It started with Ed Sullivan, the guy who built the 'Nevyas Laser', a man already under scrutiny by the FDA...

"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." [as written in The Journal of Refractive Surgery - Volume 11 (5) * September/October 1995 * News, which was removed from the url address http://www.slackinc.com/eye/jrs/vol115/news1.htm].

And the FDA knew that! From the affidavit Herbert Nevyas submitted to the FDA, it tells of Ed Sullivan building their laser. However, documents show Mr. Sullivan in teleconferences and meetings with the doctors and their laison with the FDA well **after** this article was written.

After I received inspection reports even less redacted from the FDA regarding inspections of the Nevyas' facility, the FDA promised "to do what they could to help me", but then refused after copies of the inspection reports were returned. In fact Les Weinstein, the CDRH Ombudsman, outright told me (through his secretary) he could no longer have any communication with me. It seems to me (based on my communications with the FDA) that the FDA was more concerned with being sued by the Nevyases for the information released, then by doing the right thing.

The inspection reports of Sullivan's facility below were obtained via the Freedom Of Information Act. Regardless of these reports and the articles written concerning 'Homegrown Lasers", is this what the FDA considers "protecting the public's safety"?

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PAGE 1 - *Previous inspection, 5/16/96, was a follow up to a Warning Letter issued on 8/17/95. The Warning Letter informed the firm that the FDA considered ExSull, Inc., to be a manufacturer of a Class III medical device, that was both adulterated and misbranded, in that there were no approved PMA or IDE for any of the devices and that the firm itself was not registered as a medical device manufacturer.*

PAGE 2 - *Mr. Sullivan stated that "he called the FDA and was sent material relating to the building of "custom devices", and that the FDA person he had spoken to over the telephone assured him that it was okay to build them in the Doctor's office".*

PAGE 3 - *Repeated attempts to schedule a subsequent meeting with Mr. Sullivan (via my leaving numerous messages on his voice mail) were unsuccessful. Mr. Sullivan would not commit to a date and time,*

when he returned my repeated phone calls, and in some instances did not even return my phone calls. Only after inadvertently meeting him at one of his client's (on 6/25/97), did he then agree to see me at his ExSull, Inc.,

PAGE 4 - *Mr. Sullivan stated that he did not have any standard procedures for assembling the device. He stated that the device components are delivered to each physician's office, where he then assembles the compete excimer laser. He informed me that he will then test the laser,* ***but that he does not have any performance specifications, written assembly instructions or quality control tests.***

PAGE 5 - *and that any involvement by Mr. Sullivan in a sale, would depend on the nature of the sale. He would not elaborate on that statement, but explained that it means that he is not involved in every sale.*

PAGE 6 - *Mr. Sullivan informed me that he has not contracted to build any additional units, since he assembled the device for* [redacted] *in October 1996. On 6/26/97, Mr. Sullivan showed me a copy of an IDE for that same client* [redacted]*, Mr. Sullivan explained that he was working on the document, and an examination of the IDE showed that the unit had been used to treat at least*
[redacted]
patients, without an approved IDE. Mr. Sullivan would not allow me to copy this document, and stated that the FDA already has this IDE on file.

PAGE 7 - *Mr. Sullivan did state that he will be publishing an article with a Dr. Herbert Nevyas, regarding the use of the ExSull, Inc., excimer laser for treatment of a patient with an irregular cornea, due to an eye injury.*

PAGE 8 - *According to Mr. Sullivan, this entire process (the exchange of laser beam requirements and the design specifications) is all done via telephone or personal visits, and* ***he does not have any written records of the design specifications***
. He stated that each individual physician should have those records. Mr. Sullivan stated that he knew of no injuries with the device.
He did say that in theory the laser would have some patients possibly experiencing overcorrection, but that the majority would experience a slight undercorrection, which might require additional treatment.
In addition, he explained that there has been no hazing or scaring, with the devices. He stated that the physicians handle all of the complaints from the patients, and that he is not aware of any major complications.

PAGE 9 - *Mr. Sullivan informed me that he designed the hardware for the "beam shaper" or "beam sculptor", as well as, the software that controls that hardware. He stated that his program was written in [redacted] and that three versions have been made, of that software. He informed me that he had no documentation or procedures for upgrading or changing the program (at the [redacted]. In addition, he could not provide any information regarding which of the software versions are in any of the particular devices, stating that he did not keep any of those records.*

PAGE 10 - *Mr. Sullivan gave his permission for me to observe the calibration procedure. I was allowed to*

examine the optical compartment, including the "beam shaper" or "beam sculptor", designed by Mr. Sullivan. Mr. Sullivan would not let me photograph this part of the device.

PAGE 11 - *He informed me that he is only a consultant, and that each device he assembles is considered a "Custom Device". He confirmed that he did not have any medical device manufacturing records, such as Master Device Record or Device History Record. I asked Mr. Sullivan if the firm had a Device Master Record or Device History Record. He responded that he considers himself a consultant, and that he does not keep any records of design specifications, manufacturing specifications or a device History Record. He stated that each of the physicians might have any documentation for the specifications or design, for their device.*

PAGE 12 - *During the inspection, Mr. Sullivan stated that the firm's computer, used to store all of the business records, had experienced a "hard drive crash", in the winter of 1996. He explained that consequently all records from 1994 to December 1996 have been lost.*

PAGE 13 - *He stated that he does not keep any repair or service log books, or a records of any complaints regarding the performance of the laser, by the physicians.*

PAGE 14 - *There are no Exhibits with this EIR, due to the unavailability of records at the firm.*

PAGE 15 - *The observations noted in this FDA-4B3 are not an exhaustive listing of objectionable conditions.* FDA 483 issued.

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The FDA issued warning letters regarding the lasers Sullivan built, but **STILL** allowed doctors to further modify and use these devices on people considering LASIK!

Warning Letter 1 <> Warning Letter 2