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C. Gregory Tiemeier, JD

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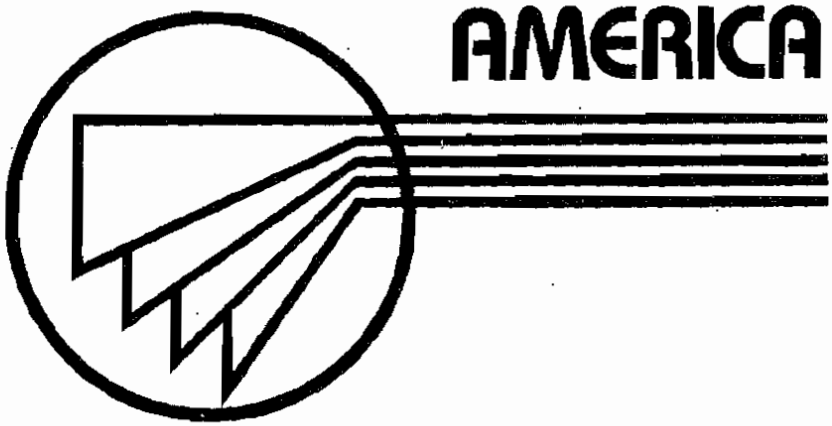

Robert L. Stamper, MD, *Consulting Editor*

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REFRACTIVE SURGERY

Richard L. Abbott, MD, and
David G. Hwang, MD, FACS, *Guest Editors*

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LEGAL ISSUES IN REFRACTIVE SURGERY AND LASER CENTER COMANAGEMENT

C. Gregory Tiemeier, JD

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 controversy that accompanied a radial keratotomy (RK) practice in the early 1980s, but many more were not. There were lessons from that era, however, that can help the refractive surgeon involved in the ophthalmic revolution of the 1990s—the excimer laser.

Many ophthalmologists in the 1980s questioned whether it was 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 RK. Although it 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 RK over a decade ago forced responsible practitioners of refractive surgery to be cautious and self-critical. Even though today's laser surgeon is not likely to hear the same questions regarding the propriety of refractive surgery, he or she should not forget that the procedure is a new and developing one, and they could likewise benefit from skepticism and introspection.

This latter statement is particularly true because the excimer laser is driven by a force that did not accompany RK, namely, financial gain. Nonphysician businesspersons and investors stand to benefit from proliferation of the excimer laser far more than was the case with RK. 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 ultrasonic 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, affecting both the way the product is presented to the eye surgeon, as well as affecting patient expectations.

Another lesson learned from a number of RK malpractice trials has to do with advertising. Overpromotion of the procedure through aggressive advertising campaigns that promised that patients could "throw away [their] glasses" or "eliminate the need for glasses" tended to backfire in the event of a bad outcome. Plaintiffs' lawyers were always anxious to get the advertising in front of the jury, and if there were a chance that the plaintiff had seen the ads, judges usually admitted the advertising into the trial. Such promises were

From Kaluk, Burg and Tiemeier, LLP, Denver, Colorado

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. Physicians should remember that the advertising executive pitching the campaign will not be on the witness stand, but they will.

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

Selecting the excimer laser manufacturer may itself be a difficult task. Choosing the VISX or Summit laser may restrict the surgeon's ability to customize their surgery. 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, as this author explains later in this article.

FDA-approved Lasers

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 for the Summit laser stated the device was indicated for myopic photorefractive keratectomy (PRK) using a 6-mm ablation zone in patients 21 years of age or older, with 1.5 to 7.0 D of myopia and 1.5 D or less of astigmatism. The refraction had to be stable—within 1 D or less—for 1 year before the laser treatment, and the *Patient Information Booklet* recommended at least a 3-month wait between eyes (i.e., 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.

These statements were 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, that 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 may be directed to the FDA's Center for Devices and Radiological Health.*

The Pillar Point Partners' license fee is a source of dissatisfaction to most laser surgeons. The agreement provides that the technology and patents necessary to build the excimer laser are owned by the Pillar Point Partners (VISX and Summit) and are licensed by the partnership to VISX and Summit. The Pillar Point Partners also exact 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 many ophthalmologists are uncomfortable with the concept. Eye surgeons instead expect to buy a machine and use it as they wish. Many surgeons object to what they think is an unethical "method" patent, which, although legal in the United States, is still controversial and is illegal in most other countries.

In fairness, Pillar Point Partners response is that they should have the opportunity to recoup their development and FDA approval costs, which are considerable. The result is that there are many surgeons who are less than happy with paying the Pillar Point fee every time they operate. This dissatisfaction has manifest itself in a few ways. The first is litigation; several physicians have brought suit against the Pillar Point Partners, alleging antitrust claims or counterclaims. Another method, used by some surgeons, is to circumvent the fee by purchasing a laser that may not be subject to the Pillar Point fee. These are known as "gray-market" or "black-box" lasers.

*Promotion and Advertising Policy Staff: (301) 594-4639, or the FTC's Bureau of Consumer Protection, Service Industry Practices Staff: (202) 326-3270.

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 here. Because many companies have been manufacturing lasers for years for markets outside the United States, these machines are readily available. Getting the laser through customs is not the end of the legal challenges for the surgeon; however, because the FDA and the Pillar Point Partners obviously do not want to admit these devices. 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 that is custom assembled to a surgeon's requirements by a company that provides the components separately. The purpose of the custom assembly is to fall within the "custom device" exception to the FDA's premarket 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 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 premarket approval is the Investigational Device Exemption (IDE), which permits the use of nonapproved 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 solve only one half of the problem, in that the Pillar Point Partners still may prosecute a patent infringement action against the user. If the surgeon publishes the results of research conducted under the IDE, this draws attention to the fact that they are using a black-box or gray-market laser.

Consequently, although 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.

If a surgeon does elect to use the black-box or gray-market laser, they should let patients know that they are not using an FDA-approved device. At this time, surgeons are not ordinarily required to inform patients of the FDA approval status of the devices they use. 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, or of the "experimental" nature of the screws. Although the respective courts ultimately may 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 informing the patient. Although such a warning is not a necessary precaution in most surgery cases, the heavy marketing involved for the FDA-approved lasers, the press's attention to the FDA's approval, and the elective nature of the procedure suggest a more conservative approach in laser surgery cases.

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

FDA and 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 may be treated as a manufacturer by the FDA and subjected to penalties. Consequently, any surgeon advertising his or her 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 include discussion of the results of clinical trials, the fact that long-term risks beyond 3 years are unknown, and a listing of the complications that could be expected.[1] The PMA letter also required that prospective patients receive the FDA's Patient Information Booklet. Whether these requirements still apply is an open question in light of the subsequent pronouncements in the May 7, 1996, FDA and FTC letter. In that letter, the agencies merely stated that "Advertising or promotional materials that discuss efficacy or safety should also con-

tain 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 suggest that any surgeon making a claim of safety or efficacy should be prepared to back those statements up with objective research data, and not just any study will do. In the RK investigation, the FTC seemed to be interested in only comparison with the results of the PERK study. Physicians should remember before they advertise that the FTC is a government agency that is well funded, determined, and unconcerned about the importance of increased patient flow from an advertising campaign. One final word on advertising: many successful surgeons report that their success with refractive procedures was built on word-of-mouth referrals, not advertising.

Consumer Protection Laws

Many states have statutes to protect consumers from fraudulent advertising. Usually these are based on the Uniform Deceptive Trade Practices Act and are enforced by either the state attorney general or in a private civil action.[7] The deception, however, must be directed to the public at large, not one individual plaintiff. The statutes, although limited in application, could be used against a surgeon who uses a misleading advertising campaign—one that describes benefits without mentioning risks, tells patients to "throw away your glasses" without mentioning the possibility that they may 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 claim fraud or negligent misrepresentation based on misleading advertising or on informed consent discussions that deceive the patient about the operation (e.g., the benefits of the operation). Negligent misrepresentation or fraud claims may also arise if the surgeon overstates his or her experience with a particular procedure in response to a patient's query.[8]

A *negligent misrepresentation* claim is predicated on a person's making a false statement with reckless disregard of its truth or falsity, and it is part of their profession to give information on which the safety of the recipient or others depends. The person to whom the incorrect statement is made must rely on the statement and, therefore, suffer some injury or loss as a result of that 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 to prove at trial.[9]

A *fraud* claim is similar but need not necessarily be part of the person's occupation, involves a false statement that 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 therefore suffer injury or loss because of it. A fraud claim also can arise from saying nothing when truthful affirmative statements have been made that will be misleading if more is not said. For example, telling a patient that he or she will not need his or her glasses if the surgery is successful may be fraudulent if the patient is not also told that eventually glasses will be needed to compensate for presbyopia. A fraud claim, which is an intentional tort, can serve as a predicate for punitive damages in most states.*

COMANAGEMENT LEGAL ISSUES

Every surgeon who contemplates a comanagement arrangement, whether with ophthalmologists or optometrists, should consider four issues: (1) is it legal (i.e., permitted by the laws of the state); (2) is it within the standard of care; (3) is it ethical; (4) and is it covered by his or her malpractice 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 whether a comanagement arrangement with optometrists is permissible. Colorado, for example, has no statute, case law, or attorney

* 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.

general's opinion that expressly forbids or permits the arrangement. In Florida, however, there is case law that establishes precedent that is not good for the aspiring comanager. Florida's case law forbids or at least greatly restricts (depending on whom one consults) referring a patient back to an optometrist to manage the postoperative care (*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: comanagement 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 these waters.) Washington surgeons can proceed with more assurance, however, given that state's attorney general's opinion finding that the Washington state 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 licenses (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 is not bulletproof.) Whether comanagement 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 supporting it.[9] 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 comanagement relationship with optometrists is permitted, forbidden, or uncertain.

Is it Within the Standard of Care?

The term *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 RK on a high myope, then that is the standard care, at least for that case.[14] In a rapidly developing area such as excimer laser surgery (as was the case with RK), standard of care probably will be judged on whether the physician has legitimate reasons for pursuing the course he or she did rather than on prevailing standards followed by most physicians because most physicians do not perform the surgery.

Consequently, it is important for the surgeon to be able to support his or her decision to provide comanagement to a patient by showing that it enhances patient care. This is not difficult to do in a well-planned arrangement, with appropriate training and communication, but using comanagement without planning or organization can be hazardous. A jury cares not that the arrangement improves patient referrals and profit margins. They will care, however, if you do not evaluate the patients postoperatively, or refer them back to a nonsurgeon without having knowledge of that comanager's qualifications or follow-up procedures.

A recommended comanagement arrangement would include several features: (1) knowing the qualifications of the comanager; (2) training or ensuring training for the comanager and his or her 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 postoperatively; and (5) guidelines for when a patient should be referred back to the surgeon for evaluation. Although these recommendations may seem onerous at first, they will pay off not only in terms of risk management but also as valuable business development tools.

Know the Qualifications of the Comanager

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 from this author's experience involved a general practice physician who referred a chronic pain patient to an acupuncturist (at the patient's request). The acupuncturist and the patient became romantically involved and produced, among other things, videotapes of their liaisons that became evidence in the case. The involvement also produced a lawsuit when the acupuncturist and the patient ended their affair. Because 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 memorable, which is why it is offered here. The lesson to the refractive surgeon is that one should know something about the qualifications of the optometrist or ophthalmologist to whom one refers the patient before or after surgery, and one should also be aware of that professional's knowledge of postoperative conditions and complications following PRK or LASIK.

Training or Ensuring Training for Comanagers and Their Staff

A study published in 1993 on comanagement purported to show that a cataract patient was at greater risk in a comanagement arrangement with optometrists.[11] The most alarming finding of this study was that optometrists did not recognize 40% of the postoperative complications following cataract surgery. Furthermore, 5% fewer patients received an "optimal" visual result when seen by optometrists, as compared with those seen only by ophthalmologists. One way to ensure that patients will be well cared for after surgery is to provide training to the optometrists and ophthalmologists with whom surgeons regularly comanage patients. The training should include some preoperative information (e.g., how to screen out poor candidates, relative and absolute contraindications to surgery, and what the patient should be told about the surgery.) Training in postoperative 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 helpful to avoid the inevitable lapses of memory and miscommunication. Training the referring doctor has the added benefit of strengthening the professional relationship and reducing the chance that the source will be lured away by a competitor offering a better deal. If in-person training is not feasible, you may consider providing written information about PRK or LASIK and guidelines on comanagement. One should try to include the staff (referral and referrer's) because they also play an important role in patient care. 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 pretrial interview with one of the defendant's nurses (a professional acquaintance of the plaintiff) revealed that she had reassured him after the informed consent discussion, saying "you won't have any of these problems, though; you're a perfect candidate."

Coordinating Informed Consent Discussions

Whether or not training is provided, surgeons should at least know what the referring doctor tells the patient about the risks and benefits of the surgery. Confusion and anxiety result when there are mixed messages from the optometrist and the surgeon as to what to expect and which risks are involved. In the event of a poor result or complication, all too often the patient remembers only the favorable things they were told about the surgery. In most states,* it is the operating surgeon who bears the ultimate responsibility for the informed consent discussion, so that the referring physician need not make a detailed statement. It may be best to keep their input to a minimum and assume the responsibility for thorough, well-documented discussions with the patient.

A Protocol for Communicating the Patient's Status

Before operating, the surgeon should know not only the patient's refraction but also the

* *Note:* 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.

stability of the refraction and any history of eye disease. These data and other history are best learned from the patient's primary ophthalmologist or optometrist. A short information sheet that could accompany the patient (or that can be filled out by the staff by means of a phone call to the referrer's office) to establish the basic requirements for a patient's operation may be useful. The FDA guidelines for the excimer laser state that the patient must have a stable refraction to within 1 D for *a year* before surgery. Although the FDA cannot dictate the practice of medicine, the guideline could make its way into a courtroom and the jury may decide that it is an important one. If you choose not to follow the FDA guideline, you should be at least prepared to explain why. 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 comanager for communicating vital information back to the surgeon for each postoperative visit. This form may contain information such as the patient's complaints, visual acuity corrected and uncorrected, refraction, and slit-lamp and funduscopic examination results. In addition to being alerted to a complication or need for a reoperation, the surgeon can also monitor how the particular technique is working, and be able to make corrections if necessary to ensure optimal results.

Guidelines for Referring a Patient Back to the Surgeon for Evaluation

Whether because of lack of recognition or an optometrist's belief that he or she can handle it, there will likely come a time when a patient has suffered a complication that requires the surgeon's intervention, but the patient has not been referred back promptly. In these instances, the surgeon's best defense is an oral and 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 as 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 comanager.

If a comanagement arrangement is established with an optometrist or nonsurgeon ophthalmologist, it is important that the patient understand the arrangement and agree to it before surgery. Consent to the comanagement 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 he or she always has the option of follow-up care with the surgeon.

The ophthalmologist should also know which resources the optometrist has at their disposal for diagnosing complications and determining patient status. If the hardware is inadequate for evaluating possible complications, then arrangements should be made either to have the comanager buy the necessary equipment or comanage with someone who already owns it. Also consider the capacity of some modern diagnostic machines to transfer data by means of telephone lines, so that the surgeon can "examine" the patient from miles away, if necessary.

Every effort made to ensure optimal patient care in the comanagement setting will benefit the surgeon in the event of a lawsuit. Conversely, every shortcut that is taken that 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 known, usually in the form of a large payment to the plaintiff.

Is It Ethical?

The American Academy of Ophthalmology (AAO) has published Rules of Ethics, which apply to all members of the AAO. These are rules interpreted and enforced by the Academy but are not necessarily enforceable in a court of law. Because of limited manpower and resources, the AAO cannot act as a policeman to enforce the code. It primarily responds to AAO member complaints. It may be supposed that, because of limited enforcement, the Rules of Ethics are of not much importance, but the reverse is quite the case, for three reasons.

1. *Government agencies.* Ethics in advertising are enforceable by regulatory agencies such as the FTC. Although 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. Ethics in advertising is, incidentally, the largest

source of complaints to the AAO about physician conduct.

2. *Other ophthalmologists.* As surgeons become more successful, they will attract the attention of colleagues and competitors who may look for ways to impede their progress. A complaint or grievance with the AAO may be used to create unfavorable publicity and decrease competitive advantage.
3. *Plaintiff's attorneys.* If a malpractice case is brought, and the practices of the surgeon violate the Rules of Ethics, one can expect to hear about it in the courtroom. 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 Rules of Ethics are not law, any plaintiffs' attorney would derive great satisfaction from hearing a surgeon admit on the witness stand that he or she did not know, or did not comply with the Rules of Ethics and were, therefore, unethical.

Regardless of economic considerations, as a professional the first obligation is to the well-being of the patient. Any comanagement arrangement must have as its primary goal to provide good medical care to the patient. For example, if the usual arrangement a surgeon has with referring optometrists or ophthalmologists is to pay them an arbitrarily set fee and immediately refer the patient to them for all postoperative care, one may need to refer to AAO Advisory Opinion 85-1, which states that the optometrist should be paid a fee that is commensurate with the market value of the services actually performed. Consequently, the surgeon should set the comanagement fee at a level that reflects the value the comanager adds. The Opinion further states that it would be remiss for the surgeon to refer every patient back to the optometrist for postoperative care automatically since "it is the operating surgeon's obligation to examine the patient postoperatively and ensure 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."

Opinion 85–4 and Rules of Ethics 7, 8, and 11, all of which discuss additional aspects of care involved in comanagement, may also be useful for review.

Is It Covered by My Insurance?

One of the more pragmatic concerns of creating a comanagement relationship is insurance coverage. Although most standard policies should not have any limitations or exclusions on covering comanagement relationships, the time to find out is before they 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 or lawyer should be able to help determine coverage.

A related insurance issue involves the comanager. Optometrists have not been in the malpractice limelight as much as most surgeons, and consequently they may not have much in the way of liability coverage. If something goes wrong with a case, the surgeon does not want to be the "deep(er) 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 to make sure that the doctors with whom one comanages patients have adequate liability insurance. It may cost an optometrist a lot less to get $1 million in coverage than it does an ophthalmic surgeon, and it may keep the surgeon from becoming a defendant when someone else is really responsible.

FEE SPLITTING, KICKBACKS, AND SELF-REFERRAL

Most surgeons are probably familiar with the Federal Antikickback and Stark I and II statutes and rules, which apply to Medicare and Medicaid patients. One may think that, because refractive surgery involves only private-pay patients, one need not worry about conforming to the requirements of these laws. Although that is technically correct, the surgeon in question may be in a state that has its own statutes that prohibit the same economic and referral relationships as do the Federal statutes. Many of these laws apply to private-pay patients and Medicare and Medicaid patients alike.

This is a hot area for insurance company lobbyists, and the legislative landscape changes frequently. Whatever is the state of the billing and comanagement relationship, it should not run afoul of state anti–self-referral or antikickback laws. One example of how problematic this area is the simple question of who owns the laser. If optometrists own a laser

facility, and they benefit financially 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 depends on precisely what is and what is not permitted in that state. Surgeons should consult an attorney to get a legislative update before investing time or money into a comanagement relationship.

Many surgeons use a billing process in which either the surgeon or the optometrist bills a global fee that is then divided between the surgeon and the preoperative and postoperative care provider. Because most states have laws prohibiting fees for referral or fee splitting, one should review the language of the particular state's statute before working out any fee division arrangements with a comanager. Often a simple adjustment to the billing procedure or a disclosure to the patient as to who is receiving which fees may avoid a problem.

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 comanager, especially one who referred the patient initially, may raise suspicions of a fee-for-referral violation.

SETTING UP AN ENTITY TO OWN THE LASER

The 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, 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 Laser

The primary concern for the physician who performs surgery in his or her 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 (e.g., a patient who has congestive heart failure due to anxiety, anesthetic, and a preexisting heart condition.), procedures for maintaining sterility, and equipment maintenance are all considerations for the physician operating in his or her office.

Corporate Owned

Corporate owned is an excimer laser ambulatory surgery center (ASC) owned by a third party, including a corporation composed of the physicians performing surgery there. Many companies have sprung up to help get physicians into a laser refractive surgery practice more conveniently, sometimes without any ownership interest. In all likelihood, there will be state licensing requirements for such a surgery center, and many states will require a certificate of need before the center can be built.

All states probably will have prohibitions against the corporate practice of medicine that must be heeded if the center is owned by nonphysicians. Specifically, a nonphysician cannot dictate how medical or surgical services will be provided by a physician. Although this may seem 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 a surgeon has an ownership interest in an ASC, one must be aware of the need for compliance with state laws regarding peer review and the extension of privileges to the medical staff. Also to be considered are the state's antikickback or anti–self-referral laws (if they have them), and whether one falls within an applicable "safe harbor." Knowledge of fee-splitting laws—if the center charges one fee for surgical and one for follow-up care, which is then handled by two different people—is also essential. Because the situation varies from state to state and may change without much notice, one should consult legal counsel about any ownership arrangement.

If the facility also handles marketing, one should be aware of claims made about the surgery performed. Marketing firms, or even corporate laser centers owned by someone other than the surgeons, may not have the same level of concern over liability for misleading a prospective patient; their primary concern, after all, is to increase patient traffic. Nor will they be called as a witness if a lawsuit is brought by a disgruntled patient who believes he or she was promised more than the surgeon delivered. As a subscriber to these consulting

or management services, the physician is held responsible for what is said. In defending several RK cases involving allegations of misleading advertising, this author has yet to see any advertising executive named as a defendant.

Joint Ownership—Physicians and Optometrists

Owning a surgical facility with nonphysicians raises some considerations about corporate medical practice as mentioned previously. If those nonphysicians are also optometrists who are a referral source for the surgeons, then one must also consider whether the arrangement violates state antikickback or fee-splitting laws. Another concern is an antitrust violation if most of the 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.)

If the optometrist and the surgeon have an agreement that all patients referred by the optometrist must have surgery performed at the facility that the optometrist owns, then that could be deemed a kickback. It also may be an ethical violation, in that the decision about 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 imply an ethical violation.

Leasing and Time-sharing Arrangements

Some regulations may be circumvented by setting up a separate entity that 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 time-sharing arrangement raises the same considerations as in the physician-owned facility with respect to ensuring quality medical care, staffing, and the like. It has several advantages, however, in that it may avoid licensing and certificate of need requirements in some states, and should circumvent the self-referral and antikickback problems inherent in independently owned facilities.

Owning, leasing, or investing in a PRK facility is not a simple proposition. It involves more laws and regulations than can be discussed in detail 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 the state in question is essential before a surgeon invests in his or her own laser or joins with a corporate facility.

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 also may attempt to limit their liability contractually by requiring the surgeon to indemnify them against a product liability claim, or even add them as a named insured on the group policy.*

These indemnification provisions may be in the purchase or maintenance agreement, so review these carefully before signing and consult with a lawyer before agreeing to indemnify anyone for anything. One may get more than is bargained for because legal fees and expenses in a malpractice case can easily run between $50,000 and $100,000, even if the surgeon wins.

In the event of a mechanical problem resulting in an unfavorable patient outcome, the manufacturer probably will be adverse to the physician, even if both are defendants. Manufacturers often defend a product liability claim by alleging improper maintenance or operation by the surgeon. If something does go wrong during surgery, follow these steps[12]:

1. Establish and maintain chain-of-evidence procedures. Have the staff familiarize themselves with evidence procedures and who should be contacted.

* 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 is 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.

2. Impound equipment, supplies, accessories, disposable supplies, and packaging until they can be inspected. To the extent possible, ensure that control settings are not changed.
3. For many microprocessor-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 investigater.
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 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 to prevent losing information that may be necessary to defend your care in the event of a lawsuit.

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Address reprint requests to

C. Gregory Tiemeier, JD
Kaluk, Burg and Tiemeier, LLP
4105 E. Florida Avenue
Suite 300
Denver, CO 80222