PHILADELPHIA COURT OF COMMON PLEAS

PETITION/MOTION COVER SHEET

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CONTROL NUMBER: 09062101

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November (*Month*) Term, 2003 (*Year*)

No. 00946

NEVYAS ETAL VS MORGAN

Name of Filing Party: STEVEN A FRIEDMAN-DFT

INDICATE NATURE OF DOCUMENT FILED:

☐ Petition *(Attach Rule to Show Cause)* ☐ Motion
☐ Answer to Petition ☐ Response to Motion

Has another petition/motion been decided in this case? ☐ Yes ☐ No
Is another petition/motion pending? ☐ Yes ☐ No

If the answer to either question is yes, you must identify the judge(s):

TYPE OF PETITION/MOTION *(see list on reverse side)*	PETITION/MOTION CODE *(see list on reverse side)*
MOTION/PETITION REPLY FILED	REPLM

ANSWER / RESPONSE FILED TO (Please insert the title of the corresponding petition/motion to which you are responding):
MTMIS - MISCELLANEOUS MOTION

I. CASE PROGRAM

NON JURY PROGRAM

II. PARTIES *(required for proof of service)*
(Name, address and ***telephone number*** of all counsel of record and unrepresented parties. Attach a stamped addressed envelope for each attorney of record and unrepresented party.)

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III. OTHER

By filing this document and signing below, the moving party certifies that this motion, petition, answer or response along with all documents filed, will be served upon all counsel and unrepresented parties as required by rules of Court (see PA. R.C.P. 206.6, Note to 208.2(a), and 440). Furthermore, moving party verifies that the answers made herein are true and correct and understands that sanctions may be imposed for inaccurate or incomplete answers.

(Attorney Signature/Unrepresented Party)	July 27, 2009 *(Date)*	MAUREEN P. FITZGERALD *(Print Name)*	*(Attorney I.D. No.)*

The Petition, Motion and Answer or Response, if any, will be forwarded to the Court after the Answer/Response Date.
No extension of the Answer/Response Date will be granted even if the parties so stipulate.

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HERBERT J. NEVYAS, M.D. ANITA NEVYAS-WALLACE, M.D., NEVYAS EYE ASSOCIATES, P.C. Plaintiffs, v. DOMINIC MORGAN STEVEN FRIEDMAN Defendants.	:	COURT OF COMMON PLEAS PHILADELPHIA COUNTY NOVEMBER TERM, 2003, No. 00946

DEFENDANT STEVEN A. FRIEDMAN, M.D., J.D., LL.M.'S REPLY IN SUPPORT OF HIS MOTION TO DETERMINE PLAINTIFF'S PUBLIC FIGURE STATUS

Defendant Steven A. Friedman, M.D., J.D., LL.M., [hereinafter "Friedman" or "Defendant"], by and through counsel, hereby submits this Reply in Support of his Motion to Determine Public Figure Status.

A. Plaintiffs' Response Ignores the Expansion of Limited Purpose Public Figures Recently Set Forth By the Pennsylvania Supreme Court in *American Future Systems, Inc. v. Better Business Bureau of Eastern Pennsylvania.*

Plaintiffs contend that Friedman's Motion should be denied because there purportedly was no pre-existing "public controversy" at issue at the time of Friedman's alleged defamatory statements. Plaintiffs are asking this Court to ignore the recent decision by the Pennsylvania Supreme Court in *American Future Systems, Inc. v. Better Bureau of Eastern Pennsylvania, 923 A.2d 389 (Pa. 2007).* There, the Court expanded the scenario by which a plaintiff may become a limited purpose public figure. A plaintiff can now become a limited purpose public figure either

by participating in a pre-existing public controversy ***or*** by virtue of their own activities, particularly with respect to widespread public solicitation and advertisements. *Id. at 923 A.2d at 401-02, citing, National Foundation for Cancer Research v. Council of Better Business Bureau, 705 F.2d 98 (4th Cir. 1983); Steaks Unlimited, Inc. v. Deaner, 623 F.2d 264 (3d Cir. 1980); Bruno & Stillman, Inc. v. Globe Newspaper Co., 633 F.2d 583 (1st Cir. 1980).*

Plaintiffs' Response focuses only on the "pre-existing public controversy" determination and wholly ignores the fact that Plaintiffs are limited purpose public figures by virtue of their own "widespread solicitation and advertisements."[1] Plaintiffs offer no opposition to the fact that they engaged in widespread solicitation and advertising. In fact, they completely ignore the issue. Perhaps by not mentioning it even once in their Response, Plaintiffs hope the Court will overlook the fact that Plaintiffs advertised extensively in a multitude of media forums about the safety of LASIK, the use of their excimer laser device, and their purported unique qualifications to perform the procedure. This widespread advertising and solicitation took the form of repeated radio advertising on numerous local radio stations, multiple airings of a 30 minute television documentary devoted to LASIK, professionally prepared brochures distributed to the public, video presentations, multiple websites, including an official websites as well as websites sponsored "behind the scenes," and seminars given several times a year. Plaintiffs annually spent hundreds of thousands of dollars on advertising. This widespread and pervasive advertising of LASIK by Plaintiffs is a sufficient basis for the Court to find them to be limited purpose public figures under the recently expanded criteria set forth in *American Future Systems, Inc., supra.*

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[1] Plaintiffs cite *Computer Aid, Inc. v. Hewlett-Packard Co., 56 F.Supp.2d 526 (E.D. Pa. 1999)* and *U.S. Healthcare v. Blue Cross of Greater Philadelphia*, 898 F.2d 914 (3d Cir. 1990) for the proposition that large corporations, such as Hewlett Packard or U.S Healthcare were not held to be limited purpose public figures despite the fact that they advertise. (Response at p. 2). Plaintiffs neglect to realize that both of these cases were decided before the Pennsylvania Supreme Court's 2007 decision in *American Future Systems* which expanded the limited purpose public figure doctrine, and that the courts in those cases predicated their rulings upon the different standard afforded defamatory commercial speech.

B. Plaintiffs Have Misinterpreted the Law With Regard to the "Public Controversy" Requirement for Limited Purpose Public Figures.

While Plaintiffs should be deemed to be limited purpose public figures by virtue of their "widespread solicitation and advertisement," they nonetheless are also limited purpose public figures under the "public controversy" analysis, because they voluntarily injected themselves into a matter of public concern."

Plaintiffs incorrectly argue that there was no such "public controversy" prior to Friedman's alleged defamatory statements. They claim that the "public controversy" requirement must be restricted to Plaintiffs' specific performance of LASIK surgery, as opposed to a broader public controversy over the safety of LASIK. Plaintiffs claim that because none of the 18 articles referenced by Friedman in his Brief actually name them, that there is no basis to view them as limited purpose public figures. Plaintiffs' analysis is simply wrong under both the law and the facts.

Notably, Plaintiffs cite no law to support such a narrow interpretation of the "public controversy" requirement. The same narrow argument advanced by Plaintiffs was rejected in *Medure v. The New York Times Company, 60 F.Supp.2d 477 (W.D. Pa. 1999)*. There, a plaintiff businessman managed gaming casinos on Indian reservations, and sought to develop a particular casino in partnership with an Indian tribe at the Fountaingrove Country Club. A local paper then published an allegedly defamatory article about plaintiff concerning the Fountaingrove project, and concerns about its possible link to organized crime. Plaintiffs sued the authors of this article for defamation. Around the same time, there had also been more national publicity by news media over the concern about casinos on Indian property in general, and the link to organized crime with such casinos. In determining whether the plaintiff was a limited purpose public figure, the court had to first "determine the nature and extent of an individual's participation in the particular controversy giving rise to the defamation." *Id. at 484*. While plaintiff advocated

for a narrow view of the public controversy to involve simply the propriety of an Indian casino on the Fountaingrove property, the court rejected such a narrow view. *Id. at 485*. Instead, it adopted the "defendant's more expansive formulation" and recognized that there was a broader public controversy that encompassed more than just the Fountaingrove project, and rather, involved Indian casino development in general in the area. *Id.*; S*ee also, New Life Center, Inc. v. Fessio, 229 F.3d 1143, (4th Cir. 2000)* (treatment center for priests with dysfunctional behavior was a limited purpose public figure, as general topic of clergy misconduct had public ramifications, had received media attention, and was therefore a "public controversy").

Consistent with the *Medure* decision, as well as the approach of other courts, this Court should reject the narrow characterization of the "public controversy" advocated by Plaintiffs. Pennsylvania law is clear that an individual becomes a limited purpose public figure by ***voluntarily injecting himself*** or becoming drawn into a particular controversy. Those plaintiffs then become a public figure for the limited range of issues in the controversy. *American Future Systems, Inc., supra, 923 A.2d at 401, citing Gertz v. Robert Welch, Inc., 418 U.S. 323, 94 S.Ct. 2997 (1974).* There is no requirement under Pennsylvania law that there first be a written publication which specifically mentions a plaintiff, before he can be viewed to have voluntarily injected himself into a public controversy.

The evidence submitted by Defendant establishes that LASIK surgery was being discussed by the media in the public forum. The risks associated with LASIK surgery was a public health concern and the procedure was subject to extensive scrutiny by the FDA during this time period. The 18 articles cited were merely a sampling of several media outlets, and were submitted simply to demonstrate to the Court that prominent media outlets were covering the debate over LASIK surgery and its safety. Defendants admit that none of these 18 articles name Plaintiffs. However, Plaintiffs are limited purpose public figures not because of those specific 18

articles – but rather due to the actions they voluntarily took to influence the public opinion about the issues being discussed in these articles.

Plaintiffs admitted in their depositions that there was much publicity about LASIK and that they sought to counter what they perceived to be "misinformation" in the public domain.[2] Rather than sit on the sidelines and remain out of the public debate on this topic, Plaintiffs voluntarily injected themselves into this debate in order to influence the public opinion. They did so most prominently by appearing on television and making representations about the safety of LASIK surgery, the use of lasers, and their purported unique qualifications to perform the procedure. Plaintiffs were the sole physicians who appeared in a 30 minute television documentary (which they paid to appear on) devoted exclusively to LASIK surgery. This documentary aired on numerous cable television channels, and Plaintiffs presented themselves to the public as pioneers and experts in the field of LASIK surgery, as well as inventers of a particular laser device. This broadcast aired multiple times on television.

Aside from injecting themselves into the public discussion about LASIK surgery through television appearances, Plaintiffs repeatedly made representations on several radio stations, magazines, and throughout numerous internet websites which Plaintiffs either designed or sponsored. In one of its many magazine advertisements, Plaintiffs stated:

> The revolution in vision correction continues! **Featured on Channel 6 Action News and reported in Time Magazine**, our exclusive three second LTK laser procedure can return your close-up reading vision – instantly, without touching the eye. … LTK is one of the safest laser procedures ever created… Exclusively available in the Philadelphia area at Nevyas Eye Associates…

[2] See Defendant's Brief at p. 20 and citations therein: Wallace Dep., pp., 252-254, 257, 314-315; Copter Dep., pp. 7, 15, 20.

(See 2001 Philadelphia Magazine Advertisement, attached hereto as Exhibit "A"). Thus, according to this advertisement, Plaintiffs' "exclusive procedure" was featured on a local news channel as well as in a national magazine publication.

Plaintiffs also published articles about LASIK surgery and disseminated them over the internet, and repeatedly sponsored and spoke at periodic educational seminars devoted to LASIK surgery. The obtained a toll-free telephone number: "1-800-9- LASER -6." The consistent message advocated by Plaintiffs in these public forums was that LASIK surgery was safe, that their excimer laser was safe and effective, and that they were innovators and leaders in the field of LASIK surgery.

Notably, Plaintiffs' Response wholly ignores the fact that Plaintiffs voluntarily undertook this conduct, and did so to convince the public that LASIK and their laser was safe, and that they were uniquely qualified to perform the procedure. Plaintiffs engaged in this conduct at a time when the media was devoting significant attention to the risks associated with LASIK. Indeed, as a result of specific representations Plaintiffs made on KYW News Radio 1060 about LASIK surgery and its safety, co-defendant Dominic Morgan ("Morgan") presented himself to Plaintiffs' offices and subsequently underwent LASIK surgery in 1998.

Plaintiffs' claim that there is no public controversy should be therefore rejected. Their narrow characterization of what defines a public controversy is not only unsupported by the case law, but it is also belied by their own conduct in attempting to influence public opinion on the safety of LASIK surgery. No one forced plaintiffs to undertake these activities. Most ophthalmologists do not engage in this conduct. However, Plaintiffs made the choice to do so, and to do so in a widespread fashion, thereby voluntarily injecting themselves into the public

controversy and discussion involving LASIK surgery. For this reason, this Court should deem them to be public figures on the limited issue of LASIK surgery.[3]

C. Even Using Plaintiffs' Narrow Interpretation of a Public Controversy, They Should Nonetheless Be Deemed Limited Purpose Public Figures.

Plaintiffs maintain that they can only be held to be a limited purpose public figure if there was a specific written publication naming them, which gave rise to a public controversy, and which pre-dated Friedman's alleged defamatory statements. As set forth above, Plaintiffs are incorrect under the law, as they have ignored *American Futures Systems, Inc., supra*. Plaintiffs are also incorrect in the facts as they have ignored the evidence indicating that they voluntarily injected themselves into the public discussion concerning LASIK surgery, and admittedly sought to influence the public debate. Yet, even under Plaintiffs' narrow and misguided interpretation of the public controversy requirement, the facts nonetheless still indicate that Plaintiffs are limited purpose public figures with regard to the defamation claim against Friedman.

The defamation claim against Friedman is predicated upon a letter he wrote to the FDA in late 2003, on behalf of his client Morgan.[4] Friedman wrote the letters to request an investigation about suspected inappropriate use of a laser and advertising in violation of FDA regulations.[5] Prior to these letters, there had been much publicity regarding LASIK surgery being performed with lasers not yet approved by the FDA. Indeed, the Philadelphia Inquirer specifically reported on this very issue in an article published on July 27, 1996, entitled "*Doctors Told Not to Use Unapproved Lasers*." (See Article attached as Exhibit "B"). In this article, the

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[3] Plaintiffs' reliance upon *Joseph v. Scranton Times, 959 A.2d 322 (Pa. Super. 2008)* is misplaced. There, the Court found that plaintiffs did not have greater access to the media than private individuals, had not made any substantive statements in the media, and did not engage in conduct seeking to influence the public opinion. Here, Plaintiffs were able to appear on television as "experts" in the field of LASIK and did make extensive, unsolicited comments about the safety of LASIK, for the purpose of influencing the public view.

[4] While Plaintiffs' Response refers to a 2005 letter written to the American Academy of Ophthalmology, that letter is not part of the claim for defamation in the Amended Complaint.

[5] Friedman's letters to the FDA and AAO, in his role as counsel to Morgan, and which concerned matters within the scope of these agencies' jurisdictions, are judicially privileged.

FDA specifically warned the public to "be on the alert" as some doctors are using unapproved lasers, and that it was "illegal" for them to do so. The article also stated that is was "illegal for doctors to advertise LASIK, as well as to use unapproved machines." See Ex. A. Similar articles were published in the same time period on the same issue: "*Homemade" Excimer Lasers are Operating Today in the US – The Rest of the Country Watches and Waits*," Journal of Refractive Surgery, July 1995; "*Unapproved Lasers for the Treatment of Refractive Errors*" Wake Forest University Eye Center, May 1998, "*FDA Begins to Act Against Unapproved Excimer Lasers: What Took So Long?*" Journal of Refractive Surgery, November 1996, attached as Exhibit "C". While Plaintiffs are not mentioned by name in these particular articles, the issue of unauthorized lasers and inappropriate advertising of LASIK is out in the public forum.. Plaintiffs are nonetheless mentioned by name in subsequent publications addressing this very issue.

In 1997 and again in 1999, Plaintiffs themselves published articles about LASIK on Quackwatch.com entitled "*Refractive Surgery.*" During the period that the FDA was warning the public about lasers, Plaintiffs sought to assure the public of LASIK's safety. Plaintiffs described LASIK, stating that "an extremely precise underlying cut (of the cornea) is made using an Excimer Laser," and that LASIK is preferred by eye surgeons throughout the world, who have access to the necessary equipment. Plaintiffs stated in the article that a few eye-surgery centers in the United States had obtained FDA approval to perform LASIK, but that some ophthalmologists had acquired devices through foreign channels which had not been approved by the FDA, but were nonetheless safe and high-quality devices. (See Quackwatch Articles, attached as Exhibit "D").

Thereafter, Morgan specifically named Plaintiffs in connection with this same issue in early 2003 when he created his website "lasiksucks4you.com." He published statements related

to his LASIK surgery, *as performed by Plaintiffs* and criticized Plaintiffs, their performance of his LASIK procedure, and expressed his belief that they engaged in illegal activity in violation of FDA regulations, due to the laser device used on him. These statements were published in the beginning of 2003. In November of 2003, Plaintiffs sued Morgan, and according to their Complaint, alleged that members of the public were aware of Morgan's website and statements he had made about them. Specifically, Plaintiffs alleged that they had received telephone calls about the contents of the website, that patients raised the contents of the website with them, and that a "google" search of the term "Nevyas" resulted in a link to the website "lasiksucks4you.com" appearing as the third entry. (See Plaintiffs' Complaint, ¶¶ 16, 21, 53, attached as Ex. "E"). Thus, Morgan's website, created in early 2003, specifically linked Plaintiffs to the public controversy involving physicians using unauthorized lasers.

Similarly, in early 2003, Jo Wills (wife of another Neyvas patient) published an article on the internet entitled "*Lasik Gone Wrong – What Happened to Keith Wills*." That article also named Plaintiffs and discussed their use of an unapproved laser device in performing LASIK surgery on Keith Wills. (See Article attached as Exhibit "F"). This Article claimed that Plaintiffs withheld critical information from them and that the surgery they performed achieved poor results. The article also expressed the view that Plaintiffs had not complied with FDA regulations with regard to the LASIK procedure performed on Keith Wills. (See Ex. F).

Plaintiffs' defamation claim against Friedman was filed in July of 2004 and is predicated upon certain letters he wrote, as counsel for Morgan, to the FDA and American Academy of Ophthalmology. Specifically, Friedman wrote to the FDA in December of 2003, and this letter was thereafter published **by Morgan on his website without Friedman's knowledge in 2004**.[6]

[6] Friedman did not know that Morgan had done this, and never gave Morgan permission to do so. Morgan also admits that he was solely responsible for the content of his website. Friedman's only directive with regard to the

As of the time Friedman drafted this letter in December of 2003, the Philadelphia Inquirer had already reported on the issue of lasers being used without FDA approval, Plaintiffs themselves had published articles on Quackwatch.com addressing the issue, and both Dominic Morgan and Jo Wills had published statements and articles on the internet specifically linking Plaintiffs to the use of unapproved lasers when performing LASIK surgery. According to Plaintiffs' Complaint filed in November of 2003, the public was already well aware of this public controversy and allegations about Plaintiffs prior to Friedman's December 2003 letter to the FDA.

So even if this Court were to adopt the narrow interpretation of a public controversy and limited purpose public figure advocated by Plaintiffs in their Response, the evidence set forth above clearly indicates that a public controversy existed, which specifically named Plaintiffs, and which pre-dated Friedman's letters. Accordingly, even under the narrowest of interpretations, Plaintiffs nonetheless should be deemed limited purpose public figures in this action.

Respectfully submitted,

Eckert Seamans Cherin & Mellott, LLC

Maureen P. Fitzgerald/s/

Maureen P. Fitzgerald, Esquire
Attorney for Defendant
Steven A. Friedman, M.D., JJM, LL.M.

Two Liberty Place
50 South 16th Street, 22nd Floor
Philadelphia, PA 19102

Dated: July 27, 2009

website was to ensure that Morgan complied with Judge Sylvester's order in this case. (See Friedman Dep., Ex. G, pp. 136-39, Morgan Dep., Ex. H, pp. 72-73, 92-93, attached hereto as Exhibits "G" and "H", respectively).

CERTIFICATE OF SERVICE

I, Maureen P. Fitzgerald, Esquire, do hereby certify that on this 27th day of July, 2009, I caused a true and correct copy of Defendant Steven A. Friedman, M.D., J.D., L.L.M.'s Reply in Support of His Motion to Determine Plaintiff's Public Figure Status to be served upon the following:

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Dominic Morgan
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Chester, PA 19013

Maureen P. Fitzgerald /s/
Maureen P. Fitzgerald, Esquire

EXHIBIT "A"

changed. While Wilson was still barred from dealing with patients, he was allowed to participate in other ways, such as coordinating lab tests, evaluating data, and ensuring that experiments proceeded on schedule. According to the Penn health system's former CEO, William Kelley, this decision was made by university president Judith Rodin: "She made the decisions on how the relationships were going to be set up and how the potential conflicts were to be monitored." The university, in its statement, denies that Rodin made the decision, and says it doesn't consider this decision "major." It was made, the university says, because as head of the institute, Wilson simply couldn't avoid getting involved with the work of his staff. But the university also says that after an exhaustive review of what went wrong in the OTC trial, it has made changes so that the committee's recommendation will finally be in effect.

GENE THERAPISTS ACROSS THE country today refer bitterly to "the Wilson tax"—the price they are all paying in delays and scrutiny as a result of Jesse Gelsinger's death. "As long we're paying this tax," says one prominent gene therapist, "I don't think Wilson will ever be absolved or forgiven."

Yet some of Wilson's supporters see him as something of a martyr. He made major contributions to his field, but his advances, these supporters say, are now being overshadowed by what was in fact an unforeseeable accident. They argue that the early side effects that researchers observed were temporary and mild and in no way predicted what would happen to Jesse Gelsinger. The patient who preceded Gelsinger in the experiment received the same dosage level—yet suffered no side effects. Just a few decades ago, a death like Jesse Gelsinger's would have been viewed as a tragic but necessary casualty of cutting-edge research. The researchers who worked on bone-marrow transplants and chemotherapy, for instance, racked up terrible body counts before they achieved success. "If people want gene therapy research to stop, that's fine; we won't have to take any risks," says Dusty Miller, a gene therapist at the Fred Hutchinson Cancer Research Center in Seattle, Washington. "But if people want us to find treatments for cystic fibrosis and other diseases, there are going to be unavoidable risks."

Wilson's defenders say there were other senior scientists involved in the OTC trial who were also in a position to halt the experiment if they felt it posed a danger to patients. Penn bioethicist Arthur Caplan points out that while Wilson oversaw the trial, the day-to-day operations and patient care were handled by other physicians who knew a lot more about the health needs of OTC patients than Wilson did. According to members of the OTC team, Wilson was intimately involved in the trial, but mainly in terms of helping his staff analyze data and lab tests, setting deadlines, and handling the back-and-forth communications going on at the time with the FDA.

The field of gene therapy marches on. In April 2000, a team of French researchers announced that they had repaired the immune systems of two infants with so-called "bubble boy" disease, which had forced the newborns to live inside sterile plastic containers. If the children continue in good health, it will be the first time gene therapy has actually cured anyone. More recently, a team of Penn researchers outside of the institute used gene therapy to cure dogs of blindness, giving hope to the 10,000 Americans born with Leber congenital amaurosis. Wilson himself has continued working steadfastly in his laboratory. He and other researchers at the institute recently devised a new gene therapy vector that combines pieces of the ebola and AIDS viruses. Penn scientists were quick to say it would not be put into human beings anytime soon.

There is a feeling among some members

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EXHIBIT “B”

NEWSLIBRARY ARCHIVE

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DOCTORS TOLD NOT TO USE UNAPPROVED LASERS< THE DEVICES HAVE BEEN USED FOR SURGERY ON THE NEARSIGHTED.< THE FDA WARNED THAT IS ILLEGAL.

By **Lauran Neergaard, ASSOCIATED PRESS**
Source: **Philadelphia Inquirer, The (PA)**; 486 words
Published: **1996-07-27**
Section: **NATIONAL** | Page **A06** | Edition: **D**

Federal regulators issued an unusually strong warning yesterday to stop eye doctors from using unapproved machines for laser **surgery** on nearsighted Americans.
The warning is the latest in a blitz of controversy to overtake a popular laser **surgery** that promises better vision without glasses to many of the 60 million Americans who are nearsighted.

Since last fall, the FDA has approved two lasers, made by Summit Technology and Visx, to help people see more clearly at a distance.
But some doctors are importing cheaper, used lasers from Europe, where they have been sold for several years, or are building their own, meaning some patients are undergoing **surgery** on machines not FDA-approved as safe.
That is illegal, the FDA warned at a meeting of eye specialists yesterday. Doctors must use FDA-approved lasers or, if they believe their own lasers are superior, obtain government permission to study them while informing patients that the devices are experimental.
``Be on the alert: We will take action against illegal products in the marketplace,'' said Dr. Susan Alpert, FDA's device evaluation chief.
The agency could seize an unapproved machine or get a court injunction to stop its use.
The FDA said it did not know how many unapproved lasers were being used. Alpert advised patients to ask their doctor before **surgery** about the machine the doctor is using and the success rate, and ask to speak with previous patients.
``This - let us be clear - is irreversible **surgery**,'' she said.
Outraged doctors said that they were offering their patients better care than the FDA-approved equipment could provide, and that the FDA had no business interfering in their practice of medicine.
``Why did I get involved in nonregulated lasers?'' asked Dr. Ralph Berkely of Houston, who built his own laser. ``My moral and ethical responsibility to do what I believe is in the best interest of my patients.''
If the FDA would speed up its review of new lasers to keep up with Europe, doctors would not be forced to use ``untested techniques,'' said Dr. Stephen Trokel of the American Society for Cataract and Refractive **Surgery**.
In photorefractive keratectomy, or PRK, a laser burns off bits of the corneal surface to flatten it and improve mild or moderate nearsightedness. About 30,000 eyes have been treated so far.
Last spring, the FDA and the Federal Trade Commission warned doctors against falsely advertising PRK. Ads saying consumers could ``throw away your glasses'' glossed over the risks and seemingly promised perfection, the warning said. While PRK usually works well, it sometimes results in patients needing reading glasses or causes glare, hazy vision and other problems.
A similar but less painful and possibly better **surgery**, called **LASIK**, has been replacing PRK in Europe. **LASIK** still is under study here, but the Summit and Visx lasers can perform it, and the FDA cannot forbid doctors from offering it. But it is illegal for doctors to advertise **LASIK**, as well as to use unapproved machines, Alpert said.

NEWSLIBRARY ARCHIVE

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Articles contain no graphics or photos.

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EXHIBIT "C"

"Homemade" Excimer Lasers are Operating Today In the US—The Rest of the Country Watches and Waits

Serious medical, legal, and ethical questions are being raised by the presence of at least two ophthalmologists in the United States who are not waiting for Food and Drug Administration approval of a major brand-name excimer laser before performing excimer laser in-situ keratomileusis (LASIK) on hundreds of patients. Their "homemade" or custom-made lasers are sending lawyers, federal regulators, major laser manufacturers, and medical societies scrambling to discover exactly what is going on, who is doing what, and what, if anything, should be done about it.

Frederic B. Kremer, MD, of Philadelphia, Pennsylvania, and D. Stephen Hollis, MD, of Columbus, Georgia, are both using excimer lasers that have not undergone FDA trials and have not received formal FDA approval. Both physicians say they are operating their lasers under an FDA exemption in a custom device category. But the FDA says these lasers do not meet the legal definition of a custom device and should undergo formal FDA review.

The FDA has been investigating Kremer for months and the investigation remains open. The agency was unaware of Hollis' activities until late April, according to sources within the FDA, but the agency has now opened an investigation into his operation as well.

"In our opinion, physicians who use such modalities are not in compliance with the Food, Drug and Cosmetic Act," said Eric Latish, Chief of the Dental, ENT, and Ophthalmic Devices Branch of the FDA's Division of Enforcement, "but because of the lack of complaints, injuries, or problems being brought to our attention, there does not appear to be an overwhelming public health issue; but there is the potential for it to be a public health issue, and that is why we cannot ignore it."

"I am looking forward to them coming," Hollis told *The Journal of Refractive Surgery*. "I decided I needed to do what was in the best interest of my patients. I had lost confidence in RK. Either I needed to switch to LASIK or I was out of business because I could not bring myself to do the old procedures." Kremer refused to be interviewed for this report, although he did speak publicly about his work at the ISRS (formally ISRK) Pre-Academy Symposium in California in October, 1994.

Kremer, who holds a degree in engineering from Drexel University and a medical degree from Thomas Jefferson University, designed and built his laser himself, according to officials within the Kremer Laser Eye Center where the device is used.

Kremer has used his custom laser for more than 2 years and has performed more than 400 Laser-K_{sw} procedures, the term he uses for his version of LASIK, according to John Sloat, an optometrist in Kremer's center, who talked about the procedure with a potential patient who contacted Kremer's center at the request of *The Journal of Refractive Surgery*. Kremer charges $2950 per eye, but encourages patients to have the procedure done on both eyes at the same time and offers patients a $250 discount if they agree to the simultaneous surgeries.

Hollis charges less than half as much: $1350 per eye, and prefers to perform the surgeries at least 1 day apart. He operates his excimer laser at The Hollis Eye Institute, claiming the same FDA custom device exemption. He began using his laser in February 1995 and had treated more than 250 LASIK patients by early May, according to a source within his office. "Our machine is not required to have FDA approval because it is a custom-made medical device," Steven Hickman, RN, told a potential patient who contacted The Hollis Eye Institute on behalf of *The Journal of Refractive Surgery*. Hickman said, "The FDA is dragging their feet" on approval of lasers in the US.

In the initial discussion with a potential patient, Hickman did not offer the information that the laser was not FDA-approved until the patient specifically asked about the laser's FDA status. Kremer's Sloat did offer, in the initial discussion about the procedure, that "this is an excimer laser which is not FDA-approved at this point." When questioned further about FDA status, Sloat said the FDA is "in constant contact with Dr Kremer. They are aware that he built it, and it is actually with their approval under that [exemption] specification."

On page four of his informed consent, Hollis warns patients that "his custom excimer laser, and its use to perform the Laser Intrastromal Keratomileusis procedure, is not being studied by the FDA and the FDA has not approved either this device or the particular procedure. If the issue of Dr Hollis using a custom-built excimer laser or non-FDA approval is of concern to you, then you should not have the surgery."

"I think people should be free to enter into contracts with each other without interference from the government, as long as they are properly informed," Hollis told *The Journal of Refractive Surgery*.

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

ARE THESE LASERS LEGALLY CONSIDERED CUSTOM DEVICES?

A serious disagreement exists about whether these lasers actually qualify as custom devices under FDA regulations. Both Hollis and Kremer say they do, but sources within the FDA and some legal experts, such as attorney Johnathan Kahan of Hogan & Hartson, Washington, DC, who has represented more than 400 device companies before the FDA and offers legal advice to major laser manufacturers such as Summit Technology, say the category does not apply. "There is a specific provision for a custom device exemption, but it is very, very narrowly viewed by the FDA," Kahan said.

"We do not consider them to be custom devices," said Latish. "This is not an exemption for which you apply; you just meet all the criteria in the statute and regulation. If you meet them all, and these [lasers] do not, you have truly a custom device." The preamble to the Act is even clearer about limiting the custom device exemption. "Congress said it was not just a loophole for getting products out" into the market without FDA approval, Latish said.

The definition of a custom device under FDA 21 CFR 812.3 describes a device that necessarily deviates from devices generally available in order to comply with the order of an individual physician; is not generally available to or used by other physicians; is not generally available in finished form for purchase or dispensing upon prescription; is not offered for commercial distribution through labeling or advertising; and is intended for use by an individual patient named in the order of the physician, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician in the course of professional practice.

"Even if the doctor builds the laser himself," said an FDA official, "that does not necessarily mean it is a custom device, if he has used prefabricated parts and just put them together. If he is going to manufacture his own laser and manufacture his own components, in effect inventing a new instrument, then that might be a custom device and largely unregulated. But if he just imports the pieces from some company overseas and puts them together in a standard system, then that is not a custom device."

"A custom device does not apply to a physician; it is a device that is being distributed by a *manufacturer* for a specific custom use," Kahan said. Instead, Kahan calls these lasers "home-brew" products. "If the physician just built the laser for his own practice, is not distributing it to anyone else, is not moving it in interstate commerce, and just treats his own patients under the practice of medicine, FDA typically leaves him alone. However, if a *company* did that, the FDA would be all over them."

Another renowned Washington attorney takes a somewhat different view. Although not directly commenting on the specific cases involved in this discussion, attorney William Appler, who has handled FDA cases for more than 20 years and recently rendered a legal opinion in support of a California company importing used lasers into the US, said a "custom device is something [a physician] builds, buys, or otherwise uses for his own practice, and which is not used beyond that practice, and is as clearly legal as anything in the Food, Drug and Cosmetic Act. Not only is there a section of the Act that says that, but there is a good bit of legislative history that supports it, and FDA has a regulation permitting it."

CUSTOM DEVICE EXEMPTION OR A PRACTICE OF MEDICINE ISSUE?

The legal debate extends beyond the battle over the custom device exemption and into other sections of the act that grant certain parties, such as physicians, exemptions from registration requirements—and touches on issues involving the practice of medicine. "Technically, we believe true physicians are exempt from registration; however, the product or device still needs to be cleared under the 510K process or needs to be subject to a controlled study, classically an IDE (investigational device exemption) to demonstrate its safety and efficacy," said the FDA's Latish. "We believe the [physicians using such devices] are not exempt; however, they believe they are."

How then are the lasers being permitted to continue to operate? In part, because the legal debate and discussions continue between the FDA and the physicians using the lasers, and because the FDA does not have evidence of serious harm being done, the agency has so far not issued immediate cease and desist orders. "We understand the need for creative modalities and we do not want to be an obstacle to the clinical practice of medicine," Latish said, "but there are certain safety and efficacy questions which naturally arise when someone fabricates something as complicated, complex, and delicate as a laser when other firms go through the IDE PMA process with teams of engineers and quality control and have trouble executing an acceptable design. We have great concerns about that. Right now [the noncompliance] appears to be more administrative than hazardous, but that is just the appearance. We do not know."

"There is an imminent but not an established health risk," Latish said. "We believe, by the fact that there were no clinical studies, or we have not had the opportunity to review the clinical studies if there have been any, and since we have not been able to review the design, the function, or the physical characteristics of the product, which is what we typically do, that there is a possibility that injuries will occur." If reports of injury were to reach

the FDA, "you better believe we would get out there immediately and administratively detain the product pending a seizure, and then seize it and take it out of commercial channels. But there is no information to suggest that is occurring."

INTERSTATE COMMERCE AND ITS LEGAL IMPLICATIONS

Another key element in the FDA review will be the involvement of interstate commerce. Sources within The Hollis Eye Institute say the laser engineer or company that manufactured the Hollis laser in Georgia used major components from West Germany and plans to build 10 more lasers in different states. The source says the Hollis device is part industrial laser made by LambdaPhysik, a reputable German laser manufacturer. "The custom part of the [Hollis] laser is the delivery system, which was built in the United States," Hickman, the Hollis RN, explained to a potential patient who asked about the device. "The laser is a West German industrial laser and is basically the same laser that ITT would use to cut computer chips or Southern Bell would use to strip cables." Engineer Ed Sullivan from New England and his company, which Hickman identified only as Laser Tech, imported the laser and added a modified delivery system, Hickman said.

"That would make [the manufacturer of the Hollis laser] a manufacturer of medical devices," Latish said, and subject to much stiffer regulations.

An FDA official says the agency could also get involved "if the laser is an example of a device that is being regulated [by the FDA], or if it is a new device that some company is trying to get approved for market and somebody puts together an equivalent, or substantially equivalent device, for the purpose of getting around the regulations."

The proposed sale of additional lasers by the same company that built the Hollis laser "may raise issues not otherwise raised," said attorney Appler, but does not necessarily push those lasers out of the custom-device category, he said. "If 10 different doctors contact a manufacturer who has excess capacity and ask that company to build something for their own particular practice, there is nothing wrong with that," assuming there is proof that it was the doctor who initiated the transaction, Appler said.

Attorney Kahn disagrees, saying "it doesn't matter" who contacts whom. If the "company is introducing into interstate commerce a medical device, or a component of a medical device, with an intended use which has never been cleared by FDA, that is illegal," he said.

What about patients who are crossing state lines to receive the treatment? Does that raise the interstate commerce question with the FDA? Some attorneys say no; the FDA regulates devices, not the movement of patients. But the FDA "has argued in the past that if someone crosses a state line to receive service, that laser or product is being offered for sale, and each time the physician uses it he is entering into interstate commerce," Latish said.

FELLOW OPHTHALMOLOGISTS TAKE SIDES—PRO AND CON

Word of the custom-made excimer lasers has quietly spread through the ophthalmic community, often in the form of whispered discussions and unsubstantiated rumors and conjecture. Both Hollis and Kremer have their supporters and detractors. The American Academy of Ophthalmology said in April it was not officially aware of the physicians' activities and had no published position—for or against—the use of nonapproved lasers. One staff member explained that the AAO does "address devices which are FDA approved, but we do not address a whole host of unknown evils." Upon learning of the existence and use of the lasers, one of the AAO Interest Groups immediately planned to discuss the situation at its next session.

A decision has also been made to put the issue on the agenda for the summer meeting of an FDA panel. This panel could take a position that would increase pressure on the compliance arm of the FDA. That could lead to a tougher interpretation of the regulations and a crackdown on the use of the nonapproved lasers. Attorney Appler admits "the agency is so short of money that it simply cannot enforce everything it believes is a violation of the law. So a lot of things go on. The overwhelming issue is, would this raise some sort of health hazard or health risk to the public?"

"We do not have the authority to tell a doctor not to use a device, unless there was determined to be a health hazard under the Act," said an FDA compliance official. "If the doctor is determined to be a hazard under the Act, then we have the authority to tell him to cease. Otherwise, we can tell him he is in violation and subject to seizure, injunction, and civil penalties."

Some ophthalmologists support Kremer and Hollis and understand their frustration with the FDA. Excimer lasers that have been approved and used for 3 or 4 years overseas are still mired in clinical trials and FDA administrative deliberations in the US. A number of patients are fleeing to Canada and elsewhere to undergo procedures their own US doctors want to perform but feel they legally cannot.

"It is within the purview of the individual ophthalmologist to do this," said Richard L. Lindstrom, MD, Immediate Past President of ISRS, commenting on the use of custom lasers. "I think it is fine and an appropriate avenue for select investigators. It is very much like an orphan drug."

"Lasers are not an orphan product," said the FDA's Latish, "so the treatment IDEs," which might provide another legal avenue of investigation, "do not appear to be a viable alternative even for clini-

cians who have not had safety problems, appear to know what they are doing, and are truly interested in treating patients and not commercializing a product."

If the custom lasers are "an appropriate avenue" of investigation, why is Lindstrom involved in formal, very restrictive FDA studies and not already practicing with a custom-made device? "We predict we are going to have an FDA-approved laser by January 1996, which is only months away," Lindstrom said. "So, for a few months head start, it just does not make sense for most ophthalmologists to buy a custom-made laser. Once FDA-approved lasers, which have been through full FDA studies, are available, these doctors will find themselves in a position of using an investigational laser and will need to justify that to their patients. Six years ago, it might have made some sense, but it does not seem to make a lot of sense today."

Hollis was not initially interested in using a custom laser, he said, because "I wasn't willing to put up with the FDA hassles. Even though you are right, you still have to fear the government because the government does not have to be correct. I can be totally within my rights, but the government could make me wish I was wrong." Hollis admits that once a major, brand-name laser is FDA approved for LASIK, "I'd like to be the first to buy one."

"The doctors may be making a simple statement about their own personal frustrations with the FDA time lag and the fact that they cannot provide their patients with the best we have to offer in terms of refractive correction," said one ophthalmologist who is performing LASIK outside the US and knows both Kremer and Hollis. "I have confidence they are not going to do anything they do not think is right."

But sources within the FDA say doctors using nonapproved lasers may be "trying to get around the regulations associated with an IDE (investigational device exemption), because an IDE involves a big effort and expense and they just want to do these procedures on patients. A lot of ophthalmologists consider the technology to be sufficiently proven to go ahead and practice. It is being done on a large scale in some other countries, but we feel there are still some serious questions which have not been answered yet."

JUSTIFYING THE USE OF A NONAPPROVED LASER BEFORE A JURY

The possible legal liability to which these lasers expose their operating physicians is another serious, inescapable issue. "They have serious malpractice concerns because they are using an unapproved product," said attorney Kahan. "They would have to have a strong, reasonable basis in the literature for doing this, and if they blinded someone, they would

"If a physician has a problem while using one of these lasers and gets sued, it would be awkward, in my opinion, to justify why he was using this custom-built, investigational laser, when he could buy a fully FDA-approved laser. I think he would be fairly vulnerable," Lindstrom said.

Some of the legal exposure could be minimized by making certain the status of the laser is clearly spelled out in the informed consent, according to attorney Appler. "If a patient [sues], he is going to have, comparatively, a lot of trouble showing that he is entitled to damages for injuries caused by the fact that this device is not approved," Appler said. "The informed consent reduces the risk of liability," but does not mean the patient cannot sue; "the bar being what it is today, you can count on that kind of suit."

"A patient typically believes when he goes to a physician that the products being used have some sort of clearance and approval," said the FDA's Latish, "and here is the physician using an untested modality. If you have informed consent, at least the patient knows, but just because the patient knows he is a paying guinea pig, that does not prevent or preclude the danger."

INVESTIGATIONS BY THE FTC INTO PROMOTIONAL CLAIMS

The advertising of these lasers moves the debate beyond the FDA and into the realm of the Federal Trade Commission (FTC). "If it is legal to use the device, it is legal to advertise it," according to attorney Appler. But the advertising of these lasers is also steeped in controversy.

Because the FTC is already deep into an investigation of the advertising of routine refractive surgery nationwide—checking to see if physicians are violating the federal law that prohibits false or deceptive advertising—it stands to reason the agency might take particular interest in any claims made in regard to lasers not yet approved by another federal agency.

In the past, "the FTC has almost always required two or more randomized, controlled trials in order to prove specific claims for medical devices," according to Appler, "and I suspect no one has done those trials. So I would be leery of a comparative claim on a custom device. The argument against it would be a pragmatic one. The FTC is accustomed to stepping on comparative claims, no matter how they originate."

Yet both Hollis and Kremer fill their material with claims about the superiority of their procedures, although Hollis says he does not advertise. "I do not advertise for patients or go to doctors to get them to send me patients. I think there is some risk in advertising" a device that is not formally approved. "I think it would be waving a red flag to a charging bull, as far as the FDA and FTC are

want his consent to speak with *The Journal of Refractive Surgery* construed in any way as an attempt to solicit patients or referrals.

One professional group, the American Society of Corneal and Refractive Surgery (ASCRS), has adopted voluntary guidelines that warn against making any claims that cannot be backed up by evidence, stating that physicians should not promote devices or drugs as approved by the FDA or promote treatments not yet approved by the FDA as safe and effective. The AAO has no clear guidelines on the use of nonapproved lasers, but has begun a discussion of the issue.

The glossy brochure sent to patients by the Kremer Laser Eye Center has only six words printed in big, bold letters across the front: "See Without Glasses . . . Or Contact Lenses." Inside, the brochure outlines some of the benefits of refractive eye procedures, inviting patients to "*enjoy freedom from glasses and contact lenses*" [emphasis is brochure's], and "improve your ability to do your job, and potentially raise your income." On page three, patients are told "*success is very likely*," and, "It's estimated that over one million refractive procedures have been done in the USA." These are exactly the kind of claims being targeted by the FTC.

It is only on the next to the last page of the brochure, midway through a paragraph in very small type, that patients are told "some patients may still need glasses; for example, a thin pair for things like night driving."

Laser-K_{SM} is described in the brochure as being developed by Dr Kremer. It says the procedure is the "*most advanced procedure available to correct nearsightedness, farsightedness and astigmatism.*" It claims Laser-K_{SM} "is generally more accurate and has fewer side effects than ALK. It decreases or eliminates the fluctuations in vision and star bursts (or night glare) sometimes seen with conventional RK. Laser-K_{SM} is more comfortable, more accurate and gives more rapid vision improvement than standard excimer laser surface ablation."

At the end of the section on Laser-K_{SM}, the brochure states, "Our instrumentation is in the FDA category of physician exemption-custom device. At the time of this printing, manufacturers of excimer lasers are seeking FDA approval."

In a newsletter produced by Kremer's marketing firm, Laser-K_{SM} is said to be "more accurate, more comfortable, and heals and stabilizes more quickly than previous techniques." Over and over, the procedure's superiority to other refractive procedures is touted.

"The more egregious their advertising and promotion, the more likely the FDA, FTC, or state authorities are going to come after them," said attorney Kahan.

In the full page hand-out distributed by Hollis, his laser intrastromal keratomileusis is described as "a procedure that Dr Hollis performs using a custom laser developed solely for his patients in his practice." It says the procedure "is much more comfortable for the patient than radial keratotomy. Laser intrastromal keratomileusis (LASIK) patients regain their vision more quickly than with any other refractive surgery."

As part of the informed consent document, Hollis outlines the possible risks, full range of complications, alternatives, and benefits of LASIK. He also states that LASIK "is a significant technical advance" and has been "successfully performed on hundreds of patients by Dr Ruiz in South America, including Dr Hollis himself, who has had the Laser Intrastromal Keratomileusis procedure performed on one of his eyes." It does not mention that Hollis' surgery was not performed using the custom device he now uses on his patients.

Hollis' informed consent also states that LASIK "is an experimental surgical procedure that is currently under investigation by experienced ophthalmic surgeons in the United States, including Dr Hollis." However, Hollis' investigation is not part of those other highly regulated US FDA investigations. Instead, his study uses his own protocol using his own laser, and has not been published or reviewed by an Independent Review Board, according to Hickman.

The final battle between the FDA and the physicians using the homemade lasers may well be waged in the courts. "I do not know what the resolution will be," the FDA's Latish said. The physicians "could just stop using the lasers, but I do not think that is going to be a viable option to the clinicians. So, if we cannot reach a consensus, it could ultimately be left to the courts to decide the interpretation of the law."

The wait for FDA-approved excimer lasers for refractive surgery has been long and frustrating for ophthalmologists practicing in the US. They have watched as their patients traveled across the border and paid thousands of dollars to other physicians operating just beyond the long arm of the FDA. Most have resigned themselves to a system they do not always like, but which they recognize often provides necessary safeguards against danger.

LISA A. KEARNS
News Reporter

FRIEDMAN

News

FDA Begins to Act Against Unapproved Excimer Lasers: What Took So Long?

At the Food and Drug Administration's (FDA) Ophthalmic Devices Advisory Committee Panel meeting held this past July, Susan Alpert, PhD, MD, laid down the law on unapproved excimer lasers. The question is, will they enforce it; and if so, when?

According to Alpert, Director of the FDA Office of Device Evaluation, there are no custom excimer lasers. Home built, black box, custom built lasers—whatever term you choose—they don't qualify as custom devices under the Food, Drug, and Cosmetic statutes. Devices that do are of types not generally available in finished form, are intended for use on an individual patient, and are made in a specific form for that patient. Or, they must meet the special needs of a practitioner and be not generally used by other members of the same profession. Alpert said, "Devices such as excimer lasers clearly don't fall into that category. They are clearly not for individual patients and they are clearly of a type that is generally used by practitioners of ophthalmology."

Imported lasers, manufactured for use outside the United States and later imported back in, also

In the wake of this hearing, ma left wondering why the FDA dela it moved against unapproved laser promised for release 2 to 3 weeks the agency waited close to 3 mont ing any further information on the until October 10, 1996, did the FD lines for the process. In a letter sig Lillian J. Gill, Director, Office of agency announced that owners of lasers, whether homemade or imp January 15, 1997 to identify thems obtain information about the IDE process, and submit an IDE applic

One prominent ophthalmologis expressed an erosion of confidenc many of those practicing within II porting clinical and regulatory em with necessary paperwork, and ma sive databases, he is unhappy with proved lasers. He said that short o ters and warnings, the FDA has dc

are unapproved unless the importer shows they are identical to approved Summit and VISX models. And users of unapproved lasers, whether imported or home built, face significant liability.

But, Alpert said, the FDA is giving everyone with an unapproved laser a chance to come into the fold. Her agency will work with users and importers of unapproved lasers to identify the requirements that they must meet for compliance. She proposed a two-tier moratorium program. One tier will be a short grace period during which affected individuals can contact the agency to find out what to do to submit an investigational device exemption (IDE) application or Premarket Approval Application (PMA). The second part will be a period for submissions made by individual or companies. Alpert said, "All will be expected to meet the law. We will publish the time periods."

After the moratorium ends, Alpert continued, the FDA will take action against illegal products with warnings, seizures, and injunctions.

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It has taken probably longer than

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have expected but I don't think people anticipated the nuances in this matter to be so difficult."

Despite numerous complaints from industry and ophthalmologists over the past two years, the agency has also been slow to act on imported lasers. It only issued an import alert against used Summit lasers last February. As a result, the US Customs Service reportedly detained a number at their point of entry. And, recently one importer has agreed to comply with FDA requirements.

Finally at the July meeting, Alpert announced that the FDA is working with the **Society for the Advancement of Laser Technology** (SALT) on a certification process for importers to demonstrate that

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The FDA did hold to its promise of a certification process. The October 10 letter also gave owners of imported lasers—if the laser was originally manufactured by the holder of an FDA-approved PMA—the option of certifying that the laser is identical to the approved ones. Owners are advised to have their lasers certified quickly; if the FDA rejects the certification, then the owner must still hand in an IDE application by the January deadline. Waxler said that the FDA established the certification process without further input from SALT beyond what that organization gave prior to the hearing.

Meanwhile many users of homemade and imported unapproved lasers argue that the FDA view distorts existing regulations and statutes. One longtime consultant in the East claimed that custom lasers do indeed exist and are devices that differ from the lasers approved by the PMA process. He added that the FDA position turns the regulation on its head. "The regulation says you have to deviate from something on the market. Alpert is saying if there is something on the market, you cannot have a custom device."

But some physicians represented by the consultant have opted to enter the amnesty program, and he has worked out general terms with the FDA on

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1. Moretti M. Federal action aims to
the border. Ocular Surgery News

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Wake Forest University Eye Center

Unapproved Lasers for the Treatment of Refractive Errors

The FDA and the Approval Process for Medical Devices

The United States Food and Drug Administration must, by law, regulate medical devices that are involved in interstate commerce. Excimer lasers that are used for the correction of refractive errors are included under the FDA's jurisdiction.

To gain FDA approval, manufacturers must submit data to the FDA proving that the devices they manufacture are safe and effective for their intended use. The law does not require that they function perfectly and achieve perfect results every time they are used, but it does require that the potential benefits of the device outweigh the risks.

In order for the FDA to decide whether a device should be approved or not, data about the device's performance must be submitted and analyzed. These data are gathered under an experimental protocol called an Investigational Device Exemption that is approved by the FDA. Typically, an Investigational Device Exemption permits the use of an unapproved device for the treatment of a limited number of patients according to a carefully planned experimental protocol. The experimental protocol is reviewed by a Human Investigations Committee composed of impartial individuals whose job is to protect experimental subjects from unreasonable risk and be certain that they are appropriately educated about the experiment in which they are about to participate.

The FDA believes that information from about 500 eyes followed for two years after excimer laser treatment are required to be certain that the laser is safe and effective for the correction of refractive errors. The approval process is long, tedious, and expensive--but it is intended to protect the American public from the health hazards posed by defective instrument design and operation. Thus far, only Summit Technology's Apex Excimer Laser System and VisX Inc.'s Model B and Star 20/20 Excimer Laser System have received FDA approval for the correction of refractive errors.

Unapproved Lasers

During the past several years, several ophthalmologists in the United States have placed unapproved excimer lasers into operation. These devices have been manufactured by individuals who believe they do not come under the jurisdiction of the FDA. There is no assurance that these devices will operate safely or produce the intended change in refractive error of the eye.

The FDA has stated that it believes these unapproved excimer lasers are being operated illegally, but the legal process that is required to prevent their operation is complex and lengthy. Therefore, the time between the placement of unapproved lasers into service and the time when the FDA acts to prevent their use may be long. The first step in this process is the issuance of Warning Letters informing the laser operator that he or she is operating outside of the law.

There have been reports of serious eye injuries from the use of unapproved "black box" lasers.

Caveat Emptor

If you are considering vision correction with the excimer laser, ask whether an approved excimer laser will be used for your surgery. Suspect that an unapproved laser might be used if the cost of the procedure is below that charged by other providers in your area. If the laser is unapproved, find out who manufactured it and how much is known about the results that it produces. Was the laser built in an appropriate manufacturing facility with stringent quality control, or was it built elsewhere? Is it one-of-a-kind (a so-called "**black box**" laser) , or is it one of many that have been operating successfully. Has the operator of the laser received a Warning Letter from the FDA?

Find out about the research experience of the physician and the institution that has reviewed the experimental protocol. Are you dealing with well-known, reputable professionals who command the respect of their peers or someone that does not? Does your surgeon know his results and publish them in peer-reviewed scientific journals?

If you don't feel comfortable with the answers to these questions, consider another opinion--and another surgeon.

Back to the Home Page

Last updated Monday, May 04, 1998

EXHIBIT "D"

Quackwatch Home Page

Refractive Surgery

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Surgical procedures now make it possible to permanently eliminate or significantly reduce the need to wear glasses or contact lenses, even for people with very large refractive errors that require thick lenses. Appropriate surgery can modify the eye to enable light rays to converge properly on the retina. Various operations can reduce or correct nearsightedness, farsightedness, and astigmatism.

Modern refractive surgery became popular in the United States through radial keratotomy (RK), which was introduced from Russia in the early 1980s. In this operation, incisions made in the outer part of the cornea cause the central part of the cornea to flatten. This can correct a mild degree of nearsightedness.

Initially, even though the procedure looked promising, many eye surgeons cautioned that there were no long-term data showing that the procedure was safe and likely to improve vision permanently. Many authorities also objected to the idea of operating on healthy eyes when the use of eyeglasses or contact lenses could enable them to see adequately.

In 1990, the Journal of the American Medical Association published the Prospective Evaluation of Radial Keratotomy (PERK) study of about 400 patients, most of whom had been followed for four years [1]. About two-thirds of the patients achieved their goal of eliminating glasses or contact lenses, and nearly all of the others improved considerably [2]. No severe complications occurred. Many patients reported seeing radiating light (flare) around light sources such as headlights or street lights at night. In most cases, this diminished as time went on. Most patients reported that it did not interfere with their normal activities, but some said it interfered severely with night driving. A ten-year follow-up study of 374 of the patients found that 70% said they did not use corrective lenses for distance vision and 53% had 20/20 vision without glasses [3].

We now know that the accuracy of this operation can be increased by varying the incisions according to the patient's age. In 1993, the American Academy of Ophthalmology noted that about 10% of ophthalmologists were doing RK, that hundreds of thousands of procedures had been performed, and that the operation usually improved the vision of patients with non-progressive low and moderate amounts of nearsightedness [4]. Today RK is used mostly for small myopic refractive errors, especially in older patients in whom the operation is more effective. The required incisions are small and far enough from the center of the cornea that postoperative flare is uncommon. Mild to moderate degrees of astigmatism can be corrected by astigmatic keratotomy (AK), in which arc-shaped corneal incisions are located far enough from the optical axis to make postoperative complications unlikely.

Newer techniques involving computerized assessment, precisely calculated cutting patterns, and lasers have made refractive keratotomy more predictable. Computerized topography can be used preoperatively to determine the best procedure and postoperatively to determine whether additional correction might be indicated. The newest apparatus measures the true elevation of the cornea and gives the surgeon an accurate topographic picture of the corneal surface [5-7]. The newer operations include the following.

Photorefractive keratotomy (PRK): An excimer laser is used to correct low to moderate degrees of nearsightedness. The correction is fairly precise but not completely predictable.

The recovery period varies, and the final refractive state may not be known for three to six months. During the procedure, the corneal surface is removed, which means that the eye will be very painful for a few days until the cornea regrows. Haziness of the cornea (with cloudy vision) is common for a few months, but goes away eventually in most cases. This procedure is being phased out by most surgeons in favor of LASIK surgery 8-12].

Automated lamellar keratoplasty (ALK): The cornea is reshaped by a microkeratome, a precise mechanical instrument that peels an outer flap and then removes a calculated amount of material from underneath. The outer flap is then put back into place and adheres firmly after just a few minutes. This operation can correct high degrees of nearsightedness. Since the corneal surface is not removed, there is little if any postoperative discomfort. However, this procedure is seldom used today because LASIK surgery is more accurate.

Laser in-situ keratomileusis (LASIK): The outer corneal flap is made as in ALK, and an extremely precise underlying cut is made with an excimer laser [13]. Each laser pulse removes just 0.25 microns of tissue (1/100,000th of an inch). LASIK techniques can be used to correct astigmatism and farsightedness as well as myopia. The results are nearly always predictable. There is usually no operative pain or postoperative discomfort. This operation is preferred throughout the world by eye surgeons who have sufficient experience and have access to the necessary equipment. Several eye-surgery centers in the United States have FDA approval to perform LASIK surgery, and many individual ophthalmologists are performing LASIK with laser devices approved by the FDA for PRK. LASIK is effective in a wide range of refractive errors (-15 to +5) and for up to 5 diopters of astigmatism. Excellent results have been reported [14-21].

Lens replacement: For people who are farsighted or severely nearsighted, an alternative approach is replacement of their natural lens with an artificial lens of a more appropriate power [22-27]. This is essentially the same operation as cataract surgery, an operation that has been perfected. In patients who are beginning to develop a cataract or who are within the older cataract age group, this approach is logical. In patients with extremely high refractive errors, it is often the best choice.

Phakic intraocular contact lens implantation: A special lens is placed either in front of or behind the iris so that it works with the eye's natural lens to bend the light rays more appropriately. In younger patients this procedure preserves the ability to focus. Some problems have been reported, but the most refined form of this procedure looks promising. It is being actively investigated and has been gaining acceptance worldwide. Only a few patients have been treated in the United States under an FDA protocol thus far.

Benefits vs. Risks

People contemplating refractive surgery should discuss the potential benefits and risks with an ophthalmic surgeon who is well regarded by the medical and optometric communities. As with any type of surgery, complications can occur. With corneal procedures, it is not unusual for the patient to experience flare around lights at night, especially younger patients who have large pupils. Undercorrection or overcorrection may occur and may necessitate a second "enhancement" procedure. Sometimes glasses may be required even after this surgery; and rarely, corneal irregularity may require even continued use of contact lenses.

With LASIK, complications in the cutting of the corneal flap can lead to corneal irregularity. Sometimes

wrinkles occur in the cap, requiring lifting and refloating of the cap; and sometimes corneal epithelial tissue grows under it and has to be removed. The excimer laser ablation itself could be off-center, resulting in reduced vision, halos around lights, and astigmatism.

Lens-replacement surgery carries with it the possibility of all the complications that could occur with cataract surgery, such as infection, bleeding, and retinal detachment. These are rare nowadays, but all patients who have lens-replacement surgery lose the ability to focus for near vision and must wear a reading glass unless one eye is purposely left focused for near vision (monovision). One advantage of lens-replacement surgery is that these patients will never develop a cataract. The phakic lens implantation bears with it the rare possibility of infection and also of producing a cataract that eventually requires cataract surgery.

Satisfaction with modern refractive surgery is very high, and complications are rare. Most patients do well, gaining a whole new world of freedom from dependence on eyeglasses or contact lenses. Even so, the risk involved may not justify the use of surgery if adequate vision and comfort can be achieved with eyeglasses or contact lenses. Individuals who wish to explore the possibility of refractive surgery should seek a qualified eye surgeon who is thoroughly experienced in the various procedures.

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For Additional Information

- LASIK Institute

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This article was revised on April 24, 1999.