



POLICY STATEMENT

Guidelines for Refractive Surgery Advertising

Statement of Purpose:

These guidelines are designed to assist ophthalmologists in providing truthful, informative advertising of refractive surgery. In addition to their ethical obligations, ophthalmologists must be mindful of the legal obligations they have in connection with the promotion of their services.

These guidelines are not intended to address every possible advertising claim that could be made in support of refractive surgery. The guidelines address specific types of claims that could confuse consumers and/or have been subject to Federal Trade Commission (FTC) review. Examples of permissible claims, as well as claims that might be considered confusing or misleading are provided.

Legal Framework:

"The Federal Trade Commission Act," as well as similar state laws, prohibits false and deceptive advertising. Advertising that is literally true, but which conveys a misleading impression to reasonable consumers, may be unlawful. Claims made implicitly in advertising, as well as explicit claims, can give rise to deception. Deception can also occur through the omission of information if the absence of the information causes the advertisement to convey an inaccurate impression about a material fact, one that is likely to affect consumer conduct or decisions with respect to the service or product at issue. Thus, ophthalmologists should ensure that statements made directly or by implication in informational, promotional and advertising materials are accurate and are not likely to deceive consumers. This is especially true in "testimonial" ads.

The Federal Trade Commission has primary jurisdiction over advertising of health care services, OTC drugs and devices. The Food and Drug Administration has jurisdiction over manufacturer product labeling and advertising, including prescription drugs. One issue of current interest concerns the advertising of "off-label" surgical applications, using an FDA-

approved device (e.g., LASIK if laser is approved for PRK for a specific indication or, PRK if LASIK is approved for a specific device for a specific indication). The decision to use the excimer laser outside the scope of the approved labeling is considered, by the FDA, to be a "practice-of-medicine" issue; that is, the FDA recognizes that physicians are permitted by professional license to use an approved drug or device for another use that they believe is appropriate for diagnostic or treatment purposes. Physicians should be aware, however, that advertising of off-label use to patients is prohibited, and is not protected under the "practice-of-medicine" rubric. Off-label use may be described in peer review articles and textbooks.

If a physician uses software that is not approved for a specific refractive indication, then treating the refractive error is unapproved rather, than the practice of medicine. For example, if a laser is not approved for hyperopia, then the software cannot be modified to treat hyperopia.

Advertising of approved devices (e.g., excimer laser) by brand name and model to the public is permissible, as long as the physician and the manufacturer disclose all relevant warnings, precautions, contraindications and side effects for the device's approved use. Generic reference to a laser may be made without detailed disclosures in the advertisement, as long as all relevant warnings, precautions, contraindications and side effects are discussed in the informed consent. Informed consent is regulated by the states. In addition, the Federal Trade Commission can assert jurisdiction over statements made in informed consent forms.

Definition of Advertising:

In addition to print, radio, and television ads, other material such as patient informational brochures, seminars, and videos may be considered advertising for purposes of these laws.

Under the "FTC Act," Internet ads also are viewed as advertising. Privileged discussions between physicians and their patients are generally not regulated by the FTC, but may have other legal or ethical implications. Irrespective of whether seminars and brochures may be considered advertising by the FTC, physicians do have a responsibility to adequately inform patients about alternative therapies.

Accountability:

Physicians and other advertisers are legally responsible for the truth and accuracy of their advertising, even if it is prepared by an ad agency or other third party.

Substantiation:

True and substantiated health claims help prevent injury to consumers. Medical advertisers, particularly with respect to surgical procedures, are held to a higher standard than those who advertise consumer products that are not health-related. The FTC requires that advertisers have a "reasonable basis" for advertising claims at the time they are made. With

respect to health and safety claims for refractive surgical procedures such as LASIK or LTK, this will usually require “competent and reliable” scientific evidence that may include, depending on the claim, the physician’s own outcomes alone or in combination with other clinical studies. Such clinical evidence is generally considered to be stronger if the study has been peer-reviewed and/or replicated in other studies. The research must be relevant to the service and benefit being advertised. In addition, the advertiser must have adequate substantiation for a claim at the time the claim is made. Anecdotal evidence is not adequate. Advertisers are responsible for all express and reasonably implied claims. Qualifying information must be disclosed if necessary to prevent deception. All disclosures must be sufficiently clear and conspicuous within the advertisement so that consumers are able to read and understand it.

Informed Consent:

Advertising need not, and as a practical matter cannot, incorporate all of the elements of appropriate informed consent disclosures. FTC staff has stated that certain advertising claims may require disclosure of material information appearing in informed consent forms (see below, Example 1, Safety Claims). Also, advertising may not contradict disclosures of risk made in informed consent forms, and informed consent forms will not compensate, legally or ethically, for misleading statements made in advertising.

Testimonials:

Advertisers cannot make claims indirectly, for example through a testimonial that they could not substantiate if made directly. A patient endorsement or testimonial will be construed by the FTC in two ways: (1) as making the performance, safety, health-benefit, or efficacy claim that underlies the testimonial; and (2) as a representation that the particular patient’s experience is typical or representative of the experiences generally achieved by the physician’s patients, unless there is a clear and conspicuous disclosure to the contrary. Therefore, patient testimonials must be supported by competent and reliable scientific evidence that substantiates both the underlying efficacy claim and the claim that the result is representative or typical of that experienced by other patients. In addition, physicians should be aware that some states prohibit the use of patient testimonials by physicians. Physicians are advised to verify state law and regulations on the use of testimonials in advertising.

MD/Expert Endorsements:

Physician experts may endorse substantiated efficacy claims for products or services, as long as the physician is qualified to evaluate the service, provides an independent evaluation, and discloses in the ad any personal or financial connection to the sponsor of the advertised product that would be important for consumers to know in weighing the expert endorsement.

Advertising Claims:

Prospective refractive surgery patients have differing needs and expectations and may experience differing surgical outcomes. Accordingly, advertising claims are not a substitute for discussions between the ophthalmic surgeon and a prospective surgery patient regarding the patient's own needs and expectations and the range of possible outcomes.

Efficacy Claims

Example 1: *This ad appears on the Internet. The banner reads: "Throw Away Your Glasses!"* A reasonable consumer may infer from this ad that he or she will be permanently free of all forms of corrective lenses (for presbyopia and hyperopia as well as myopia) as a result of the surgery. Even if the ad makes reference to nearsightedness, there is a substantial risk that a significant number of consumers would infer from the ad that if they underwent the procedure, they would achieve 20/20 vision and would be free of glasses, including glasses for reading or occasional use. Since the surgeon cannot guarantee that the prospective patient would be permanently free from all glasses, the claim is subject to legal challenge.

Example 2: *A print ad headline states, "Throw Away Your Glasses," or features a drawing of spectacles within a circle with a line crossed through it. Other text within the ad states that refractive surgery "may correct your nearsightedness and astigmatism and may eliminate your need for glasses or contacts."* Although the use of the word "may" is intended to qualify the "no more glasses" claim, the claim is likely to be understood by consumers, in light of the more prominent headline or drawing to be as unqualified as in Example 1. To avoid confusion, the overall message of an ad should not be inconsistent with the "fine print" qualifiers. A further modification of the above claim, such as: "may correct your nearsightedness and astigmatism and may allow you to function without glasses or contacts for many activities," avoids possible ambiguities about the need for reading glasses or glasses for occasional use.

Example 3: *A radio ad includes the text: "See naturally with refractive surgery!"* The reasonable consumer would interpret "seeing naturally," or similar terms such as "seeing clearly" to mean "seeing without glasses." Again, this kind of claim should be avoided for the same reasons as for Examples 1 and 2, above.

Example 4: *An ad picturing a smiling patient and physician states: "If you can read the small print, but can't see well at a distance, visit Drs. Smith and Jones to learn more about LASIK – our typical nearsighted patient – after refractive surgery – no longer needs glasses for many activities."* Such an ad is acceptable. It suggests that LASIK will treat only nearsightedness and informs consumers about the possible need for glasses for other activities.

Example 5: *An ad states: "98% of our patients see 20/40 or better postoperatively – good enough to pass a driver's test in most states!"* Since the ad explicitly claims a result for a particular physician group's patients, the physicians will need a study or analysis of patient records to substantiate the claim. In addition, this ad might be understood by some consumers to mean that since they can pass a driver's vision exam, they might not need to wear glasses for other activities. This potential problem with the ad could be eliminated by a reference to the fact that patients may still need or desire glasses for some activities.

Comparative Efficacy Claims

Example 1: An ad states: “This laser is ranked highest by the FDA.” Advertisers may not make unsubstantiated comparative claims about lasers. The Food and Drug Administration does not rate devices comparatively.

Example 2: An ad states: “We use a scanning laser so that you get the best results.” This implies that scanning lasers produce better results than non-scanning and should be avoided unless you have competent and reliable scientific evidence (i.e., comparative clinical evidence) to support it.

Example 3: An ad states: “Our (LASIK) surgeons are more experienced than any of their colleagues in (Florida).” Unless you have reliable, current evidence of the number of LASIK procedures performed by each refractive surgeon in the claimed region, this advertising tactic should be avoided.

Safety Claims

Example 1: An ad states: “Find out more about LASIK the safe and easy alternative to glasses!” The terms “safe” and “safe and easy” have attracted the concern of the FTC and FDA, as have promotional materials that fail to disclose certain significant risks associated with the surgeries that are important to a prospective patient. Generally, it is not appropriate for an ad to state that LASIK is safe and easy. Any ad that suggests that LASIK is safe should, at a minimum, include a qualifying statement such as: “Like all surgery, LASIK surgery has some risks; we will discuss these with you during your consultation.” Depending on the context of the safety claim, such an ad may also need to contain information about any significant risks associated with the surgery.

Example 2: A print ad states that, “unlike other procedures, PRK laser vision correction doesn’t involve knives or cuts to the eye.” Although it is true that the excimer laser does not use a blade to make incisions on the surface of the eye, the statement could be misleading to consumers by suggesting that PRK is a non-invasive procedure. It is not appropriate to claim or suggest expressly or through use of euphemisms such as “treatment,” “therapy,” or “vision correction,” or “enhancement” that PRK is anything other than an invasive surgical procedure. While differentiation between refractive procedures may be appropriate in order to inform consumers, it should be done in a way so as not to be misleading; PRK, LASIK and LTK are surgical procedures, and this should be made clear to the reader of the ad.

Example 3: An ad states: “The Food and Drug Administration has Determined that the Excimer Laser We Use Is Safe and Effective for LASIK.” Such an ad is acceptable. The “Federal Food, Drug and Cosmetic Act” was amended to allow references to the FDA approved status of any medical device in advertisements.

Example 4: An Internet ad for LTK states: “Now offering FDA approved NO CUT, NO FLAP laser refractive surgery. Call to see if you’re a candidate. Exceptionally safe, rapid recovery, treatment time of three seconds. The laser never touches the eye! Almost immediately the patient will notice an improvement in near vision and will be able to read without glasses! This ability will gradually diminish,

but the distance vision will then improve dramatically." This ad implies that LTK is not an invasive procedure. In fact, LTK does steepen the cornea using a laser. The ad also states claims about safety, recovery time and prognosis that must be substantiated with reliable and current evidence from the practice of the surgeon making the claim. Further, express or implied claims that LTK patients will not need reading glasses or bifocals should be avoided, as the FDA has indicated that LTK may only delay the need for eyewear in hyperopic patients.

Permanence and Predictability Claims

Example 1: *An ad states: "Achieve permanent vision correction with refractive surgery!"* A reasonable consumer may assume "permanent" to mean that their postsurgical refractive result will remain stable throughout their lifetime. FTC staff has raised questions with issues of the possibility of regression, drift, and possible instability long-term, and has objected to permanency claims because of their belief that studies of modern refractive surgery techniques available at the time of their review did not adequately substantiate such claims. The promise of a "lifetime commitment" in some LASIK ads likely overstates providers' ability to correct every post-surgical problem that arises over the long-term. At this time, physicians considering making claims of permanency or predictability should be aware that the FTC will carefully scrutinize this advertising. Accordingly, physicians should avoid permanency claims unless they are able to substantiate the claims on the basis of their own surgical outcomes alone or in combination with current scientific evidence.

Example 2: *"Visit the Smith Laser Center and leave with 20/20 vision!"* This ad is problematic. A reasonable consumer could interpret this advertisement to mean that the surgeon can guarantee, pre-operatively, exactly what the patient's surgical outcome will be (i.e., that refractive surgery results are predictable.) To advertise surgical predictability, physicians must be able to substantiate that surgical outcomes are predictable in virtually all of their cases. The use of ranges (e.g., 80 percent of our patients have 20/20 vision following surgery) is acceptable if the surgeon can substantiate the claim.

Success Rate Claims

Example 1: *"90% of LASIK patients achieve 20/40 vision or better."* If this claim is based on a clinical study, the surgeon making the claim will need to assure that the study is scientifically reliable and that he or she is performing the same procedure using the same protocol as that involved in the study. If these criteria are met, the claim would be acceptable as long as the surgeon's own outcomes did not vary significantly from the reported results.

"Painless" Claims

Example 1: *An ad states: "LASIK surgery is a safe and painless procedure."* A reasonable consumer could understand this statement to mean that the entire experience -- preparation, surgery and recovery-- is painless. Patients undergoing refractive surgery typically experience some pain and discomfort for a short time following surgery. Patients are often given prescriptions

to deal with pain or discomfort. In these circumstances, "painless" claims are almost certain to be considered false or deceptive.

As with any other surgical procedure, new information and technology in refractive surgery can be expected to evolve over time. Accordingly, these guidelines are subject to periodic review and revision to ensure that they reflect the latest information and technology in refractive surgery.

Note:

1. The "Food, Drug, and Cosmetic Act" gives the Food and Drug Administration (FDA) jurisdiction over the advertising of excimer lasers because they were cleared as restricted devices. FDA and FTC have generally agreed that FTC has primary jurisdiction for those advertisements that only discuss the physician's practice and not the excimer laser used in that practice.

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This document was provided for you courtesy of the American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery to inform you of federal laws and policies and provide guidance on FDA and FTC laws and regulations governing advertising of surgical procedures.

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