

of-medicine issue, as has been claimed by some of the ophthalmologists using his devices.(1) The agency also advised Sullivan "that any further [excimer laser] construction would be in violation of the act," and could lead to seizure, injunctions, and, eventually, civil penalties.

"He is making more than one, and even though they may be different in that they are serialized, they are all PTK and PRK lasers, are elsewhere available and not custom," said the FDA official. "It is pretty clear that what they are doing is different than a physician doing it within the auspices of his practice. This is classic manufacturing and he should not be doing this."

During the FDA telephone conversation, "it appeared that [Sullivan et al] were surprised by our position," the official said, "but they did not have the arguments to refute it at that point in time."

Patient consultants, working for ophthalmologists using Sullivan-built lasers in practices under investigation by the FDA, say Sullivan's plans were to build at least 10 excimer lasers for ophthalmologists in the US. The FDA is not certain it knows the exact number that have been built to date.

At least four homemade or custom-made excimer lasers are already being used by five refractive surgeons in the US, who had together treated more than 800 PRK (photorefractive keratectomy) and LASIK (excimer laser in-situ keratomileusis) patients by early summer, according to those surgeons or their employees.

This spring, Ronald W. Barnet, MD, and David D. Dulaney, MD, doing business as the Barnet Dulaney Laser and Refractive Institute in Phoenix, Ariz, and Kenneth K. York, MD, of Glendora, Calif, joined Frederic B. Kremer, MD, of Philadelphia and D. Stephen Hollis, MD, of Columbus, Ga, in using a "custom" excimer laser on refractive surgery patients in the US.

Kremer, who an FDA official says worked with Sullivan during the development of his laser more than 2 years ago, was one of the first in the homemade laser field. Kremer employees tell patients the doctor designed and built the laser himself. Hollis admits his laser is a clear Sullivan creation, which Hollis has used to perform more than 300 LASIK procedures.

York imported a used ExciMed (Summit Technology, Waltham, Mass) excimer laser from Canada through Hi-Line Medical, Inc, of Laguna Hills, Calif, and customized its optics and delivery system. He says he designed the instrument, which was then built to his specifications by engineers and machinists from the medical and aerospace industries. Sullivan was not one of those engineers, according to York.

When questioned specifically about the origin and FDA status of the Barnet Dulaney laser, a patient counselor said, "we had a laser engineer build our own state-of-the-art laser, one of only four in the country. It was built to our own specifications. The FDA cannot tell a surgeon what procedure they can or cannot do. The reason the FDA is looking at the laser equipment is for sales and marketing, and since we are not going to sell or market the laser, we don't need