LEGAL ISSUES IN LASER CENTER CO-MANAGEMENT

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SYNOPSIS

Because of the cost and hype accompanying the excimer laser, PRK and LASIK present new risk management challenges to the ophthalmic surgeon. Some lessons can be learned from prior radial keratotomy lawsuits. New problems arise, however, from the increased use of co-management, the cost of laser ownership, and the marketing that many feel is necessary to support a viable practice. Professional liabilty concerns are examined, and practical suggestions made for reducing the refractive surgeon's exposure to malpractice lawsuits.

I. LESSONS LEARNED FROM RADIAL KERATOTOMY LITIGATION

A revolution began in the field of ophthalmology when refractive surgery was introduced into the United States in 1979. Many ophthalmologists were involved in the turmoil of the early 1980's that accompanied a radial keratotomy practice, but more were not. There were lessons from that era, however, that can help the refractive surgeon involved in the ophthalmic revolution of the 1990's - the excimer laser.

The question posed by many ophthalmologists in the 1980's was "is it appropriate to operate on a healthy, albeit myopic, eye?" That debate has largely gone by the wayside, and has not been the same impediment to the excimer laser that it was for radial keratotomy. This may be a sign of healthy advancement of the medical art, but it can also pose a danger to the ophthalmologist. The skepticism that greeted radial keratotomy over a decade ago forced responsible practitioners of refractive surgery into rigorous introspection. Most surgeons with a substantial refractive practice carefully analyzed their cases, hoping to fine-tune their technic, improve their results, and lower the number of avoidable complications. This critical analysis led to advancements in refractive surgery that aided patients and physicians alike, refining techniques and instruments, and improving results. Even though today's

laser surgeon is not likely to hear the same questions regarding the propriety of refractive surgery, they should not forget that the procedure is a new and developing one, and they could likewise benefit from skepticism and introspection.

This is particularly true because the excimer laser is driven by a force that did not accompany radial keratotomy. Non-physician businessmen and investors stand to benefit from proliferation of the excimer laser far more than was the case with radial keratotomy. The expense of the machine and the costly FDA approval process required involvement by the business and investor community that was not necessary for the diamond scalpel and ultrasound pachymeter. These investors and business people are now expecting the promised return on their investment, creating a marketing pressure to put as many machines as possible into operation.

Ophthalmologists are now feeling this pressure, accompanied by promises of results and success that have been questioned by some. Ophthalmologists should recognize that these marketing forces exist, they are likely to affect the way the product is presented to the eye surgeon, and will also affect patient expectations as well. Exercise some critical analysis.

Another lesson learned from a number of RK malpractice trials has to do with advertising. Over-promotion of the procedure through aggressive advertising campaigns which promised that patients could "throw away their glasses" or "eliminate the need for glasses" tended to backfire in the event of a bad result. Plaintiffs' lawyers

were always anxious to get the advertising in front of the jury, and if there was a chance that the plaintiff had seen the ads, the judge usually admitted the advertising into the trial. Such promises were difficult to reconcile with the more dour informed consent forms, and at least two juries decided in favor of the plaintiff on the question of whether the advertisements promised more than the surgeon could deliver. One of the juries awarded several million dollars on a claim that relied heavily on the advertising promises, dealing the surgeon a terrible personal financial blow. Remember that the advertising executive pitching the campaign will not be on the witness stand, but you will. Judge the ad copy accordingly.

II. CHOOSING THE LASER : FDA—APPROVED, GRAY MARKET OR "BLACK BOX"

Selecting the excimer laser manufacturer is itself a difficult task. Choosing the VISX or Summit laser may restrict the surgeon's ability to customize their surgery, and preclude the performance (at least contractually) of the LASIK procedure. Choosing a gray market laser may land the surgeon in the middle of a lawsuit, either an intellectual property claim from the Pillar Point Partners or an FDA enforcement action.

The FDA-Approved Laser

The FDA-approved lasers were required by the terms of the approval letter to be used only within strict parameters.[1] The Pre-Market Approval (PMA) letter said the device was indicated for myopic photorefractive keratectomy (PRK) using a 6mm ablation zone in patients 21 years of age or older, with 1.5 to 7.0 diopters of myopia and 1.5 diopters or less of astigmatism. The refraction had to be stable -- within 1 diopter or less -- for one year before the laser treatment, and the Patient Information Booklet recommended at least a three-month wait between eyes (no bilateral PRK). It further stated that the restrictions on the use, labeling, promotion and advertising of the device were applicable not only to the manufacturer, but also to device purchasers and users.

This statement was a bit out of step with prior FDA announcements that the agency would not dictate how a physician practiced medicine: "Once a [drug] product had been approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling."[2] Apparently the FDA recognized this inconsistency and, in conjunction with the Federal Trade Commission, issued a statement to the "Eye Care Professional" on May 7, 1996 which clarified their position. "The FDA considers the practitioner's discussion of bilateral surgery or LASIK with patients, as well as the decision to conduct either of these surgeries as the practice of medicine."[3] They added, however, that the "FDA also expects manufacturers and practitioners to promote these lasers only within the scope of

their approved intended use." Although the FDA cannot regulate the practice of medicine, they and the FTC do have jurisdiction over the advertising and promotion of this medical device. Questions about the advertising and promotion of the FDA-approved excimer lasers can be directed to the FDA's Center for Devices and Radiological Health, Promotion and Advertising Policy Staff at (301) 594-4639 or the FTC's Bureau of Consumer Protection, Service Industry Practices Staff at (202) 326-3270.

The Pillar Point Partners license fee is a source of dissatisfaction to most laser surgeons. The agreement provides that the technology (including patents) necessary to build the excimer laser is owned by the Pillar Point Partners (VISX and Summit) and is licensed by the partnership to VISX and Summit. The Pillar Point Partners also exacts a license fee for the use of the laser from every surgeon who performs the PRK operation in the United States. A licensing fee for use of patented or secret technology is nothing new, but most ophthalmologists are not used to it and don't like it. They are instead expect to buy a machine and have free rein to use it as they wish. Many surgeons object to what they feel is an unethical "method" patent which, although legal in the United States, is still controversial and is not legal in most other countries.

Pillar Point Partners responds that they should have the opportunity to recoup their development and FDA approval costs, which are considerable. The bottom line is that there are a lot of disgruntled surgeons paying the Pillar Point fee every time

they operate on an eye. This dissatisfaction has manifest in a few ways. The first is lawsuits by several physicians against the Pillar Point Partners, alleging anti-trust claims or counterclaims. Another method used by some surgeons is to circumvent the fee by purchasing a laser which is not subject to the Pillar Point fee. These are known as gray market or "Black Box" lasers.

Gray market or "Black Box" Lasers

"Gray market" laser is a term sometimes applied to a laser purchased from a market outside of the United States, and then brought onshore. Since many companies have been manufacturing lasers for years for markets outside the United States, these machines are readily available. Getting the machine through customs is not the end of the legal challenges for the surgeon, however, because the FDA and the Pillar Point Partners will not suffer these machines gladly. Some surgeons using the gray market lasers have been subjected to FDA inspections and threats of further prosecution.

The "Black Box" laser is a device which is custom-assembled to a surgeon's requirements by a company which provides the components separately. The purpose of the custom assembly is to fall within the "custom device" exception to the FDA's pre-market approval process.[4] This exception permits physicians to design equipment to meet their particular needs without having to go through the expensive and

time-consuming approval process. The FDA, however, has taken the position that the "Black Box" lasers do not qualify for the custom device exception and has threatened prosecution against users of the devices. Additionally, the Pillar Point Partners have made it clear that they consider the "Black Box" lasers an infringement on many of their patents, and are prosecuting the manufacturers and users of the lasers in civil actions.

Another exception to the FDA requirement for pre-market approval is the Investigational Device Exemption (IDE), which permits the use of non-approved devices in medical research.[5] The procedures for qualifying for the IDE are extensive and will likely occupy a good deal of time and resources. They will also only solve half of the problem, in that the Pillar Point Partners are still likely to prosecute a patent infringement action against the user. If the surgeon publishes the results of research conducted under the IDE, it will likely draw attention to the fact that they are using a "Black Box" or gray market laser.

Consequently, while the gray market and "Black Box: lasers have some advantages over the VISX or Summit lasers in terms of having fewer restrictions on their use, the surgeon using these machines must be prepared for a legal battle. Once the cases now at issue have been decided, there may be some clearer precedent to permit the surgeon to predict what they can and cannot do. Until then, however, legal fees must be factored into the decision to use the non-FDA-approved lasers.

In the event a surgeon does use the "Black Box" or gray market laser, they should let their patients know that they are not using an FDA-approved device. At

this time, surgeons are generally not required to inform patients of the FDA approval status of the devices they are using. This issue has been raised on appeals in California and Tennessee, in both cases over the use of pedicle screws in back surgery.[6] In those cases, the plaintiffs claimed they were not informed that the screws were not FDA – approved, and of the "experimental" nature of the screws. Although the respective courts may ultimately conclude that no claim exists for failing to warn of FDA approval status in the informed consent discussion, the cautious surgeon may be better off avoiding the controversy by letting the patient know. While such a warning is not a necessary precaution in most surgery cases, the heavy marketing involved for the FDA-approved lasers, the press' attention to the FDA's approval, and the elective nature of the procedure suggest a more conservative approach in laser surgery cases.

III. ADVERTISING AND MARKETING: FDA/FTC GUIDELINES, CONSUMER PROTECTION LAWS, FRAUD AND NEGLIGENT MISREPRESENTATION

FDA/FTC Guidelines

The risk of promoting or advertising the laser in a manner not approved by the FDA is that by doing so, the surgeon can be treated as a manufacturer by the FDA, and subjected to penalties. Consequently, any surgeon advertising their services

should be aware of the restrictions and requirements published by the FDA in their PMA letter. Some of the advertising requirements listed in the PMA letter included discussion of the results of clinical trials, the fact that long-term risks beyond three years are unknown, and a listing of the complications which could be expected. It also required that prospective patients receive the FDA's Patient Information Booklet.[1] Whether these requirements still apply is an open question in light of the subsequent pronouncements in the May 7, 1996 FDA/FTC letter. In that letter, the agencies merely stated that "Advertising or promotional materials that discuss efficacy or safety should also contain enough information about the risks and limitations associated with PRK to prevent deception."[3]

Information gathered from the FTC's investigation into certain RK advertisements suggests that any surgeon making a claim of safety or efficacy had better be prepared to back up those statements with objective research data. And not just any study will do. In the RK cases, the FTC seemed to be interested only in the results of the PERK study, one of the more artificially constrained studies ever done to evaluate RK. So before venturing into the fringes of advertising ethics, remember who you may be dealing with - a government agency that is well-funded, determined, and does not care about the importance of increased patient flow from your advertising campaign. One final word of consolation on advertising: many successful refractive surgeons report that their success was built on word-of-mouth referrals, not advertising.

Consumer Protection Laws

Many states have statutes to protect consumers from fraudulent advertising. Many of these are based on the Uniform Deceptive Trade Practices Act.[7] They can provide enforcement by either the state attorney general or in a private civil action. The deception, however, must be directed to the public at large, not one individual plaintiff. The statutes, although limited in application, can be worrisome because they could be used against a surgeon who uses a misleading advertising campaign. This could be one which describes benefits without mentioning risks, tells patients to "throw away your glasses" without mentioning the possibilities that they will not, or overstates the accuracy of the procedure. Depending on the provisions of your states' consumer protection statute, violation of the law could result in treble damages.

Negligent Misrepresentation and Fraud

In some medical malpractice cases, plaintiffs make a claim of fraud or negligent misrepresentation against the surgeon, based on misleading advertising or on informed consent discussions which deceive the patient about the operation, for example the benefits of the operation. Negligent misrepresentation or fraud claims might also arise if the surgeon overstates their experience with a particular procedure, in response to a patient's query.[8]

A negligent misrepresentation claim is predicated on a person making a false statement, where it is part of their profession to give information upon which the safety of the recipient or third persons depends, with reckless disregard of its truth or falsity. The person to whom the incorrect statement must rely on the statement and suffer some injury or loss as a result of their reliance. The significance of a negligent misrepresentation claim is that, even if the false statement arose during an informed consent discussion, it is a claim independent of lack of informed consent, and consequently will not require expert witness testimony.[9]

A fraud claim is similar, but need not necessarily be part of the person's occupation , involves a false statement which the speaker knows or should know to be false, which is made with an intent to mislead or deceive. Again, the recipient of the fraudulent message must reasonably rely on that message, and suffer injury or loss because of it. A fraud claim can also arise from saying nothing, when truthful affirmative statements have been made which will be misleading if more is not said. For example, telling a patient that they will not need their glasses if the surgery is successful might be fraudulent if they are not also told that they will eventually need glasses to compensate for presbyopia. A fraud claim, which is an intentional tort, can serve as a predicate for punitive damages in most states.[10]

IV. CO-MANAGEMENT WITH OPTOMETRISTS: STANDARD OF CARE

Every surgeon who contemplates a co-management arrangement, whether with ophthalmologists or optometrists, should consider four issues: is it legal - permitted by the laws of the state, is it within the standard of care, is it ethical, and is it covered by insurance. An affirmative response to all four questions should avoid trouble with respect to the arrangement.

Is it Legal?

In most states, there is no definitive pronouncement by the legislature or the state courts as to whether a co-management arrangement with optometrists is permissible. Colorado, for example, has no statute, case law, or attorney general's opinion which expressly forbids or permits the arrangement. In Florida, however, there is case law which does establish precedent, and it is not good for the aspiring co-manager. Florida's case law forbids (or at least greatly restricts, depending on who you listen to) referring a patient back to an optometrist to manage the postoperative care.[11] Washington surgeons can proceed with more assurance, however, given that state's attorney general opinion finding that the Washington medical board does not have the authority to prohibit medical doctors from delegating postoperative care to optometrists if that prohibition would prevent optometrists from performing functions within the scope of their license.[12] Whether co-management is permitted in Pennsylvania is a murkier question, in that there is an opinion letter from a former Board of Medicine

president condemning the practice, but no state statute or case law backing that up.[13] Given the variations from state to state, it would be wise to find out in advance from your local medical board or lawyer whether a co-management relationship with optometrists is permitted, forbidden or uncertain.

Some states, like Colorado and Idaho, have attempted to circumvent the co-management problem by permitting optometrists to perform PRK. The Colorado Senate passed the bill, but the part pertaining to PRK died in the House. Before investing heavily in a co-management arrangement, it may pay to talk to a health-care lobbyist or someone with considerable political savvy to find out what is on the legislative horizon. If you have already invested in an excimer laser, keep close tabs on your capitol - there is a lot of money at stake here, the optometrists know it, and they tend to be much better organized than ophthalmologists when it comes to lobbying the legislature.

Is it Within The Standard of Care?

The phrase "standard of care" is confusing to most physicians, including some experts who testify in court. The legal definition of "standard of care" (with variations in wording from state to state) is essentially what a reasonable physician, with similar training and experience as the defendant, would do in the same or similar situation. In practice, "standard of care" is what a jury (or judge) believes it to be in any

given case. If the attorney and expert witnesses convince a jury that a reasonable, well-trained physician would perform 32-incision radial keratotomy on a high myope, then that is the standard of care for that case.[14] In a rapidly developing area such as excimer laser surgery (as was the case with RK), standard of care will likely be judged on whether the physician has legitimate reasons for pursuing the course she did rather than on prevailing standards followed by most physicians, since most physicians do not perform the surgery..

It is consequently important for the surgeon to be able to support their decision to provide co-management to a patient by showing that it enhances patient care. This is not hard to do in a well—planned arrangement, with appropriate training and communication. But using co-management in a haphazard fashion with no planning or organization can be hazardous. A jury cares not that the arrangement improves patient referrals and profit margins. They will care if you do not evaluate the patients post-operatively, or refer them back to a non-surgeon without having knowledge of that co-managers' qualifications or follow-up procedures.

A recommended co-management arrangement would include several features: 1) knowing the qualifications of the co-manager; 2) training or ensuring training for the co-manager and his staff about excimer laser surgery; 3) coordinating informed consent discussions so the patient hears a consistent message; 4) a protocol for communicating the status of the patient pre and post-operatively; 5) guidelines for when a patient should be referred back to the surgeon for evaluation. While these

recommendations may seem onerous at first, they will not only pay off in terms of risk management, but they can also be valuable business development tools.

1) **Know the qualifications of the co-manager.** In the law of medical malpractice, there is a doctrine known as "negligent referral." A doctor may be liable for referring a patient to another physician for treatment (often a specialist) if the physician to whom the patient is referred is unqualified or poorly qualified to handle the referral, and the referring physician knows or should know of the lack of qualification. An example I was familiar with as an attorney involved a general practice physician who referred a chronic pain patient to an acupuncturist (at the patient's request). The acupuncturist and the patient developed a romantic interest and produced, among other things, videotapes of their *liasons* which became evidence in the case. The romantic involvement also produced a lawsuit when "John The Big Stud" (as he was referred to in one video title) and the patient fell out of love. Since the referring physician had more insurance coverage than did the acupuncturist, he became a defendant in the lawsuit on the basis of "negligent referral." This is perhaps not the most classic example of the doctrine, but it is a memorable one, which is why it is offered here. The lesson to the refractive surgeon is that you should know something about the qualifications of the optometrist or ophthalmologist to whom you will be referring the patient after surgery, and their knowledge of post operative conditions and

complications following PRK or LASIK.

2) **Training or ensuring training for the co-manager and their staff.** A study published in 1993 on co-management purported to show that a cataract patient was at greater risk in a co-management arrangement with optometrists.[15] The most alarming finding of that study was that optometrists did not recognize 40% of the postoperative complications following cataract surgery. Furthermore, 5% fewer patients received an "optimum" visual result when seen by optometrists, as compared to those seen only by ophthalmologists. One way to ensure that your patients will be well cared for after surgery is to provide training to the optometrists and ophthalmologists with whom you regularly co-manage patients. The training should include some pre-operative information such as how to screen out poor candidates, relative and absolute contraindications to surgery, and what the patient should be told about the surgery. Training in post-operative management should include common and vision--threatening complications and how to handle them, when the patient must be referred back to the surgeon, and communicating refractive results and other information to the surgeon. Written guidelines are also helpful to avoid the inevitable lapses in memory and miscommunication. Try to include the staff (yours and the referrer's) since they play an important role in patient care. They can also get you into trouble with well-meaning comments. In one refractive surgery case, a

moderately myopic nurse anesthetist had some irregular astigmatism after his RK. His informed consent claim looked weak because the surgeon's documentation of the discussion was excellent, and furthermore the plaintiff had seen the procedure numerous times as a member of the surgical team. The defense suffered, however, when a pre-trial interview with one of the defendant's nurses (a professional acquaintance of the plaintiff) revealed that she reassured him after the informed consent discussion by saying "you won't have any of these problems though, you're a perfect candidate." Training of the referring professional has the added benefit of strengthening the professional relationship and ensuring that that source will not be lured away by a competing refractive surgeon offering a better deal. If in-person training is not feasible, you may consider providing written information about PRK or LASIK and guidelines on co-management.

3) **Coordinating informed consent discussions.** Whether you provide training or not, you should at least make sure you know what the referring doctor is telling the patient about the risks and benefits of the surgery. Confusion and anxiety in refractive surgery cases can come from receiving mixed messages from the optometrist and the surgeon as to what to expect and what risks are involved. And in the event of a poor result or complication, all to often the patient remembers only the favorable things they were told about the surgery. In most states[16] it is the operating surgeon who bears the ultimate

responsibility for the informed consent discussion, so the referring physician need not make a detailed statement. It may be best to keep their input to a minimum, assuming you will have thorough, well-documented discussions yourself.

4) **A protocol for communicating the patient's status.** Before operating, it is important for the surgeon to know not only the patient's refraction, but also the stability of the refraction and any history of eye disease. This historical data is best learned from the patient's primary ophthalmologist or optometrist. You may want to develop a short information sheet that could accompany the patient (or which can be filled out by your staff via a phone call to the referrer's office) to establish the basic requirements for a patient's operation. Keep in mind that the FDA guidelines for the excimer state that the patient must have a stable refraction to within 1 diopter for a year before surgery.[17] After the surgery, it is equally important that a surgeon be able to monitor the patient's refractive progress. Again, it may be helpful to create a form to be used by the co-manager for communicating vital information back to the surgeon for each postoperative visit. This form might contain such information as the patient complaints, visual acuity corrected and uncorrected, refraction, slit lamp examination and fundus examination. In addition to being alerted to a complication or need for a re-operation, the surgeon can also monitor how their particular technic is working, and be able

to make corrections if necessary to assure optimum results.

5) **Guidelines for referring a patient back to the surgeon for evaluation.** Whether because of lack of recognition or an optometrist's belief that they can handle it, there will likely come a time when a patient has suffered a complication requiring the surgeon's intervention, but has not been referred promptly. In these instances, the surgeon's best defense is a written protocol given to the optometrist describing when such a patient should be referred. The protocol should also specify what to do in case of a true emergency, such a endophthalmitis, when routine referral back to the surgeon will not be adequate. In the absence of such a protocol the surgeon may be implicated in the alleged negligence of the co-manager.

If a co-management arrangement is established with an optometrist or non-surgeon ophthalmologist, it is important that the patient understand the arrangement and agree to it before surgery. The consent to the co-management arrangement can be included on the consent form or on a separate form, but the patient's signature should be obtained. The surgeon should explain the reasons for the arrangement, answer all questions honestly, and let the patient know they always have the option of follow-up care with the surgeon herself.

The ophthalmologist should also know what resources the optometrist has at their disposal for diagnosing complications and determining patient status. If the

hardware is inadequate for evaluating the possible complications, then arrangements should be made to either have the co-manager buy the necessary equipment or co-manage with someone else. Also consider the capacity of some modern diagnostic machines to transfer data via telephone lines, so that the surgeon can "examine" the patient from miles away, if necessary.

Keep in mind that every effort you make to insure optimum patient care in the co-management setting will redound to your benefit in the event of a lawsuit. And conversely, every shortcut that is taken which sacrifices patient care for the sake of expedience will be noted by the plaintiff's attorney and laid out for the jury. When a jury suspects the doctor is processing patients rather than treating them with care, they will let their dissatisfaction be heard, usually in the form a large verdict.

Is it Ethical?

The Academy of Ophthalmology has published Ethical Rules which apply to all members of the Academy. They are interpreted and enforced by the Academy, but are not necessarily enforceable in a court of law. Because of limited manpower and resources, the Academy cannot act as an ever-present policeman enforcing the code. It primarily responds to Academy member complaints. You may think that, because of limited enforcement, the Ethical Rules are not of much importance. I urge you to think otherwise, for three reasons:

1) **Government Agencies** -- Ethics in advertising are enforceable by regulatory agencies such as the FTC. While not specifically applicable to such actions, complying with the AAO Rules of Ethics would be of great help in defending yourself in an administrative action. This is, incidentally, the largest source of complaints to the Academy about physician's conduct.

2) **Other Ophthalmologists** -- As you become more successful, you will attract the attention of colleagues and competitors, who may be looking for some way to slow you down. A complaint or grievance with the Academy may be used to create unfavorable publicity and decrease your competitive advantage.

3) **Plaintiffs' Attorneys** -- If a malpractice case is brought, and your practices violate the Rules of Ethics, you can expect to hear about it in the courtroom. Your colleagues may understand your lack of knowledge about the Rules of Ethics but the lay members of the jury probably will not. Even if the Code of Ethics is not the law, any plaintiffs' attorney would derive great satisfaction from hearing you admit on the witness stand that you did not know, or were not complying with, the Rules of Ethics --- that you were unethical!

Remember that, regardless of economic considerations, as a professional

your first obligation is to the well-being of the patient. Any co-management arrangement must have, as its primary goal, providing good medical care to the patient. For example, If your arrangement with referring optometrists or ophthalmologists is to routinely pay them an arbitrarily set fee and refer the patient back to them for all postoperative care, you may want to refer to American Academy of Ophthalmology Advisory Opinion 85-1 which states that the optometrist should be paid a fee which is commensurate with the market value of the services actually performed. The Opinion further states that it would be improper for the surgeon to automatically refer every patient back to the optometrist for post operative care - "it is the operating surgeon's obligation to examine the patient post operatively and insure that his medical condition is progressing as well as possible. . . . In accordance with Rule 8, provisions for postoperative care must be made on an individualized basis, in light of what is best for each patient."

You may also want to review Opinion 85-4, and Ethics Rules 7, 8 and 11.

Is it Covered by My Insurance?

Do not forget one of the more pragmatic concerns of creating a co-management relationship --- will your insurance cover it? While most standard policies should not have any limitations or exclusions on covering a co-management relationship, the time to find out is before you begin, not after a claim has been made. Some insurors, for example, may not cover a non-FDA approved device, while others will. Your

insurance agent should be able to help determine your coverage, or you can get out the policy and read it yourself.

A related insurance issue involves your co-manager. Optometrists have not been in the malpractice limelight as much as most surgeons, and consequently may not have much in the way of liability coverage. In the event something goes wrong on a case, you do not want to be the "deep pocket." Plaintiffs' attorneys are pragmatic --- they go after the people with the money, even if the theory of liability against them is attenuated. The bottom line is that you want to make sure the doctors with whom you will co-manage patients have adequate liability insurance. It probably will cost an optometrist a lot less to get $1 million in coverage than an ophthalmic surgeon, and it may keep you from becoming a defendant when someone else is really responsible.

V. FEE—SPLITTING, KICKBACKS AND ANTI SELF—REFERRAL

Most surgeons are probably familiar with the Federal Anti-Kickback and Stark I and II statutes and rules, which apply to Medicare and Medicaid patients. You may believe that, since the refractive surgery will involve only private pay patients, then you need not worry about conforming to the requirements of these laws. While that is technically correct, you may be in a state which has its own statutes which prohibit the same economic and referral relationships as do the Federal statutes. Many of these laws apply to private pay patients and Medicare/Medicaid patients alike.

This is a hot area for insurance company lobbyists, and the legislative landscape is changing frequently. You should make sure that whatever your billing and co-management relationship, that it is not afoul of state self -- referral or anti -- kickback laws. An example of how easy it is to get into trouble in this area arises from the simple question of who owns the laser. If optometrists own a laser facility, and they benefit from surgery performed at the facility on patients they referred to the ophthalmic surgeon, this could be interpreted as an illegal kickback or fee for referral. Again, liability will depend on precisely what is and what is not permitted in your state. You should consult an attorney to get a legislative update before investing time or money into a co-management relationship.

Many surgeons use a billing process in which either the surgeon or the optometrist bills a global fee, which is then divided between the surgeon and the pre-and post-op care provider. Because most states have laws prohibiting fee--for--referral or fee -- splitting, you should review the language of your state's statute before working out any fee division arrangements with your co-manager. Often a simple adjustment to the procedure or a disclosure to the patient may avoid a problem, such as paying the co-manager after they have begun postoperative care, or printing on the bill what portion of the payment is going to whom. The split should also reflect the reasonable value of the services provided. Many ophthalmologists will be familiar with this requirement from Medicare billing for cataract patients. Some ophthalmologists use the same split for refractive surgery patients as they do for their cataract patients.

Overpaying a co-manager, especially one who referred the patient initially, may raise suspicions of a fee—for—referral violation.

VI. SETTING UP AN ENTITY TO OWN THE LASER

Your choice of where to perform the PRK procedure raises different legal considerations, depending on who or what owns the machine. It could be owned by the surgeon himself, by a separate corporation in which the physician may or may not have ownership, jointly owned with optometrists or by optometrists solely, or leased from an independent company.

Physician Owned

The primary concern for the physician who is performing surgery in his own office is whether the patient is receiving the same level of surgical care as they would in a hospital or an ambulatory surgery center. Availability of emergency services in the event of a significant complication or health problem (for example, a patient who has congestive heart failure due to anxiety, anesthetic and a pre-existing heart condition), procedures for maintaining sterility, and equipment maintenance are all considerations for the physician operating in his office.

Corporate Owned

"Corporate-owned" refers to an excimer laser ambulatory surgery center ("ASC") owned by a third party, including a corporation comprised of the physicians performing surgery there. Many companies have sprung up to help get physicians into a laser refractive surgery practice more conveniently. There will be, in all likelihood, state licensing requirements for such a surgery center. Many states will require a certificate of need before the center can be built.

All states will likely have prohibitions against the corporate practice of medicine that must be heeded if the center is owned by non--physicians. Specifically, a non--physician cannot dictate how medical or surgical services will be provided by a physician. While this may seem only a quaint anachronism in the era of managed care, it is nonetheless the law in all states and must be considered in dealing with a laser center not owned by physicians.

If you have an ownership interest in an ASC, be aware of the need for compliance with state laws regarding peer review and the extension of privileges to the medical staff. You should also consider your state's anti -- kickback or anti self -- referral laws (if they have them), and whether you fall within an applicable safe harbor. Also be conscious of fee -- splitting laws if the center charges one fee for surgical and follow – up care handled by two different people.[18] Since the situation varies from state to state, and may change without much notice, you should consult legal counsel about any ownership arrangement.

If the facility also handles marketing, make sure you are aware of what they are saying about the surgery you will be performing. Marketing firms, or even corporate laser centers owned by someone other than the surgeons, are not likely to have the same level of concern over liability for misleading a prospective patient. Their primary concern, after all, is increasing patient traffic. Nor are they likely to be called as a witness if a lawsuit is brought by a disgruntled patient who believes they were promised more than the surgeon delivered. As a subscriber to these consulting or management services, you may well be the one held responsible for what is said. In defending several RK cases involving allegations of misleading advertising, I am yet to see any ad executive named as a defendant.

Joint Ownership --- Physicians and Optometrists

Owning a surgical facility with non-physicians can raise corporate practice of medicine considerations, as mentioned above. If those non-physicians are also optometrists who are a referral source for the surgeons, then you must also consider whether the arrangement violates state Anti-Kickback or Fee-Splitting laws. Another concern is an anti – trust violation if the majority of ophthalmologists and optometrists in a region are owners of a facility to which the patients are referred. This is usually more of a concern in smaller communities and rural areas.

If the optometrist and the surgeon have an agreement that all patients

referred by the optometrist must have surgery at the facility which the optometrist owns, then that would likely be deemed a kickback. It may also be an ethical violation in that the decision as to medical facilities is made on the basis of an economic arrangement, rather than the patient's best interest. The two are not necessarily mutually exclusive, but an automatic arrangement based on financial interests, and the availability of other facilities may raise the specter of an ethics violation.

Leasing and Timesharing Arrangements

Some regulations may be circumvented by setting up a separate entity which owns or leases the necessary equipment and space, hires personnel to staff the facility, and operates not as an independently licensed facility but rather as an extension of several physician's practices. This timesharing arrangement raises the same considerations as in the physician-owned facility with respect to assuring quality medical care, staffing, and the like. It has several advantages, though, in that it may avoid licensing and certificate of need requirements in some states, (but this varies) and should avoid the self-referral and anti-kickback problems inherent in independently-owned facilities.

In summary, owning, leasing, or investing in a PRK facility is not a simple proposition. It involves more laws and regulations than can be discussed in this article, and to make matters more difficult, the laws vary from state to state. Consultation with

legal counsel familiar with the laws of your state is essential before investing in your own laser or joining with a corporate facility.

VI. PRODUCT LIABILITY: WHAT TO DO IF THE LASER BREAKS

Although the application of product liability laws is not new to the practice of medicine, it is significant to the laser refractive surgeon because so much of the process is performed completely by the machine. Maintenance contracts, some of which specify approved vendors, add another layer of liability to the mix. The laser manufacturers may also attempt to contractually limit their liability by requiring the surgeon to indemnify them against a product liability claim, or even add them as a named insured on the group policy.[19]

Be aware that these indemnification provisions may be in the purchase or maintenance agreement, so look the papers over carefully before signing and talk to your lawyer before agreeing to indemnify anyone for anything. You may get more than you bargained for, since legal fees in a case can easily run between $50,000 and $100,000, even if you win.

Also recognize that in the event of a mechanical problem resulting in a bad patient outcome, you and the manufacturer will likely be adverse to one another, even if you are both defendants. They will not have your best interests in mind. To the contrary, manufacturers frequently defend a product liability claim by alleging improper

maintenance or operation by the surgeon. If something does go wrong when you are performing surgery, you would be w[20]ise to follow these steps[21]:

1) Establish and maintain chain of evidence procedures. Have the staff familiarize themselves with evidence procedures and who should be contacted.
2) Impound equipment, supplies, accessories, disposables and packaging until they can be inspected. To the extent possible, ensure that control settings are not changed.
3) For many micro--processor controlled devices, error codes may be stored in the device's memory. Contact a clinical engineer before turning off the device.
4) Devices should not be cleaned or processed without first discussing with an experienced third—party investigator.
5) Determine whether similar equipment should be taken out of service.
6) Conduct independent testing and analysis in cases likely to result in a claim.
7) The manufacturer may want to take the device for examination or replacement. Before releasing the device to the manufacturer, determine whether release will compromise evidence. You may want to do an "autopsy" of the equipment with the facility user, the manufacturer and an independent investigator all present.

8) Determine whether to draft and send a medical device report to the manufacturer and/or the FDA. Determine whether to send a report to a manufacturer in accordance with the FDA's medical device tracking regulations.

Following these recommendations will help prevent you from losing information which may necessary to defend your care in the event of a lawsuit. And as everyone saw in O.J. Simpson's trial, the steps taken to investigate the incident are critically important in the outcome of the trial.

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[1] FDA correspondence to Ms. Kimberly Donay of Summit Technology, Inc., (October 20, 1995).
[2] FDA Drug Bulletin 12:4-5, (1982).
[3] FDA/FTC correspondence to "Dear Eye Care Professional", from Lillian J. Gill (Director, Office of Compliance, Center for Devices and Radiological Health) and Dean Greybill (Associate Director, Service Industry Practices, Bureau of Consumer Protection, Federal trade Commission) (May 7, 1996).
[4] 21 U.S.C. 360 j(b); 21 CFR Part 812.3.
[5] 21 U.S.C. 360 j(g); 21 CFR Part 812.
[6] Vaughn v. Acromed and Nottingham No. A065356/A066163, Court of Appeal of the State of California, First Appellate District, Division Four; Shadrick v. Centennial Medical Center and Coker, No. 01A01-9604 CV-00145, Tennessee Court of Appeals, Permission to Appeal to Supreme Court of Tennessee applied for.
[1]
[3]
[7] E.g. Colorado Revised Statutes Section 6-1-101 et seq.
[8] Bloskas v. Murray 646 P.2d 907 (Colo. 1982).
[9] Id.
[10] Punitive damages are a creation of statute, and some states, like Washington, do not have a statute allowing punitive or exemplary damages in personal injury cases.
[11] Florida Bd. Of Optometry v. Florida Bd. Of Medicine 616 So.2d 581 (Fla. App. 1993) (Postoperative care is within the unique abilities of a medical doctor, and cannot be delegated to a non-MD.) In fairness, it should be noted that the OD society president, John McClane III, OD, sent out a letter to Florida ophthalmologists after this decision was rendered, stating his interpretation of the opinion was management with optometrists is permitted if 1) the MD is satisfied with the OD's qualifications, 2) the OD regularly reports to the MD on the patient's progress, and 3) the OD refers the patient back to the MD if the care needed exceeds the OD's permissible care. If you live in Florida, you should probably get an opinion letter from a local attorney before wading into that swamp.
[12] Washington Atty. Gen. Op. Of 11/14/88. Keep in mind that this is one lawyer's opinion. A new attorney general might come to a different conclusion. This is not likely, but certainly is possible. Until the matter is decided on by the state's courts in an actual lawsuit (as happened in Florida), there is no real precedent. The opinion letter is certainly helpful, but it's not bulletproof.

[13] Board of Medicine letter of 1/8/88 from former president Joseph Marconis, M.D. See also the comments in footnote 8 *supra*.

[14] E.g. Schmid v. Damiano, Denver Dist. Ct. 89CV5990 (tried May, 1990); Fisher v. Damiano, Arapahoe Cty. Dist. Ct. 89CV1266 (tried June, 1991).

[15] Battelle Medical Technology Assessment and Policy Research Center, Washington, D.C., "Patient Outcomes with Co-managed Postoperative Care After Cataract Surgery", Clin. Epidemiol. Vol. 46, No. 1:5-15 (1993).

[16] This is based simply on personal experience, not a poll of all states' cases and statutes. If you have any doubt, consult an attorney from the state in which you practice.

[17] While the FDA cannot dictate the practice of medicine, the guideline could make its way into a courtroom and the jury might decide that it is an important one. If you choose to not follow the FDA guideline, you should be at least prepared to explain why you do not.

[18] Fee-splitting laws may not apply to an ASC in all states. In Colorado, for example, the statutory language applies to a *physician* billing, with no mention of billing by a separate entity.

[19] Whether these indemnification provisions would hold up in court remains to be seen. There are significant public policy considerations against such an arrangement, but be aware that a person can contract to do just about anything, as long as it's not illegal. The addition of the manufacturer as a named insured raises even more problems, in that the insurance policy usually only covers *professional* negligence, and it is unlikely that the manufacturer would fall within that coverage. Again, much depends on the specific facts, and wording of the policy and the indemnification contract.

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[21] Excerpted from "Medical Device Reporting Under the Safe Medical Devices Act: A Guide for Healthcare Facilities", ECRI, {copyright} 1991, reprinted with permission.