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.