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.