

FDA approval." The FDA clearly disagrees.

In the first 3 months in which they had the homemade laser, Barnet and Dulaney performed more than 100 LASIK procedures, according to the counselor. She said more than 90% of those patients are seeing 20/40 or better one day postoperatively, and by the end of the first postoperative week, 96% were 20/40 or better. The center charges patients \$1695 per eye, with financing available "with little or no down payment necessary."

Barnet Dulaney tells patients its laser is "a third-generation laser which is so much more sophisticated" than what the FDA is reviewing for the major US market. "It is comparable to the lasers in Europe and Canada," the patient counselor said. "There are only four in this country, the reason being they are just so extremely expensive to have built."

Other refractive surgeons argue that few of these excimer lasers are being built because they are in violation of FDA regulations and may leave the physicians using them open to serious legal liability. The validity of the "third-generation" designation is also challenged by at least one internationally renowned refractive surgeon who says "specific excimer laser generations have yet to be defined" and such labeling is "a marketing ploy" with "suggested superiority which has not been proven."

Neither Barnet nor Dulaney responded to repeated requests for an interview.

Kremer and Hollis clearly state on their promotional brochures that their lasers have not been approved by the FDA. Barnet Dulaney does not. In the glossy, full-color promotional materials sent to a patient by Barnet Dulaney in response to inquiries about laser refractive surgery, nowhere is FDA approval mentioned. Instead, the promotional section on PRK and LASIK tells patients, "The doctors and staff at Barnet Dulaney Laser and Refractive Institute are among the most experienced in the United States at performing corneal shaping. Over 15,000 refractive surgery procedures have been performed since 1984." It does not state that at the time the material was received, Barnet and Dulaney had only performed about 100 procedures using the homemade excimer laser--and they perform only LASIK, not PRK, according to staff members.

The closest the material comes to advising patients of the investigational nature of the device is a heading that reads: "EXCIMER LASER: A Promising Instrument Still Being Tested for Many Procedures" written next to a photo of a doctor dressed in surgical garb and wearing a surgical mask and cap, apparently in the process of using the laser on a patient.

The future of these excimer lasers, and the people who make them, is in question. An FDA regional compliance official involved in the Sullivan investigation says any ophthalmologist who now contacts Sullivan to have him build an excimer laser "could make a substantial investment--and if the agency feels that these things should be off the market, they could lose the whole device.

"The current political climate is to give the companies a chance to come into