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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.