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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.

Journal of Refractive Surgery

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Volume 11 (5) * September/October 1995 * News

FDA Takes on Maker of "Homemade" Excimer Lasers

Lisa A. Kearns

- REFERENCE
- SEE ALSO

As the number of US ophthalmologists using "homemade" excimer lasers to perform refractive surgery continues to grow, the US Food and Drug Administration (FDA) is taking action against the laser engineer thought responsible for making most of these "custom" instruments.

Ed Sullivan, doing business as ExSull, Drexel Hill, Pa, has been put on notice by the FDA that the agency regards him "clearly as a manufacturer with multiple manufacturing sites" subject to FDA rules and regulations and, if he makes another one of these excimer lasers "which are unapproved devices," he will be in violation of the federal Food, Drug and Cosmetics Act and subject to legal penalties, according to top-ranking FDA officials within the national Division of Enforcement.

Sullivan was informed in mid-May in a teleconference with top officials from both the FDA Division of Enforcement national headquarters and the Philadelphia District Compliance Office that it is the FDA's position that Sullivan's excimer lasers are not "custom devices" and not exempt from regulation as a physician's practice-

of-medicine issue, as has been claimed by some of the ophthalmologists using his devices.(1) The agency also advised Sullivan "that any further [excimer laser] construction would be in violation of the act," and could lead to seizure, injunctions, and, eventually, civil penalties.

"He is making more than one, and even though they may be different in that they are serialized, they are all PTK and PRK lasers, are elsewhere available and not custom," said the FDA official. "It is pretty clear that what they are doing is different than a physician doing it within the auspices of his practice. This is classic manufacturing and he should not be doing this."

During the FDA telephone conversation, "it appeared that [Sullivan et al] were surprised by our position," the official said, "but they did not have the arguments to refute it at that point in time."

Patient consultants, working for ophthalmologists using Sullivan-built lasers in practices under investigation by the FDA, say Sullivan's plans were to build at least 10 excimer lasers for ophthalmologists in the US. The FDA is not certain it knows the exact number that have been built to date.

At least four homemade or custom-made excimer lasers are already being used by five refractive surgeons in the US, who had together treated more than 800 PRK (photorefractive keratectomy) and LASIK (excimer laser in-situ keratomileusis) patients by early summer, according to those surgeons or their employees.

This spring, Ronald W. Barnet, MD, and David D. Dulaney, MD, doing business as the Barnet Dulaney Laser and Refractive Institute in Phoenix, Ariz, and Kenneth K. York, MD, of Glendora, Calif, joined Frederic B. Kremer, MD, of Philadelphia and D. Stephen Hollis, MD, of Columbus, Ga, in using a "custom" excimer laser on refractive surgery patients in the US.

Kremer, who an FDA official says worked with Sullivan during the development of his laser more than 2 years ago, was one of the first in the homemade laser field. Kremer employees tell patients the doctor designed and built the laser himself. Hollis admits his laser is a clear Sullivan creation, which Hollis has used to perform more than 300 LASIK procedures.

York imported a used ExciMed (Summit Technology, Waltham, Mass) excimer laser from Canada through Hi-Line Medical, Inc, of Laguna Hills, Calif, and customized its optics and delivery system. He says he designed the instrument, which was then built to his specifications by engineers and machinists from the medical and aerospace industries. Sullivan was not one of those engineers, according to York.

When questioned specifically about the origin and FDA status of the Barnet Dulaney laser, a patient counselor said, "we had a laser engineer build our own state-of-the-art laser, one of only four in the country. It was built to our own specifications. The FDA cannot tell a surgeon what procedure they can or cannot do. The reason the FDA is looking at the laser equipment is for sales and marketing, and since we are not going to sell or market the laser, we don't need