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

compliance," he said. "But if the agency decides to seize these devices, it would not look very good if US Marshalls burst into the doctor's office and decided to seize the product in front of all his patients. I am not saying that is what we are going to do, but that is one option the agency has."

So far the FDA has not seen fit to shut down any of the excimer laser centers or confiscate any of the homemade devices, in part because the agency has received no reports of any patient injuries. However, within portions of the ophthalmic community, increasing questions are being raised about quality control, proper technique, development of appropriate algorithms, and other technical, legal, and ethical issues. However, none of the physicians, employees, or others familiar with the lasers' operations have apparently been willing to go on record with the FDA with any specific charges.

"We told [Sullivan] unequivocally that if we hear of any injuries" caused by the use of his lasers, said the FDA official, "that would put us in a different mode and we would be out there immediately to seize them. Right now we do not have that information and it does not appear it exists."

REFERENCE

1. Kearns LA. 'Homemade' excimer lasers are operating today in the US--the rest of the country watches and waits. J Refract Surg. 1995;11:230-235.

SEE ALSO

- Letter to the Editor regarding prior news article.
- News article in same issue, Custom Excimer Users Threaten PRK Success.
- Subsequent news article, FDA Investigates Injury Reported From "Homemade" Laser.

Lisa A. Kearns investigates and reports industry news for *The Journal of Refractive Surgery.*

- [ ] Send a letter to the editor.
- [ ] Comment to Webmaster, SLACK Inc.

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Letter to Industry Re: Lasers Oct. 10, 1996

NOTE: THE FOLLOWING IS AN UPDATED VERSION OF THE OCTOBER 8, 1996 LETTER WHICH CLARIFIES THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH CONTACTS (SEE BOLDED TEXT AT END OF PAGE 2).

October 10, 1996

Dear Manufacturers and Users of Lasers for Refractive Surgery:

The Food and Drug Administration (FDA) is confident that you share our objective of providing the American public reasonable assurance that all lasers for refractive surgery are safe and effective, and looks forward to working with you to achieve that goal.

The purpose of this letter is to clarify which lasers and indication(s) are approved by FDA, and to provide direction on what clinicians should do if they have an unapproved laser or wish to employ an approved laser for a use that is not in the approved labeling.

As you know, the FDA approved applications for premarket approval (PMAs) from Summit Technology, Inc. and from VISX Inc. for their excimer≥ ≤lasers for the correction of mild to moderate myopia in patients with minimal astigmatism. Based on the submitted data, these models were approved for refractive correction only by photorefractive keratectomy (PRK) of the corneal surface. Data were not submitted to support the use of these lasers for laser assisted in-situ keratomileusis (LASIK), laser scrape, astigmatism, hyperopia, or multipass or multizone software algorithms. Currently, these are the only lasers approved by FDA for refractive correction and the only refractive indications for which they are approved. The dioptric ranges indicated in the PMA are based on data submitted by these companies in their applications. Data on higher myopia and astigmatism were not submitted, and therefore the approvals did not provide for their treatment. All other lasers being used for refractive surgery, however manufactured or obtained, should be regarded as investigational devices and patients should have the usual human subject protection of institutional review board (IRB) protection, informed consent and an IDE approval by FDA.

Because patients who receive laser treatment for the correction of refractive error have a right to expect that the laser device being used on their eyes is reasonably safe and effective, FDA required as part of the PMAs that patients be issued with a Patient Information Booklet which provides them with essential information about the likely outcome of refractive surgery on their eyes. This information includes success and failure rates, rates of adverse events, stability of correction, and other information needed for patients to make an informed decision.

On May 7 the FDA and the Federal Trade Commission (FTC) issued a joint letter to users of the VISX and Summit lasers. The purpose of that letter was to inform practitioners that advertising of legally marketed devices and PRK treatment was regulated jointly by FDA and FTC. The letter also discussed that the use of these lasers for other than their intended use was considered off-label. FDA has long maintained that practitioners must make decisions that will best serve their patients and that FDA does not seek to regulate the practice of medicine. Although uses such as

LASIK, bilateral surgery, and treatment of astigmatism or greater degrees of myopia have not currently been supported by the data, the agency is aware that practitioners are engaging in these off-label uses with their patients. Although the term "practice of medicine" covers discussions and decisions between the practitioner and the patient, it does not allow the advertising of the device for such off-label uses. The agency believes that the best data and protection of patients are achieved when these unapproved uses are studied under an FDA approved investigational device exemption.

The agency is aware of and is currently investigating unapproved lasers manufactured as one-of-a-kind by the owner, by someone else for the owner, or by a corporate entity. Practitioners who use these lasers are not operating within the legal requirements of the Federal Food, Drug, and Cosmetic Act (the act) unless they have an IDE that has been submitted to and approved by the agency. Also the IDE regulations (21 CFR Part 812; based in Part 50; and Part 56 of the act) mandate that human subjects must not be used in clinical investigations without their knowledge and consent. A grace period will be given to owners of these unapproved lasers to identify themselves to FDA, to obtain information about the IDE application process, and to submit an IDE application to FDA. These IDE applications must be submitted with an investigational plan adequate to generate data for submission in a PMA for an FDA determination of reasonable assurance of safety and effectiveness for the laser.

Additionally, FDA is also aware of the importation of lasers for use in refractive surgery which have characteristics different from those specified in the PMAs approved by FDA. Owners of imported lasers originally manufactured by the holder of a PMA approved by the FDA have two choices. The first option is for the owner of such a laser to submit certification to FDA that the imported laser is identical in all relevant aspects to the approved ones, e.g., ablation zone size, software, calibration, and labeling. The alternative is to submit an IDE application for a clinical trial for these unapproved investigational devices. Owners of imported lasers who choose to submit certification should do so quickly. If FDA determines that the owner's certification is inadequate, then the owner will have to submit an IDE application to FDA before this deadline of January 15, 1997.

Please note that an IDE application should be submitted to FDA by January 15, 1997 to take advantage of the enforcement grace period. We, therefore, advise all potential applicants to identify themselves to FDA as soon as possible. If you are the owner of an investigational laser for refractive correction without an IDE application approved by FDA, please call our Division of Small Manufacturers Assistance at 1-301-443-6597 or 1-800-638-2041. FDA has information to send to you on how to file an IDE application and on what technical and scientific information you should submit in your application for an IDE study of lasers for refractive correction. You may choose to submit your IDE application as an individual, or you may choose to submit your application jointly with others who own comparable lasers under a single sponsorship. A one day training session will take place on both November 14 and 15, 1996 for those who wish to submit an IDE and require further assistance. Similarly, if you are an owner of an imported laser and wish to submit a cerification for your laser which may include third-party engineering certification, please call our Division of Small Manufacturers Assistance at the number(s) above to obtain additional information on certification. As with the IDE application the deadline is January 15, 1997. Note: This information can also be obtained by accessing CDRH Facts-On-Demand at 1-800-899-0381.

In summary, the end of the grace period is January 15, 1997. After this deadline your laser may be used to treat patients only if adequately certified by you or, alternatively, you have submitted an IDE study to protect the health and rights of human subjects. The grace period does not apply to individuals who have received Warning Letters or other regulatory communications from the FDA or who are importers of lasers currently under detention.

We should like to thank you for your cooperation in this matter.

Sincerely yours.

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation

Lillian J. Gill
Director
Office of Compliance

DOCTT-TSD-84E

STATE OF PENNSYLVANIA | COUNTY OF MONTGOMERY

Before me, Steven E. Kane, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Dr. Herbert J. Nevyas, MD in the county and State aforesaid, who, being duly sworn, deposes and says:

I, Dr. Herbert J. Nevyas, MD, am the founder and President of Nevyas Eye Associates/Delaware Valley Laser Surgery Institute. I am the most responsible person at the firm, in that my signature appears on all contracts and I determine what medical procedures will be performed on our patients, by all of our medical staff.

On 4/9/97, Investigator Steven E. Kane, visited me at our office located at 2 Bala Plaza, 333 City Line Avenue, Bala Cynwyd, PA 19004, where he presented his credentials and issued me an FDA-482 Notice of Inspection. Investigator Kane requested information about the excimer laser (located in this office) that we use to treat patients having nearsightedness and astigmatism, using Laser Intrastromal Keratomileusis (LASIK) technique. I informed Mr. Kane that only my daughter Dr. Anita Nevyas-Wallace and myself use the excimer laser for treatment of patients with nearsightedness or astigmatism.

I informed Mr. Kane that I had contracted with a laser scientist Edward Sullivan, President, Exsull, Inc., in January 1995, to provide all technical assistance in the design and the assembly of the excimer laser, in my office. I explained that I had met Mr. Sullivan approximately two years ago, and had inquired about his building an excimer laser, according to my requirements. I informed Mr. Kane, that Mr. Sullivan told me that the excimer laser that he would build is considered a Custom Device, and would not be regulated by the FDA. Mr. Sullivan completed the assembly of the excimer Laser in the fall of 1995, and the first patient was treated (using LASIK) in January 1996.

I provided Mr. Sullivan with my basic requirements for the excimer laser, and Mr. Sullivan then used his engineering expertise to design the laser. He advised me about the component specifications and where to order each component. The components arrived in my office (at 2 Bala Plaza, Bala Cynwyd, PA 19004),

AFFIANT'S SIGNATURE AND TITLE

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

Subscribed and sworn to before me at _____ *(City and State)*

this _____ day of _____, 19 ____.

_____ *(Employee's Signature)*

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30. 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4. 1980.