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Civil Administration

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EXHIBIT 6

The LASIK industry & the FDA have conspired since L information vital to the public in making a truly informed hope to show you what the industry and FDA would not speaking out.

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Wednesday, 27 July 2011

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Welcome To Lasikdecision.com

If you surf the web, you'll notice that most Lasik websites are advertisements for having Lasik eye surgery. They downplay the risks associated with LASIK just to sell you the procedure. The same can be said of MANY doctors in for consultation. Don't be rushed, and try to research as much as possible.

This website is to educate you to the dangers of having Lasik when you are not a proper candidate. Before you are done safely, and that you are a proper candidate. Many will view this site as anti-lasik, but the intent is to show information is here, but it is still YOUR decision!

My name is Dom Morgan, and I tell my story because it may be useful to anyone considering Lasik. I went to a doctor who said that I was nearsighted, farsighted, or had astigmatism could be done safely...that's almost everybody! I trusted them.

My websites contain material which some people do not want you to see. I know that Drs. Herbert Nevyas and Anita Nevyas-Wallace damaged my eyes do not, because they sued to shut down my website. The documents on this site are vast and you come to your own conclusions regarding LASIK.

Please be safe - your eyes are too important to risk to just anybody.

Nevyas Eye Associates

Bala Cynwyd & Philadelphia, PA and Marlton, New Jersey

My experience with Drs. Herbert Nevyas and Anita Nevyas-Wallace (Nevyas Eye Associates), the doctors who damaged my eyes

This section provides information:

Regarding their investigational study (before, during, and after) and what I believe to include improper use of a laser under the microscope. Please click the 'Read More' button below.

As noted by several renowned LASIK doctors, the Nevyses Deviation from Standard of Care;

On the threats and intimidation to shut down my websites and the legal battle to retain my free speech rights.

[Read more...](#)

The LASIK industry & the FDA have conspired since LASIK's inception to purposely withhold information vital to the public in making a truly informed LASIK decision. With Lasikdecision.com, I hope to show you what the industry and FDA would not and did not until LASIK casualties started speaking out.

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Tuesday, 09 August 2011

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[> LifeAfterLasik.com Conducting Long Term LASIK Study <](#) - if you've been damaged by refractive surgery, [PLEASE SUBMIT THIS FORM!](#)

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If you surf the web, you'll notice that most Lasik websites are advertisements for having Lasik eye surgery. These sites will list complications but severely downplay the risks associated with LASIK just to sell you the procedure. The same can be said of MANY doctors who perform this procedure when you go in for consultation. Don't be rushed, and try to research as much as possible.

This website is to educate you to the dangers of having Lasik when you are not a proper candidate. Before you consider Lasik, you must be sure it can be done safely, and that you are a proper candidate. Many will view this site as anti-lasik, but the intent is to show what can (and HAS happened). The information is here, but it is still YOUR decision!

My name is Dom Morgan, and I tell my story because it may be useful to anyone considering Lasik. I went to a doctor who advertised that anyone who was nearsighted, farsighted, or had astigmatism could be done safely...that's almost everybody! I trusted these doctors, and now I'm legally blind.

My websites contain material which some people do not want you to see. I know that Drs. Herbert Neyas and Anita Neyas-Wallace, the doctors who damaged my eyes do not, because they sued to shut down my website. The documents on this site are vast and (I believe) irrefutable however, I ask that you come to your own conclusions regarding LASIK.

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My experience with Drs. Herbert Neyas and Anita Neyas-Wallace (Neyas Eye Associates), the doctors who damaged my eyes.

This section provides information:

Regarding their investigational study (before, during, and after) and what I believe to include improper use of a laser under an IDE (Investigational Device Exemption) - Please click the 'Read More' button below.

As noted by several renowned LASIK doctors, the Neyases Deviation from Standard of Care;

On the threats and intimidation to shut down my websites and the legal battle to retain my free speech rights.

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Refractive Surgery Shock Syndrome (RSSS)

The Psychological Effects of LASIK Complications

The psychological impact of a bad refractive surgery can be devastating.

This updated version of the [2003 presentation](#), prepared by Roger Davis, PhD. Mr. Davis is a Psychologist; Damaged LASIK patient; Co-author of over 20 articles, chapters, and books in clinical psychology, and Founder of VisionSimulations.com. He tells of The Psychological Effects of LASIK Complications.

Submitted to the FDA's Ophthalmic Panel on April 25, 2008, the presentation I believe is more believable and accurate than what the FDA and refractive industry claims.

(May take a few minutes to load in new window)

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The Right To Free Speech



When I first started warning others of the potential risks of LASIK surgery, I could not name Drs. Herbert Nevyas and Anita Nevyas-Wallace (the doctors who damaged my eyes) due to litigation (medical malpractice). After my med mal lawsuit, I added the doctors' names because I believed then (and still do) that as a matter of public safety, they should be named. Their investigational study, as proven by the information (documents) posted resulted in numerous lawsuits. I posted all of the information I could get.

The Nevyases did not like this, and filed a defamation lawsuit against me. In the course of the 2 years it took for this case to appear before a judge at trial, my website was shut down 3 times, through intimidation and threats of lawsuits against my web hosting companies. On the second attempt, even after a temporary restraining order was denied twice by the courts, my site was shut down due to phone calls and a letter from Stein & Silverman, the Nevyases' attorney, misrepresenting the Philadelphia courts' order.

In July 2005, I was ordered by the court to remove the doctors' names from my website. I appealed the court's decision.

Were My Rights Being Violated?

In the Nevyas Eye Associates section of this site, I believe the documents posted support all my claims against Drs. Herbert Nevyas and Anita Nevyas-Wallace (Nevyas Eye Associates). The Nevyases have fought hard to keep these documents from the public eye.

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Newas Eye Associates

Dr. Kenneth Kenyon's Reports

The following are scanned images of Doctor Kenneth Kenyon's reports regarding Keith Wills, another LASIK casualty.

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PAGE 1

The reports of Dr. Kenyon, Dr. Salz, and Dr. O'Brien clearly states the deviation from 'Standard of Care' by Drs. Herbert Nevyas and Anita Nevyas-Wallace.

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Neyvas Eye Associates

American Academy of Ophthalmology & State Medical Boards

All documents posted throughout my website have been sent to the AAO's Ethics Committee and State Medical Boards of Pennsylvania and New Jersey. **The help received from any of them was none even though the documents clearly show deviations from standard of care, and many violations.** I strongly believe your expectations of any kind of help will be shortlived if you believe any of these agencies will help. These documents were filed with the Philadelphia Courts, and are public records.

Pages 1, 2, and 3 are the initial letter I sent to the AAO. The Newyases attorneys deemed these defamatory, however, I believe the documentation provided (as well as the documents throughout this website) DOES support this letter.

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Or in full.

I ended up cancelling the complaint with the AAO prior to the July '05 trial for several reasons, but it was apparent the AAO had already made its decision to not take action against the Newyas'. The same decision came from the Pennsylvania State Medical Board at the same time, whereas New Jersey's State Medical Board made its decision within 2 months.

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Dominic J. Morgan
3360 Chichester Ave., M-11
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February 28, 2005

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RE: Your letter 2/4/05 about Nevyas Laser

Dear Mr. Burke:

In response to your requests:

The Nevyas laser was a conventional Sullivan device, not exempt from FDA regulation as a "custom device." Nevyas (i.e. Dr. Herbert Nevyas, Dr. Anita Nevyas-Wallace, and Nevyas Eye Associates) was compelled to obtain an IDE, and was striving to obtain PMA (i.e. pre-marketing approval), like Summit and Visx had already done. **In violation of Federal regulations,** Nevyas commercialized the Nevyas laser by advertising while the device was investigational (Nevyas never did receive PMA). **Also in violation of FDA regulations, Nevyas failed to report various complications or adverse events to the FDA. Eventually, because of complaints, the FDA shut down use of the Nevyas laser, stopping its use under the IDE.** However, the FDA took no other action against Nevyas, so Nevyas kept profits from the \$500,000 taken in monthly (amount obtained during legal proceedings). Nevyas merely purchased an FDA approved laser and continued as though nothing had happened. Indeed, Nevyas even was allowed by the FDA to participate in the studies that recently earned Intacs approval for commercial distribution.

I am extremely concerned about the fact that Nevyas, while operating under an IDE for the Nevyas laser, **failed to report various complications or adverse events to the FDA. Data from Nevyas simply cannot be trusted, and now Nevyas data has helped Intacs get on the market. The potential consequences could be severe.**

I have contacted the AAO because it is a professional organization representing ophthalmologists, because it has acted a major protector of the public's eye health, **because I am concerned about Nevyas ethics, and because I am concerned that the Intacs approval may be flawed because of Nevyas participation.**

Some explanation and documentation:

1. "Custom designed" devices are not regulated by the FDA, and Nevyas improperly called his laser a "custom designed" device, in an attempt to avoid FDA regulation.

2. Ordinary prescription eyeglasses are typical of true custom designed devices; they are designed for one patient only. Devices which are designed for one surgeon are ordinarily not custom designed for FDA regulatory purposes (i.e. not exempt).
3. Nevyas bought a Sullivan laser and called it “custom designed,” by claiming that it was designed just for him. Nevyas received instruction on operating the Sullivan laser from Dr. David Dulaney in Phoenix, owner of another Sullivan laser. The enclosed article from the *Journal of Refractive Surgery* exposed how Sullivan sold lasers to doctors interested in evading FDA regulation by claiming “custom designed.” See exhibit 1.
4. The FDA, while investigating Sullivan, learned that Nevyas had purchased a Sullivan laser. The FDA allowed Nevyas to apply for an IDE (i.e. Investigational Device Exemption). At that time the FDA was interested in making sure that people using Sullivan and Sullivan-like lasers applied for an IDE. See exhibit 2, an FDA letter to Manufacturers and Users of Laser for Refractive Surgery. In that letter the FDA says that it granted PMAs (i.e. pre-market approval) for Summit and Visx lasers, and asks other manufacturers or users to apply for IDEs. Also see exhibit 3, a 1997 affidavit prepared by an FDA investigator, which Nevyas then refused to sign. That unsigned affidavit details the connection between Sullivan and Nevyas, and recounts Nevyas’ use of the Nevyas laser prior to getting an IDE.
5. The initial Nevyas laser IDE Protocol submitted to the FDA was dated March 18, 1997. See exhibit 4. Dr. Nevyas and Dr. Nevyas-Wallace both signed Investigator Agreements with the FDA dated March 18, 1997. See exhibits 5 and 6.
6. Those Investigator Agreements specifically required Nevyas to comply with 21 CFR part 812 (i.e. part 812 of title 21 of the Code of Federal Regulations, “Food and Drug law”). 21 CFR 812.7 prohibits promotion of all investigational devices until after the FDA has approved the device for commercial distribution (i.e. granted PMAs). See exhibit 7, a copy of 21 CFR 812.7.
7. **However, Nevyas did *not* wait for FDA approval for commercial distribution, but began promoting on radio and TV. In other words, Nevyas did not just plan to commercialize the Nevyas laser, he did commercialize it.** See exhibit 8, transcripts of KYW radio advertisements. Also see exhibit 9, transcripts of the TV “informational.”
8. Nevyas claimed that the advertisements were not meant for the Nevyas laser, but were intended only for a Summit laser he had leased (the Summit laser had obtained PMA status).
9. However, as shown in the radio and TV transcripts, Nevyas advertised laser treatment for *nearsightedness* and *farsightedness*, and did *not* mention that any laser device was investigational.

10. In Dr. Nevyas' July 29, 2002 answer to interrogatories, he admitted that Nevyas used a Summit laser from March 25, 1998 until November 11, 1999 but only used it for Lasik on *farsighted* patients. Thus, the intent of advertising for *nearsighted* patients was to solicit patients for use of the Nevyas laser. See exhibits 10 and 11, the interrogatories and Nevyas' answer.
11. Nevyas did not always stick to IDE protocol when doing Lasik. Nevyas operated upon patients not meeting protocol, including Dominic Morgan, Keith Wills, and Cheryl Fiorelli. Even when those patients developed complications and/or adverse events and sued Nevyas, Nevyas failed to report those complications and/or adverse events to the FDA. This is part of my challenge to Nevyas and Nevyas ethics, and I have details in exhibits on my website, Lasiksucks4u.com. For example, please see the December 4, 2003 letter by my attorney (also physician), Dr. Steven Friedman, as well as the reports and declarations of Dr. James Salz and Dr. Terrence O'Brien, which detail my ophthalmologic status, and the declaration of Professor James O'Reilly about societal issues concerning Lasik.
12. Eventually the FDA shut down Nevyas from using his laser. See exhibit 12, the e-mail Dr. Matthew Tarosky of the FDA sent to Mrs. Jo Wills, wife of Nevyas laser casualty Mr. Keith Wills. This was confirmed to me at a meeting Mrs. Wills and I attended at FDA headquarters December 8, 2004, at which time A. Ralph Rosenthal, M.D., Director of the Division of Ophthalmic Devices, stated that the FDA had shut down Nevyas from using his laser. The FDA had been concerned about how Nevyas used the Nevyas laser, as reflected in a January 20, 1999 letter from Dr. Rosenthal to Nevyas, and the May 10, 2001 report of an FDA investigator, concluding that Nevyas was not complying with the Investigator Agreement. See exhibits 13 and 14.
13. As the letter from Dr. Tarosky and the comments from Dr. Rosenthal indicated, the FDA has taken the position that it eliminated a danger to "public safety" when it shut down the Nevyas laser, and that ended the problem. However, the FDA allowed Nevyas to participate in the studies that earned Intacs approval for commercial distribution, and Nevyas currently performs Intacs surgery. See exhibit 15, an *Ocular Surgery News* article about Intacs.
14. I am concerned not only about Nevyas ethics with regard to the Nevyas laser, but about the safety of Intacs, which the FDA approved on the basis of data from Nevyas. I am extremely concerned that the Intacs study may be flawed, and thus the Intacs approval flawed, because of Nevyas participation. I have voiced my concerns to the FDA but, having recently approved the device, the FDA apparently has to wait.

As I said above, I contacted the AAO because it is a professional organization representing ophthalmologists, because it has acted a major protector of the public's eye health, because I am concerned about Nevyas ethics, and because I am concerned that the Intacs approval may be flawed because of Nevyas participation.

Thank you for your attention.

Respectfully yours,

Dominic J. Morgan

EXHIBITS

1. Article from the *Journal of Refractive Surgery* about Sullivan.
2. October 10, 1996 FDA letter to Manufacturers and Users of Laser for Refractive Surgery.
3. 1997 affidavit prepared by a FDA investigator, which Nevyas refused to sign.
4. Nevyas laser IDE Protocol submitted to the FDA dated March 18, 1997.
5. Investigator Agreements signed by Dr. Herbert Nevyas dated March 18, 1997.
6. Investigator Agreements signed by Dr. Anita Nevyas-Wallace dated March 18, 1997.
7. 21 CFR 812.7.
8. Declaration of Mr. Roy Shapiro, general manager of KYW radio, with transcript of advertisement.
9. Transcript of TV "informational."
10. Interrogatories addressed to Nevyas.
11. Nevyas' answers to interrogatories.
12. e-mail Dr. Matthew Tarosky of the FDA sent to Mrs. Jo Wills, wife of another Nevyas laser casualty, Mr. Keith Wills.
13. January 20, 1999 letter from Dr. Rosenthal to Nevyas.
14. May 10, 2001 report of an FDA investigator, concluding that Nevyas was not complying with the Investigator Agreement.
15. Article from *Ocular Surgery News* about Intacs.