of Defendant Morgan's preliminary objections are barred by Pa. R.C.P. Rule 1026(a). Plaintiff's incorporate by reference the entirety of the Opposition to Preliminary Objections. By way of further response, none of the Preliminary Objections offered by Morgan are applicable to him. The Preliminary Objections only apply to Friedman.

WHEREFORE, Plaintiffs demand that Defendant Morgan's preliminary objections be overruled and that he is ordered to answer the complaint within twenty days.

Date: January 18, 2005

STEIN & SILVERMAN, P.C.

By:

  
\_\_\_\_\_  
Andrew Lapat  
Attorney for Plaintiffs

STEIN & SILVERMAN, P.C.  
BY: Andrew Lapat, Esquire  
Attorney Identification No. 55673  
230 South Broad Street, 18<sup>TH</sup> Floor  
Philadelphia, PA. 19102  
(215) 985-0255

Attorney for Plaintiffs Dr. Herbert Nevyas  
And Dr. Anita Nevyas-Wallace

HERBERT J. NEVYAS, M.D.,	:	COURT OF COMMON PLEAS
ANITA NEVYAS-WALLACE, M.D.,	:	Philadelphia County
and	:	
NEVYAS EYE ASSOCIATES, P.C.,	:	NOVEMBER TERM, 2003
Plaintiffs	:	NO.: 946
vs.	:	
DOMINIC MORGAN,	:	
STEVEN FRIEDMAN	:	
Defendants.	:	
	:	

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S OPPOSITION TO  
DEFENDANT MORGAN'S PRELIMINARY OBJECTIONS**

The entirety of Defendant Morgan's preliminary objections are barred by Pa. R.C.P. Rule 1026(a). The preliminary objections were not filed on a timely basis and therefore should be overruled. However, even if this Court is to examine the validity of the preliminary objections, as demonstrated herein, those preliminary objections are without merit and should be overruled.

Defendant Morgan simply incorporated by reference the Preliminary Objections offered by Friedman. However, none of these Preliminary Objections are applicable to Morgan. Friedman argues that personal service was not made on him. Morgan does not complain the personal service was not made on him and personal service on Friedman has no impact on the claims against Morgan. The remained of Friedman's Preliminary Objections are based on his being an attorney and that his activities were committed as part of his representation of Morgan

and are therefore immune. This defense is not applicable to Morgan and even if Friedman's defense were successful, it has no bearing on the claims against Morgan.

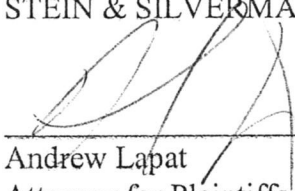
Plaintiffs further incorporate by reference the entirety of the Memorandum of Law filed in Opposition to Friedman's Preliminary Objections.

Dated: January 18, 2005

Respectfully submitted,

STEIN & SILVERMAN, P.C.

By:



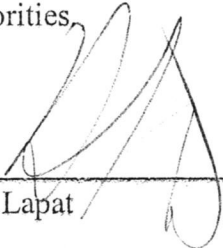
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Andrew Lapat  
Attorney for Plaintiffs

VERIFICATION

I, Andrew Lapat, Esquire hereby state that I am attorney for Plaintiffs in the within action.  
I verify that the statements made in the foregoing pleading are true and correct to the best of my knowledge, information and belief; I understand these statements made are subject to the penalties of 18 Pa.C.S. §4904 relating to unsworn falsification to authorities.

Dated: January 18, 2005

  
\_\_\_\_\_  
Andrew Lapat

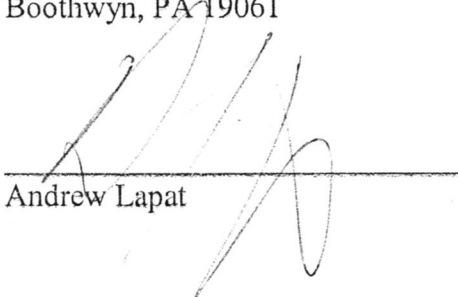
CERTIFICATION OF SERVICE

I, Andrew Lapat, hereby certify that I have caused a true and correct copy of the foregoing **Opposition to Defendant Morgan's Preliminary Objections** to be served via first class mail postage prepaid to counsel listed below on January 18, 2005:

Steven A. Friedman  
Law Office of Steven Friedman  
850 West Chester Pike  
Havertown, PA 19083

Jeffrey Albert, Esquire  
McKissock & Hoffman, P.C.  
1818 Market Street, Suite 13<sup>th</sup> floor  
Philadelphia, PA 19103

Dominic Morgan  
3360 Chichester Avenue, #M-11  
Boothwyn, PA 19061

  
\_\_\_\_\_  
Andrew Lapat

PHILADELPHIA COURT OF COMMON PLEAS  
**PETITION/MOTION COVER SHEET**

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November \_\_\_\_\_ Term, 2003  
Month Year  
 No. 0946

Herbert Nevyas, MD, et al  
 vs.  
 Dominic Morgan, et al

Name of Filing Party:  
 Herbert Nevyas, MD, et al  
 (Check one)  Plaintiff  Defendant  
 (Check one)  Movant  Respondent

**INDICATE NATURE OF DOCUMENT FILED:**

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<b>I. CASE PROGRAM</b> Is this case in the (answer all questions): <b>A. COMMERCE PROGRAM</b> Name of Judicial Team Leader: _____ Applicable Petition/Motion Deadline: _____ Has deadline been previously extended by the Court? <input type="checkbox"/> Yes <input type="checkbox"/> No <b>B. DAY FORWARD/MAJOR JURY PROGRAM</b> — Year _____ Name of Judicial Team Leader: _____ Applicable Petition/Motion Deadline: _____ Has deadline been previously extended by the Court? <input type="checkbox"/> Yes <input type="checkbox"/> No <b>C. NON JURY PROGRAM</b> Date Listed: _____ <b>D. ARBITRATION PROGRAM</b> Arbitration Date: _____ <b>E. ARBITRATION APPEAL PROGRAM</b> Date Listed: _____ <b>F. OTHER PROGRAM:</b> _____ Date Listed: _____	<b>II. PARTIES</b> (Name, address and telephone number of all counsel of record and unrepresented parties. Attach a stamped addressed envelope for each attorney of record and unrepresented party.) Jeffrey Albert, Esq. McKissock & Hoffman, PC 1818 Market St., 13th Flr. Phila., PA 19103 215-246-2100  Steven A. Friedman, Esq. 850 West Chester Pike Havertown, PA 19083 610-789-0568  Dominic Morgan 3350 Chichester Ave, M11 Boothwyn, PA 19060 610-859-8595  Andrew Lapat, Esq. Stein & Silverman, PC 230 S. Broad St., 18th Flr. Phila., PA 19102 215-985-0255
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 (Attorney Signature/Unrepresented Party)      Jan. 18, 2005      Andrew Lapat, Esq.      55673  
(Date) (Print Name) (Attorney I.D. No.)

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HERBERT J. NEVYAS, M.D.,  
ANITA NEVYAS-WALLACE, M.D.,  
and  
NEVYAS EYE ASSOCIATES, P.C.,  
Plaintiffs

vs.

DOMINIC MORGAN  
STEVEN FRIEDMAN  
Defendant.

COURT OF COMMON PLEAS  
Philadelphia County

NOVEMBER TERM, 2003  
NO.: 946

**ORDER**

AND NOW, this \_\_\_\_ day of \_\_\_\_\_, 2005, upon consideration of Plaintiffs' Opposition to Preliminary Objections and Memorandum In Support, it is hereby ORDERED and DECREED:

1. Defendant's preliminary objections are OVERRULED; and
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By the Court:

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STEIN & SILVERMAN, P.C.  
BY: Andrew Lapat, Esquire  
Attorney Identification No. 55673  
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(215) 985-0255

Attorney for Plaintiffs Dr. Herbert Nevyas  
And Dr. Anita Nevyas-Wallace

HERBERT J. NEVYAS, M.D.,	:	COURT OF COMMON PLEAS
ANITA NEVYAS-WALLACE, M.D.,	:	Philadelphia County
and	:	
NEVYAS EYE ASSOCIATES, P.C.,	:	NOVEMBER TERM, 2003
Plaintiffs	:	NO.: 946
vs.	:	
DOMINIC MORGAN	:	
STEVEN FRIEDMAN	:	
Defendant.	:	
	:	

**ORDER**

AND NOW, this \_\_\_\_ day of \_\_\_\_\_, 2005, upon consideration of Plaintiffs'

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By the Court:

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Attorney for Plaintiffs Dr. Herbert Nevyas  
And Dr. Anita Nevyas-Wallace

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ANITA NEVYAS-WALLACE, M.D.,	:	Philadelphia County
and	:	
NEVYAS EYE ASSOCIATES, P.C.,	:	NOVEMBER TERM, 2003
Plaintiffs	:	NO.: 946
vs.	:	
DOMINIC MORGAN,	:	
STEVEN FRIEDMAN	:	
Defendants.	:	
	:	

**OPPOSITION TO DEFENDANT FRIEDMAN'S PRELIMINARY OBJECTIONS**

Plaintiffs Herbert J. Nevyas, M.D., Anita Nevyas-Wallace, M.D., and Nevyas Eye Associates, P.C. respond to Defendant Friedman's preliminary objections as follows:

The entirety of Defendant Friedman's preliminary objections are barred by Pa. R.C.P. Rule 1026(a).

1. Admitted.
2. Admitted.
3. Denied. Plaintiffs made service on Defendant Friedman via certified mail. Such service was accepted by Defendant Friedman on or about July 16, 2004.
4. Denied. The Delaware County Sheriff's office made personal service of the reissued Amended Complaint on Steven Friedman January 13, 2005.
5. Denied. The Amended Complaint did not require reinstatement.

6. Admitted. Defendant Friedman had not responded to the Amended Complaint for which he accepted on July 16, 2004. Further, no counsel entered an appearance for Friedman and as of November 30, Friedman denied knowledge receiving the Ten Day letter. Friedman admitted that he had received a certified letter but had refused to accept it.

WHEREFORE, Plaintiffs demand that Defendant Friedman's preliminary objections be overruled and that he is ordered to answer the complaint within twenty days.

7. Denied. Plaintiffs state a defamation claim against Defendant Friedman. By way of further answer, the Amended Complaint is a document which speaks for itself.

8. Denied. To the contrary, Friedman's actions were not performed in his capacity as Morgan's attorney. Friedman's letters of December 4, 2003 was not provided in the course of his representation of Morgan. A true and correct copy of the December 4, 2003 letter is attached hereto as Exhibit 1. Instead, those acts were performed as an individual after the case in which he had represented Morgan had concluded. As Friedman admits in his letter of August 4, 2003, his representation of Morgan was highly limited. The letter states that his representation of Morgan was for the purpose of that letter only. A true and correct copy of the August 4, 2003 letter is attached hereto as Exhibit 2. Friedman is not entitled to any immunity for his illegal actions. Friedman's illegal acts were not performed in the regular course of judicial proceedings and which were pertinent and material to the redress or relief sought. Bochetto v. Gibson, 2004 WL 2358289 p. 3, (Pa. 2004).

9. Denied. Friedman is not entitled to any immunity for his illegal actions. Friedman's illegal acts were not performed in the regular course of judicial proceedings and which were pertinent and material to the redress or relief sought. Bochetto v. Gibson, 2004 WL

2358289 p. 3, (Pa. 2004). A true and correct copy of Friedman's other letters to the FDA are attached hereto as Exhibit 3.

10. Denied. To the contrary, Friedman intended Morgan to publish his letter on the internet. Friedman is not entitled to any immunity for his illegal actions. Friedman's illegal acts were not performed in the regular course of judicial proceedings and which were pertinent and material to the redress or relief sought. Bochetto v. Gibson, 2004 WL 2358289 p. 3, (Pa. 2004).

11. Denied. Defendant Friedman's conduct is not privileged and is defamation per se. Therefore, he is liable for his illegal acts.

WHEREFORE, Plaintiffs demand that Defendant Friedman's preliminary objections be overruled and that he is ordered to answer the complaint within twenty days.

12. Denied. The Plaintiffs' claim does not fail for lack of specificity.

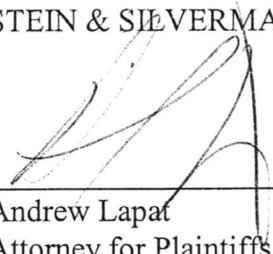
13. Denied. The Plaintiffs' claim does not fail for lack of specificity.

WHEREFORE, Plaintiffs demand that Defendant Friedman's preliminary objections be overruled and that he is ordered to answer the complaint within twenty days.

Date: January 18, 2005

STEIN & SILVERMAN, P.C.

By:

  
\_\_\_\_\_  
Andrew Lapat  
Attorney for Plaintiffs



[Experiences](#)   [FDA & Doctors Reports](#)   [Images](#)   [Links](#)   [Home](#)   [Lasik related news articles](#)

The following is a copy of the letter sent to the FDA from Steven A. Friedman, my attorney, dated 12/04/2003. It has been scanned and converted to rich text format so that you may be able to read with ease. The scanned original can be seen [here](#).

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850 WEST CHESTER PIKE, 1<sup>st</sup> FLOOR

TEL:610.789.0568

HAVERTOWN, PA 19083

E-MAIL: [md-](mailto:md-<u>jd@mindspring.com</u>)

[jd@mindspring.com](mailto:jd@mindspring.com)

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

*Physician and Attorney at Law*

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INTERNAL MEDICINE AND CHEST DISEASE \* HEALTH AND CORPORATE  
MEDICAL LAW

December 4, 2003

Mr. Terry Vermillion

Director, Office of Criminal Investigation

Food and Drug Administration

7500 Standish Place - Room 250 N  
Excimer Laser

Re: Nevyas

Rockville, Md 20855

IDE: G970088

97-001, -002, et seq.

Protocol NEV-

Dear Mr Vermillion,

I represent Mr. Dominic Morgan, and I request an investigation by the FDA Office of Criminal Investigation, and that this letter be made part of the permanent file re the above.

I have written before, to other branches or sections of FDA, regarding Dr. Anita Nevyas-Wallace and Dr. Herbert Nevyas. I regard action as urgent, because I believe federal regulation has been flaunted and patients seriously injured. I have talked on multiple occasions with multiple FDA officials, and was told words to the effect, "The FDA staff has no intention of ever presenting Nevyas' application for FDA approval of their LASIK to the FDA Ophthalmic Devices Panel (the panel that has to decide on the Nevyas' application for FDA approval)." I believe, however, that emphasis need be placed upon investigation of possible outright *criminal* activity.

I ask the FDA to exercise its regulatory authority. Since the problem was never presented to the FDA Ophthalmic Devices Panel, my client, Mr. Dominic Morgan, did not get an opportunity to address the panel. Of much more concern to Mr. Morgan, however, the Nevyases continue performing LASIK.

I now call for an investigation by the Office of Criminal Investigation, for action which would:

1. Terminate all IDEs and stop Nevyas from performing LASIK.
2. Fine and otherwise sanction Nevyas for past improprieties.

It is my sincere belief that only the FDA, or an equivalent governmental agency with power to investigate criminal behavior can properly evaluate and understand what these improprieties are. The civil justice system is not adequate to the task.

Let me explain why the civil justice system is not adequate by using the lawsuit Mr. Morgan brought, for which I was his attorney, *Morgan v.*



*Nevyas et al*, Philadelphia County Court of

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Common Pleas, April 2000 term, number 2621.

Mr. Morgan complained of three improprieties by Nevyas

1. Deceptive trade practices.
2. Failure to obtain informed consent.
3. Medical malpractice.

I will discuss these three, and then two other reasons why the civil justice system failed.

1. DECEPTIVE TRADE PRACTICES.

In 1998 plaintiff Mr. Morgan heard advertisements broadcast on radio station KYW promoting laser eye surgery (and without saying that it was investigational). Responding to those promotions, Mr. Morgan, then age 37, went to Nevyas and paid \$5000.00 to undergo LASIK in both eyes. Dr. Nevyas-Wallace told Mr. Morgan, and twice wrote in his medical record, that he was a "good candidate" for LASIK. After LASIK plaintiff Mr. Morgan's vision worsened and he became legally blind.

The Nevyas Excimer Laser is a research instrument. As such, it was operated by Nevyas under an Investigation Device Exemption (IDE) from the Food and Drug Administration (FDA). It was not approved by the FDA. The Nevyases signed agreements to comply with the Code of Federal Regulations (C.F.R.). Section 812.7 of chapter 21 of the C.F.R. (21 C.F.R. §812.7) strictly forbids any advertising of any device operated under an IDE from the FDA.

The advertisements broadcast by the Nevyases on KYW implied FDA approval since only FDA-approved devices are allowed to advertise. That certainly seemed to be both an unfair method of competition and an unfair or deceptive act or practice, as defined by the Pennsylvania Unfair Trade and Consumer Protection Law (73 P.S. § 201).

Before trial took place, the Nevyases filed a motion for summary judgment, claiming that no jury should ever hear that the Nevyas LASIK was experimental or operated under an IDE, because a jury would be confused by the terms "experimental" or "investigational," and might hold it against the Nevyases. The motion was assigned to Judge Papalini, who agreed with the Nevyases, so I was not allowed to say that the Nevyas LASIK was experimental or operated under an

IDE. Since I could not say that the Nevyas LASIK was experimental or operated under an IDE, I had no way of proving that the KYW advertising was illegal. As I will explain below, the claim of deceptive trade practices never was acted upon by either trial or arbitration.

I disagree with Judge Papalini's ruling, because I believe juries are smarter than that, and don't confuse so easily. *However, Judge Papalini's ruling was acknowledgment of the shortcomings of trial by jury (civil justice system), and the reason we must depend upon governmental agencies like the FDA to protect the public.*

## 2. FAILURE TO OBTAIN INFORMED CONSENT.

The Nevyas Excimer Laser was operated by Nevyas under an Investigation Device Exemption (IDE) from the Food and Drug Administration (FDA). The FDA required the

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Nevyases follow certain protocol in order to operate their LASIK. Those protocol listed, in writing, specific required **Inclusion Criteria** and **Exclusion Criteria**. The purpose of the Inclusion and Exclusion Criteria was to state what type patient was safe or appropriate, and what type patient was not safe or appropriate, to have LASIK. Mr. Morgan was not a safe or appropriate subject for LASIK because he did not meet the **Inclusion Criteria** and he **did** meet the **Exclusion Criteria**.

To evaluate Mr. Morgan and the Inclusion and Exclusion Criteria, I contacted James J. Salz, M.D. of Cedars-Sinai Medical Center in Los Angeles and Terrence O'Brien, M.D. of Johns Hopkins Medical Center in Baltimore. Both are nationally and internationally known experts about LASIK. Dr. Salz is Chair and Dr. O'Brien is Secretary of the International Society of Refractive Surgery/American Academy of Ophthalmology Executive Committee for 2003. Both agreed that, either with or without the written Inclusion and Exclusion Criteria, Mr. Morgan was not a safe or appropriate subject for LASIK. *Please read their reports, copies of which I attach.* Instead of telling Mr. Morgan that he was not a safe or appropriate subject for LASIK, Dr. Nevyas-Wallace told Mr. Morgan, and twice wrote in the medical record, that he was a "good candidate" for LASIK. The Nevyases then gave Mr. Morgan a "consent form" to sign. Nowhere in that "consent form" did it mention anything about Inclusion and Exclusion Criteria, and nowhere did give any information by which Mr. Morgan could have determined that he was not a "good candidate," or that PDA-approved Inclusion and Exclusion Criteria were violated. He trusted Dr. Nevyas-Wallace. He had LASIK in both eyes and, since this was neither safe nor appropriate, he became legally blind.

Before trial took place, the Nevyases filed another motion for summary judgment, claiming that no jury should ever hear Mr. Morgan's claim that he was denied informed consent, because he had signed the "consent form" and it would confuse the jury. The motion was assigned to Judge Papalini, who agreed with the

Nevyases, so I was not allowed to say that Mr. Morgan was operated upon without informed consent. As I will explain below, the claim of lack of informed consent never was acted upon by either trial or arbitration.

I disagree with Judge Papalini's ruling, because I believe juries are smarter than that, and that Mr. Morgan was not given information necessary to make an informed decision. *However, Judge Papalini's ruling was acknowledgment of the shortcomings of trial by jury (civil justice system), and the reason we must depend upon governmental agencies like the PDA to protect the public.*

### 3. MEDICAL MALPRACTICE.

Dr. Salz and Dr. O'Brien both agreed that the Nevyases committed medical malpractice when they did LASIK on Mr. Morgan. Both Dr. Salz and Dr. O'Brien explained that the medical malpractice was violating the **standard of care** for performing LASIK, and that **part of the standard of care consisted of the written Inclusion and Exclusion Criteria** (i.e. the IDE protocol required by the FDA). *Please read their reports, copies of which I attach.*

Before trial took place, the Nevyases filed yet another motion for summary judgment, claiming that no jury should ever hear any reference to LASIK being operated by the Nevyases under an IDE from the FDA, because a jury would be confused by terms of the IDE and hold it against the Nevyases. The motion was assigned to Judge Papalini, who agreed with the Nevyases,

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so I was not allowed to say that the written Inclusion and Exclusion Criteria represented part of the standard of care breached by the Nevyases, and responsible for Mr. Morgan becoming legally blind.

I disagree with Judge Papalini's ruling, because I believe juries are smarter than that, and don't confuse so easily. *However, Judge Papalini's ruling was acknowledgment of the shortcomings of trial by jury (civil justice system), and the reason we must depend upon governmental agencies like the FDA to protect the public.*

Of course, I asked Judge Papalini to reconsider his decisions, but he refused and said his decisions were made "with prejudice," which meant that I could not raise them again until after trial, because his decisions were "prejudged" as lasting until after trial was finished.

So, feeling that I was fighting with my legs legally amputated, I agreed to binding arbitration with a high-low and no confidentiality, limited to Dr. Nevyas-Wallace and the Medical Malpractice case, emasculated as it was. The deceptive trade practices and failure to obtain informed consent cases were never arbitrated, and no decision was ever made on them because I was not allowed to speak of them. The high-low meant that if we lost we still got \$100,000 and, if we



won, it could not be for more than \$1,200,000. The no confidentiality meant that nothing was confidential. The arbitrator was not allowed to go over any of the material that Judge Papalini ruled a jury should not hear, but at least there were no more judicial rulings about what a jury should not be allowed to hear. The arbitrator was only allowed to hear a very limited part of our case, as explained above. We lost but did get \$100,000.

#### 4. NOT REPORTING DATA TO THE FDA.

In my previous letters to the FDA, I detailed how Nevyas had not reported Mr. Morgan as either a complication or adverse event to the FDA, as required by law, and stated that I was concerned that other Nevyas patients also were not reported to the FDA as either a complication or adverse event. I now know the names of two other Nevyas patients not reported to the FDA as either a complication or adverse event. Both patients sued when their vision was ruined, and I have talked with their attorneys. Even though sued, the Nevyases still did not report Mr. Morgan or the other two patients to the FDA as either a complication or adverse event. The FDA should be interested in this - the Nevyases claim that these patients merely had "post-operative symptoms," and that when Nevyas examined the patients, Nevyas was able to determine that the "post-operative symptoms were neither complications nor adverse events. (This certainly seems to violate the FDA requirement that, whether or not a complication or adverse event seems or does not seem to be caused by LASIK, it must be reported.)

As the FDA is aware, the only people submitting data to the FDA about the Nevyas doing LASIK are the Nevyases themselves. If they are submitting their data after "editing" it of unfavorable results, which appears to be the case, then the FDA has been misled for years about what the Nevyases are doing to the public. I believe that *any investigation so far done by the FDA has been handicapped by lack of truthful data.*

As I'm sure the FDA knows, each lawsuit against the Nevyases must stand on its own - each lawsuit is limited to discussing only the particular patient involved. Thus, it is forbidden for any

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patient to present an overall picture (i.e. discuss Nevyas' other lawsuits) to a jury. *This is another shortcoming of trial by jury (civil justice system), and another reason we must depend upon governmental agencies like the FDA to get the overall picture and protect the public.*

## 5. THE FDA HAS MEDICAL SCIENTIFIC EXPERTISE THAT JUDGES AND ARBITRATORS DO NOT.

Lawsuits against doctors involve both sides getting medical experts to evaluate the case, both for the plaintiff and for the defendant. In Mr. Morgan's case, reports of medical experts for both sides were presented to the arbitrator. In my discussion with the arbitrator after he made his decision, I learned that he felt the experts effectively cancelled out each other. Frankly, the arbitrator did not have the medical and scientific expertise that the FDA has, and which was needed for Mr. Morgan's case.

For example, the Nevyas' defense expert publishes a brochure which he hands out to patients considering LASIK. In his brochure there are a series of question and answers. For the question, "How do I know if I am a good candidate for Laser Vision Correction?" his answer is, "Patients who are 21 years of age or older, and have **healthy eyes which are free of retinal problems**, corneal scars, and any eye disease are suitable." In his report, the Nevyas' expert admitted that Mr. Morgan's, "past ophthalmic history was **complicated and significant** for retinopathy of prematurity." Retinopathy of prematurity is a retinal problem associated with premature birth (Mr. Morgan was born about three months early). When the above was pointed out, the Nevyas' expert stated in a sworn affidavit, "The statement made in that brochure does not apply to stable retinas, such as the retina of the plaintiff at the time that he underwent LASIK surgery by Dr. Anita Nevyas-Wallace." Dr. Salz and Dr. O'Brien disagreed with this double-talk (please read their reports, copies of which I attach), but Nevyas' expert, at least in the arbitrator's mind, effectively cancelled out Dr. Salz and Dr. O'Brien. *This is another shortcoming of the trial system (civil justice system) - the lack of scientific medical expertise by arbitrators and judges - and another reason we must depend upon governmental agencies like the FDA to use their scientific medical expertise and protect the public.*

Did the Nevyases pay their expert? Yes. Did I pay Mr. Morgan's experts? Yes, but Dr. Salz and Dr. O'Brien were so outraged by the unfairness of what occurred that Dr. Salz did not charge for the last half of his service, and Dr. O'Brien did not charge anything.

Mr. Morgan created a website, Lasiksucks4u.com, to talk about his personal experiences as a LASIK victim. The Nevyases, who advertise their services in the mass media (including their own website), sued him for libel, defamation, and slander, and have threatened to sue his website carriers. The Nevyas' attorney told me they intend to confiscate the social security disability checks Mr. Morgan gets for his legal blindness.

The public needs protection. The FDA can give that protection, through criminal investigation and regulation. Please contact me if you need information or have questions.

Sincerely yours,



Friedman

Steven A.



850 WEST CHESTER PIKE, 1<sup>ST</sup> FLOOR  
HAVERTOWN, PA 19083

TEL: 610.789.0568  
E-MAIL: md-jd@mindspring.com

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

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INTERNAL MEDICINE AND CHEST DISEASE ☼ HEALTH AND CORPORATE MEDICAL LAW

August 4, 2003

Leon Silverman, Esquire  
Andrew Lapat, Esquire  
Stein & Silverman  
230 South Broad Street  
Philadelphia, Pa. 19102  
Fax 215/ 985-0342

Re: Your letter to Mr. Morgan July 30, 2003

Dear Counsel:

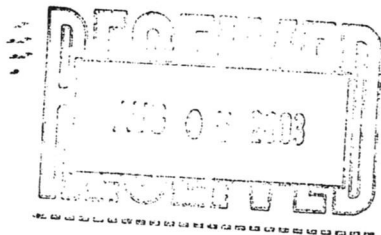
In Mr. Lapat's telephone call to me July 31, 2003, you assumed I represent Mr. Morgan. I represent him for this letter.

In Mr. Silverman's last telephone call to me August 1, 2003, he stated that the contents of Mr. Morgan's web site as of that time were legally satisfactory to him. I then asked Mr. Morgan to print out his web site and mail it to me; and he did so except for pictures; and I now mail you a copy of this. In order that there be no mistake I ask that you confirm that all this material is legally satisfactory to you. (I have not read either the material he sent me nor the web site.)

Sincerely yours,



Steven A. Friedman







December 28 , 2001

Office of Device Evaluation  
Division of Ophthalmic Devices  
Food and Drug Administration HFZ-460  
9200 Corporate Boulevard  
Rockville Md. 20850

Re: Nevyas Excimer Laser ("Investigational Device")  
Investigational Device Exemption (IDE): G970088  
Protocol: NEV-97-001 and subsequent (e.g. NEV-97-002)

I write to add specifics to my letter of December 20, 2001, and to enclose a video copy of a TV promotional.

I accuse Anita Nevyas-Wallace, Herbert Nevyas, and their professional corporations of violating 18 U.S.C. §1001 (False Statements to government), 21 C.F.R. §812 (including §812.7 Promotion of an investigational device), and 21 C.F.R. §54 (Disclosure of Financial Interest of Clinical Investigators). I also accuse them of violating 73 P.S. §297 (Pennsylvania Unfair Trade and Consumer Protection Law).



I have learned of these improprieties through my representation of Mr. Dominic Morgan, who had bilateral LASIK performed by Dr. Anita Nevyas-Wallace of Nevyas Eye Associates ("Nevyas") April 23, and 30, 1998, and is now on Social Security Disability due to legal blindness:

1. Mr. Morgan responded to a misleading radio advertisement of Nevyas for LASIK, and came to Nevyas on March 10, 1998. He was age 37, had marked retinopathy of prematurity, prior strabismus surgery, and reported that, to his knowledge, he had never seen better than 20/50 in either eye.

The radio advertisement was misleading in that it: (a) sought to promote the Nevyas Excimer Laser in violation of FDA regulations, (b) did not mention that an experimental device and an experimental protocol were involved (c) implied that only standard therapy was involved, (d) did not state that visual acuity could not be achieved beyond what spectacles or contacts could provide, (e) implied that Nevyas was part of a regional Laser Surgery Institute specializing in laser surgery, and thus more authoritative and experienced, when the Institute was a fictitious name for Nevyas, and (f) implied that Nevyas was part of a regional Refractive Surgery Partnership devoted to refractive eye surgery, when such partnership was largely fictitious. Although there apparently is no copy of the exact words used for the radio advertisements, the TV promotional is identical in virtually all significant aspects.

2. When Mr. Morgan came to Nevyas, Nevyas did not correct misrepresentations made in the radio advertisement. Neither did Nevyas make any attempt to verify stable manifest visual acuity during the prior year, as was required by FDA.

protocol (Nevyas' "study" on performing LASIK bilaterally the same day). Any chance of determining if it had been a mistake to operate on the left eye that should not be repeated on the right eye was taken from Mr. Morgan. Four days after right eye LASIK both eyes measured 20/60- and both eyes had haziness of vision and ghost images.. His vision thereafter worsened to 20/200 in both eyes and he has bilateral haziness and ghost images.

6. Mr. Morgan was assured by Nevyas that his eyes could be "fine tuned" by repeat LASIK, as promoted by Nevyas in a half-hour TV promotional during that time, but that he would have to wait. Nevyas did not correct misrepresentation made in the TV promotional, and Mr. Morgan awaited the "fine tuning".
  7. Mr. Morgan remained under the care of Nevyas through March 27, 2000, almost 2 years post-LASIK. During that time he felt that he was being encouraged to not return. He did visit other ophthalmologists seeking second opinions (Albany Lions Eye Institute, Wills Eye Hospital, John Hopkins-Wilmer, and others) and reported their findings to Nevyas.
1. Despite 21 C.F.R. § 812.7 which prohibits promoting an investigational device until after the FDA has approved the device for commercial distribution, Nevyas promoted the Nevyas Excimer Laser by frequently repeated radio advertisements, by a frequently repeated half-hour TV promotional, extensive internet web site promotionals, and elsewhere. These promotionals were misleading. They misrepresented the capabilities and results of Nevyas. The radio and TV promotionals did not state that the Nevyas Excimer Laser was and is investigational. The mere existence of promotional advertisements in violation of

- (Other states, such as California, are even stricter). The protocol limitation to 20/40 or better thus provided a "safety net" for LASIK patients unfortunate enough to lose up to two lines of vision, and Nevyas took away that "safety net."
3. Protocol NEV-97-001 inclusion criteria required one year of stable manifest refraction, and this was not verified.
  4. Protocol NEV-97-001 exclusion criteria for clinically significant abnormality on ophthalmic examination should have excluded Mr. Morgan because of his marked retinopathy of prematurity.
  5. Nevyas did not report Mr. Morgan's outcome to the FDA as either a complication or adverse event, despite this being observed by the doctors, reported by the subject, and required by the FDA protocol. This was a blatant attempt to skew statistics being reported to the FDA. It was also a violation of 18 U.S.C. §1001 (False Statements to Government).
  6. Nevyas has claimed that, even though not reporting Mr. Morgan as a complication or adverse event, he is included in the statistical compilation of outcome data. This is another false misrepresentation.
  7. In violation of 21 C.F.R. §54 Nevyas did not disclose that Nevyas would be enriched by prolonging the "study" and/or licensing the device, and would be financially affected by the study results.

Examination of IDE Supplement No. 18, The Annual Report for IDE G970088 dated March 14, 2001 (which incorporated the October 1999 report) reveals that Mr. Morgan was deliberately omitted from Nevyas' statistical compilation of outcome results:

4. Table 4-1 (Adverse Event Summary) shows no subjects reported with decrease of BSCVA greater than ( $>$ ) 10 letters not due to irregular astigmatism.
5. Table 4-1 also shows no subjects reported with ghost images.
6. Similar non-reporting is seen in the October 1999 report which was incorporated into the March 14, 2001 report, including:
  - a. Table 1.1.E.1-1 (Key Safety and Efficacy for all eyes) shows no subjects reported with BSCVA worse than 20/40 after 1 month. It also shows no subjects reported with loss of more than 2 lines BSVCA at any time.
  - b. Table 1.1.G-1 (Complications) shows no subjects with ghost images despite Mr. Morgan's complaint.
  - c. Table 1.1.G-2 (Adverse events) shows no subjects with decrease in BSCVA  $>$ 10 letters not due to irregular astigmatism.
7. Reminiscent of the "big lie" technique, Nevyas' web site advertisement (as of January 13, 2001) claims 100% of myopic patients with 4 to 6 diopter deficits saw 20/40 or better (Mr. Morgan had 6 diopter deficit). (See web site advertisements.)

Lastly, I want to emphasize Nevyas' history of not reporting to the FDA:

1. Nevyas began using the Nevyas Excimer Laser for LASIK in January 1996.
2. By February 27, 1997 Nevyas had done 147 LASIK myopia procedures in 70 patients (i.e. had "fine tuning" in 7 patients).

6. Thereafter Nevyas has continued to do LASIK, supposedly under Protocol NEV-97-001. Nevyas has managed to prolong its "investigation" under "protocol" for about 4 years, at \$2,500 per eye. Nevyas has widely advertised and promoted its investigational device in defiance of 21 C.F.R. § 812.7, which specifically forbids such promotion until after the FDA approves devices for commercial distribution. Nevyas has also purchased a FDA-approved Summit laser, and may be using it to manipulate results.

Vision is precious to all of us. If the Nevyas Excimer Laser gains market approval from the FDA on the basis of improper data submission from its sole investigator, Nevyas, the results could be catastrophic. LASIK is an extremely popular operation, and some estimate over one-quarter of the North American population are potential patients. Submitting false data to the FDA in order to improperly prolong a clinical study is bad enough, but if a rogue device were to gain entry to the billion dollar LASIK market, where improper data could lead to it being used instead of properly approved LASIK devices, the damage could be unimaginable.

In the end analysis, Nevyas stands to gain (and the public lose) if the Nevyas Excimer Laser is licensed to for commercial distribution. The only source of data regarding the safety and efficacy of the Nevyas Excimer Laser is Nevyas. Nevyas is submitting improper data and violating FDA protocol and regulations.

Please contact me for any questions.

Sincerely yours,



January 4, 2002

Office of Device Evaluation  
Division of Ophthalmic Devices  
Food and Drug Administration HFZ-460  
9200 Corporate Boulevard  
Rockville, MD 20850

Re: Nevyas Excimer Laser ("Investigational Device")  
Investigational Device Exemption (IDE): G970088  
Protocol: NEV-97-001 and subsequent (e.g. NEV-97-002)

Addition to letters of December 20 and 28, 2001

Dear Sirs:

4. **Dr. H. Nevyas wrote to the FDA on July 3, 1997: "Having a BCVA of 20/40 or better in both eyes is consistent with the screening criteria we currently use for evaluating LASIK candidates. Of course, as the FDA is already aware, the FDA has required 20/40 or better BCVA in both eyes.**
5. **M vision, like Mr. Morgan's, greatly deteriorated after LASIK.**
6. **M appears like Mr. Dominic Morgan, to have been unreported to the FDA either as a complication, or adverse event, or in statistical compilations.**

**In addition, I believe Nevyas may have been violating the federal Anti-kickback and False Claims Acts: in deposition Dr. A. Nevyas-Wallace was asked, "When you perform a lasik procedure and it's on a patient that is referred to you by an optometrist, does the optometrist receive any portion of the fee charged to the patient for the lasik procedure?" Dr. A. Nevyas replied "Sometimes."**

**I request an investigation. I am unable to determine if federal or state funds were involved, and the further circumstances, as Nevyas' attorneys will not permit such inquiry.**

Sincerely yours,

  
Steven A. Friedman

August 10, 2002

Ronald Swann  
Branch Chief  
Dental, ENT & Ophthalmic Service Branch - HEZ331  
Division of Enforcement II  
FDA  
2094 Gaither Road  
Rockville, Md. 20850

Re: Nevyas Excimer Laser  
IDE: G970088  
Protocol NEV-97-001, etc

Dear Mr. Swann:

I write to report violations of FDA regulations and protocol regarding the Nevyas Excimer Laser, a "black box" device operated under an IDE. I request an investigation. I request that this letter and its attachments be made part of the administrative record of any and all applications for pre-marketing approval. I request that this letter and its attachments be made part of the administrative record regarding any and all applications for renewal of IDE status.

Six to eight months ago I discussed some of my concerns with FDA personnel, including Dr. Jean Toth-Allen, Dr. Everette Beers, and Ms. Louise Silver, and sent them some information. I enclose a copy of my letter

or improper conduct by the Nevyases in their promotion and/or use of the investigational device.

I also enclose a copy of the TV promotion that Nevyas used for the investigational device (I did not have to use the TV promotion in the two motions that I enclose). Starting in 1998 the TV promotions have been broadcast in the greater Philadelphia area, and copies are also shown to prospective LASIK patients in Nevyas' offices..

Perhaps because of my client's suit against Nevyas, Nevyas has changed tactics. Nevyas has purchased a commercially approved LASIK unit and advertise it (copy of ad in Philadelphia magazine enclosed). However, there now appears to be a "bait and switch" tactic, with people responding to the ad being steered to the investigational device.

In the information that I sent earlier, I detailed how Nevyas had not reported my client, Mr. Morgan, as either a complication or adverse event to the FDA. I have good reason to believe that other Nevyas patients also were not reported as either complications or adverse events to the FDA..

Although I am concerned about my client's welfare, I am equally concerned (as is my client) about the possibility that the Nevyases pull a fast one on the FDA and get approval for commercial distribution. The only people submitting data to the FDA about the Nevyas Excimer Laser are the Nevyases, and they are submitting their data after "editing" it of unfavorable results. LASIK is very popular, and if a rogue device were to gain approval for commercial distribution, there would be potential for great harm.

I would like to address the FDA Ophthalmic Devices Panel whenever it

The last 2 pages have been edited to exclude patient's name only.

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## FDA news bulletin:

This was released 11/05/03:



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## FDA News

FOR IMMEDIATE RELEASE  
P03-92  
November 5, 2003

Media Inquiries: 301-827-6242  
Consumer Inquiries: 888-INFO-FDA

### **Louisiana Ophthalmologist Fined \$1.1 Million by FDA For Clinical Study Violations**

A Lafayette, La., ophthalmologist and eye care center he owns have agreed to pay the federal government a total of \$1.1 million in civil money

**STEIN & SILVERMAN, P.C.**  
**BY: Andrew Lapat, Esquire**  
**Attorney Identification No. 55673**  
**230 South Broad Street, 18<sup>TH</sup> Floor**  
**Philadelphia, PA. 19102**  
**(215) 985-0255**

**Attorney for Plaintiffs Dr. Herbert Nevyas**  
**And Dr. Anita Nevyas-Wallace**

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<b>HERBERT J. NEVYAS, M.D.,</b>	:	<b>COURT OF COMMON PLEAS</b>
<b>ANITA NEVYAS-WALLACE, M.D.,</b>	:	<b>Philadelphia County</b>
<b>and</b>	:	
<b>NEVYAS EYE ASSOCIATES, P.C.,</b>	:	<b>NOVEMBER TERM, 2003</b>
<b>Plaintiffs</b>	:	<b>NO.: 946</b>
<b>vs.</b>	:	
<b>DOMINIC MORGAN,</b>	:	
<b>STEVEN FRIEDMAN</b>	:	
<b>Defendants.</b>	:	

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**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S OPPOSITION TO  
DEFENDANT FRIEDMAN'S PRELIMINARY OBJECTIONS**

The entirety of Defendant Friedman's preliminary objections are barred by Pa. R.C.P. Rule 1026(a). The preliminary objections were not filed on a timely basis and therefore should be overruled. However, even if this Court is to examine the validity of the preliminary objections, as demonstrated herein, those preliminary objections are without merit and should be overruled.

Defendant Friedman is attempting to escape liability from his own tortious conduct by seeking to hide behind some kind of immunity. First, Friedman claims the he cannot be held liable for publishing false and defamatory statements on the internet because he is an "interactive computer service." This claim is absurd. AOL, Yahoo, for example, these are interactive computer services. Friedman is an individual who published false and defamatory statements on a website. He is not immune. He is liable for the damage he caused. Friedman next attempts to

hide behind the attorney-client relationship. The Supreme Court of Pennsylvania has, however, made clear that an attorney has not such immunity for statements which are not made to a court or in an effort to secure a judicial ruling. Not every statement by an attorney is privileged. Friedman has no immunity and cannot escape liability. He is an individual who is seeking to injure and defame two highly respected ophthalmologists and their medical practice out of spite and disgust that he brought a medical malpractice action and lost. Friedman's preliminary objections should be overruled.

### **FACTS**

Defendant Dominic Morgan brought a medical malpractice lawsuit against the Plaintiffs. The parties agree to arbitration and the arbitrator ruled against Morgan; no malpractice was committed. Morgan was represented in that action by Defendant Steven Friedman. Morgan refused to accept this judgment and instead chose to exact revenge by making vicious defamatory statements about the Plaintiffs on his website "lasiksucks4u.com." Morgan admitted that, "I carry much anger, depression, bitterness and hatred toward the Nevyas'...." Amended Complaint ("Am Comp.") ¶19. This hatred has manifested itself in a website in which he tries to destroy their reputations and their medical practice. Morgan makes a host of accusations toward the Plaintiffs, among them he accuses Plaintiffs of corrupting the legal system, of greed, professional misconduct, and of committing medical malpractice - an allegation already found to be false. When initially confronted, Defendant agreed to remove the false and defamatory statements from the website. He has breached that agreement. Am Comp. ¶¶20-21. Plaintiffs brought this action and applied for a Temporary Restraining Order compelling Morgan to cease his defamatory conduct adhere to the contract reached in August. Am Comp. ¶52.

Morgan and Friedman, who was again representing Morgan as he did in the medical malpractice action, assured the Court that Morgan had no intention of defaming the Plaintiffs and that he simply wanted to tell his story with respect to Lasik surgery. Friedman further assured this Court that changes would be made to the website and that Morgan was willing to consider the deletion of material Plaintiffs identified as defamatory. Am Comp. ¶¶53-54.

Plaintiffs were well aware of the hatred and bitterness that Morgan admittedly had for them, and insisted that the only way they could be protected from Morgan's malicious attacks, was through adherence to the August contract. Morgan refused to comply. On November 17, 2003, Judge Sylvester denied Plaintiffs motion for Temporary Restraining Order. Am Comp. ¶56. Later that week, Morgan made further modifications to the website. These modifications, along with future modifications belie Morgan's representations to Judge Sylvester that he simply wanted to tell his story. Am Comp. ¶57.

On December 4, 2003, three weeks after personally assuring Judge Sylvester that Morgan did not want to defame Plaintiffs but only wanted to tell his story, Friedman wrote a letter to the FDA accusing Plaintiffs of criminal activity and requesting criminal sanctions. Am Comp. ¶71. See Exhibit 1. Some examples of the defamatory statements in the December 4 letter include:

- (a) "I believe however, that emphasis need be placed upon investigation of possible outright *criminal* activity." Emphasis in original.
- (b) "I now call for an investigation by the Office of Criminal Investigation, for action which would: 1. Terminate all IDEs and stop Nevyas from performing LASIK. 2. Fine and otherwise sanction Nevyas for past improprieties."



(c) “The Nevyas’ attorney told me that they intend to confiscate the social security disability checks Mr. Morgan gets for his legal blindness.”

(d) “The public needs protection. The FDA can give that protection, through criminal investigation and regulation.” Am Comp. ¶72.

Friedman gave the December 4 letter to Morgan for inclusion on the website. Am Comp. ¶73. Friedman knew the statements contained in the December 4 letter were not true but sent the letter to the FDA and gave it to Morgan as part of his continuing effort to cause as much harm as possible to Nevyas. Am Comp. ¶74. Friedman had no legitimate purpose in sending the letter to the FDA. Friedman knew that the FDA had already investigated his bogus claims against Plaintiffs and rejected them. Am Comp. ¶83. Friedman wrote the letter and then gave it to Morgan simply to cause harm to Plaintiffs’ reputations and medical practice. Am Comp. ¶83. Morgan quickly posted the December 4 letter on the website. The allegations contained in the December 4 letter allege criminal activity. Such statements are defamation per se. Am Comp. ¶¶75-76.

In addition to Friedman’s December 4 letter which was written for no other purpose than for inclusion in the website and to cause harm to Plaintiffs’ reputations and business, Morgan added three older letters to the website which were authored by Friedman and sent to the Food and Drug Administration (“FDA”). See Exhibit 3. Am Comp. ¶58. Friedman’s letters to the FDA are defamatory and accused Plaintiffs of committing federal crimes, violating FDA regulations and violating the Pennsylvania Consumer Protection Act. Am Comp. ¶59. Friedman’s first letter to the FDA is dated December 28, 2001. It accuses the Plaintiffs of violating 18 U.S.C. §1001, making false statements to the government, of violations of 21 CFR

§812, improper promotion of an investigational device, of violating 21 CFR §54, failure to disclose the financial interest of clinical investigators, and violation of 73 Pa.CSA §201, Pennsylvania Unfair Trade and Consumer Protection Law. Am Comp. ¶60. The letter further states specifically that Plaintiffs were broadcasting misleading radio advertisements: “The radio advertisement was misleading in that it: (a) sought to promote the Nevyas Excimer Laser in violation of FDA regulations, (b) did not mention that an experimental device and an experimental protocol were involved, (c) implied that only standard therapy was involved, (d) did not state that visual acuity could not be achieved beyond what spectacles or contacts could provide, (e) implied that Nevyas was part of a regional laser surgery institute specializing in laser surgery, and thus more authoritative and experienced, when the Institute was a fictitious name for Nevyas, and (f) implied that Nevyas was part of regional Refractive Surgery Partnership devoted to refractive eye surgery, when such partnership was largely fictitious.” Am Comp. ¶61.

The December 28 letter also states: “The mere existence of promotional advertisements in violation of FDA regulations, and the failure of Nevyas to correct misrepresentations upon being asked specific questions by Mr. Morgan, constitute violations of 73 P.S. §201 (Pennsylvania Unfair Trade and Consumer Protection Law).” Am Comp. ¶62. The letter also further asserts that Plaintiffs violated FDA regulations by making false representations to the FDA by failing to report adverse events. Friedman later refers to the Nevyas Excimer Laser as a “rogue device.” Am Comp. ¶62. One week later, January 4, 2002, Friedman wrote another letter to the FDA. This letter is also published on Morgan’s website and upon information and belief was published with the approval and encouragement of Friedman. In this letter Friedman repeats his earlier

claims but adds a new allegation: “I believe Nevyas may have been violating the federal Anti-kickback and False Claims Acts.” Am Comp. ¶64.

Friedman wrote another letter to the FDA on August 10, 2002 and upon information and belief was published with the approval and encouragement of Friedman. He again repeats and refers to his earlier claims and now accuses the Plaintiffs of engaging in “a ‘bait and switch’ tactic.” Am Comp. ¶65. In response to Friedman’s letters, the FDA sent an investigator to the Nevyas offices to assess the allegations against them. Am Comp. ¶66. The FDA did investigate these allegations and took no action against the Nevyas’ or their medical practice. Am Comp. ¶67. Morgan and Friedman remain embittered by the defense verdict entered against them in the malpractice action against the Plaintiffs. Am Comp. ¶68.

## **ARGUMENT**

Proper service has been made on Friedman and he has no privilege for publishing false and defamatory statements against Plaintiffs. Friedman is not an “interactive computer service.” Such a service would be Comcast or a similar provider, not an individual publishing false and defamatory statements on a website. Moreover, Friedman is not immunized from liability for his tortious acts because he is an attorney. Friedman’s false and defamatory statements were not made to a court of law to obtain a ruling. Friedman cannot escape liability on the basis of any privilege and his preliminary objections should be overruled.

The standard for granting as demurrer is that if “any doubt exists as to whether a demurrer should be sustained, it should be resolved in favor of overruling the demurrer. Milliner v. Enck, 709 A. 2d 417, 418 (Pa. Super. 1998). Friedman has not satisfied this standard for any of their proposed demurrer. All should be overruled.

**A. Personal Service Has Been Made On Friedman**

Plaintiffs dispute that they have failed to effectuate proper service. However, on or about January 10, 2005, Plaintiffs filed a Praecipe to have the Amended Complaint reinstated. Plaintiffs delivered the reinstated Amended Complaint to the Sheriff of Delaware County on January 12, 2005, for personal service to be made on Steven Friedman. Personal service was made on Steven Friedman on January 13, 2005. Proof of same will be filed upon receipt by counsel.

**B. Friedman Is Not An Interactive Computer Service**

Friedman claims absolute immunity for his defamatory statements by way of federal law that does not apply to him. Friedman claims that he is an “interactive computer service” as defined by 47 U.S.C. §230(e)(2) (this statute is known as the Computer Decency Act and is referred to herein as the “CDA”) and that absolute immunity for his actions as an interactive computer service is conferred by 47 U.S.C. §230(c)( 2). Both of these claims are wrong. Section 230 does not bar this cause of action. The statute specifically states: “Nothing in this section shall be construed to prevent any State from enforcing any State law that is consistent with this section. No cause of action may be brought and no liability imposed under any State or local law that is inconsistent with this section.” 47 U.S.C. §230(d)(3). Thus, the federal law does not prevent Plaintiffs from maintaining an action against Friedman for defamation. Publication of defamatory material is its communication intentionally or by negligent act to one other than the person defamed. Restatement (Second) of Tort §577.

Friedman clearly published his letters to the FDA, especially his letter of December 4, 2003. The letters accusing Nevyas of criminal acts were sent to the FDA and Morgan, neither of

which is the person defamed. The only possible exception for Friedman to liability for his statements made in the letters to the FDA would be if he could prove that he is an interactive computer service. The only immunity from state causes of action provided by the CDA is for an interactive computer service. Friedman is not an interactive computer service. Interactive computer service “means any information service, system or access software provider that provides or enables computer access by multiple users to a computer server, including specifically a service or system that provides access to the Internet and such systems operated or services offered by libraries or educational institutions.” 47 U.S.C. §230(e)(2). An example of an interactive computer service is AOL - not an individual like Friedman. Zeran v. America Online, Inc., 958 F. Supp. 1124 (E.D.Va. 1997). Therefore, Friedman cannot qualify for immunity under the CDA. Friedman is liable for defamation for his acts pursuant to the laws of Pennsylvania. The CDA has no impact and does not apply to Friedman.

**C. Plaintiffs Have Stated a Claim for Defamation Against Friedman**

Defendants have not only defamed Plaintiffs, but the defamation constitutes defamation per se.

**1. Plaintiffs Are Being Defamed**

To demonstrate defamation Plaintiff must prove: (1) the defamatory character of the communication; (2) its publication by the defendant; (3) its application to the plaintiff; (4) the understanding by the recipient of its defamatory meaning; (5) the understanding by the recipient of it as intended to be applied to the plaintiff; (6) special harm resulting to the plaintiff from its publication; (7) abuse of a conditionally privileged occasion. 42 Pa.C.S.A. §8343(a).

The Pennsylvania Supreme Court has stated that the test is “the effect the [statement] is fairly calculated to produce, the impression it would naturally engender in the minds of average

persons among whom it is intended to circulate. The words must be given the by judges and juries the same signification that other people are likely to attribute to them.”Corabi v. Curtis Publishing Co., 273 A. 2d 899, 907 (1971).

“The threshold determination of whether a statement is capable of defamatory meaning depends ‘on the general tendency of the words to have such an affect;’ no demonstration of any actual harm to reputation is necessary.” Marcone v. Penthouse International Magazine for Men, 754 F. 2d 1072, 1078 (3<sup>rd</sup> Cir. 1985), cert. denied, 474 U.S. 864 (1985), quoting, Agriss v. Roadway Express, Inc., 483 A.2d 456, 461 (Pa. Super. 1984). A defamatory communication is one that tends to “harm the reputation of another as to lower him in the estimation of the community or to deter third persons from associating with him.” Wilson v. Slatalla, 970 F. Supp. 405, 415 (E.D.Pa. 1997), quoting, Corabi v. Curtis Publishing Co., 273 A. 2d 899, 907 (1971).

## **2. Friedman’s False Statements About Plaintiffs Are Defamation Per Se**

There are four categories of slander per se. They are words imputing (1) criminal offense, (2) loathsome disease, (3) business misconduct, or (4) serious sexual misconduct. Clemente v. Espinosa, 749 F. Supp. 672, 677 (E.D.Pa. 1990); Restatement (Second) of Torts §570 (1977).

Friedman’s statements are intended to discourage others, the vast anonymous public of the internet, which includes Plaintiffs’ current and potential patients, or business partners, employees, as well as people that simply know the Plaintiffs personally, from being treated by, working for or with, doing business with or generally associating with the Plaintiffs.

The December 4 letter, written and published by Friedman, had no purpose other than to defame Plaintiffs and try to cause substantial harm to Plaintiffs and their business and reputation. Friedman even asserts that Plaintiffs have violated federal law and should be prevented from performing Lasik surgery. Friedman does not and cannot deny that he published the information.

Publication is the “communication intentionally or by negligent act to one other than the person defamed.” Gaetano v. Sharon Herald Co., 426 A. 2d 179, 182 (Pa. 1967), quoting, Restatement, Torts §577 (1938). Friedman’s giving the December 4 letter to Morgan was publication. Even if the letter to the FDA falls within a recognized privilege, which it does not, and even if there is an applicable privilege allowing Friedman to give this letter to Morgan without fear of liability, which there is not, Friedman is still liable. On December 4, 2004, Morgan was operating the website and was making defamatory statements about Plaintiffs. Friedman knew this. Passing the December 4 letter to Morgan was at minimum negligent and thus qualifies as publication.

### **3. Friedman’s Letters to the FDA Are Not Privileged**

Plaintiffs’ actions are not intended to impede anyone’s First Amendment rights. Instead, Plaintiffs’ actions are designed to stop the false and malicious attack on them launched by Defendants Morgan and Friedman. The basis of the claim against Friedman is not that he wrote defamatory letters to the FDA. Instead, Plaintiffs bring this action against Friedman because the letters to the FDA were provided to Morgan specifically for the purpose of posting them on Morgan’s internet site. Specifically, Friedman wrote the December 4, 2003 letter for the sole purpose of posting it on the internet. The December 4 letter was not written as part of any litigation or representation by Friedman of Morgan. Instead it was written solely to slander Plaintiffs when posted on Morgan’s website. Friedman had already complained to the FDA about this exact matter and the FDA had already investigated the exact same matter and found no wrong doing by Plaintiffs.

Friedman’s letters to the FDA, specifically the December 4, 2003 letter was not written in the course of representation. Bochetto v. Gibson, 860 A.2d 67 (Pa. 2004). As admitted by Friedman in his August 4, 2003 letter, his representation of Morgan was limited to that letter.

Friedman repeated this assertion orally at the TRO hearing. By his own admission, Friedman did represent Morgan for all matters. The December 4 letter was beyond the scops of any repre4sentation.

In Bochetto, an attorney submitted a complaint which he had filed to the Legal Intelligencer, which published the allegations contained in the complaint. The defendant in that complaint, then turned around and sued the attorney for defamation. It was these exact allegations, contained in the complaint and then published in the newspaper, that were alleged to be defamatory. The attorney, now a defendant in the defamation action, asserted the judicial privilege, like Friedman in the instant case. The Pennsylvania Supreme Court rejected defendant's claim of privilege. In order for a communication to qualify for judicial privilege it must be issued in the regular course of judicial proceedings and which are pertinent and material to the redress or relief sought." Bochetto, 860 A.2d at 71, quoting, Post v. Mendel, 507 A. 2d 351,355 (Pa. 1986) (emphasis in original). The transmission of the complaint to the newspaper was not a privileged communication and the attorney was liable for defamation even though the exact same statements if merely contained in the complaint, would not have been actionable.

In Post the Court was asked to decide whether the judicial privilege attached to a letter written by counsel to the Disciplinary Board with copies sent to the judge and the attorney's client. While the letter was written during trial and referred to matters at trial, the Supreme Court held the letter was not issued as a matter of regular course of the proceedings and was not pertinent or material to the proceedings. Without satisfying these two criteria, the letter was not privileged and the attorney was not immune for statements made in the letter. Bochetto, 860 A.2d at 72, citing, Post, 507 A. 2d at 356. As stated by the Pennsylvania Supreme Court, "The judicial privilege 'is not a license for extra-judicial defamation, and there is unnecessary potential



for abuse if letters of the sort written in this case are published with impunity.” Bochetto, 860 A.2d at 72, quoting, Post, 507 A. 2d at 356 (emphasis added).

In Post the Court explained that the letter to the Disciplinary Board did not state or argue any legal position and it did not request any ruling or action by the court. Nor did it request that anything in the letter be considered by the court. The act of forwarding the letter to the court, his client and the Disciplinary Board did not make the letter part of the trial proceedings. Post, 507 A. 2d at 356.

Friedman’s argument, that he is not liable for the content of the letters to the FDA, is premised on the letters being written as part of his representation of his client. However, as Bochetto and Post demonstrate, such immunity is highly limited and Friedman does not qualify for such immunity. Friedman’s letters to the FDA, particularly the December 4 letter, were intended to make gratuitous slurs on the Nevyas’ and their business and were intended for the sole purpose of harming their business. The December 4 letter did not state or argue any legal position and it did not request any ruling or action by the court. The December 4 letter was written for the sole purpose of publication on the website.

Friedman claims that “there is no cause of action against an attorney for sending a complaint on his behalf to a governmental agency” and cites Milliner v. Enck, 709 A. 2d 417, 419-20 (Pa. Super. 1998) for support. Friedman’s assertion is completely wrong. Milliner simply interprets Post, nothing more. As shown above, Post does not provide any type of blanket immunity for defamation. Post was emphatically reaffirmed by Bochetto. The immunity claimed by Friedman for sending a complaint to a governmental agency does not exist. Any

immunity for an attorney's action must be interpreted through Post and Bochetto. Both Post and Bochetto demonstrate Friedman is liable for defamation.

**4. Plaintiffs' Amended Complaint Is Sufficiently Specific**

Friedman argues that Plaintiffs are required to provide more detailed information concerning his publication of defamatory material contained in his December 4 letter. Friedman does not cite any law which requires defamation to be plead with the type of specificity Friedman would have this Court hold is required by Pennsylvania law. This argument is nothing more than a red herring and should be ignored. The Amended Complaint states that Friedman provided the December 4 letter to Morgan. Friedman had no duty to provide Morgan with the December 4 letter as the letter did not relate to any litigation or any other matter for which Friedman was providing representation to Morgan. Instead the letter was written for the sole purpose of defaming Plaintiffs and for publication on the website. Am. Comp. ¶¶71-74, 85. Friedman then gave the letter to Morgan for publication on the website. Am. Comp. ¶¶73-75, 85.

Friedman's statute of limitations argument is inapplicable on its face. The December 4, 2003 letter could not have been published before it was written. The Amended Complaint naming Friedman as a defendant was filed on or about July 13, 2004. This is within any statutory period however it would be applied. A more specific pleading is not required

Dated: January 18, 2005

Respectfully submitted,

STEIN & SILVERMAN, P.C.

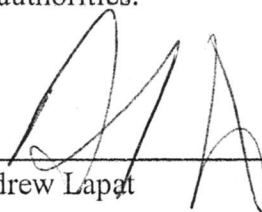
By:

  
\_\_\_\_\_  
Andrew Lapat  
Attorney for Plaintiffs

VERIFICATION

I, Andrew Lapat, Esquire hereby state that I am attorney for Plaintiffs in the within action.  
I verify that the statements made in the foregoing pleading are true and correct to the best of my knowledge, information and belief; I understand these statements made are subject to the penalties of 18 Pa.C.S. §4904 relating to unsworn falsification to authorities.

Dated: January 18, 2005

  
\_\_\_\_\_  
Andrew Lapat

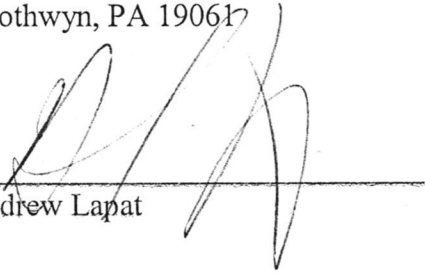
CERTIFICATION OF SERVICE

I, Andrew Lapat, hereby certify that I have caused a true and correct copy of the foregoing **Opposition to Defendant Morgan's Preliminary Objections** to be served via first class mail postage prepaid to counsel listed below on January 18, 2005:

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\_\_\_\_\_  
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