ROP patient. Indeed, the inability of Nevyas to be certain where to properly center the excimer ablation in an ROP patient is another reason why LASIK was inappropriate.

The topography following the LASIK appears to be well centered over the pupil. Because Mr. Morgan visual axis or "line of sight" is not looking through the center of the pupil, this may be partially responsible for his visual aberrations and decreased vision. It does not appear that this issue was ever discussed with Mr. Morgan as a potential problem with doing surgery on him as opposed to a truly "good candidate. The Nevyas note of 4/27/98 mentions the "patient was looking nasal to fixation target intraop" and that there was "temp decentration OS." It is possible that Mr. Morgan's line of sight to his temporally pulled macula passes through a peripheral portion of his ablation rather than the central portion and that may explain some of his decreased vision and night symptoms of glare and ghost images. Under these circumstances it may have been more appropriate to center his ablation over the line of sight rather than the pupillary center.

This mismatch between the center of the ablation and the temporally displaced macula as a possible explanation for Mr. Morgan's difficulties is also mentioned in the letter from Dr. DeJuan and the letter from Dr. Paul Maurius Bear dated 7/21/99.

2. **Violation of FDA and Code of Federal Regulations on promotion and other practices.** These regulations state that the investigator shall not : "(a) Promote or test market an investigational device until the FDA has approved the device for commercial distribution and (d) Represent that an investigational device is safe or effective for the purposes for which it is being investigated."

Mr. Morgan states and it is confirmed on his patient history dated 3/10/98 that he came to the Nevyas Eye Associates because he heard a radio commercial on station KYW. I have reviewed the script of radio advertisements, the Nevyas web pages, and a promotional Videotape of a program that was shown on cable television and may have been distributed to patients. I have been told that all of these materials were used during the FDA investigation of the Nevyas Laser. None of these materials included the FDA required warning that the device is **limited to investigational use only**. The ads also represent that the procedure is safe, and in fact the TV ad shows a simulated blurred 20/200 vision quickly dissolving into a sharp 20/20 vision. There are numerous other representations that the procedure is safe and effective. If patients were responding to these advertisements and then were entered into the FDA study, that would represent a serious deviation from the standard of care and one that I am sure the FDA would be interested in these practices.

It would also appear that the poor results obtained by Mr. Morgan with the significant decrease in his best corrected spectacle visual acuity of more than 10